

# HEPS/2016

Healthcare systems  
Ergonomics and  
Patient  
Safety



## Healthcare and Society: new challenges, new opportunities

### PROCEEDINGS

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*Presidents:*

*Vanina Mollo & Pierre Falzon*



## Foreword

This 5th edition of HEPS conference focuses on the place of healthcare in our societies as well as on the challenges and opportunities that evolutions in societies offer to healthcare organizations.

Healthcare systems operate in an increasingly cost-constrained context and are facing many challenges: aging of the population, rise in chronic diseases, technological innovations, increased requirement for safety, redistributions of the supply of healthcare between institutions in order to ensure a continuity of care, evolution of patients' and providers' aspirations and needs. These challenges deeply impact healthcare and health as a whole, but may also provide new opportunities for an improved functioning of healthcare systems.

The papers presented deal with four main topics:

### **The transitions of care**

Increased needs for healthcare and economic constraints require new organizational models to be developed, such as healthcare networks involving several care providers (hospital, ambulatory primary care practice, ambulatory specialty care practice, long-term care, home healthcare, rehabilitation facility). These new organizational models affect work activities and work conditions, setting new questions and generating new needs.

### **Patient/citizen participation and education**

Citizens and patients are more and more informed and willing to play an active role in decisions concerning their health. The issue is then to enable them to become active partners in order to improve the quality and safety of care, the quality of life of patients and the quality of work of providers, particularly in the context of telemedicine development. Reciprocally, healthcare professionals need to adapt their activity and involve patients in decision processes, including those regarding the distribution of healthcare work and the design and organization of education of both patients and providers.

### **Healthcare, work conditions and the digital society**

Technological evolutions (advanced technologies, telemedicine, workflow tools...) and management policies deeply transform healthcare activities. While they may provide opportunities to improve the quality and safety of care and to support cooperation, the pace of technological changes and the logics of management policies may also have adverse effects regarding safety and regarding work conditions and responsibility assignment if their design and implementation are not appropriately addressed.

### **Safety and resilience in healthcare systems**

Safety has become a major concern of healthcare systems. This has had several consequences: increased regulations about quality and safety, hiring of healthcare professionals devoted to safety, development of safety training, interest in patients' participation, development of tools and of simulation methods. This has also led to an increased interest in managerial issues: management decisions need to balance economic effectiveness and safety preservation.

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# **ORAL COMMUNICATIONS**



## **Patient Safety in Pediatrics: an ergonomic solution for safer care of children – the case of the Pediatric Teaching Hospital of Florence and the pediatric regional network**

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### **Abstract**

*Context:* Patient safety is a strategic activity in children's care. Epidemiological data and evidences from the literature are less for patient safety in pediatrics and there is a need for comparing experiences and applied solutions of different contexts. Patient Safety in Pediatrics requires lots of specifications comparing to the actions and solutions designed for the adults.

*Objectives:* The Teaching Hospital for Pediatrics of Florence, in collaboration with the Centre for Patient Safety of the Tuscany Region, has developed a joint program of activities for promoting safer care for children, based on ergonomics and human factor principles and methodology. The collaboration is aimed at designing and piloting patient safety practices for pediatrics and in particular two patient safety practices: the Pediatric Early Warning Score (PEWS) and the Humpy Dumpty Falls Scale, the scale for preventing pediatric patients falls.

*Methodology:* The research design followed four phases: review of international literature, design of the tools with usability test, pilots of the tool, evaluation of the user's compliance and impact of the tools on quality and safety.

*Main results:* Two pilots have been carried out in most of the hospital of the Tuscany Region in order to test the Pediatric Early Warning Score Tool and the Humpy Dumpty Falls Scale. The pilot of the PEWS is based on quantitative analyses in order to evaluate tool usability, feasibility and impact on team working, communication among member's team and work organization. The pilot of the Humpy Dumpty Falls Scale aimed to a linguistic and cultural validation of a scale for risk assessment and evaluation of the adherence to safety practice. The secondary objective was to estimate the sensitivity, specificity, PPV, NPV and ROC curve of the new instrument in Italian language. Completed results for both the tools are expected by the end of 2017.

*Conclusion:* The patient safety in pediatrics is still a challenging area of intervention as it is usually not in the top list of the healthcare management. Also the tools designed and validated for adults are usually not adequate for children and there is a need for further research in order to get evidences of their effectiveness in pediatrics. Thus, it will take a long time to have critical mass of data in this field; and research interventions are fundamental work to improve knowledge in this field.

**Keywords:** PEWS, pediatrics, patient safety

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### **1. Introduction**

Patient safety is a strategic activity in children's care. Epidemiological data and evidences from the literature are few for patient safety in pediatrics and there is a need for comparing experiences and applied solutions in different contexts. At the European level some

recommendations have been defined and the need for applying specific solutions and patient safety practices have been underlined. We have now a list of evidence based patient safety practices at the international level. These practices need to be adapted by trials in order to be useful also for the pediatric settings. The patient safety manifesto (American Academy of Pediatrics, 2001) for pediatrics underlines the importance to evaluate the patient's specific characteristics (such as degree of reached evolution, weight variation, limited capacity to cooperate in delivery of care, high level of dependency and rarity of some children's sickness) every time that you are going to design an activity for improving safety for children. It is also important to standardize and make more usable medical devices with the application of a cognitive and organizational ergonomic approach to the development of clinical processes (American Academy of Pediatrics, 2001).

A study published in 2012, conducted in 14 local healthcare agencies e 8 teaching hospitals in Canada, underlined that the 79% of adverse events in children happened in intensive care unit, the incidence on admissions is of 6,5% (3640 cases in total). 44,7% of these adverse events are preventable.

The Tuscany region network of pediatrics hospitals, in collaboration with the Centre for Patient Safety and clinical risk management has developed a joint program of activities for promoting safer care for children, based on ergonomics and human factor principles and methodology. The collaboration is aimed at designing and piloting patient safety practices for pediatrics and in particular two patient safety practices: the *Pediatric Early Warning Score* (PEWS) and the *Humpy Dumpty Falls Scale*, the scale for preventing pediatric patients falls.

## **2. State of the art**

### **2.1 State of the art regarding the Pediatric Early Warning Score**

Patients in general wards can deteriorate, up to the cardiac arrest, these patients can be early detected as the critical conditions which precedes the cardiac arrest is anticipated by a phase where the patient is unstable for a variable period of time. The signs for clinical deterioration can be detected and treated ("track and trigger") starting from the monitoring of the physiological signs (Jansen JO et al, 2010; Smith GB et al, 2008; Smith GB, Prytherch DR, Schmidt PE, Featherstone PI, 2008; Duncan H, Hutchison J, Parshuram CS., 2003; Seiger N., Maconichie I., Oostenbrink R. et al, 2013; Way C., Crawford D., Gray J. et al, 2013).

The general wards are settings where it is necessary the adoption of a structured way to identify the acute phases of a clinical case and to set up the appropriate care according to the priority criteria for intervention. The surveillance of the clinical deterioration is also appropriate in the sub-intensive areas and in the emergency room for cases under observation for more than 12 hours. Prognosis can improve according to the timing in evaluating and treating those patients with clinical deterioration (Duncan H, Hutchison J, Parshuram CS., 2003; Seiger N., Maconichie I., Oostenbrink R. et al, 2013; Way C., Crawford D., Gray J. et al, 2013).

Organizing the surveillance of physiological signs in groups of heterogeneous patients, through scales for rating the patient's state, arises the chance for early detection of clinical deterioration and for an effective evaluation of the degree of instability in order to activate the intensive care unit and the rapid response team.

A rating scale which rates the common physiological parameters and expert clinicians to monitor the patients whose conditions are getting worse are key elements for avoiding adverse events. This scale was put together with an indispensable evaluation clinic. Together they played an important role to specify the appropriate clinical responses and to support the

decision to transfer patients between different health care units. (Karen M. Tucker, Tracy L. Brewer, et al, 2009; Hillman KM, Bristow PJ, Chey T, et al; 2001).

To detect and treat the clinical deterioration, it is therefore necessary to define the structured modality of the intervention, with the assistance of the algorithms and matrixes of responsibility, to correctly manage, with resources already available in the ward, the alert of a patient in deterioration and for the eventual activation of external resources not already located in the ward (rapid response team).

The results of a detailed review of 126 children deaths which occurred in the United Kingdom has underlined that 89 of the deaths verified in the hospital (63 children, 71%) could have been prevented. From the same study, it has also been revealed that the missing recognition of the complications represented determining factors in verifying the adverse event (Pearson GA, 2008).

Thus far, however, there are no studies that demonstrate the actual correlation between the use of the scoring system based on criteria of high alert and the reduction of the mortality rate for cardiac arrest. Mainly, there are 3 scoring systems for the premature evaluation of the deterioration of the pediatric patient. (Duncan, Hutchison, & Parshuram, 2006; Haines, Perrott, & Weir, 2006; Monaghan, 2005). Two of these scoring systems demonstrated an adequate capacity to identify the premature deterioration but none of them were evaluated with respect to the reliability. Furthermore, another study was conducted (2009) with respect to the sensibility and specificity of the *Pediatric Early Warning Score* with positive outcomes. The use of PEWS was also associated with an increase of the number of patients transferred to the PICU (Pediatric Intensive Care Unit.) In 2008, a study was conducted on 2,979 patients evaluated with the PEWS system in an arch of the time of 12 months, and it demonstrated that the PEWS system is a valid and reliable instrument to identify the patients at risk for deterioration. (Karen M. Tucker, Tracy L. Brewer, et al, 2009).

## **2.2 State of the art regarding the Humpy Dumpty Falls Scale**

Adverse hospital events are frequently and potentially very dangerous. In fact, other than provoking suffering for the patient, it can also increase the duration of the patients' hospital recovery and it can cause serious health risks, reducing the duration and quality of life (Aranda-Gallardo 2013). For this reason, it is considered one of the most important legal problems for the safety of care (Wilson 1998.)

It has been calculated that the prevalence of patient falls varies between 3 and 14 for every 1,000 days of recovery (Healey F, Scobie S 2008). A study conducted in the United Kingdom in 472 hospitals revealed that there were 206,350 hospital falls between September 1, 2005 and August 31, 2006. The same study also exposed that those falls constituted 32,3% of the total accidents verified in the hospital (Healey F, Scobie S 2008). According to a 2004 study, 30 % of the Intensive care accidents had wounds/lesions. Of these, 3-4% represented wounds serious in nature including fractures, subdural hematomas and even death (Hitcho, Krauss 2004).

Even in the pediatric environment, patient falls are a widespread phenomenon. In fact, they constitute the major reason of trauma which cause hospitalization of children under 5 years of age (Pomerantz WJ, Gittelman MA 2012). A study in the United States analyzed the prevalence of hospital falls in patients under than 18 years of age. They calculated that the prevalence of patient falls was 0.84 for every 1,000 patients per day, with 48% of those falls as preventable. 47% of the subjects who had fallen were identified as risks (Jamerson Graf 2014).

The individualization of subjects at risk is one of the first duties of all the patient fall prevention programs and this is also valid in the pediatric environment. Over the course of many years, there have been many evaluation instruments for the risks for adults, such as, Downtown Scale (Downtown), the Morse Fall Scale (MFS) (Morse 1988), the St. Thomas Risk Assessment Tool in Falling Elderly Inpatients (STRATIFY) (Oliver 1997), the Tinetti test (Tinetti 1986), the Conley Scale (Coloney 1999), the Hendrich Fall Risk Model (HFRM)(Hendrich 1995) and its last version, the HFRM II (Hendrich 2003). Even if these tools have good predictive features, they are not suitable for pediatric patients.

The *Humpty Dumpty Fall Scale (HDFS)* is a tool for risk evaluation designed especially for children (Hill Rodriguez 2009). It classifies the patients as at high risk or at low risk on the basis of the presence/ absence of some specific characteristics: age, sex, diagnosis, presence of cognitive deficits, environmental factors, the reaction to sedation or to anesthesia and the prescribed medication. The final score, that can vary from a minimum of 7 to a maximum of 23, is the result of the sum of the scores collected from each item. The child is at high risk if the total score is  $\geq 12$ , while she is at low risk for a score lower than that.

The English version of HDFS has a sensitivity of 0,85 and a specificity of 0,24, while the PPV is of 0,53.

### **3. Objectives and Methods**

The study has two main objectives:

- Regarding the PEWS, the study aims at customizing, testing and evaluating the tool in terms of usability and impact on clinical practice
- Regarding the Humpty Dumpty Fall Scale, the study aims to a linguistic and cultural validation of a scale for risk assessment and evaluation of the adherence to safety practice as well as to estimate the sensitivity, specificity, PPV, NPV and ROC curve of the new instrument in Italian language.

#### **3.1 First phase: review of international literature**

The first phase of the pilot study is dedicated to the review of international literature and research of scientific articles focusing on the application of the two tools in healthcare facilities.

#### **PEWS**

##### **3.2a Second phase: design of the tool**

Starting from the international experiences, the PEWS sheet has been adapted to local facilities characteristics and team needs. A multidisciplinary working group, composed by pediatrician anesthesiologists and nurses, was required to review appropriateness of the items according to clinical practice and organization of clinical activities. A prototype was then designed following criteria of ergonomic and usability by EU certified ergonomists and patient safety experts. The following picture describes the PEWS sheet with the different vital signs to monitor and the scoring system. The sheets are differentiated by age.

Cognome \_\_\_\_\_ Nome \_\_\_\_\_ Data di nascita \_\_\_\_\_ Luogo di nascita \_\_\_\_\_ Età \_\_\_\_\_

	2	1	0	1	2	Valore
Frequenza Cardiaca	< 90	90 - 109	110 - 150	151 - 180	> 180	.....
Frequenza Respiratoria	< 20	20 - 29	30 - 60	61 - 80	> 80	.....
Pressione Arteriosa Sistolica	< 50	50 - 59	60 - 80	81 - 100	> 100	.....
Saturazione	< 85	85 - 95	> 95			.....
Riempimento capillare	TRC > 3	2 - 3	TRC < 2			.....
Ossigenoterapia	> 50% o > 4l / min	< 50% o < 4l / min	Nessuno			.....
Comorbidità						Totale .....

REGIONE TOSCANA  
**GRC** Gruppo Regionale di Certificazione  
 Sicurezza del paziente

Figure 1. An example of PEWS sheet for babies up to 3 months old

### 3.3a Third phase: Pilot of the tool

The sheet for scoring the PEWS has been piloted for 6 months in 6 regional hospitals: general pediatrics, short observation unit in the Emergency room, Post surgery unit. The targeted patients were children from 0 to 12 years.

### 3.4a Fourth phase: Evaluation

Final results are under elaboration and they will be issued by next year. A quali-quantitative analysis will be conducted in order to evaluate the impact of the Pews handout on the clinical practice and to analyze, also a survey will be conducted on involved professionals aimed at understanding their opinion on the usability and feasibility of the PEWS handout, and an analysis of the PEWS handout compliance.

### Preventing Patient falls

The pilot for Patient fall prevention has been realized through the use of some key tools:

- 1 Handout for patient falls evaluation at the admission
- 2 Handout for patient falls during the hospitalization
- 3 Evaluation scale for the daily risk
- 4 Protocol for falls prevention
- 5 Material for the identification of patients at high risk of falling.

The following pictures give an example of the material used for patients' identification in case of high risk for falls. The material has been designed by a certified European ergonomist and promoted in the entire regional network of pediatric units. As you can see there is a card where to insert the patient's name, a card for the ward board and one for the patient's bed. They are all especially designed for children and very easy to understand.



**Figure 2.** Material for patient's identification in case of high risk of fall

The handout have been piloted in 13 regional hospitals in all the wards except for the Intensive care Unit and the Emergency room. The targeted patients were children who were in the hospital for more than 12 hours and the pilot lasted for 12 months.

The pilot was realized in three phases.

### **3.2b Second phase: translation of HDFS**

The original text in English (V0) has been translated from a professional (translator n.1 - T1) and a second translator (T2) realized a forward translation. The two professionals translated in an independent and blinded way and their translations were compared by a third professional (T3). The consensus among the Italian and English version of the scale has been obtained thanks to the joint participation of T1, T2, T3 and the Principal Investigator. This translation represents the first validated Italian version of HDFS (V1). The V1 has been translated from other two translators (T4 e T5). Two different English translations have been realized (V2 and V3) of V1: the team composed of T1, T2, T3, T4, T5 and the Principal Investigator compared these versions with the original version of the HDFS (Valmi Rojjanasrirat 2011).

### 3.3 b Third phase: pilot of the tool

A piloting test on 30 nurses has been realized in order to establish the degree of comprehension of version4. Validity and reliability of the scale have been calculated on the same sample. For the validity calculation researchers used the Content Validity Index for both the items (ICVI) and the scale (SCVI). The ICVI value is defined from a group of experts. An acceptable ICVI is  $\geq 0,78$ . The items which did not reach the IVCI minimum level have been re-evaluated and modified. The ICV for the scale (SICV) is acceptable if  $> 0,90$ .

The reliability of the V4 has been estimated by calculating the Inter-rater Reliability on a sample of 100 children, who have been evaluated through the use of the V4 from two independent researchers. The values Alfa of Cronbach  $> 0,7$  have been considered acceptable.

### 3.4b Fourth phase: Evaluation

The analysis of results will be finalized next year. The collected data will permit to estimate sensitivity, specificity and the PPV and NPV.

The Index of Content Validity, for each item and for the entire scale will be evaluated (acceptable value  $> 0,90$ ), together with the Alfa of Cronbach for the Inter-Rater Reliability with acceptable value  $> 0,7$ . The ROC curve will permit to identify the more appropriate cut-off for the Italian version.

## 4. Results & Discussion

The work done in the Children’s Teaching Hospital of Meyer aimed at defining patient safety practices that can be suitable for children in the hospital but also in the regional network of pediatric units. The work done allowed the definition of a clinical protocol for actions to take according to the evaluation of patient’s deterioration realized thanks to the PEWS (see figure 3). Especially it supported the definition of a rapid response team in each hospital. This is extremely important in general hospitals where there are limited staff with competencies in pediatric intensive care.

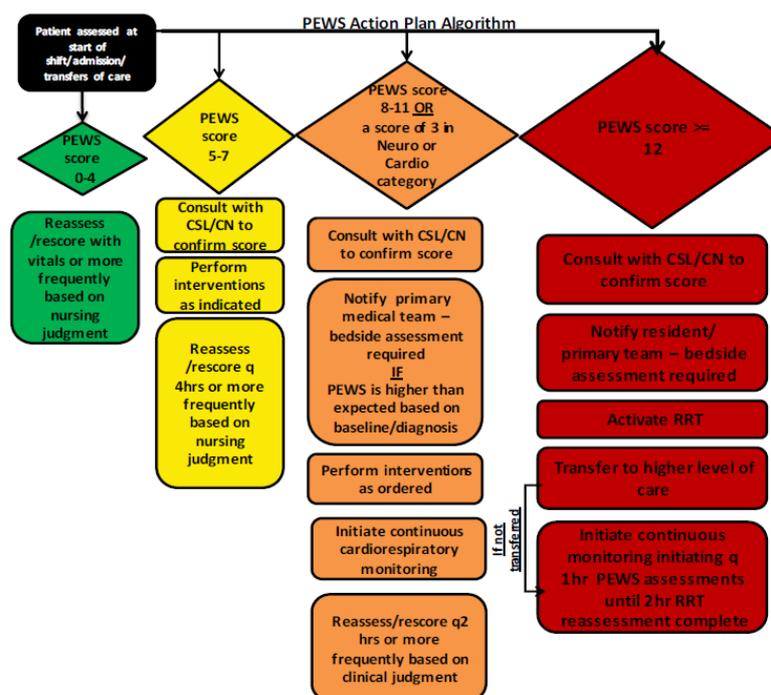


Figure 3. PEWS action plan algorithm adopted in each regional hospital involved in the pilot

The validation of the PEWS, expected to be finalized by 2017, as a tool for identification of patients' with clinical deterioration will help to better define the scoring system and the related protocol.

Concerning patients' fall the adopted sheet for falls' identification during the stay (Figure 4) is part of the analysis conducted in order to validate the Humpty Dumpy Scale and is aimed at understanding patient's and system condition that can contribute to falls. The validation of the Italian version of this scale, expected to be finalized by 2017 will represent an important result at the national level.

Figure 4. Sheet for falls' identification during the stay

Both pilots have been realized by adopting a systemic approach to patient safety with solutions designed by taking into account the principles of ergonomic and human factors and applying them for the definition of cognitive, organizational and physical ergonomic solutions. The conducted projects are challenging in terms of management for the large number of operators involved and the variability and dynamicity of the clinical contexts involved. The presence of facilitators trained in ergonomics and human factors as leaders of the projects at the local level together with the realization of training sessions on the job, was a strategic element for the coordination of the different contributions and large adoption of the designed solutions.

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## Accurate documentation of indications for antimicrobial prescribing in an electronic medication management system

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### Abstract

*Context:* To allow monitoring and targeting of inappropriate antimicrobial prescribing, accurate documentation of indications (i.e. reasons for use) by prescribers is needed. An antimicrobial's indication often serves as a trigger for antimicrobial stewardship staff to become involved and ensure appropriate prescribing.

*Objective:* To examine accuracy of antimicrobial indication documentation in an electronic medication management system (eMMS). Prescribers received a computerized alert when a restricted antimicrobial was prescribed and were required to record the indication in the comment field of the alert.

*Methodology:* The study was conducted at a teaching hospital with 320 beds in Sydney, Australia. A sample of 555 antimicrobials was reviewed. To assess accuracy of indication documentation in the eMMS, indications recorded in the electronic system were compared to indications evident in patient progress notes. If concordant, the indication recorded in the eMMS was deemed to be accurate.

*Main results:* An accurate indication was recorded in the electronic system in less than half the antimicrobials reviewed (38%). An assessment of concordance could not be made for a large proportion of cases (40%, n=223) because no indication was recorded in the electronic system or patients' notes contained no information about the clinical reason for the antimicrobials being prescribed. Indications for ceftriaxone were the most poorly recorded, with 41% of ceftriaxone indications found to be inaccurate.

*Conclusion:* Ensuring computerized alert content and user instructions are clear and unambiguous may improve accuracy of indication documentation, but gaming remains a risk when correctly documenting an indication creates additional work for prescribers. Incorporating antimicrobial monitoring and approval into the eMMS to prevent discontinuity in the ordering process would be an ideal way forward to facilitate accurate indication documentation and help tackle antimicrobial resistance.

**Keywords:** antimicrobial stewardship, computerized alert, indication, electronic medication management system.

## 1. Introduction

There is now little doubt that the inappropriate use of antimicrobials contributes to the emergence of resistance (Goossens, Ferech, Vander Stichele, & Elseviers, 2005; Okeke et al., 2005) and that improving antimicrobial use is necessary for the containment of resistance (WHO, 2001). To allow monitoring and targeting of inappropriate antimicrobial prescribing, accurate documentation of indications (i.e. reasons for use) by prescribers is needed.

In studies that assessed the accuracy with which clinicians record the reason for prescribing a particular medication in electronic systems, it was found that accuracy ranged from 29-95% (Falck, Adimadhyam, Meltzer, Walton, & Galanter, 2013; Galanter, Hier, Jao, & Sarne, 2010; Walton et al., 2011). In all cases, prescribers were presented with a computerized alert at the point of prescribing which prompted selection of one or more indications from a list of possible alternatives in the alert. None of these studies investigated accuracy of indication documentation for antimicrobial prescribing. However, documentation of indications for antimicrobial use represents a unique case because restriction to use an antimicrobial is often dependent on the clinical problem for which the antimicrobial is being prescribed.

At our study site, all antimicrobials are classified according to a ‘traffic light system’- red, orange or green (See Table 1). ‘Green’ antimicrobials are not restricted in their prescription and do not need approval for use, and all ‘red’ antimicrobials require approval from microbiology/infectious diseases (ID) staff before the antimicrobial can be prescribed. ‘Orange’ antimicrobials need approval when use is outside pre-specified clinical indications. Thus for prescribing of orange antimicrobials at the study hospital, accurate documentation of indication is critical as it serves as a trigger for antimicrobial stewardship staff to become involved and ensure appropriate prescribing.

Antimicrobial	Description	Examples
Red	These antimicrobials require microbiology/Infectious Diseases approval before they can be prescribed	Caspofungin Daptomycin Linezolid
Orange	These antimicrobials can be used without approval for specific indications but require microbiology/ID approval if prescribed outside of this pre-defined list	Azithromycin IV is pre-approved for severe CAP (in combination with IV ceftriaxone or cefotaxime) or for severe sexually-acquired pelvic inflammatory disease, but other indications require approval
Green	These antimicrobials are not restricted	Flucloxacillin for staphylococcal infections

CAP=Community Acquired Pneumonia

Table 1. Hospital antimicrobial policy

## 2. Objectives and Methods

### 2.1 Objective

In this study we set out to examine accuracy of antimicrobial indication documentation in an electronic medication management system (eMMS). Prescribers received a computerized alert when an orange antimicrobial was prescribed and were required to record the indication in the comment field of the alert.

### 2.2 Setting and electronic medication management system

The study was conducted at a teaching hospital with 320 beds in Sydney, Australia. The eMMS (MedChart®) is a closed loop system that allows prescribing, pharmacy review, and

drug administration. The system interfaces with other hospital clinical information systems, including a computerized provider order entry system for ordering and reporting of laboratory and imaging tests, paging, rostering, and clinical documentation. Patient progress notes are still completed on paper. Prescribing of an orange antimicrobial in MedChart® results in the triggering of a computerized alert. As shown in Figure 1, prescribers wishing to order an orange antimicrobial must enter the number corresponding to the clinical indication for use in a comment field at the bottom of the alert screen. If they wish to prescribe the antimicrobial for a non-approved indication, they must input “99” into the comment field and contact the antimicrobial stewardship registrar to gain approval.

### 2.3 Procedure

To assess accuracy of antimicrobial indication documentation, a sample of 555 orange antimicrobials was reviewed. Information related to the antimicrobial prescribed (drug, dose, route and commencement date), indication for use (as recorded in the alert comment field), prescriber details (name) and patient details (record number, sex, age) were extracted from the eMMS. Two experienced clinical pharmacists then reviewed patient progress notes to determine the indication for use of each antimicrobial in our sample.

To assess accuracy of indication documentation in the eMMS, we adopted a similar approach to previous studies (Falck et al., 2013; Galanter et al., 2010; Walton et al., 2011). Indications recorded in the electronic system were compared to indications evident in the paper progress notes. If concordant, the indication recorded in the eMMS was deemed to be accurate.

Vancomycin Injection						
Rules						
<b>Vancomycin IV</b>						
IV vancomycin is an ORANGE antimicrobial approved for:						
<ol style="list-style-type: none"> <li>1. Febrile neutropenia (in combination with gentamicin) in patient with immediate penicillin hypersensitivity (not taking fluoroquinolone prophylaxis) (14 days)</li> <li>2. Clinically significant MRSA infection (14 days)</li> <li>3. Empiric therapy of line sepsis in patient with MRSA, or at high risk of MRSA, while awaiting cultures (up to 72 hours)</li> <li>4. Intraoperative surgical prophylaxis in known MRSA carrier (max 2 doses)</li> <li>5. Ventricular Assist Device (VAD) prophylaxis (single dose)</li> </ol>						
99. Does NOT meet any of the above - please contact Antimicrobial Stewardship registrar for approval on pager 6663						
In the box below, please enter a NUMBER from the list above (1,2,3...or 99) corresponding to your patient's indication or a Microbiology Approval Number.						
See Also: <a href="#">Vancomycin Medicine Profile</a>						
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: left; padding: 2px;">Action</th> <th style="text-align: left; padding: 2px;">Comment</th> </tr> <tr> <td style="padding: 2px;"> <input type="radio"/> Override                 </td> <td rowspan="2" style="padding: 2px; vertical-align: top;"> <div style="border: 1px solid #ccc; height: 20px; width: 100%;"></div> </td> </tr> <tr> <td style="padding: 2px;"> <input type="radio"/> Remove                 </td> </tr> </table>	Action	Comment	<input type="radio"/> Override	<div style="border: 1px solid #ccc; height: 20px; width: 100%;"></div>	<input type="radio"/> Remove	
Action	Comment					
<input type="radio"/> Override	<div style="border: 1px solid #ccc; height: 20px; width: 100%;"></div>					
<input type="radio"/> Remove						

Figure 1. Example orange antimicrobial alert

## 3. Results & Discussion

### 3.1 Main results

Table 2 shows the concordance between indications recorded in the eMMS and indications recorded in patients’ paper notes. An accurate indication was recorded in the electronic system in less than half the antimicrobials reviewed (38%).

	Number of antibiotics	% of antibiotics
<b>Concordant</b>	210	38
<b>Non concordant</b>	122	22
<b>Un-assessable</b>	223	40
<b>TOTAL</b>	<b>555</b>	<b>100</b>

**Table 2.** Number (and percentage) of orange antimicrobials where clinical indication in the eMMS was concordant and non-concordant with indication recorded in patient notes

An assessment of concordance could not be made for a large proportion of cases (40%, n=223). This was because no indication was recorded in the electronic system (n=174) or patients' notes contained no information about the clinical reason for the antimicrobials being prescribed (n=73). Prescribers recorded an indication in the comment field of the alert in 377 antimicrobial orders (68.5%). In the 174 orders where no indication was recorded, prescribers entered the number '99', other information (e.g. "ICU"), nonsensical text (e.g. "fsdf") or entered punctuation to move past the alert screen (e.g. ".").

### 3.2 Prescribers, indications and antimicrobials

The majority of prescriptions were ordered by intermediate prescribers (three or more years post-graduate but not yet a specialist; n=289), or junior doctors (1-2 years post graduate; n=243). Senior doctors (i.e. staff specialists) ordered only 23 (4%) orange antimicrobials in our sample.

Table 3 shows the five most common indications for which orange antimicrobials were prescribed, the most common admitting specialties for patients who were prescribed orange antimicrobials and the most frequent antimicrobials prescribed.

<b>Antimicrobials</b>	Ceftriaxone 1g Injection (n=167, 30%) Piperacillin 4g + Tazobactam 0.5g Infusion (n=53, 10%) Vancomycin Infusion (n=46, 8%) Azithromycin 500mg Infusion (n=46, 8%) Ciprofloxacin 500mg Tablet (n=35, 6%)
<b>Indications</b>	Community-acquired pneumonia (n=100, 18%) Medical Prophylaxis (n=53, 10%) Surgical Prophylaxis (n=45, 8%) Aspiration pneumonia (n=29, 5%) Chronic obstructive pulmonary disease (COPD): infective exacerbation (n=27, 5%)
<b>Specialties</b>	Thoracic medicine (n=88, 16%) Lung transplant unit (n=80, 14%) Geriatrics (n=64, 12%) Hematology (n=46, 8%) Orthopedics (n=29, 5%)

**Table 3.** Top five most frequently prescribed antimicrobials, indications for use and admitting team specialty

Ceftriaxone was the most commonly prescribed antimicrobial (representing 30% of our sample). Indications for ceftriaxone were also the most poorly recorded, with 41% of indications found to be inaccurate when compared with patients' clinical notes.

### 3.3 Discussion

We found poor accuracy of documentation of clinical indication for orange antimicrobials in an eMMS. In approximately two thirds of antimicrobials prescribed, an indication was

recorded in the comment field of the computerized alert. Of these 377 indications, approximately two thirds were concordant with the indications documented in patients' clinical notes.

Failure to document an accurate indication in the eMMS may be due to a number of factors, a key one being poor alert design. As shown in Figure 1, the orange antimicrobial alerts present a list of all possible pre-approved indications for use, and as such, can be quite lengthy. For example, ceftriaxone, the mostly commonly used antimicrobial, contains 13 pre-approved indications. Our findings suggest that prescribers may not have read or misunderstood the alert instructions. That is, a large number of users did not document an indication into the comment field of the alert and a third of the indications recorded were *descriptions* of an indication, rather than the code number corresponding to the indication desired.

In addition to alert design, approval to use an antimicrobial is dependent on the indication documented by the prescriber, and as a consequence, 'gaming' (Persell et al., 2010) may be at play. That is, prescribers may enter pre-approved indications because this eliminates the requirement for them to obtain approval before ordering an antimicrobial. Gaming is influenced by a number of factors including, for example, time pressure, pressure from more senior doctors, and a lack of regular monitoring/surveillance of information entered into systems. For example, it takes less time for prescribers to enter an inaccurate indication and proceed with ordering an antimicrobial, then to step away from prescribing, make contact with the antimicrobial stewardship registrar and gain approval. We intend to complement our review of charts with interviews with prescribers to explore these potential contributing factors and identify barriers to accurate documentation.

Accuracy of indication documentation was not able to be assessed in over a third of the antimicrobials in our sample because no indication was recorded in the eMMS or in patients' clinical notes. Of a particular concern was the failure of prescribers to document antimicrobial indications in patients' clinical notes. During progress note review, determining indication for orange antimicrobial use proved to be a resource intensive and difficult process because prescribers did not often explicitly list an indication for use. The recording of indications in electronic systems is viewed as a panacea to this documentation problem, (Baysari et al., 2013) but our results suggest that accuracy of electronic documentation is likely to be dependent on a number of work process and system factors.

#### **4. Conclusion & perspectives**

Overall, we found poor accuracy of antimicrobial indication documentation in an eMMS. Ensuring computerized alert content and user instructions are clear and unambiguous may improve accuracy of indication documentation, but gaming remains a risk when correctly documenting an indication creates additional work for prescribers. Incorporating antimicrobial monitoring and approval into the eMMS to prevent discontinuity in the ordering process would be an ideal way forward to facilitate accurate indication documentation and help tackle antimicrobial resistance.

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## 10 years of reporting and learning from patient safety incidents in a Regional Healthcare Service

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### Abstract

*Context:* Patient safety is a top priority for healthcare services worldwide, given the extent of the problem and the evidence of the preventability of risks in hospitals and primary care. In Tuscany, since 2006, a multi-level reporting and learning system has been designed and developed, on the basis of systems thinking and participatory approach.

*Objectives:* To improve patient safety through the implementation of a reporting and learning system from patient safety incidents in a regional healthcare service.

*Methods:* We designed a multi-level reporting and learning system to promote the reporting of any significant event related to process or outcomes failures. Then we progressively integrated the RLS within the accreditation requirements (2006), the annual goals of the trust CEO and heads of departments (2009), the continuous professional development plan (2010), a dedicated on-line application (2011). Thanks to the improved capacity to control risks, in 2010 we decided to bring in-house the compensation of the eventual harm resulting from an adverse event. In 2014 we started the redesign of the RLS, to include the WHO taxonomy for patient safety.

*Main results:* We started the system in 2006, the first year collecting around 443 reports at the regional level. Finally, in 2014, we closed the reporting gap, when we reached 9086 reports, that is over the expected number of preventable adverse events. In 2006 we collected 96 improvement actions while in 2014 they were more than 3000.

The trend of claims is quite stable, with an average of around 1500 claims per year, slightly going down after the activation of the in-house compensation program. We observe a strong reduction of the costs related to compensation, given that we pay and reserve 45mln euros per year while we would pay around 100bln with a private insurance.

*Conclusion:* Our experience demonstrate that a supported reporting and learning system can improve patient safety, through the cultural change that bring healthcare workers to include the reflections on adverse events into their daily practice.

**Keywords:** patient safety, reporting and learning, adverse events

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### 1. Introduction

Patient safety is a top priority for healthcare services worldwide, given the extent of the problem and the evidence of the preventability of risks in hospitals and primary care (Vincent et al, 2001; Schiøler et al, 2001; de Vries et al, 2008). One of the key elements of any patient safety programme is the reporting and learning from patient safety incidents.

In Tuscany, since 2006, a multi-level Reporting and Learning System has been designed and developed through a participatory approach, on the basis of systems thinking and previous experience in aviation and other high-risk industries.

## **2. State of the art**

Incident reporting systems are a common requirement of healthcare services, following specific national or international legislations like in Europe, or accreditation schemes for healthcare providers like in the US. Incident reporting systems may have the general purpose to identify risks in one entire healthcare service or be part of vigilance and surveillance programs like in the areas of medical devices, medications, blood products, organ, tissues and cells used for transplantation. The learning component of the reporting system is not always structured within a holistic program of safety management, even though experiences from other high risk industries (Reason, 1997) and the WHO guidelines (2006) are very clear and straightforward about the need to integrate reporting with learning out of the qualitative analysis of single or aggregated cases and the quantitative analysis of the data contained in the records. We already discussed elsewhere (Carayon et al, 2011) the need to integrate RLS in an integrated system for patient safety management, where the organization provide a clear structure and processes to measure and prevent risks. At the front line, where care is delivered, the activities for patient safety shall be embodied in clinical practices, with usable tools and information systems that support the healthcare professionals to identify, analyze and anticipate risks. In the back-office, the management of healthcare facilities shall be able to measure, evaluate and control risks by using effectively and efficiently the available data with strong methods and tools. In both cases a common ground of knowledge on systems thinking, human factors methods and techniques, implementation sciences, is needed for the human resources involved with different roles on the two sides of the organization. A clinical risk manager, with the responsibility to monitor and support the RLS activity on the front line, strongly coordinated with a patient safety manager, who stands in the control room of the system, are the key roles that can develop and maintain safety management over time, also establishing and cultivating connections with other healthcare providers for collaborations and benchmarking.

Figure 1 shows the system for patient safety management. For each component, the elective methods and tools are indicated. Patients are considered a critical source of potential information to identify and measure risks and they can be effectively involved in all the activities. Reporting and learning take place when there is a coordination between the clinical and the management processes: for example, an adverse event can be identified through a patient claim, then it comes to an analysis at the ward within a Significant Event Audit (SEA) and it is also managed at the provider level to evaluate a potential compensation. Finally, the analysis results in an improvement plan, which includes a review of the relevant safe practice and the follow-up on indicators that are part of an accreditation scheme.

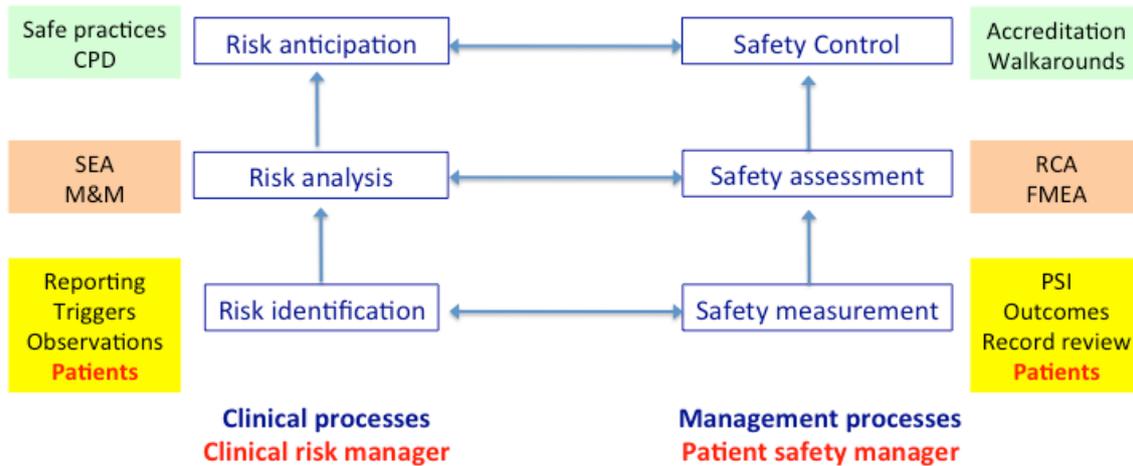


Figure 1. The system for patient safety management

Despite the widely accepted recognition of RLS as a formal requirement of healthcare services, there is conflicting evidence about their effectiveness to improve safety, due to the known barriers to incident reporting as well as the lack of a structure to provide feedback and disseminate learning (Amalberti et al, 2005; Albolino et al, 2010; Vincent et al, 2013). Recently, on one side the WHO has promoted a new approach to facilitate the effective implementation of RLS with the Minimal Information Model (WHO, 2015), while on the other side some features of successful RLS was highlighted in an international comparison of different systems (Hibbert et al 2015). Moreover, some correlations between RLS development and hospital performance have been found (Hutchinson et al, 2009).

In this paper we describe the real practice of a regional system for patient safety management, we designed and developed with an HFE approach. The regional healthcare service accounts for 3.6 millions citizens, we have 36 hospitals with around 15 thousands beds and 100 primary care facilities. In total the RHS employs 50 thousands workers and has a budget of 6bln euros. Our RHS scores high in the national programs for the evaluation of outcomes and more in general quality indicators.

### 3. Objectives and methods

The objective of our applied study is to improve patient safety, through the implementation of a reporting and learning system from patient safety incidents in a regional healthcare service.

We started from setting up a network of clinical risk managers and patient safety managers at each trust of the regional healthcare service. We organized an intensive, dedicated 120 hours training programme based on human factors and ergonomics to prepare the appointed managers on system thinking, communication and teamwork, incident reporting and analysis, implementation and measurement of safety solutions. The programme is based on an active learning approach, with short lectures followed by scenarios that the participants have to resolve and manage with the support of tutors and experts' feedback. Each participant has to conduct a project work to demonstrate the capacity to translate knowledge into practice in her own organization, then presented in a public meeting. We also offered the possibility of stage and study tour at centers of excellence in patient safety worldwide.

Besides, we started to design a multi-level reporting and learning system. First of all, we decided to promote the reporting of any significant event related to process or outcomes failures. Reporting has to happen at the unit level, so we also decided to appoint a facilitator at each unit, a role assigned to a front-line doctor or nurse after the completion of a 40 hours training programme, who has the responsibility to collect, assess and analyze the voluntary

reports from the peers healthcare workers. The proposed methods for the analysis of the event included the Significant Event Audit and Mortality and Morbidity meetings. Then we progressively integrated the RLS within the accreditation requirements (2006), the annual goals of the trust CEO and heads of departments (2009), the continuous professional development plan (2010), a dedicated on-line application (2011). We also protected clinicians from any sanctions resulting from the incident reporting and analysis, with a regional act in 2009.

Since 2007, we added the sentinel events module to the RLS, that is was then recognized as a mandatory information flow at the national level, with the launch of SIMES (National monitoring system of sentinel events) in 2009 and its inclusion in the minimum requirements for the accreditation of healthcare providers in 2011. In case of a sentinel event, a real time communication takes place between the director of the ward where the problem occurs, the clinical risk manager and the regional centre, then the local staff can ask for the support of a regional task force, composed of domain and human factors specialists, in order to manage the clinical and organizational consequences of the event, including internal and external communication.

Thanks to the improved capacity to control risks, in 2010 we decided to bring in-house the compensation of the eventual harm resulting from an adverse event, after we had started to collect and analyze claims since 2006 within the risk system for patient safety management. We accompanied this new model with a training program on how to communicate and manage the consequences of an adverse event, dedicated to the administrative professionals and the clinicians mostly exposed to claims (i.e. orthopedics surgeons and gynecologists). We also provided a regional application for claims management and monitoring, along with a regional committee providing second opinions on legal, medico-legal and risk management issues emerging from the analysis of claims over 500 thousands euros at the local level. In 2012 we published an adverse event incidence study (4), based on the retrospective review of a representative sample of records of patients admitted to hospitals in 2008, so to have a robust baseline to compare the data collected with the RLS and claims management. Finally, we have been monitoring a selection of 3 patient safety indicators (PSI) since 2008, so to have at least some outcomes measures related to patient safety and eventually to the effectiveness of our RLS: severe post-surgical sepsis, in-hospital death in low mortality DRG and acute thromboembolic events. In 2014 we started the redesign of the RLS, to include the WHO taxonomy for patient safety and in 2015 we participated at the joint EU-WHO project for the validation of the Minimal Information Model based on WHO taxonomy.

#### **4. Main results**

We started the system in 2006, the first year collecting around 443 reports at the regional level. Finally, in 2014, we closed the reporting gap, when we reached 9086 reports, which are over the expected number of preventable adverse events according to the incidence study we conducted in 2011 with the retrospective record review of a representative sample of hospital admissions. The trend of our RLS is displayed in figure 2. The trend of sentinel event is quite stable since 2011, when it became mandatory, we have on average 55 reports each year.

We also monitor the improvement actions resulting from the systems analysis of the reported events: in 2006 we collected 96 improvement actions while in 2014 they were more than 3000.

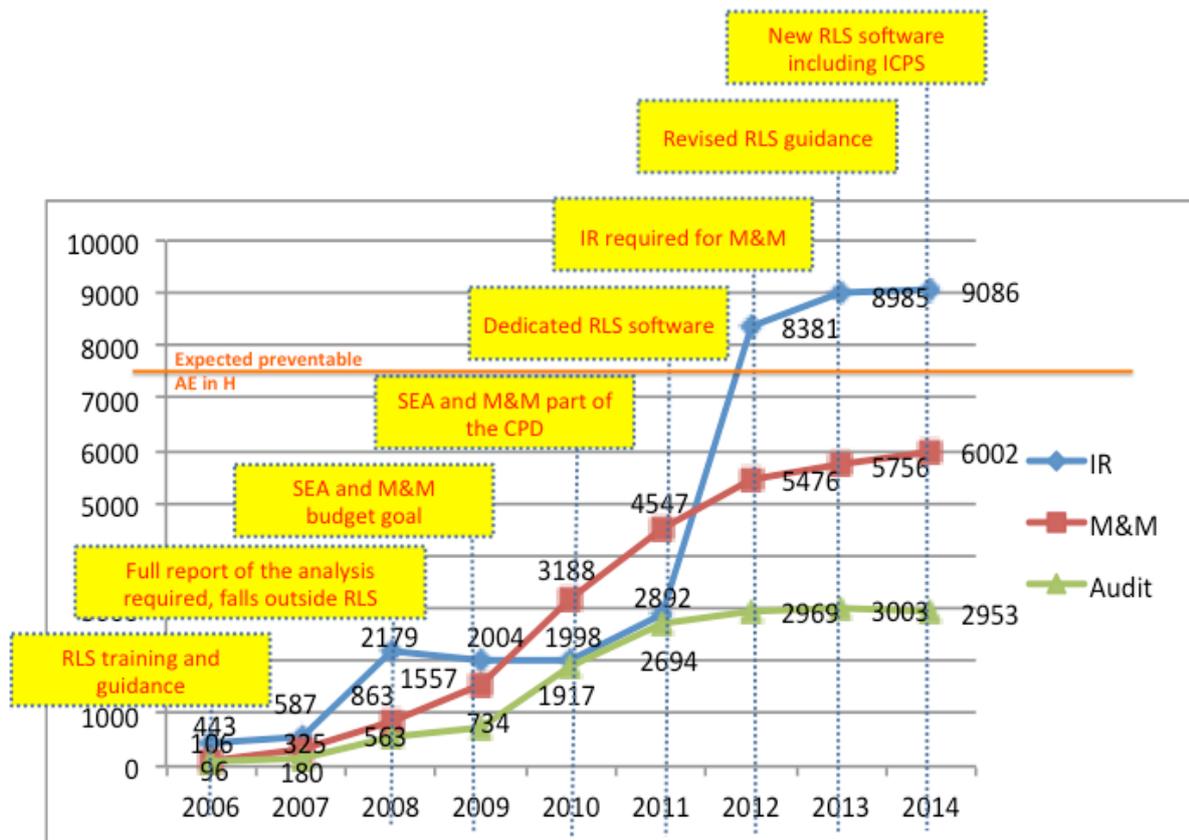


Figure 2. Trend of RLS

The trend of claims is quite stable, with an average of around 1500 claims per year, slightly going down after the activation of the in-house compensation program. Anyway, we observe a strong reduction of the costs related to compensation, given that we pay and reserve 45mln euros per year while we would pay around 100bln with a private insurance according to a formal assessment provided by a broker (5).

Regarding the trend of PSI, we observe a significant reduction of acute thromboembolic events and in-hospital deaths in low mortality DRG, while we had an increase of severe post surgical sepsis.

## 5. Discussion/perspectives

Our experience demonstrate that a supported reporting and learning system can improve patient safety, through the cultural change that bring healthcare workers to include the reflections on adverse events into their daily practice. We do not observe a strong correlation between the trend of reporting and the trend of claims, neither we have a clear understanding of the effects of the improvement actions on the risk factors assessed during the significant event audit or in the mortality and morbidity meetings. Also, we do not know whether the improvement on 2 PSI is attributable to the RLS and its output. Overall, we see that our helathcare system has a good performance in terms of quality and safety indicators and that the RLS is now embedded in daily practices in the clinical and management processes.

The main limitation of our experience, to date, has to do with the quality of the data collected through the RLS. Even though we have been using a structured record since the launch of the system, we do not systematically conduct aggregated analysis in order to find eventual correlations or similarities between, for example, the type of incident and its contributing factors, therefore the information is not transformed in actionable knowledge at the trust or the regional level. Moreover, due to the current legislation in Italy, we cannot link the report

with patient data and even if it was possible, just the discharge record is fully electronic and it contains a limited amount of data related to the patient characteristics and clinical pathway.

Finally, we believe that with the new software to support the RLS, that integrates the full version of ICPS, we may improve the quality of our data. Moreover, with a common language we can foster international cooperation, that is needed to share the lesson learnt and systematically anticipate the risks for patients in any healthcare setting at any latitude. This is the reason why we are supporting the WHO to implement MIM in Europe and in low and middle income countries.

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## Improving the association between instruments and kits in paramedics' response bags

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**Keywords:** EMS, paramedics, medical instruments, response bags, Magen David Adom

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### 1. Context

Paramedics' working environment is dynamic and stressful. Using a relatively small set of tools, in a limited space, they are the first to provide care to people in life threatening emergencies. One of the tools paramedics use as part of their daily routine are the response bags in which they carry all the medications and instruments they use. Studies have shown that adverse events in paramedic services occur in a similar rate to safety incidents in other patient care areas (e.g. Bigham, et.al 2012). Studies also found that medication safety is one of the reasons for such safety incidents (Vilke et.al 2007). However, not many research projects studied this working environment, seeking for ways to improve the way paramedics response bags are organized. We chose to work on designing the paramedics' response bags, because it is the main tool paramedics use during a call, this tool is easy to manipulate and the cost of redesigning the bags is relatively low. However, the impact of the changing the response bag setting might have significant impact on patient safety.



Figure 1. Example for paramedics' response bags with kits for instruments and medications

### 2. Objectives

Our objective was to apply user centric design principles to the design of medical instrument kits for paramedics' response bags. Following a previous project to design new paramedics

response bags (Bitan et al., 2015) we wanted to optimize the way medical instruments are distributed among the kits in these new paramedics' response bags.

Our finding from a usability study we did with these new bags demonstrate that the paramedics prefer response bags in which the instruments are organized in kits. The paramedics reported that the internal grouping by kits was helpful for finding the instruments they were looking for while providing care (Bitan et al., 2016). While the instruments the paramedics need to carry in their bags are regulated, we wanted to learn what would be the best way to organize these instruments in the bags, and how to distribute them among the kits.

### 3. Methods

Our research was designed to study few principles for organizing medical instruments into kits in paramedics' response bags. We developed an online questionnaire that was designed to collect the preferences of field paramedics. The questionnaire had two parts - in the first part the paramedics were asked to name groups of instruments they would like to use for organizing the instruments. The paramedics could also assign a color for each group to assist in identifying the groups. In the second part the paramedics got a list of all the instruments that they currently have in their response bags, and were asked to assign each instrument to one of the groups they named in the first part. The order of the instrument list was randomized between subjects.

38 paramedics from one paramedic service, Magen David Adom, the Israeli National Emergency Medical Service, participated by filling the online questionnaire. The participating paramedics working experience varied from less than a year to more than 10 years. Paramedics voluntarily enter the online questionnaire without any registration. For each participant, the online questionnaire collected the list of instruments the paramedics assigned to the groups they generated. The results from all subjects were collected into a matrix that aggregated the arrays of instruments provided by the individual paramedics. We then ranked the instruments that were most likely be assigned to the same group.

### 4. Main results

Our preliminary results demonstrate that there are common ways paramedics choose to organize the medical instruments and distribute them among kits. We identified three main strategies the paramedics used to organize the instruments by:

1. **Treatment Protocol** – Airway, Breathing, Circulation, Dressing
2. **Role** – Advance Care Paramedic, Primary Care Paramedic (EMT), First Responder
3. **Clinical Procedure** – Medication, Resuscitation, Trauma, Intubation, I.V.

Grouping Strategy	Number of subjects	Percentage of 38 participants
Treatment Protocol	7	18%
Role	4	11%
Clinical Procedure	27	71%

Analyzing the correlation between the preferred strategy and the paramedics' years of experience demonstrated that paramedics with less experience preferred the Treatment Protocol strategy, while paramedics with more experience preferred the Clinical Procedure strategy.

## 5. Discussion

Our results demonstrate that paramedics prefer to group the medical instruments they use in kits. This finding is interesting especially because it is contrary to the way the service that currently employ all the participating paramedics group the equipment. The current arrangement is in two response bags, one for medication related instrument and the other for all other instruments.

Although preferences vary, the three leading strategies we found demonstrate a strong preference to an arrangement that is grouped in a way that is related to the task the paramedics are performing.

Rearranging the response bags paramedics carry following these grouping guidelines, can be the first step toward generating a standard working environment for all paramedics. This is expected to improve the quality of the treatments patients receive from paramedics.

The current study has few limitations that originate from having all the paramedics from the same service with experience with similar working protocols and bags, and due to the small number of participants. Future studies should focus on the preferred arrangement (group by clinical procedure) and extend the study to varied paramedic services.

We are reporting the results of a small scale study, but we think that our significant results are signaling the way we should design future paramedics working environments.

## Acknowledgment

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## NASA-TLX and Cabrera Index: perceptions of workload in the emergency department

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### Abstract

*Context:* Constant flow of patients in the Emergency Departments (ED) regularly increases the workload of clinicians and can compromise the safety of patients and the quality of care delivery.

*Objective:* The primary objective of this study is to compare the current ED workload alert system (Cabrera Index) to the clinicians' perceptions of workload (NASA-TLX) in the ED.

*Methodology:* Data was collected over a one-month period in the Emergency Department of a large tertiary care center. All clinicians were asked to complete the NASA-TLX survey and the Cabrera Index number was recorded for each clinician's shift. All data were aggregated into excel spreadsheet and analyzed for correlation and descriptive statistics.

*Main results:* The researchers collected 331 NASA-TLX surveys during the one-month period. The results revealed that NASA-TLX mean score increased for all shifts that ended between 8PM and 12am (average mean score 11.9). When the Cabrera Index indicated that a clinician should stay for an extended time period, 60% of the clinicians' responded to the questionnaire agreed.

*Conclusion:* It is evident that Cabrera Index has the potential to predict workload in the Emergency Department. In this study, clinicians frequently agreed with the Cabrera index suggestion that a clinician should stay for an extended shift to help balance the workload.

**Keywords:** Emergency Department, workload, cognitive, NASA-TLX, patient safety

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### 1. Introduction

Emergency Departments (ED) are often the "gateway" to the health system and, therefore, receive a constant flow of patients with varying levels of acuity. This constant flow of patients regularly increases the workload of clinicians and, as expected, the high workload can compromise the safety of patients and the quality of care each patient receives (Carayon and Alvarado, 2007; Liu et al., 2012). Therefore, it is understandable that workload in the healthcare environment is of concern for clinicians' as their workload has the ability to impact teamwork, communication and handoffs. Having a workload that fluctuates based on shift, season and/or case severity warrants the need to explore various facets of workload, especially in a complex atmosphere of unpredictability and uncertainty.

An increased cognitive workload and increased stress have been shown to adversely affect worker performance across many industries (Liu et al., 2012; DeLucia et al., 2009; van den Hombergh et al., 2009). Cognitive workload is often referred to as the portion of an operator's limited capacity required to perform particular tasks. The assumption behind this concept is

that humans have a fixed amount of processing capacity, and if at any time the processing demands exceed the available processing capacity, performance quality decreases (Sweller, 1988). High levels of cognitive workload can lead to error and adverse patient events (Levin et al. 2007). There are various studies that provided ways for examining the workload of physicians in the emergency department (Levin et al., 2006; Weighl et al., 2014). Those studies have primarily focused on measuring tasks and equating the number of tasks to influence cognitive workload (Levin et al., 2007; Levin et al., 2006).

## 2. Objectives and Methods

The primary objective of this study is to compare the current ED workload alert system to the clinicians' perceptions of workload in the ED. The current workload alert system is called the Cabrera Index. When the Cabrera Index reaches the arbitrary number of 21, this indicates that a clinician should work an extended shift beyond his/her scheduled shift time. The Cabrera index is based on system elements such as patient counts, patient waiting and patients coming by ambulance. *The Cabrera index has never been validated and, therefore, this project goal is to determine its ability to accurately measure clinicians' workload by comparing it with the results of the NASA-TLX and the results from a questionnaire assessing whether clinicians should stay for an extended shift or not.* This study is part of a larger project to create an intelligent ED system that is capable of comparing capacity attributes against demand attributes to quantify workload, predict future state, and develop an adaptive learning system aid to inform the ideal course of action in regard to staffing needs, to enable the highest levels of quality care delivery.

### 2.1 Methods

Data for this study was collected in the Emergency Department of a large tertiary care center over a one-month period. Experienced human factors researchers collected NASA-TLX real-time surveys from medical care providers in the ED during the weekday (excluding Saturdays and Sundays). Participants were allowed to complete the NASA-TLX using a paper-based or an electronic version. The NASA-TLX is a validated self-assessment of workload, which rates the mental demand (MD), physical demand (PD), temporal demand (TD), performance (Pe), effort (Ef) and frustration (Fr) on a 20-point visual analog scale. The NASA-TLX provides an overall weighted workload score that is calculated by combining each of the rated subscales (Hart & Staveland, 1988); however the individual subscales can be retained for analysis. Participants were consented members of the ED staff that included: nurses, doctors, medical students, and scribes. The participants recorded their position and roles during their shifts. They were also required to answer questions regarding whether or not a clinician should stay for an extended shift based on the current workload. At the completion of each shift, all data were entered into an excel spreadsheet and stored for statistical analyses. The Cabrera Index score was recorded for each day.

## 3. Results & Discussion

The researchers collected 331 NASA-TLX surveys during the one-month period. The surveys were from 15 different shifts time periods (see Table 1). The results revealed that NASA-TLX mean score increased for all shifts that ended between 8PM and 12am (average mean score 11.9). The results also indicated that shift duration increases the NASA-TLX mental demand subscale (average mean score 13.76). However, all other NASA-TLX subscales (i.e. physical demand, temporal demand, performance, effort and frustration) showed no significant difference. No significant correlation exists between NASA-TLX and Cabrera Index; however, we posit that an increased sample size in each of the 15 shifts will yield a higher

correlation. In contrast, we found that when the Cabrera Index indicated that a clinician (usually a doctor) should stay for an extended time period, 60% of the clinicians' responded to the questionnaire indicating that a clinician should stay as well.

Shift	MD*	PD*	TD*	Pe*	Ef*	Er*	Raw Score	Num. of Clinicians
1	10.28	8.27	9.73	3.96	10.19	6.79	8.21	67
2	12.50	10.65	13.38	5.58	13.38	10.19	10.94	26
3	12.00	9.88	13.19	5.00	14.19	8.56	10.46	16
4	13.37	12.37	13.00	5.95	13.89	12.47	11.84	19
5	13.00	11.36	14.45	2.55	15.00	11.91	11.37	11
6	14.00	12.44	13.89	3.67	15.67	9.78	11.57	9
7	13.13	11.25	13.63	3.94	15.63	11.31	11.48	16
8	14.23	13.82	14.64	5.68	15.64	12.32	12.72	22
9	13.50	12.88	12.00	3.38	15.13	9.38	11.03	8
10	11.88	8.25	11.25	2.50	12.38	6.75	8.83	8
11	13.76	10.81	14.57	4.90	17.00	10.62	11.94	21
12	15.54	15.40	17.15	4.08	18.33	14.08	14.10	52
13	14.58	12.33	16.00	4.67	19.17	14.50	13.53	12
14	11.53	11.95	12.47	3.84	13.16	10.89	10.64	19
15	17.00	15.68	17.64	2.48	19.64	15.20	14.62	25
								331

\* Mental Demand (MD), Physical Demand (PD), Temporal Demand (TD), Performance (Pe), Effort (Ef) and Frustration (Fr)

Table 1. Average NASA-TLX Across 15 Shifts and Number of Clinicians

#### 4. Conclusion & Perspectives

While no correlation between NASA-TLX and Cabrera Index exists due to low sample size, we are pleased to know that 60% of clinicians agreed with the Cabrera Index alerts. Therefore, the Cabrera Index has the potential to predict whether a clinician should stay for an extended shift to help balance the workload. Based on the aforementioned preliminary data, we posit that the Cabrera Index could be a mechanism to help quantify workload in real-time. Having the ability to predict and monitor workload in complex and dynamic environments like the emergency department will allow us to translate the well-established knowledge on workload into practice and provide a more adequate depiction of clinician and team workload in real-time to decrease the risk to patient safety.

#### Acknowledgements

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## What can organizations learn from simulation?

### A field study in anesthesia and intensive care

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### Abstract

The main purpose for using simulators in the field of anesthesia and intensive care is staff training. It is seen as a way to enable healthcare practitioners to train on specific situations without any risk involved. As we know from the literature, in high risks systems such as anesthesia and intensive care, safety is supported by normative safety – based on organizational anticipation – and by adaptive safety produced by the operators, in order to face the variability of situations. From an organizational perspective, the ability to better understand and characterize the adaptive safety in order to support it would have positive impacts on the global safety. This study suggests considering the post-simulation debriefings with experts operators as appropriate moments for organizations to grasp how work is actually performed and the way safety is really ensured. The study is based on the analysis of 10 post-simulation debriefings with expert operators. The main findings show that in post-simulation debriefings – where trainers adopt positive attitudes without judgements – core information on real work can be revealed. Operators can discuss and share good practices, some specific rules enforcement, feedbacks or even debate work organization. As a matter of fact, debriefings constitute for organizations a place where it is possible to understand real practice and at the same time consider and discuss potential changes.

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### 1. Introduction

Anesthesia and intensive care belongs to the professional activities that acquired through the years a very high level of safety and can be qualified as ultra-safe, as the nuclear industry or commercial aviation (Vincent & Amalberti, 2016). In those environments, the use of simulators is widespread for several reasons, including high risk situations and expensive training e.g. flying aircrafts. The simulators are mainly used for training purposes, such as initial training or skills maintenance. A core part of sessions on simulators is the debriefing, where it is possible for the trainer and the trainees to discuss what happened, make explicit some practices and discuss them regarding various aspects such as performance, safety, team working or rules. In contrast to teaching beginners with simulators, it is also possible to explore how simulation and debriefings can help a whole organization improve and in particular those with highly qualified and experienced staff. Therefore, in this paper we describe an analysis of 10 post-simulation debriefings and highlight the valuable knowledge revealed about real work practices and the organizational debates that can be useful to organizations.

## 2. State of the art

In the environment of ultra-safe industries, safety barriers have been set through procedures, formalization, and a high level of training in order to avoid or limit accidents (Hollnagel, 2004). The front-end operators produce safety supported by what is anticipated by the organization, i.e. normative safety. At the same time, observational studies show that the operators, in order to ensure safety, also resort to adaptive safety, i.e. a set of practices based on initiatives, experience, team work and a careful management of the reality of situations (Nascimento, Cuvelier, Mollo *et al.*, 2014). These two types of safety are in practice combined. Thus, the requirements for the continuous improvement of safety imply that the organizations have a better understanding of real work practices (Daniellou *et al.*, 2010).

The use of simulation for training provides an ideal opportunity to observe how operators react in different situations and to approach in some ways real work practices. Sessions on simulator are divided into three main parts, the briefing where the trainers explain to the trainees the aim of the training and the specificities of the simulator. The second part is the actual session on the simulator where trainees are placed in a specific scenario and they are supposed to behave “as if” they were in a real situation. The third part is the debriefing where trainer and trainees comment and analyze the events that occurred during the simulation (Horcik & Durand, 2011). The most important part of simulations regarding the training objective is the debriefing, as it allows knowledge construction (Rall, Manser, & Howard, 2000, Fanning & Gabba, 2007). Indeed, during the post-simulation debriefing, the trainees have a chance to engage in reflective practices where they can take their work as an object of reflection (Mollo & Falzon, 2004). This activity helps to explicit the knowledge, based on practices, that supports the development of individuals and collectives at work (Mollo & Nascimento, 2014).

## 3. Objectives and Methods

The research developed here aims at considering the use of post-simulation debriefings, at an organizational level, for the improvement of safety. It is based on the observation of ten training sessions on simulators with expert practitioners in the field of anesthesia and intensive care, and more specifically the post-simulation debriefings. These sessions on simulators fit into the continuous training program proposed by the hospital. The experts involved are critical care residents, anesthesia nurses (care nurses specialized in anesthesia), nurses, doctors (specialized in anesthesia and intensive care) and medical technicians. The debriefings were audio-recorded and transcribed to perform an ethno-methodological analysis. Scenarios of the simulations include cardiac arrests, anaphylactic shocks or the arrival of a critical care patient at the hospital.

## 4. Results & Discussion

The analysis of the debriefings indicates that debriefings provide an excellent opportunity to gather feedbacks on the reality of work.

### 4.1 Sharing of good practices

During debriefings, we were able to observe the sharing of good practices where practitioners, in reference to the situation they just played in the simulator, describe also what their resources in real situations are. Here, the trainer tries to understand how the trainee identify the worsening of the situation.

Trainer: *“It seems that the first signal that alerted you was the desaturation.”*

Anesthesia nurse: *“I really pay attention to this sound since my internship where I had a supervisor that came to see me and made me aware of this little sound to which I was not attentive and that brings so so much information”*.

This beep is therefore identified as a core element for the anesthesia nurse in order to perform safely. This comment also shows that this sound is not necessarily widely used *“to which I was not attentive”*. As a follow up, the anesthesia nurse adds *“I often find myself in rooms where the beep has been cut off, but you’re on the job, [...] so after a while you give up, after you’ve been asked to turn it off once, twice, three times”*. This comment is a feedback targeting some specifics of team work that prevent the anesthesia nurse from using the beep, despite having expressed how useful it is to him in order to perform the task. This issue with the beep can be raised at two levels regarding the organization. The first one is that the anesthesia nurses could benefit from this type of informal practices that are more related to adapted safety. The second issue is more at the level of the team work. The trainee mentioned that sometimes surgery practitioners said they were disturbed by the beep. This type of feedback could lead to discussions between anesthesia practitioners and surgery practitioners on the ways they can achieve together safer surgical operations.

#### **4.2 Rules enforcement**

Below is a discussion on the rate of norepinephrine that should be given to a patient recovering from an anaphylactic shock. The anesthesia nurse chose to put 0.05 mg/h norepinephrine in order to increase the blood pressure that was estimated as too low. During the debriefing the trainer came back on that decision.

Trainer: *“Maybe in another context you would have chosen 0.2 or 0.1?”*

Anesthesia nurse: *“No, not necessarily, a patient without any medical history, on a minor surgery, I feel comfortable to start with 0.05... It’s been some months I’m doing that. Then if I have to hand off to a colleague I will carefully explain the situation [as it differs from the prescribed rules] and show him/her how it is easy to manage. Furthermore with that dilution you can put it on a catheter hub.”* A following discussion with the trainer allows us to understand that this anesthesia nurse is working in the cardiac surgical service and that, in that specific service, they are used to have patients who strongly react to noradrenaline. In that case, it is interesting to see that some anesthesia nurses choose different dilutions from the prescribed ones, and for good reasons. To go further, the trainer, if supported by the organization to do so, could during further debriefings with other practitioners raise this practice to inform them that, in some specific context, they can use another dilution or to recall the importance of communication on dilutions as sometimes practitioners do not strictly follow the prescriptions.

Another debriefing session even allowed the anesthesia nurse to live again a situation of anaphylactic shock that, in reality, ended badly. During the simulation, the anesthesia nurse administrated 10 times the prescribed quantity of epinephrine to the patient.

Anesthesia nurse: *“I said to myself he is displaying an adverse reaction to a muscle relaxant. The latest anaphylactic shock to a muscle relaxant I faced, the patient died. That’s why I didn’t dilute the epinephrine, I don’t care if the patient got a bit more.”*

Trainer: *“What does the anaphylactic shock raises for you as medication prescriptions?”*

Anesthesia nurse: *“it’s 0.1 then we wait, then 0.1, then we wait. But I did not dilute the adrenaline here because the latest victim of anaphylactic shock we had is dead. Epinephrine 0.1 by 0.1 was not enough for him.”*

Trainer: *“so your experience oriented your analysis.”*

Anesthesia nurse: *“Yes, it [in the real situation] was not just an erythema. Maybe I should have [during the simulation] diluted the epinephrine as prescribed and not think that everyone always dies from anaphylaxis.”*

In this case, the opportunity to replay on the simulator a similar incident, together with the following debriefing, is critical to come back on a situation that brought a strong emotional charge and that led the anesthesia nurse to modify her standards in terms of medication, even though she perfectly knew the prescribed procedure. In this case, epinephrine overdose could be associated with severe reaction such as high blood pressure or ventricular arrhythmia. Here we can see clearly that the debriefing is an adequate environment to frame the adaptive safety when it is required. We can also assume that replaying a similar situation on the simulator is a way to step back, regain some distance, from the difficult previous real-life situation. In order to go further, we could question to which extent organizations such as hospitals can use simulators to support medical teams dealing with emotional charges associated to dramatic situations, by replaying similar incidents on simulator and by debriefing these sessions.

### **4.3. Feedback items**

At some points during the debriefing, the trainer can take the opportunity to gather some feedback from the field. In the debriefings we analyzed, we found an example of a feedback on a cardiac arrest.

Trainer: *“what about the cardiac arrests you faced in your unit?”*

Nurse: *“The latest I had to handle was completely unanticipated, not intubated... It was not my patient so I let my colleague take the lead. But at that point I realized that it takes a very long time to assemble the BAVU [manual insufflator]. It can easily take 2 minutes to assemble it”.*

The feedback provided by the nurse here describes a specific situation she experienced in real life, and that has not occurred during the simulation session, indeed the manual insufflator was already assembled for the simulation. With this feedbacks, it appears that during debriefings it is also possible to gather feedback on real situations. Here, the feedback raises a hardware issue that can be relevant for the unit of the nurse, but also at a broader level for the organization. This hardware issue could lead to some improvements regarding safety and performance.

### **4.4 Work organization**

Debriefing is also a time when it is possible to raise collective discussions on the real work e.g. the enforcement of rules or the organization of the team.

A nurse stated: *“it’s difficult sometimes to ask you [physician and anesthesia nurses] some questions when you’re already focused on stuff. [...] It’s difficult to find the right moment”.*

In this case, the debriefing allowed a comment to be addressed by the nurse to the anesthetist doctor and a senior nurse who performed in the same simulation. Thus, debriefings convey opportunities to collectively refine work practices.

The last example we want to raise is a situation where a critical care resident, who is at the end of his studies to become an anesthesia and intensive care doctor, is discussing her position in the simulation compared to the position she usually holds in real situations.

Intensive care resident: *“I had the feeling to be in the position of the leader doctor that is new to me. During my three months residency at the ‘déchoc’ [where trauma patients are admitted when arriving in the hospital], I only held the position of the follower [main role is to perform technical tasks such as catheter insertion]. I never really made any decision on critical patients.”*

Trainer (Intensive care doctor): *“Actually, we should reposition ourselves, when we can be several intensive care doctors, and let you [the residents] hold the position of leader. We can’t really be the follower.”*

Intensive care resident: *“Otherwise it could imply to bring in two intensive care residents, one with the senior doctor saying “you manage the situation, I stay behind”, and the other to equip the patient”*

Trainer (Intensive care doctor): *“Yes indeed when it’s possible, we should possibly do it that way”.*

In this dialogue, we can see that the debriefing gives rise to organizational issues leading to possible new organizations that are debated and adjusted during the debriefing.

#### **4.5 Discussion**

Beyond their importance as a core part of simulations to perform training and provide knowledge to trainees, debriefings can be seen as appropriate time for work debate spaces, as defined by Rocha, Mollo and Daniellou (2015). Indeed the results of this study show it is possible, during the debriefings, to discuss the real work practices through the enforcement of rules, the good practices or any feedback items. The results also demonstrated that debriefings enable the discussion of organizational issues, with a possibility to transform some practices. For those reason, organizations could benefit from paying attention to the debates occurring during the debriefings as a way to “take the temperature” of the real practices and to some extent evaluate the current safety culture. Debriefings are also an opportunity for organizations to initiate debates on potential changes and a collective reflection on the safety culture.

Furthermore, if supported by the organization, trainers could play a major role in spreading the knowledge on the real work practices as it is revealed during the debriefings. It could benefit the organization, as mentioned earlier, but also support the training goal in sharing amongst the teams the knowledge of good practices (e.g. the ‘beep’), the potential good team organization or even provide an awareness of the variability of practices (e.g. the dilution topic).

A post-simulation debriefing does not necessarily lead to such open feedbacks. Another study in the field of nuclear energy demonstrated that the attitude of the trainer during the debriefing might have a direct impact on the possibility to have open discussions on real practices (Masson, 2013). For instance, trainers who see the enforcement of rules as strict and who behave as being superior or ‘better knowing’ than trainees open less opportunities for debating on real practices. On the other hand, trainers considering the real-life practice as a combination of normative and adaptive safety and who behave as peers with trainees enhance debates on real practices. Other studies describes the various possible attitudes of trainers during the debriefing (Rudolph *et al.*, 2007).

#### **4. Conclusion & perspectives**

From the study of ten post-simulation debriefings, we have provided new concrete evidence that they provide a highly relevant space where information can emerge, related to the sharing

of good practices, the enforcement of rules, the discussion on feedback items, and the opportunities for enhancement of work organization.

These post-simulation debriefings should thus be seen as major assets for organizations to grasp the reality of the many dimensions of real work, to initiate change through debates and to develop a balanced normative/adaptive approach to safety.

In the perspective of implementing an actual process of enhancement of practice in an organization, two axes to optimize the outcome of debriefings seem of particular relevance to us:

- The training of trainers, to assure that they interact with trainees in the best way to stimulate strong emergence of information on real practices within the space of debriefings
- The construction of technological tools to help gathering and consolidate knowledge from debriefings and help feeding relevant and convincing information to organizations.

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## Care activity regulation in a day hospital depending on nurses, patients and system

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### Abstract

*Context:* During recent decades, growing interest was expressed at new forms of hospitalization that reduce significantly patient stays. In order to satisfy goals of quality, safety and performance, without sacrificing their well-being; nurses continually adjust their operating procedures.

*Objectives:* Analyze individual and collective, mechanisms of adaptation and regulation deployed by nurses and their articulation with hospital organization and specify the conditions that promote their development or that impede their implementation.

*Methodology:* The study was conducted with the nurse team of a day hospital unit, devoted to the diagnosis and treatment of cancer, based on open and systematic observations, interviews preceded and provoked verbalizations.

*Main results:* In order to continue to provide care activities, nurses develop coping strategies, regulations and adjustment process, depending on the work situation characteristics and its different perception between expert nurses and experienced ones. The First developed a more complete view of the future situation, reorganize their own activities in time and space and operate "ahead of the situation" to prevent "probable future overload situations". While, aiming to immediately generate additional time, experienced nurses reduce time allotted to nurse consultation and administrative tasks to complete more "useful activities". Whereas, expert ones extend the consultation beyond the prescribed time preparing patients to be less « nurse time consumer » during the hospitalization day and consider administrative tasks important in terms for the traceability of service activity and its image for the hospital direction.

*Conclusion:* For nurses, time refers simultaneously to three dimensions: "Working time", "patient time" (related to the dynamic nature of the cancer disease) and to "benefit one". Moreover, individual and collective regulation methods adopted by experienced and expert nurses reflect their different approaches of care activity: the first "act for the patients or instead of them", while the second «do with the patient".

**Keywords:** nurses activity, regulation, care relationship

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### 1. Introduction

In France, as in many developed or developing countries, reforms have proliferated during recent decades in the public hospital, following a double awareness and mediatization of on the one hand, the importance of safety, on the other hand the necessity to avoid waste (Lega,

Preneštini & Spurgeon, 2013, Pierru, 2009). As consequences, public hospitals have been invaded by economic logics and management methods borrowed from the industrial world and aiming mainly to promote patient safety, efficiency and profitability through the rationalization and optimization of expenses (Bouzgarrou, Bouzgarrou & Benchekroun, 2014; Mas et al., 2011). Caregivers were forced to deal with these logics which were different and often paradoxical to their jobs perceptions (Acker, 2005; Mas et al., 2011). Health policies express growing interest at new forms of hospitalization that reduce significantly patient stays and the risks of undesirable events, like ambulatory hospitalization (Acker, 2005; Heyden & Mollo, 2013). These new organizations of hospitalization require healthcare teams, particularly nurses, to provide a reliable service, under a high level of time pressure, intensification and reconfiguration of the nurses' work (Acker, 2005). In this context, nurses need to adjust their operating procedures in order to satisfy goals of quality, safety and performance, without sacrificing their well-being and health. A discomfort was felt among the nursing staff with a large number of nurses leaving the profession prematurely, an important rate of absenteeism and a high number of work-related diseases developed (burnout, musculoskeletal including back pain) (Desriaux, 2009; Läubli, 2006; and Benchekroun Malet, 2012). Indeed, the quality of work desired and claimed by these professionals was undermined. They may not perform their jobs properly and their health is often affected (Clot, 2010; Ravallec & al., 2009; Desriaux, 2009; Benchekroun & Malet, 2012). Nurses are faced with an almost continuous conflict between "doing quickly" and "doing well". "Doing well" unavoidably consumes time and human resources. This is particularly important in nursing activities, since it is based on a particular form of service relationships that involves dimensions of "care" and of "taking care." (Benchekroun & Malet, 2012; Cerf & Falzon, 2005; Nascimento, Falzon, Thellier, & Jeffroy, 2009).

## **2. State of the art: Care relationship: from paternal model to co-productive one**

The activity of care is a particular service, due to the specificity of the object of the work that is the human being (Falzon and Lapeyrière 1998). For operators, this activity is characterized by a heavy physical load, high cognitive load, an emotional involvement towards patients experiencing weakness and suffering; as well as the confrontation, almost continuous, - with death or the ideas attached to it (Malet and Benchebroun, 2012). In addition, the care activity involves a dimension of "care" and "take care" as it was explained by Malet and Benchekroun (2012). The dimension of "taking care" exists even in the most technical moves such as handling. Indeed, this kind of care which is often reduced to its biomechanical dimension bears the double meanings namely "cure" and "care" (treat and care). However, as a result of the bulk of constraints imposed on nurses, especially those related to the business activity and working time; the "take care" dimension is increasingly absent in the acts of care. This loss partly explains the "discomfort in profession" (Estryn Behar et al, 2011; Malet and Benchebroun, 2012; Martin and Gadbois, 2004)

Parallel health care system users' profile is changing with patients increasingly demanding and requesting of information and the right to information. Thus, care relationship evaluated from a paternal model where knowledge is exclusively held by the care giver, to a shared and co-productive one characterized by an active participation of the patient on the treatment project (Cerf and Falzon, 2005; Falzon, 2011; Mollo, 2010; Nascimento & Falzon, 2009).

## **3. Objectives and Methods**

The objective of this paper is to understand the articulation between nurses' activities and the hospital organization during the day. More specifically, we wish to analyze mechanisms of adaptation and regulation, individual and collective, and to specify the conditions that

promote the development of these mechanisms or that impede their implementation, particularly those in relation with nurses' experiences and their perception of the care relationship.

The study was conducted in two phases with a five nurse team of a day-unit in an inter-communal hospital in France. The unit was mainly devoted to the diagnosis and treatment of bronchopulmonary cancer patients. In fact, patients are admitted in the unit, usually need either multiple heavy explorations - which required at least three technical platforms -, either extensive care and treatments, especially oral or intravenous chemotherapy with the obligation of a regularly continues monitoring. The first phase, lasted three weeks, and was dedicated to open observations. It aims to the familiarization with the field of the study, understand the global activity of nurses, their interactions with other professionals in the department and the overall hospital functioning during the day. During these observations, informal interviews were performed with all the nurses as well as the medical staff, orderlies and the chief physician and nursing supervisor framework.

The second phase which lasted nine weeks was dedicate to systemic observations, elicitation interviews and provoked verbalizations. Systematic observations were structured with a grid of observable classes and descriptors of nurses' activities and characterizing the situation of the observed work.

During the intervention, the regulations of nursing activity allowed us to distinguish between expert (02) and experienced nurses (03). The first have an experience exceeding four years and assume an informal role of referent within the team, have a direct relationship with the medical hierarchy; and they are recognized as experts in their fields by their peers. Experienced nurses have less than three years of experience; they are recognized by peers as mastering their roles and missions.

#### **4. Results & Discussion**

In the day hospital unit nurses activity combines both, technical acte of care (treatment administration, biological sample for analyze...), organization and orchestration of patient hospitalization day and administrative tasks (recording, encoding...). Indeed, nurses coordinate of the different appointment of patient in the unit (medical visit) and in the various technical platforme of the hospital (radiological exploration service, functional exploration...). Moreover, they also provide consultation for patients for whom the diagnosis of cancer was established and announced by the treating physician. This consultation is scheduled on 30 minutes and allows notably resuming - with the patient - the key elements of the announcement medical consultation and of the proposed treatment project. Finally, the nurse activity in the day hospital unit, involves non-technical care, corresponding mainly to the accompaniment and information of patient and even his family and entourage.

Since open observations, we noted that, nurse activity was subject of multiple constraints. Urgency and time constraints were the major one with which nurses composed in day hospital unit.

To continue providing care activities - while fulfilling objectives of safety, quality and productivity- nurses continually adopted, various collective and individual coping strategies and develop different regulations and adjustment process. The choice of these strategies depends both on the characteristics of the work situation, and the different perception between experts nurses and experienced ones of this situation and of the caregiver-patient-relationship.

Indeed, to achieve their activities objectives, expert nurses developed a more complete view of the future situation of the unit by collecting different data like the patients' flow and the

physicians' availability. Thus, they operate « ahead of the situation » and anticipate and plan for the prevention of "probable future overload situations". Additionally, expert nurses, thanks to their global vision of the unit activity, reorganize their own activities in time and space. Typical examples of various forms of regulations identified among experts' nurses and experienced were observed during nurse's consultation activity.

Indeed, experts extend the consultation beyond the prescribed time: they offer a consultation for a period that often exceeds 30 minutes with an average of 38min and try to prepare patients as best as they can to be less « nurse time consumer » during hospitalization day. They provide to patient information that go beyond to the "traditional" information relating to the diagnosis and treatment regimen". These additional explanations are especially about the practical progression of the hospitalization day (administrative procedure, chronological order of acts to perform and interests...), and the practical development of the various phases of chemotherapy and the "early warning indicators" of possible side effects. Experts nurses finish the consultation by administering information brochures available and insist on patients to well read and understand them before the hospitalization day. More over experts nurses encourage patient and even his accompanying to be "active" and suggest them to look for additional information on the internet if necessary, to learn about the issue and discuss.

While experienced nurses often reduce the time allotted to the consultation in order to immediately generate additional time. They conduct their consultations for 15 to 25 min and limited it to the prescriptions, which may be sometimes even incomplete. They take back the medical diagnosis with the patient and resume according to the support possible adverse effects of the treatment before providing to him informational brochures. Explanatory section of expected hospitalization day progression is often not included or reduced to an average talking time of 03 minutes.

Similarly, during the day briefing, while experienced nurses limit they change of information to medical characteristics of the patient, experts nurses exchange larger speech about medical personal and psychosocial characteristics such as illiterate, language difficulties, anguish, absence of family support, and even incident during previous hospitalization (delay on arrival, nurse's aggression by one parent..)

Moreover, regarding administrative tasks,, experienced nurses reduce the time allotted to these tasks in order to gain time and complete more "useful activities", expert nurses see these tasks as important in terms of the service activity of the unit, of its traceability and of its image for the hospital direction.

The elicitation interviews noted the important and the dimension of time constraint for experienced and expert nurses in the day hospital unit and especially two different considerations and perceptions of care activity in light of these different dimensions.

According to all nurses, time constraints in the day hospital have a threefold meaning. The first refers to "working time" in its conventional meaning: it refers to the finalization workload in the delay allotted for the act; while respecting the timing of prescribed tasks and temporal coordination with the activities of others staffs (medical team..) with whom they share the working space. The second meaning is the "time for the patient" depending on the dynamic nature of the disease. The prognosis of malignant diseases; therapeutic response, the healing process and patient quality of life are largely dependent on how early the therapeutic management is performed. Nurses develop a special awareness around this dimension of time. As they are responsible for fixing appointments, they shall aim at reducing delays, especially between the diagnosis, the nurses' consultation, and the first hospitalization for chemotherapy. The third dimension of time developed by the nurse team in day hospital is the "time benefit ". Indeed, following the adoption of the billing system to the act (fee for

service), patients flow (turnover) had become one of the most important indicators of the care activities insured and prescribed in this hospital structure. Thus, the evaluation of each nurse of the day unit and their activity (so these opportunities to advance in his professional status) is done according to the "number of acts coded" by this person.

According to nurse's interview, this last dimension, does not only impact their individual evaluation and the progress of their career, but it also determines the "weight and the power" of the unit and thus in major part the budget that will be accord to it. This is why, in addition to the various above mentioned meanings of time, nurses incorporate the question of profitability and the number of acts to be performed and the number of patients registered in unity with an extra dimension of emergency to perform their activity and more pressure related to the bigger number of patients to take care of at the same time in the unit.

The nurse's consultation is an activity that is approached with different modes of regulation especially between nurses expert and experienced, particularly in terms of the degree of patient involvement in the care process. On the one hand, the experienced nurses explained that they adjust the duration of consultations according to time constraints on the day of the consultation. Their regulations depend primarily on the immediate and impending situation. When these constraints are important, the experienced nurses reduce this time by limiting the consultation to the written documents. Experts' nurses, on the other hand, express a more global vision of this consultation activity. They agree that the conduct of their activities is strongly influenced by the patient. Depending on the degree of patient preparation for the hospitalization day, care activities will be more or less fluid. Overtime (in comparison to the time prescribed) that is invested in nurse's consultation, allows a better flow of hospital days for the patient. In this context, expert nurse regulations relate to future care situations. These nurses choose to devote more time at the first consultation to save time at future hospitalization day. They encourage patients to become more actively involved in the care process, to create additional possibilities and maneuvers to prevent situations at risk of overflow: They try to prevent especially periods when they may be overwhelmed by a significant number of activities to perform in a very limited time. So that, the patient is approached as an active collaborator that may help in preventing these situations when is well informed and prepared.

## **5. Conclusion & perspectives**

Nurses in the day hospital are particularly subject to significant time constraints (Clot et al, 2004; Ravallec et al 2009 ). These operators, to achieve their objectives, employ multiple adjustment modes, and individual and collective adaptive strategies (Clot et al, 2004). These regulations often aim to reduce the time cost of the task to create additional possibility to act. Were observed, during nurse's consultation, different regulation strategies. Were observed, during nurse consultation, different regulation strategies. In this respect, we distinguish two main methods of regulation of care work between the experienced nurses that is "do for the patient or instead him" and expert nurses that is "do with the patient."

The experienced nurses consider that the nurse consultation is an expensive task in terms of time. The adjustments are often about reducing the time of this consultation. For experts nurses, the nurse's consultation is considered as a suitable space to push the patient to become an active participant in the treatment project. They invest additional time during the consultation to well prepare and "orchestrate" the patient to become a co-producer of the health service (Falzon and Mollo, 2007) . This co-production between patients and nurses, allows to these latter to prevent overflow situations and to have additional control possibilities for care activities and margins for maneuver in terms of time (by thinking differently their future activities).

Certainly the highlighted side of this timing strategy is to keep the patient adequately informed and will not need to ask questions about hospitalization, it is thus a facilitator of the activity which becomes more fluid. Approached like this, the patient becomes an additional resource for nurses to better regulate their activities and create extra possibilities for maneuver. This process of patient empowerment can also enable active participation in the safety of care for example with early detection of adverse effects (Mollo, 2010). Similarly, it can be a more invested axis in terms of work experience for the nurse and care relationship, on the one hand, and on the quality of care, on the other hand (Starkey et al, 2003 ; AUjoulat et al 2007)..

A legitimate questioning may emerge about the possible risk of an "empowered" patient who would be more demanding in terms of explanation of the care activity with a higher time cost. This hypothesis could even be more radical. Indeed, providing the information on the treatment foreseeable risks and side effects could lead the patient to refuse treatment. In this case, can we say that this becomes a risk that reduces the quality of care?

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## An innovative example of patient education: the Family Learning Socio Sanitario

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### Abstract

*Context:* Long term conditions are profoundly challenging both the doctor-patient relationship as well as the healthcare organisational settings. Health Education, which is often still based on a traditional functionalist approach (information dissemination, control and reinforcement mechanisms), should also be affected by this challenge.

*Objectives:* The paper focuses on an innovative scheme of health education: the “Family Learning Socio Sanitario” translatable as “Health Care and Family Learning” (henceforth FLSS). FLSS has been developed by the Interdepartmental Research Centre on Health and Social Care Integration (CRISS) of The Polytechnic University of Marche using an action-research approach, the purpose being to help care providers to meet the needs of patients with chronic diseases or conditions and their families. The paper will review the overall scheme in order to point out its distinctive features in comparison with similar programmes, and to draw some theoretical considerations regarding the possible trajectories of change in healthcare settings.

*Methodology:* The paper is mainly theoretical and it is based on: the review of the international literature on therapeutic patient education and self-management programmes; the analysis of FLSS scheme and the results of the questionnaires on patients’, families’ and health personnel’s satisfaction.

*Main results:* Some features distinguish FLSS from other types of educational programmes that have been introduced over the years. It is a professionally-led intervention based on cooperative teamwork and targeted to patients together with their family members: it embraces a relational, holistic approach as it considers the relations of interdependence among patients, caregivers and professionals. The final questionnaires that evaluated the satisfaction with the programme, the competencies acquired, and improvements in the quality of life, show that patients and their kin appreciated the relationship with the health and social professionals, and the sharing of the illness experiences with other families. Patients and families felt they had gained new knowledge about the disease and how to handle it. The professionals also expressed satisfaction with the programme, especially for the cooperation with both colleagues and families.

*Conclusion:* This kind of therapeutic pathway is almost inexpensive for health-care providers and facilitates the integration of health and social care to get it closer to patients and families’ needs. It shows the possible dialogue between scholars who deal with the issues of patients’ education and Human Factors principles such as effective communication, teamwork, participatory design and community ergonomics.

**Keywords:** patient education, empowerment, health literacy, chronic diseases, doctor-patient relationship

## 1. Introduction

Italy has one of the highest old-age indexes in the world. The constant increase in the elderly expands the segment of the population which is the most exposed to chronic-degenerative health problems. Long term conditions are profoundly challenging the Parsons' paternalistic conception (1951) of the doctor-patient relationship as well as the healthcare organisational settings which were based on the acute-care model. The idea of a dyadic relationship between a 'distant' professional solely focused on the disease, and a fairly 'passive patient', dependent on medical assistance and willing to do everything the former tells him/her in order to restore health has been partially overcome. New concepts of patient's choice, activation, engagement and empowerment thus gain ground (Gruman *et al.* 2010; Deccache & Ballekom, 2010). Patients are beginning to ask for more explanations and involvement in clinical decision-making (Charles *et al.* 1997). Moreover, physicians usually have a long-term relationship with their patients and health assistance mainly occurs outside the hospital, directly involving families. On the other hand, technological improvements, such as reliable in-home self-medication devices, foster this evolution, allowing the self-management of many chronic conditions. Chronic diseases thus reshape the previous scenario and require changes both at the meso-organisational level and at the micro-relational one. As regards the former, community health centres and inpatient treatment become more important than hospitalization when long-term care is concerned. Furthermore inter-professional teams intervene in the treatment and the coordination of the whole care process and become one of the key issues for the quality of the health assistance. Individuals with chronic care needs must, in fact, access a number of diverse systems of care— specialized and non-specialized, formal and informal, medical and social - that need to be integrated.

On the other hand, cuts in health expenditure and spending review have worsened the working conditions in healthcare: both internal conflicts and those with users are increasing and, as a consequence, the level of stress and dissatisfaction of health personnel. Giving this scenario it is unavoidable to project interventions which can improve both patients' (and family's) and healthcare professionals' wellbeing, considering them as the two faces of the same coin rather than conflicting parts. Many local experiences are trying to reorganize health assistance in favour of a new partnership between health service providers, professionals and users. Health Education, which is often still based on a traditional functionalist approach (information dissemination, control and reinforcement mechanisms), should also be affected by this challenge.

In this background, the Research Centre on Health and Social Care Integration (CRISS) of The Polytechnic University of Marche has developed an innovative scheme called "Family Learning Socio Sanitario" (translatable as "Health Care and Family Learning", henceforth FLSS), the purpose being to help care providers to meet the needs of patients with chronic diseases or conditions and their families. The program has been developed using an action-research approach, in close collaboration with competent public health authorities and health personnel. The authors of this paper who are members of CRISS' work team<sup>1</sup> defined the guidelines for the program in regard to its structure, schedule, contents, length, etc. and supervised the implementation of the courses in various health-care settings. All the courses were held in Marche Region (central Italy), which shows a very large number of elderly persons with long-term conditions.

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<sup>1</sup> The research team that devised and implemented this program was coordinated by one of the author, M.G. Vicarelli and included a sociologist, the co-author M. Bronzini, a quality manager, the co-author A. Deales, a psychologist, M.T. Medi, a pedagogist, M. Serenelli and a medical internist, M. Candela.

In order to meet patients' and healthcare professional's needs the design of the intervention echoes many Human Factor principles, such as the topics of teamwork, communication, cooperative work, participatory design, community ergonomics. The paper wants to stress the possible connections between scholars who deal with the issues of patients' education, such as the authors, and practitioners of organisational ergonomics.

## **2. State of the art**

Several types of educational programs have been introduced over the years (Deccache, Ballekom, 2010; Vicarelli, 2012) according to different national health-care settings (Hoving, Visser, Dolan Mullen, Borne, 2010). Many of them have been held by health-care providers and have a strong medical focus. Often they merely bolster therapeutic autonomy, that is another way to pursuit *compliance* with prescription, disowning the ideas of empowerment and participation (Deccache, Ballekom, 2010). Critical reviews underline that they can ultimately «be seen as part of a broader pedagogic process through which the state, claiming an objective of 'empowerment', seeks to train its citizens to become more effective in delivering official objectives» (Barnes, 2011, p.168). In reaction to the former, patients' associations have begun to arrange autonomously their own programs, often relying on self-help groups (e.g. self-management or expert patient programs) (Lorig, 2003; Lorig et al., 2006). They stress the importance of the patients' perspective and their right to have a say in the care process. These courses are usually more focused on psychological and motivational contents than on clinical knowledge and their principal purpose is to strengthen self-awareness. However, these initiatives are sometimes seen as a "nightmare" (Shaw & Baker, 2008) by clinicians who are forced to interact with more informed, but sometimes misinformed, patients with a lower degree of compliance. Some authors (Eve, Mares & Munro, 2003; Taylor & Bury, 2007) underline therefore that this approach may reproduce the contrast between 'expert's knowledge' and 'lay knowledge' and the gap between formal care and informal care. As a reaction health professionals may adopt a defensive attitude and withdraw from the 'care scene', focusing exclusively on the cure dimension (Vicarelli & Bronzini, 2009). Examples of an integrated and shared learning process based on a participatory design and involving both families and the health and social services system are still rare. This is exactly what the FLSS program has tried to do. In family learning courses the relationships among health professionals, patients and families contribute to the creation of both an 'expert family' and a new type of cooperative clinical care. It is worth going into this intervention in more details, describing the way this scheme has been set-up and implemented.

## **3. Objectives and Methods**

The aim of FLSS is to foster the health literacy and the empowerment of families managing a chronic disease at either a severe stage or an early one. This approach broadens the notion of the 'expert patient' (Rogers et al., 2006; Taylor & Bury M, 2007; Wilson, Kendall & Brooks, 2007) since it considers the whole family system which is involved in the management of long-term conditions. Moreover, it embraces an authentic relational, holistic approach and focuses on the relationships of interdependence among different subjects and other elements of the environment. It intends to be a new model of intervention for the chronically ill that yields benefits in both healthcare quality and effectiveness, organizational wellbeing and the quality of life of families.

FLSS differs in some peculiar features from other health education and self-management programmes (Lorig, 2003; Vicarelli & Bronzini, 2009; Vicarelli, 2012). First of all it not intended to be a separate activity of therapeutic education based on standardized contents, but

it is rather part and parcel of the care process and context specific. A group including health and social professionals and representatives of patients' associations is established at the local level in order to tailor the CRISS's general guide-lines to the local setting, the organizational constraints and to the characteristics of the chronic condition to be dealt with. They discuss, decide and share the contents of the course and the methodology, as well as the enrollment criteria - e.g. diagnosis, seriousness, place of residence, age, etc. This is guided by an inter-professional approach: each expert shares her/his competences on the disease with the others, thus recreating the 'tiles' of a holistic knowledge that vertical and horizontal specialization has contributed to fragmenting. The presence of representatives of patients' association is critical to define all the needs of patients on which to build the objectives of the intervention of family learning. Given this joint planning, there is implicitly a second group involved in the training process: the group of health and social professionals. This is clearly not a traditional form of training but a process of reflexive cooperation (Schon, 1983) and *self-directed learning through experience* (Eve, Mares, Munro, 2003).

Secondly, the course in itself consists of 10 weekly meetings lasting on average 2 hours and 30 minutes. On each meeting, one of the health professionals briefly illustrates some aspects of the disease and mainly discusses with participants their experiences and answers any questions or doubts. This requires explicitly recognizing the importance of psychological aspects such as locus of control, self-efficacy, belief systems, but also the influence of the social contexts in which individuals are embedded. To bring the illness back to its social environment, the meetings are held in a communitarian setting, e.g. a school, library, council hall, rather than in healthcare facilities, in order to create a setting conducive to learning and to favor supportive interactions, e.g. the circular arrangement of chairs, snack, etc. (Hoving et al., 2010). The venue should in fact facilitate an egalitarian interaction. Indeed, the professionals shed their white coats and move from their dominant position in the hospital wards, or in their surgeries, to a 'neutral' setting and a situation of numerical 'inferiority' to their interlocutors. The interaction order is reversed as well, since the professionals instead of directing the dialogue are subject to a broad set of questions, doubts, stories, and sometimes even the anguish of their audience (Vicarelli & Bronzini, 2009).

#### **4. Results & Discussion**

A total of 29 courses have been carried out since 2007 in many health districts in the Marche region. They have been developed for different chronic diseases, chronic obstructive pulmonary disease (COPD), amyotrophic lateral sclerosis (ALS), acquired severe brain injury (ABI), and also for specific learning disorders (SLD). A new course for patients with heart failure using telemedicine is currently ongoing. Several health-care providers are showing a growing interest in this scheme, as the request to adapt it to Alzheimer's disease, multiple sclerosis and sleep apnea proves. The lack of an appropriate clinical assessment, so far, is a serious shortcoming, but the evaluation of clinical outcomes of the FLSS course for COPD, involving 133 patients and 12 health districts, is currently ongoing.

Nevertheless health professionals reported some changes in patients' behaviors and attitudes that influenced both their quality of life and the clinical appropriateness. A final questionnaire evaluated for each course the satisfaction with the programme, the competencies acquired, the relationship with healthcare professionals and the quality of life. We will present the main outcomes of the last courses. They show that patients and their kin appreciated the relationship with professionals (table 1), and the sharing of the illness experiences with other families and gained new knowledge about the disease and how to handle it. Many changes in everyday habits were observed as well, as regards, in particular, physical exercises and diet.

Furthermore, the participation in the program enhanced the overall attitude towards the chronic condition and reduced worries.

Courses	Satisfaction with the program:				The knowledge of the disease is:			
	Very satisfied		Quite satisfied		Greatly improved		Improved	
	%	a.v	%	a.v.	%	a.v.	%	a.v.
COPD (patients)	72%	86	26%	31	18	22	65	78
COPD (family members)	79%	38	19%	9	10	5	75	36
ALS (patients)	77%	10	23%	3	23	3	69	9
ALS (family members)	61%	20	39%	13	12	4	76	25
SLD (family members)	92%	12	8%	1	38	5	61	8

**Table 1.** Satisfaction with the program and knowledge improvements

As concerns the professionals, one common initial reaction was to reject the need for more information, but at the end of the course they realized that giving information or advice does not necessarily mean that the receivers really understand them. An anecdote concerning a patient who had been hospitalized and released not long before the beginning of the course clearly illustrated it. The physician who had treated realized during the FLSS meeting that the patient had not understood at all the recommendations he had given her during the hospitalization. Generally the health professionals involved were quite satisfied with the program (table 2), despite the organizational commitment that it required and the need to be involved in a way far from their usual approach in the clinical relationship.

Professionals' satisfaction	The program		Cooperation with colleagues		Cooperation with families		The after-effects on families	
	Very satisfied	Quite satisfied	Very satisfied	Quite satisfied	Very satisfied	Quite satisfied	Very satisfied	Quite satisfied
COPD	40%	49%	38%	40%	43%	41%	32%	48%
ALS	56%	40%	47%	46%	54%	44%	39%	54%
SLD	44%	56%	33%	44%	22%	78%	22%	67%

**Table 2.** Professionals' satisfaction

To be stressed are, in particular, the answers to the question of whether they had learned something new from the ‘lay’ participants: respectively 50%, 81% and 56% of the health professionals involved in the COPD, ALS and SLD courses said “yes” and 37%, 14% and 44% said “yes, in part”. The health professionals welcomed this new way to interact with patients, and one of them declared during the evaluation: *«it is the best initiative since I have been working here, and for me it is a defense against burnout»* (SLD course, professional). What they appreciated most was, once again, *«the involvement of all professionals in both planning and execution»* and *«sharing ideas and activities among different practitioners and especially with parents»* (SLD course, professional). The conclusion of many of these courses with a convivial event is indicative of the appreciation on the part of both families and professionals. These relational outcomes are particularly meaningful in a context in which health professionals are increasingly forced to take refuge in a ‘defensive’ medicine. In this respect it seems that FLSS scheme allows not to «lost a real opportunity to let patients enter the health system and change it with us» as Deccache and Ballekom (2010, p. 286) suggested.

## 5. Conclusion & perspectives

Some features of the FLSS program distinguish it from both the other health education and self-management programs that have been so widely implemented in the USA and in some European countries (Lorig, 2003; Lorig et al., 2006; Vicarelli & Bronzini, 2009). The traditional functionalist approach still dominant in the biomedical paradigm has been widely extended to health education, which is often based on a logic of information dissemination, control and reinforcement mechanisms. From this perspective “information, as Bateson says (1972), does not take into account the relations but only content to be transmitted” (Medi & Serenelli, 2008). This is the main difference with respect to the FLSS program, which embraces an authentic relational, eco-systemic approach and considers the relations of interdependence among those involved to be an interactive ‘dance’ which assumes specific configurations. This requires the acknowledgment that health itself is not a quantitative outcome of individuals’ decision and choices. Rather, it is a process involving the relationship between patients and their family or social networks, the relationship between patients and professionals, as well as the relationship between the two groups. It is thus necessary to combine the ‘logic of linearity’ that often underpins the development of guidelines, recommendations, and many clinical and patient education programs, with the ‘logic of complexity’ surrounding social situations and human dynamics. At the organizational level the FLSS program aims to reaffirm an integrated system of care. The growing specialization has led to large health care teams involved in the care process and to the need for coordination and effective communication among them. As we have seen, the family learning courses are designed together by healthcare professionals and patients from their needs and are managed by multi-professional, interdisciplinary and usually inter-organizational teams. This is indeed a way to share the care responsibilities among different providers (Scheid, 2004). It helps healthcare professionals to overcome the sense of isolation, due to growing specialization and fragmentation. Moreover, it aims to foster a different kind of relationship with patients and their families, a ‘high touch’ one, which can prevent or reduce professionals’ ‘burn out’ and dissatisfaction with their work.

This kind of therapeutic pathway is almost inexpensive for health-care providers and facilitates the integration of health and social care to get it closer to patients and families’ needs. Its implementation on a broader scale could also help to meet cost reduction targets for long-term care and to overcome the harmful aspects of the excessive standardization and fragmentation of health care. Therapeutic education can pave the way to the reorganization of services and involves both healthcare professionals and communities that are typical topics of organizational ergonomics.

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## Stopping incidents in their tracks: Identifying weak signals for error prevention in healthcare

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### Abstract

In order to adjust performance to ensure the success of a task and prevent error, it is necessary to anticipate, identify and respond to signals indicating changes in the system. The objectives of this study were to investigate weak signals within two different healthcare case studies by identifying key elements and behaviours of these tasks. This study investigated both Safety-I and Safety-II elements with four expert groups, two from the field of patient handling and two from the field of patient discharge. The Safety-I and Safety-II elements explored included potential errors, influencing factors, weak signals and learning opportunities arising from the investigated situations. The errors identified by the focus groups were related to skill, knowledge, inappropriate equipment, equipment misuse, lack of communication, missing or incomplete information, incorrect technique, and preconditions not being fulfilled. The influencing factors identified by the two case studies included patient-related factors, time and space-related factors as well as organizational and managerial factors such as available resources and safety culture. The weak signals identified in both case studies were analysed using the SEIPS 2.0 model. The sources of the signals were identified as originating from the work system elements “person”, “tasks”, “organization” and “internal environment”. The manifestation forms of the weak signals included the different sensory signals as well as the experience of intuition or “hunches”. Potential learning opportunities to improve signal recognition were identified and included the need for reflection and empowerment, continuous assessment and the sharing of information between the involved systems. The proposed framework and method provide a preliminary basis for the investigation of weak signals and assists in highlighting the role that the weak signals can play in safety behaviour.

**Keywords:** weak signals, errors, patient handling, patient discharge

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### 1. Introduction

Traditionally, safety has been defined as the absence of harm, whereby the number of adverse events is as low as acceptably possible (Hollnagel, 2014). Resultantly safety is measured indirectly based on the state when safety is absent and the focus is placed on incidents and adverse events, which then has practical consequences and limits the possibility of learning to events that only occur infrequently (Hollnagel, 2014). As a result of the limitations caused by the traditional definition of safety, in recent years a new definition of safety has emerged, resulting in new opportunities for assessing and improving safety (Hollnagel et al., 2013). The new definition of safety, Safety-II, focuses on the ability to succeed so that the number of planned outcomes is as high as possible under varying conditions (Hollnagel, 2014). Performance variability within a system is both normal and a necessity for the functioning of

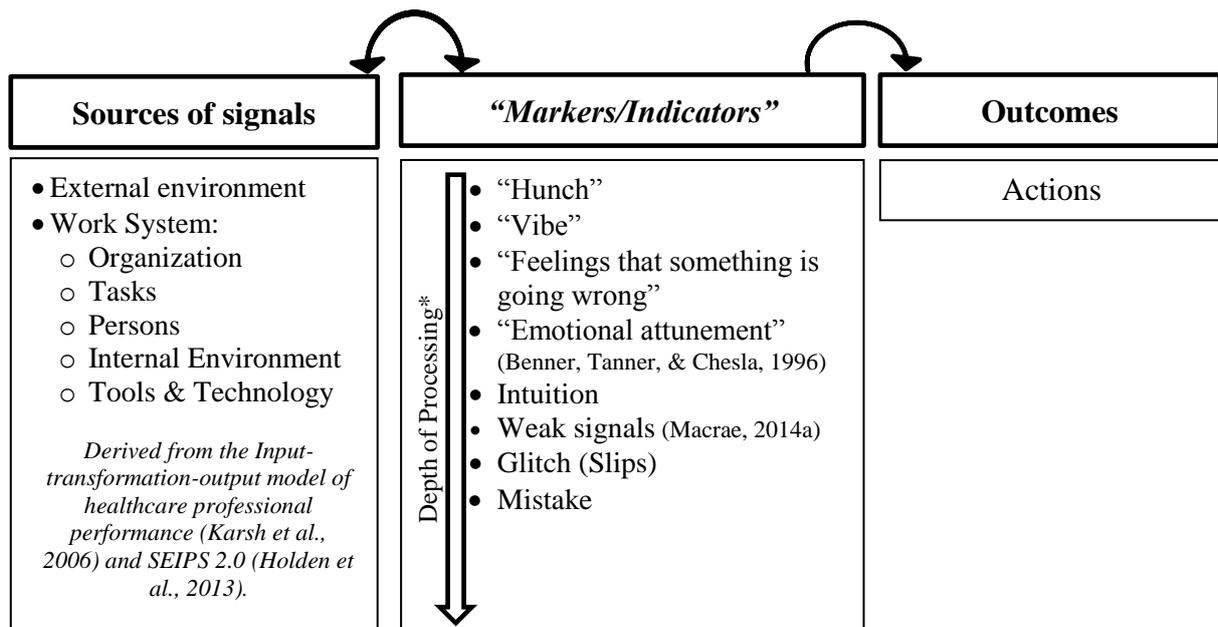
the system (Hollnagel, 2014), and Safety-II aims to provide insight into how individuals, departments and organizations within the system continually achieve planned outcomes despite adversity (Vogus & Sutcliffe, 2007). As yet, there is only very limited data, literature and methods for studying human and organizational performance success as defined by Safety-II (Hollnagel, 2014).

One element of Safety-II is the ability to adjust performance to ensure success of the task and this requires anticipating, identifying and responding to signals indicating changes in the system (Hollnagel, 2014). By anticipating potentially events, monitoring the current state, responding effectively when something occurs and learning from past experiences, a system has the potential to become more resilient to adverse events (Hollnagel, 2009). The strength of the signals of risk that can lead to anticipation are often weak and ambiguous. These weak signals can be defined as information, vague in nature, regarding imminent events (Ansoff & McDonnell, 1990), which require interpretation and sense-making (Weick, 1995). Often these weak signals need to be actively sought out and created by processing interrelated existing events, prior knowledge and future expectations in order to understand the information they provide (Macrae, 2014a). Through the early detection of unexpected events, they may be addressed in a more cost-effective and timely manner (Vogus & Sutcliffe, 2007), but failure to notice the warning signs may result in the risks being normalised, and remaining dormant until an adverse event occurs (Macrae, 2014a, 2014b).

Weak signals may provide an opportunity to achieve proactiveness through the required awareness, monitoring and constant vigilance needed for the identification of these signals and the up-to-date information regarding ongoing operations they provide (Vogus & Sutcliffe, 2007). Effective risk management requires continuous identification and addressing the problems that threaten safety (Macrae, 2014b) and identifying weak signals may offer means of reducing risk and responding early to hazards. This highlights the role that weak signals can play in safety behaviour. Increasingly accident reports include indicators or signals prior to an event that, had they been acted upon, would have altered the course of the event. Despite this, research exploring weak signals and the role they may play in safety, especially in healthcare, is limited.

## **2. State of the art**

This work draws on strategic management theory, specifically that of Ansoff and colleagues (1990), as well as traditional human factors models, while considering both Safety-I and Safety-II definitions. A framework for the investigation of weak signals was developed in order to analyse and understand weak signals in the context of the work, actions and events in the system in which they occur. This preliminary framework is depicted in Figure 1.



\*Depth of processing can be described by the Skill-rule-knowledge model (Rasmussen, 1983)

**Figure 1.** A proposed framework for the investigation of weak signals in relation to safety behaviour

This framework has been based on the Input-transformation-output model of healthcare professional performance (Karsh et al., 2006) as it provides a general multi-level model of a work system, as well as having considered open systems theory. The model was then further expanded to incorporate more specific elements from the second version of the Systems Engineering Initiative for Patient Safety (SEIPS) model (Holden et al., 2013). The SEIPS 2.0 model was selected as it provides a framework for the analysis of processes and the relationship of various elements that occur in healthcare (Carayon et al., 2006). The signal source element in Figure 1 was expanded and structured to incorporate the work system elements from the SEIPS 2.0 model. The processing and influence the signals may have on performance can be explained by the skill-rule-knowledge model of behaviour (Rasmussen, 1983). By considering the source and type of information these signals provide, insight regarding the status of the system and areas of risk may be revealed (Macrae, 2014a).

### 3. Objectives and Methods

The objectives of this study were to investigate weak signals within a healthcare context. Two different case studies were selected with the aim to explore the strategies individuals use to detect, interpret or respond to variations in the work environment. The case studies selected included patient handling as well as patient handover and discharge from a hospital setting into the community. Both case studies adopted an explorative method using focus groups and aimed to explore elements of potential errors, influencing factors, signals regarding task failure, behaviour related to failure prevention and learning opportunities.

In each case study, two focus groups were held with expert staff and were 45 minutes in length. Once an introduction to the research topic had been provided wherein the aims of the research and the pertinent information for participants had been explained, participants were asked to complete a consent form. Following this, basic demographic information comprising of the participant's age, current position, and number of years involved in patient care was collected. Subsequently the focus group commenced, whereby discussion was lead and

directed through a series of questions by the lead researcher. The discussion points addressed during the focus group were generated using the following questions:

1. What can go wrong with this task? (Error)
2. What external factors will influence this task? (External Factors)
3. How do you know the task is going wrong? (Trigger)
4. When you know it is going wrong, how do you correct yourself? Can you pre-empt the task? (Reaction)
5. Do you use this knowledge next time you do this task? (Learning)

The discussions from the focus groups were recorded using two audio recorders and one researcher recording field notes. During the discussions, the lead researcher compiled a summary of the key points raised by the groups on a white board or flip chart. The audio data was transcribed by the researcher E. Burford and analysed together with the field notes and summary points made during the discussion. The weak signals were then analysed using the Input-transformation-output model of healthcare professional performance (Karsh et al., 2006), as well as the SEIPS 2.0 model (Holden et al., 2013).

## **4. Results & Discussion**

### **4.1 Participant Characteristics**

Both case studies had two focus groups with experts who had at least 5 years of experience in patient care. The groups in the patient handling case study consisted of a group of 10 participants from the Loughborough Alumni Research Forum (LARF) in patient handling and a group of 7 manual handling advisors from Western General Hospital in Edinburgh. The group from Loughborough had a mean age of 54 years ( $\pm 7.69$  years) and had a mean total of 30 years ( $\pm 12.14$  years) involvement in patient care. The group from Edinburgh had a mean age of 45 years ( $\pm 7.17$  years) and had a mean total of 25 years ( $\pm 7.95$  years) involvement in patient care. The positions held by the participants included manual handling advisors or coordinators, manual handling area leads, back care advisors or managers, a head of manual handling and a director manual handling consultant. The groups in the patient discharge case study consisted of two groups of expert community staff with various qualifications and roles, involved in the discharge process, from two different directorates in Nottinghamshire county. The first group consisted of 7 participants with a mean age of 45 years old ( $\pm 8.91$  years) and had a mean total of 20 years ( $\pm 10.06$  years) involvement in patient care. The second group consisted of 7 participants with a mean age of 40 years old ( $\pm 9.91$  years) and had a mean total of 18 years ( $\pm 11.28$  years) involvement in patient care. These groups were comprised of registered community nurses, physiotherapists, an occupational therapist, a community matron, a team leader of a care home team, an admissions and discharge facilitator and a locality team lead.

### **4.2 Safety-I**

Traditional Safety-I elements, namely errors and influencing factors were selected to initiate the discussion as adverse events and the influencing factors are usually highly memorable elements. The patient handling groups focused on two specific tasks namely a lateral bed transfer and an assisted transfer from a seated position to a standing position. The common errors identified included errors relating to inappropriate equipment use, lack of teamwork and communication with team members or the patient, poor postures, the task preconditions not being met, a lack of knowledge or skill and incorrect techniques being applied. Potential factors that would influence the task and task-related behaviour identified by the groups included patient dynamics, time and space-related factors, poor safety culture as well as staff

stress. The one group also included policies as a negative external factor from the perspective that policies could lead to a lack of situation awareness and risks being normalised. The common errors identified in the patient discharge case study included errors relating to inappropriate or missing equipment, lack of communication between the different services involved in the process, missing or incomplete information or documentation as well as missing medication or inadequate packages of care. Potential factors that would influence the task and task-related behaviour identified by the groups included patient-related factors, time-related factors, other service providers as well as hospital organizational factors. These organizational and managerial factors may not only influence the worker and task but also may affect the identification, interpretation and response to signals identified.

### **4.3. Safety-II**

In both case studies, participants were asked to consider and discuss how they knew the task was going wrong and signals or cues that indicated this. These signals may be considered as an element of Safety-II as they have the potential to change the course of the task if they are acted upon and may aid in ensuring that the task is completed successfully. The signals identified in the patient handling case study consisted of heightened awareness due to an unfamiliar aspect or element of the task, visual or sensory signals such as seeing or feeling that the brakes on the bed were not activated prior to the patient being transferred, feedback from the patient, trained memory cues, for example a rhyme to ensure all safety aspects of the task were completed, individual checks such as those developed through personal experience, being less task orientated and more situation aware, and questioning actions. By being less task orientated and more situation aware, an individual may be more receptive to signals and be more aware of how the task is progressing. Furthermore, by questioning actions one would hopefully negate the negative effects of habituation such as risks being normalised and explained away. These behaviours may assist in making the system with regards to this task more resilient as it allows the system to function despite potential disturbances or variations (Hollnagel, Braithwaite, & Wears, 2013).

The signals identified in the patient discharge case study that assisted in detecting if a discharge may fail included signals such as seeing the patient's physical state and the state of their home, the experience of the interaction with the patient's family, for example if family is continuously contacting health services for support, as well as the behaviour of the families such as becoming intense and disengaged during interactions with community staff. Signals were also derived from patient documentation and included key elements of the patient history as well the history regarding readmissions. The staff mention in the focus groups that they felt that the identification of these signals were a key component of the work they do, in order to adapt the patient treatment plan so that the patient would not be readmitted.

From the combined results of both case studies, the information pertaining to signals could be classified according to SEIPS 2.0 model whereby the sources of signals corresponded to the work system elements and the manifestation form of the signals corresponded predominantly to the work process elements of the model. The sources of the signals could be categorized as the following elements from the work system: "person", "tasks", "organization" and "internal environment". Examples of signals originating from "person(s)" in the system included trained memory cues, individual checks, the patient's physical state and feedback from the patient and their family. Signals originating from the "internal environment" included the state of the patient's home. The forms or manifestations of the signals included the different sensory signals as well as feelings that could not be describe in more detail other than the experience of intuition and can be associated with the elements of the work processes

described in the model. These forms included heightened awareness due to an unfamiliar aspect or element of the task, and visual or sensory signals.

An additional aspect of Safety-II discussed during the focus groups included the learning opportunities needed from the identification of weak signals. These included the need for reflection, continuous assessment, the need for empowerment, and the sharing of information between the various systems involved. By incorporating reflection into the work environment, the rest of the team, co-workers or the individual themselves would benefit from the experience of learning to recognise signals more readily. Continuous assessment may provide the opportunity to identify any signals that may originate from the patient or the environment. The need for empowerment would provide the opportunity for staff to question actions and potentially change the course of action based on a signal received. These suggested learning opportunities mirror the proposed means of improving safety with regards to signals by actively producing and amplifying signals, as described by Macrae (2014a). For these learning opportunities to be realised one would need to ensure that learning and adaptation occurred throughout the organization as the organization as a whole would need to assist in ensuring that the work environment allows for reflection, continuous assessment and empowerment at individual, at unit and potentially at other levels. Here the organization's safety culture could have an influencing role in providing the potential means of training and ensuring the environment is available for identifying these signals.

## 5. Conclusion & perspectives

The method above investigated both Safety-I and Safety-II elements. The Safety-I element addressed in this study included potential errors that may result in adverse outcomes whereas the Safety-II elements investigated included signals and learning opportunities. These Safety-II elements may assist in improving the ability to succeed under varying conditions (Hollnagel, 2014) and therefore make the system more resilient. Additionally, weak signals may also provide a means for effective risk management in that through the continuous identification and addressing the problems that threaten safety (Macrae, 2014a), one may identify means of being more proactive, reducing risk and responding to hazards early. The proposed framework and method provide a preliminary basis for the investigation of weak signals and assist in highlighting the role that weak signals can play in safety behaviour. Further investigations are required in order to identify the types of signals that are present in tasks as well as identify which influencing factors promote or inhibit signal identification.

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## Implementing PC's on nurse's care-trolleys in a university hospital

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### Abstract

*Context:* The new technologies impacts a lot of situations in the society, in the work conditions and in the hospitals. From the communication systems to the last enhancing reality devices, the number of changes that we already experience, or that are coming into our work systems soon, is great. In our hospital, one of these evolutions is the digitalization of the whole patient-related-data with a central software. This paper presents the preliminary analysis of the needs for a care-trolley with mobile computer. The aim of the analysis is to help deciders in the choices for future computerized-care-trolleys.

*Objectives:* Identify the relevant criteria for a digitalized care-trolley and the nurses' work implications for the use of this new tool configuration.

*Methods:* The methods used are: direct observations and physical measures, users interviews and questionnaire, and evaluation of several actual digitalized care-trolleys on the market.

*Main results:* The actual care-trolleys are used to carry several objects that may be different from a service to another: depending on the specialty, the nurses use material to go at the bed of their patients. Today the nurses write the patient information on a "maxi-card". This maxi-card is used for the shift transmission. Then after the care operations, the nurse sits at a desk of the central desk to type the maxi-card information's in the computer.

The corporate decision to avoid the use of the maxi-cards is being implemented in the hospital for several years. The first trials of taking a PC on the care-trolley to directly type the information taken at patient's bed showed several issues, that will be presented.

*Discussion/perspectives:* Two models seem to be the "least worst" solutions for the moment. The limits of a care-trolley with computer are: the space limitations in the rooms and other workplaces implicating the difficulty to maneuver it. Adding a PC increases considerably the discomfort perceived by the user. The tentative of putting a PC on the existent care-trolleys is not successful. The typing at the patient's bed reduces the opportunities for the nurses to seat several minutes during their shift. In this project the technical and healthcare safety criterias are much more important than worker's conditions. Our aim is to integrate the human impact on our workers too. Two models seem to be the "least worst" solutions for the moment. The limits of a care-trolley with computer are mainly the space limitations in the rooms and other workplaces implicating the difficulty to maneuver it. A standard solution applicable for whole configurations can not be found today. To give nurses the possibility to choose their work devices is a necessity so that the device responds to their practical needs. Including ergonomic analysis should also prevent misfitted devices and balance the "patient-oriented" preoccupations.

**Keywords:** digitalized care-trolley, standing and sitting, age-related drudgery, computerization, nursing

## 1. Introduction

This paper presents the preliminary analysis carried out during a project initiated to improve a work device used by nurses. New information and communication technologies are extending in health care systems of OECD's countries (Anderson et al. 2006). This evolution impacts the Lausanne university hospital (CHUV) in many fields.

The population increase in the Vaud region, and the implementation or development of new specialties increases the number of patients of the hospital. The space occupancy is a recurrent issue and the maximization of space occupation rate is an important challenge for the institution.

The Lausanne university hospital employs 10'000 persons comprising 69% of women and 113 nationalities. The hospital has about 1460 beds, and an occupation rate of 87%. About 46'000 patients are hospitalized each year. There are 10 care sections: Medicine, Surgery, Obstetric-gynecology, Pediatric, Orthopedic, Clinical neurosciences, Oncology, Intensive care, Radiology, Psychiatry. Non-care sections are also comprised in the workforce, such as Logistics and Administration (« Rapport annuel CHUV 2014 » 2016).

The professions are distributed as shown in Figure 1. 37,7% of the workforce are nurses. The nurses are the professionals that are mainly concerned by the care-trolley modifications. A great number of nurses work in shift work. Depending on the specialty, nurses work in 12h/12h shiftwork or 8h/8h/8h.

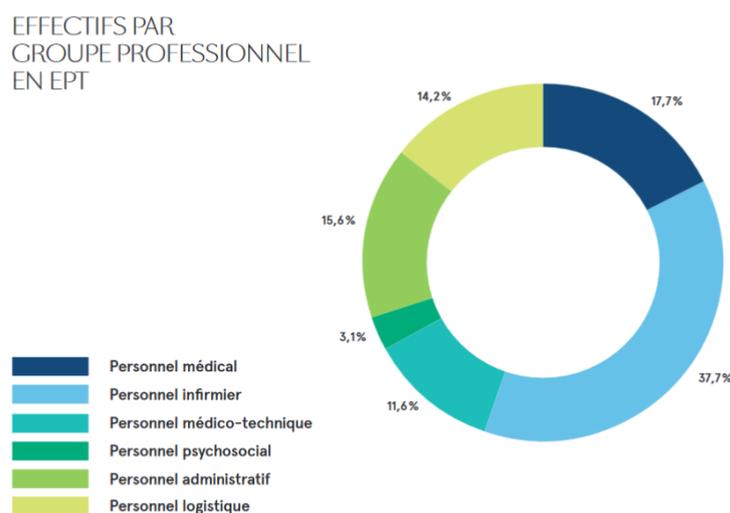


Figure 1. Professions repartition in the hospital (percent of full-time equivalents)

The author is part of the Occupational Health & Safety Team, which counts 2.2 full time equivalent (FTE) Occupational hygienists; 0.8 FTE Ergonomist, 0.5 FTE Psychologist.

The new technologies impacts not only everyday life but also hospitals work environment. From the communication systems to the last enhancing reality devices, the number of changes that we already experience is very important. Tomorrow's upcoming changes will be even more radical. In our hospital, one of these evolutions (revolutions?) is the digitalization of all patient-related-data which are stored in a central database. The goal is to achieve a paperfree system to improve work efficiency and decrease administrative work burdden. The digitization process is mainly done by the nurses and health care personal. It is done using a care-trolley which is also a support to a computer for introduction of information into the central database. Both stationary and mobile computing technologies within health care have been promoted as the approach most likely to achieve the greatest results for clinicians and their patients (Andersen et al. 2009) (Ammenwerth et al. 2000). There is a risk of work

condition deterioration if the care-trolley's configurations are inappropriate and if the work organization doesn't include seated breaks. The consequences can be an increase of workers fatigue or pains, which may cancel the benefit of a central database.

The introduction of computerized care-trolleys could decrease the occupation time of seated workstation, as the work previously done at seated workstation will be done at the care-trolley. The care-trolleys are also seen by management as an opportunity to free some office space, as the nurses will do their computer work in the patient room, or in the corridors. This will reduce the use of the central office-desk.

This change could increase painfulness due to heavier work-conditions. Indeed, the State Secretary for Economic Affairs (SECO, 2009) recommends that standing work posture has to be alternated with sitting work periods or short breaks. In addition, nurses work is known as being heavy (Malet et Benchekroun 2012); (Askenazy 2004)). The introduction of computerized care-trolleys will massively decrease sitting occasions time of nurses' work.

The implementation can also be disrupted by pervasive stereotypes of older workers: that they experience difficulties in adjusting to change and technology. “Additionally, older workers may also hold similar ideas about their own abilities and believe the negative stereotypes” (Conne and Brooks, in Duffy 2013).

This paper presents the preliminary analysis of existing computerized care-trolleys to better select the most appropriate trolley for mobile personal computer use in hospitals. This first analysis includes only the option of PC on wheels. Softwares for tablet's devices are not analyzed in this paper as they are not available yet.

## **2. State of the art**

An increase of low back pain (LBP) is expected as it is well known that the prevalence of LBP is higher when a person reports standing in a constrained position for his job than standing with the freedom to sit» (Gallagher, Campbell, et Callaghan 2014) (Messing, Stock, et Tissot 2013). It has been shown that the longer the standing work cycle is, the longer the duration of a break is required to decrease pain development. Therefore there is a risk of work-conditions deterioration. This negative impact of the computerized care-trolley's implementation may be increased by the general idea that seating position is not admitted as a work position for non administrative works, even if the work could be efficiently realized in a seated position (Messing et al. 2005).

The recommended setup for a standing computer workstation is not a simple transfer from the sitting configuration (Lin, Catalano, et Dennerlein 2016). The standing workstation in health care field is part of a dynamic work at the patient room (care giving). Therefore, static standing workstation recommendations are not directly relevant but can serve as guidelines for the workstation specifications. “The right mix of stationary and mobile devices is a significant challenge for system planners and implementers” (Andersen et al. 2009).

The nurses age has also an impact as stereotypical fears imply less self-confidence even if chronological age is a poor predictor of technical learning capacity (Conne M.B. and Brooks D., in Duffy 2013).

In addition, the electronic communication system reduces the need to meet the team members and direct social contacts should decrease. This can reduce the quality of team work if it is not compensate by organizational changes (Haberey-Knuessi, Heeb, et Morgan De Paula 2013). We have to keep in mind that there are not only physical and logistical issues with the cart-digitalization. Organisational, social and psychological changes are also appearing. These could appear by a resistance to change that has been widely studied (Bonneville et Sicotte

2008). This paper does not include the analysis of these aspects for lack of time at that point. We should pay special attention to these aspects in the futur.

### 3. Objectives and Methods

The aim of the analysis is to help deciders in the choices for future computerized-care-trolleys.

The methods used are: direct observations and physical measures, users interviews and questionnaire, and evaluation of several actual digitalized care-trolleys on the market. During the test periods, for patient's safety and workload reasons, the nurses had the possibility to use their well-known method with paper.

The tests took place between april and december 2015 in three hospitalization services.

### 4. Results & Discussion

The actual care-trolleys are used to carry several objects that may be different from a service to another: depending on the specialty, the nurses may need large tools or material at the patient's rooms. Today the nurses write all patient information concerning his health situation or the events that occurred during the work period on a so-called "maxi-card". This maxi-card is a paper form that is filled during consultation using handwriting. It also serves for information transfer at shift transmission. Then, after the care giving, the nurse sits at a desk of the central office to introduce the maxi-card information's into the central database. The same data is entered two or thee times which implies loss of time and an increased risk of error.



Photo 1. Paper documents (maxicard) used actually

The management decision to avoid the use of the paper-supports is being implemented step-by-step in the hospital for several years. The ergonomists are optionally consulted by the hospital departments. This kind of change is often initiated by the management without an early integration of the partners.

The present analysis began with the first implementations.

The fact that the care givers who tested the new devices could keep the paper if they judge it necessary has certainly distorted the questionnaire results. Four of the five users interviewed admitted that they tried whole device (Trolley & PC) maximum 3 times per day, because they were faster working with their well-known way.

This difficulty was predictable in a real situation test where priority is given to patients' safety and care quality.

#### 4.1 First devices: adapting the existing trolleys

The first trials of taking a PC on the care-trolley to directly type the information taken at patient's room showed several issues that are presented hereafter. The primary trials of adapting the trolley were to add a support on the existing trolleys: it rotates in one axis and the

height can't be adapted. These first devices have not been successful: The nurses didn't use the PC at all.



Photo 2. Modification of a care-trolley to implement a PC

The first issues that generate complaints were:

- inaccessibility of the keyboard for several nurses and the obstruction of the work surface.
- device impedes also the maneuverability in some contexts
- global discomfort
- electrical charging is also an issue: in the firsts models, the computer was sealed with the trolley (for security reasons) and only few persons could unsealed it with a key.
- when the PC needs to be charged, the place where it has to be plugged must be great enough for the whole trolley and the trolley can't be used.



Photo 3. Plug-in zone for the computerized trolleys

We saw also these issues:

- no arm support while typing
- display and keyboard positions are interdependent and cannot be adjusted independently
- standing position
- use of the mouse and keyboard at different height, introducing shoulder discomfort
- hygiene requirements not fulfilled for the PC (easiness to clean)

The analysis of this situation identifies several issues associated with the use of care-trolley with computer. The following list of criteria were identified and used for the care-trolley evaluation.

The criteria are:

- Size (easiness to maneuver and stock)
- Heaviness
- Accessibility of care tools
- Accessibility of the PC
  - Keyboard position
  - Display position
  - Mouse pad vs/ mouse

- Height of the working plan
- Accessibility of the drawers
- Easiness to clean
- Possibility to use the computer in a seated position

There are several devices for PC on wheels in the market, some propose the conjunction of PC and care trolley. These were the kind of trolleys requested by the care-services. The possibility to use it in a seated position would have been a plus to decrease nurses' fatigue due to standing posture. However, this constraint has to be set aside as it considerably complicates the trolley's design by imposing huge ranges of device adaptation.

#### 4.2 Sample of computer-care trolleys devices on market

3 models were selected by the hospital's Purchase Department:

##### A) trolley with removable PC-cart



Photo 4. Model A

##### B) Trolley with removable PC-cart



Photo 5. Model B

##### C) Currently used trolley with addition of an articulated arm for PC support



Photo 6. Model C

#### 4.3 Interviews & questionnaire

Non-structured interviews were conducted during the observation of the activity, between two tasks. The questionnaire was filled by the users having tested the trial models between 3 and 5 working days. Three different models were tested:

- A) trolley with removable PC-cart (tested by 23 nurses)
- B) trolley with removable PC-cart (tested by 10 nurses)
- C) Currently used trolley with addition of an articulated arm for PC support (tested by 6 nurses)

*Interviews*

Semi-structured interviews could not be hold during this evaluation due to lack of time and low nurses' availability. However, the author could gather comments from 5 users during the observations.

The main issues that the users reported were:

- Heaviness and non-maneuverability for both models A&B, specially for the B.
- With B model: use of the working surface is impossible when the PC is used (no sufficient place). Drawers' inadequacy for some specific tools (doppler).

All the models were perceived as not practical nor adapted to patient's rooms arrangement.

*Questionnaire results*

The original questionnaire was in french and has been translated for this paper.

Users evaluation			
	A	B	C
Heaviness for moving it (very easy 1, very difficult 10)	5	8	8.1
<b>Manoeuvrability in patient room</b> (% yes)			
possible ; possible but difficult	67%	14%	100%
impossible	33%	86%	0
<b>PC Usability</b> (% yes)			
easy and comfortable	0	0	50%
easy	83%	40%	0
difficult	17%	60%	50%
Difficult and painfull	0	0	0
<b>Working plan big enough for care material</b> (% yes)	57%	50%	50%
<b>Accessibility of the drawers (easiness to open them)</b> (% bad)	80%	20%	0%
<b>Storage capacity of drawers</b> (% sufficient)	87%	57%	100%
<b>General adequacy of the device</b> (% good)	58%	33%	67%

Table 1. Users evaluation synthesis

The proportion of situations where the trolley could not be maneuvered in the patient's room is very important for the B model. The C model, which is the actual trolley modified, is perceived as very heavy to move but can reach most positions in the patient's room. The model A's drawers were difficult to open in the first device proposed by the supplier.

**4.4 Observations and physical evaluation**

The A & B models had a modular use: the computer device was removable from the care-trolley. This option was not tested by the users: the aim was to find an adequate device with both functions. The metrical measures have been focused on the Care-trolley with PC.

Physical evaluation - synthesis			
	A	B	C
<b>Accessible working surface = 50x70 cm (+or-5 cm)</b>	no	no	yes
<b>Accessibility of the PC</b>			
Keyboard position: can the arms rest?	no	no	no
Display position: inclinable 0-20°?	yes	no	yes
Mouse space sufficient and in the same level than keyboard?	yes	no	no
Height of the keyboard between 95 and 122 cm	yes	yes	yes
Visibility during transportation worsen?	yes	yes	no

Table 2. Physical evaluation

All models showed lack of arm rest possibilities while typing. Only the A model offers a mouse support at the same level than the keyboard. The B model showed several issues with the display tested, such as impossibility to tilt it and change its height. During transportation, the visibility was poor for the tree models, but specially with models A & B.

## **5. Conclusion & perspectives**

The A and the C model seem to be the best compromise solutions for the moment but far from perfect. The limits of a care-trolley with computer are: the space limitations in the rooms and other workplaces implicating the difficulty to maneuver. Adding a PC increases considerably the discomfort perceived by the user. The user's critics have been collected after testing the devices during 3 to 5 days in real work conditions. The advantage of having a realistic test has been biased by the possibility that care-givers had to use their well-known paper method. We have to integrate this impact in the user's evaluation results. These implementation barriers for these kinds of mobile devices in healthcare practices have been noted by several authors (Andersen et al. 2009) (Martins 2005). A longer trial period with more compulsory rules should circumscribe the evaluations and give more accurate results.

The PC use will certainly be replaced by some smaller hand-held device in the next years. The tentative of putting a PC on the existent care-trolleys was not successful with the existing models. The option of installing a PC in the patient's room is also discussed. The standing typing at the patient's bed reduces the opportunities for the nurses to seat several minutes during their shift. This remains a neglected issue: for the IT team, the buyers and the healthcare managers, this seems not relevant for the choice of next generation of trolleys. As ergonomists, we have to advise about this issues and the impact of this changes on the work's drudgery level. In this project the technical and healthcare safety criterias are much more important for the decision-makers. Our challenge is to integrate the human impact on our workers too. The complexity of evaluation of the impacts of a tool change that modifies the way of working and the work-conditions is complex. General quantification of these impacts in the different healthcare services is almost impossible. A standard solution applicable for whole configurations can not be found today. To give nurses the possibility to choose their work devices seems to be a necessity so that the device responds to their practical needs. Including ergonomic analysis should also prevent misfitted devices and balance the "patient-oriented" preoccupations. It appears that the possibility for the device to be usable in a standing and a seated position, worsens both use situations. A light computer on wheels, maneuverable, compact and attached or attachable to the care trolley seems to be the best compromise. The nursing practices are in constant evolution aiming improved efficiency. The process of new technologies implementation are first challenging: we want to improve our efficiency without creating new issues. In the care-trolley's computerization case we have to think about the sitting possibilities for nurses during their work and this implies organizational adaptations.

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## Towards effective and efficient participatory systems approaches to healthcare work system design

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### Abstract

*Context:* The study is focused on patient and public involvement in the regional service development process in one county in the UK, with a wider scope provided through review of literature.

*Objectives:* The research has two main objectives: firstly to investigate the current state of service user and staff participation in the regional health service development process in the UK; and secondly to critically analyse the level of participation and systems awareness in the participatory methods used.

*Methodology:* A single case descriptive case study is used alongside a scoping review of relevant literature that follows a systematic approach.

*Main results:* The case study explored a complex service development process with the main findings being: i) varied levels of collaboration between multiple organisations of commissioners, providers and user representatives; ii) incomplete information loops with an unclear structure of information flow from service user/staff into the development process and a lack of feedback on changes made to service users; iii) difficulties in representing the views of a diverse population of service users, compounded by some single issue focus amongst service development participants; iv) an engagement gap with staff for service development events. The literature review uncovered practical issues in the application of participatory approaches and a lack of application of systems methods and models in the most widely used participatory approaches.

*Conclusion:* The review of literature and description of practice found a gap between the practical application of participatory approaches in healthcare system design and theory on systems approaches to healthcare. We propose it would be beneficial to bridge the gap between structured systems approaches to healthcare system design and the current efforts of participatory design occurring in practice.

**Keywords:** healthcare ergonomics, systems approach, co-design, participation

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### 1. Introduction

It is understood that it is necessary to take a systems approach to healthcare quality improvement to provide sustainable and significant quality and safety improvements to healthcare systems (Carayon et al., 2014). Systems approaches require the involvement of relevant stakeholders to be at their most effective (Hettinger et al., 2015), in healthcare, staff and patients bring a wealth of knowledge that is needed to understand and improve healthcare systems. Furthermore, involving stakeholders and end users in design is prevalent in contemporary Human Factors and Ergonomics (HFE) theory and practice, with collaboration

between healthcare and HFE professionals necessary for the discipline to reach its full potential in benefitting healthcare (Waterson & Catchpole, 2015).

Patients possibly have the most complete view of the care they receive and with their families could be useful problem detectors within the healthcare system (Amalberti & Vincent, 2016). However, motivations for patient involvement in healthcare go beyond quality improvement and safety, with service user involvement in the planning and development of healthcare services recognised as a democratic right in nations such as the UK (NHS, 2013). Accounts on the history of patient and public involvement in the UK health service shows involvement spanning both democratic and consumerist approaches (Butler & Greenhalgh, 2011; Coulter, 2013). The democratic and consumerist approaches to involvement are discussed by Beresford (2002) who, while recognising the approach models may blur together at times, describes significant differences between the two. The consumerist approach is said to be framed mainly in market research terms of improvement of products and services through data collection of market testing and feedback, with the initiating agency (e.g. care provider) then deciding what to do with that data and what changes to make (Beresford, 2002). Whereas the democratic approach views inclusion as the achievement of people's human and civil rights, and is concerned with enabling participants to have direct capacity and opportunity to make change (Beresford, 2002). In HFE and design these involvement models can be related to those of user centred design (consumerist approach) and participatory or co-design (democratic approach). Participatory ergonomics and design describe benefits of stakeholder involvement beyond problem identification, with increased relevance of devised solutions and in the implementation of change; with the proposition that stakeholders are more likely to accept and drive towards changes they have ownership of (Gyi et al., 2015).

This study seeks to explore the current state of involvement and participation in health service design and whether this involvement is done with awareness of the systems approach.

## **2. State of the art**

User involvement and in particular co-design has become increasingly popular in its application to public services, with examples in health (Nesta, 2013), transport and education (Bradwell & Marr, 2008). A type of participatory design has been developed for application to healthcare services in the form of Experience Based Co-design (EBCD) (Bate & Robert, 2007; Robert et al., 2015) with the use of EBCD growing since its 2005 pilot (Donetto et al., 2015). EBCD is a six stage process that can take 9 to 12 months to complete. It involves gathering staff, patient and carer experiences, and using small co-design groups to work on identified priorities and culminates in celebrating and reviewing the project (Robert et al., 2015). A toolkit for EBCD can be found on the King's Fund website (King's Fund, 2013).

## **3. Objectives**

This study set out to investigate the current state of service user and staff participation in the regional health service development process. The specific objective was to critically analyse the level of participation and the systems awareness in the methods used. The study aims to identify current implementation gaps to be addressed and the need for further research in order to achieve the effective and efficient application of participatory systems approaches to the design of healthcare services.

## **4. Methods**

The study includes both a case study and literature review.

## **4.1 Case Study**

A descriptive case study approach (Yin, 2013) was adopted to gain a detailed understanding of how participatory approaches were applied for health service development at a regional level in one county in the UK. The case study was centred on one Clinical Commissioning Group (CCG) which plans and purchases health services for a population of 366,000. Data were collected through six semi-structured interviews, documentary analysis and observations at meetings and events.

The six interviewees consisted of members of patient representative groups (n = 4), commissioning group patient experience officers (n = 1), and a member of the voluntary and community sector (n = 1). The documentation used for analysis consisted of reports and meeting minutes from staff and service user engagement events, collected for the period of January to September 2015, 35 documents were included in the analysis. Topics covered in the interviews included: descriptions of service design approaches, information flow between stakeholders, level of stakeholder engagement, barriers to collaboration and use of IT support. Observations were made at service development board meetings, engagement events and market research events. The data from observations, documents and interviews was converged and analysed thematically. Ethical approval was granted from the Loughborough University ethics committee and the research was deemed as non-portfolio work thus not requiring NHS ethical approval. All participants gave informed consent.

## **4.2 Literature Review**

The review aimed to answer the following research questions:

- What methods of participation have been used in healthcare service and system design?
- What challenges were found in applying participatory approaches to healthcare?
- What opportunities exist for future research?

The electronic databases of Google scholar, Scopus, Science Direct and PubMed were searched using combinations of the search terms healthcare/health service and participatory design/co-design/participatory ergonomics and co-creation. To prioritise articles the review includes articles on projects where patients, public and healthcare staff had been actively involved in analysing and designing a healthcare service, process, organisation or work system.

## **5. Results**

### **5.1 Case Study Findings**

The case study explored a complex service development process with the main findings being:

- i) varied levels of collaboration between multiple organisations of commissioners, providers and user representatives;
- ii) incomplete information loops with an unclear structure of information flow from service user/staff into the development process and a lack of feedback on changes made to service users;
- iii) difficulties in representing the views of a diverse population of service users, compounded by some single issue focus amongst service development participants;
- iv) an engagement gap with staff for service development events;

The involvement process most closely resembled a consumerist model, with data collected from service users and then processed and presented to commissioners and health service providers through reports and oral presentations. The providers and commissioners then decided what to do with the data and how to use it to inform design. Data collection was undertaken through surveys, short interviews and some workshop activities involving emotional mapping and the sharing of a developed vision for community health services. The main issue raised at the data collection stage regarded difficulties with representation of service users and frontline healthcare workers. Time constraints for busy working healthcare staff and service users make involvement in lengthy service development events difficult. There is also difficulty in representing the diverse population of service users and particularly seldom heard groups, these issues were expressed in the interviews e.g.:

‘The difficulty is how to get in touch with the 12,000 people though. Which is how many we represent’ - Interview 5

‘It’s the people that you never get, we’ve not yet cracked how to engage them’ – Interview 4

‘In my view you’re not necessarily getting a broad spread of people. And often it’s driven from a personal agenda rather than a wider agenda’ – Interview 2

It was unclear how the information collected from service users was translated into service changes by healthcare providers. At the same time, there was a lack of feedback of changes to service users. This was also mentioned by three interviewees:

‘And I think the next bit of the loop is how do we then go back and go full circle to make sure that the improvements or the recommendations we’ve made: A. are being taken seriously and B are being implemented.’ – Interview 2

‘They don’t tend to give us much feedback on how we’ve influenced them. As an organization it can be quite difficult to see what impact we’ve really made.’ – Interview 1

‘A lot of people have told us that they can’t see, and we said this at consultation, where have they done it? They haven’t. So there’s that kind of disconnect.’ – Interview 1

‘We’re not always very good at feeding back. And I know when I’m out talking to people, one of the things they say is that you don’t really feed back to us do you.’ – Interview 6

On the methods used within the process, there was limited application of service design methods and no evidence of HFE system design methods. The experience gathering methods used were based on EBCD, with emotional mapping in use, and there were some co-design elements within service development, however EBCD itself was not found to be carried out in its entirety.

## **5.2 Literature review**

After screening titles and abstracts, 46 articles were taken forward for full text review, after removal of theory based articles, duplicates and those without access to full text versions, 28 articles relating to 19 projects were included, a summary of these is provided in Table 1.

References	Project application	Participatory methods	Participants
Bowen & Dearden, 2010 Bowen et al., 2010 & 2013 Morrison & Dearden, 2013 Wolstenholme et al., 2010 & 2016	Outpatient services for older people	Co-design (EBCD)	Patients and staff
Cooper, Gilmore & Hogg, 2016	Adult psychological therapies service	Co-design (EBCD)	Patients and staff
Donetto et al., 2014	Survey of EBCD applications	Co-design (EBCD)	Patients and staff
Gustavsson, 2014	Neonatal care	Co-design (EBCD)	Patients and staff
Larkin et al., 2015	Mental health	Co-design (EBCD)	Patients and staff
Locock et al., 2014 Locock et al., 2014	Intensive care and lung cancer in England	Co-design (Accelerated EBCD)	Patients and staff
Mulvale et al., 2016	Child and youth mental health	Co-design (EBCD)	Patients, families and staff
Pickles et al., 2008 Bate & Robert, 2007b	District general hospital neck cancer service	Co-design (EBCD)	Patients and staff
Springham & Robert, 2015	Mental health and community services	Co-design (EBCD)	Patients and staff
Tsianakas et al., 2012	Breast and lung cancer services	Co-design (EBCD)	Patients and staff
Bowie et al., 2015	Design of a safety checklist at a general practice	Co-design – face to face workshops - Adapted Delphi technique	Staff
D'Young et al., 2014	Services for adults with haemophilia	Co-design - focus groups	Patients and family members
Elg et al., 2012	Orthopaedic, rehabilitation and gastroenterology care processes	Action research - Patient diaries - Workshops with staff	Patients and staff
Farmer and Nimegeer, 2014; Farmer et al., 2015; Nimegeer et al., 2011	Rural primary healthcare services	Action research - Card sorting	Public
Hempe et al., 2013	Specialist service for adults with intellectual disabilities	Delphi method	Carers, staff, policymakers
Anderson & Broburg, 2015	Hospital work systems	Simulation – full scale mock-ups and table-top models	Healthcare and industry professionals
Xie et al., 2015	Family-centered rounds process	Participatory ergonomics	Staff and patient representatives
Bullinger et al., 2012	Design of products and services for rare diseases	Open innovation health platform	Public, patients
Den Breejen et al., 2012	Clinical guideline development	Wiki as a participatory tool	Patients

Table 1. Summary of literature

### 5.2.1 Types of participation

All of the included projects had recognisable elements of the democratic model of involvement. Of these 12 of the 19 projects referred to co-design as the participatory method used within the project, with 10 of those using EBCD. Simulation, action research, the Delphi technique and participatory ergonomics were the other face-to-face participatory approaches used. In 2 projects the web was used, through an open innovation platform and a wiki as a participatory tool.

### **5.2.2 Effectiveness of participatory approach**

Many of the articles were limited in formal evaluation of the approaches used; however most of the reflections on co-design methods were positive about the approach. One of the main criticisms of co-design and specifically the EBCD approach is in the seemingly small-scale changes when considering the time given by staff and patients to see projects to completion (Donato et al., 2014). One previous co-design project has reported on a lack of sustainability in quality improvement, with improvements that occurred during the project beginning to reverse once the co-design had ceased (Springham & Robert, 2015). There is a lack of evidence on the long-term impact of participatory approaches.

### **5.3 Representation**

Representation is a key issue found in both the case study and literature review. Participants in the case study reported on the difficulty in representing diverse populations and a reported gap in staff engagement in participatory work. Literature reported on the difficulties in representing multiple stakeholders (Xie et al., 2015), potential bias on self-selected participants in using both the Delphi technique (Bowie et al., 2015; Hempe et al., 2013) and co-design (Tsianakas et al., 2012) and difficulties in involving vulnerable patients (Mulvale et al., 2016). There are reports of staff feeling guilty about devoting time to co-design projects causing them to drop out of the process (Bowen et al., 2010). The potential use of the web in broadening representation is considered in two studies (Bullinger et al., 2012; Den Breejen et al., 2012) this exploratory work shows early promise, however the case study element of this work found a lack of IT infrastructure in place and the use of web based collaboration may be far from everyday practice.

### **5.4 Systems awareness**

There was a lack of systems awareness in both the case study and literature review. Within the literature the Systems Engineering Initiative for Patient Safety (SEIPS) model (Carayon et al., 2006) was used in 2 projects, beyond this there was no formal use of systems models or approaches in either the literature or case study. In the approaches used it appears there is little understanding of how potential changes that are suggested and implemented could impact on other parts of the system in question. This lack of systems understanding may impact on the ability to deliver recommendations and change beyond the small-scale changes that are the most common outcome of co-design work.

## **6. Discussion**

The main findings relate to challenges in the application of time consuming participatory approaches with multiple stakeholder groups, the difficulties of implementing change in complex healthcare systems and issues of representation.

The case study found a predominantly consumerist approach to involvement with some elements of co-design, although the level of impact service users and staff had on decisions and change appeared to be low. The literature explored projects aligned more with the democratic approach to involvement with a growing use of co-design methodology. There is limited evaluation of the effectiveness of either approach in achieving long-term, sustainable improvement. In a survey of co-design projects one of the main criticisms of co-design and specifically the EBCD approach is in the seemingly small-scale changes when considering the time given by staff and patients to see projects to completion (Donato et al., 2014). Alongside the most often reported small-scale changes in previous co-design work, the case study participants found difficulty in seeing how the information gathered from patient and public

involvement was actioned and translated into changes by service providers. There appears to be a lack of systems awareness in the main approaches used. Two projects in the literature used a systems model (SEIPS) to guide improvement work, but no evidence of use of systems methods and models was found in the case study or the EBCD methodology.

From a patient safety perspective there can be interest in using staff, patients and public as quality detectors within healthcare systems. There was criticism in the public inquiry into the failings at Mid-Staffordshire trust (Francis, 2013) that both the patient involvement model and the staff whistleblowing model were ineffective in uncovering the issues at their hospital trust in a timely manner. The changes and reorganisations of the health service in the UK has meant the model of involvement investigated in this study is different to the model that existed during the Mid-Staffordshire incidents, however it is unclear how effective this model is at using patient feedback in detecting issues and analysing system performance. It is said that the use of STAMP (Systems Theoretic Accident Modelling and Processes) can improve system performance analysis, with the concept of safety constraints providing direction to identifying leading indicators for changes over time that could increase risk of accidents (Leveson, 2012). Research could follow by using STAMP to learn from both the Mid-Staffordshire incidents and to explore the feedback mechanisms within current safety control structures in healthcare systems with the potential of making recommendations for improvement.

## 7. Future direction

This exploratory study leads to planned future research involving prescriptive work applying STAMP in the participatory design of healthcare services and work systems. We see potential in finding a balance between structured systems approaches of HFE and participatory design approaches. Research will consider how using structured systems approaches will influence the analysis and design of work systems by patient safety and healthcare staff, and investigate the usability and usefulness of systems methods.

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## Collaborative processes of care managers in the detection and recovery of medication errors

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### Abstract

Using data from case management documentation in a large community-level intervention study, we examine the collaborative processes used to detect and correct medication errors in a chronically ill population. Care managers (CMs) collaborated with patients and providers to identify 608 medication errors including missing or omitted information, dosage errors, medication orders not restarted or renewed, and medication orders not discontinued. CMs participated in collaborative processes to correct errors, and we present data on the strategies used for each type of medication error.

**Keywords:** care management, care coordination, error detection and correction, medication errors

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### 1. Introduction

Medication errors cause 1.5 million preventable injuries to patients each year in the United States, adding billions in healthcare costs (Institute of Medicine 2007). Various solutions and approaches have been proposed and tested for preventing medication errors. In addition to approaches for preventing errors, we need to assess strategies for identifying and correcting errors. The process of recovering from medication errors has two key stages: detection and correction (Kontogiannis 1999, Wetterneck 2012), and can be supported by medication review and reconciliation. Medication review and reconciliation may be performed by pharmacists, physicians, nurses, or as in the case of the intervention studied here, nurse care managers (CMs). During transitions in and out of the hospital, patients are particularly vulnerable to medication errors (Coleman 2003, Kripalani, Jackson et al. 2007). CMs can help to improve transitions of care, both from one inpatient unit to another (Kim and Soeken 2005) and at discharge from hospitals to outpatient settings (Bernabei, Landi et al. 1998, Riegel, Carlson et al. 2002). Shojania et al. (2007) performed a review of systematic reviews on care coordination (including CM) and found the strongest evidence for patients with certain types of chronic conditions, such as diabetes, heart failure, or depression. This review indicated that evidence is lacking about the specific aspects of care coordination and management that are most beneficial for patients. Our study addresses this critical gap and identifies specific CM activities that can improve patient safety, in particular medication safety.

## **2. Methods**

Using data from a proprietary case management documentation system, we describe the types of medication errors identified by care managers between November 2011 and March 2013 and the collaborative processes used to recover from these errors. IRB (Institutional Review Board) approval was obtained for this study.

### **2.1 Setting**

As part of a larger project aimed at reducing emergency room visits and readmissions among high-risk patients, a system of care coordination supported by health information technology was implemented in four hospitals in a five-county region of the eastern United States. Participating hospitals included a large regional tertiary care medical center and three community hospitals. CMs are licensed nurses providing support to targeted patients, who had been diagnosed with chronic obstructive pulmonary disease (COPD) and/or heart failure (HF) or who had undergone major abdominal, thoracic or orthopedic surgery. Hospital-based CMs identified targeted patients after admission, met with the patient one or more times during hospitalization, communicated directly with staff on the hospital units and contacted outpatient providers by phone or fax. Each time that CMs contacted a patient, they completed medication review and reconciliation. They reviewed the patient's electronic and/or paper records, including both inpatient and outpatient notes. They also talked with the patient about medications that had been taken and were currently being taken. If the CMs had any questions or identified any discrepancies, they would contact an appropriate provider, such as inpatient physicians, bedside nurses, hospital pharmacists, primary care physicians or clinicians in skilled nursing facilities.

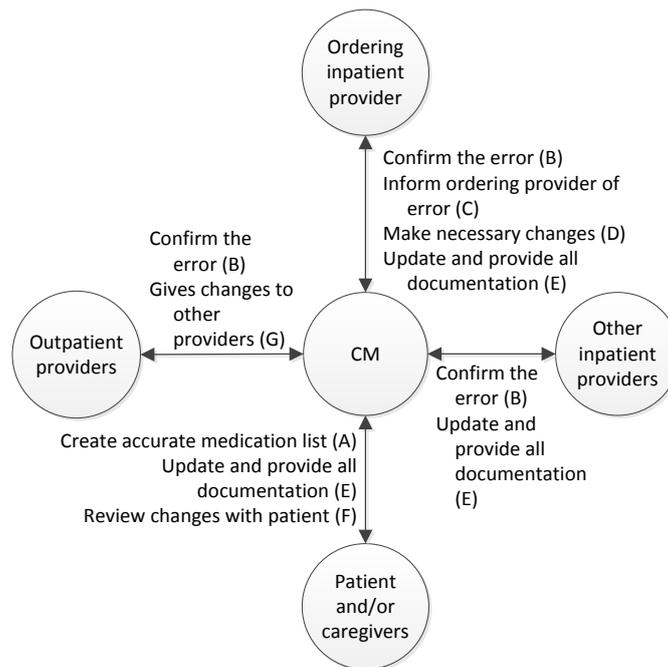
### **2.2 Data collection and analysis**

CMs entered documentation into a proprietary case management information system for each patient contact. A set of patient documentation, known as an assessment, included the data for all patient contacts during an inpatient stay. In each assessment, CMs noted any medication errors that were identified and the strategies they used to resolve the error. Strategies were selected from a drop down menu: (1) informing the ordering provider about the error, or informing another physician who would be able correct the order; (2) asking the ordering provider to make changes to correct the error; (3) gathering revised documents, including discharge instructions, patient education materials, the self-management plan and providing the corrected documents to the patient; (4) reviewing all changes to medication orders, discharge instructions and/or other documents with the patient; and (5) sharing updated documentation with other providers, including post-discharge providers, home health, durable medical equipment and community services. CMs had the option of selecting "other" and entering a description into a free-text field. As part of cleaning the data, the free-text entries were reviewed and appropriate cases were recoded into the strategies categories.

## **3. Results**

### **3.1 Communication in medication error recovery**

Figure 1 shows the communication network in the collaborative processes used by CMs to detect and correct medication errors. Table 1 describes each collaborative process, the stage in the error recovery process and the roles involved in the process.



Note: Circles indicate participating roles, arrows denote the flow of information and the arrow labels indicate the processes that the two participants work on collaboratively.

Figure 1. Communication network in error recovery

Collaborative processes		Stage	Participating roles
<b>A</b>	Create accurate medication list	Detection	CM, patient and/or caregiver
<b>B</b>	Confirm the error	Detection	CM, ordering provider, primary care physician, clinicians in skilled nursing facilities, and other inpatient providers (e.g. pharmacist, nurse)
<b>C</b>	Inform ordering provider	Detection Correction	CM, ordering provider (or a provider who is empowered to change the order)
<b>D</b>	Make necessary changes	Correction	Ordering provider
<b>E</b>	Update and provide all documentation	Correction	CM, ordering provider, other inpatient providers, patient and/or caregiver
<b>F</b>	Review changes with patient	Correction	CM, patient and/or caregiver
<b>G</b>	Gives changes to other providers	Correction	CM, outpatient providers (e.g. primary care), home health and durable medical equipment

Table 1. Collaborative processes in medication error recovery

### 3.2 Medication errors detected by care managers

The study dataset contains information on 4,137 patients and 5,851 inpatient assessments. Most patients had been diagnosed with HF (40%), COPD (28%), or a combination of COPD and HF (18%). Approximately 15% of patients were case managed after major surgery. In all, 608 medication errors were identified by CMs during the study period; this type of error was documented in 11% of patient assessments. Table 2 contains information on detected medication errors and the average number of strategies used by CMs in helping to resolve medication errors.

Types of medication error	Number of errors detected (%)*	Mean number of strategies per error (SD), N <sup>+</sup>
Orders with missing/omitted information	406 (67%)	2.0 (1.2), N=108
Dosage errors	81 (13%)	2.6 (1.3), N=14
Medication orders not discontinued	47 (8%)	3.0 (1.9), N=9
Failure to restart or renew medication	22 (4%)	2.8 (0.9), N=8
Other medication errors (e.g. drug allergies, drug interactions)	133 (22%)	2.4 (1.3), N=14
<b>Total N</b>	<b>608</b>	<b>153</b>

\* Some medication errors are in more than one category: thus, the percentages do not sum to 100.

+ Because of the data structure, these descriptive statistics were calculated for a subset of data in which only one type of error was identified in an assessment.

Table 2. Descriptive data on medication errors identified by CMs

### 3.3 Collaborative strategies for correcting medication errors

Results in Table 3 describe how frequently specific strategies, or collaborative processes, were used by CMs to resolve each type of medication error. The type of error most frequently identified by CMs is missing or omitted information about medications (N=406). An example of one such error is the case of a newly diagnosed COPD patient who was admitted for surgery. At discharge, the patient was given no orders for COPD medications. In this case, the CM contacted the resident on the inpatient unit and expressed concerns regarding the lack of COPD medications (*informs ordering provider*). The resident wrote the omitted orders (*makes necessary changes*) and updated the discharge instructions (*update and provide all documentation*).

Dosage errors were also identified by CMs (N=81). An example of this type of error was a medication order that was mistakenly written for double the intended dose. In this case, the CM brought the error to the attention of the ordering physician (*inform ordering provider*), the physician corrected the order (*make necessary changes*), and the CM ensured that documentation was revised and gave the patient the updated information (*update and provide all information*).

CMs detected relatively few cases in which a medication should have been discontinued (N=47). A typical example would be an antibiotic ordered for an acute infection that had not been removed from the patient's medication list after the infection was cured. As part of the medication review and reconciliation process, the CM would ask the patient about the medication and learn that it should have been discontinued. In just over half of these cases, the CM contacted the ordering provider to ask for the medication order to be discontinued (*inform provider*). In all of these cases, the provider discontinued the order (*make necessary changes*).

The final type of medication error, failure to restart or renew medications, is often associated with transitions across care settings (N=22). This error may occur when outpatient routine medications are not restarted on discharge from the hospital. When the error was detected, CMs contacted the ordering provider (*inform provider*) in 75% of cases. In every case, the ordering provider corrected the error by writing the orders. The CM would then work with

inpatient providers to ensure that documentation is updated and shared with the patient (*update and provide all information*).

Collaborative process used to correct errors		<i>Missing or omitted info</i> % (N)	<i>Dosage error</i> % (N)	<i>Med. order not discontinued</i> % (N)	<i>Failure to restart or renew med.</i> % (N)
<b>C</b>	Inform ordering provider	19% (21)	29% (4)	56% (5)	75% (6)
<b>D</b>	Make necessary changes (ordering provider)	12% (13)	14% (2)	56% (5)	75% (6)
<b>E</b>	Update and provide all documentation	50% (54)	36% (5)	56% (5)	88% (7)
<b>F</b>	Review changes with patient	11% (12)	21% (3)	44% (4)	0% (0)
<b>G</b>	Give changes to other providers	40% (43)	77% (11)	44% (4)	12% (1)
N		108	14	9	8

Table 3. Collaborative error correction processes by type of medication error

#### 4. Discussion and Conclusion

By describing the collaborative processes that CMs use to detect and correct medication errors in hospital settings, this study gives insight into care coordination that is clearly beneficial to patients. In this large community-level intervention, CMs identified and resolved over 600 medication errors in a 16-month period. Some of these errors may have been of minor consequence, but many – such as the case of a patient whose COPD medications and self-management instructions were omitted at the time of discharge – could have had a serious impact on patient outcomes. This research also supports the idea that collaboration is central to the work of CMs, particularly in the medication error recovery process. CMs serve as a hub in the communication network and have the potential to improve information flow among the care team, ensuring that discrepancies in medication lists are identified, investigated and corrected if necessary. More research is needed on CM processes to fully understand how these clinicians create positive outcomes for chronically ill patients.

##### 4.1 Study limitations

This study uses data from a single case management intervention, so the results described may differ from the processes of CMs in other health systems or those who manage the care of other types of patients. Also, the care management documentation system was not designed for research purposes, and consequently the data have some limitations. One is that the data on strategies are not directly linked to the care gap (e.g. medication error) that is being resolved. If an assessment contains data on two medication errors and four strategies, we are unable to determine which strategies were used to resolve each error. We therefore limited part of our analysis to the subset of cases in which only one medication error is documented in an assessment, allowing us to isolate the CM processes used to resolve each medication error care gap.

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## Work environment perceptions, shift work and health in healthcarers

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### Abstract

*Context:* Working schedules in healthcarers include frequently shift-work, a work-organization shown to have negative effects on health and well-being.

*Objectives:* Our aim was to determine whether the occupational category and working schedules affect work environment perceptions, and whether these perceptions interfere with physical and mental health in healthcare workers. In reference to the “job demands-control-social support model”, the “effort-reward imbalance Model” and the “work-family conflict model”, we assume that a combination of high job demands, low control and low social support, overcommitment, and work-family conflicts is associated with health disorders.

*Methodology:* 112 females, working a 3-shift (21.4%) or a 2-shift (34.8%) system, on day-shifts (31.3%), or on night-shifts (12.5%) rated the Job Content Questionnaire completed by two additional dimensions addressing social support by relatives and organizational job-demands, a 37-item scale exploring work-family conflicts and the overcommitment scale from the Effort-Reward Imbalance Questionnaire. Psychological health was assessed by the Minnesota Satisfaction Questionnaire, the General health Questionnaire, a self-esteem scale, and a psychological fatigue questionnaire. Physical health was addressed by quoting the frequency of self-reported illnesses and symptoms of disorders and a scale of physical fatigue.

*Main results:* A principle component analysis revealed several specific dimensions referring respectively to physical health, work environment requirements generated by the work- and non-work domains, psycho-social resources and physical constraints. Elsewhere, ANOVAs confirmed that professional category and working schedules determined job perceptions, particularly job demands, work-family interferences and control, but not social support. Furthermore, job requirement perceptions affected physical indicators of health whereas psychological resources determined only mental health. In addition, perceived physical job demands affected physical illness symptoms and psychological well-being.

*Conclusion:* Taken together, our findings underline the importance to take into account a large range of demands and resources from work and non work to gain an overall view of health determinants in shift-workers.

**Keywords:** job perceptions, physical health, mental health, healthcare workers, work schedules

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### 1. Introduction

Stress in healthcarers and its outcomes on health are still an important social issue, because of important consequences at the individual level (poor health, job dissatisfaction, deteriorated wellbeing, etc.) but also at the management level (safety of patients, absenteeism and turnover) and at a societal level (medical costs and social security). Healthcare has been identified as particularly stressful with high levels of emotional/psychological demands and

workload (Adriaenssens, De Gucht, & Maes, 2015; Trousselard et al., 2016). In addition, working schedules in the healthcare sector include frequently shift-work, a work-organization shown to have negative effects on health and well-being (Tucker & Folkard, 2012), also in healthcarers (Merkus et al., 2012; Costa, Anelli, Castellini, Fustinoni, & Neri, 2014; Dall'Ora, Ball, Recio-Saucedo, & Griffiths, 2016). Thus, the impacts on health and well-being have been studied for a large range of factors relating mostly to specific work characteristics (job demands and resources, work schedules, ...) but also in regard to work-family conflicts which were shown to induce stress and affect health (Allen, Herst, Bruck, & Sutton, 2000; Greenhaus, Collins, & Shaw 2003).

## **2. State of the art**

The “job demands-control-social support model” (Theorell & Karasek, 1996) proposes that high levels of demands associated with low control and low social support generate job strain that in turn may affect health. In healthcare workers, this pattern of results has been reported for instance concerning symptoms of depression (Berthelsen et al., 2015), sickness absence (Roelen et al., 2014), job satisfaction and mental health (Rodwell & Munro, 2013), well-being (Pisanti, van der Doef, Maes, Lazzari, & Bertini, 2011; Chou, Hecker & Martin, 2012) as well as musculoskeletal symptoms (Lee, Lee, Gillen, & Krause, 2013). According to the “effort-reward imbalance model” (Siegrist, 1996), overcommitment that reflects the need for control and approval could affect people’s health and be associated for instance with higher levels of anxiety and depression in nurses (Mark & Smith, 2012). Overcommitment at work and spillover to the non-work domain may thus be considered in regard with the “work-family conflict model” suggesting that interferences between work and family domains may have significant implications on workers’ health (Greenhaus & Beutell, 1985). In healthcarers, to our knowledge, the effects of work conditions, including shift-work, have been poorly investigated in terms of work-family conflicts (Zito, Colombo, & Mura, 2013). Likewise the impacts of work-family conflicts on health are as yet unclear (Demerouti & Bakker, 2008; Van der Heijden et al., 2008; Colombo, Zito, & Ghislieri, 2012). We propose to include these issues in an integrative approach considering that health is the result of the combined effects of several determinants relative to organizational characteristics and to the perceptions of the work environment. According to this point of view, the latter derive partly from the interdependence between work and non-work domains (Mélan & Cascino, 2014; Cascino, Mélan, & Galy, 2016).

## **3. Objectives and Methods**

Our aim was to determine whether the professional category and working schedules of healthcare workers affect their work environment perceptions, and whether these perceptions interfere with their physical and mental health. Participants’ professional category involved different tasks and responsibilities that should lead to different levels of perceived job demands and control. Thus, nursing managers were expected to perceive the highest levels of psychological demands and of control indicating an “active job situation” implying desirable stress and increased motivation. Conversely, care assistants were thought to be exposed to high physical and organizational demands and low control which are known to increase the risk of psychological strain. Further, we expected fixed night work to be associated with lower physical and psychological demands and lower social support but high control. In contrast, rotating shifts would be characterized, at least on day-shifts, by higher demands, control, social support and work-family conflicts. We also expected that a combination of high requirements at work and out of work, combined with overcommitment, low control and social support would result into a higher rate of physical and mental health disorders.

Participants were 112 females (mean age 38.45; SD 10.92), 86 were married. They were working a 3-shift (21.4%) or a 2-shift (34.8%) system, or on fixed day- (31.3%) or night-shifts (12.5%). 14 were nursing managers, 43 nurses, 31 care assistants and 24 technical assistants (laboratory technicians, dieticians, etc.). Work environment perceptions were assessed by the Job Content Questionnaire (Karasek et al. 1998) including physical (5 items) and psychological job-demands (9 items), autonomy (3 items) and skill discretion (6 items), social support by supervisors (8 items) and co-workers (7 items). We introduced two additional dimensions addressing respectively social support by relatives (6 items) and organizational job-demands (13 items). Work-family interferences (WFI) were rated on a homemade 37-item scale exploring spillover of work to family life or of family life to work. Overcommitment was assessed by the Effort-Reward Imbalance Questionnaire (Siegrist et al., 2004). Psychological health was evaluated by the Minnesota Satisfaction Questionnaire (Weiss et al, 1967), the General health Questionnaire (Goldberg, 1979), Rosenberg's self-esteem scale (1965), and a psychological fatigue questionnaire (Bucquet, Condon, & Ritchie, 1990). Physical health was addressed by quoting the frequency of self-reported pathologies or symptoms of disorders frequently reported by shift-workers (cardio-vascular, musculoskeletal, digestive ...) and a scale of physical fatigue (Barton et al. 1995). Internal consistency of each dimension and scale has been assessed by Cronbach's alpha.

## **4. Results & Discussion**

### **4.1 A Multi-dimensional perception of the work environment by healthcareers**

We performed a principle component analysis (PCA) including professional category and working-schedules and 22 scores issued of the different questionnaires. Results revealed eight factors that explained 72.81% of the overall variance of the data. The first factor (20.22%) gathered all scores of perceived illness disorders and the fatigue score and confirmed a coherent physical health dimension in the data. The second factor (12.62%) included reciprocal WFI, overcommitment, psychological and organizational job demands and psychological fatigue and seemed to refer to the work environment requirements which arise directly from the work-environment but also from the non-work life. The third component (8.34%) grouping job-satisfaction and professional support (supervisors and colleagues) would represent psycho-social resources in this job-situation. The fourth dimension (7.98%) embraced working-schedules and physical demands and could be considered as a physical constraints dimension. The fifth factor (7.73%) included professional category, autonomy and skill discretion at work and might reflect a control dimension. The last three factors concerned respectively self-esteem, social support by relatives and general well-being.

### **4.2 Impact of professional category and work schedules on job perceptions**

To test the hypothesis of an impact of healthcareers' professional category on their job perceptions, ANOVAs were performed. Main effects are summarized in Table 1. As indicated in the table, the professional category impacted WFI. Post hoc analyses of this effect indicated that nurses perceived higher perceived levels of WFI than technical assistants ( $p < .03$ ) and care assistants (tendency  $p < .07$ ), whereas WFI did not differ between the two latter categories. Nurses also indicated higher levels of psychological and organizational demands than technical assistants ( $p < .04$  and  $p < .001$  respectively), care assistants ( $p < .02$  and  $p < .001$  respectively), and nurse managers but only as far as organizational demands were considered ( $p < .01$ ). Concerning physical demands, nurses and care assistants reported higher levels than technical assistants (in each case,  $p < .001$ ) and nurse managers (in each case,  $p < .001$ ). Professional category also affected skill discretion, with higher levels in nurse managers, even

though post hoc tests were not significant. No significant effect was observed for perceived autonomy at work and social support.

		Technical assistants	Care assistants	Nurses	Nurse managers
WFI	$F[3,108]=4.51; p<.005$	83.96(14.29)	86.42(16.35)	97.37(18.88)	95.93(16.67)
Psy. demands	$F[3,107]=5.07; p<.003$	24.08(4.62)	24.03(4.01)	27.43(4.97)	27.21(3.62)
Orga. demands	$F[3,107]=10.82; p<.001$	34.21(4.85)	34.65(3.34)	39.57(4.99)	34.79(4.89)
Phy. demands	$F[3,108]=27.17; p<.001$	7.50(3.02)	12.39(3.91)	13.63(2.78)	7.43(2.79)
Overcommitment	$F[3,108]=0.85; p<.47$	69.96(8.81)	71.55(9.29)	73.51(8.38)	72.64(11.04)
Skill discretion	$F[3,108]=3.26; p<.02$	34.33(5.98)	34.19(4.57)	36.19(4.74)	38.86(6.31)
Autonomy	$F[3,108]=2.35; p<.08$	37.33(6.43)	36.65(5.94)	35.72(6.26)	40.57(4.40)
Supervisors' support	$F[3,100]=0.89; p<.45$	24.09(5.34)	24.40(4.52)	22.55(4.86)	23.25(6.47)
Colleagues' support	$F[3,105]=0.57; p<.64$	22.46(4.04)	21.35(3.38)	22.20(3.18)	21.62(3.73)
Relatives' support	$F[3,107]=2.04; p<.11$	19.17(3.42)	17.84(3.30)	19.44(3.12)	17.69(3.35)

Table 1. Main effects of professional category on job perceptions (F- value, mean score(standard deviation))

Quite surprisingly, work schedules did not affect perceived WFI, whereas significant effects appeared for job demands Results (Table 2) indicated lower levels of psychological demands in healthcarers working fixed night-shifts rather than rotating shifts (2-shift  $p<.05$  or 3-shift systems  $p<.03$ ). On the other hand, those working on fixed day-shifts perceived less organizational demands compared to those working 2-shift ( $p<.06$ ) or 3-shift systems ( $p<.001$ ). Personals working on fixed day- or night-shifts displayed the lowest levels of physical demands, that differed significantly from the levels perceived by those working 2-shift ( $p<.001$  and  $p<.08$  respectively) and 3-shift systems ( $p<.001$  and  $p<.01$  respectively). Taken together, these results tend to confirm that fixed work-schedules are characterized by fewer demands than rotating shift-schedules. Results concerning overcommitment were quite different as no significant difference occurred between healthcarers working fixed day-shifts or fixed night-shifts. However, the latter group displayed a lower level of overcommitment than 2-shift ( $p<.05$ ) and 3-shift workers ( $p<.04$ ). Work schedules also impacted control. Those who worked on fixed day-shifts presented the highest levels of autonomy, that differed significantly with 2-shift workers ( $p<.04$ ) but this difference fell short of significance with those working on fixed night-shifts ( $p<.11$ ) or a 3-shift system ( $p<.08$ ). Similarly, the highest levels of skill discretion were reported by fixed day workers with significant higher levels when compared to those who worked on fixed night-shifts ( $p<.04$ ) or on a 2-shift system ( $p<.001$ ). In addition, those working on 2 or 3 rotating shifts rated more skill discretion than fixed night-shift workers ( $p<.03$  and  $p<.001$  respectively). Finally, social support seemed to be quite similar in our population independently of the working schedules.

		Fixed day-shifts	Fixed night-shifts	2-shifts	3-shifts
WFI	$F[3,108]=1.17; p<.33$	86.97(15.74)	81.86(18.89)	82.44(18.20)	95.38(19.18)
Psy. demands	$F[3,107]=3.59; p<.02$	25.83(3.94)	22.14(5.55)	26.18(4.87)	27(4.33)
Orga. demands	$F[3,107]=6.40; p<.001$	33.97(4.44)	35.93(5.82)	37.05(4.67)	39.43(4.77)
Phy. demands	$F[3,108]=21.09; p<.001$	7.86(3.36)	10.07(4.20)	12.85(3.43)	14.04(2.55)
Overcommitment	$F[3,108]=3.25; p<.03$	72.49(9.72)	65.36(7.57)	73.05(8.28)	73.92(8.84)
Skill discretion	$F[3,108]=9.73; p<.001$	37.94(5.50)	30.14(5.11)	34.67(4.50)	36.75(3.95)
Autonomy	$F[3,108]=4.00; p<.01$	39.77(6.65)	35.14(5.01)	35.79(4.76)	35.67(6.77)
Supervisors' support	$F[3,100]=0.52; p<.67$	23.66(6.13)	24.92(4.91)	23.27(4.88)	22.7(3.74)
Colleagues' support	$F[3,105]=0.84; p<.48$	21.56(4.18)	23(3.53)	21.62(3.30)	22.45(2.48)
Relatives' support	$F[3,107]=2.30; p<.08$	17.68(3.62)	20.21(2.64)	19.05(3.42)	18.83(2.67)

Table 2. Main effects of work schedules on job perceptions (F- value, mean score (standard deviation))

### 4.3 Impact of job perceptions on psychological and physical health

Regression analyses were conducted to examine the link between job perceptions (requirements and resources) and physical and psychological health. First, it is interesting to note (Table 3) that psychological well-being was not correlated with any dimension of job environment perceptions. Self-esteem was only related to overcommitment (negative correlation) and to social support by colleagues (positive correlation). These two dimensions thus seemed to be rather independent of job environment characteristics.

	Psychological wellbeing			Self-esteem			Psychological fatigue			Job satisfaction		
	<i>B</i>	<i>R</i> <sup>2</sup>	<i>p</i>	<i>B</i>	<i>R</i> <sup>2</sup>	<i>p</i>	<i>B</i>	<i>R</i> <sup>2</sup>	<i>p</i>	<i>B</i>	<i>R</i> <sup>2</sup>	<i>p</i>
WFI	.06	.00	.55	-.17	.03	.08	.44	.19	.001	-.32	.10	.001
Psy. demands	-.08	.01	.39	.07	.01	.47	.30	.09	.001	-.28	.08	.003
Orga. demands	-.08	.01	.41	.05	.00	.61	.18	.03	.06	-.24	.06	.01
Phy. demands	-.12	.01	.22	.02	.00	.81	.04	.00	.70	-.02	.00	.83
Overcommitment	.00	.00	.98	-.19	.03	.05	.38	.14	.001	-.22	.05	.02
Skill discretion	-.11	.01	.27	.06	.00	.56	-.12	.02	.20	.26	.07	.01
Autonomy	-.17	.03	.09	.13	.02	.17	-.23	.05	.02	.41	.17	.001
Supervisors' support	-.16	.03	.10	.09	.01	.34	-.04	.00	.66	.62	.38	.001
Colleagues' support	-.08	.01	.40	.19	.04	.05	.01	.00	.93	.33	.11	.001
Relatives' support	-.08	.01	.40	.18	.03	.07	-.24	.06	.01	.18	.03	.06

Table 3. Main effects of job environment perceptions on psychological health (linear regression analysis)

In contrast, psychological fatigue and job satisfaction were more sensitive to perceptions of work environment. Thus, psychological fatigue was positively correlated with all psychological requirements (WFI, psychological demands, organizational demands, and overcommitment), and conversely job satisfaction was negatively correlated with all these indicators. It is noteworthy that neither psychological fatigue nor job satisfaction was correlated with physical demands. On the other hand, psychological fatigue was negatively correlated only with autonomy and social support by relatives, whereas job satisfaction was positively linked with skill discretion, autonomy, professional social support by supervisors and by colleagues, and to a lesser extent with social support by relatives. These results indicate a deleterious effect of work and non work requirements and a beneficial impact of resources on psychological fatigue and job satisfaction.

	Fatigue			Pathologies			Illness symptoms		
	<i>B</i>	<i>R</i> <sup>2</sup>	<i>p</i>	<i>B</i>	<i>R</i> <sup>2</sup>	<i>p</i>	<i>B</i>	<i>R</i> <sup>2</sup>	<i>p</i>
WFI	.30	.09	.002	.332	.11	.001	.40	.16	.001
Psy. demands	.04	.00	.71	.198	.04	.04	.24	.06	.01
Orga. demands	.05	.00	.63	.236	.06	.01	.28	.08	.004
Phy. demands	.13	.02	.17	.321	.10	.001	.33	.11	.001
Overcommitment	.13	.02	.16	.165	.03	.08	.31	.10	.001
Skill discretion	-.10	.01	.30	.085	.01	.35	.00	.00	.98
Autonomy	-.12	.01	.23	-.045	.00	.64	-.19	.04	.05
Supervisors' support	.05	.00	.61	-.084	.01	.40	-.17	.03	.09
Colleagues' support	.00	.00	.99	-.100	.01	.30	-.20	.04	.04
Relatives' support	-.17	.03	.08	-.117	.01	.22	-.25	.06	.01

Table 4. Main effects of job environment perceptions on physical health (linear regression analysis)

Results (Table 4) also revealed a deleterious effect of job environment requirements on physical health. The frequency of self-reported pathologies and illness symptoms were both positively correlated with all the psychological and physical indicators used to assess job requirement (WFI but also psychological, organizational and physical demands, and overcommitment only for illness symptoms) whereas fatigue was only dependent on WFI. Furthermore, the hypothesis of a beneficial effect on health of resources in the work

environment was confirmed only for illness symptoms. Negative correlations indicated that perceived illness symptoms decreased with increasing levels of autonomy and of support by colleagues and by relatives.

#### **4.4 Discussion**

This first set of results indicates that healthcare workers' job perceptions were characterized by several dimensions, i.e. physical health (illness symptoms and physical fatigue), work environment requirements generated by the work- and non-work domains (psychological and organizational demands, work family interferences and psychological fatigue), psycho-social resources (social support and job satisfaction), socio-cognitive resources (control and professional category) and physical constraints (physical demands and working schedules). These results are in agreement with the "job demands-resources model" (Demerouti, Bakker, Nachreiner, & Schaufeli, 2001), and stress the importance to have an extended view of the concepts of demands and resources that characterize a work environment. More especially, job demands would include work-family interferences in addition to more traditional intrinsic job demands. Likewise, resources at work would also involve non-work resources like social support by relatives.

As expected, healthcare workers' professional category influenced work environment perceptions. Thus, nurse managers reported high levels of psychological demands and the highest levels of control and seemed to experience an "active job situation", as defined by the JDC-S model. In contrast, nurses and care assistants were exposed to psychological strain and technical assistants were facing a more "passive job situation". Results also confirmed the previously reported effects of shift work on job perceptions, but only as far as job demands were concerned. In particular, healthcare workers who worked on fixed shifts presented the lowest levels of physical demands, even if this result may also be accounted for by an alternative explanation depending on whether we consider fixed day-shifts or fixed night-shifts. Indeed, as indicated above, day-shifts are quite often occupied by nurse managers who are more exposed to psychological demands than to physical demands and may be protected from specific demands induced intrinsically by shift-work schedules (disruption of circadian rhythms, disturbance of sleep, ...). On contrary, night-shifts concern nurses and care assistants and are characterized by less physical demands (less care, principal activity being monitoring). Furthermore, we observed lower levels of psychological demands and overcommitment in night-shift workers compared to day-shift or rotating-shift workers. These results are probably due to organizational aspects of shift work, as healthcare involves less activity during the night (fewer interactions, absence of patients' family and physicians ...). Finally, organizational demands (interpersonal coordination, ambient noise, doing several tasks at the same time, etc.) appeared to be lower for those who worked on fixed day-shift than on shift systems (2- and 3-shift systems), those latter are mainly nurses and care assistants which would be more concerned by the conditions to carry out different tasks and those associated demands. Regression analyses provided evidence of a link between work environment perceptions and physical and mental health. Thus, perceived job demands affected healthcare workers' physical health while high levels of job requirements from work and non work domains affected both their mental and physical health. Conversely, psychological resources (control and professional social support and, to a lesser extent, support by relatives) had beneficial effects on job satisfaction, psychological fatigue, self-esteem and physical health.

## 5. Conclusion & perspectives

According to these findings, each job-situation would be characterized by a specific combination of resources and requirements, each including a set of components that would reflect the effects of situation-specific variables (Mélan & Cascino, 2014; Cascino, Mélan, & Galy, 2016). This study stress the importance of taking into account a large range of demands and resources from work and non work environments to gain an overall view of health determinants. They may be usefully completed by analyses testing the interactions between organizational dimensions (professional category and working schedules) and work environment perceptions on health in healthcareers.

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## **Workloads and safety in healthcare - well-being of doctors and nurses, performance and consequences on patient safety**

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### **1. Introduction**

The Centre for Clinical Risk Management and Patient Safety of the Tuscany Region has always promoted, since its establishment in 2003 by the Regional Council resolution, the culture of patient safety and a “learning from mistakes” approach as essential conditions for a more reliable and better performing health care system. The Centre operates according to a participatory vision of patient safety. For this reason, it shares and evaluates safety practices on the field, adapting them to the operational reality and aims to highlight their effectiveness as well as their critical aspects.

This approach is at the basis of the training for Clinical Risk Managers and Facilitators for Clinical Risk network, a complex linkage that has been set up over the years in healthcare facilities and into academics hospitals all over the Region. This targeted contact with every single working environment has allowed the center to collect directly by the workers the perception that the workloads had become very different from those of a few years ago, that the time actually devoted to the patient is shrinking more and more and that these changes were heavily impacting on the well-being of the workers in our healthcare system.

Bearing these suppositions, the GRC center has met the interest of Tuscany’s Board of National Institute for Insurance Against Accidents at work (INAIL - Direzione regionale Toscana) for the realization of a field-study designed to investigate, also in the Italian reality, the results found in international literature on the relationship between staffing and quality-safety of care, exploring the link between the wellbeing of the workers on the one hand, and the characteristics of their performance on the other hand.

### **2. State of the art**

The study of the literature devoted to these issues has confirmed that staffing problems in healthcare (shortage of operators, increasing of turnover in nursing staff, and the average ageing levels) along with the weight and frequency of interruptions in workflow (Weigl et al., 2013), as well as restrictive administrative practices (more and more use of protocols and procedures that govern the clinical activity, the increasing computerization of health systems, the need to formalize a number of acts for legal purposes) may negatively affect patients’ and professionals’ safety and well-being, threatening the performance and increasing the chances of adverse events to the detriment of patients.

Numerous literature publications (Gaba et al., 2002; Landrigan et al., 2004; Rogers et al., 2004; Needleman et al., 2011; Stone et al., 2008; Gurses et al., 2009; Carayon et al., 2005, 2008, 2009; Costa, 2003; Magrabi et al., 2010; Li et al., 2012) have proved professionals' workload issues to create an array of critical safety problems for medical professionals and the public community at large.

Recently, literature has increased attention on specific risks concerning interruptions and multitasking. Simultaneous task performance ("multitasking") is common in hospital physicians' work and is implicated as a major determinant for enhanced strain and detrimental performance. Weigl, Sevdalis et al. (2013) found that about 21% of the working time, physicians were engaged in simultaneous activities, the average time spent in multitasking activities correlated significantly with subsequently reported strain ( $r = 0.27$ ,  $P = 0.018$ ) and the number of instances of multitasking activities correlated with self-monitored performance to a marginally significant level ( $r = 0.19$ ,  $P = 0.098$ ). So, physicians who engage in multitasking activities tend to self-report better performance but at the cost of enhanced psychophysical strain. Hence, physicians do not perceive their own multitasking activities as a source for deficient performance, for example, medical errors.

Kalisch BJ, Aebbersold M. et al. (2010) observed a total of 35 nurses for four-hour periods of time by experienced clinical nurses, recording 3,441 events, a total of 1,354 interruptions, 46 hours of multitasking, and 200 errors. Although nurses manage interruptions and multitasking well, the potential for errors is present, and strategies to decrease interruptions are needed. Moreover, the burden associated with frequent interruptions seems to be more prominent in the eldest nurses, according to the results of the research that Westbrook and colleagues (2010) conducted to investigate risks related to the interruptions during medication administration.

### **3. Objectives and Methods**

#### **3.1 Objectives**

The main objective of the study is to describe, as thoroughly as possible, physicians' and nurses' workload in terms of tasks composing their shifts, and its nature in professionals' self-perception, comparing results amongst 6 surgical units distributed in 6 public hospitals in Tuscany. This project specifically aims at proposing indications to work organization improvement for better healthcare governance, in terms of professionals' personal needs as individuals (more than as workers), optimal allocation of staff resources, financial requirements and efficiency of care in a patient safety frame of reference.

Specific objectives:

Investigate and classify the physicians' and nurses' workload, considering the following dimensions:

- Clinical (direct patient contact; interaction with colleagues; supervision; etc.)
- Administrative (patient notes; charting; clerical tasks);
- Continuing Professional Development (CPD) (writing articles; attending training; teaching junior operators; etc.)
- Social presence (representative meetings; teambuilding; get-togethers; etc.)

Particular attention has been given to:

- continuous/discontinuous workflow, considering and measuring distractions, as well as other threatening elements for performance;

- organizations' structural data and professionals' personal data, such as length of service (novice group vs. expert group), contract types, accidents, medications, off-work, shifts, work time etc.

### 3.1 Methods

A multicenter study was carried out involving 6 different Tuscan hospitals, including 2 belonging to academic hospitals and 4 belonging to local health authorities. The research focused in the area of general surgery, in its various settings (ward, ambulatory, operating room). Professional qualifications involved are doctors, nurses and assistant nurse.

The first phase of the study was conducted by administering a paper questionnaire (period of administration: May-October 2015) to 613 professionals (doctors, nurses and assistant nurses) identified according to the specific working activity carried out (general surgery). We collected 544 valid questionnaires, with a very high response rate (88,74%).

One project team has been set up for each participating center, and some "collectors" have been identified for each setting.

The questionnaire was divided into three sections:

- socio-demographic and occupational aspects;
- WAI - Work Ability Index (Ilmarinen, 2009), in the Italian version validated by the Department of Clinical Sciences and Community, University of Milan;
- Uwes - Utrecht Work Engagement Scale (Schaufeli and Bakker, 2003), Italian 9 item version (UWES\_ITA9, Pisanti et al., 2008).

The administration of questionnaires has been followed by a second phase of research, the observation on the field (observation period: November 2015 - February 2016), made with the technique of *job shadowing*.

This ethnographic part of the study was specifically conducted by four researchers trained in the use of a dedicated software, involved around 61 workers (doctors and nurses, all operators who had participated in the survey by filling out the questionnaire of the first phase), for a total of 150 hours of observation, divided into 111 sessions lasting an average of 1:20 hours.

The software used is WOMBAT (Work Observation Method by Activity Timing), developed by the Centre for Health Systems and Safety Research – Australia (Ballermann et al 2011). To better adhere to the objectives of the study, the original categories were chosen and adapted through some focus groups with operators, then validated with some preliminary observations by the project team until they reached appropriate interrater reliability.

Two different templates (used respectively for the doctors and nurses' observations) were then used for the purposes of data collection. The observed shifts were those of the morning and afternoon, for all 6 participating hospitals, taking care to observe the staff in all settings in which the activity was taking place (ward, ambulatory, operating room). For monitored activities (i.e. inpatient care, indoor and outdoor guard, consulting other department) actual duration of each task, multitasking and interruptions were recorded. Each activity was encoded in WOMBAT's task categories: direct care, indirect care, health documentation, administrative practices, professional communication, social presence, manage technical problems.

Data resulting from the two collection phases (subjective questionnaires and shadowing observation) underwent statistical data handling and analysis.

A multiple imputation procedure was carried out on subjective data and some variables were grouped into categories in order to simplify the statistical models. A preliminary explorative

univariate analysis (ANOVA) was carried out using the SPSS software. Multivariate ordinal logistic regression models were then used in order to estimate the association of the outcome variables with explicative variables, such as demographics (gender, age, marital status etc.), and working variables (role, team seniority, overall seniority, night shift, hospital).

The models results are presented in terms of odds ratio (OR) and of their 95% confidence interval. All the regression models were estimated using the STATA 13 software (StataCorp, 2013)

For dataflow resulting from WOMBAT, in order to evaluate if there are statistical significant differences between nurse and doctors in the duration of each activity, tasks carried out in multitasking and interruptions, some tests of comparison among proportions were carried out at the 95% significance level.

## 4. Results & Discussion

### 4.1 Results

#### 4.1.1 Results – WAI (with 5% significant odds ratio)

- For each additional year of age, the risk of a poor / mediocre WAI increases by 4%.
- Nurses and assistant nurses have a risk of more than 3 times higher of having a poor / mediocre WAI compared to doctors.
- Overall length of service of 11-20 years, involves a 96% greater risk of a poor / mediocre WAI compared to a seniority of less than 10 years.

As for the number of illnesses suffered by workers, only 30% of the sample declared not to have any, while the remainder indicates at least one. Specifically, 27% declares 2-3 and 24% (a quarter of the sample) claims to have over 4 diseases. The most noted of disease areas are, in order musculoskeletal, digestive, respiratory, the nervous-sensory and skin diseases

#### 4.1.2 Results – UWES (with 5% significant odds ratio)

- The overall seniority of more than 20 years doubles the risk of worse UWES than having less than 10 years.
- The overall seniority of more than 10 years doubles the risk of worsening in vigour compared to having less than 10 years.
- The overall seniority of more than 10 years increases of more than 87% the risk of worsening in absorption, compared to having less than 10 years.

#### 4.1.3 Results – WOMBAT

By analysing observational data of physicians, particularly interesting was the analysis of multitasking and interruptions:

- although the clinical activities represent the highest percentage of time spent on duty (about 57%), over 20% is dedicated to the documentation, a further 4% in activities purely administrative and over 6% to get around. The remaining 10% is divided between social activities, technical problems and supervised activities or training.
- in 70 hours of observation, over 35 hours of multitasking have been registered, bringing the total cognitive workload to 105 hours of activities performed;
- of these multitasking, more than 28 hours occurred during patient care, where 45% of the tasks were performed in conjunction with at least another activity, so that patient care were interrupted on average once every six minutes; similar data were found for professional communication, which covered more than 25 hours;

- 37% of all recorded interruptions occurred during the documentation of activities, with a rate of more than once every 3 minutes;
- the activity of "professional communication", which represents a very important part of the work observed, both in terms of time and resource, however, is also the most frequent cause of interruption to the detriment of all the others, responsible for up to 571 interruptions, at an average rate of 5.5 per hour (the second was the most frequent activities "social" with an average rate of 1.5 interruptions per hour);
- in general, the 5781 recorded activities were interrupted 1167 times

For nursing activities, the descriptive results of the observations are also very interesting:

- clinical activities accounts for 57% of the total of 80 hours observed, followed by documentation that covers around 18% of the time, 12% in social activities, technical problems and supervision or updates, nearly 9% for getting around and 4% in administrative duties;
- in 80 hours of observation, over 28 hours of multitasking have been registered, bringing the total cognitive workload to 108 hours of activities performed;
- of these multitasking, about 25 hours occur during patient care, with about 20% in conjunction with at least another activity; the "professional communication" has shown a 30% to multitasking
- 32% of all recorded interruptions occurred during the documentation of activities, with a rate of more than once every 3 minutes; direct care were interrupted once every six minutes.
- the "professional communication" activities, even for the observed nurses was the most frequent cause of interruption, bringing up to 754 interruption at an average rate of 7 per hour (the second most frequent cause of interruption was "social activity" with an average rate of two interruptions per hour).
- in general, the 8311 recorded activities were interrupted 1258 times

activity	Proportion of lengths (%)			Frequency of interruptions (%)			Proportion of overlapping (%)			Proportion of multitasking (%)		
	doctors	nurses	<i>P</i>	doctors	nurses	<i>p</i>	doctors	nurses	<i>p</i>	doctors	nurses	<i>p</i>
Admin	3.90	3.99	0.7933	4.11	7.47	<0.001	2.54	5.80	<0.001	13.56	21.58	<0.001
Dir Care	26.57	22.91	<0.001	23.99	15.82	<0.001	25.94	18.85	<0.001	20.38	12.23	<0.001
Documents	20.16	17.62	<0.001	37.28	32.19	0.0086	19.86	15.22	<0.001	20.56	12.84	<0.001
Edu/s.vision	6.15	8.57	<0.001	7.20	9.94	0.0164	4.94	6.75	<0.001	16.79	11.69	<0.001
In transit	6.18	15.55	<0.001	3.94	15.74	<0.001	9.05	15.81	<0.001	30.61	15.11	<0.001
Ind Care	24.47	18.13	<0.001	17.14	14.47	0.0713	25.80	28.86	<0.001	22.00	23.66	<0.001
Prof Comm	3.25	0.29	<0.001	2.40	0.48	<0.001	4.26	0.80	<0.001	27.32	39.93	0.3853
Social	7.84	11.87	<0.001	3.00	3.26	0.7135	5.86	7.19	<0.001	15.60	9.00	<0.001
Tech probs	1.45	1.04	0.0359	0.94	0.64	0.3921	1.74	0.72	<0.001	25.13	10.37	<0.001

Table 1. Comparison between doctors and nurses

Table 1 shows the comparisons between doctors and nurses activities. The distribution of the activities within the classes of the WOMBAT framework is different, with the exception of administrative tasks and management of technical problems.

Interruptions affect doctors more during direct care and professional communication, while nurses are interrupted more frequently than doctors when performing administrative tasks or when in transit (getting around) in the ward.

The proportions of overlapping (% of the length of overlapping of each activity on the total number of interruptions) and multitasking (% of the standardized overlapping time for each activity on the total time observed for each activity) are significantly different in all the observed activities, with the only exception of multitasking during professional communication. Doctors are more exposed to overlapping and multitasking in direct care, documentation and management of technical problems, while nurses during administrative practices and indirect care. In the other activities the differences between overlapping and multitasking do not match, so we see more overlapping for nurses on education/supervision and while in transit, the other way round for professional communication and social presence where doctors have more overlapping and less multitasking than nurses.

## 4.2 Discussion

The main limitation of this study is the impossibility to study any correlations between the subjective data collected with the questionnaires and the objective data of the observations, because the respondents do not match with the observed workers. Due to resource and time constraints, we were not able to conduct the observation so to have a significant sample of the workers employed at the selected surgical wards. Therefore, the analysis and the discussion can only be made separately, with some final remarks on the overall picture that we obtained with this study.

Furthermore, the results of the observations are limited to the description of the activities and lack an evaluation of the errors eventually committed during the observed tasks.

Regarding the subjective data, we may then discuss the following points. Between the two levels of seniority considered, the total length of service and seniority in current team, this last seems to have less weight. The overall seniority in healthcare was found to be a determining factor already after the 10 years of service, both in terms of ability to work, both as regards the engagement (both in total, that for all subscales: vigour - dedication - absorption). The working capacity deteriorates with aging and deteriorates more for nurses and assistant nurses compared to doctors. The analysis conducted so far show that the other variables considered in the statistical model (typically, marital status, night work, type of work, setting) does not significantly affect the work ability (WAI) and engagement (Uwes) in all its dimensions (total Uwes; Subscales: Vigour - Dedication - Absorption).

A good work involvement allows healthcare professionals to resist against an increasing workload. In summary, the doctors and nurses of 6 Tuscan surgeries involved perceive a good working ability and a good involvement, but tends to decrease with increasing seniority in the context examined, while apparently independent of age and gender.

Among the three professional categories considered, nurses exhibit a lower vigour than doctors, while dedication is generally very high for everyone. Nurses and assistant nurses have three times the chance of having a work ability index of poor or mediocre compared to doctors. While the working seniority in teams increases by 44% the likelihood of a good working involvement. 75% of operators surveyed report suffering from at least one work-related disease, with at the first place musculoskeletal disorders, followed by skin diseases and gastro-intestinal problems.

On the basis of the 111 labour observing sessions, lasting an average of 1h and 20min, following 61 health care workers in the operating room and in the ward with the technique of shadowing, using the WOMBAT tool, it was possible to classify activities from the systems perspective, highlighting the interactions and timing of the main activities, multitasking and interruptions. It is impressive to observe that more than 60% of the clinical activities took

place in multitasking, which are subject to interruptions in 15% of cases for nurses and in 24% of cases for doctors.

The nature of interruptions, multitasking and overlapping must be further analysed in order to have a better understanding of the reasons behind the differences observed between doctors and nurses. Clearly there is a potential to redesign the working activities, taking into account the different distribution of the tasks between doctors and nurses and evaluating the risks of disruptive interruptions and multitasking both on workers and patient safety.

## 5. Conclusion & perspectives

Caregivers simultaneously perform multiple tasks and therefore are exposed to a cognitive workload that exceeds long the hours actually performed, even for the frequent interruptions that in a high intensity of relationship organization like the healthcare they account for an average of 6 interruptions every hour for a doctor. Communication remains a fundamental aspect of the work in health and is a key tool to improve security, but it can also be a problem if it is not structured and if not done in a specific manner. About a quarter of the medical and nursing care is dedicated to the documentation, for a 15% of purely bureaucratic. These preliminary analysis offer many insights, that the research team will explore together with the management of 6 surgical units.

Resilient operators then, but with signs of distress which must be taken into account for a longitudinal tracking, mainly to prevent the joint effects of shift work, long working hours, with multitasking and aging of the working population.

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## Collaborative efforts between Health Information Technology Patient Safety Officer and Human Factors Specialist to deliver HIT safe use

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### Abstract

In the phase of rapid deployment of Health Information Technology (HIT) to attain meaningful use incentives, organizations that do not pay close attention to assessing HIT usability and implementation could be at risk for unsafe use, with undesired effects on cost, efficiency, and patient safety. Our organization decided to invest in two additional personnel resources, an HIT Patient Safety Officer (PSO) and an in-house human factors specialist, to collaboratively oversee the prevention of patient harm due to HIT and to increase the value of HIT to prevent harm. To our knowledge, our organization was the first to deploy a patient safety officer dedicated to HIT related topics, and to work collaboratively with Human Factors (HF). Our paper focuses primarily on the roles of HIT PSO and HF in delivering HIT safe use and implementation, as well as exemplifying the collaborative efforts between the two roles to promote HIT safety. This paper shares two success stories: 1) proactive risk assessment for an HIT implementation in Oncology department; and 2) workflow analysis for intra-operative blood transfusion process. These projects have proven that collaboration between HIT PSO and HF is an important component for project success.

**Keywords:** health IT, Patient Safety Officer, HIT safe use, implementation.

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### 1. Introduction

Health information technology (HIT) is widely viewed as an essential tool to transform health care, as it can enhance patient care, improve the efficiency of health care delivery, and is a key to satisfying the needs of diverse stakeholders (Huckvale et al., 2010; Kirkendall, Goldenhar, Simon, Wheeler, & Andrew Spooner, 2013). In 2009, the Health Information Technology for Economic and Clinical Health (HITECH) Act created meaningful use (MU) incentives to promote HIT adoption ("Health IT Adoption Programs," 2014). This incentive has stimulated enormous investment in HIT and rapid adoption of Electronic Health Records (EHR) in the US ("EHR incentive payments climb toward \$24 billion," 2014). On the other hand, a hurried deployment without careful consideration of HIT design and implementation processes can limit the benefit of HIT and even put the MU incentives in jeopardy (Riddell, Sandford, Johnson, Steltenkamp, & Pearce, 2014). Worse, the benefit of HIT may be offset by consequences of poor design and use errors that include rising costs, inefficiency, preventable errors, and reduced quality of care (Han et al., 2005). HIT will only fulfill its potential if the risks associated with its use are proactively identified and a coordinated effort is developed to mitigate those risks prior to its implementation (Pascale Carayon et al., 2011; Sittig, Gonzalez, & Singh, 2014). Accordingly, management needs to make careful decisions in order to balance economic effectiveness and safety preservation.

## **2. State of the art and objectives**

In order to address the rapidly evolving HIT and its intersection with patient safety, quality and outcomes, our organization decided in 2015 to invest in two additional personnel resources, an HIT Patient Safety Officer (PSO) and an in-house human factors specialist, to collaboratively oversee the prevention of patient harm due to HIT and to increase the value of HIT to prevent harm. To our knowledge, our organization was the first to deploy a patient safety officer dedicated to HIT related topics, and to work collaboratively with HF. Our paper focuses primarily on the roles of HIT PSO and HF in delivering HIT safe use and implementation, as well as exemplifying the collaborative efforts between the two roles to promote HIT safety. Two examples and success stories are shared.

## **3. Results & Discussion**

### **3.1 Role of JHM's HIT PSO**

A role of PSO is mainly to oversee and address patient safety concerns in the hospital. A hospital usually has multiple PSO whose discipline varies (e.g., pharmacist may hold a role of medication safety officer and would address patient safety issues related to medication errors). However, there is limited experience with a PSO who focuses on HIT-related patient safety issues. Our health system has organized a clinical informatics community that includes multiple design teams. The HIT system is composed of multiple applications each with its own design team that includes safety representatives who are empowered to raise safety issues detected from systematic review of event reports. Clinicians who excel in HIT functionality would dedicate some of their time to be part of a design team to ensure appropriate design and use of HIT. However, most of these clinicians attend to a specific subset of HIT issues.

Our hospital then created the HIT PSO position to address the gap. The position was designed for a clinician with a vision of how a high reliability organization (HRO) would use HIT, understand how HIT capability and limitation could affect patient safety, and experience leading safety and quality efforts, including successful HIT deployments. Primary responsibilities are leadership and teaching to help the organization use HIT in a highly reliable way, to identify overarching HIT issues, to help define the highest priority safety projects for HF partnership with the clinical and operational stakeholders, to select the most appropriate solutions (i.e., one solution may solve multiple problems for multiple departments), to identify appropriate IT resources to accomplish the project, and to apply the science of safety to foster HRO culture within the HIT team. A key aspect of the HIT PSO reporting structure is independence from the financial and production pressures of the IT department.

Fortunately, our HIT PSO has extensive background in computer programming, which creates a more unique opportunity for our organization. His background allows him to quickly understand HIT system capability and limitations, which assists in decision making on a redesign solution.

### **3.2 Role of JHM's Human Factors in HIT safety**

The HF discipline is increasingly recognized as a major scientific contributor to healthcare quality and patient safety, especially in relation to HIT design, implementation and use (P. Carayon, Xie, & Kianfar, 2013). HF is specialized in assessing HIT and the context in which HIT will be used, in order to redesign HIT, deliver appropriate training and communication, ensure appropriate fit of HIT in the sociotechnical context, and ensure its safe use. At our organization, the HF specialist (a macro-ergonomist) plays an active role in performing fidelity usability testing

and evaluation of a new/existing HIT system, prototyping and (re)designing system interfaces, extensively analyzing workflow with a sociotechnical approach to identify potential safety risks and create mitigation strategies prior to HIT implementation, evaluating and recommending changes in organizational policies and procedures, and participating in root cause analyses for HIT-related events.

Several hospitals in the US have integrated human factors into the design and deployment of HIT, and while most HF hold background in cognitive psychology or systems engineering, many have a limited healthcare background, making it difficult to simplify and prioritize HIT related patient safety projects. With assistance from the HIT PSO, who understands both the clinical arena and the science of human factors, the HIT patient safety projects can be appropriately prioritized, assigned, and effectively and efficiently delivered.

### **3.3 Success stories from an integral effort between HIT PSO and HF**

Two examples of collaborative efforts between HIT PSO and HF are discussed.

First example—proactive risk assessment for an HIT implementation. HIT PSO acknowledged the need to perform proactive risk assessment prior to an implementation of the HIT in an outpatient pediatric oncology department. The intention of this assessment was to determine whether the department should delay the HIT implementation due to potential patient safety concerns. In proactively identifying and assessing the concerns and generating solutions successfully, it is critical to include all disciplines involved in the workflow in the discussion. HIT PSO knew the workflow of concern, worked with HF to map the workflow, and assisted HF in identifying and inviting most appropriate people to the discussion. A total of 15 participants (i.e., 6 nurses, 2 unit managers, 2 mid-level providers, 3 pharmacists, 1 provider, and 1 unit coordinator) from multiple units attended the meeting. HF facilitated discussion, using socio-technical systems as a framework, to identify potential patient safety concerns (e.g., inadequate skill, lack of fit between software and hardware, poor system usability). Because the right people were included at this meeting, we were able to deliver a list of top concerns by the end of a 2-hour discussion. In addition, all participants established a shared understanding of all concerns, how each would affect the process upstream and downstream, and felt less overwhelmed recognizing that high-risk concerns would be mitigated prior to the implementation. A total of 8 major concerns were identified and prioritized as follows: 1) improper security assigned for some HIT platforms may forbid clinicians to access necessary information for patient care; 2) medication database were not tested to avoid take-home prescription errors. There was a change in workflow in which handwritten prescription would be replaced by electronic prescription, and would be automatically routed to pharmacy; 3) poor system-system interaction created an error prone workaround process. Because implementation only started in outpatient clinics, in order to create a complete discharge medication list, outpatient medications in a new HIT system would need to be manually transcribed into an existing system; 4) change in provider's workflow to receive lab results. Providers would no longer only receive critical lab results in their inbox, but all results that pertained to them. They might neglect important results due to message overflow; 5) poor usability design could cause improper selection lab order (e.g., standing, future and STAT order status). This could delay specimen collection time and care process; 6) poor usability could cause incorrect scheduling, especially for oncology patients whose care schedule could be more complicated than other patient populations; 7) end users lacked understanding of workflow change could cause delayed treatments; and 8) the system was not tested to ensure providers could print from the correct printer. Many of the aforementioned concerns were on poor system usability, lack of knowledge of workflow changes, and lack of trust on HIT system operability. We thus decided to create a full high

fidelity dress rehearsal that simulated real oncology outpatient scenarios. All disciplines involved in the workflow tested the simulated system. HIT PSO elevated critical concerns and got mandatory system fixed prior to the implementation. For poor system designs that could not be addressed prior to the implementation, HIT PSO communicated effectively with end users, and ensured that system enhancements were followed up appropriately after the implementation. Comparing with other projects of similar nature, it was proven that having HIT PSO collaborating with HF could facilitate the project to success more effectively and more efficiently. HIT PSO helped select and engage the right people, who knew the workflow above and beyond just their own discipline, which made the assessment process much smoother. With the understanding of HIT technicality, prioritization of both safety concerns and solutions were determined much faster.

Second example—workflow analysis of operating room blood transfusion process. The project was identified by a subject matter expert, an anesthesiologist, who was highly concerned about the blood ordering and transfusion process that would change after the HIT implementation, and its effect on both patient safety and compliance with quality measures. This project required a workflow analysis to deliver an error-proofing process for intra-operative blood transfusion. Many experts (e.g., patient safety expert, HIT PSO, human factors, lean, and quality improvement) were initially involved when the project was introduced. It was two weeks prior to the HIT implementation, thus any HIT redesigns were unlikely. The expected final outcome of this assessment was to guide departmental decision-making on selecting system functions that should be (de)activated to facilitate the workflow, and to identify potential risks and design flaws that should be addressed post implementation. HIT PSO prioritized this project as critical to patient safety and requested that the issue should be addressed by HF. HF met with subject matter expert and created a workflow process map to capture the intra-operative blood process (ordering and transfusing); the process was complicated as it involved multiple disciplines. HF determined which disciplines were necessary to include to understand the current workflow, as well as the potential post-HIT implementation workflow. HIT PSO identified and connected HF with specific people. Because the right people were included, within one week, HF was able to deliver both pre- and post- implementation workflows, identify potential changes in workflow, HIT design issues that might affect the care process, and HIT interfaces/workflow that might mis-align with quality measure compliance. Main identifiable issues included: 1) lack of fit of HIT designs to clinical workflows (e.g., *rapid blood ordering and retrieving, scanning and documenting of two-person verification*); 2) ambiguities around role (i.e., *blood order*), process (i.e., *event timeline, verification and documentation*), and policy (i.e., *documentation in relation to the two-person verification process to comply with standard*); 3) lack of adequate training; and 4) lack of trust in proper hardware-software integration. HF consulted HIT PSO about the identifiable problems and possibility to redesign at the point in time. HF subsequently recommended the department to minimize any changes to their workflow and focused mainly on getting staff effectively educated of the new user interfaces. HF worked with HIT trainers to identify critical training points to close knowledge gaps and to ensure delivery of safe care. Training material was designed with user-centered process. Contingency plans were created for potential fallible steps and thoroughly communicated with end-users. Several system and workflow flaws, as well as changes in policy would be assessed and solved after the implementation to deliver care enhancement and quality compliance. This project also proved the value for improved efficiency and effectiveness when HF and HIT PSO collaborated.

#### 4. Conclusion & perspectives

From HF perspectives, HIT projects may not have gone as smoothly and successfully without assistance of HIT PSO. Several months prior to the HIT implementation, HF could have been overloaded with HIT projects to prevent patient safety risks and to improve smoothness of HIT transition. Given that there is only one HF personnel in our organization, prioritization and selection of HIT related projects by HIT PSO has made HF roles more critical, valuable, and recognizable.

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## Access to care for people with mental disabilities getting older through the study of the accessibility to medical devices: the situation in France

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### Abstract

Thanks to progress in medicine, life expectancy for people with mental disabilities has clearly increased in recent years. In 1930, life expectancy for those affected by mental disorders was 19.9 yr for men and 22 yr for women. In 1980 it was 58.3 yr and 59.8 yr respectively (Carter & Jancar, 1983). As reported by Azéma & Martinez (2005) for this population, « there is a cumulative result of degenerative disorders linked with age in addition with pre-existing capacities. Chronic diseases occurring during the classic ageing process can « add further impairments to any age-related incapacity » ». For this reason, the issue of access to care for this population through the use of medical devices adapted to the characteristics of aged people rather than to people with mental disabilities is now of great interest. Of course, medical devices for people with mental disabilities and for the elderly obey different rules of design, and involve different norms and mode of reimbursement according the situation and country.

The main issue is to know what happens if a medical device is to be adapted not only to an ageing population but also to elderly people with mental disabilities. This article attempts to answer this question. Two questionnaires were sent to healthcare professionals. The goal was to gain an overview of the access to care for this population and their monitoring and highlight elements to improve their access to care. This article presents the methodology used and how the questionnaires were organized. The preliminary results are then presented. Hypotheses deriving from these questionnaires are proposed and future research paths are discussed.

**Keywords:** mental disorder, ageing, access to care, medical devices

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### 1. Context

Thanks to progress in medicine, the life expectancy of people with mental disabilities has clearly increased. In 1930, life expectancy for those affected by mental disorders was 19.9 yr for men and 22 yr for women. In 1980 it was 58.3 and 59.8 respectively (Carter & Jancar, 1983). Furthermore, in France, there are 635 000 people over the age of 40 with mental disabilities, including 267 000 people, who are more than 60 years old. As a result, this group

is now exposed to ageing issues such as neurodegenerative diseases like dementia of the Alzheimer's type or similar syndromes (Faculty for Learning Disabilities, 2009).

The consequences of these diseases are to be added to disorders already existing in relation with mental problems and they need to be specifically managed. In addition, for people with mental disabilities, the onset of these neurodegenerative diseases might be early (around 30 yr for people affected by Down's syndrome) (Ball & Al, 2006). As reported by Azéma & Martinez (2005), there is a cumulative result of degenerative disorders linked with age in addition to pre-existing capacities. Chronic diseases appearing during the classic ageing process can add further impairment to any age-related incapacity. In addition to the complications of ageing, mental disorders may have several consequences: difficulties in understanding the use of a medical device, personnel unprepared for the consequences of this disability and medical devices not adapted to the situation.

To date, there have been few suitable resources for such people. Accessibility to care is not adapted and, as a result, an action judged as very simple to achieve might be really hard to perform: going to the dentist, for example, might become a real challenge. To illustrate this, people in France are accepted in retirement homes or institutional housing from the age of 60 onwards. Currently, the average age of entering a retirement home is 84.2 for men and 86.6 for women (Observatory of retirement homes, April 2014). People with mental disorders live in institutional housing adapted to their disability (Medicalized Foster Home (MFH), Institute of Educational Development (IED), Specialist Care Home (SCH)...). However, when ageing issues appear for these people, the mode of care provided may not be suitable. This situation deals with the problem of the management of these people: who should accept and take care of these people?

Professionals are increasingly investigating the access to care for this population through the use of medical devices adapted to the characteristics of aged people rather than simply to people with mental disabilities. Medical devices for people with mental disabilities and for the elderly obey different rules of design, and involve different norms and mode of reimbursement according the situation and country.

The predominant issue that arises is as follows: how can a medical device meet the needs of an ageing population that could potentially suffer from mental disabilities?

## **2. Methodology:**

To investigate this issue, questionnaires were sent to healthcare professionals working in social establishments in order to assess the extent of this problem. Questionnaires are often used in human-centered design (ISO/IEC 16 982, 2002; ISO TR 18 529, 2000; ISO/IEC 13 407, 1999). In this way, the opinions of stakeholders concerned by this problem can be highlighted (Baccino et al., 2005; De Singly, 2012; Leroy & Pierrette, 2012; Martin, 2007).

The aim of this work was to obtain a current overview of access to care for this population in France and to highlight problems requiring solutions.

The questionnaire was prepared iteratively between January and March 2016. Different versions were proposed to two experts in this field: an expert in disability and a current director of a Specialist Care Home (SCH) who was previously director of a retirement home. For each item, their remarks were obtained and the questionnaires were modified. This first step highlighted the need to produce two questionnaires:

1. a first one for retirement homes specialized in the elderly;
2. a second one for establishments specialized in looking after people with mental disabilities (FHM, IED, SCH, ...).

In the end, four propositions were required to establish a general agreement. After that, two more experts were consulted (a psychologist and a director of a retirement home) in order to have their opinion on the questionnaires. This led to a few minor modifications. Then the questionnaires were definitively validated by all the experts and were sent to the recipients. Questionnaires could either be filled in on paper and sent to the author of the questionnaire to record the answer, or they could be completed online with a Google Form. The aim was to obtain as many answers as possible to obtain the most representative and reliable statistic sample. Questionnaires could be filled in by anyone working in a social establishment, i.e. a healthcare professional, a logistician, an hotelier, an administrative person or by the management of the establishment. Indeed, it seemed important to take the opinions of all the people working in an establishment into consideration. Questionnaires were sent out between April and May 2016.

### Description of questionnaire

For both questionnaires, the first part comprised a global description of the establishment (capacity, average age of admission) and the person who was answering (function, length of service, ...).

For retirement homes, there was a question to know whether their institution welcomed elderly people with mental disabilities or not. If the answer was no, an explication was requested. If the answer was yes, other questions sought to understand better the context of admission, the reason why the person was accepted and how he/she was managed. A free question also investigated quality of care.

For the other establishments, if they did not take in people with mental disabilities, the questionnaire was finished. On the contrary, if they did, more information was requested: what kind of disturbances were they suffering from, how were they monitored? If some of them left the establishment during their stay, questions were asked about the reason for the departure (care not adapted, legal problem, etc) and the future destination. In all cases, there was a free question about the quality of care and solutions needed according to the person who was answering. Figure 1 illustrates the organization of the two questionnaires.

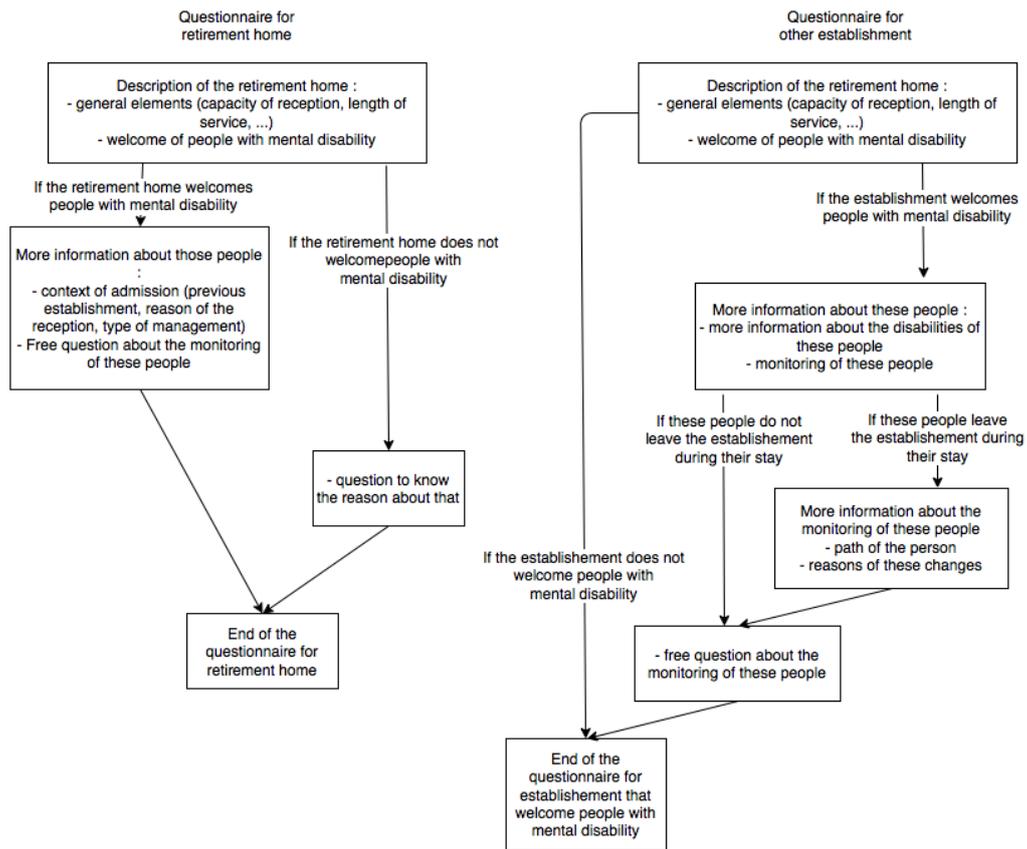


Figure 1. Organization of the questionnaire

The questionnaire for retirement homes contained 15 questions while the one for other establishments (SHC, FCH, IDE, ...) had 21. Most of the questions were multiple choice questions (some had only one possible answer, others had several possible answers). There was one free question (the question about the quality of care in the establishment) for both questionnaires. The first part of the questionnaire related to the global description of the establishment had the same questions, irrespective of the kind of establishment the person was in. Then, questions became more specific according to the establishment and the population cared for.

### Results and discussion:

We received 45 responses from professionals working in retirement homes and 33 from people working in other establishments (SHC, FCH, IDE, ...). Table 1 shows results concerning the reception capacity for each category of establishment (retirement homes vs. establishments dedicated for people with disabilities). Table 2 shows residents' age when they entered the establishment.

	Retirement homes	Other establishments for people with disabilities (SHC, FCH, IDE, ...)
Minimum - Maximum	42 - 204	7 - 135
Average (standard deviation)	80 (28)	36 (26)

**Tableau 1.** Reception capacity (number of beds) according to type of establishment

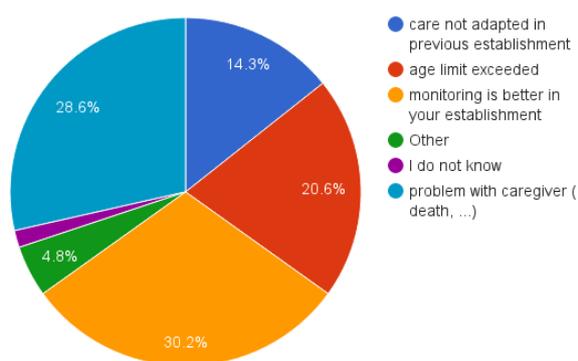
	Retirement homes	Other establishments for people with disabilities (SHC, FCH, IDE, ...)
Minimum - Maximum	55 - 90	3 – 62.4
Average (standard deviation)	79.6 (8)	32.4 (17.6)

**Table 2.** Age at admission (in years) according to type of establishment

For the retirement homes, the average reception capacity of an establishment was 80 people with an average age of 79.6 years old. These results are similar to those in other studies showing that the average reception capacity of a retirement home is 76 and the average age at admission is 85.4 years (L’observatoire des EHPAD, Avril 2014), so our sample seems to be representative.

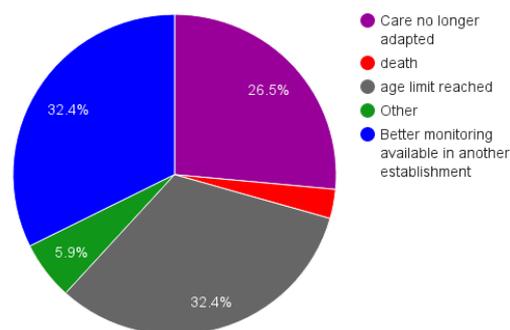
In establishments for people with disabilities, the average reception capacity was 36 people and the average age at admission was 32.4 years.

**Context of admission to retirement home**



**Figure 2:** Admission to retirement home

**Reasons explaining departure of resident from an establishment**



**Figure 3:** Reason for leaving an establishment

In spite of this representativeness, the standard deviation for age at reception in retirement homes was lower than that in establishments for people with disabilities. It shows that age of entrance into an establishment for people with disabilities is much more varied than that for entering retirement homes. As a result, the problems of dealing with people with disabilities

in the specialized establishments are more complex and more variable than those encountered in retirement homes, since more generations are present in them. Concerning the standard deviation of reception capacity, they were very close in the two types of establishment: 28 for retirement homes and 26 for the others. However, the average reception capacity was much higher in the retirement homes (80 versus 36). This shows how difficult it may be for establishments accepting subjects with mental difficulties to deal with the high demand for places.

#### *Who answered?*

Questionnaires were completed by very diverse people: directors, nurses, psychologists, occupational therapists, guardians, hoteliers and managers of both types of establishment.

#### *Length of service of people who answered*

In retirement homes, 30% of the people who answered reported working in their establishment for more than 5 years. In the other establishments, 47% had been working for more than 5 years. Most of the people who answered could be considered as experts in their field with good knowledge of their establishment and the problems on which the questionnaires focused since almost one out of two had been working in the establishment for at least five years. Moreover, they could be considered as representative of experts in their field.

The sample who answered the questions is representative of the field studied and may be considered as experts of their fields and the problems.

### **3. Results**

#### Why do patients change establishment?

Figure 2 shows admission to retirement homes of people with a mental and/or psychological disability. Figure 3 shows the reasons for the departure of a person with a mental disability from an establishment.

Figures 2 and 3 show several similarities in the reasons mentioned (in order of importance):

1. adaptation of management
2. adaptation of care available
3. age limit (which is 60 yr according to law)

The first two reasons show the difference between the fields of gerontology and disability in terms of adaptation of monitoring and care provided. There would seem to be a dichotomy and a categorization of people between the two fields (Blanchard & Mortier, 2015). As soon as problems accrue with pre-existing ones, establishments are no longer equipped to deal with them. The resident then has to leave the establishment with all the consequences that involves (need to adapt to a totally new environment, loss of his bearings, ...) There is therefore a need to rethink the monitoring of care and systemic care in a way that takes into consideration the range of people received.

This need is also illustrated by the age limit which is one of the main reasons for change: administrative factors are very important during a person's life and especially in those with a disability. After 60, it is no longer possible to obtain the status of disabled person in France. The only status available is that of elderly person (which provides access to less care). These legal issues can have a very negative impact on individuals (Roussel, 2006) and the age limit seems questionable at the least. Legal and administrative hurdles may impinge on the capacities of the individual (Azema & Martinez, 2005; Mortier & Blanchard, 2015) and people

find it more difficult to gain access to their rights as they age (Mortiez & Blanchard, 2015). This has been confirmed by studies conducted by the French government on elderly people with disabilities (Gohet, 2013). Indeed, the definition of what disability really means should be based at the very least on cognitive and motors capacities.

However, a major difference is to be noted. It concerns caregivers, a problem that is apparent in responses regarding admission to retirement homes in more than one case out of four. One of the biggest problems is that there is no help or advice available as to how the decision is to be taken. Informal caregivers are unaware of whether they can benefit from help or of what kind of help (medicine, medical devices, ...) (Magnavacca & al., 2011). Moreover, for people with disabilities living at their parents' home, the first signs of the aging process can appear when they are around 40 years of age so they will survive their parents (Grohet, 2013). When they survive their parents or when the latter can no longer care for their child, it is unclear what actions can be undertaken. As a result, either the person is hospitalized by default or is sent to a retirement home without being consulted. A new patient management and information system is therefore required so that patients are cared for suitably and that caregivers are treated properly.

### What is the trajectory?

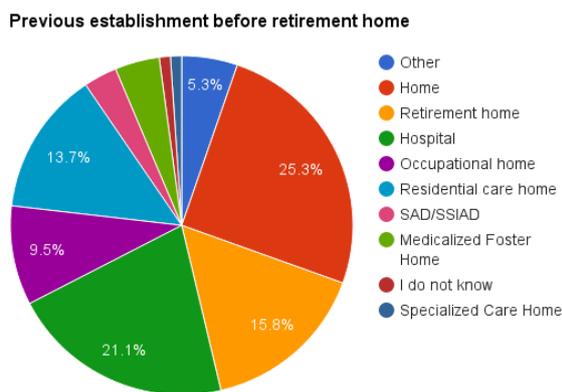


Figure 4. origin of persons before entering retirement

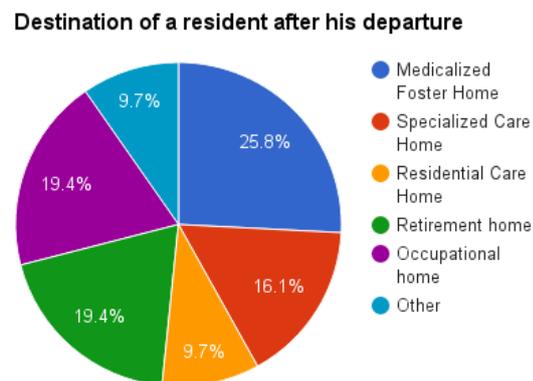


Figure 5. Destinations of persons with mental disability

Figure 4 illustrates the trajectory of a person with mental or psychological disability before they enter a retirement home. Figure 5 illustrates where people with mental disability go when they leave their previous establishment.

Comparison of figures 4 and 5 reveals two main differences:

1. Almost one resident out of two living in a retirement home does not come from another establishment (SHC, IDE, ...) but from his home (25.3%) or hospital (21.1%).
2. Few residents leave an establishment for people with disability (SHC, IDE, ...) to go a retirement home.

### How well is this population managed?

A final observation confirms this observation. When people were asked to judge the quality of the monitoring of elderly residents with mental disability in retirement homes, more than one person out of two considered that the management was ill-adapted. The main problems mentioned were behavior problems such as aggressiveness and shouting which are characteristic of the problems encountered when looking after people with mental disabilities.

#### 4. Conclusion and perspectives:

These questionnaires have provided a preliminary overview of access to care and monitoring for people with mental disabilities and especially for those who are aging. The study reveals various type of problems: legal issues (age limit), social problems (related to the caregiver) and access to care (which is not always adapted). If access to care is to be improved, not only medical devices need to be improved but also all caregiver-related issues need to be given more thought.. One of the most important results of this study is the divide between the fields of gerontology and disability. Bridges should be found between them and they should be made visible with specialized training programmes and the creation of establishments that attempt to fill the divide.

Discussions and observations will now be undertaken as a result of this study in order gain better insight into all the problems encountered by professionals and to better understand their needs. The findings also confirm the importance of the caregiver. When the caregiver can no longer take care of his relative, the latter goes to a retirement home or to hospital, but then back to a retirement home where care is not really adapted.

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## Training leaders for resilient health care: Negotiation 101 for healthcare executives

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### Abstract

*Context:* This study reports on evaluation of a two-day intensive negotiation skills training course, delivered to senior clinicians, managers, and executives within an Australian health service.

*Objectives:* The study aimed to evaluate the effectiveness of the negotiation training, by exploring whether staff members have implemented negotiation skills in their workplace in the time period since the training, and if so, how and when.

*Methodology:* The study used a qualitative approach, involving face-to-face interviews with 18 staff members who have completed the training. Interviews were transcribed verbatim, and inductive interpretive analysis techniques used to identify common themes.

*Main results:* Participants generally reported positive affective and utility reactions to the training, and all participants attempted to implement at least some of the skills in the workplace. The largest enabler for implementing the training was identified as provision of a Negotiation Toolkit, consisting of tools and worksheets to assist in preparing and conducting negotiations. The biggest barrier to implementing the skills in the workplace was identified as lack of time to reflect on the principles and to prepare for upcoming negotiations. Ongoing skill development and retention were identified by most participants as not adequately addressed; suggestions for improving sustainability included provision of refresher training, mentoring, and/or allocating each participant a 'person to call' to discuss difficult or complex negotiations as they arose.

*Conclusion:* The training was well matched to the needs of participants, with negotiation a common and daily activity for most healthcare professionals. Implementation of the skills showed potential for improving collaboration and problem solving in the Australian health service studied.

**Keywords:** resilient health care, training, negotiation, non-technical skills

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### 1. Introduction

Lack of resources is a perpetual problem in healthcare, an issue unlikely to change with the growing demands of an aging population and the rise in chronic health conditions. Healthcare professionals, especially those with management responsibilities, can often find themselves in situations where in order to maximise resources, they need to negotiate with their colleagues and patients, and sometimes a range of stakeholders including hospital boards, medical committees, politicians, lobbyists, community leaders, and business executives (Anastakis, 2003). Intensive negotiation skill training endeavours to improve engagement and

collaboration between healthcare professionals, and thereby improve resilience of the workplace. Negotiation offers a framework for increasing value in the organisation without extra cost, by promoting integrative ‘win win’ outcomes.

The location of this study, a large health service and acute hospital in regional Australia, is currently undertaking intensive negotiation skills training for executive, senior clinicians and management staff. Research suggests that the effectiveness of negotiation training depends on the design and intensiveness of the program, and that post-training evaluation is crucial (Coleman & Lim, 2001; ElShenawy, 2010). This paper reports the results of an evaluation of the training, including the implications of findings for organisational resilience.

### **1.1 Description of the training**

The health service has sponsored negotiation skills training since February 2015, with 80 staff completing the program as of May 2016. The course runs for two days, and focuses on intensive negotiation skills training using integrative bargaining, training participants to identify ‘win win’ solutions that can improve efficiency without incurring additional cost. An internationally recognised consultant and skilled negotiation specialist, from a large Australian commercial law firm, facilitated the training. During the training, participants completed a modified Thomas-Kilmann Conflict Mode Instrument (TKI) self-assessment questionnaire (Kilmann & Thomas, 1977; Shell, 2001), which identified their behavioural preferences for interacting with others. Outcome of the TKI placed the trainee on a grid with relationship/outcomes axes, and identified their natural preference for one of five negotiating styles: competitive, collaborative, accommodating, avoiding, or compromise (Figure 1). The training used a modified version of the TKI (Lewicki & Hiam, 2006), which identified three additional styles lying ‘outside’ the grid: borrower, con and rob.

### **1.2 Expected Outcomes**

This study will determine whether the two day negotiation skills training course was successful in providing staff with the skills necessary to enact integrative bargaining in the workplace. It will also add to an understanding of how such negotiations might facilitate better collaboration and resource management within complex healthcare organisations.

## **2. State of the art**

Corporate firms have long recognised the value of skillful negotiators and invested in training programs to increase the negotiation skills of their managers (ElShenawy, 2010). Healthcare professionals receive little or no training in negotiation as part of their medical training, and there is a growing need to implement negotiation training programs in the primary health care setting. In the current environment, where the required standards of care are high and the emphasis on cost-effectiveness continues to increase, negotiation is an important asset among health care providers, and probably the most important skill any clinician leader can have (Mellman & Dauer, 2007). To our knowledge, this is the first study aimed at evaluating the effectiveness of an intensive negotiation training program targeting executives, senior clinicians and management staff at a major Australian health service.

## **3. Objectives and Methods**

### **3.1 Research objectives**

The aim of the research was to evaluate the effectiveness of the health service intensive negotiation training by investigating whether staff members have implemented the integrative

bargaining skills in the time period since the training, and if so, how and when. The study used a qualitative approach, involving face-to-face interviews with staff members who have completed the training.

### **3.2 Selection of participants**

All current health service executive, senior clinicians and management personnel who completed the negotiation skills training course (with the exception of the study investigators) were eligible to participate in this project, resulting in a source population of 71 staff members. A random selection of staff members who have completed the training were invited to participate in a semi-structured interview to collect post-implementation staff perceptions of the training and its utility. The study source population was stratified prior to random selection of interview participants to ensure that a representative spread was sought from the executive, clinical and management groups.

### **3.3 Procedure**

Interviews. Each participant was interviewed face-to-face in a private room. Interviews were audio recorded, and professionally transcribed verbatim to prepare them for analysis. Participants were asked about current workplace attitudes, behaviours and processes that may have been impacted by the negotiation training, and their experiences of applying negotiation skills in their workplace. Interviews were conducted at least eight weeks after completion of the training to allow time for the skills to be translated into practice.

### **3.4 Analysis**

Interview data were analysed in an integrated fashion. Inductive interpretive analysis of transcribed interviews was undertaken to identify key themes relating to the negotiation skills training. Coding the data allowed it to be organised and used to explore connections between data elements and to develop sets of concepts. Once coded, segments of data were linked in a formal fashion to allow themes to emerge and to determine relationships that may exist between different data sets. This is a way of studying real world complex systems such as healthcare.

### **3.5 Ethical considerations**

Ethics board approval for the study was obtained from the Townsville Hospital and Health Service Human Research Ethics Committee (HREC/15/QTHS/219) and the Macquarie University Human Research Ethics Committee (MQ 5201600280). The study was funded by a small grant from the Townsville Hospital and Health Service Research Trust Fund; the funding body had no role in the conduct or reporting of the study.

## **4. Results & Discussion**

### **4.1 Participants**

Eighteen staff members who had completed the training, comprising 25% of eligible participants, were randomly selected and agreed to be interviewed. Prior to selection for the study, health service administrators stratified eligible participants into executive, clinician or manager categories. During the interviews, however, it became evident that there was no distinct line separating managers and executives, and most managers/executives also identified themselves as clinicians; therefore, the results are reported as arising from a single sample. While eight of the 18 participants completed the course within the previous three

months, the remaining 10 participants completed the training between 9-15 months previously. Six participants had either previously completed negotiation training, or had been exposed to the negotiating principles; for the remaining 11 participants, the training material was new. Participants were identified by the self-assessment questionnaire to have a natural preference for the following negotiating styles: competitive (n=1), collaborative (n=6), avoiding (n=6), compromise (n=3), and borrower (n=2). Participant demographics are in Table 1.

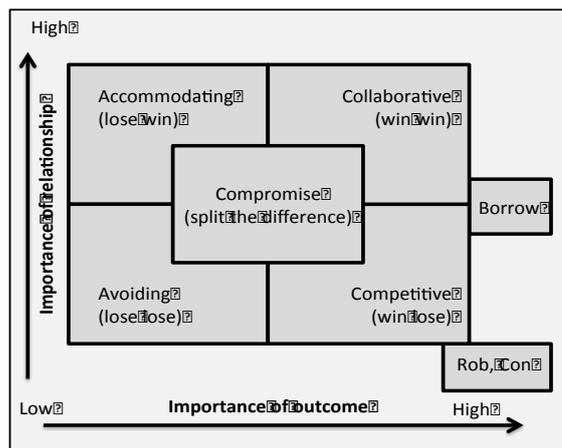


Figure 1. Negotiating style preference grid

Characteristics	Participants (n = 18)
<b>Gender</b>	
Male	8
Female	10
<b>Age (years)</b>	
20 – 30	1
31 – 40	6
41 – 50	10
51 – 60	1
<b>Time in profession (years)</b>	
< 1	5
1 – 2	6
3 – 4	5
≥ 5	2
<b>Duration at organisation (years)</b>	
< 1	1
1 – 5	7
6 – 10	5
11 – 15	3
≥ 16	2

Table 1. Demographic characteristics of study participants

## 4.2 Affective and Utility Reactions

Most participants were excited at the prospect of training: they had heard positive things from colleagues who participated in previous sessions about both the training and the facilitator, and came to the course with high expectations of learning something new and interesting. Whether this positive affect persisted following the training seemed to depend on the participants view of the facilitator. For the majority of participants, the facilitator was admired and respected as an engaging speaker and an expert negotiator; but for a minority he was seen as self-promoting and verbose.

Participants liked learning about their own negotiating style (and were interested in the styles of others); they enjoyed the opportunity to spend time with colleagues. Participants had a variety of responses to the groupwork and role play elements of the training, ranging from enjoyment and enthusiasm, to trepidation and dislike. Some participants, particularly those with previous negotiation experience, felt that two full days of training was too long.

All participants had positive utility reactions to one or more aspects of the training. For most, the useful components were the practical examples, the structured approach to negotiation, and the tools and templates: "... just having that framework in your mind around how to do it and how to prepare for it certainly keeps a negotiation on track ..." (Interview #5) The key points (or 'golden rules'), the opportunity for short practice in the groupwork, and the insight into personal negotiating style preferences were also considered useful for work. Many

participants arrived at the course with specific examples in mind of where they would use the training when they returned to work: *“I actually have quite a few meetings that are quite difficult in lots of ways, where there is a lot of negotiation ... I wanted to be there to learn how to manage those situations better”* (Interview #9). For others, however, the training was not matched to their needs. This was particularly the case for junior managers, and for some clinicians with clinical management responsibilities: *“... a lot of it was lost on me because I didn't have that work experience.”* (Interview #2). In particular, the lack of clinical focus in the training anecdotes and in the groupwork scenarios resulted in the content lacking meaning and relevance for some participants: *“the focus was on executive non-health-related interactions ... just wasn't a good fit for clinical services, for clinicians ...”* (Interview #10)

### **4.3 Barriers and Enablers**

Time was the biggest barrier to employing the skills in the workplace. Most of the participants identified the need to get organized and prepare for each negotiation, and felt that finding sufficient time to do so was a challenge: *“one of the biggest barriers for me as a clinician is having time to enact what I know”*. (Interview #6) Participants who were involved in negotiations with the state health department felt that the unwillingness of the department to negotiate, or the practice of sending negotiators who do not have authority to decide, was also a barrier to both successful negotiation and implementation of the skills: *“there are some things that you are able to negotiate but there's really some things in the structures that we have within [the health department] that you just can't.”* (Interview #1)

The biggest enabler was provision of the Negotiation Toolkit – a series of worksheets to assist in preparing for negotiations. Elements that were most used were the 7 Elements of Negotiation Scoresheet (where relationship, communication, interests, options, legitimacy, commitments, and alternatives are listed and scored), and the Negotiation Worksheet (where theirs/ours interests, Best Alternative to a Negotiated Agreement, and No Deal Option are determined and noted). Some participants had these and/or the ‘golden rules’ laminated on their desks or pinned on the wall.

### **4.4 Work practice**

Every participant indicated that negotiation formed an integral part of their daily work: *“... you always use negotiation every day ...”*. (Interview #4) Most participants had employed at least one aspect of the training in their work, and gave one or more specific examples to illustrate where they were approaching their interactions with others differently than in the past, or were more engaged in looking for ‘win-win’ outcomes. Participants could also point to examples where negotiation was starting to make a positive difference to relationships, personal performance, or organizational outcomes. Some participants felt more confident following the training, both personally, and also in their ability to succeed in resolving longstanding or complex problems.

Participants began to notice when others were employing the techniques: *“... from very, very early on I could see ... the way he was playing the game.”* (Interview#3) For some, it was enjoyable and energising to negotiate, and to notice how others negotiated: *“so in that instance [when negotiating against a difficult opponent] I find negotiation becomes more sporting to me.”* (Interview #3) The examples provided by participants predominantly involved moving from a ‘win-lose’ to a ‘win-win’ situation: *“People are trying to work through [their problems] a bit more clearly rather than putting a line in the sand and putting another line in the sand and then digging a trench.”* (Interview #5)

Participants believed that preparation was the most important element of skilled negotiation, and many gave specific examples to support this assertion. However, the healthcare workplace infrequently allowed sufficient time for preparation, particularly for clinicians, and this hampered the ability to use the skills for many participants: *“The actual time to think and work on the business instead of in the business is very difficult to ring fence and protect.”* (Interview #9)

#### 4.5 Sustainability

There was some overlap between ideas for improving sustainability and enablers for translating the training into the workplace, in that having processes for sustainability in place was considered to aid training transfer. Despite high levels of engagement, participant recall of specific learning points was variable, and was more dependent on whether the participant was using the skills in practice than how long since they had trained. All participants could recall their preference for negotiating style, and the style they reverted to under pressure, when shown a picture of the grid in Figure 1.

Many participants raised the need for assistance in translating negotiation skills to the workplace, and in sustaining learning. Most participants felt that refresher training would be useful, and had strong, but quite varied (and sometimes conflicting) views on how this should be delivered: options included repeating the course every couple of years, completing an abbreviated version of

the training (half to one day), and completing monthly sessions with other interested colleagues to work through specific practical problems. Participants also felt that coaching, whether in the form of a mentor, or a person to call to discuss difficult or complex situations, would be helpful and enhance learning and training transfer. The need for formal discussion groups was also raised by a number of participants: *“maybe a small work group of peers ... getting together and just having a half hour or so session ...”*. (Interview #5) Practice was considered to be critical for sustainability: *“the more times you practise using the template, and the more times you practise a different negotiation style, the more likely that is to start to impact on your day-to-day [work]”*. (Interview #6) Some participants also suggested the need for advanced training, for those already versed in the basic skills but needing to work through more complex, sometimes healthcare-specific, scenarios.

#### 4.6 Discussion

In healthcare, we might imagine that decisions are made, and resources allocated, by those authorised to do so, and in accordance with a structured plan. In reality, authority gradients are flat (and sometimes reversed), and clinicians and managers frequently need to convince others over which they have no authority of the need to pursue a particular course of action. Successful work-as-done therefore often depends on establishing a series of small or large ongoing agreements between individuals or craft groups, and negotiation skills are crucial. Despite the large variety of negotiating styles that were found among the participants in our study, the importance of negotiation in the workplace, and the need for tools and techniques to assist in negotiating successfully in everyday work, were universally accepted, and we found considerable evidence that the skills are being applied. These findings confirm what we know from the literature: i.e. that content relevance and opportunity to perform have a strong to moderate relationship with transfer of training to the workplace (Burke & Hutchins, 2007). Utility reactions to the training were also generally positive. In a meta-analysis of 34 studies, Alliger and colleagues (Alliger, Tannenbaum, Bennett, Traver, & Shotland, 1997) found that utility reactions correlated with learning; utility reactions have also been found to correlate with on the job performance (Alliger et al., 1997; Ruona, Leimbach, Holton, & Bates, 2002).

Word of mouth was an important element of participant affect and expected utility of the training: people talked about the course, and that talk seemed to be very positive. Despite high expectations, the course was enjoyed by most participants and perceived as more engaging and participatory than other courses offered by the health service. *“I thought his training was so good. I mean I walked out of there inspired.”* (Interview #1). Viral spread is perhaps more prevalent that realised in health services, and an important element facilitating change in complex adaptive systems such as healthcare (Braithwaite, Clay-Williams, Nugus, & Plumb, 2013; Clay-Williams, 2013).

Noticing others using the skills in the workplace provided both a revision of the principles, and also, when those observed were successful, positive reinforcement of the value of using the skills. Laminating the material for mounting on wall or desk also enabled reflection or revision on the principles, and a visual ‘aide memoire’ to use them. Unlike many training courses, the majority of participants in this training appeared to have assimilated the principles into their everyday work. Even those who trained most recently talked about their attitudes to solving disagreements involving people or resources in ways that showed the training was taking effect. Even those who did not like the training, or think it particularly useful, adopted some of the principles.

Readiness for learning is important, therefore the training should be better tailored to the immediate needs of the participants, or participants encouraged to self-select onto the training based on their perceived needs. Given the time pressures of clinicians, there might be value in modular training, where, for example, theory delivered via didactic modules or pre-reading, is followed by face-to-face training sessions interspersed with practise implementing the ideas in the workplace. Participants kept their course notes, and many said that they intended to reflect on the material, but admitted they had not got around to it. Instituting formal refresher sessions or other ongoing training strategy is important for sustaining positive changes to the way people work.

Annual negotiations between the health service and the state health department, particularly where they involve funding, can be protracted. In some cases, although participants felt that the training would be useful in preparing and conducting such high level negotiations, it turned out in hindsight to be less relevant in practice: *“We tried to put a framework around it and I believe we certainly did but the department of health had no interest really in negotiating with us.”* (Interview #1) While the health department pays lip service to the concept of negotiation, the participants were able to easily recognise that the stated intent to collaborate and negotiate was little more than an aspirational goal. Transfer climate has been found to have a major influence on whether training is transferred (Goldstein & Ford, 2002; Rouiller & Goldstein, 1993; Tracey, Tannenbaum, & Kavanagh, 1995; Warr, Allan, & Birdi, 1999), and participants become frustrated when provided with a skill then prevented from using it. Implementing the training in the health department, therefore, would improve utility of the training at the health service level.

## **5. Conclusion & limitations**

Negotiation training shows potential for improving organizational resilience in healthcare, providing synergy between the needs of professionals and how work is done. Negotiation is common in the workplace, and uptake and translation of negotiation skills to the workplace appears to be high in comparison with other health service training. Limitations of this study are that the data are self reported, with all the attendant biases. In addition, participant views of the facilitator were polarised, with the majority displaying an intensely positive affective reaction, and this ‘halo’ effect (Nisbett & Wilson, 1977) may have coloured their assessment of the training and its efficacy.

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## Clinical risk management and patient safety in the primary screening for human papilloma virus (HPV): analyses of the process

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### Abstract

*Context:* Following the Italian decision to introduce HPV test as primary screening test for screening of the cervical cancer, national authorities and research centers considered necessary to make a proactive analysis of the potential risks of the new screening pathway from the point of view of patient safety.

*Objectives:* The main goal of the project is to analyse the new path of cervical cancer screening with HPV test as primary screening test and provide a reference model to prevent adverse events and clinical risks related to them, identifying steps in which potentially failures in the system can occur.

*Methodology:* The method chosen for the critical analysis of the path was indeed the FMECA (Failure Mode, Effects, and Criticality Analysis), a tool widely used in the field of risk anticipation and management as it proposes a proactive approach to risk analysis.

*Main results:* The most critical sub-phases have been identified in the pre-analytical phase and, in particular, the reception and identification of the woman and the production and application of labels for the sample. The automation of the analytical phase contributed indeed to a clear decrease of clinical risk in the laboratory phase.

Tools drafted for the risk containment are:

- 1) A representative poster of the Standardized Operating Procedures
- 2) An ideal model of a “working desk”
- 2) A communication poster for women.

*Conclusion:* The two posters will be tested in all of the clinics of the healthcare facilities involved in the project. Questionnaires will be administrated in order to: 1) evaluate the SOP in terms of effectiveness in the daily practice and ability to intercept potential errors 2) evaluate the communication poster in terms of usefulness in providing guidance and information on the new cervical cancer screening path and HPV infection.

**Keywords:** patient safety, HPV screening, Failure Mode, Effects, Criticality Analysis

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## 1. Introduction

The Italian National Plan for Prevention 2014-2018 foresees, by 2018, the HPV test as a primary screening test for the cervix cancer (Ministry of Health 2014). After the realization of large European controlled randomized trials, including the Italian study NTCC, and after the review and analysis of the results of these studies, translated in 2012 recommendations for Health Technology Assessment (integrally adopted by the Ministry of Health), some regions started implementing the new cervical cancer screening path. The implementation of this programme started with some differences among the regions. Some Italian regions foresees to start the new screening program for the cervical cancer with the HPV as a primary screening test for women between 25/30/35 and 64 years of age with the range depending on the single region. Some region foreseen a centralization of the tests in few laboratories (from one to three depending on the region) in order to guarantee the highest quality standards, to optimize the volumes and contain costs (centralized model) while other regions decided to continue using local laboratories inside the single hospitals rather than creating a centralized one (localized model).

With the HPV test we intend the test for the identification of the high-risk HPV (HR-HPV) classified as carcinogenic (group 1) from the International Agency for Research on Cancer (IARC): HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58 and 59 (ref 4) (International Agency for Research on Cancer).

On these bases, the new protocol for the cervical screening program, diversified in different Italian region, includes:

- age 25-29/33: Pap test as primary screening test with HPV test as a triage test for women with equivocal cytology result (ASC-US)
- age 25/30/35-64: HPV screening test every 3/5 years with the Pap test as triage test in women positive for HPV primary screening test;
- for all ages introduction of the HPV test in the follow up of the cytologic alterations post – colposcopy with a negative result and for the treated pre-neoplastic lesions of high grade (CIN2+).

The entire process, strongly renewed in the last years, is based on operational procedures, from the reception of the biological material to the test execution, and result transfer which requires the traceability of samples in different phases and a continuous monitoring of the quality process.

The launch of the program at the regional level is aimed at covering the entire population with centralization of the screening tests and an epidemiological surveillance that represents an interesting prototype at the national level and in Europe.

## 2. State of the art

There is clear scientific evidence that an appropriate and well defined protocol, that consisted in a screening path with clinically validated HPV DNA test as primary screening test, is more effective in preventing invasive cancers of the cervix than the cervical cancer screening programme based on cytology as primary screening test. In a pooled analysis (Ronco, Dillner, Elfström et al., 2014) showed that HPV-based screening provides 60–70% greater protection against invasive cervical carcinomas compared with the screening based on cytology as primary screening test. Data of large-scale randomized trials support initiation of HPV-based screening from age 30 years and extension of screening intervals to at least 5 years (Ronco, Dillner, Elfström et al., 2014).

So, the principal elements of such protocol are the followings:

- HPV-positive women are not to be directly referred to colposcopy but the use of triage systems is essential. The currently recommendable method is based on performing cytology in HPV positive women.
- If the result of this test is abnormal (ASC-US+ ), the woman is immediately referred to colposcopy; if cytology is normal, the woman is invited to repeat a new HPV test after one year. In case such a test is still positive, the woman is referred to colposcopy; in case of negative result, the woman will be re-invited for a new screening round at the regular interval.
- In organised population-based screening programmes the interval after a negative primary HPV test should be at least 5 years. There is evidence that the 5-year cumulative risk of high-grade CIN after a negative HPV test is lower than the 3-year risk after a normal cytology. On the other hand, the probability of unneeded colposcopies and treatments would plausibly be relevant with 3-year intervals after a negative HPV test.
- HPV-based screening should not start before 30-35 years. There is evidence that below 30 years HPV-based screening leads to an increased over-diagnosis of CIN2 that would regress spontaneously, with consequent overtreatment. Some increase in over-diagnosis is plausible also between 30 and 34 years. Below such ages, cytological screening is the recommended test.
- Only tests for the DNA of oncogenic HPV, validated according to the European guidelines as for sensitivity and specificity for high-grade lesions (Meijer, Berkhof, Castle et al. 2009), should be applied.

The new algorithm has important consequences, because it makes a necessary a process of radical change involving the various stakeholders with a consequent reorganization of the screening path and of the management aspects and a redistribution of costs.

In Italy this changing is undergoing and several regions are implementing the passage to the new screening path with HPV test as primary screening test.

### **3. Objectives and Methods**

The main goal of the project is to to analyse the new screening pathway and provide a reference model to prevent adverse events and clinical risks identifying steps in which potentially failures in the system can occur, to define actions and tools for improvement and risk detection and to assess impact on clinical practice of such tools and actions. The project, funded by the National Center for Prevention and Control of the Ministry of Health, involved 4 Italian regions that decided start implanting the new screening pathway. The four regions belong to the centre and north part of Italy and have a population respectively of 10.008.349, 4.915.123, 3.744.398, 4.448.146 (ISTAT, 2016). For each region one centre that implements the HPV test took part in the pilot of the tool designed by the project. Three of these Centers follow the centralized model while the fourth Center continues to follow the localized model.

In order to conduct critical analyses of the new screening pathway, the Failure Mode Effects and Critically Analysis (FMECA) has been applied. FMECA is a methodology that allows researchers to detected possible failures of a system or process, the causes of these failures and the potential consequences on the patient. This methodology allows also to prioritize the areas that require a rapid improvement strategy or intervention and to definite modalities, times and responsibility for this strategy to be put in place. In order to prioritized the most critical areas, the FMEA analyses foreseen the use of grids to assess, in range from 1 to 10, how serious the failure mode is (Severity), the probability of failure occurring (Occurrence)

and how well the control can detect the failure ( Detection). The product of these tree values gives the Priority Risk Index (RPI).

The FMEA is a method used to identify the vulnerability of processes with a proactive approach; it has been devised in the United States in 1949 in the military and then applied to the health care since 1990. As in other complex systems, the implementation of new programs, procedures and practices in healthcare, requires proactive assessment of the risks related to them and the potential of occurrence of accidents and errors. It is necessary to design specific clinical risk control models, with the aim of preventing the occurrence of an error and, if this happen, contain the consequences, and this can only be done through appropriate analysis.

## 4. Results & Discussion

### 4.1 FMEA results

The working group has applied the FMEA analysis to the entire process, from macro analyses of each phase to the micro-analyses of each sub-phase. For the definition of the RPI the group customized the grids according to the characteristic of the screening path. In particular the grids defined by researchers provide more appropriate definitions for ranging the different levels of severity. The following table reports the sub-phases that presented higher RPI and that required a prompt strategy to overcome risks:

Phase	Sub-phase	RPI
Reception of the women and Pick-up	Target population identification	100/1000
	Planning and producing convocations of the women	140/1000
	Reception and Identification of the woman Producing and applying labels for the sample taken	112/1000
	Pick-up for HPV test	70/1000
HPV Test Execution	Manual plate preparation	42/1000
	Manual transfer of the sample to the mother test tube to another tube that is not properly identified	60/1000
	Incorrect denaturation of samples	49/1000
Processing of cytological specimens (Pap-test) of HPV + women	Reporting and inclusion of the results in the management software	12*/1000
Archiving	Archiving of documents documentazione e cytology slides	24/1000
Recall up to 1 year	Test Execution	42/1000

Table 2. FMEA Results

According to the rate of the IPR, tools or strategies to contain possible risks of failures for each sub-phase were then identified.

Regarding the sub-phase related to the **management of women's convocation** (Target population identification and Planning; Producing convocations of the women), while emerging a very high PRI, researchers decided to send back to the regular monitoring carried out at a local level by the regional offices of the partners of the project. Regional administrations have indeed the duty to monitor on the progress made on the integration of master data at regional and national level.

Regarding the **reception of the women and pick-up** (Reception and Identification of the woman and Producing and applying labels for the sample taken; Pick-up for HPV test) researchers identify the definition and design of a (Fig. 1) as the most appropriate strategy to reduce failures and risk for this sub-phase. The S.O.P. has been designed according to communication and ergonomic criteria and has been realized in the format of posters with graphic or photographic representations of the actions to be performed in time sequence in order to ensure a proper identification of the woman and a safe labeling of her samples along the entire process.

## Standard Operating Procedure How is the HPV Test performed?

1.

**Identify the woman correctly**  
 What's your name?  
 When were you born?  
 What is your address? (In case of local delivery without acceptance)

**Verify eligibility for HPV test**  
 Has your menstrual cycle finished by at least three days?  
 Did you performed gynecological examinations, ultrasound or had you sexual relations in the last two days?  
 Did you use vaginal suppositories, creams or douches in the last three days?


2.

**Identify biological materials**  
 In the presence of the woman, attach labels on the woman IDcard, on the test tube and on the transport document

**Identify all materials (sheet, the transport document, sample) with the same code and maintain it throughout the entire process** !


3.

**Compile the woman IDcard**  
 Following hospital procedure

**Avoid manual transcriptions of identification data (woman and sample code)** !


4.

**Prepare the pick-up**  
 Store the identified materials in the kidney tray and take it to the sampling point

**Take the sample for the HPV test**


5.

**Pack materials for sending**  
 Insert the test tube and the woman IDcard in the small transbag, seal the envelope and place it in large transbag

**Avoid the presence of labels, samples and woman IDcard of different woman** !


6.

**Sending materials**  
 Once the pick-up is completed, enter the transport document into the large transbag and send it to the collection center



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 CCM 2013 aut 91/14 cdc 721









**Figure 1.** Visual Standardized Operation Procedures (S.O.P.)

The contents of S.O.P. can be summarizing as follows:

- 1) Perform active identification of all women
- 2) Avoid manual transcriptions of identification data both related to the woman and her biological sample
- 3) Recommendation to produce the same set of data for labels that identify products related to the biological sample
- 4) Recommendation to maintain the same identification codes related to woman and samples during the entire process
- 5) Recommendation to print and apply labels on the biological sample to the woman's presence, to avoid simultaneous presence of labels and/or products of different women.

Regarding the phases " **HPV test execution and processing of cytological specimens (Pap-test) of HPV + women**" the group has agreed to define and design an hypothesis of **working desk** (Fig. 2) that visually display the logical flow of actions to be performed during the sub-phases and that reflects criteria of ergonomic and usability of the working station.

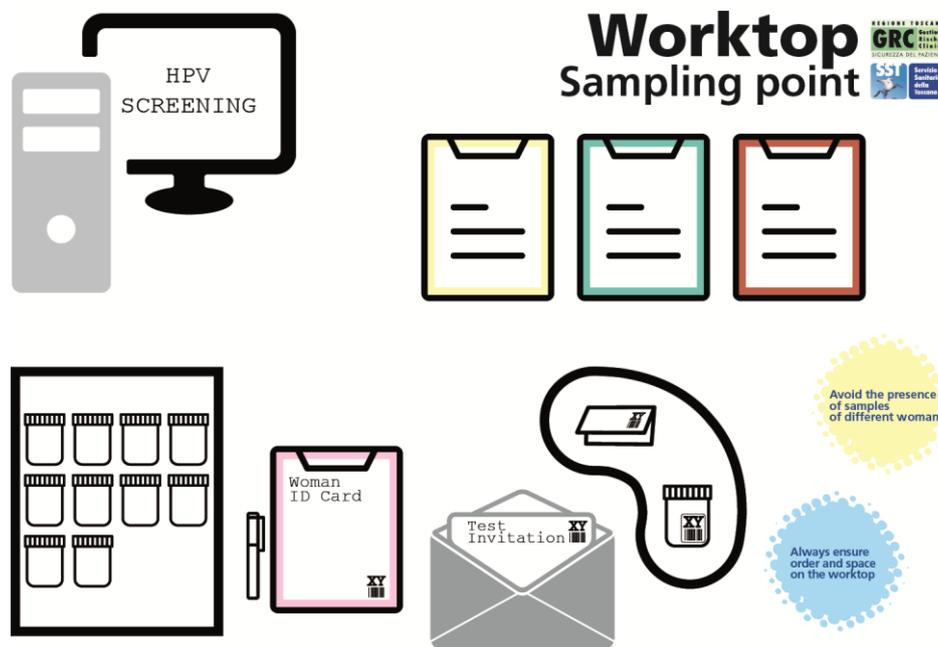


Figure 2. Worktop

A **risk anticipatory action transversal to all the phases** of the process has been also defined by the research group. A **poster explanatory of the entire screening process** (Fig. 3) has been considered as a useful tool to increase awareness among women and to involve them directly in their care process. Form observation during the pick-up sub-phase (see paragraph 4.2 *Observations' results*), emerged indeed that a poor knowledge and awareness regarding the HPV screening process was widespread among women.

The communication poster is supposed to be hanged in all waiting rooms of ambulatories where HPV screening test is performed.

# HPV Test

The new cancer screening for the prevention of cervical cancer

In the Tuscany Region, the HPV test has been adopted as screening test for a more effective prevention of cervical cancer in woman between 25-35 and 64 years old. HPV is the **Human Papilloma Virus** that causes a very frequently infection, that most women contract at least once in life.

## What is HPV Test ?

It is a test that analyzes a small amount of cells taken from the cervix to verify the presence of different HPV types responsible for cervical cancer. Sampling is performed in the same way as PAP Test. It is simple, not painful and lasts a few minutes.

## How is the HPV Test performed?

A single sample will be taken for both the HPV test and the Pap test. The Pap test is a completion test and will be read only if the HPV test is positive.

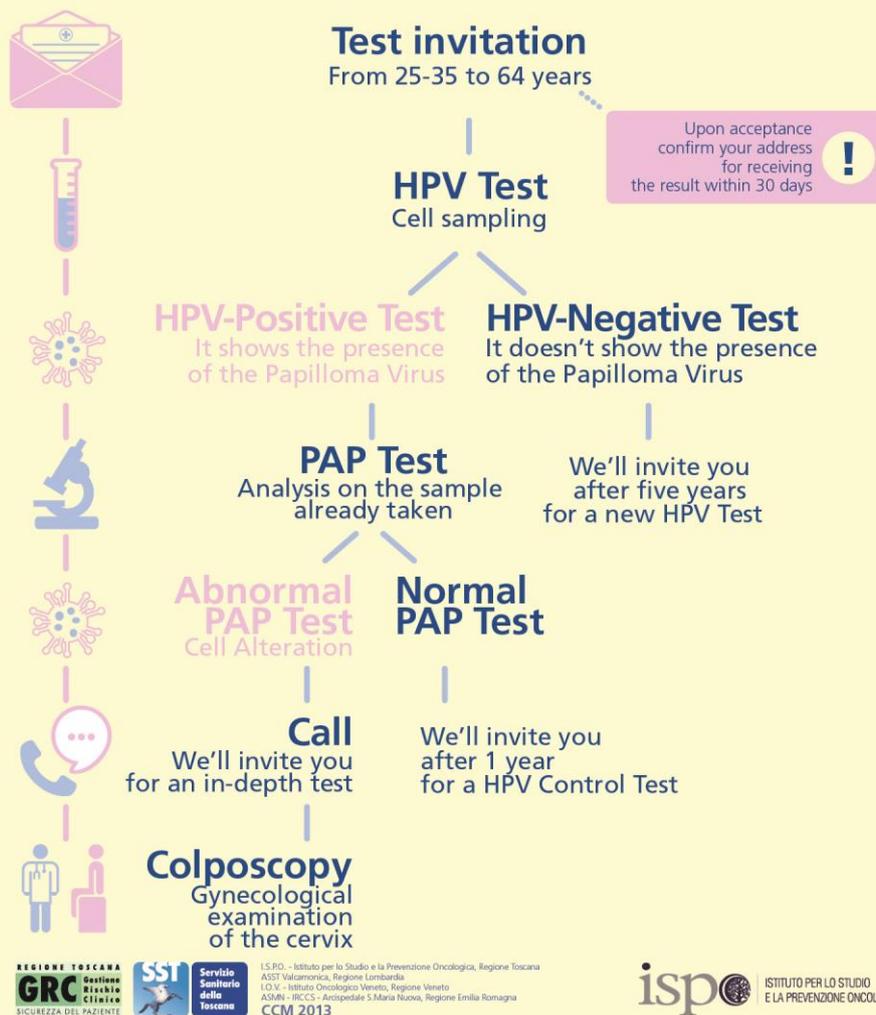


Figure 3. HPV Poster

When coming to the **analytical phase**, data show that the analysis methods and computer platforms in used in the centers that have taken part into the study, are very different one from the other for degree of automation and operation of the laboratory. Despite differences between the methodologies used in the various participating centers, from the FMEA analyses did not emerge any critical failure mode for this phase and related sub-phases.

## 4.2 Observations' results

**Sessions of observation** on the ground were performed by an external observer. The observer evaluated all the activities that health workers carried out during all the phases and sub-phases of the process and in particular focusing on the most critical sub-phases as emerged from the FMECA analysis. Observations allowed researchers to confront results from the FMEA analyses with real activities on the ground and the adherence of operators to procedure and guidelines.

The **observational grid** has been defined according to literature's evidences and in particular on Charles Vincent's the theory of the contributing factors that influence clinical practices (Vincent, 1998). Observations were conducted by a trained observer at the ISPO headquarters for a total of 40 hours over 15 days.

The dimensions used for the observation are summarized in the table here below:

FACTORS TYPE	CONTRIBUTORY INFLUENCING FACTOR
FACTORS RELATED TO PATIENT	Language and Communication
FACTORS RELATED TO THE TASK AND TECHNOLOGY	Task design and clarity of the structure, availability and use of the protocols, decision-making aids
FACTORS RELATED TO THE WORKING GROUP	Verbal communication, supervision and seeking help.
ENVIRONMENTAL FACTORS RELATED WORK	Workload and shifts patterns, physical environment.
ORGANIZATIONAL FACTORS AND MANAGEMENT	Organizational structure, safety culture and priorities.

From the observation sessions emerged that most of the critical issues are related to a poor dissemination of a safety culture among health workers including an approached to reporting adverse events orientated to learning and improving. The improvement of a well-rooted communication method among health workers and the provision of systematic moments to discuss critical issues would be consider a priority.

As outputs from observation sessions the following organizational suggestions for improvement have been given:

- Providing training through simulation for a further development of a culture of safety,
- Promoting an approach to reporting based on learning from mistake
- Increase the level of dissemination of operating protocols and integrated procedures
- Promoting regular staff meetings to share problems and find solutions (also using the adverse event reporting and learning tools)
- Increase the level of quality and safety of the work spaces and working environment following an ergonomic approach
- Increase the level of ICT development

## 4.3 Evaluation of the tools

A **questionnaire for the evaluation of the S.O.P.** has been administrate to all healthcare workers engaged in the new cervical cancer screening path with HPV as primary screening test during the pilot period. The questionnaire aims at assessing daily compliance of health workers to the tool and to collect data regarding the usability and feasibility. The questionnaire is composed by 6 multiple-choice questions (on a scale from 1 –never - to 4 - always) and open questions to assess the kind of mistakes that the tool has been able to detect.

Similarly, for the **evaluation of the communication posters**, a questionnaire has been administered to a sample of women from every center involved in the pilot. The questionnaire is composed by 9 multiple-choice questions aiming at measuring the user-friendless of the

poster and its clarity in term of information transmitted to the women regarding the new cervical cancer screening path with HPV as primary screening test.

Results of the pilot and analyses of the questionnaire are expected by the end of 2016.

## 5. Conclusion & perspectives

The FMEA analysis conducted throughout the new cervical cancer screening path with HPV as primary screening test has revealed that the most critical phases where most of failure modes could occur are the **pre-analytical and post-analytical ones**.

As for the sub-phase related to the convocation of the women to the HPV testing, results from the FMEA analyses show that it would be desirable an **adequate computerization and a continuous updating of master data**.

Regarding the pick-up phase and its sub-phases, reception and identification of the woman and the production and application of labels for the sample taken, the tools designed for preventing risk and adverse events are at the moment under evaluation. **The S.O.P., the prototype of the work desk and the communication poster have been piloting in the Centers involved in the study and results will be available at the end of 2016.**

When coming to the **analytical phase**, data show that the analysis methods and computer platforms in used in the centers that have taken part into the study, are very different one from the other for degree of automation and operation of the laboratory. Despite differences between the methodologies used in the various participating centers, from the FMEA analyses did not emerge any critical failure mode for this phase and its sub-phases. The reason of this result is related to the following characteristics of the laboratories:

- Automation of laboratory tests (higher or lower in some centers than others) means less chance of error;
- Capillary control that occurs in each sub-phase of the analytical process by the various professionals who work there (biologists, TSLB, doctors);
- Well-rooted use of checklists

The results of our analyses show indeed that the sub-phases of the analytical phase with greater PRI have been those characterized by a low level of automation.

Automation, favored by the choice to centralize laboratory activities, is an important factor for reducing the occurrence of adverse event in the entire screening process.

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## Diagnosis methods within a palliative care team

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### Abstract

The objective of this paper was to obtain a better understanding of what it means to diagnose a person at the end of life in a palliative care unit, and more precisely what difficulties residents encounter, with the subsequent aim of contributing to improving their training in line with the current thinking of the National College of University Professors and Instructors in Palliative Care (CNEFUSP). For this work, the “diagnosis” will be seen as an activity designed to understand a situation with a view to taking action; the diagnosis incorporates the prognosis (Hoc & Amalberti, 1995).

We tested a quasi-experimental situation based on a real, complex diagnosis situation in the field of palliative care with 2 professionals from 4 different categories attending the patient – the carers, nurses, residents and certificated (senior) doctors in palliative care.

The results illustrate diagnostic blocks in the medical sense of the word, combining symptoms with causes systematically tested (psychological suffering, intense pain and agitation), common to the different care professionals but implemented in different ways. The residents are conducted by eliminating the most probable and the most severe hypothesis. They implement the diagnostic blocks that they have learned during their training in a more in-depth manner than the other professionals, resulting in an increased number of tests for dying patients with the psycho-social aspects being taken into account too late and to an insufficient extent. While our results highlight the difficulties experienced by residents, they clearly reflect the medical training as well as the late, and somewhat insufficient, inclusion of palliative care and multidisciplinary approach in academic teaching.

**Keywords:** diagnosis, medical training, end of life, palliative care, skill development

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### 1. Introduction

The inclusion of palliative care in university medical courses since the beginning of the new millennium has advocated a “more humane medicine” (CIDFMEF, 2004). This new “pilot discipline” requires a holistic approach to the patient, often neglected in favor of a purely scientific approach, together with a holistic vision of the person (Mallet, 2007).

To ensure a more global approach to the patient, palliative care structures provide a specific work organization, different from other specializations. While the final decision is founded on the doctor’s prescription, an interdisciplinary approach recognizing the role of the other professionals in the medical decision-making process (nurses and carers) and facilitating collective deliberation ensures ethical reflection and promotes a medical and psycho-social approach which is essential in an end-of-life context (Crawford & Price, 2003). The development of a care project by the entire care team in collaboration with the patient with a view to improving the quality of end of life helps resolve the problems encountered.

When residents work in these structures, difficulties arise despite the palliative care curriculum during the university courses (Leclerc, 2014, Rhodes-Kropf, 2005; Shapiro, 2006; Mason, 2008; Williams, 2005; Dany, 2009; Blanchard, 2010). Very often, residents encounter this team approach to deliberations for the very first time. While they demonstrate excellent technical and scientific skills, they experience more difficulty in incorporating the psycho-social dimensions necessary to making diagnoses and are prone to misunderstanding with the other personnel involved in the care process (Mallet & Galle-Gaudin, 2009; Mino & Fournier, 2008).

## **2. Objectives and Methods**

The objective of this paper is initially to obtain a better understanding of what it means to diagnose a person at the end of life in a palliative care unit, and more precisely what difficulties residents encounter, with the subsequent aim of contributing to improving their training in line with the current thinking of the National College of University Professors and Instructors in Palliative Care (CNEFUSP). For this work, the “diagnosis” will be seen as an activity designed to understand a situation with a view to taking action; the diagnosis incorporates the prognosis (Hoc & Amalberti, 1995). Boshuizen and Schmitt conducted works on the how medical diagnoses change with experience (Schmidt, Boshuizen, & Hobus, 1988; van de Wiel, Boshuizen, & Schmidt, 2000). They emphasized the restructuring of knowledge as experience is acquired in a care situation: biomedical knowledge is acquired and encapsulated by clinical concepts of a higher level. In familiar situations, only “encapsulating” concepts are used. Biomedical knowledge is only called on if the former are insufficient, in more complex or unusual situations. We assume that such restructuring is necessary in order to develop the palliative care skills of residents and that this may lead to their encountering difficulties in incorporating information drawn from the paramedical professions into their diagnoses. These professions offer a different point of view from theirs as the information comes from “professional spheres” different from their own which form an axiological and conceptual background (Beguin, 2005).

As data cannot, for ethical reasons, be collected from a dying person in a real situation, we have developed a quasi-experimental situation based on a real, complex diagnosis situation in the field of palliative care known to the research doctor (RD). The evolving written scenario retraced the history of a deceased patient who was agitated, suffering from a tumor which disfigured her face causing considerable mental anguish and a desire to die. The patient file contained administrative elements (family situation, person to be notified), results of X-rays, scans and results of blood tests. The entire patient file provided was anonymous.

We deliberately chose a scenario representing the particularity of palliative care which requires the inclusion of psycho-social information in the diagnosis, a fact which may prove problematic to the residents (Mallet&Gallé, 2009; Mino & Fournier, 2008) and which may also highlight the skills acquired by nursing staff as their experience increases and which are little known in the organization.

### **2.1. Task analysis**

In the “real” situation, having listened to the explanations of the team concerning the patient’s condition and the recent events relating to the patient, a hypothesis of mental and/or psycho-social and family suffering can be established by consulting medical and psycho-social elements.

Meeting a patient and performing a clinical examination allows the absence of physical suffering and the diagnosis of mental suffering, described as a “fear of being abandoned by

the family”, to be confirmed. The patient was suffering from not being able to see her granddaughter to whom she felt very attached. The period was around her birthday and the family had kept the child away due to the patient’s condition and because she was disfigured by the tumor. A dressing was applied to hide the tumor so that the child could visit her. Following this visit, the patient was less agitated and did not repeat her request for euthanasia. In this case, the patient’s suffering is qualified as psychological and existential (in the scenario, it is specified that she feels no physical pain) and is linked to family suffering. Understanding family suffering makes it possible to determine the diagnosis.

In light of this request to be allowed to die from a person who claims not to feel any physical pain and who has undergone an episode of nighttime distress, her autonomy to make such a request must first be examined before checking the validity of the request then seeking further clarification.

To this end, the extent of the neurocognitive disorders must be examined (spread of the cancer to the brain or not, advanced Alzheimer’s disease or not) and the lucidity of the person must be checked at the time that the request was made. If this is acknowledged as being valid, it is necessary to identify any acute trigger event in the patient’s recent history (physical and/or psychological problem). When searching for this acute trigger event, the hypothesis of the existence of undetected physical pain must systematically be explored by the entire team, as pain is the first cause of requests for euthanasia. At the same time, it is also essential to establish whether the patient or a member of their entourage is experiencing any psycho-social suffering as this is the second most-frequent request for the right to die. Finally, it is important to check the absence of suffering among the team within the framework of this complex and difficult care provided.

## 2.2. Population

We tested this scenario with voluntary professionals from different disciplines working with the patient in the field of palliative care and with experienced *versus* trainee physicians (table 1).

		Age (years)	Gender	Experience in palliative care
Carers	CA	40	F	12 years
	CB	47	F	21 years
Nurses	NA	41	F	5 years
	NB	41	F	6 years
Resident physicians	RA	28	F	2 month
	RB	29	F	6 month
Senior physicians	SA	51	F	10 years
	SB	42	F	12 years

Table 1. Characteristics of the professionals

## 2.3. Data collection and processing

We asked professionals what they would do in this situation to care for the patient. We used the information-on-demand technique (Bisseret, Sebillote & Falzon, 1999). The RD conducting this study provided the written scenario and consulted the patient’s file on demand to answer the questions of the persons interviewed and could complete if necessary the data in a manner coherent with the case. To make a diagnosis and propose appropriate care to the end-of-life situation, the professionals had access to the biomedical and psycho-social data within this scenario where the socio-familial context was deliberately underdeveloped.

Questions on this subject therefore served as an indicator of the research conducted by the different actors.

The relevant diagnosis of intense psychological suffering related to a fear of abandonment by the family was obtained by exploring psycho-social aspects while simultaneously performing a surface clinical analysis.

In light of the work demands on senior physicians, we were unable to conduct any self-confrontation interviews with them. All interviews conducted were recorded and transcribed in full.

The protocols developed in this way can be divided into two major phases: 1) symptom and illness and 2) the patient's social behavior and their environment. The first part comprises different stages derived from the usual medical observation procedure: 1) the history of the disease (history of the symptom, treatment, habitus); 2) the clinical examination (physical examination of the body, psychological exploration); 3) the paraclinical examination (examinations including scanner imaging and biological tests) and finally 4) the therapeutic examination [usual treatments, new treatments recently introduced, undesirable effects of medication (iatrogenic events)].

In the second phase (social and environmental), the individuals involved examine the patient's autonomy to take decisions concerning themselves, the request to be "allowed to die" (which is part of the scenario and constitutes a request for euthanasia and to cease therapeutic intervention), the patient's psychological suffering, family suffering (for example in the scenario for the family, this may involve seeing their loved one disfigured), the suffering experienced by the team.

To understand the content of the diagnosis, the data were also analyzed by distinguishing which examinations the individual requests, what they prescribe or what they refuse to prescribe and the diagnoses provided. For each of these items, we distinguish the search for physiological, psychological and socio-familial etiologies which may explain the behavioral issues (refusal of care, request to be allowed to die). For example, the direct quote, "The brain scan may be discussed" is analyzed as an "examination prescribed" concerning "physiological" aspects for which the content is a "scan". It is interpreted as the search for a brain tumor which may explain the behavioral issue. The physician attempts to assess the patient's level of autonomy to take this decision.

With regard to the ecological validity of the quasi-experimentation, this situation of information on request exhibits similarities with real situations insofar as a physician, when coming on duty, consults the file and questions the carers concerning the patient's condition and progress. The limits relate to the information obtained in direct contact with the patient.

### **3. Main results**

The total number of requests submitted to the experimenter varies very little between the participants (table 2). More significant differences appear between requests for information prior to the hypothesis of psychological suffering being formulated and those subsequent to this which confirm the diagnosis. The carers, who are the most experienced staff in our sample, quickly formulate an initial diagnosis which they subsequently confirm. One resident, who is the least experienced member of staff in our sample, does not make the correct diagnostic. The data are equivalent for the remaining participants.

Number requests	of	Seniors		Residents		Nurses		Carers	
		SA	SB	RA	RB	NA	NB	CA	CB
Correct diagnosis	pre-hypothesis	4	4	9	4	4	6	1	0
Consolidation of diagnosis		4	5	-	6	3	2	5	8
Total		8	9	9	10	7	8	6	8

Table 2. Number of requests for the determination of the diagnosis

The number of manipulations required by the clinical and paraclinical examinations conducted by the residents would appear to have a negative impact on the quality of the patient's end of life (10 and 9 examinations) (table 2).

The orientations of the diagnoses of the different professions diverge (table 3): the analysis essentially concerns the symptom among physicians and residents, the treatments among the nurses and the patient's habitus (body language, posture in bed, appetite, mood, etc.) among the carers.

All the carers ask for the clinical examination to be carried out. Questions concerning therapies are primarily raised by the nurses (in particular with regard to dispensing drugs). Social behavior and the environment are examined by all the carers. Most staff examine at least 3 aspects, with the exception of RA and NB (2 aspects).

The residents examine the situation with reference to a methodology acquired in-situ: "*First the clinical elements are eliminated then, when there is no clinical answer, or no biological or clinical answer, attention turns to elements which cannot be dosed and cannot be calculated by a specific examination*" (RA). "*Reversible elements, things on which we can act, then the psychological causes and finally anxiety*" (RB). This examination is systematic and is organized by means of the "diagnosis blocks" they have learned.

The diagnosis blocks are developed by identifying one or more symptoms and trying to find all the causes and the possible relations explaining the symptom(s). This is reflected by the systematic implementation of a series of relationships between symptoms and probable causes and their gradual elimination. This leads to highly-detailed clinical examinations being conducted.

For example, RA explores the agitation diagnosis block. She looks for information concerning the urinary infection (if the patient has urinated, the frequency of urination, temperature, skin condition), urinary retention (abdominal pain), a rectal obstruction, etc. She explores all possibilities except an invasive examination which was not requested. Each block can include clinical and paraclinical examinations as well as therapeutic measures.

In comparison, senior physicians refer to the "diagnosis blocks" schematically: they use the title of the diagnosis blocks (pain, anxiety, agitation for example) but formulate few hypotheses in each case and perform few, if any, examinations (5 and 4, table 3).

They explore the patient's request (what does she mean by "be allowed to die"?), and her level of autonomy (for example the possibility of a neurocognitive disorder) then anxiety and emotional suffering (table 3). Some hypotheses are never envisaged (urinary infection or retention, for example).

		Seniors		Residents		Nurses		Carers	
		SA	SB	RA	RB	NA	NB	CA	CB
Disease and symptoms analysis phase	Historical approach - the symptom - the symptom in the patient's history - the treatment - the patient's habitus	X X	X	X	X				
	Clinical examination -Physiological -Psychological	3 2	2 2	7 1	6 2	2 2	2 2	1 2	3 2
	Para-clinical			2					
	Therapeutic -medicinal -non-medicinal -Iatrogenic events					5 1	3 1		
Social and environmental analysis phase	Autonomy	1	1			1			1
	Analysis of the request	2	2	2	2	1	1	3	1
	<b>Family suffering</b>	<b>1</b>	<b>1</b>		<b>1</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>1</b>
	Suffering of the team		1						1

Key: The number of detailed examinations does not correspond to the number of requests that we recorded (table 2): within a request (urine analysis), several aspects can be explored: what is the urine like? Urinary infection? Urinary retention?

Table 3. What is examined by the different staff members?

NA and NB initially examine the history of the treatment administered (table 3) from the standpoint of pain and psychological suffering, which are the headings of diagnosis blocks, although they do not explore them. They attempt to relieve the symptom(s) (pain and psychological suffering) by prescribing medicinal treatments then by means of non-medicinal measures such as the presence of carers in the aid relationship and the presence of family. Whenever they examine the family, they mention the possibility of family suffering.

CA and CB begin by exploring the psychological suffering which they feel a desire to die represents before both examining the habitus. CA: *"it is an emergency"*, *"it is psychological suffering that I imagine is so hard to bear"*. CB diagnoses general suffering with a strong element of emotional suffering, while reading the scenario.

They refer to the diagnosis block heading "psychological suffering" without explore them.

They suggest their presence (aid relationship through a simple human presence) while waiting for the physician to provide a prescription as quickly as possible. "More effective treatments than those available at present could possibly be prescribed?"

CA: *"it is a form of suffering like any other"* she says to the physicians who she feels tend to underestimate psychological suffering.

#### 4. Discussion and perspectives

1) We identify diagnosis characteristics (Hoc & Amalberti, 1995) guided by perspectives for action.

2) The phase in which the staff analyze the disease and symptoms is guided by their respective professional fields; symptoms for physicians, treatments for nurses and habitus for

carers. These data are consistent with a hypothesis of diagnoses based on different professional spheres.

3) The diagnosis blocks are mentioned by all the professionals but are only systematically developed by residents.

The schematic nature of senior physicians' diagnoses and the exhaustiveness of those made by the residents are consistent with a hypothesis of knowledge restructuring occurring with the acquisition of experience, a hypothesis which must be examined more closely.

In the final analysis, the results of our exploratory study support the observations of the CNEFUSP relating to the difficulties experienced by residents with regard to patient management and the skills of the other professionals. While our results highlight the difficulties experienced by residents, they clearly reflect the medical training as well as the late, and somewhat insufficient, inclusion of palliative care in academic teaching.

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## Employees' work environment and patients' rights, conflicting responsibilities when implementing patient online access to their EHR

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### Abstract

This paper is based on an interview study examining the implementation of the eHealth service *patient online access to electronic health records* in two county councils in Sweden. Our aim is to present and discuss the two councils' implementation processes and the differences between them, with particular focus on the implementers' consideration of caregivers' work environment. A theoretical aim is to shed light on the complicated situation that arises when a county council is responsible for both the implementation of an eHealth service and the effects it has on the work environment of the employees (professionals). The results from the total of 16 semi-structured in-depth interviews show that the two county councils differ in the following areas: 1) whether the implementation is interpreted as a threat for the work environment; 2) who the interviewees consider as responsible for the work environment; and 3) if it was considered important to build trust between the implementers (the county councils) and the professionals – and how this trustbuilding was accomplished. It is concluded that the differences between the two implementation processes was due in part to the difference in how the service was framed and labelled in the two respective county councils, and that one of the county councils has encountered difficulties in taking dual responsibility towards both patients and the work environment of the employees. This implies, according to Bovens' (1998) classification, that one of the county councils takes active responsibility for the work environment while the other takes passive responsibility for the work environment.

**Keywords:** Electronic Health Record (EHR), eHealth, responsibility, online access, implementation

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### 1. Introduction

In Sweden, as in many other European countries, the government and public agencies have promoted the expansion of eHealth over the past ten years. The rapidly increasing use of modern information and communication technologies in the field is commonly described as a paradigm shift for Swedish healthcare. The intention guiding the deployment of eHealth-services is a perceived need to give patients increased access and influence over their health situation, and arguments such as "patient authorization", "patient transparency" and "patient empowerment" often feature in the debate. The development has the potential to reform and alter the relationship between citizens and healthcare organizations. In early 2013, an "Action Plan" for the period 2013–2018 (Cehis 2012) was launched as part of a national strategy for eHealth services. Within this strategy document, the implementation of patient online access to electronic health records (online EHR) is noted as being one of the most important services in eHealth.

In the autumn of 2012, the Uppsala County Council (UCC) in Sweden launched a pilot project consisting of twelve eHealth services, including patient online access to EHRs. Region Skåne (RS) followed in March 2014 as the second county council in Sweden to make EHRs accessible online for patients. Even though the motivation for the service is similar in both county councils, the implementation process has been quite different and, most of all, the reactions among doctors have varied between the two county councils. In Uppsala, a conflict arose in 2012 when medical professionals actively initiated a public media debate in conjunction with the transition from implementation project to full-scale deployment in UCC. The main standpoint of the local medical association was to oppose any and all online access of patients to their EHRs, and the profession stressed several parallel arguments in the debate. A lot of the attention was directed towards physicians' work environment. Firstly, the doctors argued that the health records were their working instruments, and that patients' immediate and easy access would challenge the functionality and integrity of these instruments. Secondly, the local medical association was concerned that patients would lack sufficient knowledge to fully understand the information in their medical records. In addition to causing unnecessary fear and anxiety for the patients, the local medical association claimed, this also could negatively affect the doctors' work environment because they could be inundated by questions from alarmed and/or inquisitive patients (Erlingsdóttir & Lindholm 2015).

Contrary to the turn of events in the UCC, the deployment in RS has, been rather unproblematic, at least in terms of public debate between the local medical association and the county council. This aroused the curiosity of the authors: what differs between the implementation processes in the two county councils? What was the reasoning of key actors in UCC and RS, respectively, regarding how patient online access to EHRs would affect care professionals' work environment?

## **2. State of the art**

Research has shown that when technical systems evolve, professional groups often want to be involved in the process that takes place and influence how systems should be designed and used (Eriksson-Zetterquist, Lindberg & Styhre, 2009). Professionals in general and doctors in particular may find it difficult to embrace new ideas and technologies if these new concepts are not consistent with their own procedures and routines (Oliver 1991). According to Constantinides and Barrett (2006), numerous IT implementation projects in healthcare fail because they are not sufficiently anchored among key stakeholders (professionals). This is confirmed by While and Dewsbury (2011), for example, who describe how important it is that nurses are involved in the design and development of information and communication (ICT) systems – not only to ensure that the right features will be included but also to gain acceptance from the profession for introduction of the systems. It is therefore important that professionals are involved in developing the technologies they will use and that solutions are based on their own needs and wishes. The report “Disturbing or facilitating? On the usability of eHealth systems” (Scandurra, 2013) also notes the importance of adjusting digital systems to existing work processes so that they are adapted to the current tasks and work situation.

Our paper pivots around conflicting responsibilities, particularly in healthcare organizations guided by multiple goals and missions. Actors and groups of actors, in charge of governing and controlling the development, find themselves within a web of conflicting responsibilities, including legal, professional and managerial obligations (Roberts, 1991; Sinclair, 1995; Bovens, 1998; Cane: 2002; Messner, 2009). This is inherent to modern complex organizations such as county councils, where politicians, officials and professionals all have their different duties and responsibilities (Braithwaite & Roche, 2001). The politicians' role is to protect the rights and needs of the taxpayers (the citizens), while the county council also has legal

obligations as to follow the Work Environment Act. This, of course, can lead to conflicting interests. Bovens (1998) also describes the difference between passive responsibility and active responsibility. In his terms, passive responsibility is a question of who is to be held responsible for the wrong that has been done in the past. Active responsibility, on the other hand, is taking responsibility for the future. In other words, active responsibility may be used to avoid harm or injustice.

### **3. Objectives and Methods**

Our aim in the paper is to present and discuss research material and findings that reveal two implementation processes and the differences between them. A theoretical aim is to shed light on the complicated situation that occurs when a county council is responsible for both the implementation of an eHealth service and the effects the service has on the work environment of the employees (professionals).

An interview study was conducted with key actors in both county councils in 2015. A total of 16 semi-structured, in-depth interviews were conducted (eight in each county council); responses were recorded, transcribed and analysed. The interviews are part of a longitudinal study, encompassing a series of sub-studies, that has been conducted since 2012 on the development and deployment of the patient online access to EHR service,. Background information on and in-depth understanding of the two cases has thus been gathered in previous interviews.

As the two implementation processes in the two county councils have been organized in different ways, we have used what can be described as a *snowball sampling* where the project leader in each county has provided names of key actors in the implementation process. All interviewees were then asked if they thought there was someone else we ought to interview. Politicians and legal counsels were involved in both counties, but some other functions differed. The project manager in UCC, for instance, is the technician who has been involved in the development of the technical solution, whereas the project coordinator in RS is a nurse and a strategist within the healthcare organization.

Each interview was recorded and transcribed. The material was then coded, categorized and analysed.

### **4. Results & Discussion**

The results from the 16 interviews show that the two county councils differ in the following areas: 1) whether the implementation is interpreted as a threat for the work environment; 2) who the interviewees consider as responsible for the work environment; and 3) if it was considered important to build trust between the implementers (the county councils) and the professionals – and how this trustbuilding was accomplished.

#### **4.1 Was the implementation interpreted as a threat to the work environment?**

In both the UCC and RS, there were some misgivings about patients having online access to EHRs. In both counties the comments revolve around the following aspects. 1) The medical records are understood as a primary work tool of care professionals, and patient access could negatively affect the professionals' way of making entries in the records. In addition, the immediate transparency, without time to edit or correct entries, was perceived as a problem. 2) Some saw a risk that patients would be harmed by the information that they could read in the EHR, as patients would either be frightened by it or would not understand it. 3) A risk was seen that patients would call and disturb healthcare professionals with questions about the entries in their EHRs.

In UCC, the implementers were clearly not aware that patients' online access to EHRs could be interpreted as a threat to the healthcare professionals' work environment. The project manager states that "this [service] is not aimed at the doctors; it is a service for the patients". In UCC the attitude, from the beginning, was thus that the implementation of the service would have no impact on the professionals' work environment; therefore, no special actions were taken to involve the professionals in the implementation. When the regulative framework for the service became known to the local medical association, representatives reacted strongly and contact between the implementation project and the medical association was broken. As a result of this lack of dialogue, the resulting – and fierce – conflict took place mostly in the media.

In RS the implementers were aware of the problems that had occurred in UCC, and were determined to avoid a similar situation. Thus they made sure that representatives for the medical profession took part in different aspects of the implementation process, for example concerning adjustment of the regulation of the service in RS. The previously formulated UCC regulation served as a model, but it was adjusted to meet local needs as well as the opinions of the medical profession. Among other things, it was agreed that no EHR entries written before the day of the launch would be visible for patients. This was a requirement from the medical profession, as it was considered important that patients be given access only to entries written by medical professionals who were aware that patient access was operational. A lot of effort was also put into informing the employees and responding to their concerns. This does not imply that there has not been any negative reactions in RS, but in this situation, the type of conflict that arose in the UCC could be avoided.

#### **4.2 Who was considered responsible for the work environment?**

In the interviews, it became quite clear that there was no clear consensus in Uppsala about who was responsible for possible effects of patient online access to EHRs on care professionals' work environment. Surprisingly, several of the interviewees thought that the implementation project should have been responsible, and even the project manager himself thought that he and the project were responsible for consideration of the effects on the work environment.

In RS there was more of a consensus that the operation managers or the HR department at RS were responsible for how the work environment would be affected. This is much closer to the legislation, which holds the employer responsible, than the UCC answers; many of the UCC respondents held the implementation project responsible for the work environment.

#### **4.3 Was it important to build trust between the implementers and the professionals'?**

As the implementers in UCC did not consider the professionals to be key stakeholders in the implementation of the service, they did not go to any lengths to build trust between the professionals and themselves in the beginning of the implementation project. When the implementers discovered that the negative reactions of the professionals and wanted a dialogue with them, it was already too late. The damage was already done, and the professionals – primarily the doctors – refused to negotiate with the implementers. Moreover, this forced the communications department in UCC to back down and hardly any information about the implementation was mediated to the healthcare professionals. This further impaired the trust between the two parties.

In RS there was a continuous discussion between the professionals' unions and the board responsible for the implementation. In addition, a thoroughly planned information campaign was launched to inform as many of the staff as possible. The campaign consisted of

information meetings in all geographical areas of the region as well as published articles and films on the intranet. As the professionals felt that they could affect the formulation of service regulations, they were open to continuous communication with the implementers, and this never evolved into a controversy.

## **5. Conclusion & perspectives**

From the above, it is obvious that significant differences can be found between the implementation processes in the two county councils. In UCC, the focus on delivering a new digital service to the patient/citizen seemed to prevail, while the responsibility for the work environment of employees was not considered to be an issue. The implementation project somehow seemed to become the main actor, closely knitted to the technicians in the project instead of a board comprising both representatives from the implementation project and officials from the remainder of the county council – as was the case in RS.

In RS, the board responsible for the implementation seemed to have an awareness that the region has dual responsibility for implementing new technology for the patient/citizen and monitoring the effects on working conditions of the employees. This may be due to the different framing or labelling of the implementation projects in UCC and RS, respectively. In UCC the implementers are the same as the developers of the civic service, and they see their duty first and foremost as meeting the needs of the patients/citizens. In RS the implementation project is in the hands of a composite board that sees its responsibility as more inclusive – to develop healthcare – and that this particular service is viewed as one step in a larger transformation.

As a consequence of the above, we conclude that RS takes what Bovens (1998) calls active responsibility – responsibility from the beginning of the implementation project to prevent future damage to the work environment of healthcare professionals – while UCC took on a more passive role and was blamed for not taking responsibility for the damage that the implementation might cause. The bottom line is that RS manages to take active responsibility and recognize that it has dual responsibility, while UCC is made passively responsible and does not recognize its dual responsibility. Moreover, through active responsibility, RS builds trust between implementers and professionals, while in UCC the controversy between the medical association and the implementers has created a lack of trust that will take a long time to repair.

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## Commissioning technological innovations in radiotherapy: optimizing safety under economic pressure

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### Abstract

*Context:* Over the past 20 years, innovations in radiotherapy have enabled great improvements in the treatment of patients, but they also have become unavoidably more complex. Ensuring that a new machine works appropriately before it is used on patients is crucial to guarantee that the treatment delivered to the patient complies with the planned treatment. Medical physicists, who are responsible for this task, encounter an issue related to innovation temporality. For newer techniques, recommendations and regulations as regards to quality controls are insufficient.

*Objectives:* The objective of this research is to study the commissioning process developed by medical physicists to ensure that a new linear accelerator (Linac) and the associated innovative techniques have good performance and hence will contribute to safe treatment of patients.

*Methodology:* The study is conducted in the radiotherapy unit of a French university hospital implementing a new Linac. Observations of the interactions between medical physicists and the Linac are carried out during and after its implementation, and interviews are conducted with 5 members of the medical physics team.

*Main results:* Physicists face challenges and develop strategies to cope with them at each step of the commissioning process: when preparing the process as a whole, when completing the Linac performance measurement for TPS modeling, when performing verification and when developing quality control checks. For instance, in order to overcome the lack of consensus on the detector that should be used to measure the delivered dose, medical physicists crosscheck the data obtained with several detectors.

*Conclusion:* The paper discusses the design process of safety norms for innovative technologies and, to a larger extent, the way to manage safety under pressure. It ultimately raises the question of risk acceptability and the compromise between productivity and safety.

**Keywords:** technologies, radiotherapy, quality control, norms, risk acceptability

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### 1. Introduction & state-of-the-art

Over the past 20 years, improvements in imaging and computer science have led to tremendous evolutions in the field of radiotherapy. It has in particular enabled the development of state-of-the-art technologies, in particular linear accelerators, treatment planning software or positioning systems, as well as the development of new techniques, such as Intensity Modulated Radiotherapy, respiratory gating and stereotactic radiotherapy. These innovations have enabled great advances in the treatment of patients: the tumor is targeted

more accurately, the dose better distributed and the surrounding healthy tissues less exposed to radiations.

Machines become more advanced, but unavoidably also more complex. They run more powerful algorithms and process a greater number of parameters that can transit through infinity of paths that are not directly accessible. They are more coupled and interconnected with many other devices and Information Technology systems playing a role in the treatment process (Rosenwald, 2002). With the overall automation necessary for the management of such capacities is associated the risk that the machines become black boxes for the healthcare providers using them, making it harder for them to understand the intrinsic functioning and somehow keeping them out of the loop (e.g. Bainbridge, 1983). Recent events in the history of radiotherapy have indeed shown that a defect in the system configuration or programming can cause great harm to many patients (cf. the Toulouse accident in France).

For all these reasons, ensuring that a new machine works appropriately before it is used on patients is crucial to guarantee that the treatment delivered to the patient complies with the planned treatment. This task is assigned to medical physicists who, among others, are responsible for the whole quality assurance program and for ensuring that *“instrumentation, data and calculation processes used to determine and deliver doses and activities administered to the patient in any procedure of exposure to ionizing beams are appropriate”* (SFPM, 2012).

However, physicists encounter an issue related to innovation temporality. Often the pace of commercialization of new technologies is greater than that of norms allowing one to control that they work properly (Amalberti, 2009). Thus, regulations are relevant to existing devices but not fully appropriate for new techniques (Williamson et al., 2008). In that case, complying with rules warranties one is right regarding law, but does not ensure safe use of the device. Besides, there is a lack of methodology nationally or internationally agreed upon that could be applied. In its report presenting recommendations on the conditions of implementation of new techniques and practices in radiotherapy, a working group composed of members of the French Advisory Committee of Experts in Medical Radiation Protection (2014) comes to the main finding that *“the new techniques are currently developing with insufficient recommendations and with no specific supervision in the present radiotherapy licensing system”* (p.33).

Most reports recommend that every parameter that can be checked must be checked. However, this approach does not provide any mean allowing optimization of resources linked to quality assurance and to quality control to improve quality of care in radiotherapy. As a result, almost no radiotherapy unit has sufficient means to perform all these activities (Lisbona, François, & Tomsej, 2010). This situation is amplified with the increasing number and variety of possible clinical uses due to the introduction of new technologies and innovative techniques. There is therefore a strong need for a larger quality assurance program that takes into account patient safety and quality in accordance with the resources available in a constraining environment (professional shortage, high technical requirements, economy, etc.).

## **2. Objectives and methods**

### **2.1. Objectives**

The objective of this research is to study the commissioning process developed by medical physicists to ensure that the new Linac and the associated innovative technique have good performance and hence will contribute to safe treatment of patients. We highlight the

challenges posed by the requirements they must meet, and, in return, the choices and compromises they make and the strategies they develop to cope with them.

## **2.2. Methods**

The study is conducted in the radiotherapy unit of a French university hospital. The unit is part of a larger oncology department specializing in neuro-oncology and radiosurgery and is supplied with 4 linear accelerators. In 2015, it implements the newest linear accelerator on the market provided by the biggest vendor of radiotherapy equipment (hereafter referred to as “the Linac”). It enables the most commonly used technique – 3D conformal radiotherapy – as well as more complex and recent ones: Intensity-Modulated Radiotherapy (IMRT), Volumetric Modulated Arc Therapy (VMAT). Most importantly, it enables stereotactic surgery, a high-precision technique using small photon beams to treat brain tumors mainly and meet patients' needs in neuro-oncology and radiosurgery. Other pieces of equipment are acquired along with the Linac, among which an X-ray based monitoring system, a new water phantom and a new Treatment Planning System.

After the Linac has been installed and its acceptance signed on March 6, 2015, other pieces of equipment are set before the Linac commissioning process can start on March 30. First 3D-conformal radiotherapy treatments on patients are planned on June 15.

Observations are carried out during and after the Linac implementation, i.e. from 5 months before to 5 months after the firsts patients are delivered a treatment, and are mainly focused on the interactions between medical physicists (hereafter shortened as “physicists”) and the Linac. To complement this set of data, interviews are also conducted with 5 members of the medical physics team: the physicist in charge of commissioning, the trainee physicist who assists him, the head of the medical physics unit and 2 physicists involved in the implementation of other pieces of equipment. Access is given to documents related to the commissioning process.

## **3. Results**

In this section, we present the first results of our analysis, which is in progress. We focus on what medical physicists do to both ensure the new Linac works properly and observe the deadline. The elements are organized following 3 phases: one prior to commissioning regarding the preparation of the process as a whole, and two during the commissioning phase, namely Linac configuration and the development of quality control checks.

### **3.1. Preparation of the commissioning process**

At the time of the Linac acquisition phase, implementation schedule is drawn up. It results from negotiation between, on one hand, the hospital administration and physicians who want to start using the machine as soon as possible and, on the other hand, the physicists who try to obtain a decent amount of time to set up the machine. A compromise made between availability and safety leads to the decision that the machine will first be used on June 15, 2015, therefore allowing three months to perform commissioning – instead of the 4 months expected. Great pressure is then put on the physics team to stick to the schedule and have the machine ready on the due date.

These time constraints are due to two phenomenon. First of all, there is a will to rapidly implement more efficient techniques so that patients can benefit from better treatments. But most importantly, the radiotherapy unit introducing the Linac is embedded in a larger system – the hospital – subjected to great economic constraints. With the fee for service basis system, treatments in radiotherapy are well reimbursed by the French national health insurance and

the domain is therefore considered as lucrative activity that compensate for other less profitable departments such as geriatrics.

Another factor that contributes to time pressure relates to the vendor who also have to deal with their own constraints. Indeed, their staff is in very limited number and they have lot of implementations to handle in the geographic area they cover, hence they themselves have to cope with very tight schedule. As a consequence, physicists have to take into account the vendor's availability when planning commissioning activities and cannot postpone the vendor's interventions when falling behind. Besides, training and on-site support is considered as insufficient when first experiencing the machine.

At the medical physicist team level, the challenge during the commissioning phase is therefore to manage to set the Linac in a short and non-flexible period of time while installing all other new pieces of equipment and handling the unit routine, including breakdowns and hazards management. The following quotation extracted from an interview illustrates particularly well the elements presented above: *“We've run late because there have been problems with construction work in the room which has been longer than expected, there have been air conditioning problems they haven't found right away, there has been water damage in the ceiling, there have been various little things that have made us late [...]. So in fact, we couldn't postpone the treatment start date, first because the hospital were hopping up and down with impatience and we were asked to start on June 1<sup>st</sup> instead of the 15, so it was hard to consider postponing. And moreover we had scheduled [the vendors'] engineers to have support at the start, and when we noticed that we were running late, we thought maybe we would put the date back one week [...], except there was no engineer available to help us start, so we'd have had to start alone, we'd have had to get the training one week prior to starting, that would totally have lost sense, so it wasn't possible”.*

Several actions are set by the physics team in order to cope with demands. One of them consists of spreading the start of the various techniques over time. Instead of having to have the Linac ready for all the techniques it will eventually be used for, physicists first start the older and well-understood 3D-conformal radiotherapy, then 2 weeks later they start stereotactic radiotherapy, etc. This time phasing allows them to observe the deadline for patient treatment and gives them the opportunity to be fully ready to safely start using one technique before starting another one. Besides, it gives them some margin: should there be delay or any doubt about safety, physicists would concentrate on techniques which are priorities and postpone the start of the other techniques.

Other strategies consist of reorganizing the physics unit following 3 levers. First, tasks are distributed among the staff in order to have one referent assigned per new piece of equipment, to involve everyone in the project, and to take care of routine. One physicist is in charge of the Linac commissioning process, and he gets assistance from a trainee physicist who has been working in the unit for one year. Secondly, the unit calls on a service provider to get assistance with one part of the commissioning tasks. Finally, the team work extra hours.

### **3.2. Linac configuration**

In order to configure the new Linac, physicists go through two sequential steps: first data acquisition for TPS modeling, and secondly clinical verification for TPS modeling control.

#### ***Linac performance measurement for TPS modeling***

A Treatment Planning System (TPS) is a highly sophisticated tool used to generate beam shapes and dose distributions with the intent to maximize tumor control and minimize normal tissue complications for a given patient. By means of this critical system, a medical physicist

therefore translates the medical prescription made by the radiotherapist into computerized orders that are sent to the Linac.

TPS runs complex calculation algorithms that need to be configured according to the actual performance of the Linac being implemented. Based on a list provided by the TPS, and by means of different detectors placed in various phantoms (devices simulating a human body), physicists collect beam characteristics in numerous configurations. In particular, they measure dose profiles, depth-dose curves and Collimator Scatter Factors when varying several parameters such as beam energy, radiation field size or depth, hence covering standard configurations (e.g. a regular-sized 10 cm x 10 cm field) as well as more boundary ones (e.g. very small 2 cm x 2 cm field). This constitutes a considerable number of configurations to be set and data to be collected, especially since both TPSs (one dedicated to stereotactic radiotherapy and the other one used for all three other techniques) require specific sets of data for every technique implemented.

Although the list of data required by TPSs is clear, interviews highlight that the way those data should be measured is a lot less described and for some of them, no instruction is given regarding which detector should be used. This is directly linked to the fact that some physics problems influencing the Linac beam behavior are not very well known nor controlled yet, especially for stereotactic radiotherapy which is a newer technique; for instance, an internal report from the trainee physicist states that “*according to international literature, it seems that there is no consensus regarding the best detector to be used to measure Collimator Scatter Factors in mini-beams*”. Indeed, in order to measure the Linac performance, a wide range of detectors is at the physicists' disposal. Each detector has specific features which make it appropriate for certain configurations; for instance, such a small cylindrical detector gives valid output for field sizes ranging from 5 cm x 5 cm to 10 cm x 10 cm.

Physicists point out that using an appropriate detector is crucial in obtaining quality measures. Should the wrong detector be used, there is a risk to model TPS based on data that are not proven to be correct or accurate enough. Interviews highlight that physicists are particularly aware of the risk associated with TPS modeling for stereotactic technique since one of the most tragic radiotherapy accidents that occurred in France (the “Toulouse accident”) involved the use of an inappropriate detector and led to overexposure of 145 patients.

Regardless of the detector used – appropriate or not, some kind of data are measured. Difficulty lies in the fact that if these data are then checked with the detector that was originally used, there will be a match between both sets and the wrong conclusion will be given that TPS modeling is correct: “*The thing is, you make measurements and you say it's reality [...], so if you model with erroneous profiles, then modeling won't be correct. And actually, if you use the same detector to do checks afterwards, you'll see the same thing that you had measured. So it sees something incorrect but it reproduces it, and if you measure with something incorrect too, then you'll believe it is correct when it is actually wrong*”.

In order to reduce the risk to enter wrong data in TPSs, physicists select detectors based on information they gather from additional resources, including guidelines developed by learned societies of physicists, scientific papers published by peers and comparative studies conducted by research institutes (e.g. Derreumaux et al., 2008). They also share experience with other radiotherapy units having implemented the same Linac and faced the same issues. Besides, they crosscheck the data obtained with several detectors. If detector A gives reliable measures for fields ranging from 5 cm x 5 cm to 10 cm x 10 cm, and detector B from 2 cm x 2 cm to 8 cm x 8 cm, and if TPS needs data for a 7 cm x 7 cm field, then the physicist makes the measurements with both detectors and makes sure that they match, and moreover that they

corroborate theoretical values. Finally, they compare the measurements to some references presented in the TPS database.

### ***Verification for TPS modeling control***

The next step of the commissioning process, verification, is most important since it allows physicists to control whether TPSs have been well modeled and, as a consequence, whether the Linac produces the expected treatment. It also aims to highlight the possibilities of the machine, as well as its limits for clinical cases to be handled in operation.

The purpose is to program treatments into the Linac thanks to the TPSs which have previously been modeled, and run them on phantoms. The comparison between measured data and calculated data helps assess whether the Linac is able to deliver the treatment it has been programmed for. Verifications are made in simple conditions, but also in complex ones. Clinical verification finally aims at controlling the treatment process as a whole by means of an end-to-end test run on an anthropomorphic phantom with physiological characteristics of a human thorax. Physicists also verify what relates to the computerized network: they check that its various elements (scanner, TPS, Record & Verify, Linac, etc.) communicate well and data are transferred correctly.

Verification is a tedious process that takes a long time (a good month) since a lot of configurations are tested. For stereotactic radiotherapy however, there is no specific reference describing how to check that what happens with the technology works well algorithm-wise. It is therefore at the discretion of the physicists to establish the list of the items they think are crucial to ensure the Linac has good performance. The list of verifications to be performed is established based on what is described in the references cited previously. When physicists have any doubt about what they could identify as cracks in this list, they add their own verifications.

When performing verifications, the physicist in charge of Linac commissioning and the trainee physicist discover discrepancies from the expected data, hence they express their dissatisfaction with the modeling of the TPS dedicated for stereotactic radiotherapy which has been carried out by the service providers: *“you try to have the depth-dose curve of your machine come as close as possible from the existing one [found in the TPS library], to make sure you're not totally in a mess. And for us it didn't match well, so we thought there must be a problem”*. This confirms the doubts they had about the detector used by the subcontractors. Hence they do all measures themselves with the detector they find to be the most appropriate. Then they remodel the TPS and once again perform the verification which, this time, gives good results.

Lastly, a control performed during an external audit is an additional way for physicists to ensure their new Linac configuration has been well done. However and again, external controls do not cover stereotactic radiotherapy.

### **3.3. Development of quality control checks**

Before the Linac can be used to treat patients, physicists have to develop the frame of reference for quality control checks. In operation, such controls are very important as regards to safety because their purpose is to help detect any parameter drift of the machine. Unlike commissioning activities, quality controls are enforced by law, hence regulations constitute some norms to be followed. However, there is a lack of standards for more recent techniques such as stereotactic radiotherapy, so there again physicists have to gather information from various resources to make a list of the checks that will have to be performed in operation at different frequencies (e.g. on a daily, weekly, monthly or annual basis). Measurements, which

constitute the Linac reference characteristics with which the characteristics in operation will be checked, are completed several times by physicists who want to ensure data acquisition robustness.

Overall, the commissioning phase is the first step in the process of familiarization with and appropriation of the machine: “*at the same time it allows you to know your machine a little, to know well how to use it, to know also its restrictions, its mechanical limits*”.

## **4. Discussion**

Two topics appear as particularly relevant regarding our study.

### **4.1. Designing safety norms for innovative technologies**

Like more classical industrial domains, radiotherapy is hit by technology push generated to a large extent by vendors. When a new machine is released on the market, radiotherapy units that first implement it have the vendor's documentation at their disposal, but there is still no national or international reference yet regarding the way to control the innovative techniques it enables. Installation spreads to a larger extent and individual papers are published. Only then do working groups – usually composed of members of the medical physics learned society – get together to establish guidelines, based on research conducted by units and operational feedback. Eventually the guidelines are used by authorities as a basis for regulation.

Therefore, a long time can go by before such a referential is available, and yet technological innovations need to be implemented. Controlling if a machine conforms to a reference document is not trivial when the aforesaid reference document does not exist yet. Physicists must identify and find relevant resources describing appropriate methods and reference data, then they have to understand, interpret, assess, compare and combine the various elements, and finally they add their personal touch to fill what they consider to be cracks. In other words, they design their own set of safety norms, at their discretion. This process is essential in that it constitutes the initial configuration of the machine and the reference for its operation. Beyond high technical knowledge and skills, it requires curiosity and creativity, as well as reflection, critical thinking and conscientiousness.

### **4.2. Managing safety under pressure**

In the radiotherapy unit studied, the commissioning process went well; physicists were proud, happy and relieved to start treatments on patients. They were also confident that there would be no safety issue since they considered they had done their best to reduce risks, and indeed no incident regarding the matter of machine configuration has been declared since then.

However, organizational conditions might not be the same in all healthcare facilities and hence might not necessarily allow healthcare providers to do quality work. Should the physics team be understaffed, less experienced or less skilled regarding technologies and techniques, should financial resources be more limited, hence preventing the unit to acquire appropriate control equipment or up-to-date software, should the vendor restrict training and support even more, should the schedule be tighter or should there be a hazard narrowing down the time dedicated to commissioning, then there would be much greater risk of measurements not to be performed optimally and TPS to be incorrectly modeled, or verifications to be performed partially and an incorrect TPS modeling not to be detected. In this context, one also needs to be vigilant with the organizational solution of subcontracting due to the fact physicists on the unit might not have access to the way either of those steps are run, and they miss an

opportunity for appropriation. Put another way, we could be facing another Toulouse accident.

This tends to show that healthcare facilities behave more and more like regular companies in that they are submitted to economic constraints and motivated by profit. In particular, they face what Amalberti (2001) refers to as transgression of practices and migration towards safety boundaries under the pressure of commercial market, technology and individual concerns. The question related to risk acceptability that hence needs to be asked is: how far in the compromise between productivity and safety are we ready to go?

## 5. Conclusions and perspectives

This paper shows the way medical physicists manage to ensure safe Linac performance under pressure during commissioning. In order to study further the compromise between productivity and safety, we will explore in detail the decision-making process and the criteria used when compromises regarding time allotted to commissioning must be found. This will help enrich the larger matter of control of technological innovations.

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## Does the use of friction reducing devices actually reduce the exposure to high force lateral transfers?

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### Abstract

The activity of transferring a person from lying to lying frequently occurs in healthcare, e.g. bed to trolley, treatment tables, theatre departments and ambulance services. These positional changes can include lateral transfers (bed to bed), moving up a bed (boosting), or supine to side lying (turning). Transferring patients has long been identified as a contributory cause of MSD in healthcare processes. This study explored routes to error in a UK national healthcare provider for the range of transfers indicated and investigated the level of knowledge within the workforce to complete these transfers.

A survey (n=170) showed that a high percentage of staff reported that transfers that using slide sheet devices were being performed in a way which did not following the evidence based guidance. 31.6% of the descriptions of how to set up a transfer were incorrect and a further 13.0% were less than optimal. Only 31/170 respondents showed no errors in their survey responses.

A secondary laboratory study quantified the force differences between a best practice transfer and the various erroneous methods. The additional forces were compared to show that there could be more than 100% increase in the amount of effort that healthcare workers have to use of the preparation of the transfer is not performed correctly.

Processes and design considerations that enforce the compliance with best practice guidelines can assist in the reduction of the overall musculoskeletal effort that healthcare workers endure.

**Keywords:** patient handling, biomechanics, healthcare workers, load movement, assistive devices

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### 1. Introduction

The activity of transferring a person from lying to lying frequently occurs in healthcare, e.g. bed to trolley, treatment tables, theatre departments and ambulance services. Transferring patients has long been identified as a contributory cause of MSD in healthcare processes (Smith, 2011). Early studies reported that methods of transfer include staff reaching over one flat surface to hold a draw sheet and pulling the patient across the surface to the destination point (Zelenka et al, 1996; Bohannon, 1999; Lloyd et al, 1998). As patient handling methods have developed, interventions and equipment options have become increasingly available to improve lateral transfer methods (Derbyshire Interagency Group, 2011, Hall, 2005).

Several studies have identified the benefits of using friction reducing equipment to reduce the manual handling risks of a laterals transfer (Zelenka et al, 1996, Bohannon, 1999; McGill and Kavcic, 2005; Lloyd and Baptiste, 2006, Fragala and Fragala, 2014) and suggest that forces

will be reduced with the use of equipment. Other mechanical or assistive technologies have been evaluated to improve the methods for lateral transfers, for example: long handled transfer sheets to improve operator's posture (Derbyshire Interagency Group, 2011, Baptiste et al, 2006, Fray and Hignett, 2009); inflatable devices (Hall, 2005, Baptiste et al, 2006). Some mechanical solutions have been evaluated, including: hoisting solutions (Silvia et al, 2002; Dolan et al, 1998) and mechanically assisted rolling (Silvia et al, 2002). All of the studies and best practice guides indicate that the benefits are most effective when there are two layers of friction reduction material under the load being moved. Unfortunately more recent studies appear to show that the compliance with safer handling methods may not be developing as organisations and care delivery services would like (Koppelaar et al ., 2013, D'Arcy, Sasai, and Stearns, 2012). Safe patient handling practitioners see one of their roles as the improvement of both competence and compliance within their staff groups (Smith 2011).

## **2. State of the art**

This project explored the knowledge and applied skills of the workforce within the participating health-care provider. The data from this first survey then informed a laboratory investigation that utilised previously defined research methods (Fray and LARF, 2012) to measure the forces to move a patient in a variety of ways. The study included a novel product which aimed to improve the relative number of errors in the transfer set up. It adds to the current knowledge by quantifying the level of force that can be apportioned to erroneous use of this standard piece of patient handling equipment.

## **3. Objectives and Methods**

### *Objectives*

This study explored two items:

- To identify the level of understanding of healthcare workers regarding the multiple sizes and positions used in various horizontal transfers
- To measure the difference in force required to complete horizontal transfers with different combinations of slide sheet, transfer type and surface

### *Questionnaire Survey*

A simple questionnaire survey evaluated the knowledge and practical selection of methods for the use of friction reduction devices for the staff in a UK healthcare provider. A convenience sample was used as participants were invited as they attended their various patient handling updates or when the team were required to visit an area. The questionnaire required the individual to select the position and format of the friction reducing device for a number of activities e.g. horizontal lateral transfer, moving up a bed, turning from supine to side lying. Various options were provided and the participants selected the ones they used. The options varied for number of sheets, type of sheets, and the position of sheets under the patient and the direction of movement. The responses were categorized as correct or incorrect depending upon the response and the best practice guidance given in the local protocols. These patterns of movement and alignment defined the correct and incorrect conditions for the laboratory study.

### *Laboratory Trials*

A repeated measures design was used with three different sized patient loads (58-98kgs) for different combinations of sliding devices (n=12). The range of devices included:

1. Tube slide sheets of differing sizes
2. Pairs of single flat slide sheets
3. A novel design of tube design that allowed movement in 90 degree opposing directions
4. Transfers were aided by one solid slide board and one flexible slide board

Data was collected by the same experimental team for all the physical trials. The patients completed a series of lateral transfers starting a) on the bed, b) half on a transfer board and c) fully on a transfer board. Additionally a series of movements up the bad were also recorded with the patients only lying on the bad (as in a) above). The combinations were created to replicate both the evidence based best practice, and incorrect positions of the slide sheets for different transfers. Due to the similarity of the initial movements between supine to supine lateral transfers and supine to side lying transfers only the lateral transfer was reported in this study.

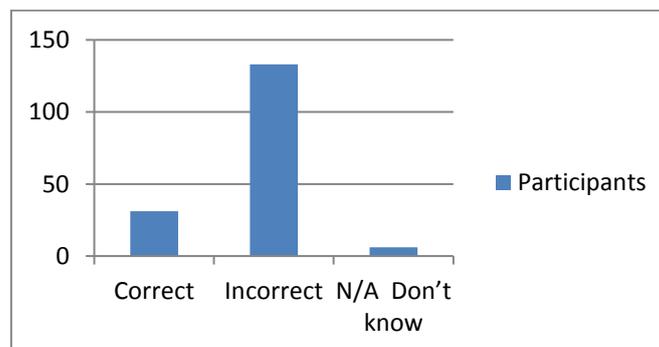
### *Experimental Scenario.*

Patient actors were formally introduced to the trial and consent in line with Loughborough University ethical approval system. During the transfers the patient was completely passive and adopted a fixed position, hands across chest, legs straight and not crossed. The range of conditions was defined by the experimental group based on the results from the survey. The correct/incorrect classification, the positioning of patient, sheet and slide sheet was based on current best practice and supported by the training and protocols agreed in the healthcare organization. The ‘patient’ started on a hospital bed with the chosen equipment in place. The forces to move the patient were measured as the minimum repeatable force to initiate movement (Fray and Hignett, 2015). To record the force at the start of horizontal movement, markers were placed on the patient and bed. The patient and observer had to agree that horizontal movement had occurred. The forces for the physical tasks were recorded using a Mecmesin AFG2500N force gauge for all pulling actions. The activity was repeated until a sample of 5 values within 5% variation around the median was achieved. The quality of the movement was noted as there were different interactions between boards, sheets, position and loads. The adhesion between some board and sheet combinations caused a build-up of force and excessive movement to occur and measures had to be excluded.

## **4. Results & Discussion**

### **4.1 Questionnaire Results**

The questionnaire response (n=170) showed that there were numerous routes to error for the use of friction reducing devices in the organisation. Figure 1 shows that 78.2% of the respondents gave an incorrect description of the position and use of the slide sheets.



**Figure 1.** Correct/Incorrect responses

The errors were shown to include incorrect selection of device including wrong number of layers, wrong type, wrong shape and wrong positioning of sheets during the transfer e.g. vertical to horizontal alignment. The survey investigated if the lack of suitable slide sheets may have contribute to the poor understanding and develop poor practice. Figure 2 shows the frequency that there was insufficient choice or equipment in the various areas.

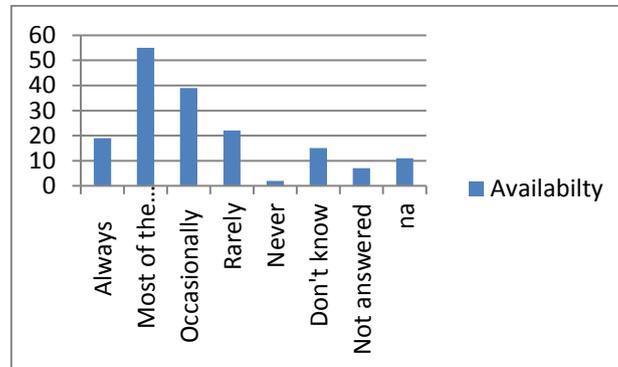


Figure 2. Are correct size of slide sheets available?

The level of confidence that staff were able to make the correct choice of size, shape and position for the three transfers was also questionable. Figure 3 reports that the 21.2% of staff were confused most of the time and a further 57.6% reported most if the time

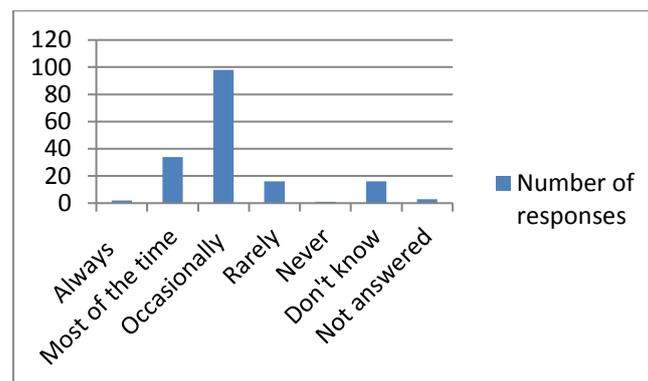


Figure 3. Do staff get confused with the variability of size and shape of slide sheets

Further investigation explored the relationship between the different transfer types and the descriptions of safe practice. Moving a person up in bed showed the highest knowledge of the set up at 64.1%, Lateral transfers next with 55.9% and turning to side-lying showed the worst understanding with only 44.7% being correct.

Transfer	Possible solution		Incorrect
	Correct	Possible solution	
Move up Bed	209		117
Turn in Bed	113	92	48
Lateral Transfer	138	16	97
Total	460	108	262

Table 1. Quality of knowledge across transfer types

The indications suggested in the evidence from this survey shows that the staff would regularly complete transfers for these three movements with the slide sheet combinations in either incorrect or less than optimum positions. This inaccuracy will inevitably lead to some

increased effort for the healthcare worker. The patterns described were used to define the force measures and the analysis for the laboratory study.

## 4.2 Laboratory Study

	Equipment	Size(cm)
1	Single layer Theatre Sheet A	70x190
2	Single layer Theatre Sheet B	70x190
3	Pair of Flat Sheets (Coated Polyester, no handles)	70x200
4	Pair of Flat Sheets (Green Plastic)	70x200
5	Pair of Flat Sheets (Coated paper)	70x200
6	Tubular Double bed size (Coated Polyester)	140x200
7	Tubular Slide Sheets (Coated Polyester, 3 of, full body length)	70x145
8	Pair of Flat Sheets (Coated Polyester Handles)	70x200
9	Redi Slide (Coated Polyester, Novel design)	90x220
10	Tubular Slide Sheets (Coated Polyester 2 of, Shoulder to hips and calf)	70x145
11	Tubular Slide Sheets (Coated Polyester 1 of, Shoulder to hips)	70x145
12	Pair of Flat Sheets Double bed size (Coated Polyester Handles)	140x200

Table 2. Equipment and position combinations

The force data was collected for 12 slide sheet combinations, correctly and incorrectly used with two different slide board combinations for the 3 patient loads recruited. Table 2 lists the different slide sheet combinations each combination was measured under 5 positional variations (directly on bed, ½ on solid transfer board, fully on solid transfer board, ½ on flexible transfer board and fully on flexible transfer board) with three different sizes of patient (58, 72 and 98kgs). The agreed reliability for the consistency of force was achieved across the range of activities (n=180 slide sheet and patient combinations and n=1123 force measures).

The forces to laterally move the patient were proportional to the body weight of the patient being moved. Some transfer board and sheet combinations showed different qualities of movement. The flexible board showed an element of adhesion so there was a higher force and staggered jerky movement. One of the problems identified with the incorrect methods was where two layers become one during the transfer. The forces Table 3, showed a significant increase for large and medium sized patients

	Single Layer	Double Layer
Heavy	214.7	104.7
Med	172.6	98.3
Small	71.5	65.2

Table 3. One layer to two layers for lateral transfer on bed

The second error identified was the lack of coverage between the patient and the bed. This can occur when narrow sheets are used under full body, trunk and legs or just trunk. Table 4 shows the force to move the patients when on a solid transfer board similarly to the previous example more than double the force was required between best and worst scenarios.

	Heavy	Med
Full length	62.5	44.3
Shoulders and legs	91.6	72.2
Trunk Only	132.8	71.2

Table 4. Force for 1, 2 and 3 sheets under a heavy and medium patient.

The trials explored the differences between solid and flexible transfer boards. The evidence was not clear as different boards interacted with different slide sheets to confuse the effects. It was however clear in most transfers that the solid boards reduced the force required for horizontal movement. Comparisons between like styles of slide sheet were also made Table 5 shows sheets of different material for the different lateral movements. The innovative product (9) compared favourably with the selection and the disposable products (4,5) were less effective.

Lateral Transfer	9	8	5	4	3
On Bed top	63	105	167	154	109
1/2 On Solid Board	101	102	149	182	140
Fully on Solid Board	79	107	97	134	80
1/2 on Flexible Board	93	118	151	195	102
Fully on Flexible Board	65	100	101	184	101

Table 5. Force (n) for different materials of slide sheets

## 5. Discussion & Conclusion

The survey clearly showed that the use of varying sizes and shapes confused the workers. It was possible to measure the differences between the efficient and non-optimum use patterns. Further analysis is required to estimate how much extra work could be being required for shift patterns based on the workload in different healthcare areas. This trial included a slightly over-sized tubular sheet of novel shape and format (9). The aim of this slide sheet is to simplify the process and learning and be the only size shape in the hospital. This study would show that a device that improves compliance with best practice could make significant reductions in the work required across the care setting. The additional forces recorded when not using the optimum operating procedures show that providers of assistive devices and safe procedures still have improvements to make. Equipment solutions need to be intuitive so as to make the correct use the only use. In addition these raised forces will add to the physical demand in an area that has reduced the demand but high load tasks are still prevalent e.g. fitting hoist slings, high risk mobility situations and plus-size care delivery.

## Acknowledgements

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## The Impact of Usability Engineering on Patient Safety

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### Abstract

98 000: The number of deaths in the U.S. each year following medical errors, as estimated by the Institute of Medicine in 1999 (Kohn, Corrigan, & Donaldson, 2000). No change, Landrigan and colleagues (2010) say, could be found in the trend ten years later. Every 1000<sup>th</sup> patient is dead as a direct result of their treatment, a German study reports (Klauber, Geraedts, Friedrich, & Wasem, 2014). Patient safety is an ongoing, international concern.

Medication, diagnostic, handoff, and surgical errors, falls, hospital acquired infections, these, Pham et al. (2012) report, are among the most common adverse events in hospitals. They also offer solutions: Administrations can implement procedures like standardizing vitamin D supplements and handoff guidelines; medical professionals can be more careful of how they place catheters and how often they sterilize their hands. However, these solutions leave out an important facet of both the problem and the solution: Technology.

About 15 years ago, usability engineering was used by a minority of medical device manufacturers as a differentiation criterion in competition to benefit from ease of use and user satisfaction as marketing factors. Triggered by the increasing discussions about errors in medicine and ongoing activities in the field of patient safety, in 2004 the first international usability engineering process standard for electro medical devices was published by the International Electrotechnical Commission (IEC).

Today we are in the third generation of usability engineering process standards always following the goal to assess and mitigate risks caused by usability problems associated with correct use and use errors.

Nevertheless, some manufacturers still struggle with how to implement usability engineering into medical device design. This article will present a case study showing how usability engineering can be implemented in the product design process to generate a successful product design and improve patient safety.

**Keywords:** patient safety, human factors, usability

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### 1. Introduction

How can normative requirements be transferred into manufacturing practice? Many manufacturers ask themselves this question when they have to translate qualitative user requirements into quantitative and measureable product specifications to ensure that the products fit the users' needs.

The same question often comes up in situations where responsible staff within a product development team needs to apply the requirements of the usability engineering standard into product design. It is often unclear to what extent the phases described in the standard must be considered for a new product.

One of the best ways to learn is to look at what others have done, but case studies that detail the steps of the development process are very rare in commercial projects, because developers do not wish to make their process open to the public. We are fortunate to be able to present one such case study here: Use-lab recently participated in a funded project called "OptoBrain". Initialized by the Swiss start-up NeMo Devices and supported by the Eureka initiative, the project's objective was the development of a system to measure cerebral vital signs such as the oxygen saturation in brain tissue, the cerebral blood volume and the blood flow. These parameters play a crucial role with regard to the examination and treatment of patients suffering from craniocerebral injuries that can lead to a stroke.

Every year, 15 million people worldwide suffer a stroke. Nearly six million die and another five million are left permanently disabled. Stroke is the second leading cause of disability, after dementia. Disability may include loss of vision and / or speech, paralysis and confusion.

Globally, stroke is the second leading cause of death above the age of 60 years, and the fifth leading cause of death in people aged 15 to 59 years old (World Heart Federation, 2016).

The NeMo system is composed of several hardware-components including the probes and patches, a control unit and a monitoring system (Figure 2). Use-Lab's role in the project was to design and evaluate a graphical user-interface that would allow for user-friendly, simple and intuitive operation. Due to the public character of the funding project, Use-Lab is allowed to share the results of the design and usability related activities.

This article will present selected results focusing on patient safety to describe the iterative design and development process, which, at the end, leads to a new innovative and successful product to save patients' lives.



Figure 2. NeMo system including a control unit for the patches and probes as well as a graphical user interface

## 2. Use Errors in Medicine

Successful stroke therapy requires monitoring of a full set of key neurological parameters as well as consistent and continuous care by dedicated personnel. The decreasing number of specialized healthcare personnel available to treat stroke patients increases the demand for accurate neurological monitoring solutions to support the clinical team during the treatment of acute stroke. It furthermore requires systems that are easy to use and not prone to errors, either in and of themselves or in conjunction with users.

Stress, a wide range of high-tech medical devices providing a variety of different user interfaces and the complexity of the diagnosis system are factors that can contribute to a use error. Per definition, a use error is a user action or lack of user action, while using a medical device that leads to a different result than that intended by the manufacturer or expected by the user.

Furthermore, it is important to note that user interface always refers to all parts of a device or system that a person interacts with, including hardware as well as software interfaces and not just, for example, the display commonly called graphical user interface. All accompanying documents are per definition also part of the user interface.

While a product's design can have a negative impact in obvious way, for example, a lever that is too difficult to pull, less obvious shortcomings can also play significant roles. Such deficits can lead to design shortcomings in the user-interface can additionally induce some people to operate devices incorrectly, lessened safety of use, but also to decreased user-friendliness. A sample of possible sources of error is given here:

- Illogical, awkward action-sequences
- Missing visual, tactile or audible feedback
- Insufficient user-guidance and status-information
- Unclear setbacks / requirements
- Hidden or confusing functions
- Default parameters that do not match user expectations
- Unclear symbols, captions or codes
- Unfamiliar terminology
- Inadequate grouping
- Inadequate safety measures
- Inconsequent formats
- Inadequate user manuals
- Unclear labelling of products and packaging
- Inadequate consideration of intercultural differences

To see just how user-unfriendly many medical device designs are, visit a clinic and count how many times you see tape or bandages used in unconventional ways. You're likely to find it wrapped around gauze that's placed over sharp corners, fastening one device to another, and providing any number of labels that the manufacturer did not (see Figure 3).



Figure 3. Tape used to improve safety

Human factors engineering can be the key to generating a user interface that is easy, effective and safe to use. The design of the user interface to achieve adequate usability requires a different process and skill set than that of the technical implementation of the user interface.

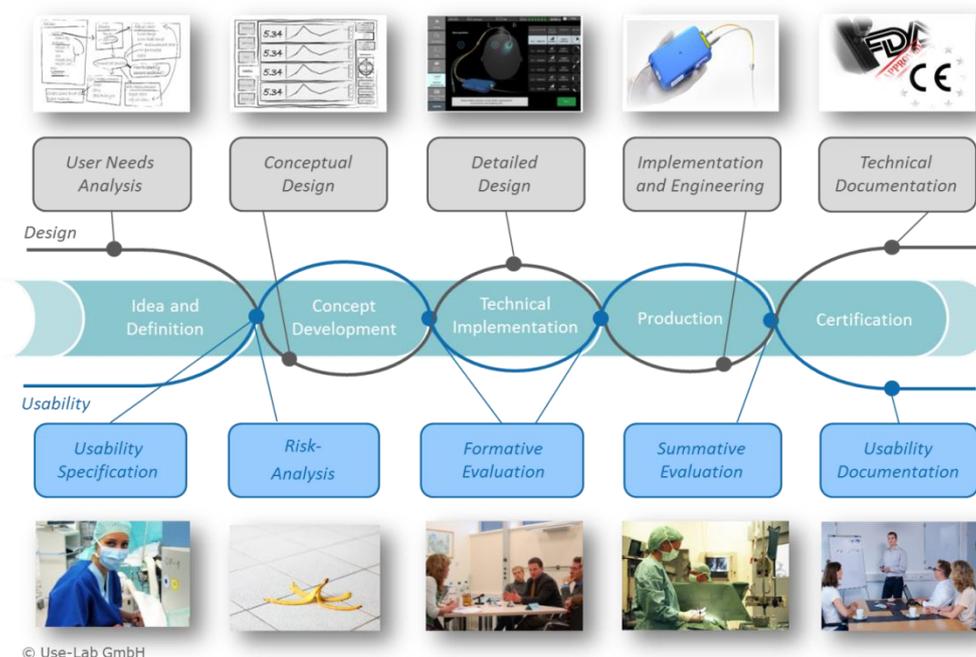
IEC 62366 - 1:2015 specifies a process for a manufacturer to analyze, specify, develop and evaluate the usability of a medical device as it relates to safety.

### 3. The Usability Engineering Process

After IEC 60601-1-6, the first usability engineering process standard, was introduced by the IEC in 2004, a continuous procedure of improving the standard has been in process. Since IEC 60601-1-6 focused on electro medical products only, there was a need to also include non-electrical device, like stop cocks, syringes but also home use related devices, like wheel chairs or even crutches, since they also provide the risk of use-errors. This was the beginning of a new, standalone standard: IEC 62366. This standard was introduced by the IEC in 2007. In 2010, the IEC provided a new edition of IEC 60601-1-6 to bridge the gap between both standards. From then on IEC 60601-1-6 referred directly to the IEC 62366. Amendment 1 in 2014 included so called legacy devices, devices that have been on the market since before the usability standard was published. Annex K provides an approach to documenting the usability engineering process for those kinds of devices.

After IEC 62366:2007 had been active for about ten years, the IEC introduce the new edition, IEC 62366- 1:2015, in February 2015. The new standard focuses more on risk management and considers some US specific requirements. IEC 62366-1:2015 is also streamlined and uses more distinctive and unambiguous terminology.

However, at the end of the day, the overall process and the recommended methodology to obtain the required data remain the same. Starting out, it is important to generally understand that usability engineering is a process and not a piece of a huge puzzle that completes the whole. Figure 4 shows how the development the design and the usability engineering process can be brought together.



**Figure 4.** Usability engineering process in relation to the product design and development process

#### 4. Sample of a Usability-oriented Development Process

To improve patient safety and generate a product that is easy and intuitive to use, it is important to understand the users' needs. Optimally, users' needs are collected by observing typical or potential users in their typical environments performing routine tasks. Deviations from the optimal workflow as well as design strengths and weaknesses of current solutions can be observed easily and the observer can get a good impression about the real needs.

In our case study an extensive user needs analysis was conducted in three countries to take into consideration intercultural differences like the education or qualifications of the users. The direct context of use was checked and potential hurdles and obstacles for a new device, like other devices that interact with the patient or the limited space in the neurosurgical unit, were observed. Hazardous situations were observed when users struggled with how to operate the system correctly, especially due to the availability of several monitoring devices and the need for the measurement of a huge number of life-saving parameters.



Figure 5. Observing users and creating first ideas for a new design during a contextual inquiry

Together with the interviewees, first scribbles were created, visualizing their thoughts and ideas on how current systems could be improved or further developed (see Figure 5). At the end, during the contextual inquiry, all relevant data required to document chapter 5.1 of the usability engineering process, the use specification, were collected. This included the medical indication, the intended user profile, the use environment, the patient population, the part of the body or type of tissue applied to or interacted with, and a rough description of the operating principles. The use specification is a very important basis for the next product development and usability engineering steps.

Taking the initial ideas and the data collected during the user needs analysis, user interface characteristics related to safety, potential use errors and foreseeable hazards and hazardous situations can easily be recognized during the risk analysis phase. Additional input can come from market surveillance data or any kind of database with reported incidents or accidents with predecessors or equivalent devices on the market. IEC 62366-1:2015 requires the documentation of these activities in chapters 5.2 and 5.3.

In the OptoBrain project, a special focus of the risk analysis was, of course, the attachment of the probes and patches to the patients' heads as well as the interpretation of the measured values and displayed curves.

Once the majority of potential sources of harm with the device are known, the development team is able to start the investigation of how they can reduce the risk related to the use of the device. The goal is to mitigate the risk or the probability of the harm occurring. Several options are provided to the manufacturer to ensure that the device can be used safely. Inherent safety by design is the option with the highest priority and the most valuable method. However, the manufacturer can include protective measures in the medical device or the

manufacturing process. Last but not least, information for safety can be used to alert users not to perform a use error.

As soon as this part of the analysis phase is done, developers can start with the specification phase. User interface specifications need to be defined based on the previously defined use specification and the risk analysis whereas some of the mitigations derived from the risk analysis can also be used as product specifications.

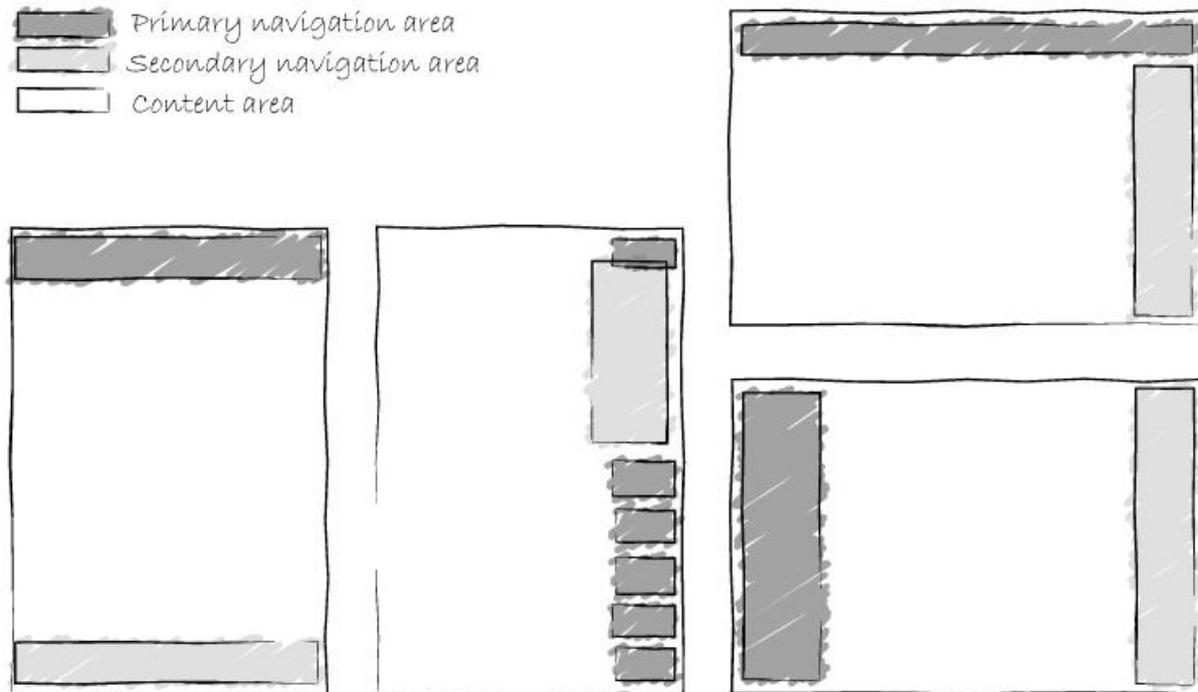


Figure 6. Alternative wireframes for the graphical user interface design of the NeMo system

In a perfect situation, product design starts now. All required information is available and the designer has a clear understanding of all the conditions that need to be considered. However, a perfect concept is often not available from the start. In a first step, several concepts compete against each other (Figure 6) and every design has its strengths and weaknesses from a user's perspective. To get this information it is worth it to involve typical user groups in this early evaluation. The users can easily rate the individual concepts and discuss what makes the concept good or bad and what the perfect catch looks like.

The benefit of this iterative process, also required in chapters 5.7 and 5.8 of the usability engineering standard, is that the manufacturer is on the safe side early on and more likely to develop the right thing (see Figure 7). For formative usability evaluation different methodologies can be applied to get feedback on the product design. In early phases expert panels, heuristic analyses and focus group discussions are often used. Later on one-on-one usability tests with potential users from different groups are commonly used. Depending on the manufacturer's market plans, multi-centric studies taking into account different countries are recommended to consider intercultural differences.

A beneficial and widely used approach is the definition of use scenarios, especially of those pointing out hazards or hazardous situations. Based on the defined use scenarios, typical workflows can be realized in the graphical user interface and be evaluated during formative evaluation. Use scenarios can also be used to perform the risk analysis. This approach is also

known as bottom up risk analysis as the opposite of the top down approach starting from potential harm.

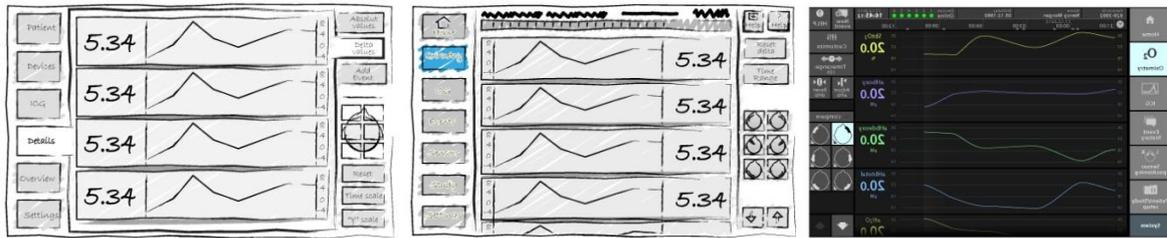


Figure 7. Iterative graphical user interface design as the result of formative evaluation

As a result of the early risk analysis in the OptoBrain project, the graphical user interface needed especially to ensure clear differentiation of the measurement values and curves of the intracranial pressure (ICP) and temperature, as well as the cerebral blood flow (CBF), cerebral blood volume (CBV) and oxygenation related to the individual application areas on the patient's skull. The user-interface also needs to clearly indicate if a patch or probe is being used (see Figure 8).

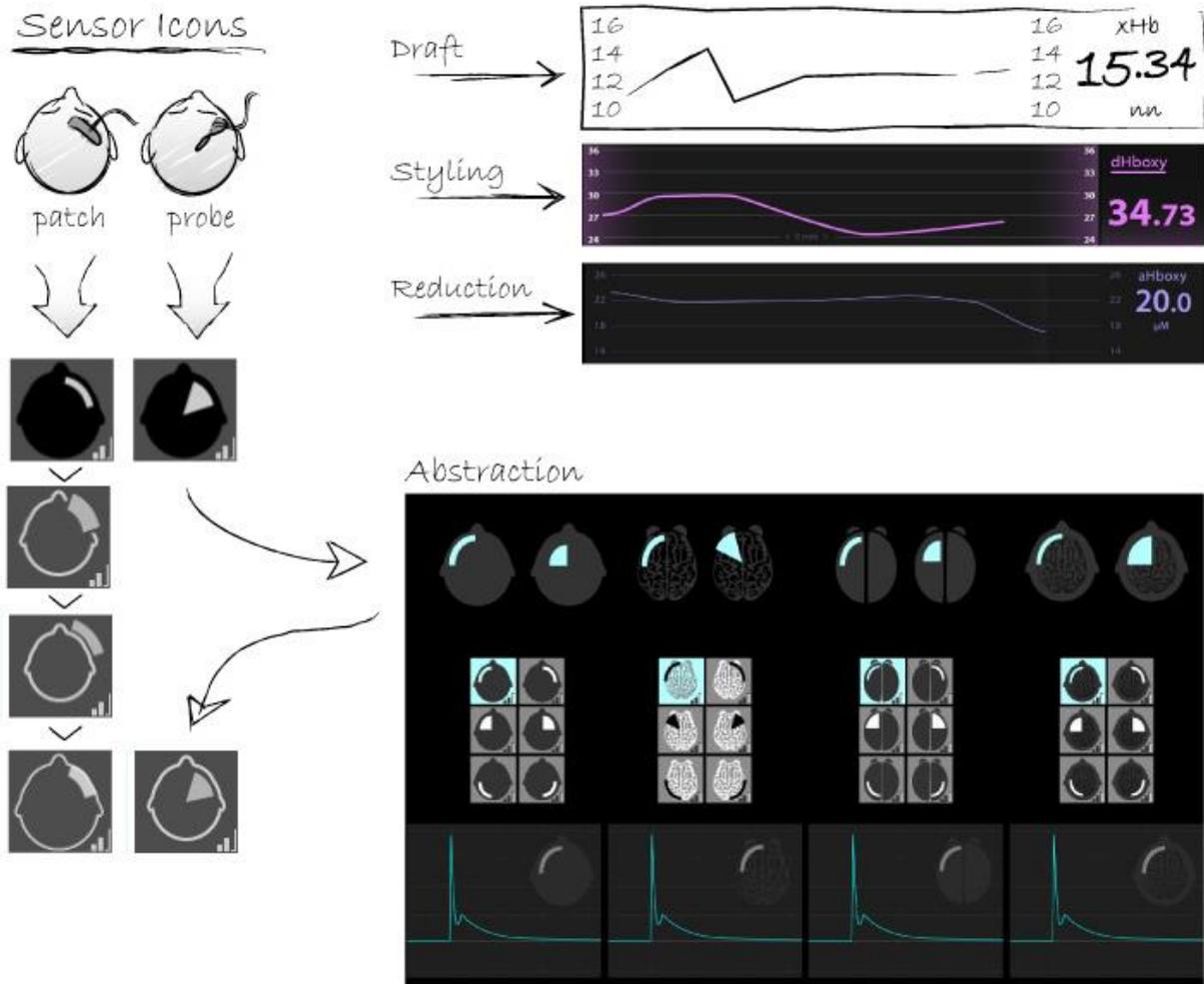


Figure 8. Graphical user interface design focusing on aspects related to patient safety

Once the user interface is sufficiently evaluated and no further highly recommended improvements are collected, all parts of the product will be engineered, produced and brought together into the final product.

To ensure that the final product, also including the instructions for use and required training scripts, is safe to use, a final usability validation is required by IEC 62366-1:2015 in chapter 5.9. The validation is conducted by a summative usability evaluation focusing on the hazard related use-scenarios defined in the previous phases. In this stage of the development process the result of the final risk analysis must provide evidence that all remaining risks are acceptable and further risk mitigation is not necessary or practicable.

## 5. Conclusion

The iterative design and development process described in the previous chapter must be documented in the usability engineering file. The document is required for CE certification and FDA submission, whereas for the last special recommendations defined in the FDA human factors guidance document “Applying human factors and usability engineering to medical devices” published in February 2016 must be considered.

In our OptoBrain case study, the NeMo probe, NeMo control unit and NeMo monitor software received CE approval in 2015. All hazard related use scenarios have been accurately analyzed, mitigated and finally evaluated. As a result, the monitor automatically detects connected NeMo Probes and NeMo Patches. The software actively guides through measurement procedures, while clearly representing trend curves as well as current measurement values. Customizable views enable the usage of NeMo system in various clinical situations.

The judging panel of the Eurostars Innovation Award 2015/2016 has selected OptoBrain project as one of the three winners of the prestigious EUREKA Innovation Award 2015/2016 in the category ‘Innovators of Tomorrow’.

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## Impact of Intraoperative Microbreak Exercises on Surgical Team Performance

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### Abstract

*Context:* Surgeon and surgical team member health is heavily impacted by work-related pain, fatigue and musculoskeletal disorders (MSDs), which can impact career-longevity.

*Objectives:* This study aimed to evaluate the impact of periodic intraoperative microbreaks with exercises performed within the sterile field on surgeon and surgical team performance and workflow.

*Methods:* Attending surgeons and their surgical team members across various surgical specialties participated in a study at a tertiary medical center as part of a larger multi-center trial. The intervention was exercises targeting the neck, shoulders and back performed in the sterile field during surgically appropriate intraoperative microbreaks throughout each case over a surgical day. Participants completed self-reported questionnaires at the end of each surgical procedure.

*Main results:* Thirty three surgeons and their surgical teams participated in 149 surgical procedures, 70 operations with the microbreak intervention and 79 without. The microbreak intervention did not statistically significantly lengthen surgical duration.

Overall, 41% of the team members felt that the microbreaks with exercises increased their physical performance and 57% were indifferent, with only 2% saying microbreaks diminished their physical performance. For mental focus, 34% of the team members felt the intervention improved their focus, 62% were indifferent and only 3.5% felt the microbreaks with exercise diminished their mental focus. These were the two primary outcome variables for this study.

For the secondary outcomes, over all the team members, 73% felt the microbreaks impacted their workflow. However, these team members reported a median distraction level of 1/10 and a median workflow disruption of 2/10 across days of surgery with the microbreaks and therefore experienced minimal impact to the workflow. Across all the team members, 83% of the surgeons and 77% of surgical team members wanted to incorporate intraoperative microbreak exercises into their operating room (OR) routine.

*Conclusion:* A large number of surgeons and their surgical teams reported that an intraoperative microbreak intervention with exercises improved their performance mentally and physically with a minimal impact on the work flow, including no increase in operative duration and they wanted to incorporate microbreaks into their OR routine.

**Keywords:** surgery, performance, musculoskeletal disorder, fatigue, provider intervention

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### 1. Introduction

Ergonomic concerns have recently been recognized as a major contributor to intraoperative pain and fatigue for surgeons, based on publications with titles such as “While patients

benefit, surgeons suffer: An upcoming epidemic” (Park, et al. 2010); “The operation room as a hostile environment for surgeons: Physical complaints during and after laparoscopy” (Sari, et al. 2010); “The aching surgeon: a survey of physical discomfort and symptoms following open, laparoscopic and robotic surgery” (Plerhoples, et al. 2012) and “Are your ORs Hurting your Docs” (Berguer 2013). However, Sir Alfred Cuschieri started talking about the tribulations of minimally invasive surgery over 20 years ago (Cuschieri 1995) and little has changed. Surgeon health is heavily impacted by work-related pain, fatigue and musculoskeletal disorders (MSDs); an estimated 9% of surveyed MIS surgeons have been required to stop practicing due to musculoskeletal pain (Sivak-Callcott, et al. 2011; Sivak-Callcott, et al. 2015). There are several studies reporting from 60% (Sari, et al. 2010; Plerhoples, et al. 2012) to nearly 90% (Park, et al. 2010; Kim Fine, et al. 2013; Cavanaugh, et al. 2012; Davis et al., 2013; Abdelrahman, et al. 2016; Park, et al. 2016) of surgeon respondents experiencing pain/discomfort during or after performing minimally invasive, gynecological, orthopedic and pediatric surgery. However, there have not been any studies involving the other members of the surgical team. Despite attempts by a few studies to link surgeon fatigue and pain to surgical outcomes for the patient, interventions to decrease this physical strain have not yet been studied. One method used in other industries to mitigate ergonomic risks is the incorporation of microbreaks. Thus, an intraoperative microbreaks with exercises intervention was studied.

## **2. State of the art**

The performance of surgery imposes physical challenges with potentially career-threatening consequences for surgeons and their teams. The surgeon operates in relatively long-held static positions and surgical team members by the bedside (Figure 1) are often in static postures as well, resulting in stiffness and pain that persists outside of the operating room (Abdelrahman et al. 2016; Yu et al., 2016). Both the physical and mental workloads are high during surgery (Szeto et al. 2009; Yu et al. 2016) for the surgeons and their team members.

Two previous studies have shown that intraoperative microbreaks can be translated to the surgical environment. One surgical study (16 surgeons) that showed that 20-second breaks every 20 minutes over the 2+ hour surgery with neck and shoulder stretch compared to control (prior to surgery) was associated with significant reduction in subjective and objective fatigue (Dorion and Darveau 2013). The most dramatic finding was accuracy of a star-tracing test with a Metzenbaum scissor which yielded an average 7-fold increase in error for “typical” non-microbreak surgeries compared with the microbreak surgeries in their study (Dorion and Darveau 2013). A second study on 53 surgeries showed that a microbreak with a 5 minute unstructured break every 30 minutes did not increase the length of surgery (Engelmann et al. 2011); in addition, it reduced salivary stress hormones, lowered the increase in fatigue and stress for the group with breaks compared to those without. These studies demonstrate that microbreaks have potential to reduce surgical fatigue, discomfort and stress and improve performance without increasing surgical duration.

## **3. Objectives and Methods**

### *Objectives*

This study aimed to evaluate the impact of periodic intraoperative microbreaks with exercises that can be performed within the sterile field on self-reported surgical physical performance, mental focus, distraction level and workflow disruption when performed by surgeons and their surgical team members.

## Methods

Attending surgeons and their surgical team members across various surgical specialties (general, pediatric, vascular, gynecology, urology, etc.) participated in this study at a tertiary medical center, as part of a larger multi-center trial (Park et al., 2016). The study intervention involved standardized (1.5-2 minute) guided intraoperative microbreak exercises performed in the sterile field at surgically appropriate time (20-40 min intervals) throughout each case over one surgical day, compared to one non-exercise day. Each day (with and without exercises) was required to have one case longer than 2 hours in order to be included in the study. The exercises targeted body parts at high risk of pain and MSD, namely the neck, shoulders and back. Participants completed self-reported questionnaires at the end of each surgical procedure. The two primary outcomes were the impact of microbreaks on the physical performance and mental focus with checkboxes for improved, no change and diminished as the answers. The two secondary outcomes were about the impact of microbreaks on surgical flow disruptions and distraction level of the participants on a 10-point visual-analog scale (10=worst), examined using the median and IQR. On the last procedure of the day, participants answered whether they would want to incorporate the microbreaks exercises into their OR routine or not. In addition, the operative duration with and without the microbreak intervention was compared using a t-test. The full methodology can be found in Park et al. (2016).

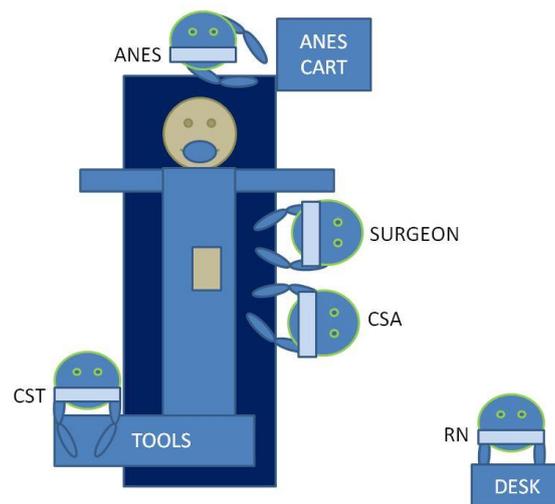


Figure 1. Representative location of the OR surgical staff during this study

## 4. Results & Discussion

Thirty three surgeons and their surgical teams (which differed daily) including a total of 25 Certified Surgical Assistants (CSAs), 36 Certified Scrub Techs (CSTs), 34 Circulating Nurses (RNs) and 15 Anesthesia providers (ANES) participated in 149 surgical procedures, 70 operations with the microbreak intervention and 79 without. The microbreak intervention did not lengthen the surgical duration ( $p=0.7428$ ) with the cases averaging about 2 hours.

The primary outcomes for this study were two questions about physical performance and mental focus (Table 1), rated as improved, no change or diminished. Overall the only 2% of team members felt that the microbreaks with exercises diminished their physical performance and only 3.5% felt the microbreaks with exercise diminished their mental focus. Whereas 41% reported an improved physical performance and 34% reported an increase in mental focus. The surgeons reported the greatest improvement in physical performance and the anesthesia providers reported the highest improvement in mental focus.

	Surgeon		CSA		CST		RN		ANES		OVERALL	
	P	M	P	M	P	M	P	M	P	M	P	M
Improved	55%	38%	39%	32%	40%	30%	27%	24%	47%	63%	41%	34%
No change	45%	55%	58%	61%	60%	68%	71%	76%	53%	37%	57%	62%
Diminished	0%	8%	3%	6%	0%	2%	2%	0%	0%	0%	2%	4%

**Table 1.** Self-reported physical performance and mental focus changes from microbreaks (P= Physical Performance, M= Mental Focus)

Secondary outcomes were the amount of distraction and the workflow disruption that the microbreaks caused during each case. Participants reported their distraction and surgical flow disruption on a 10-point Likert scale (10=worst). Over all the team members, 73% felt there was minimal (1/10 median) work disruption and minor (2/10 median) workflow disruption across surgical days with microbreaks during surgical procedures.

Eighty-three percent of the surgeons and 77% of their surgical team members wanted to incorporate intraoperative microbreak exercises into their OR routine; however the range of those percentages varied across team roles (Table 2). The ANES differed from the other groups as they are likely to be able to move about as they wish at the head of the patient. We expected the CSA to want to incorporate the microbreak into their OR routine since previous research (Abdelrahman et al. 2015; Yu et al. 2016) have found that the highest static and physical workload for the surgical team to be those of the surgeon and the CSA.

	Surgeon	CSA	CST	RN	ANES	OVERALL
<b>No</b>	17%	37.5%	19%	17%	50%	23%
<b>Yes</b>	83%	62.5%	81%	83%	50%	77%

**Table 2.** Percentage of surgical team members answering yes/no to “I would like to incorporate microbreaks with exercises into my OR routine”

The report of diminished mental focus, although low, increased with the proximity of the surgical team member to the patient. A difference in perceived workload based on proximity to bedside has been identified Yu et al. (2015), due to more involvement in the surgical task. This may explain how the intervention impacts team members based on increased engagement/proximity to the patient bedside with the surgical task by the surgical member. The proximity trend occurs in the improved physical performance and mental focus, the closer the surgical member is to the surgical field (Figure 1), the greater the benefit from microbreaks. This difference in the perception of intervention benefit could also be explained by autonomy provided to the surgeon through their ability to choose the most appropriate and convenient time to perform microbreaks during the surgical procedure based on their perspective of minimal workflow disruption and impact on the patient safety. It was expected that team members proximate to the patient bedside would experience a more extreme impact with the intervention, both positive and negative. These team members are also the ones that are more static, limited in ability to change position or move about and at the greatest ergonomic risk.

## 5. Conclusion & perspectives

Many surgeons and surgical team members reported that an intraoperative microbreak intervention with exercises improved their performance mentally and physically with a minimal impact on the work flow, including no increase in operative duration and they

wanted to incorporate microbreaks into their OR routine. It appears the trade-off of slight disruption to the workflow/distraction is likely outweighed by the positive impact on the surgical team members' well-being, as evidenced by the overwhelming percentage of surgical staff wanting microbreaks to be incorporated into their workflow. However, it is critical that changes in the OR from the microbreaks program are viewed as positive to the whole team without negative impacts to the workflow. Thus, there is still room to optimize the implementation of microbreaks with exercises to balance the improvement on physical performance and mental focus compared to the degradation of work flow and increase in disruptions.

A web-app has been devised to lead the surgical team through the microbreak exercises at predefined intervals and is currently being tested. Future studies are needed to objectively study the associations among the microbreaks intervention, change in the musculoskeletal symptoms and how these changes may relate to patient surgical outcomes. Additionally, further research is needed to refine the exercises based on procedure type, surgical specialty and pre-existing MSDs.

In conclusion intraoperative microbreaks with exercises are a feasible and well-accepted intervention within the OR with multiple benefits for surgeons and surgical team members which will potentially improve the provider (i.e., surgeon or surgical team member) health and, in turn, patient safety. Microbreaks with exercises have the potential to increase physical performance and mental focus with minimal work flow or disruption increases for surgeons and surgical team members.

### **Acknowledgements**

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## Competency-based training program based on observation of everyday clinical work and its effect on the prevention of central line-associated blood stream infection

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### Abstract

*Context:* We focused on one of the most frequent everyday work, injection from the needleless connector into the central line to respond to the sustained central line-associated blood stream infection (CLABSI) after installation of closed-type infusion line only in the department of pediatric oncology.

*Objectives:* To investigate cause of sustained incidence of CLABSI and increase acceptable outcomes, we observed everyday work of injection maneuver and constructed competency-based training program for the reduction and prevention of CLABSI. And we evaluated its effectiveness on the incidence of CLABSI.

*Methodology:* 1. We checked protocol, knowledge and observed the injection maneuver of the nurses of closed-type infusion (C-) line user. 2. We investigated bacterial contamination by simulation of injection with use of the C-line model which we originally produced. 3. We made newly competency-based training program for prevention of bacterial contamination based on these results of simulation test. We compared the incidence of CLABSI before and after introduction of this competency-based training program.

*Main results:* The simulation test revealed that the incidence of contamination was significant lower in staff with less experience of needleless connector use rather than in those with much experience. Bacterial contamination was depend on fulfillment of disinfection maneuver, not on experience, which revealed by looking what goes right in everyday work and this simulation test. Monitoring by CLABSI Surveillance revealed that incidence of CLABSI in the department of pediatric oncology was reduced dramatically and sustained no recurrence of CLABSI after introduction of this competency-based education program to clinical practice.

*Conclusion:* Learning from looking what goes right in everyday work and simulation test made us able to anticipate and provide us the information of competency for CLABSI prevention. Thereby, we could construct competency-based training program, introduction of which have been reduced CLABSI and sustained acceptable outcomes.

**Keywords:** everyday clinical work, anticipation, competency-based training program, catheter related blood stream infection

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### 1. Introduction

Central line-associated blood stream infection (CLABSI) surveillance revealed that incidence of CLABSI in the department of pediatric oncology was increased rather than stable in contrast incidence of other departments were decreased, and was significant higher than those in other departments after installation of new closed-type infusion line. Infection control board asked the department of pediatric oncology to reduce incidence of CLABSI, however

they could not be eradicated, which was unacceptable situation because the compromised patients with treatment of chemotherapy had been exposed to risk of sepsis and infectious death, even if there were no case of death caused by CLABSI at that point. Staff doctors of the department of pediatric oncology argued that new closed-type infusion line had the problem about prevention of infection, despite sufficient performance had been established in the basic study.

## **2. State of the art**

We focused on one of the most frequent everyday work, injection from the needleless connector into the central line to respond to the sustained relative higher level of CLABSI incidence. We observed everyday clinical work of injection maneuver not only in department with higher incidence of CLABSI, but also the department with few incident, what goes right in prevention of CLABSI. We learned the competency needed for the staff to prevent CLABSI from the results of observation of everyday clinical work and simulation test performing injection from the needleless connector of the C-line. Competency to prevent CLABSI is an integrated capacity composed of three elements of knowledge, skills, and attitude for certain infection control. Staff working at the department with higher acceptable outcomes, “things that goes right”, had this competency. On the bases of these knowledge, we constructed new competency-based training program and introduced this program to the all department using C-line. Competency-based training was effective on not only reduction of CLABSI, but also its durability revealed by monitoring with CLABSI surveillance. We could anticipate the CLABSI-related death.

## **3. Objectives and Methods**

**Objectives:** To reduce sustained incidence of CLABSI and increase acceptable outcomes, we analyzed the cause of CLABSI by the observation of everyday clinical work of injection maneuver and simulation, and anticipated recurrent increase of CLABSI and its related death with the introduction of new education system based on the result of observation and simulation test of the injection maneuver.

**Methods:**1. CLABSI surveillance was performed to examine compare the incidence of CLABSI between the department of pediatric oncology and also other departments after installation of closed-type infusion line. 2. We checked protocol, knowledge and observed the injection maneuver of the nurses using C-line. 3. To clarify whether disinfection maneuver failure was a cause of CLABSI or not, we made simulation system to perform injection into the C-line from the needleless connector. We assembled fluid therapy lines of a saline in clean bench beforehand and added bacterial suspension of *Staphylococcus epidermidis* type strain on the surface of needleless connector. Each subject sterilized connector with spirit cotton 2 hours after addition of bacteria suspension, and injected three times of 5mL saline. We examined the incidence of the bacterial contamination by the culture of injected content liquid (Fig.1).



Figure 1. Simulation system to perform injection from the needleless connector of the C-line

4. We made and introduced the new training program for injection maneuver based on the results of observation of maneuver and simulation test and compared the incidence of CLABSI before and after introduction of this training program (Table 1 and 2).

<b>Time</b>	<b>Item</b>	<b>Contents</b>
30 min	Lecture	Reason and needs of training Results of test (high incidence of contamination ) Proper use of the product
20 min	Demonstration	Demonstration of right disinfection maneuver by trained lecturers
30 min	Practical	Practical skill training
20 min	Assessment	Assessment of the series of procedure with check list

Table 1. Competency based training program

Item	Evaluation contents	Grade of Evaluation (A, B, C)	
		Self	Examiner
<b>Injection of Intravenous infusion</b>			
Preparation of necessary equipment	To wear mask and globes properly after hand hygiene.		
	To prepare for equipment for priming.		
	To confirm instrumental safety (Expiration date, damage of the product, having opening bag)		
Priming	To set an infusion line and close a clamp		
	1. To sterilize a part to prick with alcoholic cotton. 2. To stab needle of the administration set perpendicularly to the bottle .		
	To fill a drip chamber with around 1/2 fluid crushing it with a finger avoiding air mixing.		
	To open a clamp slowly and fill it with fluid to tube tip end.		
	To drain fluid with turning the connection part downward.		
	To make priming with flipping a filter vertical to fill up the filter-tip with fluid.		
<b>Awareness, confirmation and enforcement on injection from a needle-less intravenous connector</b>			
Injection from a needle-less intravenous connector			
Hand hygiene	To wear mask and globes properly after hand hygiene.		
Selection of injection point	To select right injection point		
Collation and confirmation of drugs with a prescription	To collate drug with a prescription and confirm it.		
A procedure before the injection	To shut the one-touch clamp upper than the injection point		
Sterilization of the injection point	To wipe off twice God side of the needleless intravenous connector with alcoholic cotton.		
A procedure at the injection	To hold the needleless intravenous connector and then connect a syringe to the needleless intravenous connector surely while being careful not to defile it.		
A procedure after the injection	To open the one-touch clamp.		
Hand hygiene	To take off gloves.		
Collation and confirmation of drugs with a prescription	To collate drug with a prescription and confirm it.		

Table 2. Check list of the training for injection from a needle-less intravenous connector

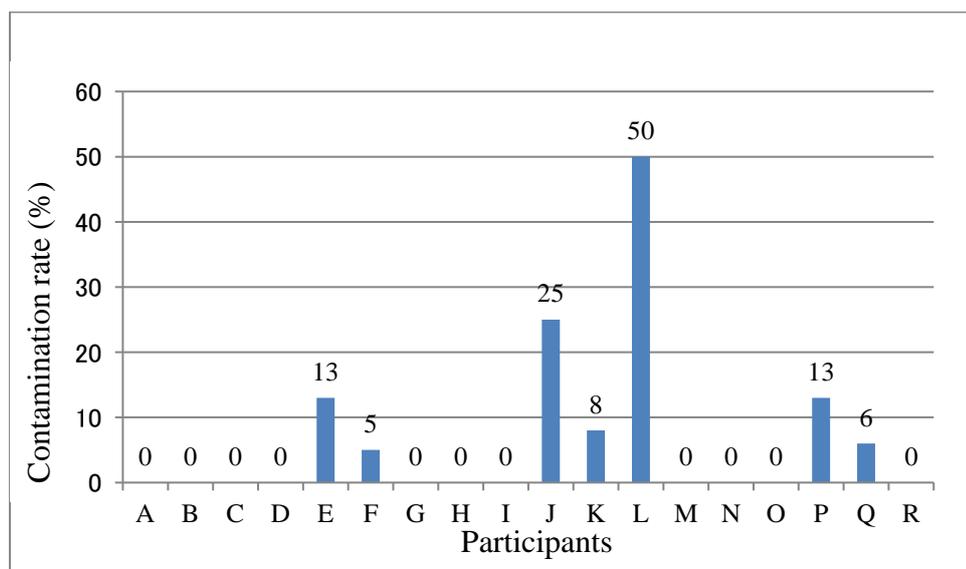
## 4. Results & Discussion

### 4.1 Learning from observation of everyday clinical work and simulation test

1. Incidence of CLABSI in the department of pediatric oncology was significant higher than the other department. Incidence of CLABSI was in proportion to the number of procedures via needleless connector in the C-line.

2. The staff of departments with less or no case of CLABSI, things what goes right, had adequate knowledge of injection protocol and infection control and certainly performed disinfection maneuver. The staff of the department of pediatric oncology had also adequate knowledge of injection protocol and prevention maneuver of infection. However, some of them did not completely performed disinfection maneuver as were taught, especially when they had to work being chased by time. They took blood samples for laboratory examination from C-line unlike other department.

3. The results of simulation test: The bacterial contamination rate of the bacteria was 4% (8/200). Seven of 18 participants (39%) made bacterial contamination (Fig. 2). The prevalence of contamination was more frequent in stuff with much experience of needleless use rather than in those with less experience. These results showed that the prevention of bacterial contamination depends on certainty of the disinfection maneuver.



**Figure 2.** Contamination rate on simulation test

### 4.2 Effects of the competency based training program

4. No bacterial contamination was observed in this simulation test after feedback of these results to the staff and introduction of the new education program.

5. Our surveillance showed that CLABSI was reduced dramatically and no case of CLABSI was observed continuously after the competency-based training program.

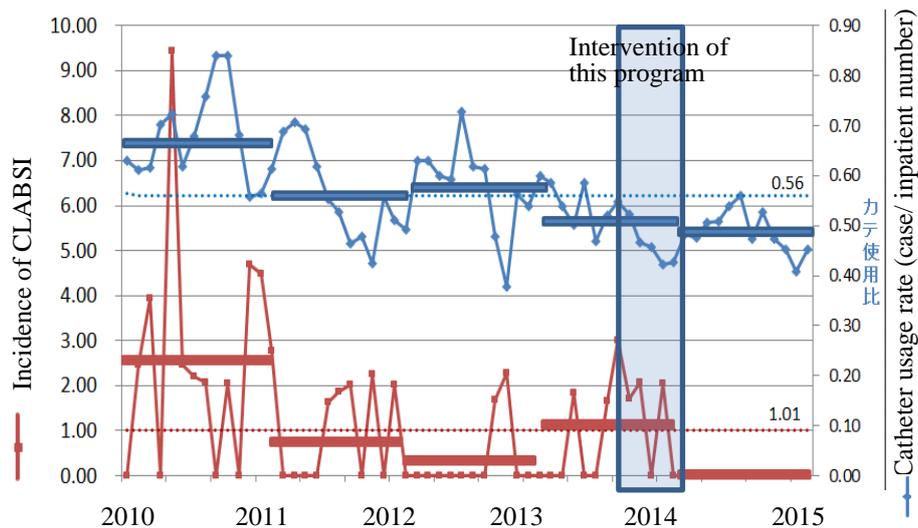


Figure 3. Change of CLABSI incident after introduction of competency based training program

Observation of everyday clinical work in the department where things go right provide us the information for the increase in acceptable outcome. And simulation test of injection into the C-line based on the observation of everyday clinical work makes the difference of performing disinfection procedure more clearly between what things to right or wrong. Prevention of CLABSI needs attitude for certain infection control, not experience. Continuous suppression of CLABSI after introduction of competency based training program has been achieved despite several disturbance, such as staff without experience of injection into the central line from the needleless connector or situation to work being chased by time. These results of reduction of CLABSI indicate that competency to prevent CLABSI is an integrated capacity composed of three elements of knowledge, skills, and attitude for certain infection control. Therefore, observation of everyday clinical work is essential to construct competency based training program and also makes us to be able to anticipate CLABSI.

It could not prevent CLABSI when staff had inadequate competency for infection control even if medical equipment has adequate performance. We learned that prevention of CLABSI is needed three components, medical equipment with adequate performance, staff with competency for CLABSI prevention by obtained by this training program and its evaluation, and continuous monitoring by surveillance of CLABSI, not individual experience. Approach according to resilience engineering, learning, responding, monitoring and anticipating (1), is effective to increase safety.

## 5. Conclusion & perspectives

Learning from the observation of everyday clinical work provide us the information of competency for the CLABSI prevention, which is essential to construct effective competency based training program. Competency based education program is effective on CLABSI prevention. Approach according to resilience engineering, learning, responding, monitoring and anticipating, is not only effective on prevention of CLABSI, but also applicable to increase safety in healthcare.

## Acknowledgements

We appreciate the cooperation to this study of department of nursing and of clinical laboratory medicine of Fukushima Medical University Hospital.

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## Impact of electronic forms for patients on workflow in primary care clinics

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### Abstract

Nowadays, most communication takes places electronically. Recent developments have also made it possible for patients to communicate with their healthcare providers. This can take place in a non-standardized (e.g. secure message) or a standardized way, for example through the use of electronic forms (e-forms). In this study, we examined user experiences with e-forms, the impact of e-forms on workflow of healthcare providers and staff in primary care clinics, and the perceived impact on quality of care and patient safety. We used observations, interviews and a survey in a multiple case study design. Results show that, overall, user experiences with e-forms are positive, e-forms have both a positive and negative effect on workflow of clinicians and staff, and that, overall, clinicians and staff think that e-forms have a positive effect on quality of care, patient safety and patient satisfaction. To conclude: e-forms can have a positive effect on workflow of clinicians and staff in primary care. Clinicians, staff and patients are satisfied with e-forms. However, this does not mean that the use of e-forms cannot be further improved.

**Keywords:** health information technology, primary care, e-forms, workflow, patient safety

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### 1. Introduction

Recent developments have made it possible for patients to interact with their healthcare providers electronically, using technologies such as the patient portal that allows patients to access their medical information on the Internet and software that allows patients to upload information, e.g., blood pressure or blood sugar measurements. In this study, we examine e-form software that allows patients to fill out electronic forms and provide healthcare providers with information about their medical condition. Several studies have shown that health information technologies that allow patients to exchange information electronically can benefit quality of care and patients safety (de Lusignan et al., 2014; Goldzweig et al., 2012; Grant et al., 2008). However, we know little about the impact of these technologies on clinical workflow (de Lusignan et al., 2014).

### 2. State of the art

There is a surprising lack of literature on the use of e-forms in primary care. As far as we know there are no studies that examined the impact of e-forms on workflow in primary care.

### 3. Objectives and Methods

In this study we examined user experiences with e-forms and the impact of e-forms on clinical

workflow and perceived outcomes, e.g., quality of care, patient safety and patient satisfaction. The study was part of a larger study that examined the impact of patient-provided information technologies on workflow in primary care clinics (Carayon, Hoonakker, Cartmill, & Hassol, 2015). One clinic in our study used a headache e-form; another clinic used a signs-and-symptom checklist e-form and a patient-reported outcomes (PRO) e-form.

### 3.1 Design and setting

Using a multiple case study design (Yin, 2009), we collected data using three different methods: observation, interview and questionnaire.

### 3.2 Procedure

We conducted observations and interviews with clinic managers, physician leaders, physicians, clinic staff and patients. Totally we observed and interviewed 27 clinicians, 7 staff members and 13 patients. During the semi-structured interviews, questions were asked about the impact of e-forms on workflow and perceived outcomes of the use of e-forms. We also conducted a survey of clinicians and clinic staff to collect data on their experience with e-forms. Twenty-five clinicians and 12 staff in the two clinics filled out questions on e-forms. Survey response rate for the two clinics was 77%.

### 3.3 Data analysis

#### 3.3.1 Data analysis interview data

The interview qualitative data were coded by two researchers as a barrier or a facilitator to workflow on dimensions described in Table 1.

	<b>Dimension</b>	<b>Barriers</b>	<b>Facilitator</b>
Impact on workflow	Amount of work	The amount of work has increased	The amount of work has been reduced
	Task complexity/ simplicity	Task complexity has increased	Tasks have become more simple
	Inappropriate use	The technology is used for purposes for which it is not intended	Not applicable
	Workaround	Not applicable	Because of barriers users have to find a work around to achieve their goal
	Usability	Poor usability and low user-friendliness	High usability and high user friendliness
	Communication/IF	Communication and information flow has improved	Communication and information flow has been deteriorated
	Ambiguity/clarity	It is not clear what the user is supposed to do	It has become clearer what the user is supposed to do
	Organization of work	The organization of work has become difficult and/or complex	The organization of work has become easier and/or less complex
Impact on perceived outcomes	Satisfaction with technology	User are dissatisfied with the technology	User are satisfied with the technology
	Patient satisfaction	Patient satisfaction has decreased because of the technology	Patient satisfaction has increased as a result of technology use
	Quality of care/patient safety	Quality of care and/or patient safety have been reduced as a result of the technology use	Quality of care and/or patient safety have improved as a result of the technology use

Table 1. Definitions of workflow barriers and facilitators

### 3.3.3 Data analysis survey data

We used a statistical program (SPSS v20) to perform descriptive statistics.

## 4. Main results

Dimension	Clinicians (N=27)		Staff (N=7)		Patients (N=13)	
	Facilitator	Barrier	Facilitator	Barrier	Facilitator	Barrier
Amount of work	44%	11%	71%	14%	54%	0%
Task complexity/simplicity	4%	7%	0%	0%	8%	15%
Inappropriate use	NA	7%	NA	14%	NA	0%
Workaround	7%	NA	0%	NA	0%	NA
Usability	11%	33%	14%	6%	15%	38%
Communication/information flow	44%	26%	56%	14%	69%	8%
Ambiguity/clarity	7%	0%	0%	0%	0%	0%
Organization of work	41%	41%	71%	29%	23%	0%
Satisfaction with technology	15%	19%	29%	14%	62%	46%
Patient satisfaction	15%	30%	29%	56%	NA	NA
Quality of care/patient safety	30%	0%	29%	0%	8%	0%
Mean dimensions per interview (SD)	2.9 (1.74)	2.3 (1.38)	3.4 (1.68)	2.1 (1.81)	2.4 (1.27)	1.1 (0.82)

Table 2. Workflow barriers and facilitators to e-forms as reported by clinicians, staff and patients

Results in table 2 show that the most frequently mentioned facilitators were: amount of work, communication and information flow, and organization of work. The most frequent barriers were organization of work and poor usability. Nearly one third of clinicians and staff think that e-forms increase quality of care and patient safety, but only 8% of patients do.

The quotes below summarize the advantages of e-forms, including the advantages of standardization:

“I can focus on the patient in the room and ... make sure that I’ve asked all these salient questions regardless of whether I’m tired or the patient’s distracted. So it makes me more comprehensive. I do ferret out things that I wouldn’t have ferreted out in the past, like their husband is beating them or they’re drinking too much, or they want more information about stress, or they’re sleeping poorly, or they’re angry with me” (Clinic 1 Physician).

“A lot of patients, for some reason doctors make [them] nervous. ... But, you can just answer those questions on the computer. And that way they know, and you don’t have to get uncomfortable, anxious where you forget what you wanted to tell them” (Clinic 4 Medical Assistant).

“A lot of times when you come in the doctor’s office, you forget everything that you planned to talk to the doctor about. I think it gives you a chance to remember. ... Then it gives you a helping hand. When you get in [the exam room], they’ll say I see you checked this. And you’re like, oh, yeah, I forgot about that” (Clinic 4 Patient).

Survey results in Table 3 show few differences between clinicians and staff in their experience with e-forms. None of the differences is statistically significant. Clinicians and staff think that e-forms make communication with patients more efficient, save them time, have a positive effect on patient-physician communication (question was only asked to

clinicians) and improve quality of care. They do not think that e-forms have a negative impact on their workflow or on patient care.

Item	Group	Disagree	Neither	Agree
E-forms make communication with patients more efficient.	Clinicians	0%	28%	72%
	Staff	0%	23%	77%
Overall, e-forms save me time.	Clinicians	12%	16%	72%
	Staff	0%	31%	69%
E-forms have a negative effect on my workflow.	Clinicians	76%	20%	4%
	Staff	54%	39%	8%
E-forms reduce my workload.	Clinicians	20%	44%	36%
	Staff	23%	46%	31%
The information I get from e-forms makes my work easier.	Clinicians	12%	20%	68%
	Staff	0%	46%	54%
E-Forms improve the quality of patient care.	Clinicians	0%	24%	76%
	Staff	0%	33%	67%
E-forms have a positive impact on patient satisfaction.	Clinicians	8%	60%	32%
	Staff	0%	54%	46%
Overall, I am satisfied with e-forms.	Clinicians	8%	21%	71%
	Staff	0%	23%	77%
The information I retrieve from e-forms makes an impact on my decision making*.	Clinicians	12%	8%	80%
E-forms have a positive effect on patient-clinician communication*.	Clinicians	0%	21%	79%
E-forms have a negative impact on patient care*.	Clinicians	76%	20%	4%
E-Forms reduce patient care errors*.	Clinicians	16%	48%	36%

\* These questions were only asked to clinicians

Table 3. User experiences with e-forms, clinicians (n=25) and staff (n=12)

## 5. Conclusion and perspectives

There is a surprising lack of literature on the use of e-forms in primary care. One possible explanation is that patients and their health problems are too diverse to be measured with standardized questionnaires in primary care, and that only specialized primary care clinics (in clinic #1 one primary care physician was specialized in headaches, nearly half of his patients were headache patients; the second clinic was a HIV clinic) have use for these standardized forms. Results of our study show that, overall, e-forms can improve communication and information flow, and organization of work, and reduce workload. Clinicians and staff think that e-forms can enhance quality of care and patient safety. One of the most frequent barriers to e-forms is poor usability. The benefits of e-forms are related to the fact that e-forms increase standardization of the patient visit, and that patient scores on specific topics that are higher than cut-off scores can automatically trigger protocols, such as a suicide ideation or domestic violence protocol. A barrier to the use of e-forms is that the e-forms are often administered on stand-alone computers with software that is incompatible with the electronic health system (EHR); this requires that clinicians and staff perform extra steps to enter data from the e-forms into the EHR system. Patients are sometimes dissatisfied because of the length of some of the e-form questionnaires. This is especially the case with the PRO-form that is used in clinic #2. The PRO form can consist of more than 100 questions, depending on the patient's responses. Apart from the length, there are several very sensitive questions in the

PRO form (Kozak et al., 2012). This is one of the possible explanations for the relatively high percentage of clinicians (30%) and staff (56%) in clinic #2 who mention that e-forms can have a negative impact on patient satisfaction.

Apart from standardization of the clinic visit, e-forms can also provide other advantages. First, e-forms can be administered online and can be used to *monitor* the patient status. This monitoring could have as a result that the patient does not have to come in for a clinic visit, which in return improves workflow of physicians, staff and patients. Second, when an e-form is used repeatedly over time the data can be captured and used to show results over time and in this way provide feedback to the patient, including results of interventions. For example, when a (standardized) headache e-form has been administered repeatedly for a period of time, results can show improvement (or deterioration) over time, for example as an effect of a prescription for a new medication. Third, data collected from all patients can be collected in a database, and the data can be analyzed to examine the effectiveness of interventions in large groups. Finally, apart from being used by some specialized primary care clinics, e-forms are not yet used on a large scale in primary care clinics. A possible explanation is that the patient population in primary care is too diverse to use standardized questionnaires. However, the patient population *across* clinics is more uniform. As a result, several healthcare organizations are currently experimenting with e-visits. E-visits are online consultations for specific problems, such as headaches, low back pain, sinus problems, urinary tract infections, etc. Patients are currently charged a (small) amount of money to do an e-visit consultation. If the e-visit is successful, and the patient does not have to come in for a clinic visit, this improves workflow of patient, clinicians and staff.

### 5.1 Study limitations

Primary care clinics are often relatively small. That means that sample sizes are also small. Further, it was difficult to find clinics that use e-forms. We only found two primary care clinics that use e-forms in a standardized way. The small numbers make it difficult to generalize the results to the overall population. In this study our goal was to compare user experiences of clinicians, staff and patients. Implementation of e-forms has as a result that very few staff is involved in the process, and therefore we only had interview data from 7 staff members and survey data from 12 staff members.

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## **An ordinary Friday - Managing for adaptation in uncertain work settings; graphing adaptive sequences to reveal work as done**

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### **Abstract**

*Context:* The neonatal intensive care unit (NICU) provides a reference case of advanced technology applied in a fast-changing, high-risk domain. Critically ill, highly vulnerable premature neonates often tax the adaptive capacity of the work system. Substantial expertise is required to anticipate, monitor, and exploit available resources under varying conditions in the NICU.

*Objective:* To describe how a difficult and fundamentally surprising situation emerges during an ordinary work shift in a NICU and how the know-how of first-line managers is utilized to adjust available resources in order to coordinate and facilitate safe neonatal intensive care.

*Methodology:* The case is based on observations, interviews, documentation (i.e. occupancy charts, workload measures and staff rosters). The data is analyzed for patterns using a process tracing method and discussed as to how work is coupled within the investigated ward.

*Main results:* The case illustrates the NICU system's early and continuous investments in the work force's ability to apply lessons learned from dealing with complications in everyday work. The pay-off that can be exploited through *expertise* to shape effective responses to disturbances is revealed when workers find and use every available tool as an adaptive response to multiple competing demands given limited resources. Maneuverability can be achieved by changing staff roles and on what grounds professionals are forced to sacrifice certain goals in order to achieve higher level goals.

*Conclusions:* Safety in the NICU, a complex, costly and unpredictable environment where lives are at stake, is by and large a product of the system's early and continuous investments in systemic degrees of freedom within the operating environment, and development of staff expertise to use these freedoms under varying conditions. These investments are difficult to and need to be grounded in a qualitative understanding of the workers within their specific domain.

**Keywords:** patient safety, NICU, resilience, Safety-2, degrees of freedom

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### **1. Introduction**

The unique aspects and complexity of the neonatal intensive care unit (NICU) environment, in addition to the vulnerability of the neonatal population, increase the risk for medical errors. Medical errors leading to adverse events in the NICU are rarely intentional or the result of any

single factor (Handyside, Suresh, 2010). There has been ample improvement in patient safety over the last 6 years, but gaps in how medical errors, handoffs and patient care transitions are managed still exist (Agency for Healthcare Research and Quality, 2013).

## **2. State of the art**

Much of the success of neonatal care results from a multitude of strategies, such as bundles of evidence-based practices for catheter-related infections (Cooley, Grady, Short, 2009), electronic medication ordering, structured communication and bar coding (Morriss, Abramowitz, Nelsen, 2009) and standardization and development of communication (Salas, Wilson, Burke, et al., 2006).

But despite all of these achievements, we must face the fact that we still cannot control complex processes by application of linear thinking (standardization) (Eurocontrol, 2013). There is a need to consider ‘resilience’ as well as ‘safety-II’-thinking to deal with the challenges of increasingly complex conditions, in order to substantially improve patient safety in the NICU (Wears, 2006).

## **3. Objectives and methods**

To describe how a difficult and fundamentally surprising situation emerges during an ordinary work shift in a NICU and how the know-how of first-line managers is utilized to adjust available resources in order to coordinate and facilitate safe neonatal intensive care.

### **3.1. Data collection**

Various process-tracing methodologies with a variety of data collection techniques are used to study complex behavioral situations (Woods, 1993). Critical incidents that have already occurred and short informal talks with staff are processed in a retrospective analysis. Additional data sources are staff rosters, patient occupancy charts and workload measures.

### **3.2 Analysis**

The data regarding physical movements of patients and staff are sorted along a timeline and sequenced in several snapshots (figures). This sequence is analyzed for patterns using a process tracing method (Woods, 1993).

### **3.3 Setting**

This particular NICU is a regional center for infants from a gestational week of 22. It is located in a hospital offering pediatric surgery. The NICU has a capacity for 18 patients ranging from those demanding the highest level of care to those ready for discharge either for home or homecare. During on-call hours, which include weekends and night shifts, there are six to seven teams on duty. Each team consists of one registered nurse (RN) and one assistant nurse (AN). Teams are directly assigned to certain NICU rooms on a shift-by-shift basis. The ward is staffed with one physician on-site and one senior physician on-call. During on-call hours support functions (e.g., laboratories & radiology) are also stripped down to a bare minimum. One nurse, assigned the role of *shift manager*, has the responsibilities and mandate to coordinate patient flow and staffing.

The ward consists of several clusters of rooms with different purposes and equipment (Figure 1). Rooms 1-8: Babies and their parents can stay here together in preparation for discharge and are monitored through a central monitor – Each room in use requires 1/5<sup>th</sup> of a nursing team.

Rooms 9 and 10: Equipped and staffed for intermediary care in a 1:1,5 staff to patient ratio. Respiratory care is normally not given here.

Rooms 11, 12, 14 and 15: ICU rooms staffed and equipped for the highest level of intensive care. The staffing ratio is 1:1 (i.e. one nursing team per room, with capacity to treat up to two patients at the highest level).

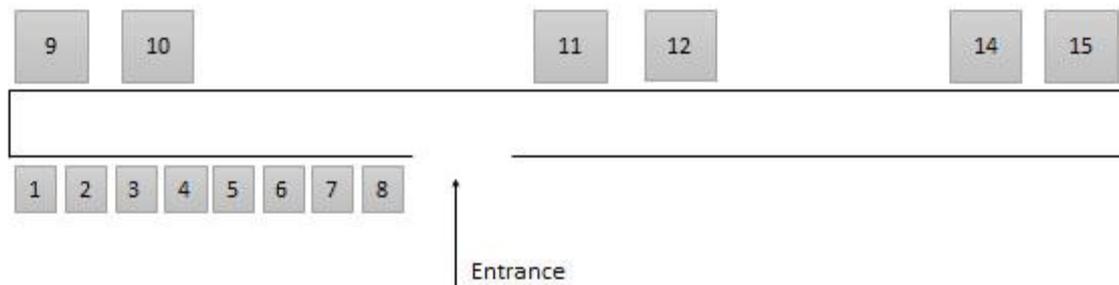


Figure 1. Ward layout with room numbers

## 4 The case

### 4.1 Startup meeting, setting the stage in preparation for the night shift

At 21:15, there is a startup meeting where the senior physician meets the incoming staff to share information on the current state of affairs on the ward and the general plan for the coming shift. Teams are formed and allocated to their respective rooms. During this shift, specific strategic planning for three of the six incoming teams is performed.

- 1) A patient in room 14 is being prepared for an emergency abdominal surgery, the incoming team are supposed to receive a status report and continue preparations for transfer to the pediatric operating ward (OR) as soon as possible.
- 2) The team in room 11 is caring for a cohort of patients with a suspected multi-resistant bacterial strain, meaning that it is not eligible to help out on the rest of the ward.
- 3) The staff assigned to room 9 will also be responsible for the patients in rooms 3 and 4. The patient in room 4 is planned to be moved into room 9 because of suspicious neurological symptoms which require more advanced neurological monitoring.

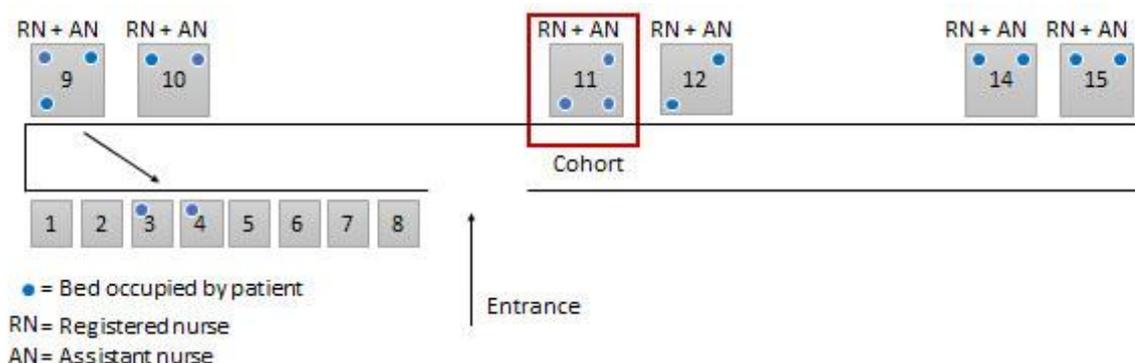


Figure 2. Status at the start of the night shift

### Early shift

At approximately 22:00, just 30 minutes after the night shift has started, a rapid chain of events unfolds. The delivery ward coordinator calls on the NICU's ward physician to inform

that there will be an emergency delivery of a baby of gestational week 24. A bed in room 12 is prepared for the expected new baby, while the NICU ward physician and two nurses (from rooms 10 and 12) leave for the delivery ward.

An anesthesiologist from the pediatric OR is called to assist with the transport of the patient from room 14. Because of the patient's unstable condition, the decision is made to use a team of two nurses from the NICU (from rooms 11 and 14) for safe and expedient transport. The number of nurses is quickly diminished by close to 70 percent. The remaining staff utilizes all their creativity and skill in adapting to this emerging situation. As one of the nurses puts it *"We have experienced many nights with lots to do. We know that we are completely alone. There will not be anyone coming in for about 10 hours. We work without a safety net. Somehow, we usually work it out."*

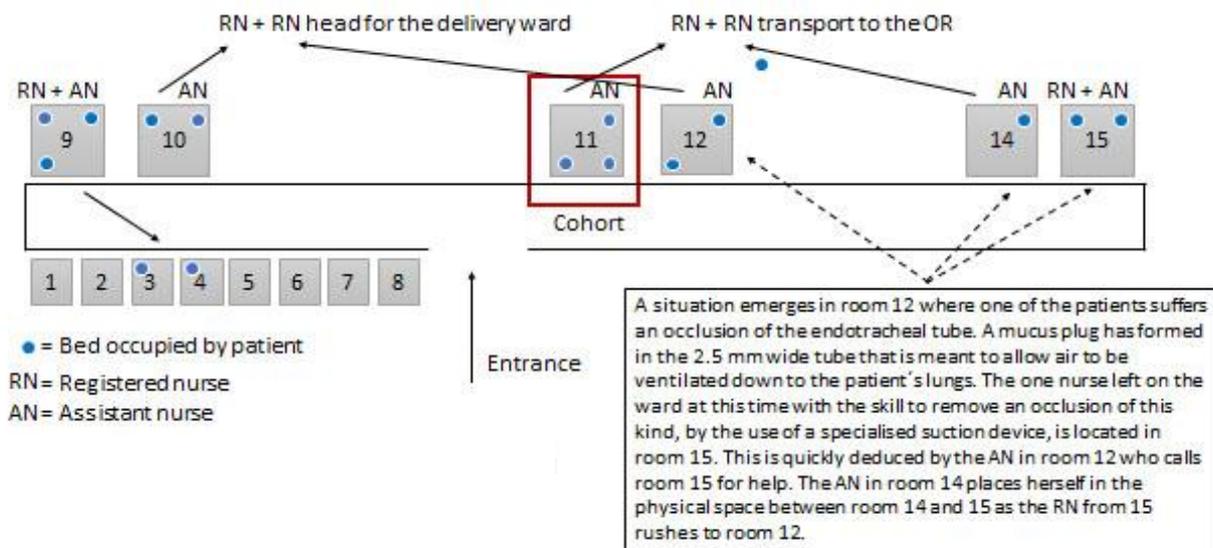


Figure 3. Status of the ward during early night shift with movements of staff and patients

### Mid-shift

The rapid succession of events continues with the discharge and transport of a patient from room 9 to a neighboring delivery ward. The AN from room 9 executes this transport in order to open up a bed for the patient from room 4 who now urgently needs neurological monitoring.

The team that was previously dispatched for handling the delivery of a baby of gestational week 24 is being held up because of complications with the mother. An acute situation emerges in room 12 just before the OR transport team with nurses from rooms 11 and 14 returns to the ward. The staff remarks that: *"Parents were present in several rooms. The parents could see how staff ran around, switched patients and rooms, called for aid, restocked supplies, guarded multiple rooms at the same time and did not have time to answer questions or administer drugs on time; it did not create a feeling of safety in the parents."*

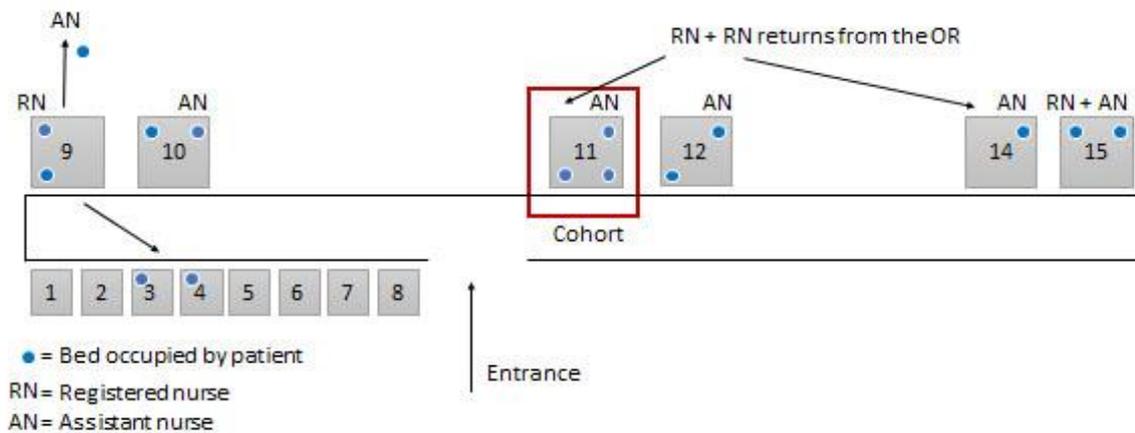


Figure 4. Status of the ward around midnight with movements of staff and patients

### Late shift

During the end of the shift, the appointed shift manager has called in an extra resource in the form of an on-call nurse from the pediatric emergency transport team (PETS). Unfortunately, this nurse is held up in a traffic accident on her way in to the hospital. She arrives, but only after a delay and some phone calls. At 23:00, the returning nurse from room 14 is called in to assist with startup and calibration of the neurological monitoring device in room 9. She is, however, held up for a short while with her own patients. Meanwhile the baby of week 24 is delivered and transported to NICU room 12. The ward physician is located in room 12 and is working hard to stabilize the new patient. This requires him to work with sterile procedures and to use one of the nurses as an assistant, which makes her unable to assist anyone else.

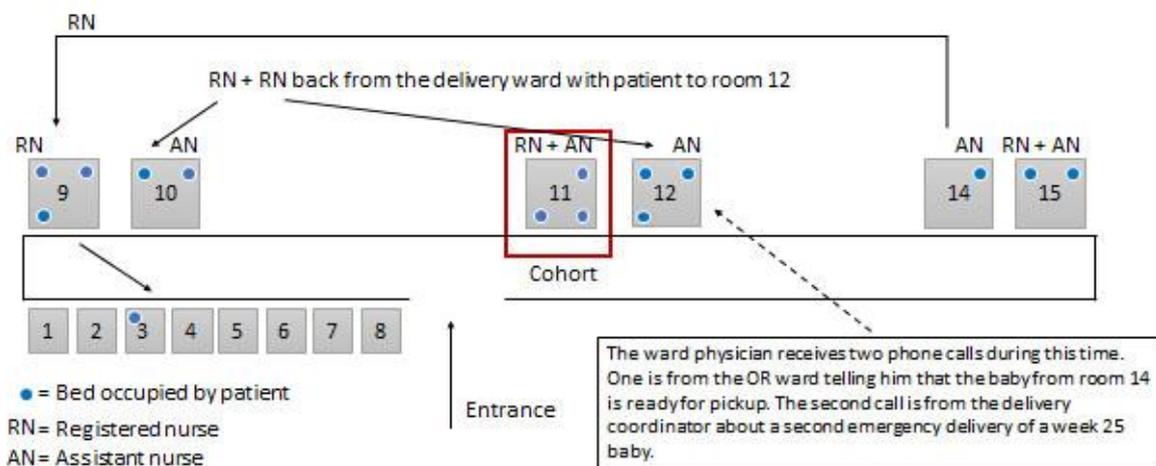


Figure 5. Status of the ward during the end of the night shift with movements of staff and patients

In response to a couple of phone calls there is some deliberation between the physicians and the nurse shift manager about how to handle a second acute admission. The decision is made for the nurse from room 10 to head out again to assist the on-call physician with stabilizing the patient of a second acute admission - delivery of a baby of gestational week 25. This second emergency caesarean goes smoothly and the new patient is finally admitted to room 10, as the room's third patient. In order to sustain a high level of safety under the varying conditions, lower level goals like *maintaining stockpiles* and *social support of parents* are sacrificed. The staff's remark is that: "Patient safety was at risk, since we didn't have time for nursing tasks beyond the most necessary for the other babies."

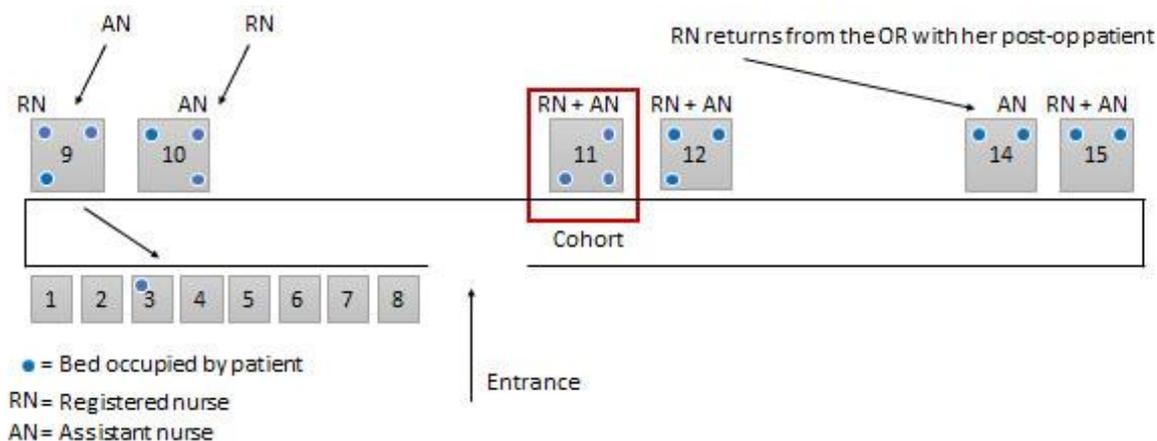


Figure 6. End of shift, ward returns to normal status for handover to the next shift

## 5. Analytical discussion

According to recent literature on patient safety and resilience engineering, a prerequisite for safe work is the system's ability to monitor its own current status and respond to unexpected disturbances (Eurocontrol, 2013). This case illustrates that NICU is a complex system in the sense that it is unpredictable in terms of both available resources and the workload it is subjected to (Cilliers, 1998). The challenge for managing the complexity in NICU is the creation of sufficient systemic degrees of freedom (SDOF) for the possible range of disturbances (e.g., resilience engineering) (cf. Ekstedt & Cook 2015). Unexpected disturbances have an immediate effect on the professional's bedside clinical work. The response to disturbances was either prepared, tailored in response to the specific situations or consisted of ad-hoc solutions based on the maneuverability that was available. In this case we can observe expressions of resilience. Expressions of resilience illustrated in this case are actions that draw upon whatever resources that are present and can be made available in an emerging situation. Some of the resources are the products of years of efforts, embedded in the system, such as the professionals' experiences, knowledge and skills, which allow them to adjust their most basic functioning in response to disturbances. Other resources are needed and present for a short period of time, such as an anesthesiologist from the pediatric OR called in to assist with the transport and an extra on-call nurse called in from the PETS team.

Management in this kind of organization is very much a question of providing resources and facilitating for the team to provide care. According to Perrow (1984), organizations with loose couplings are best managed through distributed authority and responsibility which allow autonomous decisions at the sharp end, where the time for decision-making is short. Although the NICU is an organization with a high degree of tight couplings, it is likely to function best in a decentralized mode when faced by unexpected events. The investments made in development of professional expertise create space for maneuvering and the capacity of perceiving and exploiting such space. The SDOFs allow practitioners to tailor responses to disturbances, as seen in the flexibility to shift between roles of worker and manager: changing staffing ratios, overcrowding rooms, ceasing with mundane tasks and re-prioritizing goals. It is easy to see how the absence of experienced professionals would eliminate expressions of resilience in this case.

Resilience in this case is a hidden capacity for maneuverability that can be used when needed. This capacity is not specified in any documents, policies or instructions. SDOFs are created and maintained by the workers themselves. It is a process that must be supported by management over long periods of time. What we have seen here is that authority can be

centralized or decentralized based on the needs of the moment, sanctioned for example through the *shift manager* role of the nurses. It is our belief that the investments in sufficient systemic degrees of freedom and the capacity to exploit them in the face of disturbances must be made explicit in a deeper examination of the specific domain.

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## Safety climate scale for assessment of healthcare organisation: validity and reliability applying to dialysis facilities

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### Abstract

This paper reports elicited safety climate scale in the dialysis setting, and confirmed its important properties as an assessment tool, in particular test-retest reliability and criterion validity. For these purpose, surveys were carried twice, collecting about 11,000 responses from doctors, nurses and technologists in the dialysis department of 443 facilities. Annual records of performance indicators were also obtained from 36 facilities surveyed safety climate.

Eleven safety climate factors were elicited by applying the principal component analysis with 47% cumulative variance accounting for. Test-retest comparisons identified no or at most two items that were significantly different between the two surveys in 95% of dialysis facilities. We identified associations of each safety climate factor with several performance indicators related to safety, quality, quality of working life and employee development, as its confirmation of criterion validity.

**Keywords:** safety climate, dialysis clinics, criterion validity, test-retest reliability, blame culture

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### 1. Introduction

It has been well understood that safety performance is influenced not only by safety management structure but also by cultural factors. Therefore, a number of studies have been conducted to measure and assess *safety culture/climate* in healthcare (Colla et al., 2005; Nieva & Sorra, 2003) for the last two decades. In particular, culture for promoting organisational learning, by which right conclusions will be drawn from past experiences, i.e., learning culture, has been highlighted as one of the key elements for a “safe” culture. For this purpose, a hospital needs to equip with an effective reporting system, and to foster a culture that healthcare professionals would report their errors and incidents timely and properly, i.e., reporting culture. It is a key point to establish a *just culture* – an organisational atmosphere of trust in which they are well treated and encouraged for providing essential safety-related information (Reason, 1997; Reason & Hobbs, 2003).

In this study, we targeted at the dialysis work setting for its unique characteristics: There were 320,448 people who regularly received dialysis therapy in Japan at the moment of December 2014 (Japanese Society for Dialysis Therapy, 2016). Regular tasks for the dialysis therapy are controlled in more proceduralised than those in many other healthcare settings. During dialysis therapy, a patient’s blood is circulated out of his/her body for its purification process, and therefore it is more likely to cause a critical situation when something goes wrong. In addition, dialysis staff needs to provide his/her patient with continuous, constant care, since

the patient must stay long and frequently in a hospital/clinic for the therapy – typically three times of four hour therapy per week.

A rationale behind safety climate assessment of an organisation or work unit is a possibility of its application to *proactive* risk management (Rasmussen & Svedung, 2000). One can identify “weak points” in the attitudes, norms and practices of the target groups, and implement intervention programmes aiming at improving patient safety *before* an accident takes place. Behind safety climate applications to proactive risk management, its positive correlation with safety outcomes were assumed – this property is referred to *criterion validity* (Flin et al., 2006). In addition to this property, some other properties are required as an assessment tool, particular test-retest reliability, which assures that the tool will yield the same results for the same population surveyed repeatedly.

In this paper, a survey tool of safety climate for the dialysis setting is developed with emphasis on blaming and error-reporting properties within the workplace. A scale of dialysis safety climate is elicited as a framework for its assessment. We confirm the scale’s test-retest reliability and criterion validity as important capabilities of the assessment tool. Applying the safety climate dimensions to a number of facilities, we extract current characteristics of safety climate in the dialysis setting.

## **2. Methods**

### **2.1 Safety climate survey**

We developed a dialysis questionnaire, in which a majority of question items were selected from the one used for former safety climate surveys (Itoh & Andersen, 2008) and adapted them to the dialysis context. Additional items were included in the questionnaire particularly connecting to blame culture, error reporting and organisational learning, composing of 50 items concerning staff attitudes to and perceptions of their jobs, management of dialysis department, and factors that might impact on their safety performance. Respondents were asked to indicate their level of agreement with each statement on a five-point Likert scale. Surveys were carried out anonymously twice in a short-term interval, i.e., first in November-December 2013 and subsequently in January-May 2014, collecting a total of 10,972 responses from dialysis staff of 443 hospitals/clinics in Japan.

### **2.2 Performance indicators**

We collected annual records of 59 performance indicators pertaining to safety, clinical quality, staff’s quality of working life (QWL), employee development, organisational efficiency, etc. between 2011 and 2013 from 94 dialysis facilities. Thirty-six facilities of them were also surveyed safety climate. A mean value of each performance indicator over the three years was used for correlation analyses with safety climate dimensions.

## **3. Survey Results**

### **3.1 Safety climate dimensions**

Applying principal component analysis with the Varimax rotation to all questionnaire responses, we elicited 11 dimensions as dialysis safety climate scale with 47% cumulative variance accounted for. Each dimension was labelled based on the items highly loaded. A result of the analysis is shown in Table 1. Cronbach’s alpha for half of dimensions were higher than or close to a regular limit of acceptance level ( $\alpha > 0.70$ ; Spiliotopoulou, 2009), but those of some dimensions were rather low.

Dimensions Label [Variance (Cumulative variance)]	Items highly loaded Cronbach's $\alpha$	Loading	Dimensions Label [Variance (Cumulative variance)]	Items highly loaded Cronbach's $\alpha$	Loading
<b><u>I. Safety syst. &amp; mgt. commit. [12% (12%)] <math>\alpha=0.872</math></u></b>			<b><u>V. Attitude to stress &amp; workload [4% (29%)] <math>\alpha=0.492</math></u></b>		
	Mistakes are handled appropriately in the dialysis dept. where I work.	0.700		Even when fatigued, I perform effectively during critical phase of activities.	0.612
	Reporting syst. is useful for improving patient safety in this dialysis dept.	0.695		When I am interrupted, my patients' safety is not affected.	0.574
	Whenever action is made, safety level in dialysis dept. is tracked for evaluation.	0.685		I am more likely to make errors or mistakes in tense or hostile situations.	-0.554
	I receive appropriate feedback in our dialysis dept. about errors I reported.	0.677		I am less effective when stressed or fatigued.	-0.541
	Staff members often discuss safety issues with their leader/supervisors.	0.675	<b><u>VI. Error reporting [4% (33%)] <math>\alpha=0.577</math></u></b>		
	The dialysis dept. provides adequate, timely information that affect my work.	0.675		If I see problem with pt. mgt., I will speak up, regardless who might be affected.	0.652
	Safety procedures & rules in this dialysis dept. are useful for preventing errors.	0.648		I always submit an incident report even for an error that cannot be revealed.	0.610
	Staff in our dialysis dept. is properly provided with necessary safety training.	0.647		I am encouraged by my leader to report any incident I may observe.	0.408
	This dialysis dept. is doing more for patient safety than one year ago.	0.544	<b><u>VII. Collectivism-individualism [4% (37%)] <math>\alpha=0.350</math></u></b>		
	Department leadership listens to staff and cares about their concerns.	0.543		I value compliments about my work.	0.744
	Incident & near-miss is reported within the day in our dialysis dept.	0.512		Good reputation of professional activities is important to me.	0.533
	Protection from exposure to HIV, hepatitis C, etc. is high priority for senior mgt.	0.496		Important my competence be acknowledged.	0.506
<b><u>II. Power distance [5% (17%)] <math>\alpha=0.615</math></u></b>				Doctor's responsibilities include coordination between work team and other support areas.	0.320
	Junior team members should not question decisions made by senior dialysis staff.	0.715	<b><u>VIII. Safety structure awareness [3% (40%)] <math>\alpha=0.542</math></u></b>		
	Junior staff should follow experienced staff except for emergent situation.	0.670		We have enough staff to handle the workload in our dialysis dept.	0.762
	Doctors who encourage suggestions from team members are weak leaders.	0.560		Medical equipment and materials in this dialysis dept. are adequate.	0.651
	Errors are a sign of incompetence.	0.526		All necessary information for therapeutic decisions are routinely available to me.	0.315
<b><u>III. Communication &amp; learning [5% (21%)] <math>\alpha=0.636</math></u></b>			<b><u>IX. Systems approach [3% (43%)] <math>\alpha=0.202</math></u></b>		
	Pre-session team briefing is important for patient safety and effective team mgt.	0.746		Adverse events occur as result of system failures, but not attributed to individuals.	0.596
	Regular debriefing of procedure & decision is important for effective team mgt.	0.731		Human error is inevitable.	0.448
	I often learn how to perform my own job from mistakes made by other dialysis staff.	0.542		Senior person should take over and make all decisions in life-threatening situation.	0.423
	To resolve conflicts, team members should openly discuss differences with each other.	0.344	<b><u>X. Competence awareness [3% (45%)] <math>\alpha=0.266</math></u></b>		
<b><u>IV. Job satisfaction [5% (26%)] <math>\alpha=0.785</math></u></b>				As long as the work gets done, I don't care what others think of me.	0.668
	I like my job.	0.775		It bothers me when others do not respect my professional capabilities.	-0.483
	I am proud to work for this dialysis dept.	0.748		Team members should monitor each other for signs of stress or fatigue.	-0.320
	I enjoy working as part of a team.	0.686	<b><u>XI. Blame culture [2% (47%)] <math>\alpha=0.350</math></u></b>		
				In our dialysis dept., reported incident is often requested to make revisions.	0.744
				In this dialysis dept., staff is not punished for errors reported.	-0.464
				This dialysis dept. has clear criteria on punishment to staff involved in event.	0.359

Table 1. Safety climate dimensions in the dialysis setting

### 3.2 Safety climate in dialysis facility

Safety climate in the dialysis setting perceived by doctors, nurses and technologists is shown in Table 2 in terms of percentage of positive and negative respondents, and significance level between three professional groups for each dimension. The percentage of positive and negative respondents was computed as follows: Before calculation of the indices, an item that has a negative loading for a given dimension has its figure reversed, i.e., responses of 5 and 4 were reversed to 1 and 2, and vice versa. A mean score of a dimension is calculated across all its component items for each respondent, and he/she is categorised into three levels based on his/her score: (1) negative [1.0, 2.5]; (2) neutral (2.5, 3.5); and (3) positive [3.5, 5.0].

There were significant differences in the levels of all safety climate dimensions between doctors, nurses, and technologists. As an overall trend, doctors exhibited the most positive perceptions of all safety climate dimensions among the three professional groups for most dimensions. Regardless of these differences, shared perceptions of safety climate were observed in the dialysis setting: All three professional groups indicated positively high awareness of communication and learning, safety systems and management commitment, and error reporting. They exhibited high job satisfaction, and well agreed with blame-free culture and systems approach – conception of safety that adverse events occur as results of system failures, but not attributed to individual operator errors. In addition, they perceived no or small power distance, and their competence awareness and attitudes to stress and workload were not too strong – this refers to *realistic* attitudes, meaning that they realistically acknowledged effects of stress and workload on their own performance.

Dimensions	N=	Dr. 780	Ns. 6,931	Tech. 3,021	Total 10,972	<i>p</i>
I. Safety system & management commitment		76% 1%	55% 9%	49% 10%	54% 9%	***
II. Power distance (perceive large)		2% 89%	1% 88%	1% 89%	1% 88%	**
III. Communication & learning		97% 0%	96% 0%	96% 0%	96% 0%	**
IV. Job satisfaction		82% 4%	64% 8%	64% 8%	65% 8%	***
V. Attitudes to stress & workload (realistic attitudes in negative)		18% 40%	12% 45%	16% 40%	13% 43%	***
VI. Error reporting		66% 5%	65% 4%	59% 6%	63% 5%	***
VII. Collectivism-individualism (collective trend)		23% 26%	14% 33%	17% 31%	16% 32%	***
VIII. Safety structure awareness		54% 9%	21% 31%	26% 26%	25% 28%	***
IX. Systems approach		75% 2%	44% 5%	61% 3%	51% 5%	***
X. Competence awareness		3% 67%	3% 62%	4% 59%	3% 61%	***
XI. Blame culture		1% 82%	2% 73%	2% 71%	2% 73%	***

Figure upper row: % positive respondents, lower row: % negative respondents

\*:  $p < 0.05$ , \*\*:  $p < 0.01$ , \*\*\*:  $p < 0.001$

Table 2. Overall trend of safety climate in the dialysis setting

## 4. Validity and Reliability

### 4.1 Test-retest reliability

A test-retest comparison was performed for each sample of 240 dialysis facilities from which more than ten responses were collected in the two surveys. It was not possible to examine one-to-one agreement of all question items for each respondent since the surveys were made anonymously. Therefore, we confirmed the test-retest reliability by applying Mann-Whitney test to responses to each item between the two surveys in every facility sample. As the results, 139 facilities (58%) had no item for which a significant difference was observed between the test and the retest staff responses. In 66 facilities (28%), only a single item was significantly different. In 95% of dialysis facilities surveyed in this study, no or at most two items were significantly different. Thus, it was suggested that the questionnaire's reliability was almost assured.

### 4.2 Criterion validity

To confirm criterion validity of the safety climate dimensions, correlation analysis – Pearson's  $r$  – was applied to the sample composed of 36 facilities which provided both safety climate responses and performance indicators. The analysis results are summarised in Table 3. There were significant correlations between each safety climate dimension and one or more performance indicators.

Regarding associations with safety-related outcomes, non-realistic attitudes to stress and workload (Dimension V) – staff members do not accept these effects on safety – brought decreased reporting rate of incidents. Systems approach (IX) – they view that an adverse event occurred as consequence of system's faults but was not caused by human errors – contributed to increase of reported incidents. Accepting "safety assumption" of incident reporting (Edmondson, 1996), the association with these two dimensions might be implied safer conditions in dialysis clinics. In addition, blame culture (XI) was associated with higher rate of blood infection and needle stick events. In contrast, strong awareness of safety systems and management commitment to safety (I) contributed to reduction of needle stick events.

Dimension I and error reporting (VI) were associated with an indicator related to clinical quality, frequency of cardiopulmonary arrest during dialysis therapy. Staff's realistic attitudes to stress and workload (V) seemed to contribute to higher performance of another quality-related indicator, frequency of hypotension during dialysis. This dimension also yielded preferable effects on employee development, e.g., academic journal papers and rate of dialysis licensed staff, and on organisational efficiency such as utilisation of dialysis bed per day.

As association of safety climate with other management goals, for instance, job satisfaction (IV) was negatively correlated with nurses' and technologists' turnover ratio – staff turnover is a representative indicator of QWL. Blame culture (XI) might cause the increase of doctors' and technologists' turnover, i.e., degrading staff QWL.

Performance indicators	I	II	III	IV	V	VI	VII	VIII	IX	X	XI
Incident/near-miss reporting rate					(-)*		(+)*		(+)‡		
Vascular access infection rate							(+)‡				
Blood infection rate			(-)‡								(+)‡
Needle stick event rate	(-)*						(+)*				(+)*
Frequency of cardiopulmonary arrest	(-)‡					(-)*	(+)‡				
Frequency of dialysis hypotension					(-)‡						
Haemodialysis efficiency	(-)*	(+)*		(-)‡	(-)‡	(-)*	(+)**				(+)*
Doctor's turnover rate			(-)**								(-)*
Nurse's turnover rate	(-)*			(-)*	(-)*						
Technologist's turnover rate				(-)**							(+)‡
Academic journal papers by nurses					(-)*						
Academic journal papers by tech.					(-)*						(+)‡
Conference presentations by nurses					(-)*						(+)*
Conference presentations by tech.											(+)*
Rate of dialysis licensed nurses					(-)‡						
Rate of dialysis licensed tech.					(-)*						
Doctor's FTE per dialysis bed		(-)*	(+)*						(+)‡		
Nurse's FTE per dialysis bed		(+)‡			(+)*	(+)‡					
Technologist's FTE per dialysis bed									(+)*		
Utilisation of dialysis bed per day					(+)*				(-)‡		

I~XI: Safety climate dimensions (see Table 2). (+): positive, (-): negative correlation; ‡:  $p < 0.1$ , \*  $p < 0.05$ , \*\*  $p < 0.01$ .

**Table 3.** Correlations of safety climate dimensions with performance indicators

In summary, it was seen that each safety climate dimension positively contributed to one or multiple clinical outcome measures. For instance, realistic attitudes to stress and workload yielded preferable effects on various aspects such as safety, clinical quality, employee development and organisational efficiency. Staff awareness of safety systems and management commitment was positively correlated with safety and clinical quality. Blame culture was negatively associated with safety and staff QWL. In contrast, systems approach contributed positively to safety in the dialysis setting. From these correlations, it might be suggested that criterion validity for the safety climate scale was ensured.

## 5. Conclusion

The present paper developed an assessment instrument of safety climate for the dialysis setting. The safety climate construct elicited in this study, which was composed of eleven dimensions, covered not only common themes on safety culture suggested by former studies (Flin et al., 2006) but also important issues on patient safety, e.g., workload and stress, blame culture and power distance. The construct was assured test-retest reliability and criterion validity. Using the construct and performance indicator scores, we investigated the current states in dialysis safety climate and its associations with clinical performances in Japan. As a major outcome obtained in this study, an overall safety climate in the dialysis setting was uncovered: Dialysis staff was highly aware of communication and learning, safety systems and management commitment, and error reporting. There were generally no or very small power distance, blame-free culture and systems approach concept within the organisation. In addition, they shared realistic attitudes to stress and workload, which seem to contribute safety, clinical quality, employee development and organisational efficiency. Blame-free culture and systems approach were also associated with safety – and the former component also contributes to improvement of staff QWL – in the dialysis setting.

From the results obtained in this study, we believe safety climate assessment by the use of an instrument like the one developed in this study can be applied to *proactive* risk management, in which one can identify “weak points” of organisational factors – which are periodically tracked – and take improvement actions *before* an adverse event happens. The safety climate

scale is applicable for other types of hospitals or clinical departments by adapting question items to a specific type of organisation.

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## Developing personas for use in the design of dementia care environments

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### Abstract

*Context:* Dementia has a high global prevalence, and the number of people with dementia (PWDem) worldwide is expected to rise in coming years. The various symptoms associated with dementia can cause difficulties for PWDem when engaging with activities of daily living (ADLs) as the disease progresses. However, designing a care environment which enables PWDem to successfully engage with ADLs is not a simple task, in part because PWDem may find it difficult to communicate their needs to a design team. For this reason, design personas which aimed to represent PWDem at different stages of the disease were created as a means of communicating these needs to designers. This paper describes an evaluation study on these personas.

*Objectives:* To consult design stakeholders and obtain feedback on the use of the personas in the process of designing a dementia care home.

*Methodology:* Interviews and focus groups were used to obtain feedback on the personas.

*Main results:* Participants suggested several improvements for the personas. These included (1) diagrams (images and symbols) rather than text, (2) focusing less on specific design guidance, and (3) including a wider range of symptoms and needs.

*Conclusion:* The wide range of suggested changes from the participants indicated both engagement with, and potential for, the initial personas. The personas have been revised and will be tested in care homes to explore how far they accurately represent the needs of PWDem both with caregivers and PWDem.

**Keywords:** personas, dementia, human factors, care home, design

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### 1. Introduction

Designing dementia care homes is challenging, not least due to the complex nature of dementia. Symptoms which affect cognition, functional abilities, behaviour and perceptual abilities mean that a poorly designed care environment can have negative consequences for quality of life and wellbeing (Day, Carreon, & Stump, 2000). Conversely, a well-designed care environment can improve quality of life and promote independence (Cioffi, Fleming, Wilkes, et al., 2007; Day, Carreon, & Stump, 2000; Fleming & Purandare, 2010).

Due to some of the cognitive difficulties such as communication problems which are commonly present in dementia, it is not always possible for people with dementia (PWDem) to explicitly state what they need from a care environment. This poses a problem when designing dementia care homes. One way in which this could be overcome may be through the use of design personas which represent the needs of archetypal PWDem. These could provide stakeholders with access to the information that they require, avoiding the need to rely on PWDem being able to communicate their needs to them. This could be particularly

useful for representing the needs of people in the middle to later stages of the condition, where communication abilities deteriorate further.

## **2. State of the art**

Currently no existing design personas have been identified which focus specifically on PWDem or dementia care home design. Preliminary personas (Figure 1a) were developed after a scoping study which looked at the activities of daily living (ADLs) that may be relevant to PWDem (Jais, Hignett, Habell, et al., 2016).

## **3. Objectives and Methods**

This study aimed to evaluate the initial set of personas by seeking feedback from potential users (design stakeholders). The study assessed whether the proposed format and content were appropriate for use in the design of dementia care environments, and explored how they might be further developed. Potential users of the personas were consulted with the intention of identifying where the personas might best fit within the design process and ensuring that the personas would meet their needs.

### **3.1 Methods**

Participants were recruited from the scoping study. Interview schedules and focus group protocols were designed to cover two main topics, the content of the personas and the format of the personas. These were written in a semi-structured style to allow participants the freedom to contribute other ideas or comments that may not have been covered otherwise. Audio recordings were made of the interviews and focus groups. Two recordings were made during each session to avoid losing all audio data in the event of technological problems. Interviews were carried out over Skype. After each session, a contact summary sheet was completed to note points of particular interest, and anything that might have been missed out that would need to be discussed during the next session. An ethical checklist was filed for the study in accordance with Loughborough University's ethical procedures.

### **3.2 Interview procedure**

Participants were sent copies of the information sheet, consent form and personas before the interview; this provided the opportunity to ask questions about the research and give informed consent. Sending this information to participants before the interview also meant that they had time to familiarise themselves with the personas before the session. Two researchers were present for all interviews. Participants were called over Skype. Once the call had connected, participants were asked to confirm that they were happy to take part in the study. Audio recording was started once they had given verbal consent. Participants were then briefed on the session content, and were given an overview of the aims of the personas. They were asked if they had any initial thoughts or comments on the personas before proceeding with the interview. The researchers and participants discussed specific aspects of the personas, such as the content and layout. Participants were asked about each section of the personas, e.g. social information and clinical condition. Once participants had no further points to make, the researchers summarised what had been said and asked if there were any other questions or comments. Participants were thanked for their time, and reminded to email the researchers if they had any further questions or comments about the research. At this stage, each researcher completed a contact summary sheet detailing anything that was particularly interesting as well as extra points to bring up in future interviews or focus groups.

### 3.3 Focus group procedure

The focus group session was held in London as this was mutually convenient for participants and researchers. Although four participants initially agreed to take part, one participant was unable to make the session and was interviewed via Skype instead. Another did not attend, meaning that two participants attended the focus group. Participants were given information sheets and consent forms to read and complete. After consenting to take part in the study, each participant was given a copy of the personas to read through before the session began. Participants were encouraged to make notes on the personas if they found this helpful. Once participants were familiar with the personas, the audio recordings commenced and the session began. Each persona was examined in turn, and participants were asked about content and format in line with the focus group protocol. After all four personas had been covered and when participants had no further comments, the researchers summarised the main points made during the discussion and the session was brought to a close. Each researcher then completed a contact summary sheet as with the interviews.

### 3.4 Participants

The 6 participants included:

- P1 (architect) and P2 (architect, wife has dementia) interviewed together over Skype;
- P3 (care home developer) and P4 (care worker) interviewed separately over Skype
- P5 (head of dementia innovation) and P6 (architect) attended the focus group together.

## 4. Results & Discussion

Data were coded and analysed in NVivo10.

### 4.1 Personas

A number of suggestions were made to develop the personas. Participants suggested that the social background section could be expanded, with a wider range of social backgrounds, to highlight that anybody can develop dementia. Including some information about the person's family, as well as their likes and dislikes, was thought to be beneficial in providing some context for the personas and giving the design team a clearer idea of the range of people who might use a dementia care home. The importance of incorporating such things as preferred leisure activities was stressed. This supports the findings of a recent scoping study (Jais, Hignett, Habell et al., 2016) which suggested that activities other than those which are typically classed as ADLs are also important for PWDem.

It was felt that the inclusion of too many clinical details may not be helpful to a design team, as care homes are designed for a range of people rather than for specific individuals. It was suggested that instead describing a range of symptoms may be more useful, perhaps by outlining typical symptoms that PWDem might experience on a bad day, an average day or a good day. Including a short description of typical symptoms in each persona was deemed to provide enough information without going into too much detail. Similarly, including a range of different ages in the personas was thought to be useful.

Some suggestions for the layout of the personas were also made. Whereas version 1, which was presented to participants during the study, was largely text based, it was recommended that the second version should be more visual in appearance:

*"Maybe a way to do it is to have the person in the middle and then, sort of have circles radiating out"* – P5; head of dementia innovation.

It was noted that users of the personas may gain more from using something presented as a diagram rather than something which is solely text based, particularly those on the design team whose work is likely to be more visual in nature. A visual method of presenting the personas was therefore explored during the development of version 2 to ensure that the personas would facilitate communication between all stakeholders including both the design team and PWDem.

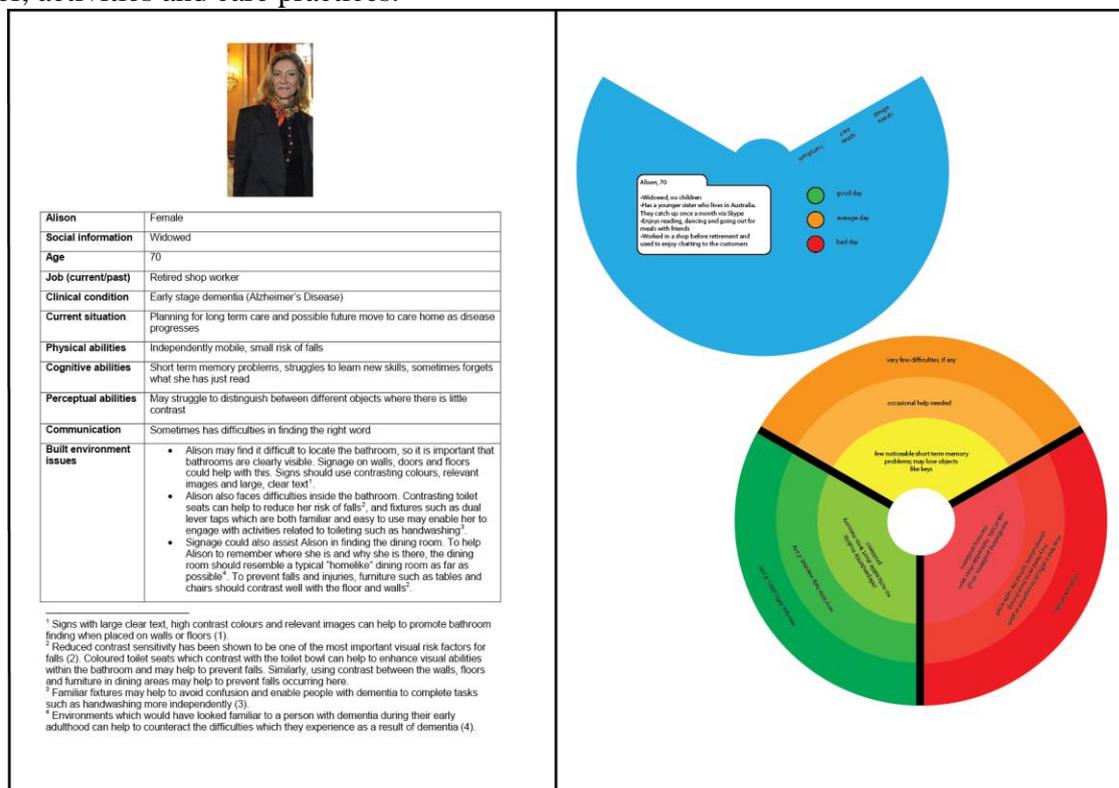
One participant highlighted that it is becoming more common for couples to move into care homes together and that therefore it may be useful to have a persona which represents a couple. As well as this, it was suggested that having a persona which represented family carers may also benefit the design team in that it would highlight what this group may need from a care home.

Participants also discussed where the personas could fit into the design process. It was suggested that they could be used as a discussion tool during the development of a design brief, as they could help all parties to identify the requirements of the proposed care home. This suggests that personas would likely be most useful in the pre-design phase of the design process (Taylor, 2016). As well as this, stakeholders could discuss the needs of the intended users and how they were similar to or different from those described in the personas.

Including detailed design guidance was not thought to be particularly useful as it was noted that those working on the design of a dementia care home would likely already possess this knowledge. If this were not the case, this information is already well covered by existing design guidelines, including space standards and building regulations.

## 4.2 Other findings

Various other topics were raised, broadly including the symptoms of dementia, the stakeholder involved in the design of a dementia care home, design considerations, the design brief, activities and care practices.



Figures 9a & 1b. Examples of personas from version 1 (left; 1a) and version 2 (right; 1b)

Participants noted that some symptoms such as perceptual issues are commonly attributed to dementia but in fact such symptoms could also arise as a result of general ageing. Different types of dementia were discussed, as were the different stages, and it was suggested that these factors contributed to some of the challenges when designing for groups of PWDem in that this group has diverse needs and abilities.

It was recognised that culture could present challenges for signage; as certain symbols or icons may be familiar to people from some cultural backgrounds but not others. The needs of various stakeholders, including the families of PWDem, the design team and other residents in the home who are not living with dementia were also considered.

Many different aspects of design were considered. The use of colour and contrast were generally thought to be an important factor in care home design, which supports previous literature on this topic (Day, Carreon, & Stump, 2000). However there were areas in which participants weren't sure of the relevance of colour:

*“Although I would say, tongue in cheek, how the colour is relevant as you back towards the toilet seat, I don't know”* – P1; architect

Cost was also explored, and it was noted that the financial implications of certain design features meant that compromises often had to be made between the design team and the client. Participants brought up design guidance and suggested that while dementia design guidelines were useful, Health Building Notes (e.g. Department of Health, 2015) were not always particularly useful as they were perceived to be outdated. Participants emphasised the importance of using familiarity in care home design and creating environments which looked homely, and the use of signage was thought to be important in helping PWDem with navigation. This supports the design guidance described in the literature on this topic (Day, Carreon, & Stump, 2000). It was suggested that using carpet throughout the care home could help to reduce high levels of noise which can be problematic for PWDem (Fleming & Purandare, 2010). Safety was also brought up, and it was noted that tasks such as trying to make a cup of tea or coffee could be potentially dangerous for people with advancing dementia:

*“I've seen people put the actual teabag inside the kettle and sort of putting coffee in the kettle as well, sort of thinking they have to make a cup of tea that way”* – P4; care support worker

The layout of the home was also mentioned, and the locations of bathrooms were thought to be particularly important in that they needed to be easily accessible and visible. This again supports previous research findings on this topic (Day, Carreon, & Stump, 2000).

Participants stressed the importance of putting together a good design brief:

*“If you don't get the brief right, you won't get a good build. It's really important.”* – P6; architect

It was suggested that the personas could be useful here as they could promote discussion amongst different stakeholders.

While activities such as eating and toileting were considered to be important, participants also emphasised how crucial it is to enable residents to take part in their preferred leisure activities and complete everyday household chores to maintain a sense of normality. This again provided support for the findings of a recent scoping study in this area (Jais, Hignett, Habell, et al., 2016). Discussions on care practices also touched on this and it was acknowledged that person centred care was likely to be the most suitable approach to dementia care as it encouraged carers to treat residents as individuals.

## 5. Conclusion & perspectives

These data have been incorporated into the next stage of the persona development (Figure 1b). Whereas version 1 was more text based, version 2 is much more visual in nature. In version 2, the two elements fit together so that the bottom section can be rotated to reveal different sections under the blue cover. The social information section (in the blue cover of version 2) has been expanded. Version 2 also covers a wider range of symptoms and needs by showing what the person's symptoms, care needs and design needs could be on a good day, an average day and a bad day. These are represented by different coloured sections in the bottom section, with green representing a good day, orange an average day and red a bad day. Version 2 of the personas focuses more on the specific issues experienced by PWDem rather than the ways in which these issues could be addressed through design as participants had indicated that they were, more often than not, already aware of the relevant regulations and guidance. It was also noted that if this were not the case, this information is readily available to the design team and that therefore it does not need to be included in the personas.

The results of this study showed that there were several ways in which the personas could be improved. These suggestions were taken into account and influenced version 2 (Figure 1b). As participants were able to identify a specific stage of the design process at which the personas would most likely be useful, it is intended that these will be used as a discussion tool for those involved in drawing up a design brief for a dementia care home. This will help to ensure that all parties are able to contribute to the design brief and fully discuss the needs of the future residents of a proposed care home, while considering how the design of the home will need to account for these needs. It should be noted however that the sample used in this study was small, meaning that these findings cannot be generalised to all designers or care workers. For this reason, the development of the personas will continue to be an ongoing process to ensure that more varied perspectives and viewpoints are also incorporated.

Once development of version 2 has been completed, the personas will be taken into care homes to evaluate current care home design for PWDem. Additionally, PWDem will be consulted to seek feedback and ensure that the personas accurately represent their needs. The personas will then be reviewed once again and revised accordingly, leading to a final version.

## Acknowledgements

Thanks to the Design Star Doctoral Consortium for funding this PhD studentship.

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Taylor, E. (2016). Anticipate to Participate to Integrate: Bridging Evidence-Based Design and Human Factors Ergonomics to Advance Safer Healthcare Facility Design [Powerpoint slides].



## Management of dilemma under sleep deprivation in anesthesiology residents and the impact on mobilization of skills: a simulation based study

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### Abstract

Since the 90s, several reports highlighted the role of the so-called “non-technical skills” in medical error and emphasized the necessity to improve those skills to ensure patient safety. This model of skills, was transferred directly from the aviation field. According to Granry et al. (2012) these skills allow to enhance human performance in critical situations where and when procedural and craft skills were not enough to manage them. The aim of this research is to study management of dilemma under sleep deprivation and the impact on mobilization of non-technical skills. A total of 17 residents in anesthesiology were randomized to undergo a simulation session after an on call night or after a rested night. Technical and non-technical skills were assessed in double-blind by two experts using Anaesthetists Non-Technical Skills (Flin et al., 2010) and a technical checklist containing 16 items regarding anaesthesia induction and anaphylactic shock management. Preliminary results show that mobilisation of non-technical skills was better for rested residents than for sleep deprived residents. Moreover, confidence level was also negatively impacted by sleep deprivation. The results lead us to discuss non-technical skills framework and challenge the segregation between technical and non-technical skills.

**Keywords:** non-technical skills, skills, critical situation, dilemma, simulation

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### 1. Context

Since the 1970s, accidents or incidents analysis in civil aviation revealed the significant role of non-technical skills among the contributing factors of accidents. In 1977, the analysis of Tenerife accident, the greatest air disaster, has shown that human and organizational factors were involved in the accident. In medicine, awareness was later following the publication of a series of reports in the 1990s. Despite the progress made, in United States, it is estimated that medical errors that could have been prevented, are responsible for 44,000 to 98,000 deaths every year (Kohn et al., 2000). The accident analysis showed that their cause lies not in lack of medical knowledge, but rather associated with a lack of mobilization of skills called “non-technical” skills, such as how to manage internal and external resources, especially in critical situations.

## 2. Management of critical situation to enhance patient safety

In medicine, the environment is dynamic and complex, with many risks (Hoc & Amalberti, 2003). In this context, health professionals have to cope with critical situations where both internal (fatigue, stress, workload) and external (environment, emergency) factors make these situations deviate from controlled situations by the subject on the basis of rules, procedures and specific knowledge. Physicians have to make crucial medical decisions often under sleep deprivation, by evaluating risks associated with potential solutions, particularly in emergency situations. They may have not enough time and resources to review and compare outcomes of every possible solution, including ethical dimensions.

One of the possible features critical situations concerning moral or ethical judgments, which may find themselves in situations requiring a dilemma, frequent in medicine, for the operator. Physicians have to choose between two solutions of high risk or generate irreversible consequences. Besides, they have to cope with dilemma under sleep deprivation knowing that fatigue alters capacity to integrate emotion and cognition for decision-making in case of moral dilemma (Killgore et al., 2007).

Management of critical situations does not require only "professional skills", technical and procedural. It also mobilizes a set of skills that relate to "intermediate knowledge" (decision making, communication, leadership, situational awareness, team work) (Flin et al., 2008; Altet, 2012). Non-technical skills can be defined as "the cognitive (decision making, situation awareness) social (communication, leadership, team working), and personal resource skills (managing stress, coping with fatigue) that complement technical skills, and contribute to safe and efficient task performance" (Flin et al, 2008). Technical and non-technical skills are two dimensions of skills involved in management of critical situations and thus ensure safety of care. Segregation between these two dimensions could be discussed and even challenge.

## 3. Objectives and Methods

This work is a part of a wider project aiming at designing simulation-based training of on-technical skills for management of critical situations in two fields: medicine and car driving. This paper refers to the first part of the research that was focused on the management of dilemma under sleep deprivation and the impact on the mobilization of non-technical skills.

17 Anaesthesiology residents from Paris academic hospitals were randomized to undergo a simulation session after an on call night (sleep deprived (SD) group; mean age  $26 \pm 2.29$ ) or after a rested night (rested group (R); mean age  $27 \pm 2$ ). They were informed of the anonymous recording of data and gave signed consent. All participants had already experienced high fidelity simulation.

The scenario consisted in a rapid sequence of induction for emergency general anaesthesia. All scenarios were performed with the assistance of an anaesthetist nurse, facilitator of the scenario. The patient was admitted for in emergency for acute peritonitis complicated by an anaphylactic shock secondary to the injection of succinylcholine. In a second step, after patient stabilisation, a surgeon entered in the operating room to create a dilemma regarding the decision to be made about the patient: either continue the surgery or to bring him in the intensive care unit. Both decisions are associated with specific risks in terms of patient safety.

The simulation sessions followed three steps: a briefing, the simulation *per se* and a debriefing on trainee's feelings and performance analysis afterwards.

Demographical data on participants were collected. Questionnaires were filled a few days before the simulation to assess global confidence and global level of sleepiness (The Epworth

scale). On the day of simulation instant confidence and instant sleepiness (Karolinska Sleepiness Scale) were also assessed.

Two anaesthetists experts assessed in double blind the individual score of non-technical skills by the means of the Anaesthetists' Non-Technical Skills (Flin et al., 2010) and the individual score of technical skills, assessed by the completion of a technical checklist that reflects the appropriate application of procedure and actions.

All simulations were video recorded and debriefing sessions were audio recorded to allow subsequent data processing.

## 4. Results & Discussion

### 4.1 Technical and Non-technical Skills and confidence level

Previous results showed a significant increase of perceived fatigue among the sleep deprivation group compared to the rested group (Job et al, 2015).

Results show that no significant differences were observed between the two groups on technical skills scores. However, figure 1 shows that non-technical skills score was significant higher in the rested group compared to the sleep deprivation group (Inter rater correlation:  $.65 \pm .09$ ).

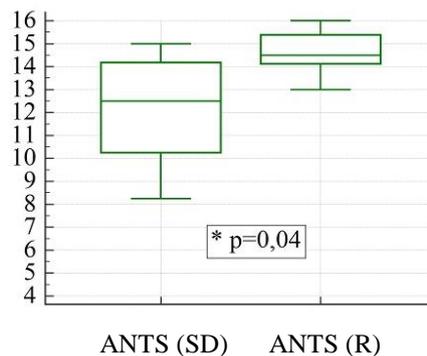


Figure 1. ANTS scores depending on sleep condition

Sleep deprived residents reported significant lower confidence level than rested residents ( $64,1 \pm 10,5$  vs  $84,8 \pm 14,2$  respectively;  $p < 0,01$ ). Furthermore, results showed a positive and strong correlation between the level of confidence and the non-technical skills scores ( $r = .608$ ) (Figure 2).

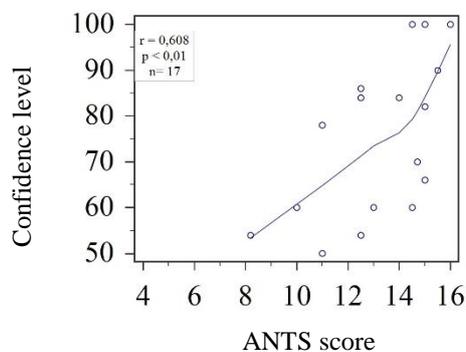


Figure 2. Correlation between ANTS scores and confidence level

## 4.2 Dilemma management

Simulation videos analysis of dilemma management allows to identify 4 types of decisions presented in table 1.

- Resident did not express decision and decides to follow surgeon's decision
- In spite of surgeon's pressure, the resident decides to maintain his initial decision
- After surgeon's intervention, the resident ask for time to make his decision
- Under surgeon's pressure, the resident decides to follow surgeon's decision

	Follow surgeon's instruction	Keep initial decision	Ask time	Change the initial decision
Rested	2 residents	2 residents	4 residents	
Sleep deprived	1 resident		3 residents	3 residents

Table 1. Residents' decision depending on sleep condition

Depending on sleep condition, residents developed different strategies. Sleep deprived residents show a trend to change their initial decision to follow surgeon's decision, none of them keep their initial decision under surgeon's pressure. Rested residents mostly tended to ask time to reevaluate the situation or maintained their initial decision despite surgeon's intervention.

Debriefing recording are being analyzed.

## 5. Conclusion & perspectives

Results analysis showed a significant effect of sleep deprivation on self-confidence. This could explain why residents are more prone to change opinions under the pressure of a supervisor. Confidence level seems show a significant correlation with the capacity to mobilize non-technical skills. The implications of these results will be discussed from an organizational point of view as well as regard to the training of residents.

These results confirm that the appropriate application of procedures is not sufficient to ensure care quality particularly in critical situations. Current framework of non - technical skills define these skills in opposition to technical skills because they are not references to "core competencies", procedures acquired in initial training (intubation, resuscitation ...). Skills dimensions involved in critical situation were multiple. The segregation between technical and non-technical skills is not theoretically relevant and could be challenge.

## Acknowledgements

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## **Improving medication safety through an inpatient portal for families of hospitalized children**

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### **Abstract**

*Context:* Hospitalized children are particularly vulnerable to medication errors, experiencing harm at a rate three times that of adults. Outpatient patient portal use can engage patients and families in error recovery and harm prevention; however, little is known about portal use in hospitals.

*Objective:* Using surveys, we evaluated the impact of a patient portal application on a tablet computer given to parents of hospitalized children) on parent detection and reporting of medication errors and error reduction.

*Methods:* This cross-sectional study was conducted over 6-months with parents of children and their healthcare team (HCT) on a unit at a US children's hospital. The portal provides a real-time medication list, including dosing, route, schedule and online information. Parents completed a discharge survey and HCT members completed pre- and post-implementation surveys on perceptions of the portal's impact on medication errors. Variables were described and compared using percentages, chi-square and z-tests.

*Results:* Of HCT pre-implementation respondents, 70% anticipated parents would find medication list errors using the portal. Of 296 parent portal users, 90 responded and 8% reported finding errors in their child's medication list using the portal. Compared to pre-implementation HCT respondents, a higher proportion of parents agreed that portal use reduced errors in care (45% HCT vs. 89% parents,  $p < 0.001$ ). Of HCT respondents, 5% reported parents notifying them of medication list errors found using the portal post-implementation.

*Conclusion:* Parent portal users may detect and report errors found using a patient portal during their child's hospitalization. Further characterization of parent-reported errors and the impact on patient safety is needed.

**Keywords:** patient portal, family-centered care, pediatrics, hospital medicine, patient safety

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## **1. Introduction**

Hospitalized children experience alarming rates of medical error. An estimated 5-10% of inpatient pediatric medication orders and 55% of pediatric admissions are associated with medication errors, a rate three times that of adults (Kaushal et al., 2001). Children are particularly vulnerable to medication errors and their potentially hazardous effects due, in part, to weight-based dosing, limited physiologic reserves, and immature communication skills. Relying on adults to convey information, most children are not able to warn their healthcare team (HCT) about mistakes in medication dosing, administration, and/or adverse effects. Consequently, healthcare organizations have focused substantial efforts on tools to engage patients and families as partners in reducing medication errors (AHRQ, 2014; Stucky, 2003).

## **2. State of the art**

Patient portals, personal health records tethered to electronic health records (EHRs), are proposed as a mechanism to engage patients in care to improve patient safety (Agrawal, 2009). Portals provide patients and their families' access to their health record, such as their medication information, while also allowing communication with their HCT via secure messaging, such as asking medication regimen questions. Although outpatient studies have suggested medication safety can be improved using portals, a systematic review indicates limited evidence of portals improving patient safety (Mold & de Lusignan, 2015). Furthermore, literature evaluating the implementation of patient portals in the inpatient setting and the impact of their use on patient safety is still in its infancy (Prey et al., 2014; Vawdrey et al., 2011).

In this study, we evaluate the implementation of a new patient portal application given to parents of hospitalized children on a tablet computer. We explore the role of parent portal use in the detection of potential medication errors in the hospital.

## **3. Objectives and Methods**

### **3.1 Objectives**

We examined HCT and parent perceptions of the impact of use of an inpatient patient portal application given to parents of hospitalized children on parent detection and reporting of medication errors and overall error reduction.

### **3.2 Methods**

This cross-sectional study was conducted with HCT members (nurses, physicians and ancillary staff) and English-speaking parents of children <12 years old hospitalized on a 24-bed general medical/surgical unit at a US tertiary children's hospital. From December 2014 to June 2015, 296 parents were given a hospital tablet computer with a portal application to use during their child's hospitalization (see Figure 1). Tethered to the inpatient EHR, this portal provides the child's real-time hospital medication list, including dosing, route, schedule and an electronic link to online medication information. The portal also provides the child's vitals, lab results, HCT information and a way for parents to send the HCT requests and free-text, secure messages. Parent portal users completed an electronic tablet survey upon discharge. HCT members completed paper surveys pre- and 6-months post-portal implementation. Survey items included perceptions of the impact of portal use on parent detection and reporting of medication errors, reduction of errors in care, and open-ended questions on challenges, likes and suggestions for portal improvement. All surveys were voluntary and

anonymous. Parent message content was collected from tablet metadata. Variables were described and compared using percentages, chi-square and z-tests. Qualitative content analysis was performed on medication-related data from open-ended questions and messages.

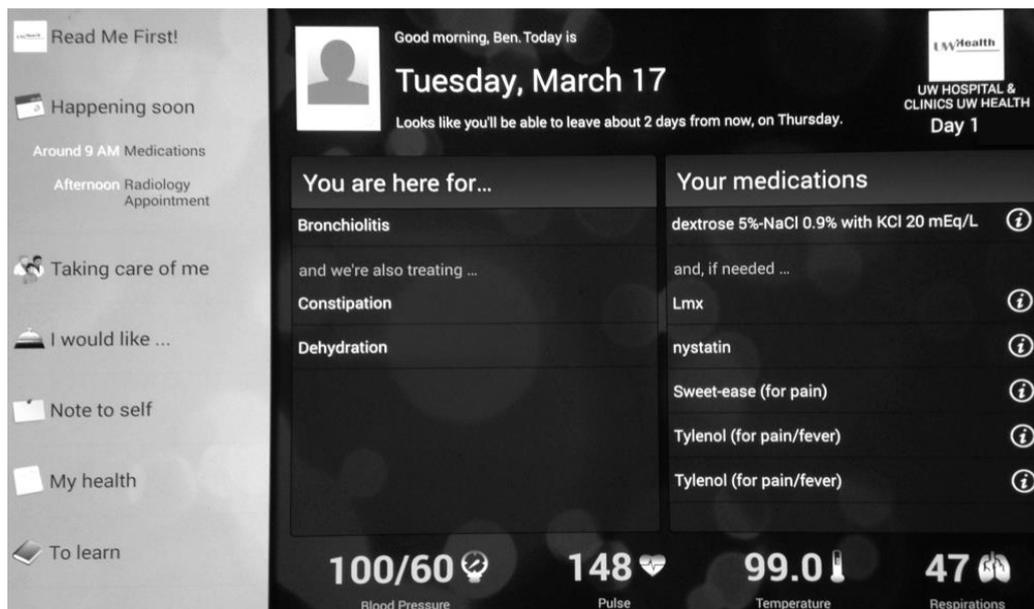


Figure 1. Patient portal homescreen (MyChart Bedside, ©2016 Epic Systems. Used with permission.)

## 4. Results & Discussion

### 4.1 Results

Out of 296 parent portal users, 16 sent a total of 36 messages to the HCT. Of these, only 3 were medication-related (e.g., “I was wondering if we can get something different than Milk Mag instead of liquid so she will take her meds”). Out of 90 parent survey respondents, 8% reported finding errors in their child’s medication list using the portal. Compared to HCT respondents pre-portal implementation, more parents agreed that portal use reduced errors in care (45% HCT vs. 89% parents,  $z=6.3$ ,  $p<0.001$ ). In response to a question about what they liked most about the portal, parents submitted 159 responses. Of these, 21 were medication-related (e.g., “Med order updated regularly and noted changes,” “[The medication list] helps me learn routine for med faster before discharge”). Parent respondents also suggested providing more detailed, family-friendly medication lists (“The dosages of the medications are all in mg. Most parents don’t know how many mg a syrup or pill contain per unit, especially if the drug is new to them”).

Pre-implementation, 94 of 100 HCT members completed the survey (response rate 94%). Most HCT respondents anticipated parents would find errors in their child’s medication list using the portal (70% agreed). Fewer agreed portal use would reduce errors in care (45%). HCT respondents anticipated medication-related challenges related to portal use, including the premature release of medication information (e.g., “Parents will see errors before pharmacy can check the orders”) and concerns about late medication administration (e.g., “Parent concern with med timing—med may not be available to give”).

Six-months post-portal implementation, 70 of 88 HCT members who worked on the unit during the study period completed the survey (response rate 88%). In all, 5% of HCT respondents reported parents notifying them of errors in their child’s medication list found

using the portal. Of all anticipated medication-related challenges cited pre-implementation by the HCT, none were mentioned 6-months post-implementation.

## 4.2 Discussion

In this study, parents reported finding medication errors using a patient portal during their child's hospitalization and disclosed potential errors to the HCT. These results are consistent with outpatient literature suggesting that patients can detect medication errors using portals. However, our results indicate that while parent portal users notified HCT members of medication errors, use of the portal's secure messaging feature to report medication errors may be less common. DeJong et al. (2016) examined whether patients reviewed their medication information using an outpatient portal that provided a way to communicate with pharmacists. Results showed that 18% of patients communicated potential errors to the pharmacist. Heyworth et al. (2014) examined the impact of a portal Secure Messaging for Medication Reconciliation Tool (SMMRT) on medication safety. Results showed that discharged patients found and reported several medication discrepancies and potential adverse drug events.

Outpatient literature suggests two approaches for improving medication safety through patient portals: a passive and an active approach. In a passive approach, patients and/or their proxies are provided their medication list and left to their own initiative to take action, e.g., checking their medications and notifying their HCT of any discrepancies. In an active approach, patients are asked through the portal to identify discrepancies and, if found, notify their HCT. Studies using a passive approach have mixed results (Staroselsky et al., 2008), while those using an active approach had a more positive effect on medication safety (Schnipper et al., 2012; Weingart et al., 2008).

## 5. Conclusion & perspectives

Our preliminary findings suggest that parents may find and report medication errors using a patient portal during their child's hospital stay. Future evaluation of hospital patient portals should evaluate when and what types of errors patients and families detect using the portal, whether and how they report errors, and if steps are taken by the HCT to rectify and/or prevent errors if notified. Future development of hospital portals should focus on designing medication lists that are patient and family friendly and potentially an active approach to inpatient medication reconciliation, for example asking parents to examine their child's hospital medication list and report any incongruences during or after admission. Based on limited experiences with outpatient portals, this may increase the likelihood parents would detect, report and prevent harm from medication errors.

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## Be Proactive in Improving Pediatric Patient Safety. Understand the Effects of EMR on Communication

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### Abstract

Electronic Medical Records (EMR) have much potential to enhance safety of patient care and improve communication. However, only a little is known about how EMR can improve communication, and how communication contexts and modalities change after EMR implementation. Our project addressed these knowledge gaps. Human factors specialist interviewed and observed Pediatric emergency department staff to analyze pre- and post-EMR implementation workflows, as well as changes of system interface in relation to communication. Our findings clarified problematic communication contexts, in particular patient status, patient acuity, and process for orders, and showed that communication modality was primarily visual in the post-EMR workflow. The new EMR could potentially reduce duplicate communications (i.e., both verbal and visual modality). There were two main significant design differences that were addressed thoroughly in training.

**Keywords:** Pediatric Emergency Department (Ped ED), Electronic medical record (EMR), workflow analysis, proactive risk assessment, communication.

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### 1. Introduction

Electronic Medical Records (EMR) have much potential to enhance safety of patient care and improve efficiency of care delivery. Some of its reported benefits included reducing medication errors (Huckvale et al., 2010), improving communication and job satisfactions (Kirkendall, Goldenhar, Simon, Wheeler, & Andrew Spooner, 2013), and enhancing providers' and non-providers' efficiency (Pascale Carayon, Smith, Hundt, Kuruchittham, & Li, 2009). While EMR may provide opportunities to improve patient care, poor designs and lack of proper implementation can cause user resistance, use errors and adverse events that may outweigh its benefit (Ayatollahi, Mirani, & Haghani, 2014). To avoid these problems, an organization should appropriately perform workflow assessment, analyze the organizational context (sociotechnical system) in which EMR will be used in (P Carayon, Xie, & Kianfar, 2013), and prepare for all potential changes (Sittig, Gonzalez, & Singh, 2014).

Caring for patients in a pediatric emergency department (Ped ED) is complicated and prone to err as it requires numerous hand-offs, decision makings by multiple clinicians, and frequent cross discipline communication, which happens in a highly interruptive environment (Woods et al., 2008). A well-designed EMR in such an environment could contribute to improving communication and reducing errors (Esquivel, Sittig, Murphy, & Singh, 2012). Nonetheless, only a little is known about how EMR promotes team communication and how communication modalities change after EMR implementation (Walsh et al., 2013). Some

providers may develop trust in the system and utilize it as the main source of communication (in which modality became primarily visual), while others may refuse to use it fully as they perceive it to be difficult to use (in which modality continues to rely heavily on verbal). To prevent EMR induced communication errors, it is extremely critical to understand how it will be utilized (Chase et al., 2014).

## 2. Objectives and Methods

Organizations that understand workflows and proactively identify changes in the workflows could thoroughly plan and be more prepared for the implementation. In preparation for a new EMR transition in our Ped ED, we performed workflow analysis to understand how team communication would change post-EMR implementation. The three main objectives for our project were to identify: 1) changes in workflow (in particular, how changes affect team communication); 2) changes of communication contexts and modalities (i.e., visual and/or verbal); and 3) system designs that may induce errors.

In understanding the Ped ED's workflow and identifying how changes in the workflow could affect team communication, a human factors specialist (AK) performed interviews and observations. The human factors specialist interviewed Ped ED's nurse manager to obtain a full understanding of a typical unit workflow and key disciplines involved in the workflow. Key role players were then interviewed and observed (i.e., registration staff, triage RN, Ped ED RN, Ped ED MD, and the charge RN) for team communication, communication contexts and modalities.

To understand the post-implementation workflow and how communication modalities would change, the human factors specialist interviewed Ped ED EMR's trainers. The trainers thoroughly explained the new EMR workflow with system demonstration. During this process, the human factors specialist identified changes in the workflow and changes of interfaces that could affect visual communication.

## 3. Results

Figure 1 shows a pre-implementation workflow (i.e., an existing workflow at time of assessment), and figure 2 shows a potential post-EMR implementation workflow. Both workflows started with a referral facility calling an ED MD and ended after an ED RN documenting medication administration, and/or the posting of lab results. The workflows illustrate steps in which communications occurred, their modalities, and individuals involved in communication. For example, in figure 1, after an ED MD received a phone call about referral patient, s/he had to verbally communicate with ED RN about the patient. The context and modality of communication captured "**Verbal communication from ED MD to ED RN.**" In figure 2, after an ED MD received a phone call from a referral facility, created a referral chart and documented referral note, the system would automatically create a temporary patient chart, which was then presented on registrar's 'Expected' list. These steps elicited a "**visual communication from an ED MD to registrars**" about this soon-to-arrive referral patient. All parallelogram shaped steps present in figures 1 and 2 illustrate EMR system automatically generated visual cues. There were several steps in which both verbal and visual communication modalities were used and occurred concurrently. For example, in both figures 1 and 2, after an ED MD created and signed the orders, the system would create visual cue for those orders on the track board. To ensure that an ED RN recognized the orders, the ED MD also verbally communicated with the ED RN.

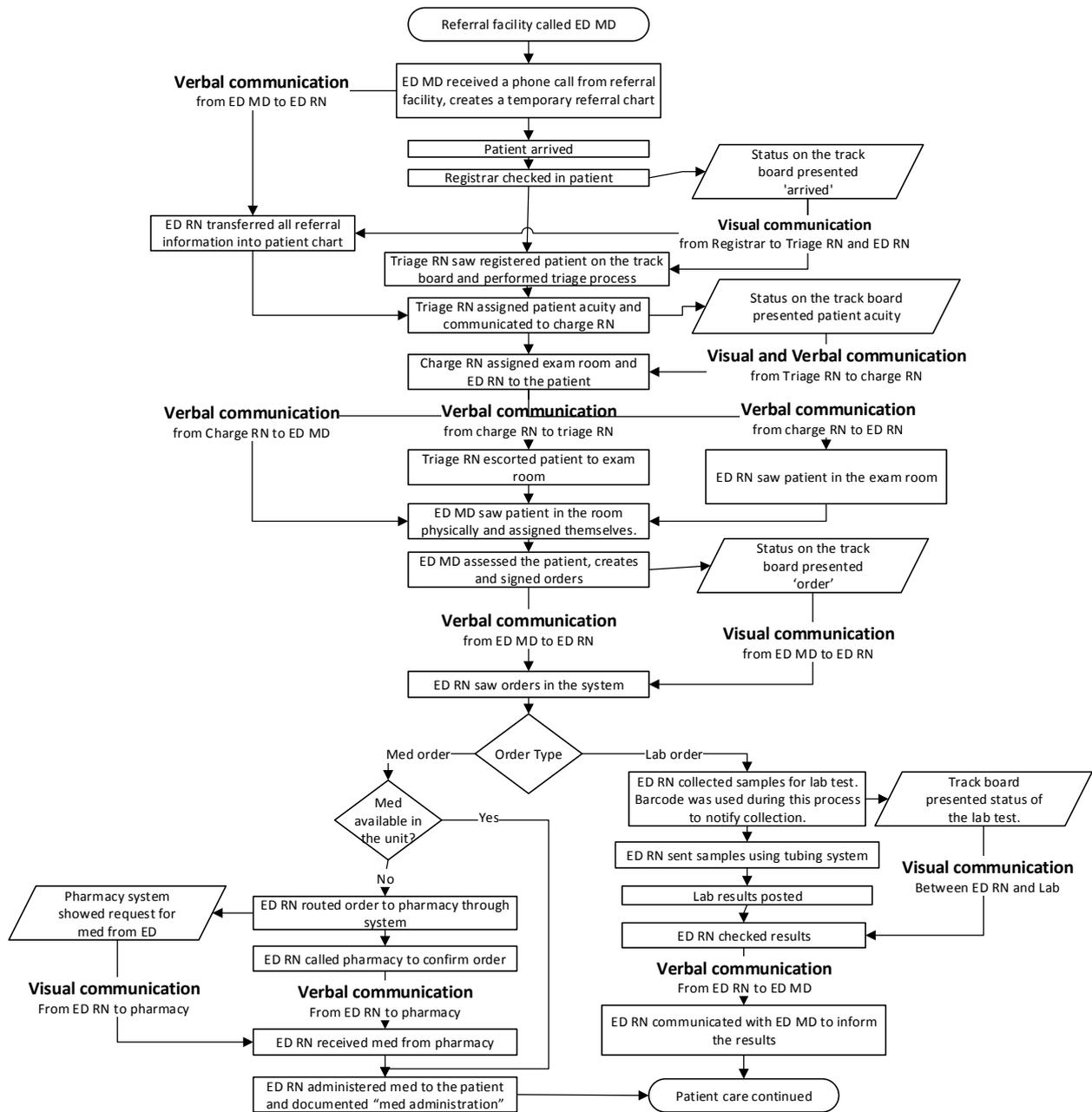


Figure 1. Pre-implementation workflow

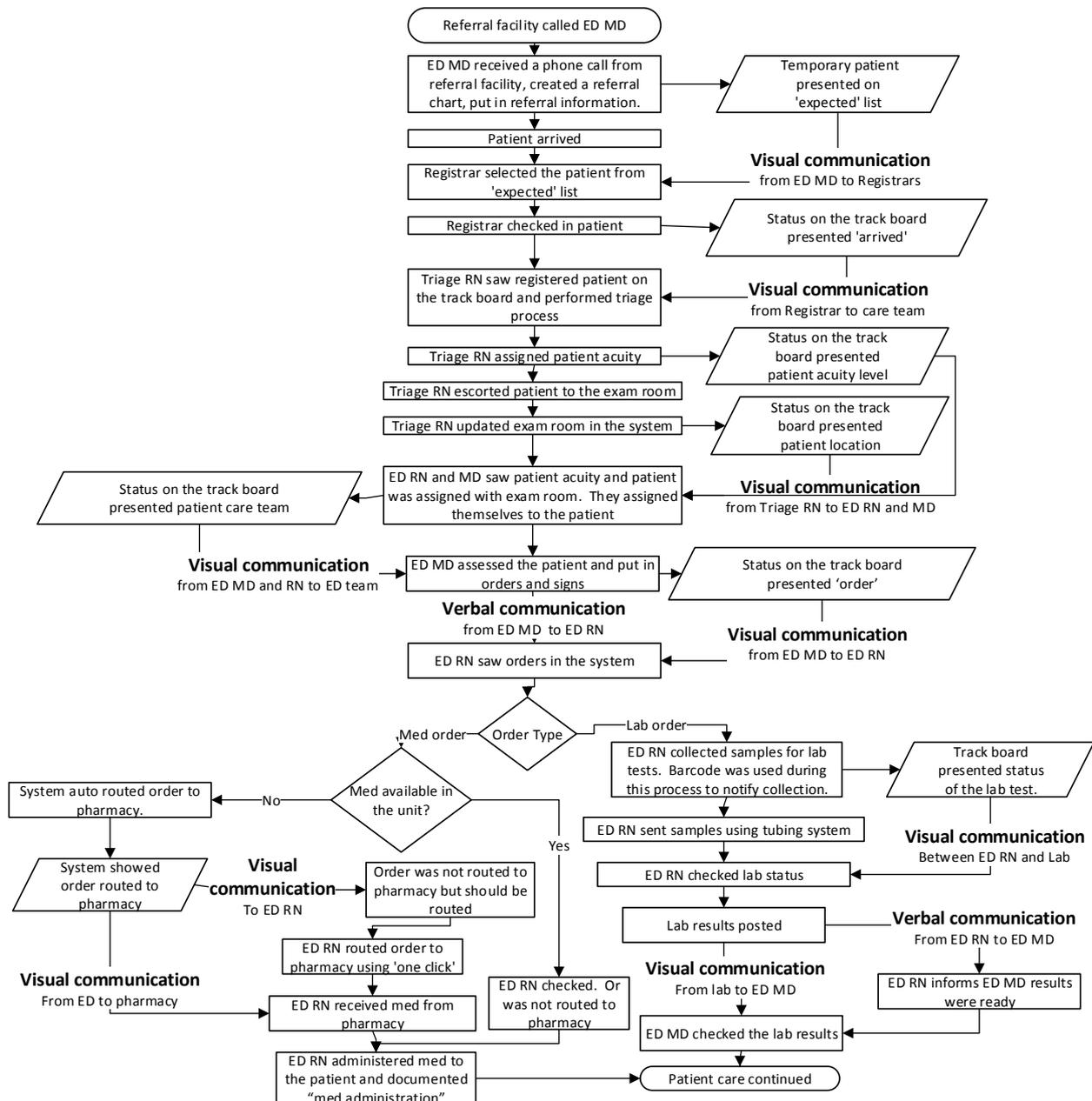


Figure 2. Post-implementation workflow

Table 1 summarizes steps in the workflow that required communication and compares communication contexts and modalities in pre- and post- implementation workflows. The first communication in pre-implementation workflow was when an ED MD **verbally** communicated to an ED RN about an expected referral patient, after s/he received a call from a referral facility. This step was not included in the post-implementation workflow; post-implementation column for this step is then highlighted in black. The second step was when an ED MD created a referral chart, which triggered a visual cue for registrars (i.e., **visual** communication from ED MD to registrars). This step was only for post-implementation. Next step, “after registrar checked in patient and system created visual cue to communication patient status,” was highlighted in grey to indicate that the step was included in both pre- and post- implementation workflow. There were a total of 8 main steps that required communication in pre-implementation workflow; 3 steps utilized verbal, 2 utilized visual, and 3 utilized both visual and/or verbal modality. Some steps required more than one communication, such as when charge RN assigned exam room for the patient, she had to

communicate with 3 groups of people (i.e., triage RN, ED RN, and ED MD). Post-implementation workflow included 10 communication steps; 1 utilized verbal, 8 utilized visual, and 1 utilized both verbal and visual modality. Four communication steps remained after implementation (highlighted in grey in table 1); all four steps mainly used visual as a communication modality. The human factors specialist thoroughly identified interface design differences for these five steps.

<b>Workflow steps that required communication and communication contexts</b>	<b>Pre-implementation</b>	<b>Post-implementation</b>
ED MD communicated to ED RN about a referral <i>(Only pre-implementation process)</i>	Verbal	
ED MD created referral chart, the system created visual cue for registrars <i>(Only post-implementation process)</i>		Visual
After a registrar checked in the patient, system created visual cue to communicate patient status (i.e., arrived) with the care team	Visual	Visual
Triage RN assessed the patient, assigned acuity level, and updated the system. System created visual cue to communicate with care team.	Visual and Verbal	Visual
Triage RN assigned an exam room for the patient and updated the system for the care team <i>(Only post-implementation process)</i> .		Visual
ED MD and ED RN assigned themselves to the patient and updated the system <i>(Only post-implementation)</i>		Visual
Charge RN assigned exam room for the patient, s/he verbally communicated with the triage RN, ED RN, and ED MD <i>(Only pre-implementation process)</i>	Verbal	
After ED MD put in orders, ED RN saw the orders in the system. ED MD verbally communicated with ED RN	Visual and Verbal	Visual and Verbal
If the lab order was placed, all lab status (e.g., order placed, lab in progress, lab finished, results posted) would show on the track board.	Visual	Visual
ED RN verbally communicated lab results to ED MD <i>(Only pre-implementation process)</i>	Verbal	
ED RN verbally communicated to ED MD that the lab results were ready to be seen <i>(Only post-implementation process)</i>		Verbal
ED MD saw alert for lab results <i>(Only post-implementation process)</i>		Visual
If the medication order was placed and pharmacy needed to fill the order, RN would route the order to pharmacy, which created a visual cue in the pharmacy system. ED RN then called pharmacy to confirm. <i>(Only pre-Implementation process)</i>	Visual and Verbal	
If a medication order was placed and pharmacy needed to fill the order, either ED RN or system would route order to pharmacy, which created a visual cue in the pharmacy system. <i>(Only post-implementation process)</i>		Visual

Note: Highlight in grey indicates the step remained after implementation. Highlight in black indicates the process did not exist for that workflow.

**Table 1.** Comparison of communication contexts and modalities in pre- and post- workflows

Table 2 compares system interfaces for these four common steps in pre- and post-implementation workflows. The first visual communication display was the display of patient status after registrar checked in the patient. In the existing EMR, patient would be highlighted in grey and moved to the top of the patient list; ‘arrived’ status is shown next to patient name. For the new EMR, patient would be attached with green dot on the track board and would disappear from the registrar’s expected referral list. There were two steps in which interfaces would critically change after the implementation: 1) display of patient acuity in which the color coding scheme would completely change; and 2) display of lab status from color coding to numeric display.

Visual display for the five common steps	Previous EMR's display	New EMR's display
Display of patient status after checked-in. (Visual communication from registrars to ED care team that patient arrived and ready to be seen)	Patient highlighted in grey and moved to the top of the patient list. Status shows "arrived"	Green dot, indicated patient arrived and checked in, would appear in front of the patient name. Patient disappeared from expected list.
Display of patient acuity (visual communication from triage RN to ED care team that the triage process was completed and acuity level was assigned)	Color dot, indicate acuity levels, appeared next to patient name. Level 1 = red; 2=blue; 3=green; 4=teal; 5=magenta	Color dot, with acuity number presented in the middle, appeared next to patient name. Level 1 = red; 2=orange; 3=yellow= 4=green; 5=blue.
Display of orders placed by ED MD (Visual communication from ED MD to ED RN). At this step, ED MD also verbally communicated to ED RN.	Drug and/or lab icon appeared on the track board indicated orders were placed	Drug and/or lab icon appeared on the track board indicated orders were placed. Icon designs were different but intuitive.
Display of lab status (e.g., order placed, lab in progress, lab finished, results posted) (visual communication between ED care team and lab).	Color dot in the lab column. Green for lab results posted, yellow for lab test done, and red for lab tests in progress.	Numeric system. For example 1/3/4 presented 1 lab result posted, 3 lab tests in progress, and 4 tests ordered in total.

Table 2. Comparison of the previous and new system interfaces for the four communication steps that remained in the workflow

#### 4. Discussion

This project focused on understanding communication contexts and modalities in the Ped ED, and changes in communication post-EMR implementation. We sought to proactively reduce EMR use errors and communication breakdown prior to the implementation. Table 1 shows 3 verbal communication steps, those actually include 5 different communications. The step in which charge RN assigned exam room for the patient, s/he had to communicate with 3 different driplines, which could create inefficient process. There were three steps in pre-implementation workflow that required both visual and verbal communication because the previous EMR system design did not promote effective communication. In the post-implementation workflow, only one step would need both communication modalities, which was when ED MD verbally communicated with ED RN after they placed orders. This seemed to be the unit's culture. Our findings were consistent with study by Esquivel et al. (2012) that EMR can play significant roles to improve communication, as seen from our project that an effective system design could reduce duplicate communication (i.e., the use of both verbal and visual communication modality). The other verbal communication required in the post-implementation workflow was to compromise a workflow change (i.e., lab results would no longer be accessible by ED RN, ED RN thus needed to communicate the lab status to ED MD to prevent delay). Our study also proved that EMR could fundamentally change the way clinicians coordinate their work activities, and communicate to deliver high-quality, and safe care (Campbell, Kramer, Kelsey, & King, 2014).

Previous study showed that there were numerous hand-offs and communication by multiple clinicians in the ED (Morey et al., 2002), and that problematic communication contexts included the communication process for orders, consultations, acuity assessment, management of surgical and medical patients, and the discharge process (Woods et al., 2008). Our findings clarified communication modalities and contexts for some of the aforementioned problematic areas. We did not extend our analysis beyond Ped ED.

Design differences were identified and addressed thoroughly in training to promote its appropriate use. Error provoking designs were addressed for short-term in training. Our analysis was performed proactively prior to the implementation. There were multiple system

redesigns to follow this analysis. Error provoking designs were address long-term using user centered redesign method.

## 5. Conclusion & perspectives

Caring for patients in Ped ED is especially prone to errors because its environment is often hectic and chaotic, with frequent workflow interruptions and communication challenges. Impulse EMR implementation in the Ped ED without careful assessment of EMR design and its impact on the workflows could inadvertently be harmful. We thus deepened our analysis into how the new EMR could affect communication in the Ped ED. Our findings showed that despite the fact that the new EMR design could potentially improve communication (i.e., more efficient and effective), some of the design changes and lack of fit to the workflow could lead to errors. With our proactive analysis, we were able to identify and mitigate these potential errors prior to implementation. Our frontline users were thoroughly trained and perceived that the new EMR had distinct advantages over the previous one. Our trainers were more prepared for the roll-out as they created contingency plans for dealing with potential use errors.

## Acknowledgement

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## The design and use of ergonomic checkpoints for healthier human care work

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### Abstract

Awareness is growing internationally of the need to apply multifaceted ergonomic measures for improving safety and health of healthcare and nursing personnel and other care providers. As practical means of facilitating the application of these measures, ergonomic checkpoints in human care work have been compiled on the basis of recent experiences in participatory approaches for improving human care workplaces. Comparing good examples from these approaches with those from participatory approaches in other work settings, ten technical areas are identified as important areas for human care work. The technical areas include materials handling, machine safety, person transfer, workstations, physical environment, hazardous agents, infection control, welfare facilities and work organization. To cover the ten areas, 60 ergonomic checkpoints are selected by focusing on low-cost ergonomic measures for improving human care work. Each checkpoint is designed to describe why and how simple actions can reduce relevant work-related risks such as overwork, musculoskeletal risks, job stress and emergencies. The applicability of these checkpoints to actual human care work settings are then confirmed by examining the results of pilot applications of action checklists comprising typical checkpoints. The effectiveness of applying the selected checkpoints in improving care work is further confirmed by examining their relevance to basic ergonomic principles suited to improving care work. By referring to recent intervention studies on effective steps taken for participatory application of ergonomic and stress prevention measures, the validity of the proposed checkpoints in improving human care work is discussed. Main contributing actors leading to positive achievements in taking these steps are simple procedures aimed at multifaceted risk reduction, a clear focus on locally feasible improvements and the use of action oriented tools such as action checklists adjusted locally. The compiled checkpoints are found suitable to ergonomic improvement of human care work.

**Keywords:** human care work, ergonomic checkpoints, participatory programmes, low-cost improvements, stress prevention.

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### 1. Introduction

Human care workers, including healthcare and nursing personnel and other care providers, are faced with various work-related risks in different local settings. Awareness is growing internationally that the broad-ranging impacts of their work on safety and health at work need to be addressed by facilitating the implementation of multifaceted ergonomic measures (Bourbonnais et al., 2006; Kogi, 2008; Scott et al., 2010; Dul et al., 2012; Yoshikawa, 2013; Kogi et al., 2016). Learning from the wide application of ergonomic checkpoints, compiled

through collaboration between the International Ergonomics Association (IEA) and the International Labour Office (ILO), it is useful to present low-cost actions applying basic ergonomic principles in the form of ergonomic checkpoints also in human care work (Yoshikawa et al., 2006; Lee et al., 2009; ILO, 2010, 2012).

The practical ways to apply ergonomic measures in human care work have been compiled by a working group of the Human Ergology Society (HES), an affiliated member of the IEA, in the form of serial ergonomic checkpoints. This working group has edited draft 60 ergonomic checkpoints in human care work as a contribution to the IEA work. The new checkpoints need to be examined to know their wide applicability in this sector. The initial draft checkpoints were examined by a review meeting jointly organized by the IEA and the HES during the 19th Triennial Congress of the IEA 2015 held from 19-24 August 2015 in Melbourne. This review meeting confirmed the usefulness of the compiled checkpoints for field use. It has been suggested to complete the editing of the proposed checkpoints by examining their practical applicability. It is therefore useful to examine the validity of the proposed checkpoints and know the practical steps to apply action-oriented training tools based on the checkpoints.

Ergonomic checkpoints, published by the joint initiative of the IEA and the ILO, have been widely applied in both industrially developed and developing countries (ILO, 2010, 2014). The checkpoints present simple ergonomic measures that can reduce safety and health risks at work and improve quality of working life in various work settings. The original IEA/ILO Ergonomic Checkpoints, first published in 1996 and revised in 2010, have been translated to different languages and have contributed to spreading action-oriented training in varied industrial settings (ILO, 2010; Kogi, 2012). This led to the subsequent publications of the ILO Stress Prevention at Work Checkpoints (ILO, 2012). Similarly developed ergonomic checkpoints covering multifaceted work-related risks are in use in construction sites, home-based workplaces, waste management, seafarers and health care workplaces (Itani et al., 2006; Yoshikawa & Kogi, 2010; Kogi et al., 2016). It is therefore useful to design and apply systematically compiled ergonomic checkpoints in human care work for their wider application in healthcare, nursing and other human care settings.

The design principles of these serial ergonomic checkpoints are important. All these checkpoints are compiled for their direct use by workers and managers in different local conditions and therefore keep the presentation format focusing on practical low-cost ergonomic measures and providing guidance on selecting and applying locally feasible measures. They are put together in the action-oriented format so that their users, i.e., workers and managers, can select immediate actions having real impact on existing workplace conditions. An additional merit of using the ergonomic checkpoints is to formulate action-oriented tools that can be utilized by workers and managers in assessing existing workplaces and implementing practical improvements. The locally adjusted design and use of 'action checklists' listing locally feasible ergonomic improvements is particularly useful. These composite features of ergonomic checkpoints are addressed in compiling the checkpoints in human care work. The emphasis of this paper is therefore placed on multifaceted low-cost improvements, their application through the use of corresponding action checklists and the workplace-level processes for applying locally feasible improvements that can have real impact.

## **2. Objectives and Methods**

In promoting the wide application of ergonomic measures for improving human care work, it is important that workers and managers of human care services are able to examine their own workplace conditions and propose feasible improvement actions. The editing process of

compiling ergonomic checkpoints in human care work by the working group within the HES is therefore examined to assess the design procedures and the applicability of the compiled ergonomic checkpoints in human care work. The contents of the newly assembled checkpoints are studied by comparing them with the IEA/ILO Ergonomic Checkpoints (2010) and the recent action checklists used for improving workplace conditions in small enterprises, agriculture and various industries or for preventing stress at work.

The action checklists compared include those utilized in workplace improvement programmes applying participatory methods, such as WISE (work improvement in small enterprises) (ILO, 2004), WIND (work improvement in neighbourhood development in agriculture) (ILO, 2014) and POSITIVE (participation oriented safety improvement by trade union initiative) (Kawakami et al., 2004) programmes as well as the Mental Health Action Checklist (Yoshikawa et al., 2007) and the checklist tested by the HES (Japan) working group. The composition of these checklists and the participatory steps taken in applying them in actual working situations are compared and discussed.

The format of presenting the new checkpoints and their validity in guiding practical risk-reducing measures at human care work are then examined in view of pilot activities applying the proposed checkpoints. Attention is paid to participatory steps utilizing these checklists through group work of participants. The results of intervention studies on the effectiveness of participatory steps in reducing workload and job stress are also referred to. Main factors contributing to the effectiveness of applying these checkpoints in human care work settings are discussed.

### **3. Results & Discussion**

#### **3.1 Ergonomic areas relevant to improving human care work**

In editing the new checkpoints applicable to various human care settings, the working group has collected good ergonomic practices in these settings and identified commonly relevant technical areas. The newly proposed ergonomic checkpoints in human care work thus cover a broad range of ergonomic measures. These broad-ranging technical areas are covered also by the sample action checklist presented in the annexes of the new checkpoints. It is useful to compare these measures with the composition of the IEA/ILO Ergonomic Checkpoints (ILO, 2010). Table 1 compares the distribution of the items in different technical areas among the action checklists utilized in WISE (small enterprises), WIND (agriculture) and POSITIVE (various industries) programmes as well as the Mental Health Action Checklist and the new human care work checklist.

Technical area in the IEA/ILO Ergonomic Checkpoints	Number of corresponding items in the checklist					
	WISE (2004)	WIND (2003)	POSITIVE (2011)	Mental Health Action Checklist	Human care work checklist	
Materials handling	9	6	7	1	3	
Workstations and tools	5	6	8	2	3	
Machine safety	7	5	6	1	3	
Physical environment	11	6	11	3	6	
Welfare facilities	8	5	6	1	2	
Work organization	3	3	4	2	3	
Not in the IEA/ILO Checkpoints	Communication	2	11	12	7	1
	People transfer				3	
	Infection control				3	
	Preparedness				4	3
	Other areas				9	
Total number in the checklist	45	42	54	30	30	

WISE: for small enterprises; WIND: for small-scale farmers; POSITIVE: for trade unions in industries.

**Table 1.** Relations between the IEA/ILO Ergonomic Checkpoints and items in action checklists

These checklists for participatory workplace improvement activities commonly cover the main technical areas within the ILO/IEA Ergonomic Checkpoints. The Mental Health Action Checklist additionally covers the areas corresponding to communication, emergency preparedness and other areas including social support. In the case of the sample human care work checklist being newly tested, all these technical areas are covered since its emphasis is placed on multifaceted ergonomic and stress-related aspects. It also includes check items specific to human care settings such as people transfer and infection control. These wide areas covered by the human care work checklist reflect the broad-ranging good practices in human care work collected by the HES working group. It is therefore reasonable that the new human care work checkpoints cover the broad technical areas indicated in Table 2. The ten technical areas of the proposed checkpoints include materials storage and handling, machine and hand-tool safety, people transfer, workstations, physical environment, hazardous agents, infection control, welfare facilities, emergency preparedness and work organization. As indicated by the examples of measures, these ten technical areas are concerned with physical, mental and social aspects relevant to safety and health risks in human care services.

Technical area	Examples of measures	Technical area	Examples of measures
1. Materials storage and handling	- racks, carts, labels	6. Hazardous substances and agents	- isolation, shielding, labelling
2. Machine and hand-tool safety	- guards, safety devices, wiring	7. Infection control	- hand hygiene. Safe procedures, protective gear
3. People transfer	- mobile equipment, lifters	8. Welfare facilities	- toilets, resting, meetings
4. Workstations	- reach, height, coding	9. Emergency preparedness	- plans, anti-harassment measures, extinguishers
5. Physical environment	- lights, indoor climate, partitions	10. Work organization	- schedules, stress prevention

**Table 2.** Ten technical areas identified for ergonomic checkpoints in human care work

### 3.2 Types of low-cost improvements for human care work

The experiences in applying WISE, WIND and POSITIVE checklists and the Mental Health Action Checklist clearly show the importance of focusing on low-cost improvement actions that have real impact on reducing work-related risks in each work setting. These experiences

are well taken into account in assembling the 60 checkpoints for the ten technical areas. A special attention has been paid to selecting low-cost improvement actions that reflect basic ergonomic principles in respective technical areas. Table 3 shows these practical and basic ergonomic principles incorporated in the typical low-cost actions of the compiled checkpoints. These basic ergonomic principles may help achieve the reduction of multifaceted work-related risks. The application of these basic ergonomic principles can lead to improvements in physical, mental and social aspects of human care work. It should be noted that the low-cost improvements to be planned by applying the checkpoints may have limited impact in real working situations. Nevertheless, these improvements reflecting basic ergonomic principles may promote the stepwise progress in each work situation.

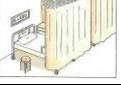
Technical area	Basic ergonomic principles	Examples of the impact
A. Materials handling	Organized storage, easy transport	Less physical demands
B. Machine-tool safety	Guarding, safe equipment/wiring	Reduced accident risks
C. People transfer	Proper transfer procedures	Reassured safe procedures
D. Workstations	Natural posture, efficient operations	Efficient work with less load
E. Physical environment	Good climate, isolating hazard sources	Comfortable, barrier-free space
F. Hazardous agents	Proper isolation/shielding, labels	Reduced contacts with hazards
G. Infection control	Safe procedures, specific protection	Reduced risks of infection
H. Welfare facilities	Sanitary/resting facilities, recreation	Refreshing effects and relations
I. Preparedness	Emergency/anti-harassment planning	Shared emergency/violence steps
J. Work organization	Restful schedules, better communication	Shared plans for better teamwork

**Table 3.** Practical basic ergonomic principles extracted from the checkpoints in human care work

It is of particular interest that these basic ergonomic principles in multiple technical areas can be translated into low-cost types of ergonomic improvements also in human care work. This fact is confirmed by the pilot activities in healthcare and nursing workplaces. The action checklists used in these pilot activities contain low-cost ergonomic improvement actions in all these technical areas.

### 3.3 Participatory action-oriented steps for improving each workplace

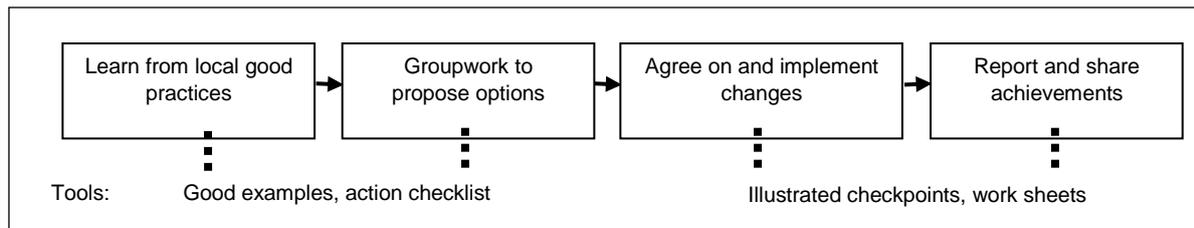
The pilot activities applying the new checkpoints have shown the effectiveness of the steps taken for applying the compiled measures. The planning of low-cost improvements is shown to be facilitated through the use of an action checklist listing typical improvement actions extracted from the compiled ergonomic checkpoints. Examples of the check items included in the action checklist for human care work designed by the HES working group are shown in Figure 1. Since each of the 60 ergonomic checkpoints includes some simple improvement options with illustrations showing improved workplaces after applying the options, the action checklist also contains typical illustrations corresponding to the check items.

Technical area	Typical check item and its illustrated example	Do you propose action?
A. Materials storage and handling	Use multi-level racks and small containers to minimize manual transport of materials. 	[ ] No [ ] Yes- └─ [ ] Priority
B. Machine and hand-tool safety	Establish safe handling procedures of sharps and use safety devices and safe disposal containers. 	[ ] No [ ] Yes- └─ [ ] Priority
C. People transfer	Utilize safe lifting or transferring devices when lifting of the person is involved. 	[ ] No [ ] Yes- └─ [ ] Priority
D. Workstations	Adjust the working height for each worker at elbow level or slightly below it. 	[ ] No [ ] Yes- └─ [ ] Priority
E. Physical environment	Use partitions, curtains and other arrangements for protecting privacy of persons cared. 	[ ] No [ ] Yes- └─ [ ] Priority
F. Hazardous substances and agents	Label and store properly containers of hazardous chemicals to communicate warnings and to ensure safe handling. 	[ ] No [ ] Yes- └─ [ ] Priority
G. Infection control	Ensure regular and proper use of personal protective equipment adequate for protecting potential infections. 	[ ] No [ ] Yes- └─ [ ] Priority
H. Welfare facilities	Provide refreshing resting facilities and, for night shift workers, restful napping facilities. 	[ ] No [ ] Yes- └─ [ ] Priority
I. Emergency preparedness	Establish emergency plans to ensure correct emergency operation, easy access to facilities and rapid evacuation. 	[ ] No [ ] Yes- └─ [ ] Priority
J. Work organization	Arrange working schedules avoiding excessive work hours and securing enough resting periods and short breaks. 	[ ] No [ ] Yes- └─ [ ] Priority

**Figure 1.** Typical check items incorporated in an action checklist listing low-cost improvement actions corresponding to the proposed ergonomic checkpoints in human care work

The action checklist asks each participant to tick either ‘No’ or ‘Yes’ to the question ‘Do you propose action?’ for each check item. This is practical since each check item is expressed as an improvement action for changing the existing conditions. The answer ‘No’ means that the action is not proposed because that action is already implemented or not applicable. The check items ticked by ‘No’ may mean that existing conditions may imply already implemented good practices. The answer ‘Yes’ means that the action is proposed for improving the existing conditions. After going through all the check items, the participants may select some of the ‘Yes’ items as ‘Priority’ items. In this way, the checklist can be used to identify good practices and propose necessary actions.

The participatory steps for applying the ergonomic checkpoints through the use of such an action checklist may consist of the four stages shown in Figure 2. The initial steps are concentrated on learning from local good practices and organizing group work to propose locally feasible options for improving existing workplace conditions. As in other participatory action-oriented programmes, the participatory activities then proceed to group work for agreeing on immediate improvement actions that are implemented and reported.



**Figure 2.** Participatory steps commonly valid for applying the ergonomic actions in human care work

The use of the action checklist listing feasible improvement actions can facilitate these participatory steps, because the participants can relatively easily understand the types of actions to be taken and select priority actions that have real impact on their existing working conditions. In this way, the use of the action checklist illustrating locally feasible actions can facilitate the participatory steps aimed at concrete results. Through the participatory steps utilizing the local good practices and an action checklist, the participants can plan and implement some locally feasible improvements selected from multiple technical areas. The compiled ergonomic checkpoints combined with an action checklist can thus help the participants understand available improvement options and propose simple actions similar to some of these options indicated in the action checklist.

### 3.4 Supporting improvement steps at varied human care services

These results suggest the importance of utilizing the proposed ergonomic checkpoints as practical means of facilitating participatory steps for proposing and implementing appropriate measures in varied human care services. The main contributing factors of the reported achievements include simple procedures aimed at multifaceted risk reduction, a clear focus on feasible improvements and the locally adjusted use of action-oriented tools. The close link between the proposed checkpoints and the participatory tools such as good-practice examples and action checklists is particularly noteworthy. Each checkpoint is expressed as an improvement action to be taken by workers and managers of the workplace concerned. This makes it easy to use the ergonomic checkpoints for identifying available good-practice examples or for formulating a locally adapted action checklist. The merit of this link is further confirmed through pilot activities for participatory steps in healthcare and nursing services. The low-cost nature of the improvement actions compiled in the action checklist is apparently favourable for implementing feasible improvements.

A series of intervention studies on participatory programmes applying ergonomic checkpoints have examined the effectiveness of these programmes. The results of selected intervention studies and review papers on these studies are indicated in Table 4. It is confirmed that the participatory application of ergonomic checkpoints can lead to reduced workload, less musculoskeletal disorders and improved mental health among the workers concerned. As some of these studies and reviews refer to healthcare and nursing services, it is suggested useful to organize participatory programmes utilizing action checklists based on these checkpoints.

References	Target	Effects confirmed
Kogi et al., 2003	Small enterprises	Reduced muscle load and disorders
Itani et al., 2006	Participatory projects	Reduced physical load
Kobayashi et al., 2008	Small enterprises	Decreased stress scores, better work life
Tsutsumi et al., 2009	Assembly line work	Better mental health, job performance
Lee et al., 2009	Hospital nurses	Decreased musculoskeletal disorders
Yoshikawa et al., 2013	Participatory steps	Multifaceted outcomes in stress reduction

**Table 4.** Intervention studies and reviews confirming the effectiveness of applying action checklists

The sustainability of the participatory activities aimed at feasible multifaceted improvements is also proven by the follow-up results reported in these studies. It is suggested that the wide application of the ergonomic checkpoints in human care work, combined with the use of locally adjusted action checklists, may contribute to the promotion of workplace improvement activities in many countries.

#### 4. Conclusion & perspectives

For facilitating multifaceted improvements in human care work, it is useful to design and apply action-oriented tools incorporating low-cost options extracted from the new checkpoints. As indicated from pilot activities, local good examples and 20-30 item action checklists are useful. Recent intervention studies confirm reductions in workplace risks through participatory programs utilizing these tools. Main contributing factors leading to positive achievements are (a) simple procedures aimed at multifaceted risk reduction, (b) a clear focus on locally feasible improvements and (c) the use of locally adjusted action-oriented toolkits. It is recommended to design and use the ergonomic checkpoints in human care work by compiling multifaceted ergonomic measures. The practical use of these checkpoints will facilitate participatory interventions in the various workplaces of this sector.

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## The Irish Paediatric Early Warning System (PEWS): Protocol for a national service evaluation of hospital safety culture and situation awareness in acute paediatric hospitals in Ireland

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### Abstract

Little is known about the impact of early warning systems on the knowledge and confidence of clinicians to detect and respond to clinical deteriorating children. Alongside this, despite increasing evidence highlighting the importance of integrating situation awareness interventions into healthcare cultural contexts and patient safety/risk fora to supplement early warning scoring systems, to date, understanding the current culture of safety in paediatric settings in Ireland is limited. Consequently, the aim of this service evaluation is to establish clinicians' (doctors and nurses) perceptions of their ability, and confidence, to detect and deal with clinically deteriorating children and their perceptions of situation awareness and safety culture in acute paediatric hospitals in Ireland in advance of the implementation of an Irish national Paediatric Early Warning System (PEWS). A mixed method formative service evaluation is being undertaken comprising of a series of semi-structured interviews with clinicians' in three paediatric hospital settings and a quantitative phase involving a descriptive cross-sectional survey with clinician's in seven paediatric hospital settings nationally. Participants are required to be clinicians' (nurses and doctors) working full or part-time on the inpatient paediatric units/wards in the paediatric hospital study sites/units. Data collection is currently complete and the results are in the process of analysis. The qualitative (interview) data is being subjected to thematic analysis and the quantitative data has been entered into SPSS version 23 on which descriptive statistics (including frequencies, means, and standard deviations) are been performed, as appropriate. The baseline data gleaned from this evaluation will provide a platform from which comparison may be made post implementation of the national Irish PEWS. We hope this will in some way inform future directions and recommendations for the establishment of safety processes in inpatient units treating paediatric patients across Ireland.

**Keywords:** safety culture, paediatrics, hospital, clinical deterioration, early warning system

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### 1. Introduction

This presentation reports on an ongoing service evaluation commissioned by the Irish Department of Health, the aim of which is to collate baseline data to establish clinicians' (doctors and nurses) perceptions of their ability, and confidence, to detect and deal with clinical deteriorating children, in addition to, clinicians' perceptions of situation awareness and safety culture in acute paediatric hospitals in Ireland in advance of the implementation of an Irish National Paediatric Early Warning System. It builds on substantial ongoing national

work in relation to the implementation of an Irish National Paediatric Early Warning System which arose in response to a report into patient safety investigations by the Health Information and Quality Authority (2013) from which the Irish Minister for Health requested that the Department of Health National Clinical Effectiveness Committee commission and quality assure a number of National Clinical Guidelines; including an early warning scoring system for implementation in paediatric healthcare settings nationally.

## **2. State of the art**

Paediatric Early Warning Systems (PEWS) are generally defined as bedside tools to help alert staff to clinically deteriorating children by periodic observation of physiological parameters, generation of a numeric score (early warning scoring tool) and predetermined criteria for escalating urgent assistance (escalation protocol) with a clear framework for communication (e.g. ISBAR). In using these physiological ‘track and trigger’ systems the goal is to ensure timely recognition of children with potential or established critical illness and to ensure timely attendance from appropriately skilled staff. Clinician education and training is crucial to ensure these observation monitoring systems are used to their full potential. However, there has been little evaluation of the impact of these ‘track and trigger’ tools on the knowledge and confidence of clinicians to detect and respond to a clinical deteriorating child (Lambert *et al.* 2014).

While available evidence highlights positive directional trends in improving clinical based outcomes (e.g. reduced cardio-pulmonary arrests, earlier intervention and transition to PICU) for children who are clinical deteriorating, findings from the systematic literature review on early warning systems for use in acute paediatric healthcare settings drew attention to the importance of recognising PEWS as much more than a numerical score; rather it is one piece of a complex intervention supporting clinical judgement and situation awareness (Lambert *et al.* 2014).

PEW scoring systems should never replace clinical judgement, instead through creation of a common language they should stimulate a heightened sense of situation awareness, enhance multi-disciplinary team work, communication and confidence in recognising, reporting and making decisions about clinical deteriorating children. Indeed, there is a strong evidence base for human factor significance in healthcare systems with increasing evidence highlighting the importance of the integration of situational awareness interventions into healthcare cultural contexts and patient safety/risk fora to supplement early warning system scores (Brady and Goldenhar 2013, Brady *et al.* 2013). However, to date understanding the current culture of safety in paediatric settings in Ireland has been limited.

## **3. Objectives and Methods**

The specific objectives of this service evaluation, as set out in the Department of Health tender document, are: (1) to establish clinicians’ (doctors and nurses) ability, and confidence, to detect and deal with a sick or clinical deteriorating child and (2) to evaluate patient safety culture, teamwork, situation awareness, leadership, prediction and planning, communication and decision-making within the context of caring for a child at risk of deterioration from the perspectives of clinicians working in acute paediatric inpatient hospital settings in Ireland.

A mixed method formative evaluation approach is being employed. This is comprised of a qualitative phase involving a series of semi-structured individual and focus group interviews with clinicians’ in three paediatric hospital settings and a quantitative phase involving a descriptive cross-sectional survey with clinician’s in seven paediatric hospital settings in Ireland. Ethical approval was granted by the relevant University Research Ethics Committee

and all respective local Research Ethics Committee for each of the seven hospital study sites. Access to each of the seven hospital sites was negotiated in writing with the relevant local hospital governance structures e.g. general manager, chief executive officer, directors of appropriate services such as medical clinical directors and divisional nurse managers.

For the qualitative phase, in our protocol, we proposed to conduct a total of three focus group interviews (with 8-10 clinicians' at three paediatric hospital sites) and two individual interviews (with one nursing and one medical leader across three paediatric hospital sites) with the total of participants estimated to be in the range of 30-36. However, as a consequence of staff availability and release, competing clinical demands, and difficulty getting a multi-disciplinary group of staff together, the conduct of focus groups with staff nurses and NCHDs and individual interviews with clinical leaders was inhibited. As a result, we conducted a combination of individual and focus group interviews separately with staff nurses/nurse leaders and separately with non-consultant hospital doctors/consultant doctors. In total, we conducted 6 focus group interviews (with 2-3 clinicians' in each focus group) and 5 individual interviews. The total sample for this qualitative component comprised of 33 clinicians', inclusive of 15 nurses and 18 doctors across 3 study sites/units. Both the individual and focus group interviews were directed with a semi-structured interview guide developed by the research team in liaison with members of the PEWS steering group. The individual interviews lasted from 16 to 26 minutes. The majority of the focus group interviews lasted from 25 to 38 minutes; with one focus group lasting 55 minutes. All interviews were digitally recorded (with clinician consent) for later transcription and analysis.

For the quantitative phase, the survey questionnaire was developed using exiting validated instruments, including; the Safety Attitudes Questionnaire (Sexton et al. 2006) for measurement of patient safety culture according to 30-items capturing frontline clinician's attitudes on teamwork climate, safety climate, perceptions of management, job satisfaction, working conditions and stress recognition and the Recognition and Management of Deteriorating Patients Questionnaire (Featherstone et al. 2005) to rate clinicians experience, knowledge and confidence levels in recognising and managing deteriorating patients. We also captured demographic information relating to respondent gender, staff position, years working in current ward/unit, years working in paediatrics, highest paediatric qualification, and any previous training in relation to child clinical deterioration. The survey questionnaire was piloted prior use with clinicians not involved in the study to establish clarity of instructions, question readability and length of time to complete. In liaison with the principal investigator, nominated gatekeepers at each hospital study site were responsible for the distribution and collection of the paper questionnaire locally within a 6-8 week timeframe. At the outset of the evaluation we estimated a total distribution of 285 questionnaires across seven paediatric hospital settings in Ireland with an estimated response of 142 clinicians (50% response rate). We achieved a distribution of 303 questionnaires across the seven paediatric hospital settings with a total response number of 188 clinicians (127 nurses and 61 doctors), hence achieving an overall response rate of 62% (this ranges from 48%-78% across the seven study sites) (see Table 1).

Site (coded)	Number of responses	Number of questionnaires distributed	% Response rate	Percent of whole sample
1	33	43	76	17.6
2	25	46	54	13.3
3	24	50	48	12.8
4	30	52	58	16.0
5	12	18	67	6.4
6	32	53	60	17.0
7	32	41	78	17.0
Total	188	303	62	100.0

**Table 1.** Responses and response rates per site (unnamed)

#### **4. Results and Discussion**

Data collection is currently complete and the results are in the process of analysis. The qualitative (interview) data is being subjected to thematic analysis drawing on Braun and Clarke's (2006) six-phased framework. Preliminary findings indicate five emergent themes including; (i) the process of recognizing the deteriorating child; (ii) listening to parent concern; (iii) escalating and responding to the deteriorating child – including barriers and facilitators; (iv) practices to support the creation of a safety culture for children at risk of deterioration and (v) anticipated expectations of PEWS. The quantitative data has been entered into SPSS version 23 on which descriptive statistics (including frequencies, means, and standard deviations) are been performed, as appropriate. Frequency data on clinician (both nurse and doctor profession) experience, knowledge and confidence on recognising and managing deteriorating patients will be presented, alongside demographics of the sample. Safety attitudes will be assessed across all six domains of safety culture (i.e. teamwork, safety climate, job satisfaction, stress recognition, work conditions and perceptions of management at both unit and hospital level) for the whole sample, by hospital study site (for any notable differences) and for demographics such as profession (i.e. nurses and doctors), length of time working in paediatrics, length of time working on current paediatric ward/unit and/or training attended in relation to child clinical deterioration).

#### **5. Conclusion & perspectives**

This service evaluation provides an opportunity for clinicians' to share their expertise and experience of caring for, recognising and responding to clinically deteriorating children, as well as their perceptions of safety culture and situation awareness in acute paediatric hospitals in Ireland in the context of caring for clinically deteriorating children. With limited previous evaluation on clinician experience, knowledge and confidence in detecting and responding to clinically deteriorating children and limited understanding of the safety culture of paediatric inpatient services in Ireland, and with Ireland leading the way on a the implementation of a national PEWS, this baseline data will provide a platform from which comparison may be made post implementation of the national PEWS. We hope this will in some way inform future directions and recommendations for the establishment of safety processes in inpatient units treating paediatric patients across Ireland.

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## Patient and public involvement in national clinical effectiveness processes: a systematic review

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### Abstract

Ensuring that clinical effectiveness processes (i.e. clinical practice guidelines and audit) reflect the needs and concerns of patients may help translate recommendations into practice. However, uncertainty exists on how best to integrate patient and public involvement (PPI) in clinical effectiveness processes (CEPs). This review systematically reviewed available evidence on PPI in the development and governance of national CEPs. Drawing on the Centre for Reviews and Dissemination guidance for undertaking systematic reviews in healthcare and the Preferred Reporting in Systematic Reviews and Meta-Analysis criteria we used a comprehensive search methodology to retrieve published and unpublished evidence nationally and internationally; including electronic databases, grey literature, clinical audit and clinical guidelines organizations. Eligible documents had to refer to PPI in the development, and or governance, of CEPs at a national, or equivalent, level. Data were extracted on PPI benefits, barriers, enablers, approaches, supports and evaluation in CEPs. Narrative synthesis was employed. From a total screening of 2,515 documents, 41 documents were identified as eligible for inclusion in the review. Of these 41 documents, 13 were descriptive papers, 7 were primary research studies, 7 were toolkits/reference manuals, 6 were secondary reviews, 3 were evaluation studies, 2 were protocols, 2 were policy/strategy documents and 1 was a research briefing. The review revealed evidence that PPI does take place in CEPs internationally. However, robust empirical evidence on which PPI strategy or approach is most effective was limited. Despite a lack of empirical evidence, the documents appraised in this review do provide baseline data and valuable insights into the complex process of integrating PPI into CEPs. Further research is needed to establish the effectiveness of different PPI programs used in CEPs. Better evaluation of PPI approaches in CEPs could potentially enhance the wider acceptance and development of PPIs if seen to be effective.

**Keywords:** patient, public, involvement, clinical guidelines, clinical audit

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### 1. Introduction

This presentation reports findings from a Department of Health (Ireland) commissioned systematic review with the remit of identifying available evidence (published and unpublished) to support, or not, public and patient (defined as patient or patient advocate) engagement/involvement in the development and governance of national clinical effectiveness processes (CEPs).

## 2. State of the art

There is growing consensus about the crucial role of patient and/or patient representative, public advocate involvement in CEPs, including clinical guideline development and audit processes. This is important as health professionals perspectives on healthcare processes, priorities and outcomes may differ from the perspectives and priorities of patients. Ensuring that CEPs reflect the needs and concerns of patients may help with achieving the translation of recommendations into clinical practice. However, difficulties can ensue in making patient and public contribution effective as it remains unclear on how best to conduct this process of lay stakeholder engagement in the context of clinical practice guidelines and clinical audit processes. If the goal of involving patients and the public in CEPs is enhanced quality in health care then there is a need to understand the design, processes and mechanisms of PPI in CEP.

## 3. Objectives and Methods

The specific objectives of the review, as outlined in the tender document by the Irish Department of Health who commissioned the review, were to;

1. Identify the available evidence on the benefits of patient engagement for clinical practice generally, and, more specifically, in clinical effectiveness processes
2. Ascertain, from the evidence sourced, what barriers and enablers exist to patient engagement for clinical practice generally and, more specifically, in clinical effectiveness processes
3. Synthesis the evidence on the clinical effectiveness processes that patients are engaged in; including
  - i. Summary of approaches used e.g. consultation, committee membership etc.
  - ii. Describe the reported benefits and weaknesses of each approach
4. Synthesis the evidence on the methods and systems, including training, that are in place to engage and support patients in the development and governance of the CEPs of clinical audit and clinical guidelines at national (or equivalent) level
5. Identify what measurement or evaluation has occurred in relation to patient engagement or the systems and methods used to support patient engagement.

The review was conducted and reported in accordance with the Centre for Reviews and Dissemination (2008) guidance for undertaking systematic reviews in healthcare and the Preferred Reporting in Systematic Reviews and Meta-Analysis (PRISMA) criteria (Moher et al. 2009), as far as possible. Alongside having an expert by experience as a key member of the review team an Expert by Experience Advisory Group was established prior to commencement of the review with the remit to offer expertise through lived experience, patient advocate and service user involvement expertise on considering the emergent evidence on PPI in CEPs.

A comprehensive search methodology was used to retrieve published and unpublished evidence nationally and internationally; including electronic databases, grey literature, clinical audit and guidelines organizations. We also scanned bibliographies of all included documents and identified any other relevant information on unpublished and ongoing work by contacting experts in the field. To be included eligible papers had to refer to PPI in the development, and or governance, of national CEPs; inclusive of clinical audits and guidelines at a national, or equivalent, level. No study design limits were applied and we included primary and secondary research, descriptive pieces and reference manuals, toolkits, policies and strategies produced by national, government and/or other relevant organizations with remit for clinical guideline and audit processes.

A two-stage screening process was undertaken where titles, abstracts and full text (as appropriate) of potentially eligible documents were assessed independently by two reviewers with any discrepancies resolved by discussion with a third reviewer. Duplicate data extraction was also conducted by two independent reviewers with any discrepancies resolved by consensus with a third reviewer. Initially data was extracted on the characteristics of the document including bibliographic reference, aim, design/type of document and sample/methods as appropriate. Following this, a table mapping each document to the review objectives of benefits, barriers, enablers, approaches, support and evaluation was developed to assist with data extraction from each document according to each of the review objectives.

To take account of diverse study design, we used three appraisal instruments to quality assess primary and secondary research studies including; the critical appraisal skills programme (CASP) tool for qualitative studies, a modified version of an appraisal tool designed by Tsimicalis et al. (2005) for quantitative studies and AMSTAR (A Measurement Tool to Assess Systematic Reviews) for secondary review papers. Owing to the heterogeneity of evidence retrieved it was not possible to conduct a meta-analysis and/or a meta-synthesis, therefore results were summarized narratively according to the review objectives.

#### **4. Results and Discussion**

From a total screening of 2,515 documents, we identified 41 documents as eligible for inclusion in the review. Of these 41 documents 13 were discursive/descriptive/opinion pieces, original 7 were primary research studies, 7 were toolkits/reference manuals, 6 were secondary review papers, 3 were evaluation studies, 2 were protocols, 2 were policy/strategy documents and 1 was a research briefing. The results of the quality assessment of the 13 primary and secondary research studies found the majority of studies to be of moderately high quality, despite some limitations of the appraisal tools used. Quality ratings are representative not only of study quality but are also reflective of methodological reporting and the match between the quality appraisal tool and the design of the research studies.

This review revealed evidence that PPI in national CEP does take place internationally. However, robust empirical evidence on which PPI strategy or approach is most effective was limited. The majority of documents reviewed reported on PPI in clinical guideline development with a dearth of data on PPI integration in clinical audit processes. In considering the review objectives, some of the main findings identified are summarized below.

##### *Benefits of PPI in CEPs*

Despite a general consensus that patient and public representatives should be involved in CEPs, the added benefits of PPI in CEPs has yet to be established empirically. Notwithstanding this, the difficulty, or perhaps impossibility, of examining the effects of patient participation using randomized controlled trials was acknowledged, in addition to, the fact that decision-making processes may need to be studied in different ways.

##### *Barriers and facilitators to PPI in CEPs*

The review identified a number of potential barriers and facilitators to PPI in CEPs. As dual barriers and facilitators to PPI, core issues to take account of included; the representation and selection process for patient and public representatives; transparency in terms of the roles and responsibilities of patient and public representatives; training and support mechanisms, use of a range of PPI approaches, being committing to and valuing PPI and working in a mutually respectful environment.

### *Approaches to PPI in CEPs*

The three main PPI strategies identified in this review were consultation, participation and communication. While there was limited data available on evidence based outcomes on the strengths and weaknesses of these three PPI strategies it was recognised that each strategy has its own strengths and limitations. Consequently, it was acknowledged that effective involvement should begin with finding the best approach tailored to the specific PPI goal in any given context; and the level of involvement should be clear and transparent for all concerned. Representation of lay members was often restricted to a select number of patient or patient representatives/organisations and did not by large include a diverse population of patients and/or the general public.

### *Methods and systems to support PPI in CEPs*

The consensual evidence is that patient representatives should be trained, prepared, guided and educated for their role. Practical, emotional and financial assistance, as appropriate, should be provided. Limited reporting existed on the model, mode, delivery, timing, content, trainers, cost, evaluation of and effective impact of various training and support mechanisms.

### *Evaluation of PPI approaches or systems to support PPI in CEP*

There was a paucity of rigorous process and impact evaluations to determine the effectiveness of PPI approaches, and/or methods and systems to support PPI, in CEPs.

## **5. Conclusion and perspectives**

This review provides baseline data and valuable insights into the complex process of integrating PPI into CEPs. Some key principles to consider for integrating PPI into national CEPs are outlined below:

1. Consideration should be given to the integration of PPI into these processes to strengthen public participation in healthcare decision-making and to bring expert experiential knowledge to these processes.
2. The three PPI strategies of consultation, participation and communication can be employed as required in each CEP, and full active public/patient participation should be explored where appropriate.
3. The most appropriate patient and public representation should be examined for each case, drawing on public, patient, carer and other peer or lay representatives; while there is no evidence to recommend one approach to the selection and recruitment of patient and public representatives though a transparent process is required.
4. There is a need for comprehensive support for patient and public representatives, specifically in terms of support from the chair of the guideline development group, training, remuneration/compensation, physical, psychosocial and emotional support.
5. Several international organisations (e.g. NICE in the UK, SIGN in the UK, G-I-N International Network, HQIP in the UK) have developed structured PPI programmes, with supporting resources, to underpin their clinical effectiveness approaches. These offer potentially valuable models to examine further for any framework development.
6. There is a need for further research into the effectiveness of different approaches to integrating PPI into clinical effectiveness processes. Better evaluation of PPI in clinical effectiveness processes could potentially enhance the wider acceptance and development of PPI's if seen to be effective.

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## When mobilization of workers is a condition for the efficiency of hospital level intervention

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**Keywords:** intervention, mobilization, prevention, efficiency

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### 1. Context

French hospitals are subject to new economic constraints akin to those of businesses, substantially altering the organization of the caring work and practice of nurses. These evolutions have implications for the nurses' health : Musculoskeletal Disorders (MSDs) and mental disorders (RPS) (Estryn-Behar & Fouillot, 1990 ; Villate, Gadbois, Bourne & Visier, 1993 ; Grosjean & Lacoste, 1999 ; Martin & Gadbois, 2004). The upkeep of employment becomes increasingly difficult : a growth in absenteeism and inabilities to work.

### 2. Objectives

The sustainability of Primary approaches in occupational health prevention depends on which internal workers are implied in this type of prevention approach (Coutarel & Daniellou, 2007). The aim of this communication is to show the conditions promoting the mobilization of stakeholders in a preventive approach. To understand this issue, we explore three hypotheses: the influence of the practitioner in the mobilization process (hypothesis 1), the role of the individual activity of each worker (hypothesis 2) and building of team collective work (hypothesis 3).

### 3. Methods

Our methodology is based on the observation of the implementation of ORSOSA study (ie French Organization of care for nurses and health care) (Bonneterre, Liaudy, Chatellier, Lang & De Gaudemaris, 2008) financed by the CNRACL (National Pension Fund Officials local government). This approach aims at providing a comprehensive reflection of the organization of care between the different internal stakeholders of the institution (occupational doctor, care management, human resources management, manager, doctors, nurses ...) and contributes to the improvement of work organization at initiating a discussion about the organization of care units (Pavillet & al., 2013).

The implementation of the primary approach of risk prevention in the care units, carried-out by an external practitioner, is declined in several steps (from the presentation of the approach, meetings with the head of care, to the support of recommendations). To carry out an assessment of risk factors, the practitioner presents a questionnaire to nurses and nurses'

auxiliaries in the chosen health units. Stakeholders can use the data collected to debate on the real activity of the nurses and such improvement of work organization in units.

To observe the implementation of this study in 3 hospitals, we used a qualitative method (41 interviews of stakeholders), 65 observations of meetings, 85 brief interviews after meetings, 103 comments of practitioner about intervention by logbooks) and 3 self-confrontations with him.

Using a literature review, we made categorizations of type of involvement of each of the stakeholders of the process at different times of the approach thanks to observations and interviews: verbalization about its individual and collective activity, participation in meetings, participation in care service, lack of participation, observations, opposition with approach and finally disengagement. Then we determined if the implication of stakeholders supported the prevention of occupational risks. For example, managers-they identify the problems encountered in health care services ? Are collective solutions found ? The stakeholders -do they work more together and go to the care services ?

#### **4. Main results**

The results of this research point out several conditions for the mobilization of stakeholders in the implementation of a primary preventive approach:

First, the practitioner uses five main strategies to engage stakeholders in the prevention approach: strategies related to research involving stakeholders, temporal strategies, strategies to create links between the implementation process and organizational context observed in hospitals, strategies to justify the relevance of the approach, and finally strategies to make interaction between the results of study and organization of care service. When the work environment facilitates the implementation of the study, the practitioner uses more strategies for creating links between the process side and the operational side of the service to allow workers to develop their skills. Whereas when the unit stakeholders is reluctant to carry out the study, the practitioner uses strategies to justify the relevance of the approach and to involve workers to modify their own representations so they can find interesting and mobilizing in the prevention approach.

Then, our results show that stakeholders get mobilized in a preventive approach, when the study can be relevant and supports their individual activity. The approach allows stakeholders to discuss about activity, difficulties, think about solutions. For example, the process allows them to implement new projects, to work together and to develop new skills.

Finally, the results show that stakeholders mobilize in a preventive approach when this study enables them to develop collective work. The spaces of debate during the process allow stakeholders to discuss collectively about their work and the difficulties encountered. For instance, more cooperation to improve the work organizational and expanding the network of relationships between stakeholders. This collective work sometimes facilitates individual activity of stakeholder.

#### **5. Discussion/perspectives**

The efficiency of sustainable prevention of risks in hospital depend on the mobilization of stakeholders. Mobilization of stakeholders on complex risks prevention is a long process, and is built in stages that depend on the context of institutions and internal stakeholders. When stakeholders mobilize, they are able to improve work organization of units and interaction with others projects in hospital, and network with stakeholders. But the mobilization requires several conditions: deployed by the practitioner in relation to the workplace and stakeholders'

strategies (Landry, 2009), the opportunity for stakeholders to make the link between their individual activity, the process of implementation of study and cooperative work (Caroly, 2009). The mobilization of stakeholders in primary prevention of risks contributes to better working conditions and preservation of the occupational health of nurses.

This research proposes a new methodology but also a fresh perspective to practitioners and researchers for a better mobilization of stakeholders and as early as possible when deploying a preventive approach.

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## Doctor's experiences of mobile devices and electronic patient observations in hospital wards

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### **Abstract**

This paper presents medical staff experiences of a technology deployment and change in working practice within a hospital environment. Mobile devices were deployed to change from paper-based documentation of patient bedside observations to electronically reported and stored observations (eObs). This paper reports on the findings of an interview study carried out to elicit doctor's experiences of the technology deployment, immediate and short term use and perspectives about how the new technology impacts working practices, within and across wards. Doctors were hesitant about how the eObs system would impact the way in which they work, with management of expectations and adequate training being an area in which the deployment process could have been improved. It was evident from the interviews that doctors with differing levels of experience and role within the hospital responded to the change in practice in a variety of ways. Despite the new software being developed to improve adherence to current hospital policy regarding patient observations and escalations there was a perception amongst senior medics of increased workload. Junior doctors provided a more positive appraisal of the technology from the start of the deployment as they quickly began to utilize the device and software to their own advantage, providing them with a tool for personal development and time management. The technology has provided different utility for different medical roles and understanding of this will bring benefit to the workforce and organization.

**Keywords:** eHealth, doctors, electronic observations, mobile devices, user experience

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### **1. Introduction**

Between December 2014 and September 2015, a large teaching hospital trust in the UK oversaw a large scale deployment of mobile phones and tablets (with novel software package) to nurses and doctors working in hospital wards across two large secondary care sites. These mobile devices were provided with a software package that would enable a change in practice from paper-based documentation of patient bedside observations to electronically reported and stored observations (eObs). The implementation of this new technology system would represent a wholesale change in the way that routine observations would be carried out and the use of that information assimilated and used within clinical practice. The driver for the development and deployment of an eObs system was to improve adherence to current policy around Early Warning Scores (EWS) (RCP 2012) locally within the hospital, for early identification and management of the deteriorating patient (NICE 2007). Previous studies have shown how electronic systems for patient monitoring and issuing of automatic alerts

(escalations) to relevant staff can improve clinical attendance, awareness and potential patient safety and reduce mortality rates (Jones et al 2011; Schmidt et al 2014).

This paper reports on the qualitative interview study that was carried out to elicit doctor's experiences of the technology deployment and understand the impact of this technology intervention on the working practices and conditions of medical staff. It particularly focuses on the varying experiences as reported by different medical roles, from experienced Consultants and senior medical clinicians to junior doctors with relatively little experience of the hospital environment and working conditions.

## **2. State of the art**

Previous studies have reported on the benefits accrued from the deployment of eObs systems and other electronic health record ICT solutions. There is a constant proliferation of research occurring in this space as technology capabilities improve and the rapid accumulation of knowledge around eHealth interventions (electronic/ digital health records) being developed for and used in hospitals continues to rise.

Over the last decade there has been a notable increase in publications providing insight into the use of these systems and their impact on patient safety. It is well established that physicians require *"systems which provide access to data, resources and people where and when they undertake work"* (Prgomet, Georgiou, Westbrook & 2009) but that these systems are only as good as the design and development processes which have to ensure that system capabilities meet the needs and workflows of the users. It is well documented the wide range of challenges and opportunities associated with the development and use of electronic toolkits for healthcare service provision and prevention of patient deterioration within complex clinical environments. Several studies provide evidence of how electronic ICT systems have improved service provision in the form of faster identification, assessment and treatment of deteriorating patients (Prgomet, Georgiou, Westbrook 2009; Umscheid, Betesh, VanZandbergen, et al 2015). However when the design and implementation of ICT solutions does not account for the users and systems in which they have to operate then problems can occur with regard to record keeping, workarounds and paper persistence, all of which can potentially compromise patient safety (Stevenson 2016).

Reddy et al (2005) examined the use of alert pagers for automatic calculation and displaying of early warning scores. This study found that workload was a significant factor in uptake and that physicians perceived an increased workload due to the electronic notifications from the system, a finding also support elsewhere in the literature and in relation to alarm fatigue (Elliott D, Allen E, Perry L, et al. 2015). The study by Reddy et al (2005) also reports on the benefits of information accessibility due to mobile devices and the opportunities associated with visibility of data for clinical work and audit processes. Interestingly, the observation that *"wireless technologies can lower or remove boundaries among levels of hierarchy"* was replicated within more recent work, whereby an eObs system was cited as the reason for improved collaborative working within clinical teams (Glenister 2015). More recently, Kruse et al (2016) discuss the way in which electronic systems can be developed for compatibility and how integration of technology can reduce workload for healthcare staff through the ability to transfer data and reduce the duplication of tasks and data input as occurs within an organization where ICT systems do not integrate

### 3. Objectives and Methods

The interview study aimed to address the following enquiries.

- To understand the doctors experiences of a large scale mobile technology deployment and implementation into clinical practice
- To capture and evaluate the impact of the eObs system and mobile technology on medical practice by doctors in hospital wards

It reports on the data set obtained from doctors and also clinical ICT specialists who were able to reflect on the uptake and use of the technology by doctors.

A total of 25 interviews were carried out to elicit views about doctors' experiences of the deployment and use of the eObs technology system (Table 1). Eighteen interviews were carried out with doctors working in hospital wards who had experienced the deployment of the handheld devices and been using the new system for a period of 1-6 months post deployment. The interviews with medics were stratified to ensure that the sample population represented the range of job roles operating in the hospital; this is represented in Table 1. Seven interviews were carried out with the clinical ICT team who had experience of training the clinicians; including handing out and setting up the mobile devices with doctors, and providing support to medical staff in their first week of utilising the new hardware and eObs software in clinical practice.

	Completed (female/male split)	Completed
Consultants	5 (3f/2m)	18 Doctors
Registrars	5 (2f/3m)	
Locums	1 (1f)	
Junior Doctors	4 (1f/3m)	
CCOT (Critical Care Outreach Team)	3 (1f/2m)	
Clinical ICT Team (CICT)	7 (4f/3m)	7 Clinical ICT

Table 1. Sample of Doctor's Interviews and gender split

Thematic analysis of the 25 medic interviews elicited themes to represent the doctor's experiences with the new system and the impact on their working practices. The results are reported in relation to the stratified job roles and levels of experience of the medics interviewed.

### 4. Results & Discussion

Doctors generally reported good usability of the software app and mobile devices, indicating that the main interface with the colour coding of patients healthstate was clear and intuitive to use. Nearly half of the doctors interviewed stated a requirement for better visualization of data trends within the software. Previous practice of reading off large paper charts was perceived to be quicker and more 'straightforward' whilst the transition to processing information from graphs on the small mobile device screens was perceived to be less easy. *"It just feels that I'm continually scrabbling on the screen to get the information that I want and, you know I can pick up a piece of paper and look at it and say, right fine. But you know, I would estimate that it takes me two to three times longer to look up information on the little phony thing"* (Int20 Consultant). Whilst there was a general statement of requirement from medics that larger scale graphs would make the data interpretation easier, the difficulty of information processing from the mobile devices was more pervasive in senior level medics. Junior doctors perceived it to be less of an issue, potentially due to the fact that they were less practiced and

ingrained in using the paper chart system. *“just for trends and things like that, like, broadly it’s actually really good, and actually it’s been a good tool” (Int19 JD2)*

Doctors were provided with their own personal phones and as such were able to make use of those devices constantly, getting used to the new electronic system and also in customizing their devices with other functions and applications that were useful and relevant to their roles. Consultants were not provided with individual devices; instead having to share a ‘baton’ device system, which accommodates their ‘on call’ shifts and as such may not have been able to invest the time or interest in the devices they were not individually responsible for. When asked however they did not want their own device. Junior medical staff adapted more quickly to the use of the mobile devices on their ward rounds and found added value and utility in the device when they were working around the hospital. This opportunity arose due to their willingness to explore the mobile technology. *“I think I had this predisposition in the first place to use my phone as a learning tool. The other thing I use it, like, looking up stuff, like using Safari to Google things..... I used the flashlight as well quite often to look at the tonsils, checking pupils etc., because you can imagine getting a flashlight on the wards that actually works.” (Int27 JD)*. This behavior by junior doctors led to remote accessing of additional information and data sets to support their learning on the job. Another benefit of this was how it facilitated communication with nursing staff and senior medics, breaking down barriers for upstream communication and also improving efficiency of communication downstream. *“I think it does break down a barrier to speak to the reg, because there have been times where, in the past...it might still need discussing with the reg and I haven’t. Whereas now, like last weekend ... I rang the reg and said, oh yes, I know whatever patient, it came up on my phone. So it just made the handover a lot easier.” (Int19 JD1)*. This benefit to communication within teams was also expressed by more senior staff and particularly specialists within the Critical Care Outreach Team (CCOT) for whom the observation data is an important factor in deciding when to intervene in a care provision. *“Yes, so it makes referrals a little smoother I think, because we’ve got a lot of information there, and we can check the information that’s there.” (Int12 CCOT)*

Consultants and other senior doctors were generally more resistant to the change and ultimately did not engage with the change in practice as readily as the more junior doctors. It was suggested by members of the clinical ICT team that it would have been useful to have senior medic ‘champions’ within the roll out teams to try and combat some of the hierarchical and organizational barriers to consultant engagement with the technology intervention and subsequent changes in practice. *“I’m quite happy to have the learned helplessness that comes with being a consultant. I expect my juniors to put the information in front of me so I’m quite happy to let them be more technologically advanced than I am” (Int20 Consultant)*. Reasons cited within the interviews for senior medics not engaging with the new system were reluctance to embrace change, anxiety over perceived workload and burden of device use (issues around baton device usage but reluctance generally for ownership of personal device). *“I don’t think you are ever going to get all the consultants carrying the devices round all the time and using them to look at observations. Some of it’s due to them saying, well what do I gain from it? I don’t think they will see what the benefit for them is over having a doctor that they work with day in day out and trust to tell them when there are problems.” (Int24 Registrar)*

There was significant discussion by the physicians interviewed about the training provided during the deployment of the eObs system and also the management of staff expectations about the organizational changes occurring. Many clinicians expressed frustration at the lack of training opportunities and felt relatively unprepared for the deployment of both the handheld devices and integral software. This was reflected in the accounts of the clinical ICT

team who had to manage the roll out and train people in the eObs software whilst they continued delivering care to patients. It was evident that there was a wide variety of expectations and feelings within the workforce, with some people experiencing stress and anxiety during the early days of the deployment. Individuals who were engaged with the technology and adapted well often had a requirement for more of their paper systems to be integrated and reduce the ‘juggling act’ between paper and electronic devices. *“A lot of people were very open to it and could see the benefits for it, then some people were completely opposite and weren’t up for it, whereas there were a few people that I experienced that were quite frightened of coming into a shift and having to do everything on here and they were quite scared” (Int6 CICT)*

Doctors reported challenges associated with the initial deployment and adaptation to change with a few suggesting ways in which the training and uptake of the system could have been improved. It was suggested that a process of continued support and a feedback system to communicate positive experiences and functionality of the device and eObs system would have assisted staff experience of use initially and over time.

With regard to workload, registrars felt an increased burden during and after the deployment of the technology as they experienced patient observation data and information about very ill patients being ‘pushed’ to their individual devices. There was additional burden initially as the settings within the software did not enable them to act on certain decisions and required a consultant to sign off the specified treatment or patient management pathway. This led to frustration for registrar clinicians who felt that they were being provided with information that they could not then independently act on and that the algorithms were not flexible enough to deal with the complex clinical scenarios in hospital. *“I might know she’s ill and think why on earth is it pinging every hour, yes we want to know her blood pressure every hour, that’s because when I go back in four hours I want to know what it has been I don’t want it pinging off every hour... So you actually use information in a much more subtle way than the machine allows you to. But then it is too complex.” (Int7 Consultant)*. This issue of workload was also considered by the clinical ICT team who had to deal with queries around increasing workload through notifications of patient healthstate through escalations. Their responses consistently tried to put the issues in context of hospital policy and considering the discrepancies about how work was actually occurring and what should have been occurring with regard to patient escalations. *The issue for me now... if a patient is poorly and scoring a six or a seven, the doctor must be told and the registrar must be told. Trust policy, straight up. It didn’t happen historically ...there’s been lots going, ‘our work load has tripled’. Well, yes, it will because you’re actually finding out about patients that you should know about, that you always should’ve known about. This isn’t new and this isn’t eObs fault.” (Int5 CICT)*. There was also initial confusion about the roles and responsibilities of attending to scoring patients when escalations had occurred within the system. Protocols around this issue were not well communicated to clinical teams in the short term and caused frustration for the users. *“It has the potential to improve communications... but also requires agreement as to who is taking responsibility for review and action following receipt of the information...the volume of alerts for patients with abnormal EWS who are sent through ‘for your information’ ...it is sometimes uncertain who is taking responsibility and when.” (Int40 Registrar)*

The provision of electronic observations made the visibility of patient health state more readily available and junior doctors and registrars used this accessibility of information to ‘check’ on patients that they had treated, either from a different location of work in the hospital. Additionally junior doctors utilized it after their shift had ended and they wanted reassurance about patient progress. When the system enables distributed working around the hospital it was considered a positive impact on working practices associated with the early

detection of patient deterioration, however when devices are checked at home and medics are not ‘switching off’ from their work then this was considered a negative effect. Consultants and registrars who were interviewed after a period of time using the technology reported the benefits of visibility of data and patient healthstate within the ward, as having a positive impact on their time management where paper working had previously taken longer. “*The whole good thing about the electronic observations is it’s there, it’s in your pocket, if you look in observations it’s there you can you know you don’t need to hunt down for folders.*” (Int29 Consultant/ CCOT). For junior doctors this visibility wards and patients within those environments was of value during night shifts and when they are working on multiple wards, particularly during out of hours when staff numbers are low. “*Another important thing, which is very useful especially when you do your on-call nights, you see the location of the patients. So, this is a very time consuming task, finding the patient at night, especially if the nurses are not aware of the patients being moved about by other nurses.*” (Int26 Junior Doctor)

## 5. Conclusions

The findings of this interview study demonstrate how use of mobile devices and electronic observations has impacted different doctor’s roles in different ways. Senior medics have experienced some difficulties with the transition to technology which are not replicated by more junior staff. During the development and deployment, the needs of these different user groups (medics as stratified by experience, not just treated as a homogenous population) should be considered as it is evident from this data set that there will be different training requirements and also the opportunity to exploit added value from the technology for some users. This technology intervention has resulted in positive and negative changes to practice depending on the perspective of the users and this is reflected in the staff experience of the deployment and early use of the system. Further work needs to be carried out to ensure that positive impacts on clinical practice can be communicated throughout the workforce to benefit users more widely, whilst negative changes can be addressed through user involvement and subsequent development of the system.

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## Understanding organizational efficiency by understanding work activity in medication errors

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### Abstract

*Context:* French public hospitals have experienced profound changes that were gradually accompanied by new demands and new management methods. Among those demands, the performance at work of healthcare workers is required to promote high quality care. However, years after years the number of medication errors remains an increasing problem.

*Objectives:* The aim of this study was to provide an advance understanding of medication errors in hospitals by identifying and analyzing situations where organizational efficiency was favoured or prevented. We also analyzed how changes in the management of medication errors could promote quality and safe care for patients, preserve good health at work of healthcare workers and also prevent the occurrence of medication errors.

*Methodology:* We conducted a multi-method approach to have a better comprehension of the occurrence of medication errors, analyzed the working conditions of pediatric nurses and also analyzed the effects of the prevention measures on the work activity of healthcare workers. We collected data via internal documentation, observations of work situation and interviewed healthcare workers (n=10).

*Main results:* Observations and interviews questioned the organizational efficiency and identified risk factors that can promote the occurrence of medication errors (working conditions and working environment, task interruptions, work schedule, lack of communication in transmission and lack of coordination between the different teams...). Our analyze also helped us to understand how some prevention measures allowed nurses to work in more confident environment, leading to a better performance and designing a better organizational efficiency.

*Conclusion:* Hospital managers must considerate with more importance that interventions to reduce medication errors are not only good to reduce the high cost related to the reparation of damages but there are also good to promote quality and safety care to patients, preserve hospital workers health at work but and also foster organization efficiency.

**Keywords:** errors analysis, medication errors, organizational efficiency, safety, health at work

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## 1. Introduction

Over the past decade, French public hospitals have experienced profound changes that were gradually accompanied by new demands and new management methods (intensification of the pace of work, work pressure, increasing use of new technologies, organizational changes, budget reductions, downsizing and job insecurity). French public hospitals actually try to deal with the evolution of society, face a great number of challenges and try to adapt themselves to a number of increasingly demands in order to be more competitive, efficient and profitable. Among those demands, the performance at work of healthcare workers is required to promote the quality of the health services and to respond to the high quality strictness in the offer of cares. Actually, and like in other organizations, it is asked to hospital workers to do more with less means. Such demands may bring to uncomfortable professional issues. In this special context, some questions are raised concerning major undesirable events related to medication errors. Several researches have demonstrated that distractions and interruptions during medication administration affect performance, safety of care and contribute to increase medication errors and the appearance of adverse events (Tucker & Spear, 2006; Biron, Loiselle & Lavoie-Tremblay, 2009; Elfering, Grebner & Ebener, 2015). Researchers have also shown that medication errors may lead to serious consequences for patient health and can even lead to death (Hayward & Hofer, 2001; Makary & Daniel, 2016). As a response to this concern and in order to prevent undesirable events, our research has paid a special attention to the practice of pediatric nurses in their work activity. We have conducted a survey on the efficiency of a system of prevention of undesirable events in order to determine how such preventive measures can promote the security of patients cares and the development of health at work of healthcare workers.

## 2. State of the art

### 2.1 Adverse events in healthcare institutions: the example of medication errors

Medication errors are likely the most common adverse events in hospitals (Gonzales, 2010; Lisby, Nielsen, Brock et al., 2010). The definition and categories of medication errors vary throughout the literature (O'Shea, 1999). Aronson (2009) stipulated that it is important to have a clear knowledge of the term of "medication error" and to classify the different types of medication errors in order to be able to identify appropriate prevention strategies.

#### 2.1.1 Definition

Bates, Boyle, Vander Vliet et al. (1995) defined medication errors as errors that occur at any stage in the process of ordering or delivering of medication. For Eslami, Abu-Hanna, de Keizer et al. (2006) medication errors refer to "any error in the medication process that involves the prescribing, dispensing or administering of medication" (p.803). The French Agency for Safety of Health Products (AFSSAPS) defines medication error as an omission or the unintentional realization of an act which occurred during the care process involving a drug, which can cause of a risk or an adverse event for patient. The World Health Organization (WHO) defines medication error as a preventable event where a dose of medication received by the patient differs from what had been prescribed or do not correspond to the policy and procedures of the hospital.

Literature reveals that medication errors can occur at any stage of the process (prescribing, transcribing, ordering, dispensing, monitoring, administering) from the time the drug is ordered until the patient received it (Bates, Teich, Lee et al., 1999; Fortescue Kaushal, Landrigan et al., 2003; Cimino, Kirschbaum, Brodsky et al., 2004; Eslami et al., 2006). Medication error is rarely an isolated act but it is the sequence of various events that include

different actors. All healthcare workers are concerned by medication errors. However, the scientific literature reveals that medication errors are often due to the nursing practice (last in the health process) (Kazaoka, Ohtsuka, Ueno et al. 2007) and often occur when administering drugs to patients (Clifton-Koeppel, 2008). Literature allowed to identify the categories of medication errors as followed: omission errors, wrong dosage, wrong drug, unauthorized drug, wrong form, wrong rate error, wrong route error, wrong patient, wrong time medication, wrong preparation, wrong administration technique, etc.

### 2.1.2 Factors contributing in medication errors

Factors contributing to medication errors have been widely debated. Frequency of errors can increase if predisposing factors are present (Benhamou, Auroy & Amalberti, 2009). Researchers identified several factors that contribute to the occurrence of medication errors. These factors can be classified into four groups: failure in the system, human factors, working conditions and environment factors.

*Failure in the system:* mislabeling or note information; inappropriate packaging of the drug; policies and procedures.

*Human factors:* communication problem (verbal, written); healthcare workers experience, knowledge of medications and skills; insufficient training level; non-observance of the procedure or regulation; error in calculating; error of product distribution and storage; error of preparation of doses; physical state (overwork, stress, fatigue, etc.); extra-professional problems.

*Working conditions:* workload; distractions and interruptions; lack of adequate staffing; patient acuity levels; working hours; pressure.

*Environmental factors:* insufficient lighting; insufficient equipment; sound level.

According to Gonzales (2010), most of the errors are not due to individual negligence, but are due to failures in the system, wrong procedures, poor working conditions that cause people to make mistakes or not to be able to prevent them.

As a consequence, medication errors are often associated with the decreasing of healthcare workers' health, the decreasing of patient health and safety (Cheragi et al, 2013) and the high costs for hospitals. The European Medicines Agency (EMA) indicates that the annual cost of medication errors is estimated in the worldwide at several billions of euros.

## 2.2 Medication errors, preventive measures and patient safety

More and more attention is being paid on patient safety. Beside this attention, adverse events occur every day at hospital and total safety for the patient can't be reached. On the other hand, more and more errors are being declared by healthcare workers. These declarations are not linked with an increase of errors, it is just that declaration is made easier and that workers understand the right purpose on declaring errors. Even though nurses are more inclined to declare adverse event, it appears to be a little more difficult for physicians. Amalberti, Benhamou, Auroy et al. (2011, p. 391) reported that physicians seem puzzled about declaring medical adverse event, not seeing the interest in a security approach and they do not believe that improvements will follow the declaration. Also, declaration may sometimes represent a bias in the gathering of information on adverse event. Fichet and Amalberti (2012, p. S9) indicated that: "More traceability increase automatically the number of errors inventoried (bias of revelation), inclusion which can be different of what is being called medication errors (bias of definition), and may also be the increase of prescription of more active molecule (bias of volume and toxic effect)."

Beside this point of definition and declaration gathering, the most important is to understand in which frame adverse events can be considered as prevention. For Amalberti et al. (2011, p. 390): “Patient safety in healthcare is the equivalent of systems safety in industry, which is usually built in four steps: (1) measuring risk and planning the ideal defense model, (2) assessing the model against the real behavior of workers, and modifying the model or inducing a change in behavior when there are gaps, (3) adopting a better micro- and macro-organization, (4) gradually re-introducing within the rather rigid, prescriptive system built in steps 1–3 some level of resilience enabling it to adapt to crises and exceptional situations.” It is clear that workers’ behavior is to be considered on the same level as organizational determinants. To take in consideration the behavior of workers only, without questioning the effect of the organization shouldn’t be reasonable. It would be a major lack of understanding the work situation. The assessing of an adverse event must consider the behavior of a professional in an organizational context and also in its temporality. The same authors declare on that topic: “We tend to concentrate on what immediately precedes the adverse events (we shall call this an “in-window” (timeframe) rather than on the entire time-span leading up to the adverse events (‘out-of-window’ timeframe), which may be as important. We need to consider the past to understand the future and, when analyzing adverse events, should look both backwards and forwards...” (p. 392). This consideration is a very interesting tool to investigate adverse event in the work activity.

Authors also indicated that prevention of adverse events must be included in a culture of safety. Garouste-Orgeas, Perrin, Soufir et al. (2015, p. 274) argued that: “The terms “safety culture” and “safety climate” are often used interchangeably. However, the “safety climate” is a component of the safety culture consisting in staff attitudes about patient safety within the organization.

### **3. Objectives and methods**

The two main objectives of this study were set on two different levels:

- 1 – Identify situations where organizational efficiency is favored or prevented,
- 2 – Identify how changes in medication errors management can promote quality and safe care for patients, preserve good health at work of healthcare workers and also prevent the occurrence of medication errors”

This study has been conducted in a French public hospital, most specifically in a pediatric service. This service receives children from birth to 18 years old for pathologies around cancer. The patients are most of the time accompanied by their family (one parent at the time). Data collections were made by using a multi-method approach for a better and deeper understanding of the problem of medication errors and to analyze the effects of prevention measures on the work activity of healthcare workers. A collection of data such as internal documentation (meeting report, adverse event declarations, procedures...), observations of work situation and interviews with workers have been made (n=10) in order to analyze the organizational context of this service and the working conditions of pediatric nurses. The first step of the study consisted in meeting the senior manager of this service in order to introduce the research (objectives, questions, and methodology). We also gathered general information (length of service, absenteeism...). In the second step, pediatric nurses were met to present the study and also to analyze and understand the occurrence of medication errors and to evaluate the measures set to prevent them. We observed pediatric nurses in their daily practice and interviewed volunteers. The observations allowed us to understand their real activity and helped to get more precise information about the factors and the working conditions involved in medication errors.

## **4. Results and discussion**

### **4.1 Results**

The results which are presented in the following paragraph are first results and will be strengthened in further works: a thesis in psychology at work on proactivity and a thesis in ergonomics on health at work. Observations and interviews allowed us to question the organizational efficiency and also allowed us to identify different risk factors that can promote the occurrence of medication errors: 1.1. working conditions and working environment: low lighting to prepare treatment in patient's room, lack of space for nurses to prepare treatment in their preparation room, lack of equipment, no specific room to prepare treatment, etc., 1.2. task interruptions: pediatric nurses were often interrupted by parents, colleague, delivery, phone calls during preparation about 5 times per hour, 1.3. work schedule: excessive working hours, short term rest, 1.4. lack of communication in transmission and lack of coordination between the different teams, 1.5. important workload which doesn't allow nurses to do what they want in the time they may choose, 1.6. great variability of the patients and of their health. Nurses may have to rethink what they have planned. It happens quite often, 1.7. the parents' presence which can be disturbing as they participate in the administration of some treatments (turn off pumps...), or on a psychological demand, 1.8. skills of the junior hospital doctors, 1.9. the last but most important factor discussed with the healthcare workers is the lack of convergence between medical and paramedical. They are not yet developing a work design all together. These factors also helped us to understand how some prevention measures (location of medical prescriptions, use of a special robe chasuble to prevent interruptions...) allowed nurses to work in a more confident environment for they were protected against task interruption, leading to a better performance and designing a better organizational efficiency.

In a second time, and closer to our question on understanding organizational efficiency through the assessing of work activity, we observed that the nurses were functioning in a different frame from the frame of the group which is working on preventing adverse event. The nurses are working into a quality approach; they are declaring a lot of adverse events. It became natural to declare adverse events. The prevention group is working more on a security approach; security for the patient and for the workers. The two approaches may appear in opposition at the moment must become complementary. Placing themselves in a quality standpoint, allowed nurses to consider adverse events as normal in the work. A kind of trivialization of adverse events occurred.

Also, it has been observed that the work design (task to be done) is created all day long. The nurses don't set a time apart to elaborate their actions through the day with other nurses or nursing auxiliaries. The outcomes of such a practice results in continual interruptions and decision made at the last time, being difficult to re-design the work if needed.

### **4.2 Discussion**

This study highlights different reasons for the occurrence of some medication errors and how prevention measures helped to develop a better organizational efficiency by reducing medication errors and promoting health at work. It is possible to enhance a context of work which allows healthcare workers to do their job in the most valuable conditions and promote quality and safety care to patients. In this study we considered the physical environment (work conditions, workplace environment...) but without setting apart the major role of organizational environment.

## 5. Conclusion & perspectives

Hospital managers must considerate with more importance that interventions to reduce medication errors are not only good to reduce the high cost related to the reparation of damages but there are also good to promote quality and safety care to patients, preserve hospital workers health at work but and also foster organization efficiency. The organizational efficiency is to be questioned, linked with the question of performance. This performance may be evaluated on an individual level or organizational level (Caroly & Barcellini, 2013; Clot, 2008; Daniellou, 1995; Falzon 2013; Gouédard & Rabardel, 2012). Those results will bring the researchers to open wider research on 1 – the development of proactivity at work on the individual level and 2 – the development of empowerment in work activity.

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## Patient handling as an healthcare activity: a simulation-based training methodology

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### Abstract

Patient handling, a thankless, under valued task, generates each year many occupational accidents. 'Gestures and postures' training programs, that propose a behavioral and biomechanical approach, prove to be inefficient in terms of prevention (Kay, Glass & Evans, 2014; Nelson, 2006; Hignett, 2003), sometimes leaving caregivers powerless in certain situations. This contribution presents a training program whose goal is not to learn the 'right way' or to transpose a handling technique imported from industrial, commercial or building contexts. The goal is to support caregivers in the construction of a relevant and efficient gesture, integrating the variabilities of the situation, preserving health and encouraging the autonomy of patients: the "reasoned handling care". This learning perspective changes the goals and the teaching methods. Role play simulations, based on scenarios of real activity, lie at the heart of the device. The training simulations presented in this contribution have been performed in a surgery department. Video recordings of the sessions were transcribed and analyzed. Caregivers were able to develop and test various modes of action, choosing whether to integrate new knowledge and know-how offered during training. These exercises, performed without risk to the patient, have allowed professionals to share and discuss the choices made during the debriefing. These exchanges between peers time enrich the resources available in actual practice and allow caregivers to develop skills regarding a "reasoned handling care".

**Keywords:** training, simulation, patient handling, development

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### 1. Introduction

What is at stake in patient handling is both the patients' health and well-being and the caretakers' health. Patient handling is most often perceived as a source of biomechanical constraints, leading to work-related accidents and pathologies and generating human and financial costs (Malet & Benchekroun, 2012). Training programs are often proposed in order to alleviate these difficulties. These programs are numerous. The most widespread (in France) focus on "gestures and postures", or PRAP (prevention of risks related to physical activities). These courses offer essentially a gestural and behavioural education approach, it is to learn the 'good' gesture, by transposing the principles of handling of inert loads to person-object handling.

In this paper, patient handling is considered as a healthcare activity in its own right. This places patient handling in the core of caretakers' mission. This standpoint takes advantage of the concept of "proper role" defined in the French "Code of Public Health". Activities that

belong to caretakers' "proper role" concern the patients' fundamental needs and are achieved without any medical prescription. This proper role is an opportunity for caretakers to develop their autonomy (Lheureux, 2010), to increase job satisfaction and to gain recognition. Understanding the patient as a subject, not an object, in a "reasoned handling care" necessitates the development of new skills. It means building, in collaboration with the patient, appropriate, effective care, tailored to the uniqueness of the situation, to its inherent variability while preserving health, safety and the autonomy of the patient. The paper presents a simulation-based training program elaborated following these lines.

## 2. State of the art

As a consequence, the issue with patient handling cannot be reduced to the prevention of fatigue or physical harm: the issue is also to preserve the meaning of work and to allow caretakers to build their own health through the realization of a quality care activity (Malet & Benchekroun, 2012). A quality care activity results from "the desire of caretakers [...] to be innovative when using their resources and skills and to find pleasure in the results they obtain" (Hesbeen, 2002, p.147, our translation), i.e. an effective care action, respecting the comfort of the patient and maintaining a quality relation with them (Douguet & Munoz, 2005). Such a perspective transforms deeply the objectives and the means of patient handling training programs.

The continuing education of healthcare professionals in France is strengthened since 2013 by the CPD (continuing professional development) regulation. The caregiver is required to follow a recognized CPD program every 3 years. Furthermore, the European directive 89/391/EEC imposes a duty on employers: "Each worker receives adequate safety and health training". Training in patient handling can refer to this double framing.

Besides these regulatory aspects, training remains the primary means to promote the construction of knowledge essential to the development of the skills. Training programs, and especially simulations, are a way to develop these skills (Lagerström et al., 1998) and enable *learning by action* but also by the analysis of the action (Delgoulet & Vidal-Gomel, 2014; Schön, 1983). In this way, "learners learn something that is not yet there. In other words, the learners construct a new object and concept for their collective activity, and implement this new object and concept in practice" (Engeström & Sannino, 2010, p.2). The goal is to develop courses that engage learners in a dynamic process of construction of the learning object.

Handling requires expertise that cannot be limited to the simple learning of a gesture. Indeed, gestures are a "component of the action and [...]. Their relations with the other components must not be ignored". (Leplat, 2013, p.11). In order to guide the choice of a procedure, some prevention programs have developed decision aids (Chao, 2009). These resources allow the caregiver to define, depending on the level of participation of the patient, the type of aid to be used. However they do not fully encompass the determinants of the situation. Finally, as regards existing handling techniques, some, such as particular transfers made by rotating the patient (Waters, 2007), have proven to be dangerous (Powell-Cope, & al, 2008).

Simulation can be a tool for learning (Salas & Burkner, 2002; Vidal-Gomel & Fauquet-Alekhine, 2016). In the health sector, "the introduction of human patient simulation toward the end of the 20th century was a major step in the evolution of health science education." (Rosen, 2008, p. 157). Simulation in the health sector involves "the use of device, such as an model a task trainer, virtual reality, or standardized patient, to emulate a real device, patient, or patient care situation gold environment to teach therapeutic and diagnostic procedures, processes, medical concepts, and decision making to health care professional."(111th Congress, 1 st session, H.R.855, February 4, 2009). According to Granry and Moll (2012, p.

11) "simulation enables a genuine involvement of the individual" as well as an improvement of the professional performance of persons and collectives facing a situation of support." The method includes 3 steps: a briefing, a simulated situation and a debriefing. The debriefing encourages a reflexive analysis of participants on the activity. It involves the double process outlined by Schön (1983): reflection during and about the action. The debriefing can become a space of exchanges, of debates on professional practices, of collective sharing (Mollo, & Falzon, 2004). Training is thus transformed into a discussion of professional practices (Mollo & Nascimento, 2014).

### **3. Objectives and Methods**

We wished to understand how the knowledge provided during the first phase of a program dedicated to patient handling (a few days before the simulation) is mobilized by trainees during the simulations. Does simulation facilitate a reflective activity regarding handling practices? Does it lead to the development of new practices? The debriefings that follow simulation sessions should allow the simulated activity to be analyzed and everyday practices to be evoked and discussed. It should also allow trainees to identify ways of doing that are consensual, those that are not consensual but acceptable and those that are undesirable in healthcare practice.

Open observations were conducted in order to identify the characteristics of relevant professional situations and design ecological training situations to be used during simulations. Scenarios were assessed and validated by a caretaker. Simulations were conducted in a standard hospital room slightly transformed in order to accommodate a "scenic space" and a group of trainees.

Two training sessions are discussed in this contribution: 5 care assistants (4 females, 1 male) and 1 nurse participated in the first session, 5 nurses to the second. Caregivers belong to different departments of the same hospital: cardiology, surgery, emergency and intensive care in cardiology. Time since the graduation varies from 2 to 39 years, with an average of 13.8 years.

The scenario was the following: Ms. MURE, aged 70, 1.60 m, 70 kg, underwent a right-hand hip replacement (total hip prosthesis) surgery this morning after falling at her retirement home. Additionally, her left forearm is immobilized. She has stayed a week immobilized by traction before being operated. The surgery went well. The patient was moved to the post-anaesthesia recovery rooms 2 hours ago. She is infused at the level of the right forearm and has a redon drain at the level of the left lower limb. Next care are planned within 2 hours... The patient has slipped to the bottom of her bed and complains of being improperly installed.

In order to avoid anticipations, trainees involved in the simulation discovered the scenario when they began "acting". The patient's role was given to the trainer (first author) –this allowed the situation to be adapted in real time, to a trainee –this allowed the trainee to experience the patient's feelings. Scenarios were used at least twice (for a given group) in order to compare different ways of handling the patient. Videos are then used during the debriefing. The trainer then acted as a facilitator (Dismukes, & Smith, 2000). Verbal interactions were audio-recorded, transcribed and analyzed. Further, auto-confrontations were conducted in order to obtain more precise feedbacks, in particular regarding some elements difficult to verbalize in the presence of the group. However, due to organizational requirements, only four individual auto-confrontations could be conducted, several months after the end of the training.

## 4. Developing a reasoned handling care during the simulation

### 4.1 Elaborating situational know-how and diversifying practices

During the simulation, the goal of the caregiver is to install the patient, who has slipped to the bottom of her bed, in a position suited to her condition, using her available capabilities, while preserving her comfort and the safety of the caregiver. Six operating modes were developed by participants to meet the situation. First, there is some variability in time of completion and in the use of devices (table 1).

SESSION		1			2		
Sequence		1-1	1-2	1-3	2-1	2-2	2-3
Care giver		Care assistant	Care assistant	Care assistant	Nurse	Nurse	Nurse
Duration	sequence	3'	2'45	5'10	5'	6'	6'
	repositioning	0'16	0'24	0'12	0'38	0'30	0'16
Equipment used		mattress	mattress and pull handle (photo 1)	sliding sheet (photo 2) and pull handle	sliding sheet	sliding sheet	sliding sheet

Table 1. Sequences: conduct and materials used

Participants have chosen three of the devices that were available, in combination or not. Two of these devices are commonly available: the mattress pad and the pull handle (photo 1). Sliding sheets (photo 2) is a device facilitating the repositioning of a person in the bed by eliminating friction forces. It is available when needed.



Photo 1. Pull handle



Photo 2. Sliding sheet

The time of task completion varies from 3 to 6 minutes. This difference is explained by the time taken for selecting the operating mode. The lifting itself, i.e. the time needed for moving the patient from the initial position to the final one, varies from 12 seconds to 38 seconds. This does not include the time of preparation and final completion of the care: covering the patient, providing the remote control, etc).

In sequences 1-1 and 1-2, the mattress pad is taken full hand (photo 3) before moving the patient by lifting and pulling her to the top of the bed. In sequence 1-2, the tow handle has been proposed to the patient so she collaborated and participated in the care action (photo 4).



Photo 3. Sequence 1-1



Photo 4. Sequence 1-2

In sequence 1-1, subjects expressed a difficulty regarding the end of the lifting action: “... what a dead weight!... we should have looked for the sliding sheet”. As a matter of fact, the choice has forced health care providers to get involved physically to lift the person since she absolutely did not participate. Involving the patients to the movement promotes their autonomy (Nelson, & al., 2007) and limits the efforts of the caregivers.

Regarding sequences 1-3, 2-1, 2-2 and 2-3, learners have made the choice to use a sliding sheet: patterns of use varied both by the mode of introduction of the sheet in the bed (from the top, on the side -photo 5- or bottom -photo 6) and by the way in which it was seized for lifting the patient: seizing the sheet as one seizes a mattress pad (photo 3) or inserting their hands flat between the patient and the sheet (photo 7).



Photo 5. Sequence 2-1



Photo 6. Sequence 2-2



Photo 7. Sequence 2-3

Depending on the operating mode, the capacities of the patient are more or less enlisted: no involvement of the person (sequence 1-1), or a push of the left lower limb (sequences 2-1; 2-2 - 2 - 3), a traction with the right arm on the tow handle (sequence 1-2) or a combination of the two last options (sequence 1-3).

However, regardless of the operating mode being implemented, at the end of treatment, the patient has been properly lifted in her bed.

#### **4.2 Discussing collectively professional practices during the debriefing**

The diversity of operating modes encourages participants to express themselves, to discuss. Since the simulation takes place in the presence of all participants, it happens that these debates emerge prematurely, thereby contravening the initial instructions. However most of the debates take place during the debriefing, a fundamental phase of simulation-based training (Vidal-Gomel & Alekhine, 2016).

Caregivers discuss what they have done, or what they could have done: a caregiver of the first group, who did not use any technical device, said "it would have been well with the sliding sheet" because actually she found it hard to achieve the lifting. Professionals also evoke what they observed during the simulation phase. For example a nurse of the second group, after having viewed sequences with use of the sliding sheet, said: "Yes, that's what's funny: 3

different techniques with the same... uh... utensil... among the 3, I preferred method B. [...], not because it is easier, but because it is faster... ». The simulation allows one to compare different procedures and to define choice criteria (handiness versus speed).

Discussions also allow to discuss actual transformations of practices. Thus three caregivers exchange on the impact of the training program on their daily activity. The proposed example refers to a piece of knowledge provided on the first day of training, regarding the functioning of the shoulder. A caregiver indicates, while mimicking an axillary hold, "but it is true that, since the training, I don't do it any longer. Before I used to grab..." She is interrupted by a colleague who says "oh yes, below the arm [...] because they (i.e. patients) have pain under the arms [...] we were not aware of that". The first caregiver concludes "and for us it was easy.". Thus the debriefing shows that the training has allowed caregivers to become aware of the potential harm of their practices and to amend them.

Finally caregivers share difficulties related to differences in practices between colleagues. A caregiver explains: "... it depends on colleagues: with P. (nurse) no problem, we share the same methods, but with J. (nurse), it is more complicated". The new procedures, which some would like to integrate, face resistance from colleagues, sometimes leading to tensions. The debriefing turns into a space to share one's difficulties, however without immediate solution.

Results indicate that the simulation is effective in allowing trainees to experiment new practices and assess the knowledge previously acquired. New ways of doing are elaborated and tested, showing that different and legitimate modes of action can be designed for the same given situation, each of them integrating occupational health and quality of care.

## **5. Conclusion and perspectives**

As pointed out by St. Vincent, Lortie, & Tellier (1989), after completing the handling training program, operators often do not use the recommended procedures. The program presented in this contribution differs from many others since its purpose is not the prescription of a technique, of a procedure. It is grounded in the core of the profession of learners, so it is not so much the prevention aspect which is put forward from the outset but rather the concept of care. The training focuses on the construction of a relevant and effective gesture, preserving the health and comfort of the persons: the 'reasoned handling care' which is experimented and discussed during the training session through role-play simulations.

Trainees also recall actual situations and evoke anecdotes, thus sharing their experiences. This allowed trainees to elaborate pieces of operational knowledge beyond the formal knowledge provided in the initial phase (Rogalski, 1995) and to discuss the difficulties met in the daily activity.

Additionally, the simulation itself had a psychosocial effect. Trainees were led to play a part (patient, caretaker) in front of their colleagues. This created bonds between the members of this "ephemeral collective" (Maureira, 2015). As a matter of fact, a form of solidarity, of mutual assistance, emerges when trainees are faced with a difficulty (Alter, 2010). The collective then forgot the instructions given before the simulation ("watch silently") and trainees co-designed a solution adapted to the occurring situation.

This training operates as a learning and dialogue space about professional practices. Learning takes place through the attempts made during the simulated activity and through the reflective and prospective analysis (Schön, 1983; Mollo & Nascimento, 2014). What is meaningful in work is elaborated collectively. To quote Alter (2010, p.205, our translation): "Meaning does not emerge from the messages sent by the organization, but through their analysis by the actors themselves".

The training situation allows participants to share their experience, both the past experience and the present one, i.e. the simulation experience. Trainees need to feel trust in one another, so that they can dare "play a role", theirs or the role of a patient, without fearing of being judged. This is a necessary condition for them to discover the modes of action of their peers.

This simulation technique encourages creativity and enriches the resources of trainees through the learning of new operating modes and the fostering of reflective activities (Falzon, 2015). Such training situations thus are "potential situations of development" (Mayen, 1999, our translation) and help preserve the "potential function of work as a health promoter" (Clot, 2010, our translation).

Finally, more broadly, one can wonder about the unexplored possibilities of the use of simulation in training. The discussions and exchanges during the simulated activity and the debriefing help learners establish a set of resources, individual and collective, to cope with the diversity and variability of handling situations. However how to enable professionals to pursue this dynamic of construction of resources beyond the training? How to use the scenarios design phase as a new tool for learning and sharing? Finally one can also wonder about the impact of the status of the learning object: what is the difference between a training program that considers handling in terms of risk prevention or one that considers handling as a care activity?

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## Usability of Medication-related alerting systems: where do we stand?

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### Abstract

*Context:* Medication alerting systems are promising technologies but suffer from a poor usability.

*Objective:* In order to help manufacturers of medication-related alerting systems improve the usability of their systems, this paper aims to provide evidence-based usability design principles.

*Methodology:* Two independent analyses of the literature have been performed to identify, on the one hand, usability flaws known in these systems and their consequences and, on the other hand, usability design principles specific to medication alerting systems. Once the design principles synthesized, they have been matched with the usability flaws.

*Main results:* All in all, 60 usability design principles were matched with usability flaws and their consequences for the users and the work system.

*Conclusion:* This evidence-based knowledge may help improve the usability of medication alerting systems and ultimately decrease negative unforeseen side effects from the poor usability of that systems.

**Keywords:** usability, alerting system, evidence, design

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### 1. Introduction

Medication alerting systems are promising technologies. They display in real-time an appropriate pharmaceutical or clinical knowledge at the point of decision-making to help clinicians make informed decisions. Those functions are supposed to “achieve large gains in performance, [to] narrow gaps between knowledge and practice, and [to] improve safety” (Bates et al., 2003). Those systems help improve providers’ performance with drug ordering (Jaspers, Smeulens, Vermeulen, & Peute, 2011). The implementation of Computerized Physician Order Entry (CPOE) augmented with such decision support systems enhance healthcare quality and safety (Gandhi et al., 2005), even more so when advanced decision support functions are available (Ammenwerth, Schnell-Inderst, Machan, & Siebert, 2008). However, this intended positive impact is not always achieved (Hunt, Haynes, Hanna, & Smith, 1998; Ranji, Rennke, & Wachter, 2014). On the contrary, acceptance and usage problems, including use errors, are often noticed (Ash, Berg, & Coiera, 2004; Kuperman et al., 2007; van der Sijs, Aarts, Vulto, & Berg, 2006).

A poor usability is a well-known cause of those issues (Bates et al., 2003; Seidling et al., 2011). Usability is the “extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specific context of use”

(International Standardization Organization, 2002). When considering a particular category of technology or tool, usability refers to those characteristics of the product that make it easy to use and easy to learn how to use by their intended users. Poor usability may lead users to reject medication-related alerting functions or to adopt workarounds even if this technology is of benefit.

Improving the usability of medication-related alerting systems is a necessity in order to optimize their impact and prevent from usability-induced use errors or other negative outcomes. One way to prevent such usability issues in medication-related alerting systems is to provide manufacturers, designers, evaluators and Human Factors experts with usability design principles that are supported by clear evidence. Currently, existing lists of usability design principles regarding medication alerting functions are scattered across several publications and are mainly based on authors' experience not on empirical evidence.

## **2. Objectives**

The paper at hand presents a project carried out in order to identify and gather usability design principles dedicated to medication-related alerting systems that are supported by evidence from the literature. In line with previous work by Nielsen (Nielsen J., 1994), we aim to match the list of usability flaws with a structured list of usability design principles.

A first step in that direction is to systematically comprehend the usability flaws of medication-related alerting functions and to identify their consequences for the clinicians (usage problems), for the patient and for the work system (negative outcomes).

In a second step, the usability design principles dedicated to medication-related alerting systems that have been published must be identified and organized; finally, they must be matched against the list of flaws in order to assess the coverage of those principles and to illustrate them with actual instances of their violation.

## **3. Methods**

Two independent analyses of the literature have been performed. On the one hand, medication-related alerting systems' usability flaws and their consequences for the clinicians and the work system have been searched through a systematic review process. Then, they have been organized by two Human Factors experts based on existing heuristics and on an inductive classification process.

In parallel, a targeted literature review has been performed in order to identify existing sets of usability design principles specific to medication alerting systems; once identified, usability design principles have been synthesized and organized in a comprehensive way.

Ultimately, the final lists of usability flaws and of usability design principles have been matched together by two Human Factors experts.

## **4. Results**

### **4.1. Usability flaws of medication-related alerting systems:**

A total of 26 papers were included in the systematic review analysis. The analysis of the papers identified 168 instances of usability flaws classified into 13 categories. Those instances represent either violations of general usability principles applicable to any technology, e.g. guidance, workload, explicit control, adaptability, error management, consistency, significance of codes) or infractions specific to medication-related alerting functions (issues of low signal-to-noise ratio, incomplete content of alerts, transparency, presentation mode and

timing, missing alert features, tasks and control distribution, more details in Marcilly, Ammenwerth, Vasseur, Roehrer, & Beuscart-Zephir, 2015).

#### **4.2. Usage problems faced by users**

One hundred and eleven instances of usage problems due to reported usability flaws were gathered from the literature. They deal with four main types of consequences for the clinicians: behavioral issues (e.g. increased workload, workarounds), cognitive issues (e.g. information missed, understanding difficulties, use errors, misinterpretation), emotional issues (e.g. annoyance, stress, cynicism) and attitudinal issues (e.g. users questioning the alerting system, alert fatigue/desensitization, more details in Marcilly et al., 2015).

#### **4.3. Negative outcomes on the work system**

Twenty instances of negative outcomes were identified that deal with issues of workflow (e.g. increased communication, alert responsibility shifted), issues of technology effectiveness (e.g. expected usefulness not found), issues of medication management process (e.g. diminished efficiency) and issues of patient safety (e.g. decreased quality of care, more details in Marcilly et al., 2015).

#### **4.4. Usability design principles**

As for the usability design principles, a total of 9 papers that present sets of usability design principles dedicated to medication-related alerting systems were identified and analyzed. The 9 papers contribute differently to the principles synthesized: collating together several sets of usability design principles found in the literature allows improvement in the variety of the topics represented in each individual set. Overall a large consensus between the authors of the authors appears. Together, they provide a list of sixty usability design principles dedicated to medication-related alerting systems. Those principles are synthesized in six themes: improve the signal-to-noise ratio, fit clinicians' workflow, support collaborative work, display relevant information, make the system transparent and provide useful tools.

#### **4.5. Matching between usability flaws and design principles**

The match of the principles present in the literature with a set of usability flaws collected through a systematic review allows identifying limited gaps in those principles: indeed, two principles not found in the literature had to be added and the context of application of 9 principles had to be extended. The organization of the design principles proposed in the present paper represents an improvement with respect to the 9 papers analyzed: even if the principles extracted from those papers have not been changed, instead simply combined and synthesized, the principles are now clearly identified, listed, and organized into a comprehensive, consistent, and structured synthesis.

### **5. Discussion & perspectives**

As far as we know, this is the first project that aims at providing a picture of the evidence available in the literature that support usability design principles dedicated to medication-related alerting systems. This work must be regularly up-dated and completed by analyzing new publications on that topic and other sources of data (e.g. incident reports).

As a result, a list of usability design principles illustrated by actual instances of their violation has been developed. This list has been presented during an international workshop to usability experts, designers, and developers of alerting systems. The audience was enthusiastic about the list of usability design principles supported by evidence because it could help them make

informed design decisions during the design/evaluation process. A design work has been undertaken with members of the audience in order to turn the list into a practical tool to be used during the design/evaluation process of medication-related alerting systems (Marcilly, Monkman, Villumsen, Kaufman, & Beuscart-Zépher, 2016).

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## Evaluation of the reliability of a touchless interface for surgery

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### Abstract

Our research investigates the design of an interactive system for supporting the activity of surgeons in the operation room, targeting at the integration of touchless interaction. Our process integrates two perspectives: the design of a reliable touchless system and the formalization of a method for evaluating these interactions. We have run tests in order to choose between different touchless interaction modalities. Results show that the best choice is a mixture between two different interaction modes. On the one hand, this first testing phase allowed us to develop an operational interface which can be tested in real surgical condition, and on the other hand, we have generated a replicable method for the evaluation of NUIs.

**Keywords:** Natural User Interfaces, touchless interaction, surgery, evaluation method

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### 1. Introduction

The recent advances in surgery have led to the transformation of the activity of surgeons that have to deal with operation rooms that are more and more digital (Dubuisson & Chapron, 2003; Bharathan & al., 2013).

For a single operation, the user may have to manipulate multiple devices, and modify operational parameters and values on a real-time basis (modify the angle of the operation table, ask for a different visualization angle for a portative camera, etc). For hygiene and safety reasons, these manipulations cannot be done by the surgeon himself. Instead, he has to rely on his surgical team assistants. Because of the complexity and the precision of the activity, it can sometimes be difficult for surgeon to have others do some actions for him.

As a consequence, we proposed the development of a touchless interface that allows surgeons to interact directly with the equipment without impeding the conditions of sterility of the operating field. Nowadays, design and evaluation methods of NUIs are not yet formalized. So our objective was also to propose a testing method that would be suitable for the NUIs design process. First, we have worked on the touchless interaction modalities and on the development of an efficient sensor. Then, we have tested those modalities to identify which one was the most efficient. After the state of the art and the presentation of our methodology, we present the results and the perspectives of our study.

## 2. State of the art

### 2.1 Surgical activity and environment

Surgery has undergone profound and especially rapid technological changes during these years with the introduction of minimally invasive surgery and surgical robotics (Blavier & Nyssen, A-S., 2010).

The recent advances have led to the transformation of the activity of surgeons that have to deal with operation rooms that are more and more digital (Dubuisson & Chapron, 2003 ; Bharathan & al., 2013). Surgery requires a high level of intellectual preparation, an efficient and controlled workspace, fine motor skills, physical endurance, problem-solving skills, and emergency-response skills (Berguer, 1997). Hence, surgical procedures are complex processes that involve the cooperation and coordination of several team members. In Minimally Invasive Surgery, two surgeons cooperate during the procedure: one main experienced surgeon, and another generally less experienced. They are attended by a team of nurses or others operators (radiographers, anesthetist, nurses, etc.).

Many instruments are used during the operation: camera, screen, electrical surgical instruments, lights, etc. the adjustment of these instruments is pre-configured according to each operation, but changes are sometimes required by surgeons during the same operation. Indeed, surgeons may have to modify the parameters of these multiple devices multiple times during an operation, on a real-time basis. For example, they would modify the angle of the operation table, ask for a different visualization angle for a portative camera, activate the video recording or playing some content, etc.

But because of the sterility constraints, surgeons can't touch the technical devices by themselves. They request other members of the surgical team (nurses for example) to manipulate those under their instruction.

Because of practice, the surgical team knows surgeon's habits and preferences, as well as surgical procedures. The collaborative work is efficient because team members could create a unique representation of work situation, which allows each operator to coordinate their own action according to a shared representation of work situation (de Terssac & Chabaud, 1990; Leplat, 1991).

However, because of the evolutions of work organization, or some unforeseen events, teams are not usually composed of the same operators, and surgeons have work with different people, who doesn't know well the surgical protocol. Furthermore, team members are not always available, producing frustration and delay.

Thus, surgeons need to manipulate the devices by themselves. They sometimes use strategies to manipulate non-sterile equipment while keeping their gloved hands sterile during a procedure (O'Hara & Al., 2014).

### 2.2 The Natural User Interfaces

The « Natural User Interfaces » allow the user to interact with the machine by using natural way of communication as opposed to computer language (Drouillat, 2013). The interface become invisible or implied, so it become easy to use (O'Hara & Al., 2012). It is easy to control them because of their intuitiveness and because human being can use familiar skills: body motion, gaze tracking, voice control or hand control (Djelil, Otmane, Wu, 2013). However, the interaction modality is defined by the designers: what is obvious for them could not be obvious for every users. Then a learning process is necessary, indeed natural interfaces are not so "natural" (Norman, 2012).

Natural User Interfaces requires a specific technological environment. A technical data capture support on the one hand, and all steps of information's treatment and analysis on the other hand. Those steps are hidden for users, but they require a substantial development: data processing methods, extraction of relevant features, pattern recognition algorithms and natural command interpretation (Chen & Al., 2003) all of which should be tested and validated.

But these touchless interactive devices led to other questions such as the nature of the feedback: visual, sound-based, etc. (Birkehøj Jensen, 2011). It also raises the question of intuitiveness and how to lead the surgeon to have some very intuitive commands during the operation. But then, the transformation of the interaction modes raises the question of the learning cost to these devices, and how much they may impact on current habits based on years of practice with a known tool (Rabardel, 1995).

Thus, the problem of the application of these devices and their normalization for the integration in the operation room leads to wonder how performant and reliable these interactions could be. The context is much more critical than in public or gaming applications. The use of these gesture interfaces during an operation can interfere with the cognitive load required to deal with the surgery itself (Leahy & Sweller, 2011).

It then pushed us to focus on the question of intuitiveness and reliability: How much risk does it represent to use such a system? Can one have a false manipulation? Are these gestural interaction adapted for the current interfaces? Or should these interfaces be remodeled according to the capacity of gesture recognition?

All those steps of IT development and those new purposes raise a question on the validity of NUIs and so of the adequate testing methodology to implement.

### **2.3 Design and evaluation of interfaces**

The state of the art brings us precious elements about the essential features required to ensure satisfaction, utility and efficiency of the interfaces.

The concept of affordance (Gibson, 1979; Norman, 1988) reminds us the importance of thinking the interface like a meaningful mean for human being to interact with the environment. For that we have to work on the gesture which will be chosen for its suitability. We have to ensure the usability, the utility and the acceptability of our interface (Nielsen, 1993). The eight golden rules of interface design proposed by Schneiderman (1987) advise us for this design. For example, designing the system so the user cannot make a serious error, or reducing the short-term memory load, are crucial regarding our context.

Those methods are known and proofed in Human Interface conception, but we can wonder if they are suitable for the conception of NUIs.

Djelil, Otmane & Wu (2013), compile some conditions for the design of NUIs such as the ease of use, ease of learning, the system's ability to interpret the most natural actions of the user, or real time restitution. In a specific environment like surgery, it is all the more crucial to guarantee usability and security of our interface regarding the issues.

These elements are useful for the design of the interface, but today there is no proven method to assist designers. The goal of our study is to propose a testing methodology suitable to NUIs evaluation in the surgery context.

## **3. Objectives and Methods**

As a preliminary study, we wanted to focus on the question of the comparative evaluation of the reliability of these gesture-based devices, independently of the interface that was

represented. Our process relies on an evaluation method for the touchless interaction, in comparison with classical devices or concurrent systems, in order to evaluate the reliability in a comparative way.

For the gesture recognition we have chosen to focus on Leap Motion which according to the market is an interesting option, but may have issues of reliability. We have so worked to produce a benchmark system to be able to evaluate this device and to test it with users.

This way, we wanted to evaluate several interaction modalities with the same sensor, but also to elaborate on their comparative reliability. Indeed, the issue of the visual feedback and how the user knows where he is clicking is an important factor in such a system. We have compared two clicking modes: one by crossing a virtual boundary (advance mode) and the other by clicking with the finger (key tap mode). For that, we have proposed a benchmark interface made of mock-up buttons, and we have applied that on the touchless interface (Leap Motion). In order to have a comparison, we also asked participants to run the clicking task on a desktop computer with a mouse and screen device.

We have tested these configurations in order to define an ideal setup between device and interaction modalities. For this first part of testing phase, we have recruited 6 engineering students. We wanted to keep our surgeons panel for a second testing phase, because of their schedule and of the difficulty to find a significant number of surgeons available multiple times.

Our testing interface was composed of two series of 7 buttons to click. One series with “big” buttons (4 cm diameter), one series with “small” buttons (2 cm). The task for the participants, was to click on these button as fast as possible without error. First, participants were asked to begin the task with the mouse and screen device. Then they realized the task with the leap motion condition. To avoid bias, half of the group began with the advance mode, and the other with the wait mode. An automatic log collected all the quantitative data so that we could easily obtain error rates, time to click, and even pre-click trajectories.

After the task, we invited the participants to fill in a qualitative questionnaire. This provided us information about the participant’s preferred mode, the greatest difficulties and their suggestions for improvements. By now we present the results.

## 4. Results & Discussion

### 4.1 First test results

As expected, time to achieve the task and error rate was more important with the leap motion condition (table1).

	Mouse & Screen	Leap Motion : Advance Mode	Leap Motion: Key tap Mode
Average time (sec)	10,24	50,77	60,75
Average time between 2 click (sec)	0,83	3,20	3,58
Error rate (per)	2,62%	19,91%	30,85%

Table 1. Average time and error rate for mouse & screen and leap motion conditions

Results show that error rate and average time are more important for the key tap mode. Indeed, key tap mode was less intuitive than advance mode, because it was more difficult for participants to hold the finger straight during the entire task. With the advance mode, it was easier to realize a click, because of the gesture’s similarity with touchscreen devices, according to the participants. But the error rate of the advance mode was all the same too high

to choose this mode. Indeed, because of the future context of use, surgical environment, we have to prevent all the more the risk of error with the system. That is why we have developed another mode based on the advance mode but enhanced with another modality, the waiting mode. We called this mode “touch and wait mode”.

#### 4.2 Touch and wait mode

The principle of this interaction mode is that user have to move his finger toward the target, but the click is validated after a latency time.

In fact, when the finger of the user translates at a speed inferior to a threshold value  $V1$ , a time counter starts (timer  $T$ ) and some concentric circles appear and start closing down on the target until validation. During this delay  $T$ , if the user moves again over another speed threshold  $V2$  ( $V2 > V1$ ), the timer resets and the circles get large again. Until the user gets under speed threshold  $V1$ , the click is not performed. Once the user has a static finger over the target, the circles definitively close down and a blinking green light appear to indicate that the click is validated.



Figure 1. Touch and wait mode

So we made a second testing phase to experience this mode. This time, 8 students were recruited. We used the same protocol than the first testing phase, but this time we only had the touch and wait mode for the leap motion condition.

#### 4.3 Touch and wait mode test results

	Mouse & Screen	Leap Motion : Touch and wait mode
Average time (sec)	9,27 sec	37,18 sec
Average time between 2 click (sec)	0,81	2,86
Error rate (per)	3,57 %	25,89 %

Table 2. Average time and error rate for mouse & screen and Touch and wait mode

This test reveal better performance for the touch and wait mode than the two previous mode (advance and key tap). Indeed, the average time to complete the task, 37,18 sec, is reduced of 26,76 % in comparison with the average time of the advance mode (50,77 sec). But the error rate of 25,89% is more important than the error rate of the advance mode (19,91%).

Participants appreciated the circles that indicates when they were about to click. They also quickly realized that if they put away their finger, the click was not taken into account. In comparison with the first testing phase, they realized the task faster and easier, and more intuitively because they asked less questions about the way to interact with the interface.

### 5. Conclusion & perspectives

This experiment allowed us to develop a touchless interface for surgery that will help surgeons to be more independent during surgical procedure. A future phase of test is going to prepare with real users in ecological condition. But more than a dedicated tool, we also have proposed a method for the conception of NUIs. The development of furthers modes of

interaction and the concurrent phase of tests, based on agile methods processes, enable the development of the most efficient solution in short time.

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## Improving teamwork in surgery by design: a contextual design approach

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### Abstract

The quality of teamwork during surgery highly impacts the quality of care and safety in the operating room (OR). The aim of the design research project described here was to investigate how design interventions can improve teamwork during surgery. Eight groups of four industrial design master students observed different orthopaedic surgeries and analysed their findings using work modelling techniques from the contextual design approach. Based on these insights potential directions for teamwork-based interventions were identified.

**Keywords:** teamwork, OR, work modelling, contextual design

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### 1. Introduction

Teamwork during surgery is critically important to provide safe and effective care. Poor or inefficient teamwork might lead to misunderstandings affecting situation awareness and patient safety (Melles, Anastasiadis & Moes et al., 2014, Hull, Arora & Kassab et al., 2011) and repetition of tasks leading to delays in the procedure (Lingard, Espin & Whyte et al., 2004). In this study we investigate teamwork in surgery from an industrial design perspective using a systems approach by combining design thinking and contextual design methods, with the aim to develop design interventions that improve teamwork. The focus is on orthopaedics teams consisting of professionals from four different specialties; surgeons, anaesthesiologists, nurses and radiologists.

The required collaboration between the multiple teams during surgery makes the operating room (OR) one of the most complex working environments in healthcare. In order to design products or services that meet all requirements posed by such complex environments a systems approach is recommended (Cross, 2011, Vincent, Moorthy & Sarker et al., 2004). A systems approach to surgical safety in particular implies that it is necessary *"to study all aspects of the system that comprises a surgical operation, including such issues as equipment design and use, communication, team coordination, factors affecting individual performance, and the working environment"* (Vincent, Moorthy & Sarker et al., 2004, p.477). Contextual design (Beyer & Holtzblatt, 1998) is a design method that very well fits in with a systems approach. It is a user-centred design method that provides a structured approach to the collection and interpretation of data from fieldwork with the purpose of using it for product development. The method involves seven steps: contextual inquiry, work modelling, consolidation, work redesign, user environment design, mock-up and test with customers, and putting into practice. For the purpose of this research the first two steps are particularly interesting: contextual inquiry and work modelling. The interesting aspect of contextual inquiry is its strong focus on the actual activities of the potential users in their actual work

environment. Work modelling is interesting because it takes into account the influence of (and consequences for) the complete work system. Work modelling consists of five different perspectives on a work situation. These different interpretations are expected to lead to a better understanding of needs and work context, eventually leading to more suitable products.

## **2. State of the art**

Multiple factors are known to influence teamwork during surgery. Next to the expertise of each team member and previous experiences with each other, examples include the design of the artefacts that are used (e.g. Melles, Anastasiadis & Moes et al., 2014). For example, during certain types of orthopaedic surgery the scrub staff wears helmets, complicating the visual and oral communication between team members. Or the required handling of specific tools in a confined incision area might block the surgeon's view from the incision. Still, most medical products are designed from a clinical perspective only. This investigation explores what and how products should be designed to contribute to teamwork.

## **3. Objectives and Methods**

To investigate what types of interventions could improve teamwork, we started a collaborative project between orthopaedic surgeons and industrial designers. Design Thinking (Cross, 2011) was used as the overall design research approach. Following this approach, designers first empathise with the target group and their context until a thorough understanding is reached. Next is an iteration period consisting of ideation, prototyping and user testing. In this project, eight groups of four design students observed four types of orthopaedic surgeries (total hip replacement, hip arthroplasty, total knee replacement and hand- and wrist surgery). Two design teams were linked to each orthopaedic specialty. Every team had a reference surgeon providing feedback on the research outcomes, evaluating ideas and giving suggestions for improving the design concepts. Also, the teams collaborated closely with other members of the OR teams, such as nurses, anaesthetists and radiologists. In most cases, they could benefit from a collaboration with the whole OR team to test or evaluate early ideas. In total the design teams observed for approximately 64 hours. Work modelling techniques (Beyer & Holtzblatt, 1998) were subsequently used to analyse the activities within the OR on several levels - the setup of the space, how artefacts move around it, lines of communication, work flow, logistics and the cultural rules and practices. This led to the identification of the five work models (the work flow model, the sequence model, the artefact model, the cultural model and the physical model), problem areas and design opportunities. Eight concepts for products or methods to improve teamwork were developed and evaluated with OR staff by means of functional prototypes and storyboards.

## **4. Results and Discussion**

The analysis of OR teamwork resulted in five work models, the definition of ten opportunities for improving teamwork and eight example interventions for facilitating teamwork in surgery. Here we will discuss the physical model, the cultural model and the flow model and conclude with the opportunities for improving teamwork.

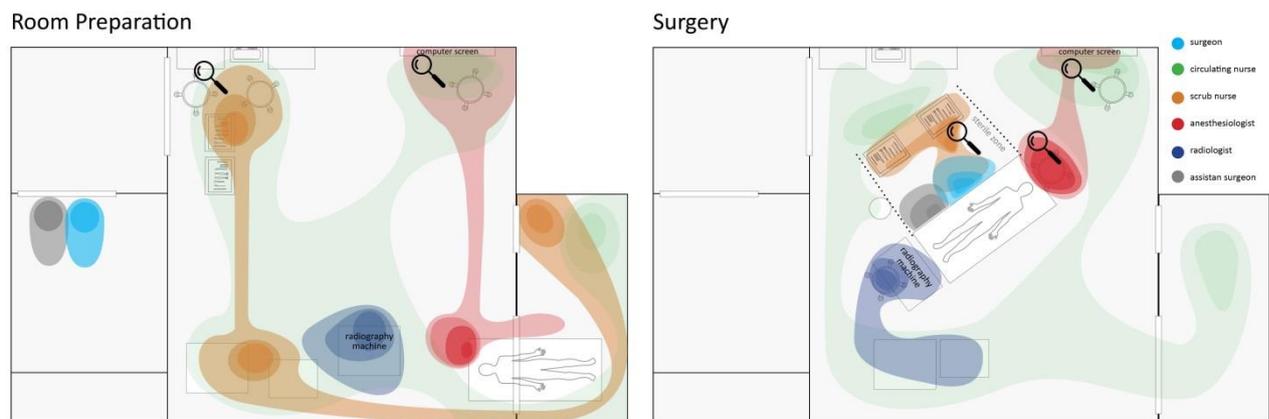
### **Physical model**

A physical model shows the environment, how it obstructs or supports the work performed, and how different people move around the space. All design groups noticed that there were different zones occupied by different staff in the OR, with some staff moving around a lot and others confined to a small space (see figure 1). Also, two distinct phases of the physical model were identified: a room preparation phase in which the staff arrange the furniture and set up

their equipment (figure 1-left), and the surgery itself (figure 1-right). In the preparation phase, staff move freely around the OR and actively interact with the space to rearrange it. In the second, all staff apart from the circulating nurse are confined to small work areas beside their equipment, which is not moved. The physical model highlighted how physical setup obstructs OR work; in many instances the design teams found lines of sight between staff blocked by equipment. Furniture was also identified which was never used during the operation but which acted as an obstacle to easy movement in the OR.

Main observed problems that impact teamwork related to the physical model:

- Many moving tables, hardly used during the operation, make the room crowded and represent an obstacle during the room preparation;
- The computer keyboard table is saturated with unneeded objects and paper sheets;
- The circulating nurse loses the overview on the operating room when she works on the computer, or goes in the adjacent room;
- The scrub nurse position in the room doesn't allow for direct view on the operation flow;
- The anaesthetist has restricted moving space.



**Figure 1.** Physical model of teamwork before (left) and during (right) surgery, showing the zones occupied by each staff member, with darker colours showing more frequently occupied spaces

## Cultural model

The cultural model attempts to define the culture and policies, both formal and informal, which constrain the way in which work is done. Informal, cultural rules in the workplace are often defined by the desires of each staff member, their expectations of others and their influences on others. Figure 2 shows the cultural model of an orthopaedic OR. The surgeon is the person with the most influence in the OR, with other staff members dependent on him or her for information or to direct the course of the surgery. This also means that the surgeon expects the other staff to perform their jobs well so that the surgery runs smoothly. In some cases, a breakdown of influence occurs because of a mismatch in expectations. For instance, the surgeon expects the radiologist to be immediately available when required, but the radiologist finds it difficult to pay attention because he is not involved in the progress of the surgery. In addition, there is no formal rule requiring that he should be. Some design groups also identified culturally-defined responsibility over physical space. Two groups identified that the scrub nurse 'should' be in control of the tool table on which instruments are stored until immediately before surgery. However, sometimes other staff members also used this table, violating the cultural rule. Other culture and policy groupings that were identified, were the 'zone of earshot'; only staff close enough to hear the surgeon speak are directly informed

about progress and decisions in the surgery, and the 'sterile zone'; sterile and non-sterile staff are limited in how closely they can interact with each other.

Main observed problems that impact teamwork related to the cultural model:

- Radiologist is only needed occasionally so loses focus, but surgeon expects immediate reaction;
- People who wander out of earshot of sterile staff miss out on operation information;
- Scrub nurse controls tool table but sometimes surgeon and resident take tools directly.
- Scrub nurse has more experience but the resident in training formally has the authority;

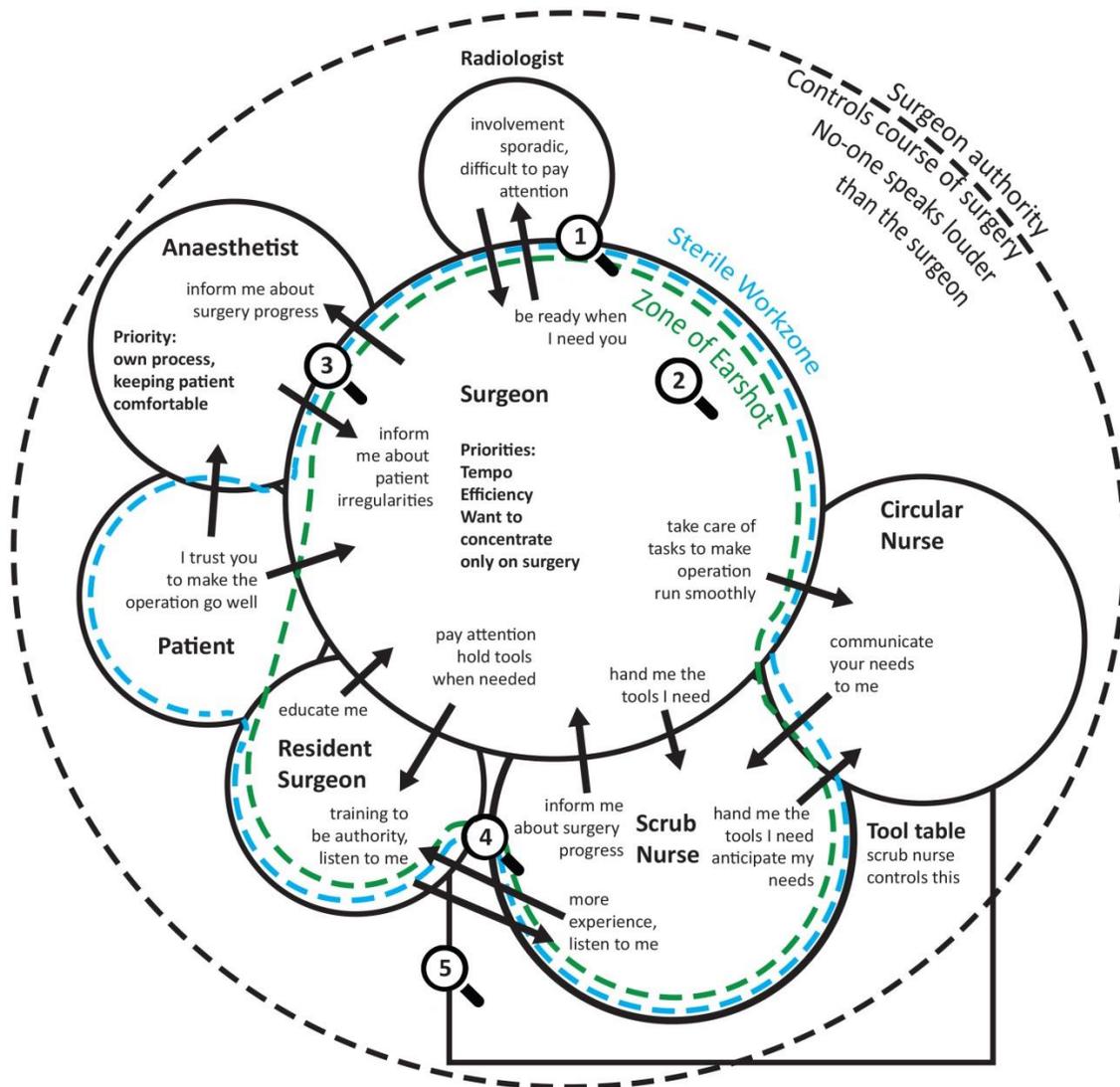


Figure 2. Cultural model of teamwork during surgery

### Flow model

Where the cultural model shows rules and expectations, the flow model shows at a detailed level the individual interactions that are governed by these rules. The flow model defines for each staff member formal and informal responsibilities. Formal are those roles defined in the staff's member job description (e.g. the scrub nurse prepares sterile items and the anaesthetist administers drugs) and informal are those which are not official but are still performed by that staff member. Informal roles may differ between teams and surgeries. For instance, in some ORs the anaesthetist also operated the OR phone because he sat close to it, in others, where he

was not, this job was done by the circulating nurse. The OR flow model (figure 3) shows the communication between staff members, both through information and through artefacts and physical contact. Flows of information are divided between explicit communication (in which one staff member speaks to another to question or inform them) and anticipation, in which a staff member watches another to anticipate their next requirements. Anticipation was found to play a large role in many operations, especially since verbal communication was obstructed by face masks. Staff members described that anticipation between experienced team members who knew each other was easier than with new members. Several common breakdowns or difficulties in the communication were identified, notably that communication to hospital staff outside the OR was often limited, causing delays as progress of the operation could not be anticipated.

Main observed problems that impact teamwork related to the flow model:

- At various moments during surgery, the sub teams seemed not fully aware of the current operation phase;
- Communication from surgeon to circulating nurse does not go directly, but via the scrub nurse;
- Inefficient communication about prosthesis caused delays;
- Low awareness outside OR of operational status.

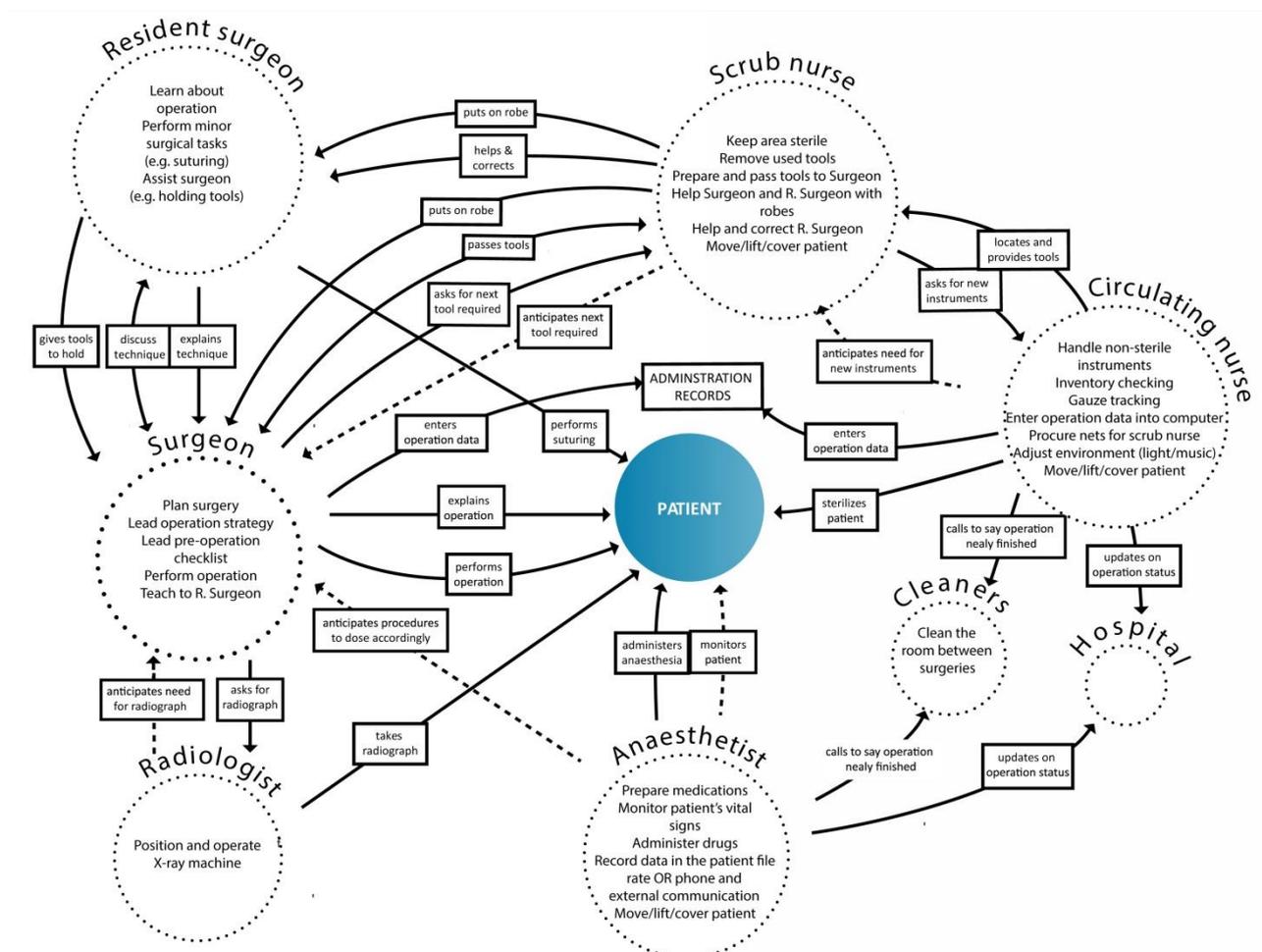


Figure 3. Flow model of teamwork during surgery

## Opportunities for improving teamwork

Based on the insights generated by the observations and work models ten opportunities for improving teamwork were defined (table 1). Most often the design groups observed the unequal activity and cognitive load among the team members. Improving the debrief session by using the session to improve communication issues between team members was mentioned three times. The session could for example be used to make staff aware of the unequal cognitive load. A third cluster of opportunities relates to the build environment including the organization of instruments and lines of sight that are blocked by the physical space.

Opportunities for improving teamwork	n
Equal activity/situation awareness of all team members during surgery	5
Communication with staff outside the OR	4
Debrief session	3
Organization of the operating instruments	3
Movement that is currently restricted by the physical space	3
Communication that is currently restricted due to sound not traveling well	3
Line of sight/communication currently blocked by physical space	2
Line of communication between surgeon and rest of team	2
Integration of new team members	2
Teamwork issues because of changes in the team composition	2

**Table 1.** Overview of opportunities for improving teamwork in the OR (n is the number of groups that reported the opportunity)

## 5. Conclusion and Perspectives

Industrial design methodologies such as design thinking and work modelling are powerful tools to define requirements and opportunities for effective interventions for changing team behaviour in complex medical domains. The method's strong points were that it provided rapid insights into the key users and major requirements for innovative design. Eight interventions were developed ranging from a post-surgery communication game to help the OR team evaluate performance, to a checklist system to prevent errors in finding orthopaedic surgical parts, to an easy to use bin. Three categories of intervention types emerged: designs to improve communication, designs to address cognitive load differences and product-based interventions. One concept has been put into practice by the OR staff and is currently being assessed with the use of survey instruments.

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## Sensomotor performance in a microsurgical setting and as a function of optical magnification: development of an instrument for conducting user studies

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### Abstract

*Context:* Microsurgical hand-held tools are under continuous development. In the usability engineering process, prototypes of the tools are evaluated and the results are fed back to improve the product. User testing is an advantageous method of evaluation when it is required to be fast and reliable for the development of the tools.

*Objectives:* The aim of this project was to set up an instrument for evaluating microsurgical hand-held tools by means of user testing. The instrument should enable to conduct performance based evaluations considering a naturalistic setting. The instrument was validated by assessing the effect of magnification on sensomotor task performance and comparing the results to the literature.

*Methodology:* We set up an instrument with which Fitts' pointing task was executed in a simulated microsurgical environment. In our instrument, participants carried out Fitts' task using a microsurgical hand-held tool while observing a magnified real-time image of their pointing movement. Validation of the instrument was conducted using 13 participants.

*Main results:* In agreement with the literature, we found that the effect of magnification on sensomotor task performance is limited. Increasing the magnification beyond an optimum does not increase performance. The results were also interpreted in light of processing information related to the pointing task. Our method enables the assessment of cognitive load in terms of information throughput (bits/s) while using microsurgical tools.

*Conclusions:* Our instrument offers a valuable contribution to the standardized, quantitative evaluation of microsurgical hand-held tools. In particular, our method enables the assessment and optimization of cognitive loads in microsurgical tasks. Evaluations of microsurgical hand-held tools were carried out within an acceptable timeframe and remove the need for risky testing in real surgery.

**Keywords:** microsurgery, microscope, optical magnification, microsurgical instrument, fine motor control

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### 1. Introduction

Microsurgical techniques are applied in various medical fields, including ophthalmology, neurology, otolaryngology, and so on. Such techniques necessitate the use of microsurgical hand-held tools. Hand-held tools are continuously improved. Such enhancements are aimed at

increasing the quality and efficiency of interventions. Physical factors, such as size, shape, weight, dimensions, material, and surface of the instrument, as well as the type of grip and coupling with the surgeon's hand, affect performance when operating a tool (Strasser, 2007).

An important step in the development of microsurgical hand-held tools is the evaluation of prototypes. Usability engineering offers various techniques with which prototypes are assessed. User testing of prototypes has become an established, efficient, and reliable approach. The present work is aimed at developing an instrument that enables the conduction of user studies into microsurgical hand-held tools. Validation of the instrument encompassed assessing the effects of optical magnification on performance while carrying out a microsurgical task and comparing effects with the literature.

## **2. State of the Art**

The effects of optical magnification on microsurgical performance have been reported in previous literature. On one hand, it has been found to exhibit a positive effect on performance. For instance, Rooks, Slappey & Zumanis (1993) reported an increased accuracy in suture puncture placement with enhanced magnification. When a microscope (magnification 8x - 30x) was used, the suture puncture was placed with better accuracy than when the task was carried out by means of a loupe (magnification 3.5x - 4x). On the other hand, Vasilakos & Glass (1998) showed that the beneficial effects of optical magnification are limited. By means of an electronic device, the authors continuously recorded the position of the index finger in participants who were attempting to keep the finger in a constant position. After digitally introducing a magnification, the position was displayed in real-time by means of a cursor (shaped as a line) on a monitor. The cursor served as visual feedback for the observers. Recordings were repeated for levels of magnification corresponding to 1x, 4x, 10x, 20x, and 40x. Results showed a significant reduction of tremor in terms of a decrease of standard deviation of finger position when increasing the magnification from 1x to 4x. Tremor did not vary significantly when magnification was increased beyond 4x. The authors suggested that reduction in tremor when increasing magnification from 1x to 4x was, in part, due to an optical artifact (resolution of the monitor). Since tremor was not further reduced when magnification was varied beyond a level of 4x, Vasilakos & Glass (1998) concluded that physiological tremor is the limiting factor in microsurgery. Further studies have shown the limited effect of optical magnification. Safwat, Su & Gassert et al. (2009) studied hand dynamics while manipulating a cursor by means of a stylus-like device (PHANTOM Desktop, SensAble Technologies, MA, USA). In their experiment, the visual feedback of hand movement was investigated under magnifications of 1x, 10x, 15x, 20x, and 40x. The authors concluded that the motor performance was improving up to a magnification of 10x. In a study conducted by Ananda, Latt & Shee et al. (2009), micromanipulation accuracy was assessed in tracing, tracking, and pointing tasks. Visual feedback was provided either by an LCD screen or by a microscope. The researchers concluded that a magnification beyond 16x did not improve task performance, which was also the case when the LCD screen or microscope was used to provide visual feedback. In addition, their results demonstrated a speed-accuracy tradeoff in both viewing conditions.

From the literature reported above, we may conclude that the positive effect of magnification on performance, in microsurgical manipulation, peaks somewhere between a level of 1x and 16x. As in microsurgery, micromanipulations are also affected by a speed-accuracy tradeoff.

## **3. Objectives and Methods**

The objective of the present study was to set up an instrumentation to support the development of microsurgical hand-held tools. This instrumentation allowed for the

conduction of user studies, by means of which the hand-held tools were tested in a standardized and quantitative manner. The instrumentation was validated by assessing effects of the magnification of the visual feedback on performance of micromanipulation. Effects were compared to the literature.

A total of 13 participants (3 females and 10 males) took part in our study. An apparatus was developed (Abt, 2014) that enabled the recording of performance, according to Fitts' pointing task (Fitts, 1954), while using microsurgical instrumentation in combination with a microscope. The microscope (Leica M651) was equipped with a Point Grey Flea3 USB camera. A purpose-made, 36.5 mm long, conical spike was mounted on the commercial handle of a microsurgical hand-held tool (Renaissance Advanced Handle, Alcon Grieshaber, Switzerland). The handle was equipped with an electrical switch, which was activated by actuating the handle in a similar way to how one grasps when using a microsurgical instrument. The microscope's camera tracked the tip of the spike. Nominal levels of magnification were 6x, 10x, 16x, 25x, and 40x. Corresponding effective magnification factors of the microscope were computed after calibration, and were 4.8x, 7.4x, 12.3x, 20.2x, and 31.5x.

A purpose-written program presented the image of the tip in combination with a target (disk) on the display (14.1") of a notebook (Lenovo TS430s). Diameter, location, and onset time of the disk were set randomly. The distance between the disk's center and the starting point of the pointing movement, as well as the width of the disk, were adjusted to enable the investigation of performance within a range of task difficulties (ID, according to Fitts' law), as is recommended when testing pointing devices (Soukoreff & MacKenzie, 2004). In our study, investigated ID values covered a range of 1.1 bits to 5.8 bits, with an average of 2.9 bits. For each effective magnification of the microscope, columns 2-4 of Tab. 1 list minimum and maximum values for the target distance, and for the target width, in millimeters. The distances reported in Tab. 1 correspond to real spatial dimensions of the pointing task. The target distance denotes the amplitude required of the pointing movement in order to hit the center of the target. For an observer sitting at a viewing distance of 50 cm from the display, minimum and maximum target distances subtended angles of 67' and 464' (minutes of arc), respectively. Except when using a magnification of 4.8x, the minimum and maximum target widths subtended angles of 13' and 67', respectively. Minimum and maximum widths when using the 4.8x magnification were set to 7' and 67', respectively.

Effective magnification	Target distance [mm]		Target width [mm]	
	min	max	min	max
4.8x	1.02	7.14	0.10	1.02
7.4x	0.66	4.61	0.13	0.66
12.3x	0.39	2.76	0.08	0.39
20.2x	0.24	1.68	0.05	0.24
31.5x	0.15	1.08	0.03	0.15

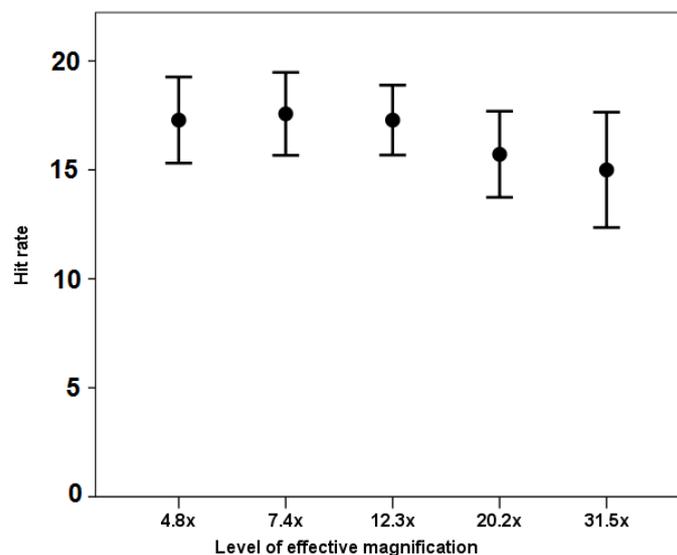
**Table 1.** Real spatial dimensions in Fitts' pointing task as a function of the effective magnification of the microscope. When seen by the observer at a viewing distance of 50 cm, minimum and maximum distances, as seen on the monitor, subtended angles of 67' and 464', respectively. Except when using a magnification of 4.8x, the minimum and maximum target widths subtended angles of 13' and 67', respectively. Minimum and maximum widths, when using the 4.8x magnification, were set to 7' and 67', respectively

Participants were seated in front of the display at a viewing distance of 50 cm. They were asked to use the microsurgical hand-held tool with their dominant hand (11 right, 2 left). After a delay varying between 0 and 1 seconds, a disk of random diameter appeared at an indiscriminate location on the display. Participants were instructed to move the tip to the inner area of the disk as fast as possible and to confirm the end of the movement by actuating the handle. When performing the latter, the disk disappeared if the tip was inside the disk. If the disk remained visible, participants were required to repeat the task. A new trial was started after storing the movement time, the number of attempts to complete the trial, and the task difficulty ID in a log file. Each participant performed 20 pointing trials at each level of magnification.

Data analysis encompassed an analysis of the number of attempts to complete the task as well as an analysis of information throughput TP in bits/s. The number of attempts to complete the task may be considered as a measure of accuracy, which may have affected the completion time of an operation. Variation in the number of attempts could be a cause or a symptom of the fatigue of a surgeon. The information throughput IP, as per Soukoreff & MacKenzie (2004), denotes the performance by means of which information related to a motor action is processed. Fitts' pointing task and TP were introduced over a decade ago in international standards (ISO 9241-9) for testing non-keyboard-like input devices. Since then, a large body of literature has emerged in which ISO 9241-9 has been used to test devices.

#### 4. Results and Discussion

The average number of trials in which the task was completed at a first attempt is defined as the hit rate, and is plotted in fig. 1 as a function of the effective magnification. Because of incomplete data, data of one participant was discarded.



**Figure 1.** Average number of attempts to complete the task (hit rate) as a function of effective magnification of the microscope. Error bars denote 1 SD. 12 participants

The maximum hit rate (20) was not achieved at any of the magnifications tested (fig. 1). The average hit rate peaked somewhere between a magnification of 7.4x and 12.3x. An ANOVA, considering magnification as a five level within subject factor revealed a significant main effect of magnification on the average hit rate ( $p = 0.002$ ,  $F(4, 8) = 5.194$ , partial  $\eta^2 = 0.321$ , power = 0.951), and also a significant inter-individual variation ( $p = 0.000$ ,  $F(11) = 1664.5$ , partial  $\eta^2 = 0.993$ , power = 1.000).

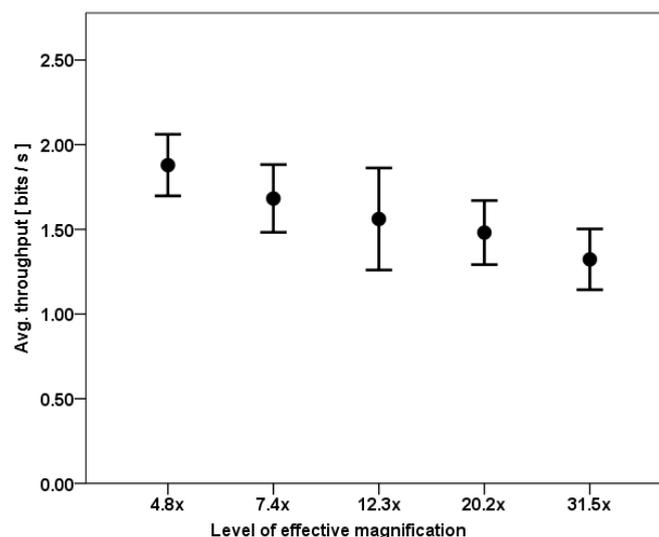
Individual levels of throughput were computed by averaging the 20 values of throughput recorded in each participant and at each magnification. Individual levels of throughput were averaged across participants and plotted as a function of magnification (fig. 2).

As shown in fig. 2, the highest throughput was achieved when the lowest magnification (4.8x) was installed. Throughput decreased with increasing magnification. An ANOVA considering magnification as a five level within subject factor reveals a significant effect of magnification ( $p=0.000$ ,  $F(4, 8)=27.652$ , partial  $\eta^2=0.715$ , power=1.000) as well as a significant variation of average throughput among participants ( $p=0.000$ ,  $F(11)=469.459$ , partial  $\eta^2=0.977$ , power=1.000).

Considering the effect size (partial  $\eta^2$ ), hit rate and average throughput are more greatly affected by inter-individual effects than by magnification.

## 5. Conclusion & Perspectives

We set up an instrument enabling the evaluation of microsurgical hand-held tools, quantitatively and by means of user studies. The instrument was validated by recording the effect of magnification of a surgical microscope on performance in a micromanipulation task. Effects were compared to the literature.



**Figure 2.** Average throughput TP as a function of the effective optical magnification of the microscope. Error bars denote 1 SD. 12 participants

We found an improvement in reliability in terms of attempts to complete a pointing task at the first attempt up to a level of magnification ranging between 7.4x and 12.3x. Other researchers (Rooks, Slaphey & Zumanis et al., 1993, Safwat, Su & Gassert et al., 2009, Ananda, Latt & Shee et al., 2009) reported similar effects of magnification on micromanipulations. In addition, we found that improvement in reliability followed an inverted U-shape function of magnification, which is in agreement with the literature (Safwat, Su & Gassert et al., 2009, Anada, Latt & Shee et al., 2009).

Since the effect of inter-individual variation in accuracy is stronger than the effect caused by magnification, it is imperative to consider individual preferences when adjusting the magnification of a surgical microscope.

Performance in fine motor control, as expressed by the throughput TP, was found to be negatively correlated to magnification within the whole range of tested magnifications. This

finding seems to conflict the results reported by Vasilakos & Glass (1998), who found that physiological tremor is not affected by the magnification of visual feedback. However, these authors used a static task (attempting to keep the index finger in a constant position), whereas the information throughput in our study was assessed for a dynamic task in which participants were instructed to perform as accurately and quickly as possible. The two tasks differ in various aspects. The dynamic pointing task may be subdivided in different temporal phases. In an early phase, after visual detection of the target, motor action is programmed and the execution of the action is started. This phase is followed by a cruising phase and one of approaching the target. Finally, a phase of attempting to keep the position of the instrument constant concludes the pointing movement. Only this last phase is comparable to the task investigated by Vasilakos & Glass (1998). In our study, optical magnification of the visual feedback affected earlier phases of the pointing task.

According to fig. 2, the information throughput (TP) when using the hand-held microsurgical tool under the microscope is 1.3 bits/s to 1.8 bits/s. Bachmann, Weichert & Rinkeauer's (2015) recorded TPs in Fitts pointing task when using a PC mouse and a gesture device for augmented and virtual reality (Leap Motion). In their experiment, target distance was varied between 40 mm and 160 mm for target widths ranging between 40 mm and 10 mm. For IDs varying between 1 bit and 5 bits, Bachmann, Weichert & Rinkeauer (2015) recorded TPs between 3 bits/s and 5 bits/s when using the mouse and TPs between 2 bits/s to 3.1 bits/s when using the gesture device. Performance when using microsurgical devices in a pointing task is therefore inferior to performance when using the mouse to point in a PC task. We therefore conclude that the cognitive load when using microsurgical hand-held tools in a pointing task carried out under a microscope is about twice the load of performing Fitts pointing task when using a PC mouse.

The developed methodology has been demonstrated as being a useful setting for investigating the handle design of microsurgical instrumentation. Evaluations of microsurgical hand-held tools were carried out within a realistic timeframe, obviating the need for risky testing in actual surgery. We plan to further develop and validate the proposed method of evaluating hand-held microsurgical tools. Developments will encompass the study of the effects of bimanual operation of microsurgical instrumentation (as suggested, for example, by Ovari, Nemeny & Just et al., 2016) and the impacts of handle diameter on the performance of micromanipulations.

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## Workflow Management Emerging Practices: Taking care of cooperative work in radiotherapy

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### Abstract

This communication presents a research grounded in a project aiming at developing software to support radiotherapy workflows. The aim of our research is to characterize activities dealing with management of workflows that are developed and implemented by care providers to take care of cooperative work. Taking care of cooperative work in radiotherapy is seen as an activity per se, different from the treatment production activity itself. In this way we aim at characterizing both the Workflow Management Emerging Practices (WMEP) developed and used by radiotherapy care providers and the emerging regulations of work implemented by them to deal with the variability of situations not provided by the WMEP. Data was gathered by direct observation, 32 interviews and study of workflow-related artifacts used by care providers in both nominal and non-nominal situations. The WMEP is composed both of artifacts (software, files and its location, notes, etc.) and unwritten rules of use. We show that for nominal situations WMEP is a way to support articulation work in radiotherapy setting. This function can be achieved only if the care providers have elaborated specific knowledge about how to interpret the actions of others seen as cooperative signs. For non-nominal situations, we describe emerging regulations performed by care providers to deal both with the variability of treatments and patient safety. In conclusion, our research contributes to outline that software supporting radiotherapy workflow systems is only a part of the WMEP. The building of a physical environment by care providers and the rules for interpretation of signs produced by care providers for others and supported by artifacts are really useful to develop the cooperative work in radiotherapy. The outcomes of such a study can contribute to the (re)design of systems and workflows that better suit the actual work situation of such professionals.

**Keywords:** workflow systems, artifacts, emerging regulations, exception situations, activity

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### 1. Introduction

This paper presents a research grounded in a project aiming at developing software to support radiotherapy workflows

A set of media such as electronic medical files and information systems are used in the medical community to support coordination in teamwork (Schmidt, Wagner & Tolar, 2007). The irradiation sheet in radiotherapy, which circulates in the service according to the phases of treatment preparation is an example of this type of coordination media. Besides these conventional tools, care providers have turned to information and communication technologies in connection with the research field of Computer Supported Cooperative Work (CSCW) (Fitzpatrick & Ellingsen, 2013). These systems allow shared access to related data or

documents to the teamwork. Workflow tools are an example of such systems. They support the management of workflow in an organization by facilitating the definition of coordination and communication flow and by assisting specify automatic actions. However, they often implement a model of structured and predefined process (Medina-Mora, Winograd, Flores & Flores, 1992; Dourish *et al.*, 1996).

According to Schmidt (1997), these artifacts reduce the complexity of cooperative work by identifying dependencies between tasks. However, he argues that workflow tools should be designed to allow professionals to act outside the pre-defined process implemented in the software. It must support the handling of exceptional situations in care production by allowing professionals “to change, flexibly, their preferred mode of cooperation” (Rasmussen *et al.*, 1994, p. 4). In this sense, the detailed understanding of the design and administration of the treatment (the media used, the developed informal practices) is essential in defining software-supported workflow (Schmidt & al, 2007 ; Fitzpatrick & Ellingsen, 2013).

In this context, our goal is to characterize activities dealing with Workflow Management Emerging Practices (WMEP) that are developed and implemented by radiotherapy care providers. The outcomes of this study can contribute to the (re)design of systems and workflows that better suit the actual work situation of radiotherapy professionals.

## 2. State of the art

Radiotherapy involves a “transverse team” (i.e. a collective of professionals with different competences and tasks). Design and administration of the treatment require a series of different steps, involving four types of care providers who need to cooperate in order to deliver patient care safely. Administrative staff are also involved in the quality of care and plays an important role in patient welcome. Radiotherapy care production is characterized by safety and efficacy of the treatment requirements, transverse and asynchronous nature of cooperative work and variability in care situations. Thus, articulation work becomes essential to guarantee the quality of care.

"Articulation work" (Strauss, 1992, p. 191) refers to "extra work required for the team's efforts (that) is finally more than the chaotic assemblage of scattered fragments of work.". In Schmidt's terms (2002, p. 162), “articulation work is cooperative work to make cooperative work works”. In a transverse team, the articulation work consists in adjusting one own activity (Schmidt & Simone, 2000) to incorporate contributions of others taking into account the uniqueness, the variability of a concrete situation. This is one component of what we call “taking care” of cooperative work.

Articulation work is supported by spatial arrangements. Professionals shape and create their environment and adapt it to action, which in turn influences their practices and development. The more completely prepared an environment is, the easier is the task accomplishment (Kirsh, 1995). This construction of environment is required both for their own tasks and for teamwork. Concerning radiotherapy, it was demonstrated that professionals construct signs for their colleagues with the objective to give important information for production, even when workflow is already software supported (Munoz, Barcellini, Mollo & Nascimento, 2015).

In this context, we propose to see the quality of care process not just as the sum of the quality of each individual technical contribution, but including also a "care taking" of cooperative work, supported by technical and organizational devices present in the work of each one. “Taking care” of cooperative work is understood as the concern to carry out care production in a singular way, that is to say considering the particularity of each situation or patient.

Taking care of cooperative work in radiotherapy is seen as an activity per se, different from the treatment production activity itself.

### 3. Objectives and Methods

Our objective is to reveal the “care taking” of cooperative work in relation to the production of quality of care in radiotherapy. To do so, we aim at characterizing both a Workflow Management Emerging Practices (WMEP) developed and used by radiotherapy care providers to cope with nominal situations but also emerging strategies of work they implement to deal with the variability of situations not supported by the WMEP.

Our approach is grounded in ethnographic approach as it is performed in the CSCW field (Blomberg and Karasti, 2013) and in ergonomics’ work analysis (Guérin et al., 2006). A first study aimed at characterizing WMEP developed and implemented by professionals in a French radiotherapy center. This was based on work observations (around 200 hours) and interviews specifically targeting artifacts (physical or electronic) mobilized by professionals to cope with nominal work situations and functions of these artifacts. Data analysis concerns dimensions and functions of WMEP.

A second study was conducted to understand how professionals cope with the workflow in exceptional situations (non-nominal). Data was gathered by performing 32 interviews with professionals involved in the radiotherapy process at all levels (medical, paramedical and administrative staffs). To target workflow management, interviews were supported by presentation of actual elements of WMEP (e.g. annotated planning) of the center. Verbalizations were audio-recorded, transcribed and analyzed by means of a content analysis method. The analysis is focused on description of exception situations and emerging regulations associated to these situations.

### 4. Results & Discussion

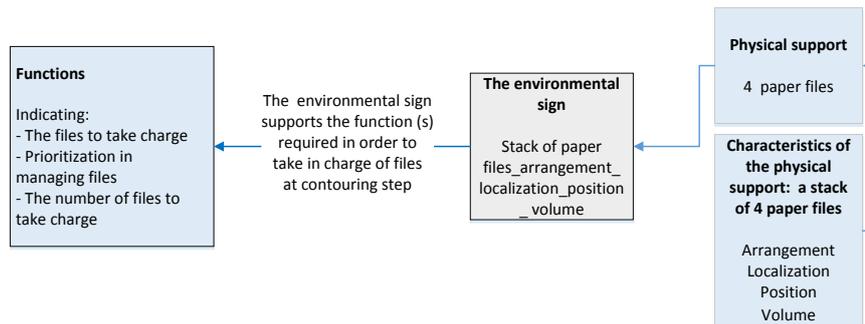
#### 4.1 Workflow Management Emerging practices: a way of preparing environment for oneself and for others

Our result reveal that as a workflow management activity, care providers build environmental signs to ensure the progress of files between the different stages of design treatment. For example, placing the file in a vertical position indicates that this file must be handled by a specific colleague of the next step of the process (cf. Figure 1). This set of signs of the environment and the interpretation rules that accompany it constitutes the Workflow Management Emerging Practices (WMEP).



Figure 1. File in the vertical position indicating that job was done in this step

Two dimensions of WMEP are identified. The first one is a **physical dimension** composed of physical media that are part of a stable environment (e.g. the place and the form regarding storage of stack of files, notes written in the file, e-mails, etc.). However, actions on physical dimensions of WDEP can be understandable by professionals only if they have elaborated specific knowledge about how to use the WDEP and how to interpret actions of others. In this sense, these first results show how professionals develop and use signs for others in their physical work environments and how these signs become cooperative ones when they are “augmented” by rules to produce and interpret these signs. Knowledge of the environment and of local practices are as much necessary as physical media in the collective management of workflow. The second one concerns the **shared symbolic dimension** that is composed of the rules of "reading/understanding" and using artifacts and their mobilization. As an example, Figure 2 outlines the physical dimension of the WMEP on a file in phase of contouring of the tumor.



**Figure 2.** Representation of environmental sign of items from the illustrative example “stack of files to support by contouring”

In addition to these dimensions, two functions of WDMs can be identified:

- **Functions supporting management of the information flow of treatment**, that refer to six relevant functions regarding actual mobilization of physical media in order to advance the workflow. They assist the prioritization of treatment, the arrival of treatment designed on time at the administration room (in order to respect of the date of start of treatment), the management of all treatments, the dispatching of file records, the patient synchronization / file, and the indication for treatment to be taken in charge.
- **Functions supporting the development of a common representation of the state of workflow**. This function deals with information of professionals in radiotherapy regarding the state of the workflow: feedback regarding work, information on the number of remaining treatments, information on the total number of files to be handled, information processing in progress, information on professionals in charge of the files.

WMEP is well suited to support nominal situations: it supports articulation work in a normative context. WMEP are organizational inventions of professionals who target workflow management and the quality of healthcare. However, WMEP is not sufficient to cope with exception situations (not-nominal). In this case we identified emerging regulations.

#### **4.2 Emerging regulations: to deal both with the variability of treatments and patient safety**

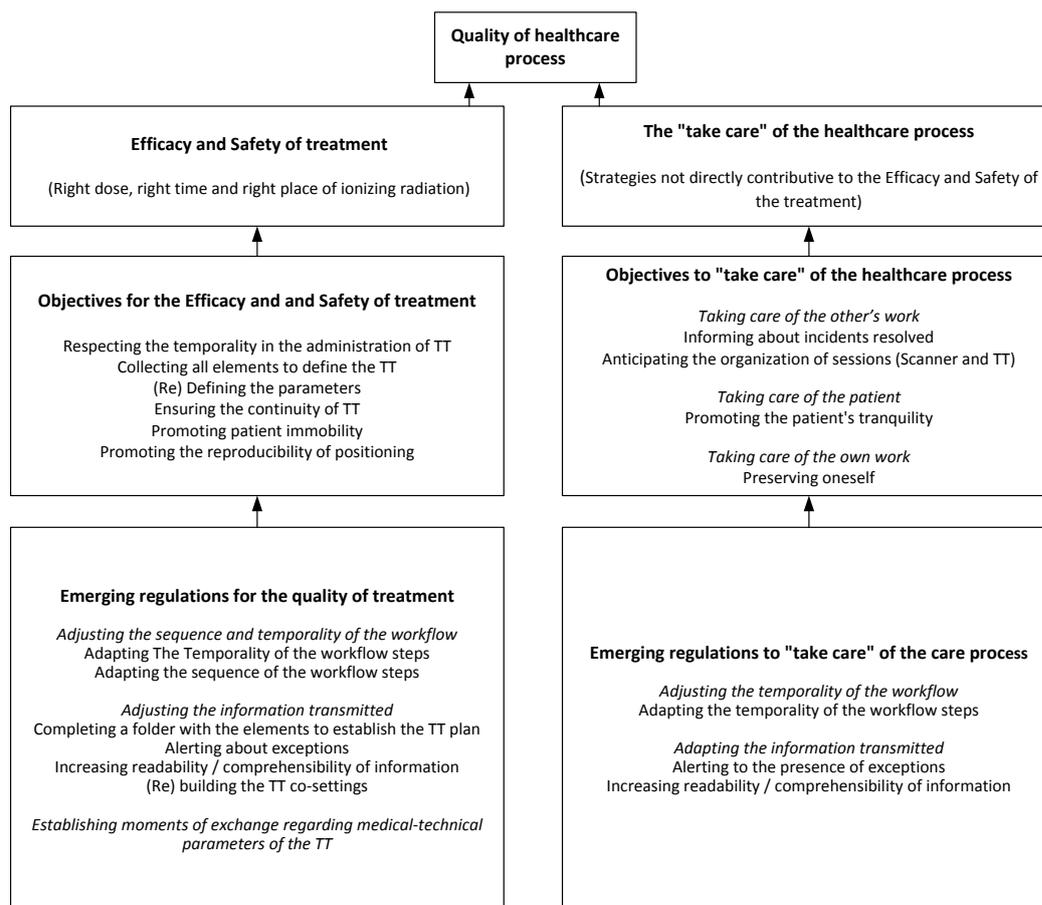
Our second set of results reveals that, in case of exception situation (not-nominal), care providers implemented emerging regulations that aim the production of safe and effective

treatments. These emerging regulations target safety and efficiency of the treatment but also taking care of the cooperative work and of the care and cure production process. Emerging situations concern ad hoc adaptation of the temporality of the workflow or anticipation of difficulties at one step of the process that may impact the work of colleague.

A total of 112 exception situations were observed. They can be categorized according to their causes: exceptions by lack of resources (40/112); exceptions related to the patient (29/112); therapeutic exceptions (43/112).

For 83 of the 112 exception situations, emerging regulations involve professionals from various trades. For example, a medical assistant who includes documents for a clinical study of a medical electronic file, or a radiation oncologist who requests a radiographer to receive the patient before their time of appointment. For 29 of the 112 exception situations, emerging regulations concern professionals of the same trade. For example, a physicist who marks on the medical file that a patient has to go into surgery to put metal benchmarks to ensure the application of radiation to the target area. This way, if another physicist were to handle the file, he/she would be informed.

Figure 3 synthesizes these emerging regulations. It enhances their two main objectives: improving the quality of treatment (efficacy, safety) and taking care of the healthcare process.



**Figure 3.** Emerging regulations according to their two objectives

## 5. Conclusion & recommendations for design

The literature on electronic workflow describes the need to take into account the normative model of the process to support to design software tool (Winograd, 1994; Dourish et al., 1996). It also highlights that the detailed understanding of the design and administration of the treatment (the media used, the informal practices) is essential in defining electronic workflow in medical domain. Our results address the development and the support of the workflow process in relation to the conceptualization of the quality of care and the care taking of cooperative work.

Functions supported by the WMEP refer to "taking care" of articulation work in a transverse team. Moreover, our results contributed to pragmatic issues related to development and support of actual workflow in radiotherapy both by characterizing the WMEP and identifying emerging regulations to cope with exception situations.

In this context, a workflow tool should allow to:

- Support the management of the workflow in accordance with the prescribed requirements (medico-technical and regulatory requirements of the care process). However, a workflow tool thought only in terms of support for medical-techno-regulatory process can produce rigidity and hinder the treatment of exception situations. Supporting emerging regulations must also be considered in the definition of workflow tools (Salembier & Zouinar, 2004).
- Support the management of the workflow in exceptions situations. The workflow tool should support the expected and unexpected exceptions. For this, it must support synchronous or asynchronous coordination dealing with exception handling, and support stabilized practices regarding exception situations, and those that have to be built.

In summary, this research shows that the work of professionals consists also in transforming their physical environment in order to make it a resource for ensuring a safe medical flow. Thus, the physical environment becomes a safety tool, as important as the supporting software. In this way, this research helps in conceptualizing healthcare quality by adding taking care of the cooperative work to the classical safety, efficiency and ethics dimensions (Berwick, 2002). Finally, this research helps in conceptualizing that taking care of cooperative work as one additional dimension to address quality of teamwork.

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## How technology and training can promote Resilience?

### A case study in robotic surgery

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#### Abstract:

*Context:* New technologies in healthcare are in constant and considerable evolution. They often constitute a type of change implying new knowledge and new skills. It is not unusual that the organization relies on the medical staff to deal with these technical changes and to adapt their practices in order to keep the level of performance and safety. The data presented here are the same as previously published in detail by Nyssen & Blavier (2013).

*Objectives:* Our goal was to better understand how expertise is sensitive to this required flexibility in order to better construct resilient system.

*Methodology:* We carried out three studies in robotic surgery and classical surgery to successively examine three relevant dimensions of the issue of technology / flexibility/ expertise and resilience.

*Main results:* Our results showed how the classical approach of training and safety based upon standardization and protocols encourages routine expertise but militates against adaptive expertise and, in turn, against resilience.

*Conclusion:* This brings us to a critical question: How to keep these routine skills to be able to mobilize them when confronted with uncertainty, when and for how long? Should we make mandatory recurrent practise with 'old' technology? Should we use training simulators?.

**Keywords:** new technology, resilience, robotic surgery, adaptive expertise

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### 1. Introduction

New technologies in healthcare are in constant and considerable evolution. They often constitute a type of change implying new knowledge, new skills and new cooperation modes. These new demands are rarely assessed before the introduction of the technology. It is current that the organization relies on the medical expertise to deal with these changes and to adapt their practices in order to keep the level of performance and safety. Because of the rapid advancement of the technology development, the capacity to switch smoothly from one technique to another is key to promoting safety and system resilience. The data presented here are the same as previously published in detail by Nyssen & Blavier (2013).

### 2. State of the art

Several authors have attempted to operationalize the concept of resilience in real world using the idea of flexibility that reflects the system's capacity to reorient their strategies in order to cope with uncertainty (Hollnagel et al. 2006). Because of the speed of the technology development, flexibility appears as a critical strategy to promote resilience. Yet, the term 'flexibility' is primarily used to refer to the capacity to switch from one strategy to another

whereas the term ‘adaptivity’ deals with the capacity to select the most appropriate strategy (Feltovich et al. 1997, Baroody & Rosu 2006).

The meaningfulness of flexibility/inflexibility is a key element in Hatano’s distinction between adaptive-creative and routine-reproductive experts (1982). The experts are adaptive and creative in the sense that they can modify a procedure according to the situation’s constraints and invent new strategies when none of the known procedures are effective. In contrast, the routine experts rely on algorithmic procedures, reproducing strategies by which the skills can be performed more accurately and rapidly. However, they are perceived as lacking flexibility in new situations; being able to make only minor adjustments to the procedure, relying on trial and error when confronted to a novel type of problem.

The distinction between the two types of expertise is largely hypothetical. However, several researchers have recently supported this idea by examples from mathematics education or hypermedia design (Verschaffel et al. 2009). Further, the distinction does not imply that there are only two categories of expertise. Rather, the acquisition of expertise is referred as a continuous process and people’s position along this continuum can shift as a result of task conditions or personality factors.

The path towards adaptive expertise might be different and even in opposition to the path toward routine expertise that is acquired through repeated practice in standardized context. Hatano & Inagaki (1984) have suggested that the socio-cultural context may influence the acquisition of adaptive expertise. The more the system is constrained, the more the work conditions are standardized, the less people will encounter novel problems, the less need to adjust their skills and the less they will have the opportunity to discuss their performance and to acquire new related conceptual knowledge.

### **3. Objectives and Methods**

The method and the results are the same as previously published in detail by Nyssen & Blavier 2013. Our goal was to better understand how expertise and technology are sensitive to this required flexibility. We used robotic surgery to study how the system is robust to changes and how a technique promotes or not resilience.

We carried out three studies to successively examine three relevant dimensions of the issue of technology / flexibility/ expertise and resilience.

First, we studied how the system is robust to a change of technology. We compared surgical operations that were performed with a robotic system with classical laparoscopy. In the two conditions (robotic and classical laparoscopy), the surgical procedures and the team members were identical. We used analysis of communication between surgeons as a sign of adaptive demands within the surgeons’ team when confronted to unfamiliar situations (Blavier & Nyssen 2009). *Investigating Expertise, Flexibility and Resilience in Socio-technical Environments : A Case Study in Robotic Surgery*. In E. Hollnagel, J. Braithwaite, R. Wears, *Resilient Health Care*. Surrey, England : Ashgate Publishing. We recorded all the verbal communication between the surgeon and the surgeon’s assistant. We analysed their content and identified seven categories: 1) verbal demands concerning the orientation and localization of organs, 2) verbal demands concerning the manipulation of instruments and/or organs, 3) explicit clarification concerning strategies, plans and procedures, 4) orders referring to tasks such as cutting, changing instruments, and cleaning the camera, 5) explicit confirmation of detection or action, 6) communication referring to state of stress communication referring to state of relaxation.

During our study, we observed four conversions. Each conversion requires, in emergency, a change of strategy from robotic to laparo or open surgery regarding the type of surgery. For each surgery, we recorded all the verbal communication between the surgeon and the surgeon assistant and analysed their content in order to grasp how surprises are managed and how the robotic technique facilitates or not the robustness.

Finally, forty medical students without any surgical experience were randomized into 4 groups (classical laparoscopy with 3D-direct view or with 2D-indirect view, robotic system in 3D or in 2D) and repeated a laparoscopic task 6 times before to experience a technical (robotic to classical surgery) or perceptive switch (3D to 2D). This allowed us to study the robustness of the system when there is no expertise.

The average duration of the intervention was significantly longer ( $p < 0.05$ ) with the robotic system than with classical laparoscopic.

#### **4. Results & Discussion**

The average duration of the intervention was significantly longer ( $p < 0.05$ ) with the robotic system than with classical laparoscopic. Results show that not only was there more acts of communication with the robotic system, but also that different types of communication between the surgeon and the assistant were used. The significant increase in the number of communication acts referring to orientation, manipulation, order and confirmation within the robot system suggests that a breakdown occurs in the collaboration between the surgeon and the assistant. The robot introduced a distance between the surgeon and the assistant that impedes face to face implicit communication and prevents the assistant from anticipating, the surgeon then continually needs to ask the assistant about the orientation and the placement of the instrument (which is manipulated by him) in order to facilitate the identification of the organs. Therefore, it seems clear that the robot changes the feedback loop and that verbal communication used by surgeons is an adaptive process to compensate the loss of face to face feedback, absent in the robotic configuration. The socio-technical system, here, can be considered relatively resilient to technological change but resilience comes at a cost of requiring more explicit communication from the members of the team that is time and resource consuming and, in some way, “unnatural” in terms of adaptation process for the team.

In each cases of conversion, we observed that the success of the adaptation process implies the return to routine man-machine system and classical expertise. Each of these conversions is associated with an increased number of verbal communications. These communications concerned stress, explicit clarification of strategies (replanning) and expectations concerning orientation and manipulations. We also observed less communication that referred to confirmation. During crisis, the surgeon does not take the time to verify the receipt of his action or request. This pattern of verbal communication reveals “ emergency adaptation” process.

Results of the third study revealed that each technical system is not equal in terms of system’s resilience. Learning curves were significantly different among the 4 conditions: the 3D view (classical and robotic laparoscopy) allowed a great and fast improvement, whereas the improvement was very weak for classical laparoscopy with 2D-indirect view. After the technical switch, performance decreased in all conditions, reaching the same score as the first trial. We also found a strong impact of the perceptive switch. Performance significantly decreased from 3D to 2D condition in classical and robotic system and significantly increased from 2D to 3D condition in classical and robotic system. These results showed that learning with the robot impairs learning with laparo techniques, suggesting that the robot could lead to

a relative rigidity in acting and thinking and, in turn, to a reduction in cognitive flexibility. This rigidity effect has not been observed in the direction of laparo to robot.

## 5. Conclusion & perspectives

Up to now, safety has been improved using technology development, standardization, protocols and training. Our studies showed that the choice of technologies and training programs may be strategic for promoting resilience. The system's resilience emerges through the history and the diversity of agent-technology interactions that enhance surgeon's autonomy towards the unforeseen constraints and surprises. It is the repeated application of the skills in diverse socio-technical environments that leads to adaptive expertise and allows the surgeon to inhibit perseveration and to switch between strategies in his or her repertoire. Therefore, it seems clear that the current approach of safety based upon standardization and protocols encourages routine expertise but militates against adaptive expertise and, in turn, against resilience. This brings us to critical questions: How to keep these routine skills to be able to mobilize them when confronted with surprises, when and for how long? Should we make mandatory recurrent practise with 'old' technology? Should we use training simulators? Our results demonstrated that the most valuable approach in term of risk management seems to require environmental conditions that cultivate flexible technologies arranged with diversity.

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## Innovations to support people in the physical environment in homecare – a workplace for one, a home for the other

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### Abstract

The amount of care provided in the home will grow significantly as care transforms to meet the challenges of an aging population. When care services move into the home, this environment becomes a workplace for a number of professionals, while still being a home for the care recipient. Much equipment and material is needed in the care situation and tends to turn parts of the home into a hospital. In an ongoing research project with home care organizations in Sweden, we are examining the need for improvements in the physical environment in home care and generating solutions to meet these needs. The solutions need to be functional for the home care workers and at the same time be attractive and preserve a homelike atmosphere. We have observed how issues related to hygiene, working surfaces, disposable materials, and lighting can result in non-ergonomic work postures, eye strain, and other risks for the practitioner and the care recipient. Emanating from these issues, university students have been engaged to generate a number of concepts and prototypes from a product development and design perspective. These prototypes are now ready to be evaluated in the home care context to gain feedback from care recipients, relatives and home care workers. The close collaboration with the actual healthcare setting in which these solutions are meant to be used has called attention to the fact that there is no existing business model or market for these types of products. This paper presents some of the innovations and discusses the problems that are connected with the marketization of these types of new products.

**Keywords:** home care, transition of care, physical work environment, design, business model

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### 1. Introduction

Healthcare is increasingly provided in the home as a means to save resources and to make the care more efficient, but also as a service to the citizens who prefer to be cared for in their own home (Genet et al., 2011). When care services move into the home, this environment becomes a workplace for a number of professionals, such as assistant nurses, nurses, physicians, and physiotherapists who perform services ranging from assisting with personal hygiene or preparing breakfast to more healthcare-related activities such as giving injections, dressing wounds or managing medical devices. Much equipment and material is needed in the care situation and it becomes part of the home environment. The home should not be turned into a hospital for those who live there, while efforts need be taken to create a good work environment for the home care workers. Merging these often contradictory needs can be a challenge and home care often generates zones in which a hospital-like feeling dominates.

## 2. State of the Art

The homelike atmosphere is important for older adults. It represents personal values and lifestyle and it provides a feeling of safety (Gillsjo, Schwartz-Barcott, & von Post, 2011). Preserving this atmosphere is hence central when introducing changes related to homecare. Designing for a homelike feeling in special care residences for elderly has been studied to some extent (de Veer & Kerkstra, 2001; Vihma, 2013) as well as interventions for increasing the independency of the care recipient (Hjalmarson & Lundberg, 2015; Rechel et al., 2013). While research related to receiving care in the home and its impact on the older adult's sense of "being at home" has not gained much attention (Gillsjo et al., 2011).

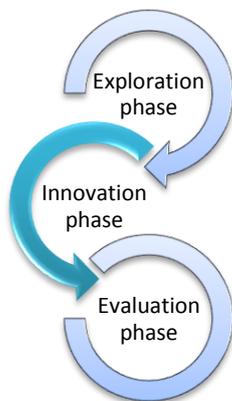
On the other hand, working in home care is associated with several occupational hazards (Hignett, Edmunds Otter, & Keen, 2016; National Institute for Occupational Safety and Health, 2010). These can be due to lifting, pushing or pulling and uncomfortable work postures. Contamination, slips and falls are other risks. Absences due to long-term sick leave are common among Swedish home care assistant nurses and nurses (38.4 and 23.7 of 1000 employees, respectively), where musculoskeletal disorders and mental illness are most common (AFA Insurances, 2014). Improvement of this environment related to providing care is thus highly motivated.

The integration of these two sides: designing for a homelike feeling and independency for the care recipient, and an improved occupational situation for the home care worker needs further research attention.

## 3. Objectives and Methods

In a research project with home care organizations in Sweden, we examined the need for improvements in the physical environment in homecare with the aim of generating both useful and attractive solutions to meet these needs. The focus is not on generating new technical aids, such as a new lifting device, but on understanding how a smart working surface or lighting can be designed to support home care workers in the care situation and blend into the home of the care recipient.

The research project is divided in three phases: the exploration phase, the innovation phase and the evaluation phase. The exploration phase has been concluded and the results were presented at the 19th Triennial Congress of the IEA in Melbourne 2015 (Johansson, Persson, Olander, & Erlingsdóttir, 2015). The objective of this paper is to present the results of the innovation phase, in which several concepts have been developed, and to discuss problems that are connected with the marketization of this new category of products.



1) The *exploration phase* involved observations and analyses of the home care situation to identify areas that would be relevant to further investigate.

2) The *innovation phase* followed in which the problem areas identified in the exploration phase have been scrutinized to generate concepts and prototypes. This phase is the focus of this paper and will be described in more detail further on.

3) The project will be concluded with an *evaluation phase* in which the most promising concepts and prototypes from the innovation phase are further developed and tested in the home/working environment for feedback from home care workers, care recipients and relatives. This phase will be implemented in the autumn of 2016.

### 3.1 The innovation phase

The physical environment of homes where care is provided was studied in the exploration phase to identify areas in need of innovation. This was done through interviews and by shadowing home care workers when they were working in people's homes (Czarniawska, 2014). The areas that were identified included hygiene, working surfaces, disposable materials, and lighting (Johansson et al., 2015). These needs areas were presented to Master and Bachelor level students (students in industrial design, product design, and mechanical engineering) with the task of designing and developing concepts and prototypes aimed to meet the needs identified.

The work process differed depending on if the students were carrying out the assignment in a shorter course or as a project for their Bachelor's or Master's degree. The main approach was similar though, emanating from a product development process that included aspects related to both the usage and aesthetics (Ulrich & Eppinger, 2014). The students have had access to the collaborating home care organization, the researchers' material from the exploration phase and the researchers as supervisors and sounding boards. An occupational therapist is also involved in the project to contribute knowledge about ergonomics, such as strain and stress, in order to guide the students in these aspects.

## 4. Results & Discussion

Several concepts and/or prototypes have been generated (see table 1).

Needs area	Number of concepts/prototypes
Work posture	3
Material storage and work surfaces	5
Lighting	4
Handling medicine	21
Other (e.g. new technology)	3

Table 1. Overview of concepts/prototypes generated in the innovation phase

Some of these have been developed on a briefer conceptual level, while others have been elaborated to the point that physical prototypes could be built and tested. A great part (16 of 21) of the concepts generated for the medicine handling needs is the result of a complete class of students in mechanical engineering that approached this topic in their group project assignment. It resulted in 16 3D-printed prototypes for extracting pills from blister packs, which had been identified as a source of hand strain problems in the medicine handling situation. Hygiene was not presented as a needs area of its own, even though it was presented as one in Johansson et al. (2015). Instead, it has been present in all the concepts by requiring the students to generate ideas that had to meet hygienic requirements, such as materials that tolerate cleaning and disinfection. Two of the concepts will be presented in more detail in this paper to exemplify the process and the results: a piece of storage furniture that includes a portable work surface, and a lighting concept.

#### *Storage furniture concept*

The aim of the storage furniture is to have a placeholder in which all the material related to the care situation (e.g. medicine, disposable material such as gloves and material for dressing wounds, and written information related to the care recipient's health status), can be kept in one place. The full process and resulting drawings can be found in Lokøy & Zagar (2016). One early and one late version of the concept is shown in figure 1. The product consists of three modules that can be configured in various combinations, supplemented with a base block and a tray top to complete the configuration. The three modules are individually

designed to fit specific needs: one standard cupboard for storage of standard material such as disposable gloves; one module for medicine handling including a foldable, designated working area for the task; and one drawer for storage of larger volumes such as a two-week consumption of diapers. This design creates a piece of storage furniture that is flexible enough to fit the diverse needs of different care recipients. The top tray is also removable so that material can be put there and carried to the location of the care recipient for further interaction. The idea is to also offer the furniture in various materials so that the care recipient can choose an exterior that fits in with their home environment.



**Figure 1.** Early (left) and late (right) versions of the storage furniture concept. Concept and images by Lise Lokøy and Viktoria Zagar

One example where this type of furniture would be useful is when an injection is given. The medicine and material for performing the injection can always be found in a furniture module, be prepared on the tray and then transported to where the care recipient is located. In current practice, this procedure is different at different care recipient's homes. Since it is not always clear where the material is kept, the preparation may have to be done on the kitchen table or something similar. If the care recipient is not near a table, the material is often placed on the floor or directly on the care recipient's body during the actual treatment.

### *Lighting concept*

The lighting concept shown in figure 2 is a flexible spotlight, the function of which is to provide sufficient lighting when treating the care recipient. Examples of this are when giving an injection or inspecting a wound. Demands on brightness and colour are important aspects to ensure the ocular inspection is performed correctly. The light is designed so that it can be easily attached to an existing lamp in the home and expanded when the home care worker needs it. At other times it can be hidden inside the lamp or used by the resident as a reading light.



Figure 2. The lighting concept consisting of a flexible spotlight that can be integrated into existing lighting solutions. Concept and images by Martin Cavdarovski, Per Croona, Albin Loeb, and Linus Malmberg

#### **4.1 Putting the product on the market – who is the customer?**

The exploration phase analysis identified a need for products that are useful in the caring situation. The innovation phase has generated several interesting, useful and attractive solutions to meet these needs. However, there is no clear organization for the provision of these types of products in home care. The needs of the care recipient are currently evaluated when the caring situation arises, and healthcare aids are prescribed that are relevant to adjusting the home environment to those needs. If the home care workers have their own special needs for an aid or device that helps them perform certain activities in a safe manner, it is the employer's responsibility to attend to it. Still most of the present solutions and aids are focused on the care recipient, not the caregivers. A piece of storage furniture, like the one presented in this project, is not included in the organization of the home/work environment.

A number of questions emanate from this: Who should be responsible for supplying these types of aids? Who should pay for them? Is the aid for the home care workers so that they can more easily find the material they need? Or is it for the care recipients so that they do not need to have the material lying in plain sight on the kitchen table? Does the care recipient, who is often an elderly person, want a new piece of furniture in the home? Will the aid just be a loan that is later handed back? Should the staff move around the aid between users? All these issues are affecting the market for the product. The project results have illuminated a fundamental problem that does not have a solution in the Swedish context in today's home care organization. Activities to highlight and further discuss this issue will be carried out within the framework of the project. This paper is one way of initiating the discussion in an international context.

#### **5. Conclusion & Perspectives**

Students from design and engineering have served as partners in the project. They can approach the problem areas with a product development and design perspective. This approach has resulted in a number of innovations that aim to improve the physical work environment in home care without affecting the home-like feeling for the residents. This differs from a more pragmatic and function-based approach that is the current standard for developing care support products.

In the next step of the project we will evaluate some of the products designed in the project in different home care setting. In parallel, we will contact and meet different companies to discuss their interest in these types of product and their view of the market situation. We will also lift the discussion to various authorities in the society responsible for working conditions and for elderly care in order to highlight the problems.

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## **Training the operating room staff in a virtual multiplayer and real-time environment to prevent adverse events: study of team situation awareness and decision making using the learning game 3D virtual operating room**

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### **Abstract**

Many studies show that communication defaults are the most current contributive factor of adverse events in the operating room. A successful surgery depends on how accurately a dynamically evolving situation can be assessed on the basis of the information exchanged. First, this paper describes the use of 3D Virtual Operating Room, an innovative virtual multiplayer and real time environment which features a communication system designed to be used in a training context. A voting system is available to debate and make decisions on predefined topics. An experiment took place with anesthetist-nurse students and their trainer in order to analyze their behavior when they have to manage a non-standardized but real-life situation. We study different variables to analyze how information flows between the members of a team, how they make decisions and how much they are aware of the situation when they make a decision.

**Keywords:** team situation awareness, decision making, operating room, learning game, training situation

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### **1. Introduction**

In healthcare, 65% of adverse events in healthcare are related to surgery (Zegers et al., 2011). 54% of surgical adverse events occurring in industrialized countries are considered as avoidable events (Gawande, Thomas, Zinner, & Brennan, 1999). Many studies show that human factors are most often listed among the multiple causes of an accident or a near-miss. They also point that the most current root causes of adverse events in the operating room is due to a communication problem (Halverson et al., 2011; Kohn, Corrigan, & Donaldson, 2000; Lingard et al., 2004). The composition of the team is heterogeneous and each team member has their own technical skills and responsibilities. There are multiple interactions that influence the evolution of the system but a successful surgery depends on what information is dynamically exchanged to understand what is going on (Hempel et al., 2013; Plasters, Seagull, & Xiao, 2003).

## 2. State of the art

Flin et al (Flin, Patey, Glavin, & Maran, 2010) point the importance of non-technical skills that are not directly linked to anaesthetist's technical expertise. Non-technical skills are divided in two categories : interpersonal skills and cognitive skills (Neyns, 2011). Interpersonal skills as communication, leadership and coordination... are skills that make teamwork effective to reach a common goal. Cognitive skills are composed of task management, situation awareness (Endsley, 1995; Kaber & Endsley, 1998) and decision making.

Situation awareness is based on pieces of information that can be seen during the situation. From all the information collected, each one makes their own mental representation according to what they have collected, memorized and understood.

Decision making skills consist in assessing the situation, listing the possibilities, identifying their costs and benefits and then decide the most suitable action to do or make a diagnostic on what's happening (Gaba, 1989).

Keyton & Beck (Keyton & Beck, 2010; Keyton, Beck, & Asbury, 2010) stress the difference between the macro-cognitive framework and the communication framework. "The two approaches differ in the role of communication: as information exchange in macro-cognition as compared with verbal and nonverbal symbols composing messages for which senders and receivers co-construct meaning" (Keyton & Beck, 2010). Here, the word "communication" refers to macro-cognition framework. The team members make their decisions based on their own representation of the situation. The lack of communication can lead the team to build a restricted mental and erroneous representation which could breed inadequate decision-making regarding the real living situation.

Team situation awareness is one of the critical factors in effective teamwork (Salas, Prince, Baker David, & Shrestha, 1995) and can impact the success of the final achievement. Mathieu et al (Mathieu, Heffner, Goodwin, Salas, & Cannon-Bowers, 2000) showed the influence of shared mental models on team process and performance.

Sharing information could allow the team to build a common and more realistic representation of the situation. Therefore, decisions are likely to be more suitable. The collaborative decision making problems (Serman, 1989) can be addressed through argumentation and collaboration between the users involved.

On the basis of video clips recorded during real-life surgery operations, Devreux (Devreux, 2015) studied how professionals communicate according to the level of experience they have<sup>2</sup>. His findings highlight how experts adapt their strategies by collecting the same information from different sources in order to check their coherence.

Some researches focus on the risk management in healthcare and highlight the importance to develop habits of action (Norros & Klemola, 1999).

Learning is a process which is constantly modified by experience (Kolb, 1984). So, involving the teams to investigate inter-professional collaboration in a virtual environment should enable them to experiment risky conditions, to identify errors, adapt their behavior, make suitable decision and then evaluate miscellaneous causes of near-miss.

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<sup>2</sup> For further details, see the poster named "The impact of operators' profession and experience and informational uncertainty during an advert event occurring in a surgical operation: A combined evaluation of situation awareness using SAGAT and eye tracking" presented at HEPS 2016. This study is part of a PhD work, supervised by J. Cegarra et A. Chevalier and financed by the 3D VOR project.

### 3. Objectives and Methods

This paper describes the use of 3D Virtual Operating Room (3DVOR), an innovative virtual multiplayer and real time environment which features a communication system designed to be used in a training context. 3DVOR represents with great fidelity the structure and complexity of an operating room. It allows controlled manipulations of the decision context and controlled information available to the subjects. It is composed of an operating room (medical equipment, patient record, drugs...) and avatars for the patient, the surgeon, the anesthetist and the nursing staff. It aims to train them on non-technical skills. They need to communicate, act, share information and make the most suitable decision with respect to the situation. The individuals, grouped in a virtual team, play the role of professionals in the virtual scene of the operating room system.

The team can experiment educational situations based on real-life situation of Surgery Theater. These situations are designed to train them to manage these situations, anticipate failures, identify and correct errors. The communication system is neither based on voice-chat nor branching dialogues but features graphical tags representing pieces of information and that can be manipulated as tangible objects in the virtual operating room.

Graphical interactions allow users to act, collect, memorize, listen and broadcast pieces of information. The Users can also ask questions and give answers thanks to information tags stored in a graphical panel representing their virtual memory. A voting system is available to debate and vote on predefined topics. Each participant can argue with pieces of information that have already been collected in the universe.

First, we check the usability of the application and then study some variables to analyze if teams are aware of the situation when they make a decision. The variables explored are:

- Pieces of information exchanged inside the virtual environment,
- Piece of information used as argument during the collaborative discussion,
- Anomalies found and exchanged,
- Decisions made by the leader after each collaborative discussion,
- Anomalies discovered and naturally spoken out during the debriefing with the trainer after the game session.

The scenario used in this experimentation focused on two adverse events: wrong patient and wrong site surgery which should be avoided using the Surgical Safety Checklist recommended by the World Healthcare Organization. The two first checklist's items concerned are: "Is the patient's identity confirmed?" and "Is the patient's operating site confirmed?"

The scenario is divided into 3 steps: (i) Verifying patient's identity (ii) Verifying patient's surgical site (iii) Move the patient to the operating room. The scene takes place when the patient has been transferred from their room to the operating room. The mission shown to the team of students consists in preparing the patient from his arrival in pre-operating room until the end of the anaesthesia procedure.

The students are unaware of the hidden educational objectives which are: "Reducing the wrong patient risk applying the checklist", "Reducing the wrong patient risk applying the checklist" and "Adapting the security procedure to the context". A briefing was shown at the beginning to explain the main visible objective. The scenario embeds some hidden anomalies as patient's bracelet is unreadable, patient can't say his name because of his disease, pieces of information relative to operating site mentioned under the different medical and nurse files are incoherent...

Pieces of information are dispersed throughout the environment and available depending on the character's role so as to encourage players to communicate.

This paper aims to analyze teamwork inside this virtual environment. We analyze how subjects interact with each other's, collect and ask information to build their own representation of the situation. Finally, we analyze if the team succeeds to share a common representation of the situation by exchanging information and then, how they make the final decisions. The method consists in using this virtual environment in a real training session with a trainer and their students.

The 18 students involved were in their last year of Anesthetist Nurse School and they already worked in the operating room. Trainer splits the students into 3 teams. The experiment was planned at the end of their grade and had no impact on it. They were not allowed to talk but to use the communication system provided by the virtual universe. Sessions were video-recorded and logged computer data were stored.

## 4. Results & Discussion

The learners are expected to follow or adapt clinical and paramedical tasks from the admission of the patient to the operating room. During the experiment, the teacher supervises in real time the team's activity by means of a specific graphical interface. At the end, the trainer discusses with the students in a debriefing period to make them verbally express the anomalies found, their own representation of the situation and the risks they have been faced to.

### 4.1 Usability

The system was designed with advanced user-friendly features, including interactive broadcasting, listening, announcement, request and answer systems. The first step consists in observing the teamwork timeline to make sure that the communication system is operating and readily useable.

Checking this point, individual representations of the situation should be built during the session.

Figure 1 and Figure 2 show the global activity grouped by character's role and communication features for team 1 and 2. On average, 562 events were recorded by the tracking system during the a session and every communication features (except voting) was used during the first five minutes of the training sessions. For every session, the communication started between the team members during the first minute of game session. The dialogue is initiated between 2 players most often by a request. During the first minutes of the game session, students discover that triggering an action makes a sound and they have fun with it.

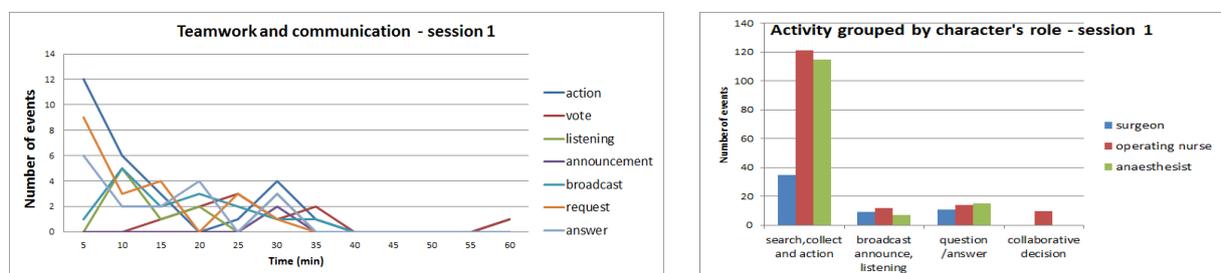


Figure 1. Teamwork activity: team 1

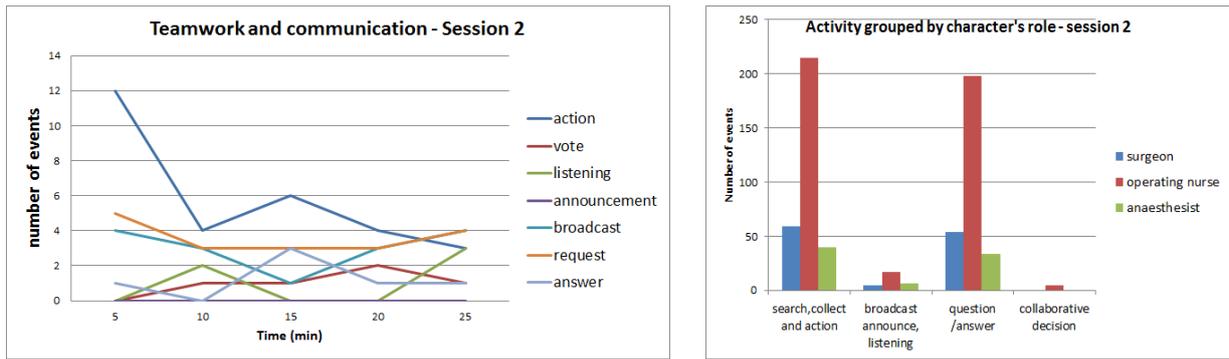


Figure 2. Teamwork activity: team 2

On average, the checklist form has been read 6,2 times, the anaesthetist form had been read 1,3 times, surgical planning 2,5 times, MRI 0,8 times, doctor's letter 1 time and clinical department nurse form 1 time. Each character's role can access to a limited number of documents. Figure 3 shows how many times each character reads a document according to his access rights.

The quantity of information collected from objects is significantly higher than other related interactions like transmissions or requests. The global activity during the game and the behaviors observed as gestures, postures, facial expressions... points out that teams were engaged in the scenario and succeed to operate a dialogue and collect information reading documents.

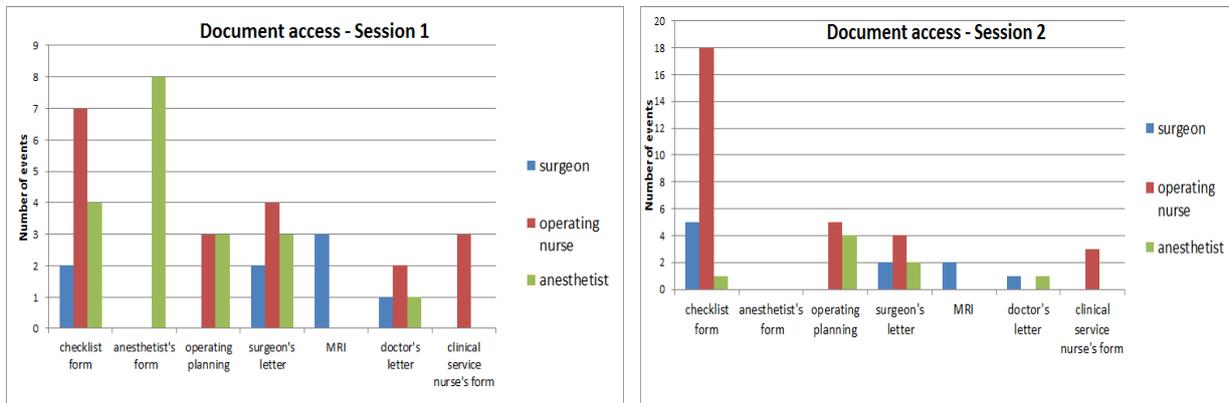


Figure 3. Distribution of document access according to the character's role

#### 4.2 Situation awareness and decision making

Analyzing the topics of dialogue, the patient's identity was the first topic of discussion or collected information (158 for team 1, 163 for team 2) and the operating surgery site was the second one (89 for team 1 and 78 for team 2). Different strategies were observed: the first one consists in collecting pieces of information from documents whereas the second one consists in collecting information asking questions to teammates. For all teams, every anomaly hidden was found and exchanged them between the team members. The surgeon's character used the most relevant piece of information to help the leader to make the most suitable decision but 2 team leaders out of 3 decided not to trust the surgeon when he confirmed it was their patient during the voting period. During the debriefing, they expressed verbally all the anomalies found and the leaders explained that the surgeon are not used to be present during this step in real-life. They all expressed that if a similar situation (i.e. if the patient can't say their name

and the identity bracelet is unreadable) was to happen in real life, they would rather ask a nurse outside the operating theater to confirm the patient's identity than trusting the surgeon.

## 5. Conclusion & perspectives

We have presented an innovative virtual environment designed to be used in fully digital educational context. It aims to control the conversation topics and facilitate the conversation by implementing some implicit conversation rules and proposing decision making features. Experiments were conducted in a healthcare training context, using a collaborative scenario taking place in a virtual operating room and dealing with risks related to the wrong patient or the wrong site surgery. It reveals the team situation awareness and their behavior. It may stress their disagreements managing a near-miss situation that could be discussed with the trainer on the debriefing session, based on tangible recorded events. Future work will enhance the collaborative learning environment with new features to improve the virtual experience of collaborative teamwork with students from different medical and nurse schools.

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## Resilient performance in the containment of an outbreak of ESBL-producing *Klebsiella* in a neonatal intensive care unit

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### Abstract

*Context:* In June 2015 there was an outbreak with ESBL-producing *Klebsiella* pneumonia at the neonatal intensive care unit (NICU) at the County Hospital Ryhov in Jönköping, Sweden. This was a possible dangerous situation. An outbreak group was formed to work with the containment of the outbreak.

*Objectives and methodology:* We wanted to evaluate the work of the outbreak group. Resilience is of importance for safety in socio-technical systems as health care. Resilient performance in the containment of the ESBL outbreak was studied with content analysis of interviews with staff and of written documents from the outbreak group work. Results were categorized according to the abilities of resilience: learning, anticipating, monitoring and responding.

*Main results:* Evidence of resilient performance was found in the work of the outbreak group and staff at the NICU to contain the ESBL outbreak. To establish an outbreak group in outbreaks is in itself an expression of resilience. Resilient performance in all four abilities was found in the outbreak group work. Anticipation and monitoring was less evident in the work at the NICU and are areas of possible improvement in safety at the NICU. Work-as-done in the everyday work at the NICU differed from work-as-imagined expected in the outbreak group.

*Conclusion:* Resilience can be used as a key concept to analyze work in health care. It is an important feature in containment of outbreaks of multiresistant bacteria. From analyses of resilience in health care improvement to enhance safety can be found.

**Keywords:** resilience, outbreak, patient safety, content analysis

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### 1. Introduction

Outbreaks of multiresistant bacteria in a neonatal intensive care unit (NICU) are events that are feared of. Since the outbreaks can spread fast, and the neonates are vulnerable, they are associated with potentially high morbidity and mortality (1).

In June 2015 there was such an outbreak with ESBL-producing *Klebsiella* pneumonia at the NICU at the County Hospital Ryhov in Jönköping, Sweden. 5 infants were infected; however none of them developed invasive disease from the infection. The outbreak subsided in two months. It was still regarded a serious threat to the infants at the NICU.

To handle the outbreak a multidisciplinary “outbreak group” was established that organized the actions taken during the outbreak.

Resilient performance in a system is its capacity to sustain required operations under both expected and unexpected conditions (2).

We have performed a study to identify resilient performance in the work with the containment of the ESBL outbreak.

## 2. State of the art and background

Healthcare can be described as a complex socio-technical system. In such a system resilience or resilient performance is important for safety, and the theory of resilience is therefore applicable in health care (3). A system is resilient if it can adjust its functioning prior to, during, or following events, and thereby sustain required operations under both expected and unexpected conditions (2). Four different properties of a system have been proposed to be important (3). They have been named capacities, abilities or possibilities. In this paper we use the term abilities. The four abilities are: anticipating – to foresee what might happen; monitoring – to observe what is happening; responding – to act to deal with what is happening; and learning – to learn from what has happened.

In Sweden many hospitals have a routine according to which an “outbreak group” is formed if there is an outbreak of contagious disease that threatens the hospital and its patients, for example in an outbreak with bacteria that are resistant to many antibiotics. The outbreak group normally consists of the chief medical officer at the hospital, experts on infections and hygiene, management from the department or ward in danger and a communication officer. Even though outbreak group routines are regarded important, to our knowledge the work of outbreak groups has not been evaluated in a study.

## 3. Objectives and Methods

The aim with the study was twofold: to identify resilient performance in the containment of the outbreak; and to evaluate the work of the “outbreak group” for improvement.

Data collection was through: notes taken during the meetings of the “outbreak group”; interviews with members of this group and staff of the NICU; and written material such as promemorias and written information to staff and parents. The interviews were recorded and subsequently transcribed verbatim. The notes from the meetings include detailed time log of events and descriptions of precise actions taken.

The data were analysed by means of inductive content analysis (4). The findings were categorized according to themes being the abilities of resilient performance: learning, anticipating, monitoring, and responding (3). *Quotations from the interviews are in italics.*

## 4. Results & Discussion

### 4.1 Learning

Aspects of learning were found both in the interviews and the protocol from the outbreak group.

A. Management and staff found that information to staff was crucial and sometimes lacking. Hence new routines were introduced during the outbreak to enhance staff information. “*After a while we took up an afternoon meeting, besides the morning one*”.

B. A new routine about handling of breastmilk was decided by the outbreak group, thought to minimize risk off bacterial spread: the parents were not as usual allowed to handle the milk themselves. After a while the NICU staff found the routine troublesome and not logic to other

procedures. They argued their point to management and the outbreak group and the new routine was abandoned.

C. The experience of the ESBL outbreak was a reminder and learning to the NICU staff about the risk of bacterial spread and outbreaks as well as a reminder of the importance of hygiene in the care of their infant patients.

From the observation of the parents taking care of their children in NICU care and reflection of their own work they realized that they themselves often were a greater risk for bacterial spread than the parents. *“It’s the parents that are careful and thorough; it’s us that mixes things up”*.

D. The NICU staff expressed a need to learn more about the spread of ESBL at the ward, and what happened to the infected children onwards, to better know and understand the overall situation and the result of their work and efforts.

E. In the outbreak group it was decided to do an investigation with a root cause analysis of why an eco-culture was missed at the start of the outbreak.

A and B are examples of learning that had an impact on work during the outbreak. C is an example of learning that facilitates situational awareness. In D and E a need to learn more is expressed.

#### **4.2 Anticipating**

Aspects of anticipation were found both in the interviews and the protocol from the outbreak group.

A. Anticipation about future evolvement of the outbreak is a major part of the work of the outbreak group. *“If these cultures turn out positive we will...”*. *“Since many of these children are expected to stay in the NICU for the whole summer then...”*.

B. To learn the result of the eco-cultures increased the NICU staff anticipation and preparedness to further events.

C. When information reached the NICU about the incoming ESBL-infected child it was a clear message that set the ward in a state of anticipation about measures to take.

D. NICU staff discussed and wondered about the parents’ thoughts and understanding of what was going on, about hygiene precautions and of their fear that they themselves could be infected. They anticipated fear and uncertainty and were frustrated to have to face that when they also themselves felt some uncertainty.

E. The children are patients for long periods at NICU, the staff gets to know the families, there is continuity in the contacts. Hence the staff anticipated good possibilities to evaluate the parents’ abilities and to safely give them responsibilities in the care of their children.

Anticipation was an important aspect of the outbreak group work, to anticipate and evaluate future events, to be prepared to deal with them (A). To be informed of relevant important matters and reflect over anticipated events increases the NICU staff abilities to deal with the outbreak (B, C, D and E). However we could not find any signs of active structured anticipation amongst staff and the anticipation work going on in the outbreak group did not incorporate staff.

#### **4.3 Monitoring**

Aspects of monitoring are found only in the protocol from the outbreak group and not in interviews with staff.

A. According to standard routines monitoring was done of possible infection and bacterial spread with eco-culture controls according to routines.

B. Monitoring was also done according to standard routines that were adjusted to give better abilities to monitor the outbreak situation. Environment cultures (of furniture, instruments and the like in the rooms in the ward) were conducted at several occasions. Additional routines for taking cultures were instituted, for example cultures taken at discharge from the NICU and additional eco-cultures.

C. A list of bed occupancy was instituted to follow which children had been in the same room to give a better chance to trace and monitor bacterial spread. This was later introduced as a function in the electronic medical record.

D. Number of available beds at other NICUs in Sweden was recorded daily to have preparedness to transfer patients if the ward should be overcrowded.

Monitoring is a part of the work in the outbreak group, both from standard routines and also in new activities adopted during the outbreak. Monitoring activities do not seem to be an integrated part of the staff work.

#### **4.4 Responding**

This is the resilient ability where most resilient performance was found. Aspects of learning are found both in the interviews and the protocol from the outbreak group.

A. Activities in the outbreak group, according to general guidelines for the group: planning for information meeting for parents; outbreak group meetings; decisions on where (which rooms) the infected children should be cared for to minimize risk of spread; decisions about information to other wards at the hospital and other hospitals in the region, other NICUs in Sweden, etc.

B. Activities in the outbreak group, work adjusted to the outbreak situation: they discussed and answered questions from the NICU staff regarding practical care matters and risks; decisions was taken on altered or new routines; new work practices was instituted to be prepared to deal with situations with outnumbered bed occupancy at the NICU.

C. Discussion about social media in the outbreak group, to minimize anxiety among other families in the community, NICU parents were asked not to share the NICU events on such media, and the parents followed that advice.

D. NICU staff work responses and actions according to decisions from the outbreak group.

*“It is good that there is an outbreak group that can take decisions”. “We did what we were told to do, sometimes even more”.*

Sometimes decisions were unclear, or difficult to adhere to. As for example decisions about cohort care: *“But we managed anyway”.*

E. NICU staff also responded and took actions from own initiatives.

When routines and decisions in the outbreak group were deemed unrealistic and unwise, the staff immediately responded by talking and giving their opinion about it to ward managers.

When managers were not at the ward, for example during night-time and weekends, and problems arose, the staff solved problems together – everyone gave their hands and thoughts in a joint effort.

F. Non-functioning responses - when things did not work out.

Routines were sometimes decided upon that the NICU staff either was not informed about, or did not understand. The routines were sometimes not manageable since there was not rooms or staff enough to follow them.

*“The outbreak group would function even better if someone of us, from the staff, were in the group”.*

The eco-culture routine broke – *“everybody’s responsibility became no one’s”.*

Resilient performant responding was evident in the outbreak containment work both in the outbreak group and the NICU staff, with both activities according to routines and activities that were adaptations to the events and situation (A, B, D). Some of the actions were in cooperation with NICU parents (C). The staff had difficulties to follow some of the routines and procedures; they managed problems anyway with their own adaptations. The staff’s suggestion to reconcile this work-as-imagined versus work-as-done example is to have staff representatives in the outbreak group (D, F).

## **4.5 General findings**

### Culture promotes the ability to respond

Several cultural or value-based aspects contributes positively to the work during the outbreak. The staff commits in the work, individual responsibility and loyalty is important. *“Action is fun”, “everyone is helpful”, “we do not value and treat families with infected children differently”.*

### Priorities

In stressful situations, like high bed occupancy concomitant with an ongoing outbreak, prioritizing is necessary. To save lives and to deal with emergency medical situations always have priority, even over those, to the staff very well-known and accepted, important hygienic precautions that are necessary to minimize risk of spread of infections like cleaning, decontaminizing procedures, using protective gloves and others. To not follow routines, both knowingly and unknowingly, were described.

### Information

Information about the outbreak situation was given to the parents at several occasions. The NICU-staff thought that was important, it made things easier to the parents, but also to the staff, who took part in the information meetings.

Formal information about the outbreak situation was given orally to the NICU staff at morning (and later also afternoon) meetings. Written information was also given to the staff on boards in the ward.

Informal information was also important to the staff with time for talking and chatting in-between the staff, so that if anything was unclear they could help each other to sort things out or ask the ward managers.

The NICU staff however from time to time experienced uncertainty about routines and procedures. Information was sometimes divergent; doctors sometimes at ward rounds gave information that was contradictory to other sources.

## 5. Conclusion & perspectives

We found resilient performance in the containment of this NICU outbreak. The outbreak was small and none of the neonates developed invasive disease from the infection. It is not possible to judge to what degree the work with the outbreak in the outbreak group contributed to the containment.

The concept to form an outbreak group in itself seems to be a resilient performance of a hospital since its task is to: evaluate and coordinate information (monitor); analyze the situation and evaluate different outbreak possibilities, and spread information (anticipating); to take actions (responding); and finally to after an outbreak evaluate the work (learning).

Among the four abilities of resilient performance, we found most evidence of resilient performance in the outbreak work in the abilities learning and responding. Monitoring and anticipating was an evident part of the work in the outbreak group, but not so amongst staff. In general health care staff from a management point of view is expected to perform well based on their professional training and by adherence to routines and guidelines. These are management principles according to a Safety-I perspective (5). It has been proposed that these principles must be complemented with other principles including supporting necessary performance adaptation to deal with the variability in everyday work, and learning from, and supporting the everyday work of health care staff, i.e. Safety-II (5).

We found resilient performance, and lack of resilient performance, in the outbreak work in the NICU. Means to support the NICU staff abilities to monitor and anticipate should reinforce safety in everyday work at the NICU, including dangerous outbreaks.

This is a small study of a small outbreak. Still, important lessons can be learned from it, and form the analyses. Experiences, like the exposed difference between work-as-imagined from an outbreak group perspective versus the work-as-done staff perspective, can lead to improvement of outbreak work and outbreak group routines.

The categorization of findings according to the abilities of resilient performance was not always clear-cut. This is not surprising since the abilities are in some ways overlapping and interdependent. We believe that this is not important as long as the findings are taken account of in the overall analysis.

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## Hospital cleaners and gender differences in selecting health good practices before and after the downsizing

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### Abstract

*Context:* Hospital cleaning within an important Roman University where cleaners were mainly women whose socio-demographics characteristics were already studied. During the study outsourcing company changed and the new one decided a reduction of 3000 hours of hospital cleaning work per month and 12 % of the work force was dismissed.

*Objectives:* very useful hospital cleaning good practices selected by a group of cleaners before and after downsizing taking gender differences into account.

*Methodology:* Nineteen good practices within questionnaires (n. 84 cleaning workers, of whom 73% women) were selected before (n. 50) (2013) and after downsizing (n. 34) (2015).

*Main results:* after downsizing the very useful good practices decreased significantly with the only exception of *two consecutive days off per week* increased among women and men; *occupational health monitoring* only among women and *gender balance* among men. *Professional growing, more training on hospital cleaning risks, working with a co-worker, moral reward, information on cleaning chemicals, improving fair wages reward* maintain their relevance after downsizing. *Moral reward* was still highest in the selection among women.

*Conclusion:* Cleaning workers reduced their good practices' selection probably for the fear to be fired. Patient's health can also be affected by the downsizing. Gender differences and relevant organizational changes have to take into account. Good practices for health are less selected when employment rate is at risk.

**Keywords:** health good practices, hospital cleaning, gender difference, downsizing, participatory approach

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### 1. Introduction

Cleaning, including hospital cleaning, is considered a *low skill job* where majority of workers are frequently trying to combine several cleaning jobs. Women represent the majority of the workforce in European *cleaning sector* (77%) and are mainly part-time workers (ILO, 2008). High risk of accidents in cleaning sector explains the need of European Occupational Health and Safety Agency [OSHA-EU 2001, 2006, 2009] to publish three fact-sheets towards injuries risk prevention in cleaning sector. "A literature review on the occupational safety and health of cleaning workers" (OSHA-EU, 2009) was also published. Hospital cleaners *are exposed to* physically and labour intensive demanding. About 80% of hospital cleaning is done *manually* using non powered tool due to hospital environmental constraints. *Hospital cleaning* enrolls thousands of workers in Europe and Italy but no specific employment rate in this important cleaning sector was found. Hospital cleaning represents an important activity in

promoting patients' health and in reducing hospital acquired infectious diseases that are increasing world-wide together with antibiotic resistance (Hamad A, Maxwell S. 2008).

In a preliminary study in a roman University hospital (Salerno S., Kolman V., Livigni L. et al., 2012) we found many organisational constraints such as: working outsourcing, washing personal equipment at home, standing, long walking, early morning and night shift (h. 6.00 a.m.), high monotony (>10 actions per hour), contact with biological and chemicals materials, working in a healthcare setting, hot microclimate, interruptions, working alone, no occupational risks training. Eighty % of the hospital cleaners were women, 50 years old, low educational status, married with two children (mainly >18 years old), 16 years of work duration in cleaning and 79 % had a previous work in other activities such as employee, trade retail, handicraft. Women were working exclusively in the morning shift (starting at 6.00 am) (41 %), manually, taking care of each specific hospital ward. Women's mental health was poor (65%).

A new research was conceived in order to analyse gender differences in selecting health good practices for mental and social health (OSHA-EU, Mental health promotion in the workplace - A summary of good practice report) taking results on work organization and main literature on good practices into account. In 2015, during the research study, the outsourcing cleaning company was changed and the new company decided a reduction of 3000 hours of hospital cleaning work per month and 12 % of the work force was dismissed.

The selection of good practices was then considered before and after the company downsizing in order to study its impact on good practices approach among cleaners.

In Italy occupational health law (D.L. 81/2008) promotes good practices as “*organizational solutions or procedures congruent with law and good technique. The solutions are voluntary adopted in order to promote health and safety at workplaces reducing risks and improving working conditions towards wellbeing*”.

## **2. State of the art**

Hospital cleaning is a 24 hours activity particularly in specific hospital wards such as first aid, surgery, oncohaematology. Although very important for patient's healthcare, healthcare workers and environment (hospital waste), hospital cleaning is a low-status job. Hospital cleaners workers are exposed to accidents at work (slips, falls, etc.), musculoskeletal diseases, infectious diseases, skin diseases, respiratory diseases (Lee SJ, Nam B. Harrison R. et al. 2014) and mental diseases (Gamperiene M., Nygard J., Sandanger I et al. 2006). Cleaners have a twofold higher risk of disability pension compared to control group due to persistent shoulder and elbow pain together with carpal tunnel syndrome (Jensen LD, Bonde JP, Christensen MV. Et al. 2016). In France a study found asthma and cleaning agents association among 179 hospital cleaners of whom 136 women and relative risk of 2.38 (IC 1.06-5.33) (Dumas O., Donnay C., Heederik DJ. et al. 2012). In Québec, Canada, a study on gender differences in hospital physical job demand found persistence of musculoskeletal disorders in cleaning tasks after 12 years. In a low-status job, worksite design is lacking (Calvet B., Riel J., Couture V. et al., 2014). In Texas the prevalence of musculoskeletal disorders in hospital cleaners was lower back pain most commonly than in other hospital employees (Salwe K., Kumar S., Hood J., 2011). High prevalence of neck and upper limb disorders and a high physical workload were also found (Unge J., Ohlsson K., Nordander C. et al. 2007). All hospital workers are exposed to biological risks such as hepatitis B, C, tuberculosis, HIV, etc. Hospital acquired infections (HAIs) (i.e. coliforms, Staphylococcus aureus, Clostridium difficile, and Candida albicans) can be reduced by cleaning products. Microbial cleaning represents an effective strategy in continuously lowering the number of

HAI-related microorganisms on surfaces (Vandini A, Temmerman R, Frabetti A. et al. 2014). Hospital cleaning practices are then critical to prevention of nosocomial infection transmission (Rutala WA & Weber DJ, 2016). Cloth towels soaked in disinfectants are commonly used to clean and disinfect hospital surfaces. Cloth towels used for cleaning hospital rooms contained high numbers of microbial contaminants. In this case, hospital laundering practices appear insufficient to remove microbial contaminants and may even add contaminants to the towels. Towels can interfere with the action of common hospital disinfectants. Either independently or in combination, these factors may increase the risk for transmission of pathogens in hospitals. These observations indicate the need to critically reevaluate current hospital cleaning practices associated with reuse of cloth towels (Sifuentes L, Gerba GP, Weart I, 2013).

Hospital cleaners activities and good practices should be considered in this framework.

### 3. Objectives and Methods

Nineteen good-practices (n. 19, see table 1) were selected taking preliminary hospital cleaners study results and the main literature on good practice for women's mental and social health into account (Osha Eu- Gender issues in safety and health at work, 2003) (Osha-Eu, Mental health promotion in the workplace - A summary of good practice report 2011). Participatory methods for ergonomic workplace improvement "*following a good-practice approach*" easily adjustable according to local needs inspired the study [Kogi K, 2006].

A group of hospital cleaners (tot. 50 before the downsizing (2013) of whom 70% of women and 34 afterwards (2015) (76 % of women) were asked to select the good practices in terms of their usefulness (*very useful, useful, not useful*) for improving their mental and social health and to list any other good practices not mentioned among the nineteen practices selected.

N.	Good Practices	Reference among others
1	shift starting at 7.00 am	Costa G. 2010
2	two consecutive days off per week	Lin PC, 2012
3	having more week ends off	OSHA-2003
4	more information on cleaning chemicals	Italian law 81/2008
5	more materials for cleaning	Sifuentes, 2013
6	protective equipment washed at the hospital	Morgan DJ, 2012
7	training on hospital cleaning risks	Italian Law 81/2008
8	a place for personal belongings within the cart	Ramesh J, 2008
9	periodical evaluation of job satisfaction	Osha-Eu, 2011
10	professional growing	Messing K., 2014
11	moral reward	Messing K., 2014
12	fair wages effort/ reward	Siegrist J, 2016
13	improving occupational health monitoring	Italian Law n. 81/2008
14	improving mobility home-work: public or private collective transport	Olabarria M., 2013
15	improving work life-balance such as care services for elderly and young	Härenstam A. 2009
16	combi-job: proposal to work also as health assistant	OSHA-EU, 2009
17	working with a co-worker	Estryng-Behar M., 2007
18	possibility to change hospital unit	Levi L, 1989
19	gender balance in hospital cleaning	Bryngelson A., 2011

Table 1. Selected Good practices in hospital cleaning

Statistical analysis has been performed by  $\chi^2$  test and variables 2x2 have been analysed to evaluate the main gender differences.

#### 4. Results & Discussion

In table 2 the selection of very useful good practices are shown (n. 84) without taking the before and after downsizing effect.

	Very Useful Good Practices	F N. 61 %	M N. 23 %	Total N. 84 %	$\chi^2$	P
1	Starting at 7.00	55,7	60,9	57,1	0,18	NS
2	More materials for better cleaning	59,0	65,2	60,7	0,27	NS
3	Equipement washed at the hospital	44,3	52,2	46,4	0,42	NS
4	Professional growing	86,9	78,3	84,5	0,95	NS
5	Training on hospital cleaning risks	82,0	73,9	79,8	0,67	NS
6	Combi-job	45,9	52,2	47,6	0,26	NS
7	Two consecutive days off per week	57,4	39,1	52,4	2,23	NS
8	Having more week ends off	36,1	39,1	36,9	0,07	NS
9	Working with a co-worker	82,0	65,2	77,4	2,68	NS
10	<b>Possibility to change hospital unit</b>	<b>16,4</b>	<b>34,8</b>	21,4	3,35	<b>0.05</b>
11	<b>Moral reward</b>	<b>93,4</b>	<b>78,3</b>	89,3	4,02	<b>0.05</b>
12	A place for personal belongings within the cart	68,9	52,2	64,3	2,02	NS
13	Information on cleaning chemicals	86,9	91,3	88,1	0,31	NS
14	Mobility home-work	63,9	56,5	61,9	0,39	NS
15	Improving work-life balance	62,3	47,8	58,3	1,44	NS
16	Gender balance	14,8	21,7	16,7	0,59	NS
17	Periodical evaluation of job satisfaction	77,0	87,0	79,8	1,02	NS
18	Improving occupational health monitoring	91,8	91,3	91,7	0,01	NS
19	Fair wages reward	100	100	100	-	NS

**Table 1.** Very useful good practices (%) (n. 84)

Moral reward (93 %), improving occupational health monitoring (91.8 %), information on chemicals (86.9 %), working with a co-worker (82 %) are the most selected good practices among women. Men mainly selected: improving occupational health monitoring (91.3 %), information on cleaning chemicals (91.3 %), periodical evaluation of job satisfaction (87 %),

professional growing (78.3), moral reward (78.3). Only two good practices present a statistical significance by gender: moral reward that is very important for women ( $p < 0.05$ ) and possibility to change hospital unit among men ( $p < 0.05$ ). This picture does not take into account the downsizing effect in 2015.

In table 3 the before and after selections data are shown by gender.

In 2013 (before downsizing) more than 50 % of women hospital cleaners selected 75 % good practices as very useful. In 2015, after downsizing, a drop off was found with only 44 % of women ( $p < 0.10$ ). In 2013, before downsizing, more than 50% of men hospital cleaners selected 78 % of good practices as very useful. In 2015, after downsizing, a drop off was found with only 44 % of good practices selected as very useful ( $p < 0.05$ ).

After downsizing a single good practice “two consecutive days off per week” increased among women (73% vs 43%) ( $p < 0.05$ ) and men (63 vs 27%) ( $p < 0.10$ ) and “*improving of occupational health monitoring*” only among women (92 vs 91%) ( $p < 0.01$ ). “Gender balance” increased among men (25 vs 20%) without statistical significance together with “having more week ends off” (women 38 vs 34%; men 50 vs 33%).

All others good practices such as: starting at 7.00; more materials for better cleaning; equipment washed at hospital; professional growing; more training on hospital cleaning risks; combi-job; working with a co-worker; possibility to change hospital ward; moral reward; a place for personal belongings within the cart; information on cleaning chemicals; improving work-life balance; mobility home-work; periodical evaluation of job satisfaction; fair wages reward decreased among all the group of cleaners.

This change can be considered as an effect of the occupational crisis leading cleaning workers towards a less attentive behaviour for their health in order to keep their job. Although the fear due to organizational change towards downsizing some good practices remain still very useful among the majority of hospital cleaners ( $>70$  %) such as: professional growing, more training on hospital cleaning risks, two consecutive days per week, working with a co-worker, moral reward, information on cleaning chemicals, improving occupational health monitoring, fair wages reward. *Moral reward* is becoming “visible” by positive consideration of their work. This is very important among women (Messing, 2014) that are also less paid and asked less wages increase. Moral reward should be implemented because increases self-esteem and does not need any economic investment.

New company decided to reduce to only one day per week the weekly rest this change explains the importance for workers to consider two consecutive days as it was in the past. Material for cleaning was apparently ameliorated. The new company organizational changes are now object of a more in deep evaluation. Downsizing, resizing, personnel reductions are frequent in Italy and Europe particularly in hospitals in order to reduce costs. These approaches (Weil TP, 2003) certainly increase the alienation of workers, reduce the health demand and the quality of cleaning is affected. Patients may be also affected by the reduction in hospital cleaning quality. These results underline also gender differences when responding to the downsizing.

	Very useful GOOD PRACTICE	WOMEN				MEN			
		<i>Before</i> %	<i>After</i> %	$\chi^2$	p	<i>Before</i> %	<i>After</i> %	$\chi^2$	p
1	Starting at 7.00 am	60	50	0.60	NS	60	62.5	0.013	NS
2	More materials for better cleaning	89	19	29.6	<b>0.001</b>	93	12,5	15.02	<b>0.001</b>
3	Equipment washed at the hospital	60	23	8.24	<b>0.001</b>	60	37.5	1.05	NS
4	Professional growing	94	77	3.94	<b>0.05</b>	80	75	0.07	NS
5	More training on hospital cleaning risks	86	77	0.78	NS	80	62.5	0.82	NS
6	Combi-job	63	23	9.5	<b>0.001</b>	67	25	3.63	<b>0.05</b>
7	Two consecutive days off per week	46	73	4.56	<b>0.05</b>	27	63	2.81	<b>0.10</b>
8	Having more week ends off	34	38	0.11	NS	33	50	0.6	NS
9	Working with a co-worker	86	77	0.78	NS	67	62.5	0.039	NS
10	Possibility to change hospital unit	26	4	5.2	<b>0.05</b>	53	35	6.54	<b>0.01</b>
11	Moral reward	100	85	5.76	<b>0.05</b>	93	50	5.75	<b>0.05</b>
12	A place for personal belongings within the cart	80	54	4.75	<b>0.05</b>	60	37.5	1.05	NS
13	Information on cleaning chemicals,	91	87	1.48	NS	100	75	4.1	<b>0.05</b>
14	Improving work life-balance	74	50	3.81	<b>0.05</b>	53	37.5	0.52	NS
15	Mobility home-work	74	46	5.02	<b>0.05</b>	60	50	0.21	NS
16	Gender balance in hospital cleaning	17	11.5	0.37	NS	20	25	0.07	NS
17	Periodical evaluation of job satisfaction	83	69	1.56	NS	93	75	1.54	NS
18	Improving occupational health monitoring	91	92	0.01	NS	100	75	4.1	<b>0.05</b>
19	Fair wages reward	96	95	0.01	NS	95	87	2.50	NS
	Euros	278	287			393	373		

**Table 3.** Gender differences in selecting good practices before and after the downsizing

### Limits of the study

The hospital cleaners interviewed represent half of the hospital cleaners personnel. However it should be important to have the results of all the cleaners group in order to confirm that no involuntary selection was made. Moreover the before and after group consists of different workers so, although improbable, differences in the selection of good practices could also due to other reasons than downsizing. The poor number in the men group is a limitation when considering gender differences although this limitation is due to the segregation of women in this sector. The new company changes in work organization are still in progress. An improvement in knowing these changes is important to better understand the workers' selection.

## 5. Conclusion & perspectives

This research enlightens part of the underground world of hospital cleaning work, already described as “invisible”. It also underlines the importance of taking the effect of downsizing into account and gender differences when implementing good practice-approach for hospital cleaners. Participatory approach is fundamental for any organizational improvement.

Hospital cleaners have to be considered as “professionals” because their work is very important for patient’s health and hospital environment. Their cleaning activities may reduce hospital acquired infections. Implementing good practices in this holistic approach can greatly improve women’s health in this sector where women.

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## Why do healthcare organisations struggle to learn from experience? A Safety-II perspective

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### Abstract

*Context:* Healthcare organisations are investing significant resources into learning from adverse events, but despite these efforts organisations struggle to create actionable learning to improve patient safety.

*Objectives:* To examine learning from experience in healthcare based on a Safety-II perspective.

*Methodology:* An illustrative example about learning from incidents in the discharge of patients who are on warfarin is analysed.

*Results:* Failure to learn from past experience is in part due to organisations' lack of appreciation of the contribution of dynamic trade-offs and adaptive behaviour. Such performance variability is at the heart of keeping complex systems safe and functioning.

*Conclusion:* Healthcare organisations should consider everyday clinical work as a complementary focus for learning from experience in order to improve patient safety. Shifting the focus of learning from negative outcomes to everyday clinical work might support organisations in establishing a more sustainable culture of learning and improvement.

**Keywords:** resilience, organisational learning, healthcare organisations, Safety-II

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### 1. Introduction

Over 15 years ago, the National Health Service (NHS) in England set out to become an organisation with a memory, which would learn from past experience and improve patient safety (Department of Health, 2000). However, major scandals, such as the failings resulting in patient deaths at Mid Staffordshire (Francis, 2013), as well as the large number of adverse events documented in the literature suggest that patients frequently suffer preventable harm (de Vries, Ramrattan, Smorenburg et al., 2008). Questions have been raised about whether care was getting safer at all (Vincent, Aylin, Franklin et al., 2008). The need to learn from experience in order to improve patient safety was reaffirmed more recently by the Berwick report (National Advisory Group on the Safety of Patients in England, 2013), which provides lessons for the NHS after Mid Staffordshire. The report title sets the agenda: "A promise to learn – a commitment to act". Why have healthcare organisations been struggling to learn, and why have they failed to act to improve patient safety?

In this paper, we argue that failure to learn from past experiences is in part due to the focus on incidents and adverse events as the dominant source of learning. This focus on negative outcomes is characteristic of a traditional safety engineering perspective, where safety is perceived as the absence of such negative outcomes (Safety-I) (Hollnagel, 2014). This view

can be contrasted with an alternative perspective that regards safety as the ability to succeed under varying conditions (Safety-II). We use an example of the discharge of patients on warfarin in the following, to analyse why learning predicated on Safety-I failed to provide improvements in this instance, and to explore some additional insights a Safety-II perspective might offer, based on recent developments in the area of resilient healthcare (Hollnagel, Braithwaite, Wears, 2013; Wears, Hollnagel, Braithwaite, 2015). We propose that healthcare organisations should direct their attention towards learning not only from that which goes wrong, but also consider that which goes right most of the time, in the form of everyday clinical work. Learning from everyday clinical work might provide additional insights about the complexities and tensions that healthcare professionals need to navigate and resolve in order to provide high-quality and safe care. We argue that such insights would provide a better foundation for creating actionable learning and improvements to healthcare practice.

## **2. State of the art**

In healthcare, incident reporting systems are a key mechanism for learning from past experience (Anderson, Kodate, Walters et al., 2013). These reporting systems were modelled on experiences from other industries, such as commercial aviation (Barach, Small, 2000). They are based on the assumption that the collection of incident data can lead to useful learning about precursors and contributory factors (Reason, 1997). The specific issues identified could then be remedied and guarded against to prevent similar incidents from happening in the future (Hollnagel, 2008).

Incident reporting in the NHS has been very successful if measured by the staggering number of incidents are reported every year. However, despite the large number of potential learning opportunities questions have been raised about the effectiveness of incident reporting systems to contribute to improvements in patient safety (Braithwaite, Westbrook, Travaglia et al., 2010; Macrae, 2015; Pasquini, Pozzi, Save et al., 2011; Sujan, Furniss, 2015; Vincent, 2004). There are now many studies that document barriers to effective incident reporting in health care. Such barriers include, for example, fear of blame and repercussions, poor usability of incident reporting systems, definitional problems about what constitutes an adverse event rather than a complication, perceptions among doctors that incident reporting is a nursing process, lack of feedback to staff who report incidents, and lack of visible improvements to the local work environment as a result of reported incidents (Benn, Koutantji, Wallace et al., 2009; Braithwaite, Westbrook, Travaglia et al., 2010; Lawton, Parker, 2002; Macrae, 2015; Sujan, Ingram, McConkey et al., 2011; Sujan, 2012). Among management staff in particular, there continues to be widespread misperception that incident reporting systems might be useful for monitoring incident frequencies, despite evidence that suggests that incident reporting data are poor indicators of actual incident frequencies (Westbrook, Li, Lehnbohm et al., 2015).

One could argue that learning from healthcare incidents has been focussed too much on the collection and categorisation of data (Anderson, Kodate, 2015; Macrae, 2015), whereas successful learning from experience should inherently be a social and participative process (Lukic, Littlejohn, Margaryan, 2012; Macrae, 2015). Healthcare professionals might perceive incident reporting systems as a management tool, and this might act as a barrier to such a social and participative process. Approaches such as lunchtime discussions and informal cross-departmental improvement groups, which give greater ownership to healthcare professionals, might be useful to encourage greater local learning and improvement (Sujan, 2015).

### **3. Objectives and Methods**

The objective of this paper is to examine learning from experience in healthcare organisations from a Safety-II perspective. This is done in order to point out weaknesses with current approaches, and to suggest productive alternatives that might be explored.

To this end, we first describe a specific example of learning from experience that was triggered by a number of incidents. In the following sections, we then critique the learning that was generated and the improvements implemented from a Safety-II perspective.

#### **3.1 Case study – Discharge of patients on warfarin**

A large inner city hospital sustained a number of incidents whereby patients were prescribed warfarin (a blood thinning medication that requires active monitoring) and were then sent home without being given a follow-up appointment. This resulted in both under and over thinning of the blood, with potentially serious outcomes for the patients. The incidents were reported and formally reviewed in accordance with the hospital's risk management and clinical governance policies.

This review and learning process resulted in the recommendation to create and implement a discharge policy (a standard operating procedure, or SOP), where no patient was allowed to be discharged without a follow-up appointment being made first. On face value, this SOP sounded eminently sensible and safe practice.

However, what was not recognised was that there was no 24-hour appointment booking system for the anticoagulation clinic. This led to patients staying in hospital extra days (overnight or over the weekend) to ensure that the policy was adhered to. This affected both the patients, who stayed in hospital longer, and the wider organisation, which had fewer available beds for patients waiting to be admitted.

At a Junior Doctor Forum for foundation year doctors (early career), a case was presented of a patient, who was ready for discharge from the acute ward on a Friday afternoon. In line with the SOP, the patient needed an appointment made at the anticoagulation clinic before they left. The appointment system is accessed by telephone, but as it was Friday afternoon there was no one available to take the call. There was no alternative means of making a referral. The formal and mandated solution was for the patient to remain on the ward all weekend in an acute bed until the clinic was open on Monday.

The junior doctor weighed up the benefits of following the SOP with the needs of the numerous patients waiting for beds. The doctor decided that, as the patient was lucid, sensible and mobile, they could go home, but they had to return to the ward in person to ensure that they had follow-up arranged for them. The patient was discharged and duly returned to the ward on Monday. Another hospital policy is that patients do not return for follow up arrangements to an acute ward. The appointment was made and arranged, but an incident form was submitted as the patient had been discharged without formal follow-up having first been made.

### **4. Results & Discussion**

#### **4.1 The problems with Safety-I as a basis for learning**

When adverse events happen, organisations as well as patients want to know why they occurred, and how they can be prevented in future. The focus on negative outcomes is one of the defining characteristics of traditional safety management approaches. From a Safety-I

perspective, safety management aims to reduce harm and adverse events as far as possible, by either eliminating the causes of harm or by controlling the risks associated with these. Safety-I management frequently leads to the implementation of additional safeguards or defences in order to reduce or eliminate vulnerabilities in the system. Specific safeguards and defences often include attempts aimed at eliminating human error – by constraining behavior and reducing variability through standardisation of practice (Reason, 2000).

This is illustrated by the example above, where the incident analysis suggested that the “root cause” was the fact that patients were discharged without a follow-up appointment. The intuitive response was to standardise practice, and to eliminate variability through the introduction of a new standard operating procedure (SOP). The logic dictates that if everyone follows this procedure, then patients would be safe.

This view on the system by those who design and manage clinical work has been referred to as work-as-imagined (WAI) (Hollnagel, 2015). However, the way everyday clinical work actually unfolds is markedly different, and never standard or routine (work-as-done, WAD) (Hollnagel, 2016). This is because modern healthcare systems are not simple, linear systems, but might be more accurately described as complex adaptive systems (Braithwaite, Clay-Williams, Nugus et al., 2013). While some limited aspects of healthcare can be described in a relatively tractable and linear fashion, there are many aspects where this is not the case, and interactions can be both non-linear and complex, and the resulting behavior of the system is emergent (Robson, 2015). When learning from experience is confined to the tractable and linear analysis of incidents, there is the danger that lessons and resulting interventions are not grounded in a thorough understanding of everyday clinical work. Rather than leading to improvements in practice, the resulting interventions can all-too-often introduce additional constraints, tensions and contradictions for the practitioner, and thereby widen the gap between WAI and WAD (Sujan, Pozzi, Valbonesi, 2016).

This gap can be seen in the example, where its designers failed to consider the interdependency between the new SOP, and the availability of the appointment booking system. The latter was available only during office hours, and the introduction of the new SOP put healthcare professionals in a difficult double bind during the nighttime and over the weekend. Healthcare professionals were forced to make a trade-off between following the mandated procedure and promoting the safety of all patients, including those who were waiting to be admitted.

#### **4.2 Safety-II learning**

Situations such as this might appear quite simple, but often require complex decision-making skills. Safety-II regards such trade-offs and performance adjustments as essential components of organisational resilience (Braithwaite, Wears, Hollnagel, 2015; Sujan, Spurgeon, Cooke, 2015). From this perspective, we argue that the focus of learning from experience should be not so much on the extraordinary failure, but rather on the ordinary, everyday clinical work (Sujan, Pozzi, Valbonesi, 2016). Learning from everyday clinical work can lead to an appreciation of how performance adjustments are a necessary part of transforming WAI into safe practice.

Notably, failing to build such an understanding and appreciation of the role of performance adjustments, might lead to situations where the trade-offs made by healthcare practitioners are regarded as unnecessary deviations from and violations of best practice guidance. This can have seriously detrimental effects on the ability to learn from experience, and on patient safety. When practitioners work in a culture where performance variability is regarded as one of the root cause of adverse events, they might be tempted either to refrain from making the

difficult trade-offs, thereby threatening patient safety, or they might wish to keep the performance adjustments they make “under the radar” – lest they are reprimanded or penalised. In either case, managers become unaware of the widening gap between the work they are imagining, and its practice (Debono, Braithwaite, 2015). The inaccurate beliefs thus introduced into the system are detrimental to resilience of organisations, and could lead to more brittle systems of care.

In the example introduced earlier, the junior doctor decided to violate the new formal SOP, and to send the patient home without an appointment. Their decision resulted from deliberations that included consideration of the risk to the patient, as well as the risk to all the other patients waiting to be admitted. The effort-to-benefit ratio of making the trade-off was high for this clinician. In order to ensure the safety of patients, they deliberately went against organisational policy, asked the patient to do something outside of their expected plan (coming back in again later), and also increased the workload of another colleague, who needed to arrange the appointment at a later time. Practitioners, like the clinician in the example, most of the time receive no support to resolve their dilemmas and complex tensions. But they receive all the blame when they fail.

## 5. Conclusion & perspectives

Why do healthcare organisations still struggle to learn from experience? Based on the analysis presented in this paper, one might conclude that this is in part because they are committed to safety management approaches that were fit for improving the safety of industrial systems in the 1960s – 1980s, but which have clear limitations when applied to modern healthcare systems. Healthcare systems are more complex and less tractable, and they rely much more on performance variability as a means to provide organisational resilience and to deliver safety, high-quality care.

What does this mean for the future of learning from experience? Learning from experience remains a key component of any safety management system, but organisations need to consider learning processes that can complement and provide an alternative to the existing incident reporting systems. Such alternative processes need to be able to generate actionable learning from everyday clinical work so that the contribution of trade-offs and performance variability can be adequately accounted for. Learning from experience does not necessarily have to be a centralised activity – learning from experience should happen at all levels of an organisation, and through different processes, both formal and informal.

A word on culture: many practitioners still work in a culture where performance variability is regarded as the root cause of adverse events. Transforming learning from experience and transforming culture likely go hand in hand. Shifting the focus of learning from negative outcomes to everyday clinical work might support organisations in establishing a more sustainable culture of learning and improvement.

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## **Risk analysis by healthcare professionals in radiotherapy: assessing difficulties, developing a method**

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### **Abstract**

Following the Epinal (2006) and Toulouse (2007) radiotherapy accidents, risk management requirements for radiotherapy have increased. Radiotherapy centers are requested to apply corrective and preventive methods in working groups. The research presented in this article addresses the implementation of an a priori method (the Failure Mode Effects Analysis method – FMEA, AMDEC in French) in radiotherapy centers. Unlike risk industries, working groups in radiotherapy using the FMEA method rarely include a risk manager: only a quality specialist and health care professionals are involved. This research presents how FMEA is generally used in radiotherapy centers and determines the limits of the method. Different FMEA meetings were recorded. One of them was transcribed, coded and the exchanges between group members were analyzed. Results question the FMEA method, challenge some of its founding principles and suggest another way of tackling patient safety issues. New methodological principles for conducting safety-oriented working groups are proposed.

**Keywords:** risk management, FMEA method, activity analysis, radiotherapy.

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### **1. Introduction**

For healthcare professionals, assessing benefits and risks of treatments is a common dimension of providing care. This paper addresses another human and organizational dimension of risk, the risk of not delivering the “right dose, to the right patient, at the right place, at the right time”.

In the context of safety research, high-risk industries have proposed several methodologies to conduct risk analysis:

- corrective methods, that analyze past undesirable situations;
- preventive methods, that seek to anticipate potential undesirable situations and use scenarios (Prior Risk Analysis) or risk maps (Failure Mode and Effects Analysis – FMEA).

This paper focuses on the application of the FMEA preventive approach in radiotherapy working groups. This method has been selected because the French Nuclear Safety Authority (ASN) and radiotherapy centers mostly use it due to its –supposed- simplicity.

In radiotherapy, as in medicine in general, the preventive approach does not begin with analyzing the initial medical decision, i.e. the choice of a treatment by the physician, but focuses on what follows, i.e. the process that transforms the decision into action. Quality and safety are seen as depending mainly on healthcare professionals’ practices. In theory, the

purpose of the FMEA method is to identify and analyze potential risks at all steps of the patient care process from failure modes. The aim of the FMEA method is to define actions for reducing patient risks.

First this article proposes to describe exchanges in working groups with the FMEA method. Secondly the aim of this paper is to consider differently patient safety and to propose new methodological principles of these specific spaces of discussion for future experimentations.

## **2. State of the art**

“The modern meaning of being safe is not being exposed to danger” (Hollnagel, 2014). To protect people from hazards, risk industries have developed various methods, particularly FMEA. This method was adapted in the United States to the health domain (HFMEA), in order to protect patients from undesirable care events. Whereas a majority of authors have positively assessed the FMEA method in terms of patient safety improvements, others (Amalberti, 2014; Hollnagel, 2014; Merad, 2010; Dassens & Launay, 2008; Lederman, 2008; Peretti-Watel, 2001) have questioned some of its aspects: its sequential approach (assessing each step of a procedure rather than the interaction between steps and the global activity), the causal relationships it establishes (causes and effects of failures), the use of probability and predictability (risk assessment), and the focus on human errors. For example, it is unrealistic to believe that the predictability of human and organizational behaviors are comparable to that of technical systems, even if human behaviors are framed by procedures (Thellier, Falzon & Cuvelier, 2015). Perhaps the expectations of benefits are too high and the link between risk identification and safety improvements is set too direct. The method tends to simplify the work reality, while its complexity should be understood and taken into account. Complexity is used here as defined by Morin (2005): a significant amount of interaction with uncertainty, presence of random phenomena. The numerous daily interactions between caregivers and the various levels and timing of their operations question the relevance of this method for the medical domain. The method may overlook what is actually happening in daily work. However, the care complexity itself could hinder the ability of the working group to detect risks.

Some participative methods, meant for studying risks, have been developed in the medical domain and in high-risk industries. Risk is easily identified when participants analyze events or accidents (Caroll & Fahlbruch, 2011; Schöbel & Manzey, 2011), “non-nominal situations” (Nascimento & Falzon, 2014) or “rule deviation situations” (Mollo & Falzon, 2008). Risk is less immediately apparent when reflecting on organizational or on strategic dimensions of work. Yet, these dimensions are central to everyday work.

Continuous changes and increasing complexity in organizations, together with technological advances require the development of new approaches. Hollnagel & al. (2014) encourage studying adjustments in work and Detchessahar (2001) encourage the firm to consider working situations in which professionals’ subjectivity lies at the heart of the production. This article suggests that these points of view allow one to connect daily work complexity to the risk borne by patients. However, discussing work is a difficult task, which requires equipping these spaces of collective reflection.

## **3. Objectives and Methods**

A previous study (IRSN, 2014) investigated the difficulties encountered by radiotherapy centers in performing the “Failure Mode and Effect Analysis”. The present study wished to better evaluate these difficulties and to define and assess other methodological principles. Several meetings of a FMEA working group were recorded; one recording was transcribed,

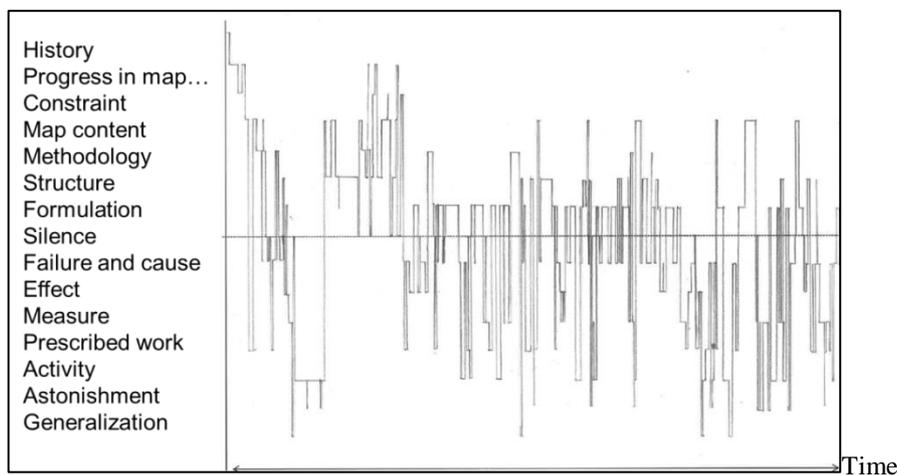
coded and analyzed according to the topics discussed. A debriefing was done after each FMEA meeting to identify what was learnt regarding patient risks and how it contributed to healthcare safety. The transcribed meeting was analyzed in order to understand how the group used the FMEA method, to identify the difficulties that were met and to define methodological principles permitting to circumvent FMEA limits and its use without a risk manager.

## 4. Results & Discussion

### 4.1 FMEA: a simple or complex method? a resource or a limit?

Results show that it is difficult to distinguish difficulties related to the FMEA method itself and to implementation conditions.

In the FMEA group, participants discussed two main topics (figure 1): the preparation of risk mapping (history, progress in map completion, constraints, map contents, methodology, structure, formulation) (upper part of the graph), and its items (failure and cause, effect, measure, prescribed work, activity) (lower part of the graph). Additionally, discussions show signs of astonishment and attempts at generalization.



**Figure 1.** Chronicle of a discussion on two main topics: preparation of risk mapping and its objects

Nearly half of the discussion time is dedicated to filling the map, mainly by formulating simple, precise and short sentences. That is the way chosen to convey risk analysis. Sometimes, the care process needs to be redefined during the exchanges. In practice, care activities do not always follow sequentially from one phase to the next. This requires reviewing the map structuration. But it is not possible to restructure it.

The topics in the upper part of graph are:

- **History:** “we have obtained Evreux’s mapping”;
- **Progress in map:** “we are debating the preparation stage today”;
- **Constraint:** “we haven’t got all the trades at this meeting, we must include a new reading of the risk map”;
- **Map content:** “it seemed bizarre to find “technical control” here in the map”;
- **Methodology:** “one should not go into all the details” or “the scoring will be done at the end of the mapping”;
- **Structuration:** “we wrote “dosimetry not validated” after “medical prescription”. This is not the good place”;

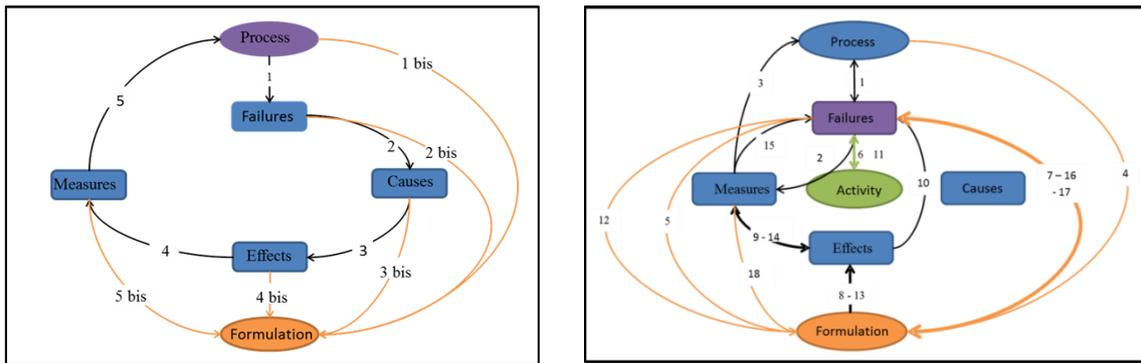
- **Formulation:** “in brackets, you can write “exporting of the plan” or “correction of points of reference”.

The lower part of the graph addresses the items of the risk map. As an example, participants discussed a double validation procedure and said what follows:

- **Failure:** “failure, ok, it can be an omission of the double calculation”;
- **Cause:** “we try to save time in the validation by the physicist”;
- **Effect:** “if the calculation result is what we were hoping, an error can 'fall through the cracks””;
- **Measures:** “the physicist validation exists”;
- **Prescribed work:** “The physicist validation allows one to see if the double calculation has been forgotten”
- **Activity:** “for us, a dual calculation is a control that has already been done. We can't review all the data entered in the software”;
- **Astonishment:** “you can validate a calculation in tolerance limits without checking it?”;
- **Generalization:** “Whatever the problem...” – “In any case, if he does not validate...” – “the same is true for physicists...”.

More generally, when participants reflect on failures and causes, they talk about human errors as requested in ASN guide: actions not completed, data error, action forgotten, incomplete validation, procedures not applied, documents filled incorrectly. They have difficulties in specifying the causes and effects of the failures. The causal analysis is superficial and focuses on the identification of human errors, rarely on organizational, managerial, contextual and strategic dimensions of activity. The causal analysis requires to investigate these different background causes of failures but fails to address actual work conditions and context. Perhaps because such an analysis highlights characteristics and constraints of the activity, that are difficult to resolve at the time of the collective reflection. When discussants reflect on the effects of the human errors, they consider the impact on the daily work (delayed care, blockage of the patient file), the effect on their performance (delayed work, loss of time, discrepancies) and on their working conditions (duplicated work, overload). The effects on patients are rarely mentioned. When they are, discussion is interrupted or concludes that there was no risk. Concerning measures, participants most often refer to the prescribed work (anticipation of the physician leave, validation of trades, quality control, comparison between calculations, record check and use of check-list).

The analysis shows that discussants seek to follow the logic of the map (figure 2), initially vertically to define the step of the process that they need to analyze, then horizontally to fill the mapping. The ASN guide requests the participants to use the FMEA table and to complete it in six stages to draw up an inventory of risks: identify failures, determine possible effects and causes, indexes of severity frequency and criticality. In a second step, participants have to use the FMEA table to define and formalize organizational and technical measures. During discussions, repeatedly, the quality specialist reminded the participants to stick to the order of the risk map. A detailed analysis of exchanges has shown that participants often fail to follow the linear logic of the risk map (figure 3).



**Figure 2.** Theoretical reflection with FMEA method **Figure 3:** Real reflection with FMEA method

Some of the mapping objects may not be discussed and the pathways in the mapping can be different. In the example of figure 3, causes of failure are not discussed. In other exchanges, other elements, such as the care process or the measures, may be neglected. Furthermore, pathways of reflection vary and depend on the topics under scrutiny. A measure related to a failure can be discussed before its causes and effects, or two steps of the process should be discussed simultaneously. For example, validations by the physician and the physicist have been debated together while they are not part of the same step of the care process.

In addition, a new object is discussed: the actual daily work, also called activity but activity does not exist in the risk map. Yet mentioning the activity helps participants to contextualize the objects of the map. In the example of figure 3, discussing their daily work allows caregivers to better grasp the failures, or the measures, more rarely the causes or effects. More precisely, discussing the activity allows participants to identify potential weaknesses of measures, practice adaptations, specific processes and uncertainty in work. Such weaknesses are for example:

- a gap between the expected practice and reality (non-application of the procedure regarding the absence of the physician, incomplete controls);
- some unusual events within the organization (Clinac organization, patient planning);
- unsolved problems or unanswered questions (changes during the care, software changes, failure of detection of wrong exported data).

In other words, discussing the activity enriches exchanges. Activity-related topics are interesting because they make participants capable of addressing some dimensions of work rarely taken into account in this type of meeting (organization issues, and individual or collective practices), sometimes considered as taboo or latent (unresolved or unknown problems). The debates on risk mapping items and on “interesting topics” are often interrupted. Interruptions occur for various reasons (from most frequent to least frequent):

- **a progress in the risk map** (move from box to box): “*what is the cause (or the effect)?*” – “*do you detect failures?*”;
- **the formulation of exchanges** (clear and explicit wordings): “*you can write “deferring the start of the treatment” – “written RT Chart in brackets”*”;
- **recalling the methodology** (sharing the development principles): “*we were always told not to go into details*” – “*follow the order of risk map*”;
- **discarded subjects** (off-topic, already dealt with, without risk, individual and collective feeling of control, existing measures dormant but still valid): “*shh! stop, that is off topic*” – “*It was supposed to have been done already, it’s enough for me*” – “*we already talked about contouring for planning treatments*”;

And less frequently:

- **uncertainty** (an unanswered question must be dealt with in the future): “*we don’t know what to write, the radiation oncologist will be allowed to do it*” – “*or that is absolute chance?*”;
- **subject considered as treated** (subjects feel that the matter has been covered): “*it’s ok, a measure already exists*”;
- **shift of topic** (development of a new idea): “*however, how is the system calibrated?*” – “*we did not talk about flash treatment*”.

To summarize, interruptions were most often driven by the logic of the methodology and sometimes by natural links between different topics (interlinking topics, following up ideas) and varying degrees of judgment and uncertainty.

In short, participants mainly discussed known human errors and their effects on the quality of the treatment. One of their difficulties was to connect characteristics of the activity to consequences on the safety of the treatment. They rarely considered the risk for the patients. The over-exposure or under-exposure risks for patients related to individual or collective work were not easily identified. The phase of risk identification for the patient appeared difficult to complete despite references to “interesting topics” that emanate in daily real work. In addition, these debates regarding interesting topics are often interrupted by the FMEA-induced constraint of formulating and mapping risks. Consequently, these topics are poorly developed.

#### **4.2 Definition of new methodological principles**

The risk analysis based on failure modes represents a challenge that radiotherapy centers cannot overcome. In other words, the will to describe risks in terms of causes and effects failures orient discussions towards negative aspects and overlook a large part of work. FMEA meetings question the quality and accuracy of the collected and used data.

How can radiotherapy centers analyze risks when risk identification is not self-evident? Part of the answer may lie in connecting risks to daily work, as the emergence of “interesting topics” has shown. This article seeks to provide the methodological principles and tools for connecting these two dimensions of work (daily and risky). As a consequence, we suggest to change the composition of the working groups, the object and the pathways of reflection and we propose new methodological principles to be experimented, in order to switch from the FMEA method to “activity sharing spaces” (table 1).

	<b>Purposes and principles of FMEA</b>	<b>Limits of FMEA</b>	<b>What was learnt from the analysis of FMEA actual use</b>	<b>Methodological principles to experiment</b>
<b>Aim of reflection</b>	Anticipate risks and protect against them	Emergence of known failures and risks	Difficulties in imagining new risks	<i>Current reflection</i>
<b>Topics discussed</b>	Analyze failures	Focus on negative aspect	Overlooking a whole facet of the caregivers work	Reflection on positive and negative aspects
	Items of analysis (failures, causes, effects...)		Emergence of interesting topics re. daily work	Activity becomes the first subject of the group discussion
<b>Pathway of reflection</b>	Use the map logic	Follow the map logic for formulation	Taking distance from the map for reflection	Use colored post-it notes
	Failures → Risks	Superficial analysis	Risk identification is not straightforward, intuitive	Do not refer directly to risks: go through daily work narratives
	Risks → Measures	Focus on operating logic	Numerous actions, few implementations	Well-balanced between constructive and productive actions
	Exhaustive approach: analysis of the whole care process	Lack of exhaustiveness	Focus on only a few dimensions of work	Enlarging the reflection to work complexity dimensions and regulations
	Traceability of reflection	Formulation interrupts the caregivers reflection		Disconnect traceability and exchanges : record meetings
<b>Aim of method</b>	Legal protection	Focus on filling of the risk map	Complying with the ASN regulation	Identify daily work risks for patients
<b>Updating</b>	According to specific criteria. Usually annually	Obsolescence of risk map		One meeting every three month
<b>Group composition</b>	One representative by trade	Lack of debate		Two or three representatives by trade

**Table 1.** Transition between FMEA meetings and “Activity sharing spaces”

The analysis of FMEA use in radiotherapy centers has enabled to describe the purposes and principles of FMEA, to determine FMEA limits and to propose methodological principles that are more suitable with radiotherapy activity. The “risk map meetings” have been redefined as “activity sharing spaces” (Thellier, Falzon & Cuvelier, 2015). Daily activities (rather than potential failures) are placed at the heart of the exchanges. Discussants are invited to share their views and expertise regarding their actual individual and collective work.

“Activity sharing spaces” propose two steps during the period of reflection. First, participants are requested to identify success modes in activity stories (complex activity, day-to-day regulations) rather than to detect failure modes. This approach would be consistent with the objectives of caregivers (successful care) and with the daily reality. Therapeutic failures do not occur every day and undesirable events may go unnoticed due their control. Second, we suggest that the analysis of risks should be based on the analysis of combined dimensions of activities and of situations in which safe regulations are undermined. We assume that risks are not immediately apparent in the activity story phase and are not always identified by participants. For example, the following scenario can be risky in certain situations (that participants need to specify): management of a patient by an intern + unavailable senior physician + incomplete patient file. A radiotherapy technologist can detect an intern’s error (regulation) if he/she is experienced (situation). For example also, situations in which

regulations are undermined: a change in prescription during the treatment or a change of machine can foster human errors. We suggest to change the pathway of reflection: the objectives should be first to produce a diagnosis of some complex healthcare activity dimensions, second to identify situations which undermine daily work regulations. A reflection is in progress to help participants to imagine unknown scenarios.

## 5. Conclusion & perspectives

This article suggests doing a link between daily work and risks for patients, the risk of not delivering the “right dose, to the right patient, at the right place, at the right time”, whatever the severity of consequences. The hypothesis is that a minimal event could have serious consequences in a specific context. We propose to set up “activity sharing spaces” as autonomous forums (i.e. forums that do not involve activity analysis professionals) that allow healthcare professionals to produce a diagnosis of complex healthcare activities and to analyze known or unknown situations that undermine caregivers regulations. In this particular configuration, appropriate resources should be developed to help professionals in accessing or elaborating dimensions of their activity.

This research is consistent with different methodologies or concepts:

- Methodological: spaces of discussion, activity diagnosis, information’s fusion, systemic method, anticipation approach, scenario-based reflection.
- Conceptual: interest in normal operating mode of daily work, adaptive capacity (performance adjustments), complexity of situation, constructed approach.

We propose to take some distance with mathematical model (probability, attribution of risk value...), causal relationship, failure modes and simplification or segmentation care process, action logic. The methodological principles seek to define a daily-work risk model by relationship and data coupling (rather than by causal relationship), complexity activity diagnosis (rather than by simplification), success logical than event logical, enlarging reflection (rather than by framing). Our assumption is that the method we propose will be felt as better adapted than the FMEA method. Filling in the risk map was indeed perceived as artificial and was only completed in order to satisfy prescriptive regulations.

Future experimentations should demonstrate that radiotherapy professionals will be able to identify and diagnose situations which undermine regulations. We will also investigate the elements that cannot be analyzed with “activity sharing spaces” and the limits and constraints of the method.

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## Safe Transitions of Care: a comprehensive human factors approach for improving safety in the communication of healthcare organizations

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### Abstract

Care transitions are critical moments which may expose patients to adverse events and generate organizational failures. Ineffective care transition processes lead to higher hospital readmission rates and costs and patients can be harmed when the many moving parts of their care process are not effectively coordinated. The human factor and patient safety approach can provide effective methodologies for the design of tools to improve the ability of health care workers to make available key information at the right time, ensuring patient safety and continuity of the clinical pathway. In order to unveil what promotes or hinders effective communications at care transitions we involved health care workers of 10 dyads of inpatient care units (250 operators accounting for 1500 care transitions) in an action research process. The aim was to endow the participants with the skills necessary for evaluating the organizational context in which the handovers occur and give them support in prompting the interventions for constructing an organizational context underpinning safer communications at care transitions. In particular through the application of the FMEA technique the highest priority of interventions have been assigned to 7 pitfalls which need to be taken into account in order to amplify the capability of organizations to implement the handover patient safety practice and fruitfully maintain it. Communication at care transitions is a fundamental testbed for the resilience of complex healthcare organizations. We attempt to increase the safety of communication during care transitions in order to allow healthcare organization to sustain required operations, in the presence of continuous stress. To achieve that we tried to endow the healthcare workers with the methodological tools for analyzing the current situations and adapt it in order to embrace the handover patient safety practice.

**Keywords:** handover, care transitions, Human Factors

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### 1. Introduction

Handover is "the transfer of professional responsibility and accountability for some or all aspects of care for a patient, or group of patients, to another person or professional group on a temporary or permanent basis" (9). The handover is then a communicative process aiming to achieve effective continuity of clinical care within the patient care pathway, regardless of when the transition occur. In recent years the complexity of the health care system have been growing rapidly and health care team are distributed in time and space. From the patient perspective is getting more and more difficult to identify a single health professional in charge for the process of care. Care coordination is not anymore a complementary element but instead a backbone of clinical activity which need to be mindfully designed and maintained.

In general care transitions are critical moments which may expose patients to adverse events and generate organizational failures. Ineffective care transition processes lead to higher

hospital readmission rates and costs and patients can be harmed when the many moving parts of their care process are not effectively coordinated (2,4,7).

## 2. State of the art

The contemporary distributed structure of health care system are making necessary the construction of an ecosystem that enables the sharing of information (4). The World Health Organization (WHO) has identified the handover as a key process for patient safety and the Alliance for Patient Safety released an important document "Communication During patient Handover" (13), in which is explicitly stated that the transfer of information about a patient from one healthcare practitioner to another, between medical teams and from health care practitioners to the patient and to the caregiver, should ensure patient safety and continuity of care.

Communication and cognition are imbricated activities. Human mind evolved for communicative purposes and the human cognition is an eminently social process deeply superimposed on our communication skills (11). Consequently human communication can be hardly studied without considering the social context in which communication occurs. In the healthcare sector human factors and ergonomics propose a set of methods which can be used to study the context in which activities occurs. The main focus of HFE is the interactions between humans and the elements of a systems. HFE is fundamentally endowed with a contextual approach which turns to be useful for accounting of communicative events and to underpin the redesign of workflows.

In order to scan the critical elements of care transitions (5) the analysis of handover documentation alone does not account for important contextual elements which needs to be considered in order to improve the safety of care transitions. The direct observation of handovers is then particularly important to make explicit contextual elements which may be otherwise taken for granted. Such insight regarding the contextual nature of handover has been confirmed by the research performed in the last years (1,3). There are two important aspects that emerged as far as safety in care transitions. Handover as every human communicative endeavor is characterized by interdependence; that is the joint participation of both social actors taking part in the communication activities. Therefore the analysis should include the way in which the dyads of actors interacts. Moreover it should consider the various type of media used to support such interactions (written and verbal communication mediated by ICT, paper, face-to-face).

In this regards the aim of the pilot study which originated the handover patient safety practice (PSP) of Tuscany region (10) was to evaluate the communicative ability enabled by the social context during cross-unit handover between high and medium intensity of care. The study was intended to investigate if the sharing of a common conceptual ground could reduce the potential threats to patient safety.

The study traced the transfers of information and responsibility for 11 patients between two chosen settings (an intensive care units as a source and a sub-intensive therapy as a receiving unit), for a total of 22 observations in 2 hospitals, with the aim of assessing the level of information sharing between the two units involved and the communication tool adopted. The overall analysis

of data and the findings from the focus groups detected discontinuities in the information transferred between health care practitioners which in some cases were connected with a lack of common ground in communication. It is suggested that handovers are most of the time unidirectional, with the sender's vision as a primary scaffold of the communication, rather than being bidirectional endeavors. An important aspect highlighted by this study was the

different way in which doctors and nurses are participating to the handover process. In fact, while doctors participate to direct handover (face-to-face or telephone) and have the opportunities to lay the foundations for the creation of common ground, nurses remain outside these dynamics.

The second important aspect regards organizational ergonomics. The handover is a communication process located in a context that involves many actors, teams and micro-organizational systems. Despite the attention given to the handoff moments - the “here and now” of communication among healthcare workers - the overarching workflows, which encompasses the singles handoffs moments and the interactions with other processes, needs to be carefully assessed in order to amplify the benefits of the standardized communication of relevant cues for patient care.

In particular, patient transitions among different settings, such as the step down from critical care to medical care or the transfer from emergency department to the medical wards, constitute critical touchpoints whose safety and effectiveness relies both on well-structured handover and on the way in which the wider workflows unfolds. We argue that the latent factors crystallized into the history of the organization needs to be elicited and considered in order to maximize the introduction of handover patient safety practice given the profound link between communication and the organizational context in which communication occurs.

Under this perspective the recent work carried out (9) outlined the correlations between safety and the way in which the handover was integrated in the whole health care organization.

Under this perspective it was investigated the correlation between the effectiveness of handover and the occurrence of adverse events. The study aimed to determine whether the introduction of an handover bundle improved quality and safety. In particular the bundle was composed of the following elements: standard tool for verbal Handover, constitution of an integrated team (nurses and physicians) , regular supervision, introduction of a computerized system, reducing interruptions during the Handover. In particular, the study tried to correlate the introduction of the bundle with the reduction of medical errors and preventable adverse events, with a reduction of the loss of information in the written documentation and improving the verbal handover. The results shown that after the implementation of the bundle errors decreased from 33.8% to 18.3%. preventable adverse events decreased from 3.3% to 1.5%. Moreover It was detected a decrease in the losses of key information in written handover.

### **3. Objectives and Methods**

The human factor and patient safety can provide effective methodologies for the design of tools

to improve the ability of health care workers to make available key information at the right time, ensuring patient safety and continuity of the clinical pathway.

In order to unveil what promotes or hinders effective communications at care transitions we involved health care workers of 10 dyads of inpatient care units (250 operators accounting for 1500 care transitions) in an action research process. The aim was to endow the participants with the skills necessary for evaluating the organizational context in which the handovers occur and give them support in prompting the interventions for constructing an organizational context underpinning safer communications at care transitions.

The project started with construction of an handover team consisting of a doctor and a nurse for each dyad involved (sender and receiving unit). In each setting a clinical risk management team trained in human factors had the role of detecting the base-line of handover through a

wizard-based data collection of process and outcome indicators about continuity of treatments at care transitions. The practitioners team supervised by clinical risk manager was responsible for the definition of a minimum set of handover information shared between the dyads, that suited both written and verbal handover, and which integrated the medical and nursing staff.

The selected handover local groups of health care workers have been trained to use a toolbox of instruments – the FMEA (Fault Modalities and Effect Analysis), the value stream map and the flow matrix – to evaluate how the actual organizational context could respond to the implementation of the handover patient safety practice. The intervention was articulated in two steps. Initially the local groups addressed the organizational latent factors preventing the implementation of a seamless and effective handover during patient care transitions. Secondly the group worked on the implementation of the requirements of the patient safety practice: adopting a standardized format (e.g. SBAR - Situation Background Assessment Recommendation) , using both oral and written channels in order to create redundant handover systems, involving disciplines and professions in the handover process, enabling the participation of patient and the family caregiver before the transitions occur and the definition of training sessions for the all the health care workers (8).

The implementation of the requirements and the analysis of the wider workflows are part of the interventions carried out by the local handover groups. The latent factors have been addressed and considered in order maximize the capacity of the organization to integrate standardized handover into existing workflows by means of tailored handovers adaptations to local needs. Moreover the impact on the intervention was be measured before and after using a three pronged approach consisting in a) the compliance to the handover patient safety practice requirements b) the extent to which continuity of care is guaranteed throughout the transactions between the dyads of healthcare unit c) the perception of the health care workers regarding the handover process before and after the intervention.

#### **4. Results & Discussion**

Before and after the intervention the clinical risk managers gathered the data related to the process and outcome indicators of handover by means of the structured review of medical records the observation of transitions of patients and a questionnaires to the professionals involved.

For the review of medical records it was used a dedicated tool that considered the data in the health care documentation until 72 hours after the transition occurred. The planned sample size is of 200 patients transferred to each participating unit before the interventions and 200 patients transferred to 3 months after the start of the intervention. Direct observation of the transitions was conducted on 30 patients before the intervention and at a distance of 30 patients 3 months after the intervention.

The questionnaire for measuring the satisfaction of healthcare workers regarding handover was given to doctors and nurses in the source and receiver units before the interventions and again at 3 months after the intervention.

The planned statistical analyzes are descriptive, with an examination of the significance of changes in the endpoint before and after the local intervention, using both linear regression analysis of covariance techniques to evaluate the possible impact of the individual instruments of the handover patient safety practice.

## 5. Conclusion & perspectives

In this section we will show the preliminary outcome of the analysis of the latent factors carried out by the local handover groups by means of the methodological toolbox. In particular through the application of the FMEA technique the highest priority of interventions have been assigned to 7 pitfalls which need to be taken into account in order to amplify the capability of organizations to implement the handover patient safety practice and fruitfully maintain it:

Continuity of information – communication network
Integrated workflow
Team working and common ground construction
Tailoring of handover PSP to the local context
Management of beds and human resource management
Support from general management
Patient participation and patient involvement

Many handover groups identified the access to a stable network of communication lines as enabling factors allowing for timely communication and exchange of information among health care workers. The presence of a reliable communications system is considered as relevant as electronic health care records for accessing to time-sensitive patient information.

The bed management, especially in the transitions from emergency department to medical wards, may absorb many of the time healthcare workers spend in communicating and may compress the time allocated for handover. The lack of an inter-professional workflow supporting the shared responsibilities of physicians and nurses in the care transitions is considered crucial for the success of handover process.

Communication at care transitions is a fundamental testbed for the resilience of complex healthcare organizations (4,7). We attempt to increase the safety of communication during care transitions in order to allow healthcare organization to sustain required operations, in the presence of continuous stress. To achieve that we tried to endow the healthcare workers with the methodological tools for analyzing the current situations and adapt it in order to embrace the handover patient safety practice.

The absence of designed communication strategies at care transitions may lead to an increase in the duration of patients stays, claims, and costs. Standardized ways for constructing patient handover has revealed effective in reducing the numbers of errors and potential adverse event (4). Moreover communication research has demonstrated the profound symbiotic relationship between communication and the social context in which communications occurs (5). Introducing from above constraints on communication performance disregarding the wider organizational context may lead to scarce implementation results. We focused on the way in which the handover practices are integrated and supported by the pre-existing workflows in order to enhance the capacity of the organization to retain organizational changes and improve communication safety.

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## Assessing the effect of interruptive events on task completion time: a multi-site study

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### Abstract

*Context:* The impact of disruptive events on task completion times in clinical work has implications for both safety and efficiency. However, this has received minimal attention to date due to the methodological challenges of evaluating this association in uncontrolled observational settings.

*Objectives:* The aims of this study were use a newly developed statistical technique, the Poisson mixture model, to assess the impact of interruptions on task completion time, and to determine the extent to which the association differs between settings.

*Methodology:* Interruptions are conceptualised as prompted task-switches, that is, switching from one task to another in response to some external prompt resulting in the original task being completed in several fragments. The Poisson mixture model was applied to 600 hours of observational data from several hospital settings: emergency departments (ED), intensive care units (ICU) and general wards. The model was used to generate expected mean task lengths assuming no task-switching effect, which were then compared to observed means via a hypothesis test.

*Main results:* In the ICUs, general wards and one of the two EDs, there was strong evidence that tasks were shorter when completed in fragments due to task-switching. For tasks with one instance of task-switching, decreases were highly significant ( $p < 0.001$ ) and ranged from 46 to 152 seconds, or 27% to 42%. For the other of the two EDs there was no evidence of a task-switching effect. Across all settings there was no evidence that tasks increased in length due to task-switching.

*Conclusion:* This study addresses a persistent gap in knowledge about the impact of interruptive events on clinical work. The shortening of tasks fragmented by task-switching is a significant finding, and provides impetus and direction for further inquiry including the differential impacts of task-switching and the examination of other types of disruptive events.

**Keywords:** task-switching, interruption, clinical work

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### 1. Introduction

Interruptions have been an ongoing area of research in healthcare, with many studies focusing on their potential to cause error or contribute to inefficiency in clinical practice. However, quantitatively linking interruptions with safety and efficiency outcomes is challenging in the complex non-experimental settings in which clinical work occurs (Walter, Dunsmuir & Westbrook, 2015). Studies to date have reported associations between interruptions and a

range of outcomes, including clinician-level effects such as self-reported workload (Weigl, Müller, Vincent, et al., 2012), task-level effects such as failure to resume an interrupted task (Drews, 2007) and the time cost of resuming such tasks (Grundgeiger, Sanderson, MacDougall, et al., 2010), and clinical outcomes such as dispensing errors (Flynn, Barker, Gibson, et al., 1999) or medication administration errors (Westbrook, Woods, Rob, et al., 2010).

One particular outcome that has received relatively little attention is the impact of interruptions on the time taken to complete tasks. Resumption lag – the time taken to reorient back to a task after having been prompted to switch to another task – has been measured in computer-based experiments (Altmann & Trafton, 2004; Monk 2004) and also in an ICU through use of eye tracking software (Grundgeiger, Sanderson, MacDougall, et al., 2010). In applied settings, including healthcare, there is potential for interruptions to reduce task completion time, and also to increase it through mechanisms other than resumption lag. This suggests that the effects of interruptions in uncontrolled settings cannot just be assessed by measuring lag times associated with switching from one task to another.

Identifying changes in task lengths due to interruptive events from direct observation of clinicians is analytically challenging. Longer tasks will naturally have more interruptions even if there is no interruption effect on task length. This form of *length bias* means that comparing tasks with and without task-switching is not appropriate and could generate a false positive result. For tasks fragmented by one or more interruptions we wish to estimate their average length had they not experienced any interruptions, and these expected values need to be specific to the number of interruptions to account for the length biasing effect. Westbrook, Coiera, Dunsmuir, et al. (2010) were the first to tackle this question by developing and applying a statistical method to predict counterfactual task lengths assuming no interruption effect and a constant probability of interruption occurrence over time (see corresponding technical note: Brown & Dunsmuir, 2010). These predicted task lengths can be compared to observed mean task lengths via a hypothesis test to assess the interruption effect. We have developed a new method, the Poisson mixture model, that extends the original approach by allowing more flexible assumptions that better align with the heterogeneous data from direct observation of clinical work (Walter, Brown & Dunsmuir, 2016).

Due to the inconsistent and unclear use of the term ‘interruption’ in both experimental and healthcare literature we use alternative terms to describe the disruptive aspects of clinical work. A *prompt* is an event that has the potential to elicit a change in workflow. In observational studies these are necessarily restricted to observable external events such as phone calls, questions from other staff, and so on. Clinicians switch between tasks prior to task completion for many reasons, one of which is to respond to external prompts. Thus the act of suspending a primary task, having received an external prompt, then addressing the task related to the prompt (secondary task) is considered *externally prompted task-switching*, however, for brevity we use the shorter form *task-switching* in this paper. The purpose of this study was to assess the impact of these events on task completion time.

## 2. State of the art

The original method of Brown and Dunsmuir, the basic Poisson model, has only been applied in the study for which it was developed. Despite the pervasiveness of various manifestations of length bias in observational data on clinicians’ work, the issue is almost never discussed in the healthcare literature and at times has resulted in studies claiming effects that are potentially just a symptom of this bias (Trbovich, Griffin, White, et al., 2010; Wiegmann, ElBardissi, Dearani, et al., 2007). The key assumption of the original method, that prompted task-switches occur according to a homogeneous Poisson process, is not often satisfied when

applied to the typically heterogeneous task-switching rate observed in clinical work. The Poisson mixture model has been developed to specifically capture that heterogeneity in a more appropriate way. It is currently the best available method to assess fundamental questions about the relationship between task-switching and efficiency, and this study represents its first full scale application to observations from healthcare settings.

### 3. Objectives and Methods

The aims of this study were to apply the Poisson mixture model to more than 600 hours of observational data on doctors in several hospital settings to assess the impact of task-switching on task completion time, and to determine to extent to which that impact differs between settings. The model was applied to data from four studies. Of these, two were conducted in emergency departments (ED), and the first ED study involved 210 hours of observations on 40 doctors (Westbrook, Coiera, Dunsmuir, et al., 2010), while the second followed 36 doctors for 122 hours (Walter, Raban, Douglas, et al., 2016) (ED 1 and ED 2, respectively, in Table 1). Another was conducted in intensive care units (ICU) at two hospitals with 161 hours of observations on 26 doctors (Li, Haines, Hordern, et al., 2015). The fourth study involved 19 doctors observed over 151 hours on four general wards in one hospital (Westbrook, Ampt, Kearney, et al., 2008).

Each study used the same observational methodology, namely a workflow time study approach (Lopetegui, Yen, Lai, et al., 2014) implemented with the Work Observation Method By Activity Timing (WOMBAT) software on a handheld tablet (Westbrook & Ampt, 2009). Doctors were observed directly and time-stamped information about their activities was recorded according to predefined task categories.

Study	Departments	Hospitals	Participants	Hours observed	Task-switching rate (per hour)
ED 1	1	1	40	210	6.0
ED 2	1	1	36	122	5.4
ICU	2	2	26	161	3.5
Wards	4	1	19	151	2.9

Table 1. Summary of data sources

The rate of prompted task-switching is known to vary considerably with factors such as task-type or between individual doctors (Walter, Li, Dunsmuir, et al., 2014). In the Poisson mixture model each task is assumed to have a different task-switching rate per unit time, and those task-specific rates are assumed to follow a gamma distribution to capture the heterogeneity of the task-switching rate. Hence the task-switching process is conceptualised as a mixture of rates at task level, rather than a homogeneous rate as per the original approach of Brown & Dunsmuir (2010). The statistical details of the model are described by Walter, Brown & Dunsmuir (2016), but we give a brief outline here.

The Poisson mixture model estimates the expected mean task lengths,  $\tilde{\mu}_k$ , for a given number of task-switches,  $k$ , under the assumption that task-switching has no effect on task length. The estimator of the mean for each value of  $k$  is based on a ratio of sample moments, and the expected variance of task lengths,  $\tilde{\sigma}_k^2$ , is calculated in a similar way,

$$\tilde{\mu}_k = \frac{\sum_{i=1}^{n_0} t_{0i}^{k+1} (1+\beta t_{0i})^{-k}}{\sum_{i=1}^{n_0} t_{0i}^k (1+\beta t_{0i})^{-k}}; \tilde{\sigma}_k^2 = \frac{\sum_{i=1}^{n_0} t_{0i}^{k+2} (1+\beta t_{0i})^{-k}}{\sum_{i=1}^{n_0} t_{0i}^k (1+\beta t_{0i})^{-k}} - \tilde{\mu}_k^2.$$

From this it can be seen that estimates of the expected lengths of tasks with one or more task-switches are derived from lengths of tasks unaffected by tasks switching, represented by  $t_{0i}$ , of which there are  $n_0$  such tasks. In addition to being impervious to any task-switching effect,

these tasks conveniently also tend to be the most numerous. To obtain a value for the  $\beta$  term, an intercept only negative binomial model is fitted to the task level data and the estimated overall rate  $\hat{\lambda}$  and dispersion  $\hat{\alpha}$  are used to estimate  $\beta$  using  $\hat{\beta} = \hat{\lambda}/\hat{\alpha}$ . These expected mean and variance estimates then enable comparison of observed mean task lengths,  $\hat{\mu}_k$ , and expected mean task lengths via a standard Z test (assuming asymptotic normality for sufficiently large samples):

$$Z = \frac{\hat{\mu}_k - \tilde{\mu}_k}{\sqrt{\tilde{\sigma}_k^2/n_k}}$$

where the denominator is the standard error (SE) of expected task lengths. When calculating observed task means, the length of each task completed in fragments is considered to be the sum of those time fragments. A significant p-value provides evidence that task-switching has an effect on the time taken to complete tasks.

Since the four datasets also contained information on multitasking, adjustment was made to avoid multiple counting of time due to overlapping tasks and to avoid multiple counting of task-switches where they occurred during two or more tasks progressing simultaneously. Although some individual tasks had more than 10 instances of task-switching these were very rare and analyses were restricted to tasks with up to three task-switches.

#### 4. Results

There was no evidence of a task-switching effect for the first ED study. Specifically, there was no difference in observed and expected task lengths for tasks with one switch, while for tasks with two or three switches differences went in opposite directions and neither was significant (Table 2). In contrast, observed task lengths in the second ED study were significantly shorter than expected for tasks with either one or two task-switches. In the ICU data, observed tasks were shorter than expected for all numbers of task-switches considered, but this was only significant where there was one task-switch despite large absolute and relative differences for two or three switches. Similarly for doctors on general wards, observed task lengths were shorter than expected but this was only significant for tasks with one task-switch.

Data source	Number of task-switches	Number of tasks	Mean task length			Comparison	
			Observed	Expected (SE)	% Difference	Z score	P-value
ED 1	1	519	193.7	193.7 (10.6)	0.0	-0.003	0.997
	2	153	315.8	308.8 (25.2)	2.2	0.3	0.78
	3	62	369.3	418.4 (45.9)	-11.7	-1.1	0.29
ED 2	1	521	116.9	162.9 (10.9)	-28.2	-4.2	<0.001
	2	72	198.2	321.8 (41.7)	-38.4	-3.0	0.003
	3	18	424.4	465.2 (98.9)	-8.8	-0.4	0.68
ICU	1	375	133.3	181.6 (16.7)	-26.6	-2.9	0.004
	2	26	233.5	408.0 (107.6)	-42.8	-1.6	0.11
	3	10	337.0	672.3 (230.6)	-49.9	-1.5	0.15
Wards	1	274	208.6	360.5 (42.2)	-42.1	-3.6	<0.001
	2	21	448.0	805.3 (226.6)	-44.3	-1.6	0.11

Table 2. Application of the Poisson-mixture model to assess the effect of task-switching on task completion time

#### 5. Discussion

This study represents the first application of a unique statistical method that assesses a fundamental question in the observational study of clinical work. These results indicate a

shortening of tasks in the presence of task-switching in three out of the four settings, while there was no significant evidence that tasks increased in length due to task-switching in any setting. The statistically significant decreases ranged in magnitude from 46 seconds to two and a half minutes and relative decreases from 26.6% to 42.1%. These effects represent considerable changes within a clinical work environment.

The results suggest no immediate loss of efficiency due to task-switching. Rather the findings suggest the opposite, since time costs related to task-switching appear overshadowed by some other mechanism that decreases task length. The authors of the first ED study suggested that a shortening effect may indicate that doctors compensate for a perceived loss of time due to task-switching (Westbrook, Coiera, Dunsmuir, et al., 2010) and this has also been indicated in experimental studies. Monk (2004) found that resumption times were faster on average with increasing numbers of interruptions, and frequent interruptions did not result in increased task length. Also, several studies found a decrease in the lengths of interrupted tasks with no loss of quality (Mark, Gudith & Kocke, 2008; Zijlstra, Roe, Leonova, et al., 2010), while others found a similar decrease only for simple tasks but not for complex tasks (Burmistrov & Leonova, 2003; Speier, Valacich & Vessey, 1999).

Rushing or corner cutting to compensate for having to switch tasks to deal with prompts would clearly be a safety issue as it could increase the risk of various forms of error. However, the experimental evidence discussed above suggests that task shortening occurs in scenarios of relatively low cognitive load without loss of quality, while task lengths do not shorten under high cognitive demand. In other words, there is more flexibility to vary the pace of work when there is spare cognitive capacity. A similar phenomenon has been observed in other occupational settings where the work rate varied in response to time constraints (Latham & Locke, 1975).

The results of this study may therefore represent doctors adjusting to evolving workload demands, in the form of prompts, under largely manageable cognitive load conditions. Healthcare professionals are known to use strategies to manage work demands through interleaving, prioritising and sequencing of tasks (Grundgeiger & Sanderson, 2009). They are likely habituated to the typical prompt types and have honed strategies over time to deal with them, thus mitigating their cognitive impact. The lack of evidence of a task-switching effect for the first ED study may be related to workload. Although workload measures were not available across settings for comparison, the first ED study had the highest interruption rate, a measure associated with workload (Weigl, Müller, Vincent, et al., 2012).

The experiments cited above reported an increased emotional cost, despite participants maintaining their quality while working quicker. This included increases in perceived effort (Zijlstra, Roe, Leonova, et al., 2010), stress, frustration and time pressure (Mark, Gudith & Klocke, 2008). So although the observed task shortening may indicate resilient and flexible clinical practice, task-switching could still contribute indirectly to error risk through its influence on affective state.

When interpreting these results it is important to consider the way in which task intervals are delineated during the observation process (Walter, Dunsmuir & Westbrook, 2015). There may be differences in the way observers and doctors perceive the start, end and switch points of tasks. Therefore the mechanics of data collection may influence estimated task-switching effects and this needs to be taken into consideration in the design of future studies.

The combination of the Poisson mixture model and Z test, has some strengths and limitations. The power to detect task-switching effects is limited by the sample,  $n_k$ , of tasks for each number of task-switches. As seen in Table 2, tasks with one switch are the most numerous and this rapidly decreases for tasks with two or three switches. A small number of tasks

results in a smaller Z score, and hence reduced significance of the comparison test, despite the absolute difference often being considerable. On the plus side, the method has the potential to be applied to events other than externally prompted task-switching. It could easily be applied to other forms of task-switching since clinicians frequently switch between tasks of their own volition, that is, internally prompt task-switching. Also it could be applied to events that don't necessarily cause a task to be completed in fragments, for example, it could assess the effect of multitasking on task completion time.

Another important result of this study is that it highlights several directions for further research. Given the potential for task-switching to have variable effects on different task types or on different individuals, analyses stratified by such factors would provide more nuanced detail about the impact of task-switching. The experimental evidence indicating that cognitive load can modify the effect of task-switching on task length suggests a need for explicit workload assessment to determine the influence of high and low workload on task-switching effects.

## 6. Conclusion & perspectives

This study addresses a persistent gap in knowledge about the impact of interruptive events on clinical work. While the results give a strong and consistent indication of the effects of prompted task-switching on task length, they do not give a comprehensive picture of their safety and efficiency implications. It may be that we have evidence of resilient practice where clinicians adapt to constantly evolving demands, rather than cutting corners or rushing. That tasks appear to get shorter when they are fragmented by task-switching across multiple settings is a significant result, but this opens up many questions, providing impetus and direction for further inquiry. In particular, how task-switching has differential impacts across task types, individuals and workload intensities, and the role of the observation process in influencing estimated results.

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## Social and Organizational Factors Shaping Human Factors Integration (HFI) within Healthcare – A Comparison with the Nuclear, Defense and Rail Industries

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### Abstract

The aim of the study was to compare a set of social and organizational factors shaping Human Factors Integration (HFI) within healthcare and to compare these against similar processes involving HFI within the nuclear, defence and rail industries. A total of 58 interviews were carried out over the period January 2013 – May 2015. Eight participants worked in the nuclear industry; eight participants in the rail domain; twenty-five participants in the defence industry; and fifteen participants in healthcare. Lack of visibility within the wider industrial organization, the view that HFE was surplus to requirements and lacked scientific credibility were frequently cited as barriers to HFI across all industries. The various improvement strategies employed by HF teams also shared some similarities across the 4 sectors. The use of success stories and HFE case studies to ‘open doors’ and break down barriers with other organizational groups was frequently mentioned. The process of achieving healthcare HFI is similar, but also very different to that found in other industries. Part of this may be due to the fact that healthcare HFE is less well-established as compared to many other industries. The importance of formal procedures (e.g., safety cases) in defence and the nuclear and rail industry mean that the involvement of HFE teams is almost always mandatory. The process of what Theberge and Neumann (2010) call ‘doing organizational work’, negotiating, convincing and ‘selling’ the case for HFE, may take longer and, in some cases, face more opposition/be more challenging within healthcare. Likewise, gaining the respect of clinicians and other healthcare staff may take time given the resistance sometimes experienced by HFE teams when confronted with what might be termed the ‘medical mindset’, as well as the realization that we may need different types of HFE for different healthcare contexts.

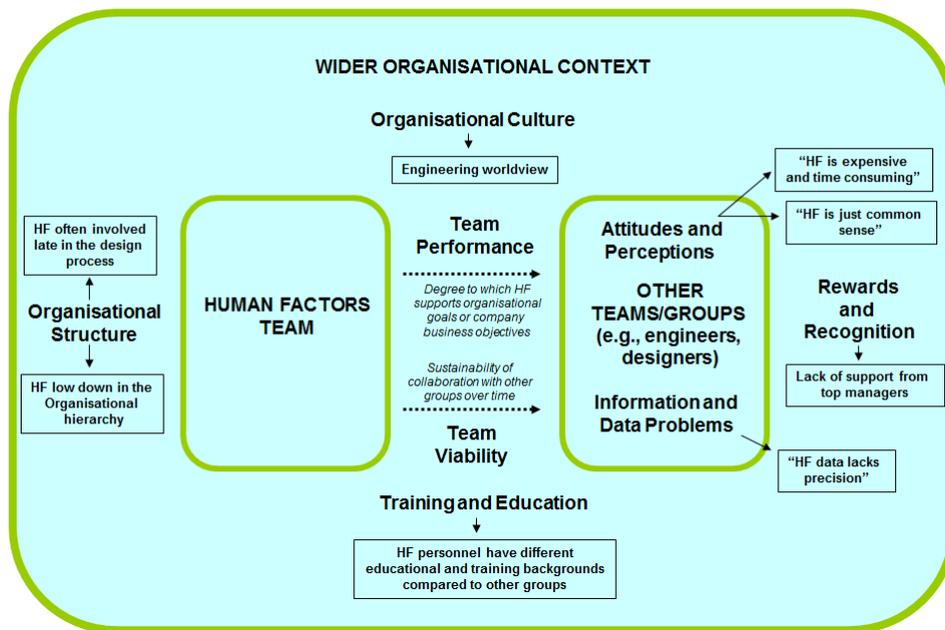
**Keywords:** Human Factors integration, patient safety, cross-industry comparisons

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### 1. Introduction

Over the years there have been many accounts of the problems involved in applying human factors and ergonomics (HFE) within industry. Past research has identified a range of human factors integration barriers including: lack of training in the use of HFE tools and methods; the relatively weak position of the HFE professional within the larger organizational context (Perrow, 1983). More recently, there have been calls to raise the profile of HF as a whole (Kirwan, 2012) and improve integration within specific sectors. Calls to integrate Human Factors and Ergonomics (HFE) within healthcare and patient safety for example, have become increasingly frequent in the last few years (Gurses et al., 2012). Despite this it is clear that a

number of significant barriers to integration, some of them unique to healthcare remain (Waterson, 2016; Waterson and Catchpole, 2016; Waterson and Anderson, 2013). The present study draws on our earlier efforts to develop a framework to capture the social and organizational enablers and barriers of HFI (Waterson and Lemalu-Kolose, 2010, figure 1). The framework was used as a basis with which to compare HFE across four industries: defense, nuclear, rail and healthcare. In this paper, we summaries the main findings from the study as they relate to the challenges faces by healthcare HFI, as well as some of the differences between healthcare and the other three HFE application domains.



**Figure 1.** Framework for understanding the social and organizational aspects of HFI (Waterson and Lemalu-Kolose, 2010)

## 2. Methods of study/data analysis

A total of 58 interviews were carried out over the period January 2013 – May 2015. Eight participants worked in the nuclear industry; eight participants in the rail domain; twenty-five participants in the defense industry; and fifteen participants in healthcare. Participants drew on a range of experience (1 year to 30 years) with the average number of years working in a particular industry being approximately 3-5 years. Interviews were either conducted face-to-face or by telephone. Audio recordings were made, manually transcribed and then uploaded into the NVivo qualitative data analysis software package. Charts were created based on the data from the nodes illustrating the barriers and facilitators (divided into social and organizational factors) for each industry. Table 1 shows an example of the coding framework which was used to analyze data from the interviews.

Main code	Sub-code	Lower level codes
<b>Work of the HF Team</b>	Type of involvement	Mandatory involvement (“pull”)
		Informal request for involvement
	Role	Internal consulting (providing expertise) Suggesting involvement (“push”) Information provision
<b>Social and organizational influences</b>	Company culture Relationships Personalities Learning and integration Communication	Lack of HF visibility Relationship building Individuals Mutual learning Conflicts, data incompatibilities, style of communication
<b>HFI Barriers and Facilitators</b>	Attitudes towards HF Gaps in knowledge and experience Costs and resources Late involvement  Improvement strategies  Organizational factors	Common sense Cultural clashes  Expense of HF input Lack of adequate resources Experience and age of team Turnover and size Education Use of examples Visibility Selling HF Commination

Table 1. Summary of coding framework (adapted from Waterson and Lemalu-Kolose, 2010)

### 3. Findings

Across all four industries there was broad agreement with the main components of the original HFI framework (figure 1). Lack of visibility within the wider industrial organization, the view that HFE was surplus to requirements and lacked scientific credibility were frequently cited as barriers to HFI across all industries. Organizational factors such as the size of the HF team and their lack of power/influence relative to other groups such as engineering and safety groups were also frequently mentioned. The various improvement strategies employed by HF teams also shared some similarities across the 4 sectors. The use of success stories and HFE case studies to ‘open doors’ and break down barriers with other organizational groups and senior managers was frequently mentioned. Strategies such as getting HFE into the organization ‘through the back door’ were common all four sectors. Sometimes this would involve ‘rebranding’ human factors as something else (e.g., risk, safety, improvement science) which was more likely to be acceptable to engineers, medical staff and other specialists. In other case, it would involve running workshops and informal sessions, the aim of which were to explain what was meant by HFE and demonstrate its added value within the organization.

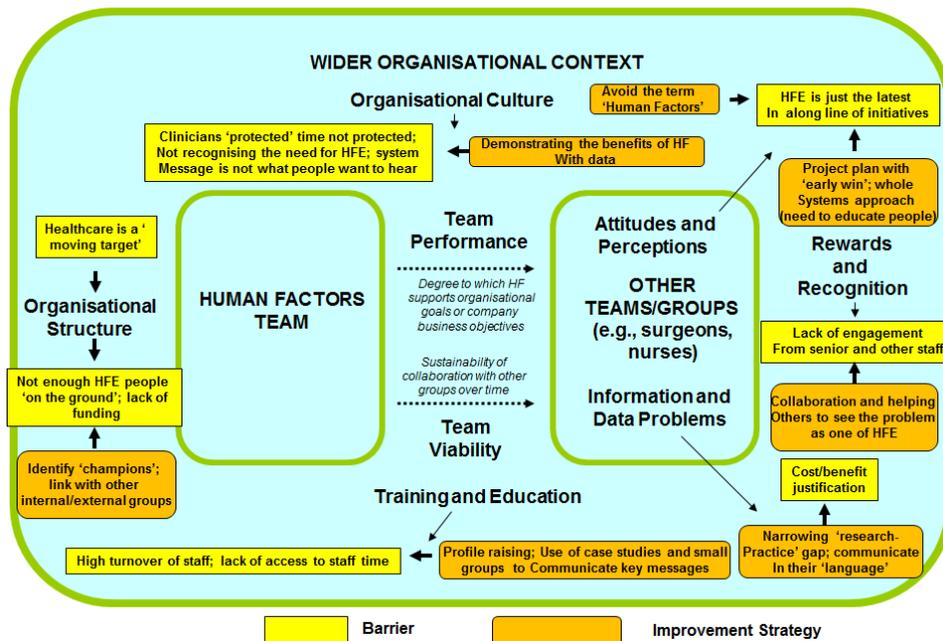


Figure 2. HFI framework applied to healthcare

Figure 2 summarizes some of findings from the barriers and improvement strategies as they apply to the findings from healthcare. One of the main problems is the difficulty of gaining access to clinicians and healthcare workers, even when their time was 'protected' and supposedly given over to learning and professional development. A related issue was the need to deliver results over very short timescales and the need to manage expectations about the likelihood of achieving results which would be perceived as useful and applicable to clinical practice. In the case of academic HFE research teams, lack of time was also seen as a barrier in achieving other goals such as establishing sufficient quality (e.g., sample sizes, pre-/post-intervention studies) in order to publish the results in scientific journals. Other problems proved to be more intractable, such as the fact that healthcare contexts vary enormously and the types of attitudes towards HFE and types of work expected of HFE teams may be very different (e.g., conducting assessments of medical device usability vs. conducting a safety culture assessment).

#### 4. Discussion

One of the clearest messages that come across from our dataset is that the process of achieving healthcare HFI is similar, but also very different to that found in other industries. Part of this may be due to the fact that healthcare HFE is less well-established as compared to many other industries. The importance of formal procedures (e.g., safety cases) in defense and the nuclear and rail industry mean that the involvement of HFE teams is almost always mandatory. Part of it also may be due to the level of complexity and variability of the various types of socio-technical systems which operate within healthcare relative to other industries. As Vincent and Amalberti (2016) argue safety within healthcare is very much a 'moving target' and the various strategies employed by HFE teams may need to be tailored to the requirements of specific contexts. The process of what Theberge and Neumann (2010) call 'doing organizational work', that is negotiating, convincing and 'selling' the case for HFE may take longer and, in some cases, face more opposition/be more challenging within healthcare. Gaining access to the medical curriculum for HFE-related content for example, is unlikely to happen overnight (though it is starting to happen). Likewise, gaining the respect of clinicians and other healthcare staff may take time given the resistance sometimes

experienced by HFE teams when confronted with what might be termed the 'medical mindset' (e.g., the dominance of the randomized control paradigm - Marchal et al., 2013), as well as the realization that we may need different types of HFE for different healthcare contexts.

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## Noticing errors in blood transfusion prevents harm to patients

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### Abstract

Errors in blood transfusion can lead to serious patient harm, including death or major morbidity, especially as a result of ABO incompatibility. The transfusion process is a complex sociotechnical system and relies on multidisciplinary teams (MDT) of healthcare professionals, hence there are many opportunities for error. Serious Hazards of Transfusion (SHOT) is the United Kingdom (UK) independent, professionally-led haemovigilance scheme, which has collected and analysed anonymised information on adverse events and reactions in blood transfusion since 1996. The emphasis has been to learn from what goes wrong in these incidents, but the recent development of the safety II concept helped to see the importance of learning from what goes right. Investigation of near miss errors (what eventually goes right) can show where resilience/recovery within the transfusion process could be enhanced. Therefore, SHOT near miss incidents in calendar years 2014 and 2015 were analysed for how noticing actions prevented harm to patients, including what was noticed, by whom and what action they took. To do this, the near miss reports were searched for the words notice/noticed/noticing and various synonyms of these words. A total of 778/2410 (32.3%) near miss incident reports showed noticing actions had prevented patient harm. Of these, 552/778 (71.0%) were noticed by clinical staff and 226/778 (29.0%) by laboratory staff. Clinical staff performing the final 'bedside check' before administering the transfusion are the largest group to notice errors 327/552 (59.2%), showing the final check is crucial to patient safety. Noticing actions can prevent transfusion-related patient harm and demonstrate the value of situation awareness throughout the complex transfusion process.

**Keywords:** blood, transfusion, noticing, situation, awareness

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### 1. Introduction

Errors in the transfusion process can lead to serious patient harm, including haemolysis or death caused by ABO incompatibility. Serious Hazards of Transfusion (SHOT), which is the United Kingdom (UK) independent, professionally-led haemovigilance scheme, is beginning to incorporate human factors and ergonomics (HFE) as tools to investigate incidents or to understand the complex sociotechnical systems involved with the transfusion process. Since 1996 SHOT has been collecting and analysing anonymised information on adverse events and reactions in blood transfusion from all healthcare organisations where transfusion of blood and blood components occurs. SHOT recommends changes which can improve patient safety which are published in an annual report and circulated to all relevant organisations including the four UK Blood Services, the Departments of Health in England, Wales, Scotland and Northern Ireland and all relevant professional bodies. The report is also sent to all the

reporting hospitals. As haemovigilance is continuous, SHOT also monitors the effect of implementation of its recommendations.

SHOT receives reports of over 2,500 error-related incidents every year of which approximately half are near miss events, defined as “any error which if undetected, could result in the determination of a wrong blood group or transfusion of an incorrect component, but was recognised before the transfusion took place” (Bolton-Maggs, Poles, Watt et al., 2014). The emphasis has been to learn from what goes wrong in the incidents, but the recent development of the Safety II concept tells us that it is equally important to learn from what goes right. Investigation of near miss errors can show where the transfusion process could be made more resilient (Wears, Hollnagel & Braithwaite 2015). Near miss errors are detected before transfusion often as a result of the noticing actions of staff and therefore avoid patient harm. The ability to notice and respond to signals indicating potential threats are key elements of resilient systems, but little is known about it.

### **3. Objectives and Methods**

The aim of this study is to introduce the Safety II approach into the transfusion process by investigating how errors in near misses were noticed/responded. This study of SHOT near miss reports in calendar years 2014 and 2015, investigates how the noticing actions prevented harm to patients, including what was noticed, by whom and what action they took. To investigate how noticing actions prevented patient harm, a total of 2410 SHOT near miss reports from calendar years 2014 and 2015 were analysed for evidence of which of these errors were detected by noticing actions and then these incidents were reviewed to discover who noticed the error and what action they took to prevent harm. Incident reports are made to SHOT via a bespoke online database, which has an interactive dataset. The questionnaires are designed to help categorise incidents and to elicit an understanding of what went wrong, including how the incident was detected and resolved. The reports are put into Excel spreadsheets for analysis. All near miss reports from 2014 and 2015 (n=2410) were searched for synonyms of the word ‘noticing’. The limitations of this method include that spelling errors in these words would not be found and the observation that some words were not always synonymous, so some searches found unrelated references, e.g.:

- ‘Notic’ – notice as a noun, e.g. a notice being displayed.
- ‘Detec’ – scientific tests, such as an antibody or a different group was detected by the testing, rather than detected as in ‘noticed’
- ‘Note’ - patient notes, or a note being made related to the incident investigation

When searching the initial word found was sometimes in a negative context, e.g. “Did not ‘notice’ X was incorrect...”. All those returning a negative use of the search term were searched for the other synonyms, so a further positive aspect of noticing would sometimes be found e.g. “...but another staff member ‘realised’ X was incorrect”.

## **4. Results and Discussion**

### **4.1 Evidence of noticing actions in SHOT near miss reports**

A search for the word noticing and appropriate synonyms in SHOT near miss reports from 2014 and 2015 returned 778 occurrences out of a total of 2410 near miss reports submitted to SHOT in that 2-year period (32.3%). Unsurprisingly the search for ‘notic’ returned the most examples, n=194/778 (24.9%) of the total cases identified. The addition of other synonyms identified the remainder of the 778 reports where some kind of noticing action was apparent.

From the reports it was observed that use of the words realise/realised tended to be a retrospective discovery of an earlier error made by the same person, whilst noticing and the other synonyms tended to be more prospective detections of errors made by others elsewhere in the process.

#### 4.2 Who noticed the error and what did they do about it?

The transfusion process is complex, consisting of nine major steps, as described by SHOT in 2014: 1) Request; 2) Sample, 3) Sample receipt; 4) Testing, 5) Component selection, 6) Labelling, 7) Collection, 8) Prescription, 9) Administration. The full transfusion process occurs in this sequence starting with a request for a patient who needs a transfusion now or might in the future and ending when the transfusion is administered to the patient. Errors can be made at every step of that process and can also be noticed at every step.

Steps 1, 2, 7, 8 and 9 are normally undertaken by clinical staff. Steps 3, 4, 5 and 6 are laboratory (lab) steps carried out by transfusion staff, who control the stocks of blood components and carry out the testing to match the appropriate component to the correct patient. Therefore, the results of who noticed the error and what they did about it splits naturally between errors noticed during the clinical steps (n=552/778, 71.0%) and those noticed within the laboratory environment (n=226/778, 29.0%). Figures 1 and 2 show the outcomes of that analysis.

The largest group of clinical staff to notice errors (n=327/552, 59.2%) are the pre-transfusion checkers, i.e. those at the final stage of the process who perform the final ‘bedside check’ before administering the transfusion (Figure 1). There are not many noticing actions by porters or equivalent staff who collect blood (n=12). This places added importance on staff undertaking the final check before administering the transfusion to notice errors that could have been detected at the collection stage.

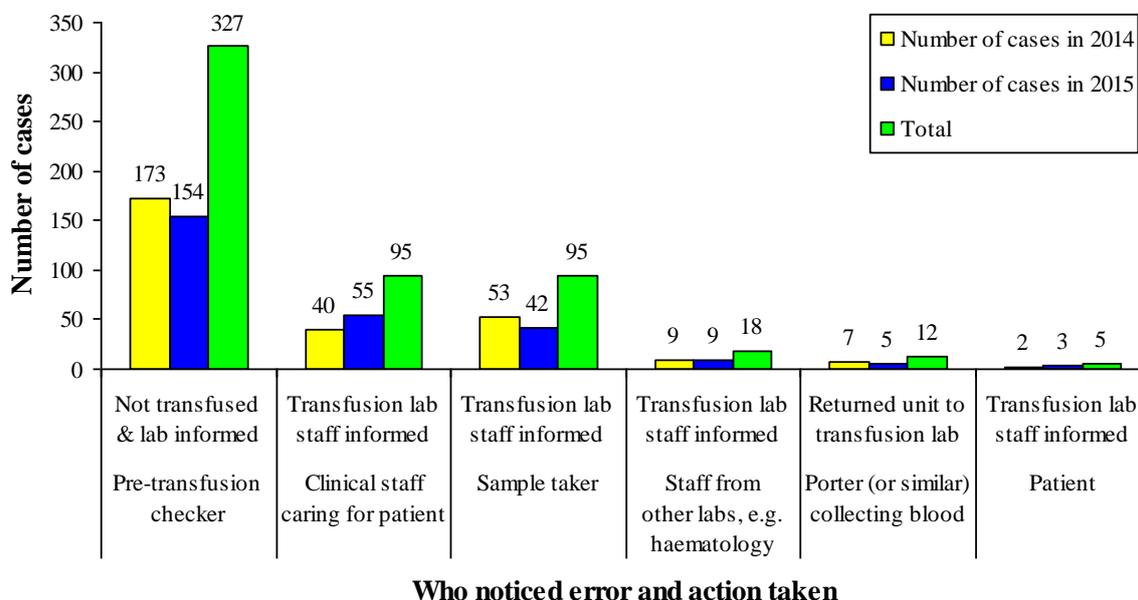
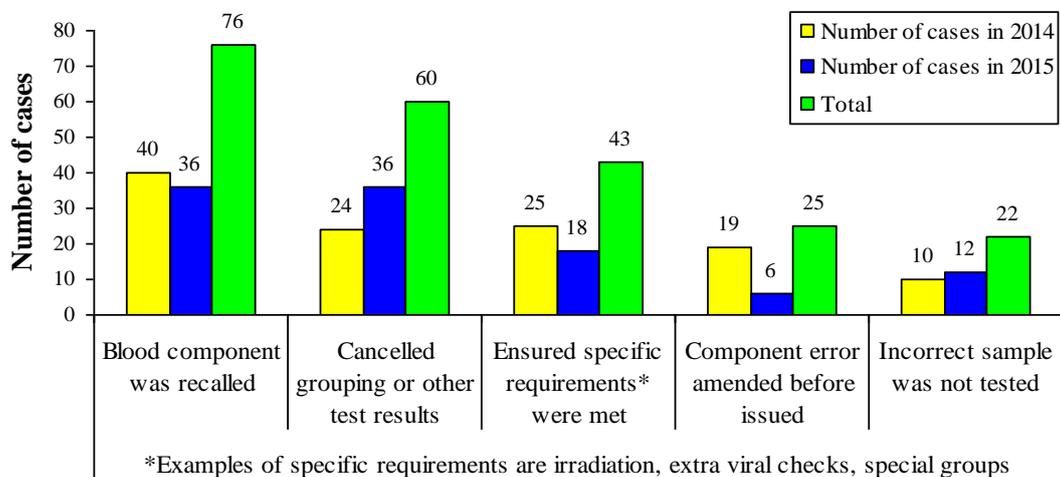


Figure 1. Errors noticed outside transfusion laboratory (lab), n=552

Outside the transfusion laboratory, the actions of those who noticed an error were largely to inform the transfusion laboratory staff that an error had occurred. That may include returning the blood component to the laboratory, which should not be taken to indicate that errors are made more often by laboratory staff. The reason for the key action being to inform transfusion laboratory staff is because these staff can either stop the process, which has been found to be

erroneous, or may repeat their steps in order to issue another suitable component. Very often the error originates in the clinical area at an earlier step in the process, e.g. an error made with the request or when taking a sample from the patient. That error may then be noticed at a later stage in the process, e.g. when the sample taker realises their mistake or the pre-transfusion checker notices an error has occurred at an earlier step. It should be noted that a small number of adverse incidents (n=5) were prevented by the patient themselves noticing something was wrong.

Figure 2 shows the actions taken when laboratory staff noticed an error. The most common action (n=76/226, 33.6%) was to recall the blood component, which would have been necessary if the error was noticed after the component had been issued ready to be transfused to the patient. Often in non-emergency situations the component being recalled will not have actually left the laboratory, because it would be awaiting collection. If the blood has already been collected, then prompt action would be needed to recall the component before any harm comes to the patient.



**Action taken when transfusion laboratory staff noticed error**  
**Figure 2.** Errors noticed by transfusion laboratory staff, n=226

### 4.3 What could the outcome have been?

In some cases the noticing actions prevented ABO-incompatible transfusions (n=64/778, 8.2%) and in others prevented an incorrect component being transfused (n=300/778, 38.6%) some of which could have been ABO incompatible, but those case reports do not specify the ABO groups involved. Patient harm could result from other errors, including the patient getting components without their specific requirements (n=103/778, 13.2%), or those stored or handled incorrectly (n=120/778, 15.4%) (Figure 3).

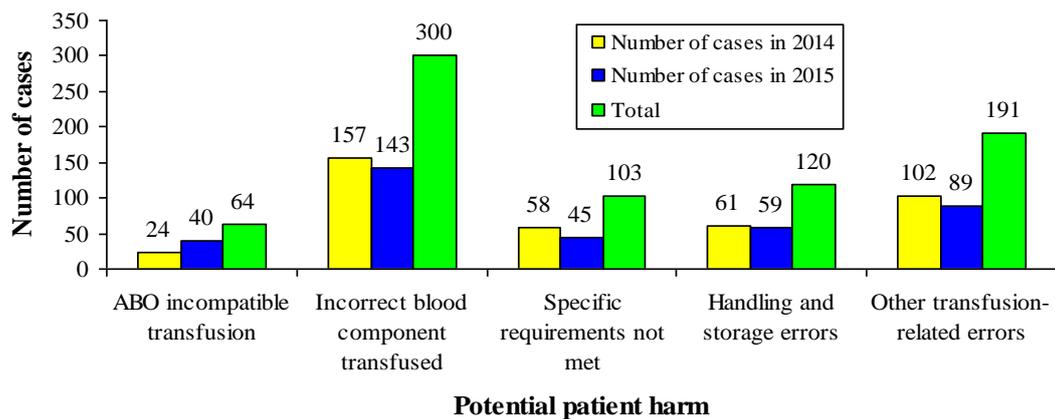


Figure 3. Potential outcomes if noticing actions had not taken place, n=778

A frequent near miss incident that can lead to an ABO incompatible transfusion, is a ‘wrong blood in tube’ (WBIT) sample, i.e. blood is taken from the wrong patient, but labelled with the intended patient’s details, or is taken from the intended patient, but labelled with another patient’s details. These errors can lead to serious patient harm. A study in Scotland (Pickup, Atkinson, Hollnagel et al 2015) using the Functional Resonance Analysis Method - FRAM technique (Hollnagel 2012) showed many contributing factors to WBIT errors. Standard transfusion processes will detect WBIT errors where the samples give different results from historical records. Analysis of the 778 near miss incidents that were detected by noticing actions showed 239 were WBIT-related reports (30.7%). Therefore, situation awareness in this study helped to prevent potential patient harm from WBIT errors. These figures compare to only two cases of actual patient harm from WBIT events in 2014 and 2015 (Bolton-Maggs, Poles, Watt et al., 2014).

## 5. Conclusion and Future Perspectives

The main goal of the current study was to determine and evaluate whether noticing actions contributed to patient safety, by detecting errors before a blood transfusion took place. This study has identified situation awareness in the form of noticing actions was responsible for preventing patient harm in almost a third of the total near miss cases reported to SHOT in a two-year period (778/2410, 32.3%). The research also identified the staff most likely to notice an error were those performing the ‘bedside check’ prior to transfusion (300/778, 38.6%). This finding highlights the critical importance of the final checking procedure before administering a transfusion.

This is the first study to investigate the importance of situation awareness specifically in blood transfusion and confirms previous research which observed that situation awareness is one aspect of high reliability organisations (HRO) that can be incorporated into healthcare (Goldenhar, Brady, Sutcliffe et al 2013; Wilson, Burke, Priest et al 2005). HROs such as aviation and the nuclear industry provide a template from which healthcare institutions can learn, but there are limitations, because patients are much more diverse than aeroplanes or nuclear reactors. This research will serve as a base for future HFE studies in the field of blood transfusion.

The major limitation of this study is that it was a retrospective analysis of near miss incidents and the SHOT reporting questionnaire does not specifically ask about noticing errors. Many other near miss transfusion errors are likely to have been detected by someone noticing something unusual, but that may not have been recorded as such in the incident report, hence those incidents would not have been found by the search for ‘noticing’ and its synonyms.

Further studies could be carried out to validate these results, including the possibility of adding questions about noticing into the SHOT near miss questionnaire. An alternative would be to get prospective data by interviewing those involved with incidents to ask questions such as “how do you notice errors?” and “what signals of errors are you most likely to notice?”.

### Acknowledgements

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## How can we support the implementation and maintenance of the medication review process at hospital to secure the transitions of care?

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### Abstract

*Context.* Healthcare organizations meet difficulties to implement and maintain the medication reconciliation (MRec) and medication review (MRev) processes at hospital. Both are employed to secure and optimize the patient's medication treatment.

*Objectives.* The aim of this study is to perform a deep Ergonomic and Human Factors (E/HF) analysis of the MRec and MRev processes to identify their work key factors and link them with the observed/reported difficulties. This will enable to develop a model on which the different stakeholders (professionals, hospital deciders, health authorities, etc.) can rely on to make informed choices for the work system (re-)design depending on the corresponding constraints and resources.

*Methods:* A literature review has been undertaken in three databases to extract studies providing reported E/HF work system elements about the MRec & MRev processes. Work systems analyses have been performed in three different French hospitals with different MRec and MRev work organizations.

*Main results.* 28 papers met the inclusion criteria and were fully analyzed. Observations and interviews represent a total of 161h. The main features of the MRec and MRev processes (actors, tasks, tools, organization, etc.) have been clearly identified for the three sites. Most of the problems/barriers identified in the literature were observed and precisely described with the corresponding causes and consequences on the processes. These results lead to the description of seven main key factors defined as components of the work system which influence positively or negatively the processes according to the work's conditions. These first results are promising and give the first elements of a future model.

*Perspectives.* The physician-pharmacist partnership appears to be critical. A depth analysis of the collective decision making between physicians and pharmacists is envisaged for further work.

**Keywords:** medication review, medication reconciliation, ergonomics, Human Factors, work system

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### 1. Introduction

It is increasingly recognized that most incidents related to medication occur when a patient changes of care environment, especially from community to hospital, or from hospital to community (Curatolo, Gutermann, Devaquet & al., 2014; Doerper, Morice, Piney & al., 2013; Van Sluisveld, Zegers, Natsch & al, 2012; Kent, Harrington & Skinner, 2009; AFSSAPS, 2011, 2008). Medication reconciliation (MRec) and medication review (MRev) processes both are solutions known to secure and optimize these transitions of care. Many studies show

their positive clinical (and financial) impact on adverse drug events (Tong, Roman, Smit & al., 2015; Holland, 2015; Graabaek, Bonnerup, Kjeldsen & al., 2015; Curatolo, Gutermann, Devaquet & al., 2014; Doerper, Morice, Piney & al., 2013; White, Schoettker, Conway & al., 2011; Boockvar, Santos, Kushniruk & al., 2011) at hospital. Nevertheless, both processes are also considered difficult to implement and maintain by healthcare institutions and professionals (Curatolo, Gutermann, Devaquet & al., 2014; Lesselroth, Adams, Tallet & al., 2013; Boockvar, Santos, Kushniruk & al., 2011; Dieckhaus, Martin & Clark, 2009; Endo & Jacobsen, 2006; Bartick & Baron, 2006). Several barriers are identified in the literature, the most reported are the problem of turnover, lack of resources, absence of leadership, unfamiliarity with procedures, lack of access to patient information, lack of multidisciplinary approach, lack of Computerized Physician Order Entry (CPOE)) (Wawrzyniak, Beuscart-Zephir, Marcilly & al., 2015; Curatolo, Gutermann, Devaquet & al., 2014; Van Sluisveld, Zegers, Natsch & al., 2012; Boockvar, Santos, Kushniruk & al., 2011; White, Schoettker, Conway & al., 2011; Bartick & Baron, 2006; Endo & Jacobsen, 2006). While most of these elements are related to Ergonomics and Human Factors (E/HF), very few E/HF studies on these two processes are reported in the abundant literature on the topic.

## **2. Objectives and Methods**

The aim of this study is to perform a deep E/HF analysis of the MRec and MRev processes to identify their work key factors (including the tasks, the actors, the environment, the organization and the technology/tools) and link them with the observed/reported difficulties. This will enable to develop an explanatory model on which the different stakeholders (professionals, hospital deciders, health authorities, etc.) can rely on to make informed choices for the work system (re-)design depending on the corresponding constraints and resources: what works? what does not work? what is important? why? Etc.

A literature review was undertaken to identify (i) the few E/HF studies on MRec and MRev processes if they exist and (ii) the studies from which work system elements on the MRec and MRev processes at hospital can be extracted even if the studies are not E/HF labeled. Three databases were searched: Pubmed, Web of Knowledge and ScienceDirect.

As the elderly are particularly vulnerable to Adverse Drug Events (many drugs and compliance problems), the study focuses on geriatric departments. Work analyses are planned in five sites presenting different organizations of the MRec and MRev processes (Table 1). Three sites have been already analyzed. Three E/HF experts rely on classical methods of the ergonomics domain (shadowing observations; meetings observations; individuals interviews based on the 5Ws method (Who, What, Where, When, Why); and collective interviews) to collect data on the work environments (e.g. actors, tasks, tools, etc.) with a special attention to the information flow supporting both processes. Observations and interviews concerned at least one representative of each type of actors of the MRec and MRev processes (Physician/Pharmacist/Nurses, junior/senior).

Sites (beds) Units (beds)	Organisational characteristics
<b>Lille (3500)</b> Acute geriatric (28)	- Limited human, technical and financial resources - MRev = weekly multidisciplinary meeting - Processes depend on the presence of students - Regular student turnover - Limited human, technical and financial resources - Only pharmacist/physician pair ; no nurse
<b>Lomme (400)</b> - Acute geriatric (20) - Follow-up and rehabilitation care (20)	- Limited human, technical and financial resources - MRev = weekly multidisciplinary meeting - Processes depend on the presence of students - Regular student turnover - Limited human, technical and financial resources - Only pharmacist/physician pair ; no nurse
<b>Denain (600)</b> All units; only patients up to 75 yo with specific inclusion criteria.	- Substantial human, technical and financial resources - MRev = multidisciplinary meeting as soon as patient admission; reconducted if necessary at discharge - MRev performed by a mobile geriatric team (nurse, pharmacist and physician; no student)
<b>Bruxelles* (-)</b> -	- MRev = daily performed during medical rounds - Substantial human, technical and financial resources
<b>Nîmes* (2000)</b> All units, excepted: psychiatry, gynecology, pediatrics.	- Substantial human, technical and financial resources (European project)

Table 1. Main characteristics of the selected fields of study (\*=analyses not performed yet)

## 4. Results

### 4.1 Description of the MRec and MRev processes

4134 articles were first included in the literature review. After a screening of titles and abstracts, 28 articles met the inclusion criteria and were fully analyzed. Only one paper is E/HF-oriented. Even if the rest of the papers adopts a different perspective (medical or pharmaceutical), many elements of the work system supporting the MRec and MRev processes could be extracted and exploited.

As regard to the work analyses, 50 observations were carried out corresponding to 140 hours 30 minutes and 20 interviews corresponding to 20 hours. First of all, the results show that both processes are completely intertwined: the MRec process is part of the MRev. Moreover, most of the healthcare professionals - excepted senior pharmacists – did not distinguish the two processes: they name the entire process “the medication reconciliation”.

Tasks	Main actors	Outcomes
Identifying and listing patient to be included in the processes (only sites where resources does not sufficient to include all the patients)	<b>Physician</b>	List of patients to be included
Establishing the best possible medication history (BPMH)	<b>Physician</b> *, <b>pharmacist*</b>	Necessary data for MRev meeting
Documenting the patient compliance, geriatric summary and medical antecedents	<b>Physician</b> *, <b>pharmacist*</b>	
Comparing the BPMH with the hospitalization treatment and checking for potential ADEs	<b>Pharmacist**</b>	
Reviewing medications regarding patient's characteristics, home environment and supposed future health status	<b>Physician,</b> <b>pharmacist, IDE</b>	Optimized treatment and justifications (BPMDP)Proposals to improve the patient's overall care
Transmitting MRev instructions to the patient, patient's GP and caregivers	<b>Physician</b>	Discharge letter with MRev outcomes and justifications (BPMDP) Interview with the patient and his caregivers

Table 2. Main tasks of MRec & MRev processes along with the actors and outcomes (\*=performed by a resident or a student; \*\*=performed by a junior and supervised by a senior; actors in bold are systematically present, actors with normal format can intervene)

One of the main result of the literature and work analyses shows that despite differences in the work organizations, the MRec and MRev processes **main tasks** are similar whatever the site (Table 2):

1. the identification of the patients to be included in the processes;
2. the elaboration of the BPMH, i.e. a list which accurately and reliably provides the medications the patient is actually taking prior his/her admission to hospital;
3. the retrieving of all relevant information on the medication compliance at home (e.g. drug dispensing and administration processes, use of pillbox, swallowing troubles);
4. the MRec, i.e. the comparison of the BPMH with the hospitalization treatment checking for potential ADEs;
5. the MRev, i.e. the review by a multidisciplinary team of all the patient medications to optimize as far as possible the treatment as regards to the state of the patient and the conditions of compliance at home;
6. the transmission of the Best Possible Medication Discharge Plan (BPMDP) to the GP and sometimes also the patient.

But the instantiation of these steps is different depending on the work organization. Even if the distribution of tasks may vary between the actors, the same three **actors** are mostly involved: nurse, pharmacy and medical staffs. Physicians and pharmacists are key actors: they both may be leading the process and are in charge of the medication decision making. Nurses when involved, as residents, are rather in charge of data collection.

The **tools** used to support the processes are considerably different, from a basic paper-based support to an advanced computerized system (they are always designed and improved by the actors all along the implementation). One of the recurrent results concerns the added-value of a computerized tool to make easier the coordination and reach patient safety.

#### **4.2 Identified problems and work key factors**

Work analyses lead to a list of problems linked to four main consequences on both processes (Table 3). Two main causes have been identified: understaffing and turnover. Understaffing causes lack of resources and difficulties to allocate tasks among actors. The turnover generates lack of expertise and understanding about MRev issues among newcomers (students and residents) and also seniors who never experienced the processes before.

Consequences	Problems	Causes
<b>Meeting cancellation</b>	Key actors missing (leader or pharmacist)	Understaffing
<b>Unreviewed patient</b>	BPMH not documented on the MRev support	Lack of expertise (student or novice in the MRev process)
	Patients listing incomplete (unidentified patient for the MRev meeting)	Unplanned discharge Suboptimal task allocation Lack of shared dedicated support Actors do not trained to patient computerized identification
	MRev team is not informed of the patient discharge	Lack of coordination between unit actors and MRev team Physicians turnover and lack of coordination in medical units
<b>Diminution of MRev quality</b>	BPMH incomplete or not reliable	Pharmacy students turnover Difficulties to retrieve information
	Missing information in clinical pharmacy section on the MRev support	
	Patients listing incomplete (patient identified just before the meeting; prescription analysis cannot be done)	Suboptimal task allocation Lack of shared dedicated support
<b>Diminution of MRev process efficiency</b>	MRev meeting cannot be prepared by actors	Actors do not have time MRev tasks are not priority
	Geriatric summary and medical antecedents not documented on the MRev support	Resident physicians turnover Lack of time of resident physicians Perceived as a double documentation task by resident physicians
	Time of students' task learning	Students and residents turnover

**Table 3.** List of main consequences with their associated problems and causes recorded during observations

Seven main **key factors** have been identified from the literature review. They are defined as components of the work system which influence positively or negatively the processes according to the work's conditions. They are systematically observed in the three analyzed work situations:

- Human resources must be sufficient and must be trained.
- A clear distribution of roles and tasks is mandatory.
- A design and implementation strategy should be anticipated and planned to ensure an efficient deployment and maintenance of the processes.
- Both MRec and MRev are inherently collective processes. The coordination tasks are critical, especially between the hospital actors directly involved, but also with patients/caregivers and with the community setting.
- A certain number of data is mandatory for the MRev. This data should be available and considered reliable by the actors during the MRev.
- A computerized tool is a real added-value. It should be designed with specific characteristics and its implementation should be anticipated and planned.
- The processes' perception by the actors is important, especially the feeling of usefulness.

## 5. Conclusion & Perspectives

Based on the work analyses, the main features of MRec and MRev processes (actors, tasks, tools, organization, etc.) are clearly identified for three of our five study sites. Most of the problems/barriers identified in the literature were observed and precisely described with the corresponding causes and consequences on the processes. These first results are promising and give the first elements of a future model. MRec and MRev processes are entirely intertwined; more especially, MRec appears as a condition to perform MRev; thus, we now automatically consider MRec when we talk about MRev process. The results also highlight that MRev is a complex process. MRev is distributed through time (the process takes place

over several days), through space (not always dedicated places), and among several actors whose function and position differ. The work organization of the process may greatly vary: the MRev itself (decision making) may be a dedicated meeting (as a multidisciplinary meeting) or exchanges between the actors during the daily medical rounds. Among the many possibilities of organizations, the physician-pharmacist partnership appears to be essential.

A depth analysis of the collective decision making between physicians and pharmacists is envisaged for further work. From a cognitive point of view, the cooperation activities between the two types of actors may be characterized as *integrative and debative* (Schmidt, 1994) - perspective, skills and knowledge are complementary and confronted - and *horizontal* (Rogalski, 1994) - actors share and perform tasks of the same levels without hierarchical links. The decision then supposes that physicians and pharmacists share knowledge and complementary representations of the situation in order to participate in the decision, each with a global vision on the process. This requires compatible representations that Leplat (1991) defined as the fact that "*everyone should understand what others are doing even if he differently apprehends the situations*". Develop and maintain a common frame of reference will then require a "*mutual critical assessment*" phase.

From a practical point of view, these perspectives allow us to identify what are contributions of each actor and so, what are risks whether one of them is excluded of the MRev process. From a scientific point of view, we take this opportunity to study the MRev process to explore the collective decision making process and more especially the cognitive collective planning process (Hoc, 2000, 2001).

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## **Affordances of household features important to personal health information management: designing consumer health information technology for the home**

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**Keywords:** affordances, consumer health information technology, personal health information management, virtual reality

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While much of health care happens in clinics and hospitals, even more occurs in intimate places such as homes (Zayas-Cabán & Valdez, 2012). Features of homes possess affordances, which give cues about managing personal health information to home dwellers. By exploring a unique stimulus of 15 3D virtual replicas of actual homes, participants identified features important to personal health information management (PHIM). This abstract reports the features identified and their associated affordances. The long range goal of this work, known as the vizHOME study (AHRQ R01HS022548) is to generate criteria to guide designers and home health professionals interested in the development and use of consumer health information technologies (CHIT).

### **1. Context**

The home environment is one of the most commonly used but poorly understood health care settings (Zayas-Cabán & Valdez, 2012). PHIM is a set of cognitive and behavioral tasks that patients perform toward meeting their health goals. It is critical that CHIT created to support PHIM be designed with a consideration for the home environment in which they will be used (Or et al., 2011). However, we currently lack evidence-based guidance for the development of CHIT for use in the home that accounts for the home environment.

Affordances of features (objects and spaces) of the home can provide information about how the environment shapes work performed. We consider affordances as a feature's perceived and actual properties that determine possibilities for how it could be used (Norman, 1988). Understanding the affordances of household features might inform design recommendations for CHIT.

However, research in home environments can be challenging (Or et al., 2009). For example, researchers are typically limited in the time they can spend in a house, constrained in the number of visits to a home, and may be restricted to a certain number of homes due to travel or cost limitations. Virtual environments have the potential to allow experts to perform in-depth critical assessments of home environments to identify features of the environment that are important to PHIM and to investigate the affordances of those features (Brennan, Ponto, Casper, Tredinnick, & Broecker, 2015).

## **2. Objectives**

This study employed the use of a 3D virtual reality CAVE that enabled experts to investigate virtual renderings of actual home environments to identify and assess features of homes important to PHIM. To better understand the way in which household features shaped PHIM, we assessed and categorized the affordances of the identified features. The objective of this study was to develop a new way of conceptualizing PHIM in the home by considering affordances of features of the home environment important to PHIM.

## **3. Methods**

Six experts (members of the research team) viewed full 3D visual replica of 15 actual homes (obtained in the parent study vizHOME, [www.vizhome.org](http://www.vizhome.org)). Homes represented four types (detached, semi-detached, multi-unit, mobile). Home exploration occurred during two non-contiguous weeks. Homes were randomly assigned with adjustments to avoid order effects. Each home was viewed by 3 experts; each expert viewed 8 homes. Data from one expert in one home was discarded due to technical display issues. Total assessments were 47.

Experts spent a maximum of 15 minutes in each home. The task was to walk through the home and tag any features that were considered important to PHIM task performance (barriers or facilitators). After each home assessment, experts responded to a survey and were given 10 minutes for washout before viewing the next home.

A group debriefing session involving all participants was held at the end of each week to ensure consensus of tagged features as important to PHIM. A grid of the tags was generated to enable inspection of features by room and by house. Finally, an enumerated list of feature-room pairs was created.

Using the enumerated list of tagged features identified in the data collection, two experts met and analyzed these features based on the features' potential affordances. Each feature was assessed individually and affordances were considered independently from any action taken on the feature. Affordances were presented to a multidisciplinary group of experts (human factors, nursing, industrial engineering, informatics, and library sciences) for discussion and revision until consensus was reached.

## **4. Main results**

Participants identified 68 features of the home environment as important to PHIM (Table 1).

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Enumerated List of Features

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Backpack	Floor	Shelves
Bag	Free weights/exercise equipment	Slide holder
Basket	Inhaler	Smart phone
Bookshelf	Keyboard	Sofa/couch
Cabinets	Laptop	Steps
Cabinet, file	Letter holder	Storage bin or box
Calendar	Light switch	Stove
Cane	Magazine rack	Table, coffee
Chair	Magazines, books, publications, documents	Table, dining
Clock	Mirror	Table, end (vanity)
Clock radio	Nightstand	Table, library
Closet, inside	Picture frame	Tablet
Closet, top	Pill bottles	Telephone
Coffee maker	Pill organizer	Toilet
Commode	Printer	Toilet tank, top
Computer	Purse	TV & remote
Counter	Radio	TV tray
CPAP	Refrigerator, artifacts	Walker
Desk	Refrigerator, medication storage	Wall above sink
Door	Refrigerator, top	Waste basket
Drawers	Reminder cards	Water dispenser
Dresser/bureau, drawers	Scale	Whiteboard
Dresser/bureau, top	Scooter	

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**Table 1.** The enumerated list of features identified as important to personal health information management

From those 68 features, we identified and described a set of 14 affordances, which are detailed in Table 2.

<b>Affordance Identified</b>	<b>Description of the Affordance</b>	<b>Example</b>
<i>Visible</i>	The feature can be viewed without taking any action	Calendar that is posted on the wall
<i>Information repository</i>	The feature is a place where content can be stored (but not artifacts)	Date book where appointments are written down
<i>Storage</i>	The feature can hold other physical objects	File cabinet where health information is stored
<i>Manipulable</i>	The feature can be picked up in the hand	Tablet device that is used to track glucose levels over time
<i>Portable</i>	The feature can be carried within the house	Tray that is moved around the house and is used to prepare medications
<i>Transportable</i>	The feature can be carried outside of the house	Purse that holds a glucometer that moves around both inside and out of the house
<i>Durable</i>	The feature has a high level of resilience with use over time	Backpack is a more durable container than a paper bag for daily use to transport medical information and supplies
<i>Hazard resistant</i>	The feature prevents external household threats from acting on the feature	Pill box would prevent external household threats from acting on the pills it holds
<i>Protective</i>	The feature shields physical objects and/or content	Storage bin that holds papers inside that a person wishes to keep shielded and/or out of site
<i>Cognitive support</i>	The feature specifically aids cognitive activity – e.g., content or computational support or interpretive support	Smartphone that provides computational support for blood glucose levels to quickly show what is low, normal and high
<i>Physical support</i>	The feature can physically aid other features or agents	Counter that is used to layout medications in the order they will be taken throughout the day
<i>Content presentation</i>	The feature can be used for content output	Laptop displays test results on the patient portal
<i>Communication</i>	The feature can be used for output and/or input of content	Telephone is used to receive calls from the pharmacy that remind the patient about a prescription that needs to be refilled soon
<i>Alert/Cue</i>	The feature serves as a reminder	A posted reminder card serves as a cue to call the doctor to make an appointment

**Table 2.** Affordances identified, description of the affordance, and examples

## 5. Discussion/perspectives

This study is an important initial step in developing evidence-based design guidance for the development of CHIT to support PHIM in the home. These results suggest that features of the home have specific affordances and these affordances can be used to better understand the home environment and how it shapes PHIM.

It is possible that the importance of features is shaped by a confluence of both the affordance(s) of the feature and some other aspect of physical context. Specifically, the interaction between the affordance of the feature and its location in space, or its proximity to other features of the room. For example, drawers would have the same affordances, but could take on different importance for PHIM depending on the location (e.g., hallway versus bathroom). Similarly, a nightstand has similar affordances to a dresser but takes on different importance for PHIM due to its location in the room. Future work should explore these interactions to further develop design guidance based on the physical context of the home environment.

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## UX barriers of handsfree communication devices in nursing work

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### Abstract

*Context:* Hands-free communication devices (HCDs) are implemented in nursing work systems. They provide conveniences and flexibilities for the nurses. However, they have not realized their full potential because of user experience (UX) barriers. Current research lacks a systematic investigation of the HCD UX barriers.

*Objectives:* The objective of this study is to investigate the HCD UX barriers in real-world nursing work systems. We expect our findings can inform ideas of both product and system design interventions, and eventually improve the safety and quality of the systems.

*Methodology:* We conducted 15 individual interviews with registered nurses working in two pediatric intensive care units in a children's hospital. We transcribed the interview data, and analyzed them using thematic analysis.

*Main results:* The UX barriers were situated in specific contexts. We identified five themes representing the UX barriers of HCDs in the nursing work system. They include: (1) battery volume and indicator, (2) voice recognition, (3) signal reception, (4) voice interference, and (5) the required healthcare protective clothing in isolation rooms.

*Conclusion:* The UX barriers impact the effective use of HCDs for the nurses' work. A joint optimization of both social and technical sub-systems may address the UX barriers of HCDs.

**Keywords:** UX, HCDs, nursing communication, macroergonomics

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### 1. Introduction

Hands-free Communication Devices (HCDs) are implemented in nursing work systems. HCDs bring many benefits to the nurses' work. First, they provide convenience and flexibility to the nurses (Yang & Rivera, 2015). Wearing a HCD, nurses can simply touch a button on the device and say the name of the intended recipient to get a call connected immediately. When nurses receive a call, they can use simple voice commands to accept a call and start the communication, or to decline this call to minimize interrupting their current workflow. Second, HCDs reduce nurses' workload. Research has shown HCDs reduced the nurses' walking distance during work and the percentage of time spent on communication (Ernst, Weiss, & Reitsema, 2013; Pemmasani, Paget, van Woerden, Minamareddy, & Pemmasani, 2014). Third, HCDs may facilitate better work performance. From a cognitive ergonomics perspective, nurses may perform better by using HCDs than face-to-face communication because they do not have to look away from their current task while talking using HCDs (Wickens, 2008).

Despite the potential benefits, HCDs may not have realized their full potential due to user experience (UX) barriers. UX encompasses all of the aspects of the end-user's interaction with HCDs (Norman & Nielsen, 2004). The first and foremost consideration of UX is to

evaluate whether the product is usable, accessible, and desirable (Goldberg et al, 2011). Previous research has identified some technological issues leading to difficulties in use and failures in connections (Yang & Rivera, 2015). However, from a systems perspective, HCD UX is not limited to the evaluation of the technology/product itself. HCDs are one of the components in complex socio-technical work systems (STS). The systems are composed of people, tools and technology, tasks, physical environment, organization, and their interactions (Carayon et al., 2006). Therefore, the use of HCDs does not occur in a vacuum; the HCD UX needs to be evaluated within the context of use. We need to understand how well HCDs are integrated into the system and whether they are compatible or incompatible with other components in the work system (Karsh, 2004). To achieve this understanding and avoid unintended consequences, taking a macro-level approach when studying this problem space is valuable (Karsh, Holden, Alper, & Or, 2006; Yang, Rivera, Fortier, & Abernathy, 2014).

There is currently no research that systematically studied the contextual-based HCD UX barriers using an STS framework. As a part of a larger study of HCD-mediated interruptions, the objective of this paper is to investigate the HCD UX barriers in the real-world context of nursing work systems. We expect our findings can inform ideas of both product and system design interventions, and eventually improve the safety and quality of nursing work systems.

## **2. Methods**

All procedures in this study were approved by the Institutional Review Board (IRB) in the hospital conducting this research. We conducted 15 individual interviews with registered nurses (RN) working in Pediatric Intensive Care Units (PICUs) in a children's hospital located in the Midwestern United States. The participants were recruited using a convenience sampling method. The interviews were led by two human factors engineers, in August to September, 2016. Each interview session lasted 25-40 minutes.

The interview protocol was developed based on pilot observations. Since "Vocera" is the brand name of HCD in this work system, we used "Vocera" in the interviews to refer to HCDs. The interview questions were related to HCDs and their relevance to other elements in the socio-technical work system. Nurses were asked probing questions to facilitate answers with in-depth insight. Sample interview questions are in Table 1. The audio recordings were sent to a professional transcriptionist external from the study, who transcribed the recordings verbatim (Padgett, 2008).

One human factors engineer (YY) analyzed the transcriptions using the qualitative method of thematic analysis (Strauss & Corbin, 1990) in NVivo 10© (QSR International Pty Ltd., Melbourne Australia). First, an inductive method was used to generate a list of descriptive codes. Second, the codes were compared and integrated into themes that are relevant to UX barriers. Third, another human factors engineer (AJR) critically reviewed the coding structure. Discrepancies between coders were discussed and changes were made when consensus was reached.

## **3. Results**

The HCD UX barriers were situated in specific contexts. We identified five themes representing the primary barriers in the nursing work system. They include: (1) battery volume and indicator, (2) voice recognition, (3) signal reception, (4) voice interference, and (5) the required healthcare protective clothing in isolation rooms. These barriers can lead to various negative consequences in the nursing work systems.

### 3.1. Battery volume and indicator

Vocera needs to be recharged every time after a nurse's shift. Despite this, the battery may still not last a nurse's entire 12-hour shift, especially when they are busy. When the battery is low, it is indicated by a sound emitted from the device, but that sound might be too low to be heard by the nurse. In the noisy and chaotic PICU environment, the sound may even be ignored, and the Vocera might shutoff automatically without the nurse realizing it. The insufficient battery life and unnoticeable low-battery indicator may result in workflow inefficiency when nurses have immediate needs for communication from both the initiator and receiver of the call perspectives. A participant described it like this: *"If you're using it a lot... your battery can [run] low, which can be inconvenient sometimes. Sometimes people don't realize like that it's [turned off]."*

### 3.2 Voice recognition

Voice command is a distinguishing feature of Vocera. Nurses use voice command, such as the names and the roles of the receiver, to initiate outgoing calls. However, for some names and roles, especially the international names, Vocera has consistent troubles understanding them. The caller may have to repeat the name several times, mispronounce the name in the way Vocera wants to "hear" it, or try to spell the name. This interrupts workflow and nurses may become frustrated when they have to try several times to initiate a call using Vocera. A participant described it like this: *"It doesn't always understand your voice, doesn't recognize what you're trying to say, so you have to say over and over some names, or it connects you to somebody you don't want to talk to."*

### 3.3 Signal reception

Vocera relies on the hospital's wireless network. However, certain locations in the PICU have been identified as poor signal reception zones. These are generally patient rooms located in the corners furthest away from the nursing station. In these locations, communication via Vocera is interrupted with static, or the call may not even be able to get connected. This signal reception issues may also cause inefficiency of workflow and delay of patient care when nurses have immediate needs for communication. A participant described it like this: *"I thought it was a patient room at the high end that had kind of like a dead zone."* And another participant described it like this: *"[When I was in the dead zones], I didn't have a signal. My patient had some really significant blood pressure changes while I was unreachable, and so as soon as I walked [out of] the zone I had all these calls and messages."*

### 3.4 Voice interference

PICU is a work environment that is very busy and noisy due to alarms from patient monitors, ventilators, call lights, people talking in the halls, and patients crying. This noise may interfere with Vocera, which makes the voice command more difficult to be understood by Vocera. Also, due to the environmental noise, nurses may have difficulties understanding what the nurse on the other end is saying via the Vocera. This can lead to potential miscommunication and medical errors. A participant described it like this: *"It's sometimes difficult having the Vocera understand [the voice command], especially if there's a lot of background noise, your ventilators, the alarming, things like that."* Another participant described it like this: *"If you're in a room and some kid is screaming, then you can't hear [what the caller is saying] on the Vocera."*

### 3.5 The required healthcare protective clothing in isolation rooms

The PICU has patients that need to be isolated for infection prevention purposes. The isolation rooms for those patients have two sets of doors with an anteroom in between that protects the patient's environment from the hallway. Additionally, while in the patient room, nurses must wear personal protective equipment (PPE) generally consisting of a gown covering their front and tied in the back and gloves. When the nurse is inside the patient room, it is nearly impossible to seek help from people in the hallway using face-to-face methods, because in doing so, the nurse must remove PPE by de-gowning, taking off their gloves, washing their hands and opening each set of doors, which is inconvenient and very time consuming. Therefore, in this situation, the best option for seeking help is to use Vocera. However, the gowns that are required cover Vocera, limiting voice command functionality and muffling the caller's voice. Also, the combination of the gown covering Vocera and wearing gloves makes it difficult to touch the main button on Vocera to initiate a call. Despite these, nurses have to overcome the challenges and adapt in order to effectively communicate using Vocera, creating opportunities for errors. One participant described it like this: *"The gown will rub on the Vocera, and it's very difficult to hear people sometimes. I honestly have had to stick my face in my gown to talk to the Vocera so that it will understand what I'm saying to call a person."*

## 4. Discussion

From the results of this study, we identified a number of contextual-based UX barriers of HCDs in the PICU nursing work system. These issues may contribute to nurses' frustration, unsuccessful communication, reduced work efficiency, and even opportunities of medical errors. These UX barriers are not only related to the technological performance and reliability of HCDs, but also related to many other components in the nursing work systems.

To address these barriers, we must take a macroergonomics perspective, to jointly optimize the healthcare system inputs in both social and technical subsystems (Hendrick & Kleiner, 2001). Regarding the design of Vocera, its performance and reliability may be improved by increasing the life span of the battery, and creating a low-battery indicator that is salient by using multi-modality hints, such as a flashing light, vibrations, and a distinguished sound. The accuracy and intelligence of the voice recognition functionality needs improvement, accounting for the pronunciation of unique names. Redundant ways may be designed to initiate a Vocera call, such as hot keys triggered by voice, or numbers to represent coworkers.

Regarding the PICU environment, the wireless network needs to have full signal coverage to eliminate "dead zones", especially in areas away from the nursing station. It is also important to reduce unnecessary noises, especially inside the patient room, where nurses tend to engage most in Vocera communication. This can be achieved by conducting a work system analysis to understand the sources of noises and how they are perceived by the healthcare providers. Based on this understanding, we can (1) reduce the volume and frequency of unnecessary sounds in the PICU that are not perceived as value-added; (2) design regulations and training programs to standardize when, how and where the nurses and other staff can have discussions and conversations that add to the environmental noise.

Compatibility of other tools and technologies should be considered. More healthcare organizations are starting to implement and use HCDs. Therefore, while wearing gowns for infection prevention purposes is required by regulation, the incompatibility between the gowns and HCDs needs to be addressed. The gowns could be redesigned using a material that has better sound penetration, making the communication easier and legible. Also, an ear piece

may be designed that wirelessly connects to Vocera for nurses who are taking care of patients in isolation.

Implementing these recommendations could greatly reduce HCD UX barriers, enhancing nurses' the work performance and increasing patient safety. While implementing the recommendations, it is important to keep in mind how the different recommendations interact with one another and the potential for contextual fallacies (Karsh & Brown, 2010). Taking a macroergonomic, systems perspective is valuable throughout the process, which takes considerations of organizational and sociotechnical context and can limit unintended consequences (Carayon et al., 2013).

This research has several limitations. First, due to resource constraints, the study was only conducted in one hospital. The transferability of this qualitative research can be enhanced by a future large-scale study. Second, the method of interview is retrospective. While we created probe questions to facilitate nurses' in-depth thinking, there may be certain experiences that cannot be recalled by the interviewees, resulting in abstract answers. This can be improved in the future by conducting interviews immediately after observations.

## 5. Conclusion

In this paper, we investigated the HCD UX barriers in nursing work systems using a STS approach. While HCDs brought convenience and easiness of communication to the nurses, they have not realized their full potential because of several UX barriers. To address these barriers, recommendations must jointly optimize the social and technical subsystems of the nursing work system. While many of the solutions are contextually based, the methods presented in this study can be applied to other systems, to improve the safety and quality of nursing communication and work.

Overarching Questions	Probing Questions
How do you use Vocera in a typical day?	Who do you communicate using Vocera? What types of calls do you initiate and receive using Vocera? When do you communicate using Vocera?
Can you describe your experience using Vocera during work?	How do you feel the ease of use of Vocera? ○ In what situations are Vocera easy to use? ○ In what situations are Vocera difficult to use (e.g., when you are performing a particular task, at a particular location, or to comply with certain regulations)?
If you get a chance, what do you like to improve the use of Vocera?	

Table 1. Sample interview questions

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## “10 Minutes of Human Factors” – An innovative training approach for healthcare

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### Abstract

A series of ten-minute presentations on human factors, known as "10 Minutes of Human Factors", was introduced as a novel means to deliver the science of human factors without requiring too much meeting time and disruption. "10 minutes of Human Factors" encouraged unit/shift leaders and chairpersons of meetings to, whenever possible, spare 10 minutes of their meeting time to include human factors into the meeting agenda, thus creating simple awareness of human factors concepts. Preliminary surveys were conducted to test the viability of this idea. Results revealed very positive support from clinicians, nurses, and allied health professionals. Whilst the "10 Minutes of Human Factors" will undergo more refinement, this paper suggests its universal applicability, and recommends it as a means of introducing human factors concepts to busy healthcare professionals.

**Keywords:** training, Human Factors, education.

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### 1. Introduction

Healthcare errors are a leading cause of death in America. The Institute of Medicine (IOM) estimated that between 44,000 and 98,000 deaths each year occur from medical adverse events (Kohn, Corrigan, & M., 1999), which mostly result from design of care processes and systems that fail to recognize human capability and limitations. However, error prevention in healthcare has primarily focused on individual caregivers (i.e., improving individual's proficiency) and less on the design of systems (i.e., the dynamic interactions of individuals with system factors) (Kizer, 2001). In moving towards preventing errors and achieving safety culture, health care organization needs to change the prevailing "blame" culture, eliminate the misnomer of "perfect performance" from healthcare staff, create an understanding toward "to err is human" regardless of how well the training is, and that most errors are preventable by appropriate process and system design (Kizer, 2001). Human Factors (HF) is a scientific discipline that take into account human capability and limitations when design, evaluate, and harmonize the work system (i.e., task, tool, environment, and organization). In 2005, IOM identified HF as a tool to aid in understanding and improving system design to enhance human performance, hence promoting patient safety as well as safety culture. More recently, the Joint commission also outlined benefits of deploying HF to aid in delivering both worker and patient safety, as well as high reliability organization (Braun, Riehle, Donofrio, Hafiz, & Loeb, 2012).

Benefits of applying HF in health care have been recognized exponentially, which subsequently have increased the demand for healthcare organizations to hire an in-house HF specialist and/or expand education on HF for their staff (Gurses, Ozok, & Pronovost, 2012;

Xiao & Fairbanks, 2011). With limited HF resources, most organization could only hire one HF specialist, who then perpetually encounters an overwhelmingly handful of expectations. Worse, an organization that rushes into deploying HF without a full understanding of this discipline could eventually assign inappropriate tasks for HF impeding HF to deliver full benefits. Health care staff and leaderships at all levels should be educated on the roles of human factors and basic human factors concepts to promote an adequate project assignment, appropriate deployment, and to create awareness around the science of HF.

## **2. Novel Means of Introducing Human Factors Content**

A great barrier to training success in health care is time (Ward & Wood, 2000). Despite positive interest and curiosity, healthcare professionals often have too busy a schedule and do not have dedicated time for an additional training. Department that gives dedicated time often has an improper assumption that staff would be able to apply HF concepts immediately after the training.

To overcome the aforementioned challenges, an HF specialist (SY) innovated a training model, “10 minutes of Human Factors,” to deliver the science of HF without requiring an absurd time commitment from frontlines and building improper expectations. A “10 minutes of Human Factors” encourages unit/shift leaders and chairpersons of meetings to, whenever possible, spare 10 minutes of their meeting time to include HF into the agenda to discuss a HF topic of interest. The aim is to allow frontline staff to learn one basic human factors concept in 10 minutes, which cumulatively will create simple awareness of HF concepts and allow them to be more mindful of their own actions at the workplace. It is important for all health-care workers to be mindful of situations that increase the likelihood of error for human beings in any situation.

## **3. Objectives and Methods**

The “10 minutes of Human Factors” was initiated by a human factors specialist (SY) with a list of 11 HF related topics, which focused mainly on cognitive ergonomics concepts (e.g., visual search, memory). A human factors specialist (AK) from the Johns Hopkins Medicine, adopted the model and started a collaborative effort. The training module was revised and finalized to comprise both micro- and macro- HF concepts. A total of 16 HF topics were included. A survey was created as a means to assess the feasibility of pursuing this initiative more rigorously. The survey was kept simple, with two 5-point likert-scale questions polling their opinions about the presentation's duration and the topic's relevance. Subjective feedback about the presentation was also sought. The survey ended with a final open-ended question asking if participants might be able to identify any relevant examples in their workplace based on the topic presented. A survey was distributed at the end of each presentation to assess participants' perceptions.

The pilot of “10 minutes of Human Factors” started in April 2016 at KK hospital. Presentations were conducted at meetings across different levels: from frontline shift briefings, to department meetings, to even at the hospital management level with senior executives. A survey was distributed at the end of each presentation. At the Johns Hopkins hospital, this training module would be piloted with the Comprehensive Unit Based Program (CUSP) (AHRQ) teams. The module was introduced to executives, unit/department leads, and CUSP leads in April 2016 at the quarterly meeting. HF specialist led discussion at the end of the introductory presentation to gather feedback. CUSP team leads were asked to contact the HF specialists if interested to participate.

This paper shares the results from pilot surveys collected from KK Hospital, and initial impression and engagement from the CUSP teams at the Johns Hopkins hospital.

## 4. Results & Discussion

### 4.1 Survey Results from KK Hospital, Singapore

A total of 587 surveys were collected, 386 (67%) from nurses, 120 (21%) from allied health professionals, and 81 (14%) from clinicians. The surveys generally polled the participants on the relevance of the topics and the duration of the "10 minute" presentation. Amongst the nurses, 67% felt the presentation duration was "just right", while 19% felt it was too short. 80% of the nurses mentioned that the topics were relevant to their work, while 18% were neutral about the presentation content. Similar trends were found among the allied health professionals. 47% felt the duration was "just right" whereas 36% felt it was too short. 74% of these allied health professionals felt that the topics were relevant to their line of duty. With the clinicians, 38% felt the duration was perfect, whereas 47% felt it should have been longer (i.e.: too short). 70% agreed that the topics were relevant, while the remaining 30% were neutral.

Subjective feedback included: *"a good brief overview, more details can be discussed when needed"*—radiologist, *"short and sharp to the point"*—Nurse, *"interesting new knowledge. Good to share with all nurses"*—Nurse, *"should be 15 minutes"*—Nurse. Right after a 10 minute-presentation, 55% of all participants could share at least one relevant example to the topic. For example, participants responded in relation to 'attention': *"booby-traps: phone calls, enquiries, interruptions at work."*—Nurse, *"stuff giving medication and patient asking and calling for help so staff focus is divided"*—Nurse, *"too many "alarms" in the ward, e.g. phone ring, door bell, call bell, equipment alarm."*

Overall, the survey results revealed strong positive support for the 10 Minutes of Human Factors, with participants showing growing interest for more in-depth discussions about human factors topics.

### 4.2 Engagement at Johns Hopkins Hospital, USA

The "10 minutes of human factors" was introduced at the quarterly CUSP meeting, where hospital executives, department leads, and a total of 10 CUSP team leads attended. At executive and management level, their initial feedback were positive. Some comments included: *"Slicing down topic and present each for 10 minutes is smart"*—patient safety officer, *"Great method. Staff won't feel overwhelmed with another training"*—executive management, *"the topics are interesting. I want to attend all presentations"*—director of patient safety, *"I like the idea and the topics, you can start with my unit"*—unit manager.

After the introductory presentation of this training module, seven of 10 CUSP teams requested to include this series of "10 minute of Human Factors" presentations in their monthly meetings. The pilot will start in August 2016.

## 5. Conclusion & perspectives

As HF discipline grows in health care, the need to educate frontlines on HF becomes exponential. Despite the fact, organization did not commit to provide a dedicated training time to frontlines, or else would inappropriately expect frontlines to be capable of applying HF methods after training. Limiting each presentation to ten minutes could tone down the training expectations as well as making it easy for frontline staff to find windows of learning opportunity, especially if the meeting agenda was expected to be short. While the "10 Minutes

of Human Factors” presentations do not replace more formal means of imparting in-depth HF knowledge, it could very well serve as an effective ice-breaker to introduce HF to frontline staff, as well as an initial step to promote safety culture.

A noteworthy finding is the common trend of results across the two different countries. Healthcare professionals globally are faced with very tight schedules with increasing demand to attend to patients. As such, meetings and presentations need to be concise and effective. Regardless of the different organizational cultures, both institutions showed strong positive responses toward the "10 Minutes of Human Factors" presentations. We opine that these bite-sized knowledge tidbits might be an effective way for other human factors specialists to get a foot in the door with busy healthcare professionals.

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## The role of nurse managers in facilitating nurses' participatory actions for improving their workplace environment

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**Keywords:** nurse managers, workplace environment, participatory methods, ergonomic measures, action checklist

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### 1. Objectives

Participatory action-oriented methods are increasingly applied by healthcare workers to improve their workplace conditions. Awareness is growing that managers can support participatory action-oriented activities of nurses and other healthcare staff including ergonomic measures and stress prevention. The role of nurse managers in facilitating the participatory steps addressing multifaceted improvements at healthcare facilities was examined through their training workshops on participatory methods. Attention was paid to the use of an action checklist adjusted to local needs of nurses and other healthcare staff and on group work methods suitable for reducing their multifaceted work-related risks in the workplace environment.

### Methods

The training process and its outcomes of a workshop for 45 nurse managers on participatory workplace environment improvement in healthcare facilities were examined to discuss the roles of the nurse managers in promoting the improvement actions. The three-hour workshop was held by utilizing local good practices and a newly designed action checklist as training materials. The 30-item checklist listed low-cost improvement actions extracted from the ergonomic checkpoints in human care work assembled by a working group of the Human Ergology Society (HES), Japan, in collaboration with the International Ergonomics Association (IEA). The workshop consisted of a lecture on participatory methods, an action checklist exercise and group discussion on existing good practices and improvement actions to be taken at participants' workplaces. An emphasis was placed on multifaceted actions reflecting basic ergonomic measures and stress prevention norms. The role of nurse managers in facilitating the participatory steps having real impact.

### Main results

For use by nurse managers, a 30-item action checklist was prepared by modifying the simplified list of ergonomic checkpoints proposed by the working group of the HES. The PowerPoint slides used for the orientation of the participatory methods at the workshop were arranged by covering the check items extracted from the proposed checkpoints and by incorporating photographs of local good examples. The focus of the selected check items and the examples was placed on low-cost improvements feasible in healthcare facilities where the

participating nurse managers worked. The low-cost options for improving the workplace environment in the checklist are listed in Table 1.

Technical area	Existing good points		Necessary improvement actions	
	No. of groups*	Good points agreed on by the group discussions	No. of groups*	Necessary actions agreed on by the group discussions
Work methods	6	Organized storage, carts, sharps procedure,	6	Storage places, work height, wiring for safe work
Work environment	5	Infection control, hand hygiene	1	Lighting in bedside care
Work organization	3	Emergency plan, anti-violence procedure	6	Securing breaks, emergency response, anti-stress training

\*No. of groups that mentioned one or more points in the corresponding technical area

**Table 1.** Existing good points and necessary improvements identified by the six groups

The group discussions in small groups were organized after the lecture and a subsequent voting exercise of identifying photographs showing good examples. These group discussions centred around agreeing on three existing good points and three improvement actions concerning the participants' own workplaces. The participants were guided to focus on low-cost improvements achieved by the joint effort of managers, nurses and other healthcare staff and locally feasible improvement actions that could contribute to improving the nurses' working environment including psychosocial aspects. The six groups of the participants identified multifaceted good practices and improvement actions as summarized in Table 2.

Technical areas	Main check items
Work methods (Materials handling, workstations, person transfer)	Racks, passageways, trolleys, guards, wiring, transfer equipment and procedures, posture, coding
Work environment (physical environment, hazardous agents, infection control)	Lighting, ventilation, partitions, noise, radiation, labelling of chemicals, hygiene, protective gear, standard operation
Work organization (Social support, welfare conditions, schedules, training)	Mutual support, emergency plans, scheduling, breaks, resting facilities, informal gathering, stress prevention

**Table 2.** Check items incorporated in the action checklist used by the nurse managers

The participating nurse managers identified good practices in different technical areas including the recent progress in infection control measures and emergency plans including anti-violence procedures. Concerning necessary actions, all the groups mentioned the need to improve both work methods and work organization. As necessary measures for work methods, they pointed out improved storage, elbow-level work height and safer wiring practices. They also pointed out organizational measures concentrating on securing breaks, emergency responses including drills and training sessions on stress prevention. The workshop enhanced the nurse managers' awareness of multifaceted actions for improving the workplace environment including psychosocial aspects. The usefulness of applying a brief checklist of low-cost actions was confirmed.

The replies to a brief questionnaire about the workshop indicated its good learning effects. About the contents of the lecture, 49% of the 45 participants replied that they were satisfactory and 51% replied they were very satisfactory. About the training materials, 38% replied they were comprehensible and 62% replied they were very comprehensible. As free comments, 36 participants mentioned the importance of applying participatory methods in improving nurses' workplace environment with remarks on the merit of drawing attention to existing good practices.

These results suggest the importance of utilizing a relatively concise action-oriented checklist and good examples as practical means of facilitating participatory steps leading to concrete changes. The emphasis placed on multifaceted low-cost actions combined with this use of action-oriented tools is beneficial. The results also confirm the active role of nurse managers in facilitating participatory workplace environment improvement by nurses and other healthcare workers. The results of intervention studies on the participatory workplace improvements in the healthcare sector confirms the effectiveness of participatory steps. This direct involvement of nurse managers in applying participatory action-oriented methods is useful for supporting workplace environment improvement activities of nurses in various healthcare facilities.

### **Discussion/perspectives**

The present study confirms the adequacy of applying participatory methods as practical means of facilitating multifaceted improvements of the workplace environment in healthcare facilities. The clear focus on low-cost ergonomic measures and stress prevention is useful for planning locally feasible actions and reducing existing work-related risks.

It is suggested to apply action-oriented tools incorporating low-cost options so as to support the role of nurse managers in facilitating participatory multifaceted activities for improving workplace environment in healthcare work. The use of action checklists and guidance materials focusing on simple procedures aimed at good practices and on locally feasible improvements that have real impact on risk reduction can certainly support this role.

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training in building an Asian network for occupational safety and health of health care workers. *Journal of Science of Labour*, 83, 182-187.

# **POSTER PRESENTATIONS**



## How do people with dementia use technology?

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### 1. Introduction and Context

Over 46.8 million people live with dementia worldwide, and this number is set to increase to 131.5 million by 2050; the need to support these people is of paramount importance (Alzheimer's Disease International, 2015). While research continues to work towards effective treatments, there is need for research to improve the lives of people living with the symptoms (Alzheimer's Society, 2014); ergonomics and design research has a key role in this challenge.

As technology-rich environments are becoming increasingly commonplace, and society becomes increasingly automated, people with dementia (PWD) will be exposed to technological interfaces through necessity as technology becomes impossible to avoid (Wallace, Mulvenna, Martin, et al., 2010). Yet as technologies are developed in a 'hyper-cognitive society', where assumptions about cognitive ability are implicit (Brittain, Corner, Robinson, et al., 2010), there becomes an increasing risk of PWD being excluded from society as the demands of technologies are beyond their capabilities. It is therefore important to ensure that technologies are usable by PWD, by identifying and addressing the barriers to technology use. This could lead to a range of future accessible and usable technologies (e.g. everyday ICT, assistive technologies, or telemedicine) for PWD, to support increased independence.

### 2. State of the art

Literature discusses the interaction of PWD with a variety of technologies such as washing machines, laptop computers and telephones, to assistive technologies (Nygård & Starkhammar, 2007; Blaschke, Freddolino & Mullen, 2009; Gell, Rosenberg, Demiris et al., 2013; Cash, 2003). Whilst PWD use many technologies, a range of barriers that may be faced when using them. Potential barriers include inappropriate physical design, unusable graphical interface design, the demands that technologies make on the user, lack of training, cost, and rejection of technology (Gell, Rosenberg, Demiris, et al., 2013; Arning & Ziefle, 2009; Wallace, Mulvenna, Martin, et al., 2010; Astell, Ellis, Bernardi, et al., 2010; Rosenberg, Kottorp & Nygård, 2012; Agree, 2014). However, the method of identification, and the extended range of potential barriers to technology uptake and use remain under-explored.

### 3. Objectives & Methods

This systematic literature review addresses how PWD use technology. It explores barriers faced when using technology and identifies where technology does not meet the needs of PWD due to a lack of human factors design consideration.

Searches to identify relevant studies were conducted within the following online databases: Medline, PubMed, Ergonomics Abstracts, Scopus, Web of Science, Science Direct and ASSIA, using a search strategy based on terms from initial scoping. 1297 retrieved articles

were screened for relevant content that met the inclusion criteria. The 40 included papers were critically appraised for methodological quality using the Mixed Methods Appraisal Tool (Pluye, Gagnon, Griffiths, et al., 2009). All studies were of medium to high methodological quality. Included studies were analysed using thematic coding.

## **4. Results & Discussion**

### **4.1 Technologies**

Assistive technologies (ATs), everyday technologies, and therapy-provision technologies were evaluated. ATs were the focus of the majority of the included studies, in terms of their incorporation into the lives of PWD (Arntzen, Holthe & Jentoft, 2014; Lindqvist, Nygård & Borell, 2013; Boger, Quraishi, Turcotte, et al., 2014) and their usability. Everyday technologies, such as commercial devices including telephones and computers were evaluated for their intended use, and when being utilised as AT. Technologies for rehabilitation and therapies, assistive ambient living systems and eHealth were also evaluated within the reviewed literature.

These results demonstrate the diverse range of applications where technologies have been developed for use by PWD, in different settings, and for different stages of progression of dementia, from PWD living independently at home, to those living in residential care settings.

### **4.2 Barriers**

A range of barriers were identified within both the uptake and use of technology by PWD. These barriers were mostly identified by caregivers, rather than PWD themselves.

Lack of awareness and high cost of available technologies are two key barriers to the uptake of AT (Boger, Quraishi, Turcotte et al., 2014; Rikonen, Mäkelä & Perälä, 2010; Gibson, Dickinson, Brittain, et al., 2015). Negative attitudes of both PWD and their caregivers are another barrier (Arntzen, Holthe & Jentoft, 2014; Boger, Quraishi, Turcotte, et al., 2014). PWD were sometimes found to be sceptical of the usefulness of a technology, and carers felt that technology could not be a solution to the challenges that they faced. It is therefore vital that all stakeholders perceive a need for the technology if it is to be successfully incorporated.

The design of technologies is core to the usability and acceptability of devices, with ergonomic and aesthetic considerations required (Abbate Avvenuti & Light, 2014). Technologies can be problematic due to their physical complexity and the excessive demands they place on the user due to extensive operation procedures (Arntzen, Holthe & Jentoft, 2014; Boger, Quraishi, Turcotte, et al., 2014; Chen & Leung, 2012; Faucounau, Riguet, Orvoen, et al., 2009; Gibson, Dickinson, Brittain, et al., 2015; Jentoft, Holthe & Arntzen, 2014). This makes technologies incompatible with the capabilities of users.

Technologies need to support learning, and to fit within users' habitual practice (Arntzen, Holthe & Jentoft, 2014). PWD are more at ease with familiar objects, and unfamiliar design can be a deterrent for using technology (Cahill, Begley, Faulkner, et al., 2007). If technologies are not accessible and usable, they can evoke negative emotional reactions, including anxiety, frustration and incompetency, as well as the feeling of being stigmatised (Arntzen, Holthe & Jentoft, 2014; Gibson, Dickinson, Brittain, et al., 2015; Rikonen, Mäkelä & Perälä, 2010). These emotional reactions can result in non-use of devices.

## 5. Conclusions & Perspectives

A range of barriers were identified across the use of a variety of technologies by PWD. Many of these barriers exist due to poor compatibility between the technology design and the users' capabilities. It is believed that better accessibility and usability of technology could be achieved by implementing a human-factors approach to the design process, in which PWD and caregivers are fully integrated into the process.

**Keywords:** dementia, technology, Human Factors design

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## **12-hour shifts: determining the role of temporal flexibility allowed by extended work periods to manage sleepiness variations of nurses and nursing work requirements**

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### **1. Introduction and context**

12-hour shifts are increasingly common in the hospital sector. In France, 2/3 of the hospitals and 10.55% of hospital workers are concerned by these atypical work schedules (ATIH, 2014) which affect nearly 26,000 nurses in Europe (Estryn-Béhar & Van der Eijden, 2011).

### **2. State of the art**

Working 12 consecutive hours induces fatigue accumulation during shifts, which can be significant in the final hours (Chen et al., 2013), and adds to physiological desynchronization during night shifts. 12-hour shifts extend the waking period which impacts on sleepiness at work (Folkard & Åkerstedt, 1992), exposing caregivers to potential risks to their safety and to the reliability of their work. However, operators are not passively subjected to these risks as they implement regulation processes in their work activity. Regulation is a control mechanism (Falzon, 2004) which aims to maintain a balance between an operator's resources (cognitive, physical and/or psychological) and the characteristics of his/her work environment (Gonon, 2003). In night work or shift work, operators develop ways of regulation enabling them to manage changes in their sleepiness and achieve their work outcomes. Two types of regulation have been identified. First, operators anticipate changes in their workload and oncoming sleepiness. Depending on their task requirements, they keep margins of manoeuvre for unexpected events and to manage their future variation in sleepiness (Toupin, Barthe & Prunier-Poulmaire, 2014). Second, to handle sleepiness peaks as they occur, operators adapt their activity rate (less travel, fewer actions). They speed up performing tasks by avoiding or changing some procedures to make them suitable for their current status (Barthe & Quéinnec, 2005), and cooperate to ensure reliable work or sleeping and resting (Barthe et al., 2016).

### **3. Objectives and Methods**

The purpose of this study was to identify types of regulation used by nurses and nursing auxiliaries in a hospital department during 12-hour shifts. It was hypothesized that caregivers implement regulation strategies aimed to anticipate and manage sleepiness and work to be done during the day and night shifts.

The study was conducted at the intensive care unit of a French hospital. With 8 beds, it receives patients with critical failures. Their care involves the use of replacement methods such as mechanical ventilation and renal replacement. The systematic collection of data concerned 13 nurses and 6 nursing auxiliaries observed during three 12-hour day shifts and

four 12-hour night shifts. The methodology combined the measurement of the caregivers' sleepiness levels during their shift (Karolinska Sleepiness Scale ; Åkerstedt & Gillberg, 1990), the observation of work activity during the first 10 hours of the shift, and an individual self-confrontation interview in the last 2 hours.

The variables tested were the shift (day/night) and the period during the shift (the shift length was divided into 5 periods). The indicators of strategies of regulation (anticipation/managing sleepiness) were: saving energy at work and controlling the service by anticipating while progressing with work, and adjustments to breaks and rest times for managing sleepiness.

## **4. Results & Discussion**

### **4.1. Results**

There was an effect of the shift period  $F(3,90) = 20.91$ ,  $p < .05$ , and an interaction effect between shift period and shift  $F(3,90) = 5.07$ ,  $p < .05$ . Sleepiness increased throughout the shift in both shifts.

Several anticipatory strategies were identified. Interviews showed that several tasks were done at different times during both shifts: tracing biological parameters, blood glucose, nursing care, syringe preparation or blood test labelling. Anticipatory strategies were used throughout the shift in both shifts: making progress on tasks did not differ significantly between day and night ( $t = -1.305$ , ns) and between the times of the post  $F(4,24) = 1.874$ , ns.

Sleepiness management strategies differed between day and night: the work activity remained constant during the day, and decreased during the second half of the night ; rest times were scheduled during the day, and more random at night. The time spent in the break room was longer at night than during the day  $F(2,10) = 5.7$ ,  $p < .05$ .

### **4.2. Discussion**

12-hour shifts oblige caregivers to work over long periods while their sleepiness gradually increases. But the lengthening of the care period extends their margins of manoeuvre to organize their work, in both day and night shifts. Caregivers continually try to update their representation of their service in order to anticipate potential changes in workload and in their own abilities (Barthe, Quéinnec & Verdier, 2004). They will optimise time and energy by changing the task scheduling of their posts. They advance tasks to make themselves available in case there is a work overload or a high level of sleepiness (Toupin, Barthe & Prunier-Poulmaire, 2013). They postpone tasks to spend more time on another task or to rest.

## **5. Conclusion & perspectives**

The option to advance or postpone a task freely enables caregivers to better manage the unforeseen events that arise in hospital work, but also variations in sleepiness resulting from 12-hour work shifts. Given the success of 12-hour shifts in hospitals and the potential risks associated with them, we advise developing and enhancing temporal leeway for caregivers.

**Keywords:** 12-hour shifts, sleepiness, work regulation, nurses, night shift.

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## **The experience of the Safety Walk around in Tuscany Northwest ASL Territorial Area of Massa and Carrara**

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### **1. Introduction and context**

The Safety Walk around (4) is a methodological tool that is used to carry out the risk assessment in conjunction with health professionals on safety issues and the causes that can trigger adverse or critical situations.

It develops through meetings agreed with the professionals in the workplace; where we try to focus on what are the operational work areas where there are greater risks and indicate any improvement actions. (1) Are programmed in the implementation of assessment meetings of the identified assumptions and, if necessary, if the assumptions of improvement do not find adequate application, they identify other assumptions with subsequent verification over time. All this favors the mutual commitment of operators and managers in implementing improvements for the development of a culture of responsible safety.

The identification of areas of greatest risk allows the Strategic Management Company to implement preventive measures in order to reduce litigation and therefore claims for compensation from the user.

As a result of the Safety Walk around activities should result in a final report, in which the Strategic Direction is informed.

### **2. State of the art**

ASL in Tuscany Northwest Territorial Area of Massa and Carrara was borrowed this methodological tool to verify functional structures within individual hospitals the presence of critical situations that may pose a risk to patient safety .

The limitation of intervention to hospitals is justified by the fact that in planning it was decided to intervene in the areas from where the major claims and where it was easier to have an overview of the place of the activity in question also taking consider what were the relationships between the various operational units (2,3) . In addition, the organizational change due to the transfer in the New Apuan Hospital where it is expected the Cure Intensity model favors the possibility of implementation of major changes.

### **3. Objectives and Methods**

The U.O. Quality Assurance and Clinical Risk Management ASL Tuscany Northwest Territorial Area of Massa and Carrara agreed with Strategic Direction planning for scheduled visits within individual functional structures; such planning has been included in the budget and objectives. Of the Quality Assurance also in the reduction of the litigation. Programming provided the prior submission to the visit of disclosure in which the operators were explained the aims and methodology of the instrument with the declination of the questions which

would arise from the discussion. When visiting health professionals was also given a check list in which the essential requirements for implementing good practices to be identified by the Tuscany Region have been identified ..

It was decided to agree with the directors of Functional Structures dates of meetings, specifying that the invitation to participate was extended to all the professionals operating within the individual structures. The review team was made up of the Clinical Risk Manager and Patient Safety Manager.

#### 4. Results and Discussion

In the year 2014 two rounds of visits were made : the first took place from 18 February to 15 May and the second from October 13 to December 19 . They have been visited 27 functional organizational structures : 12 Hospital of Massa , 8 Hospital of Carrara; 4 Hospital of Pontremoli and 3 Hospital of Fivizzano .

The visits have followed the reports sent to the Director of Strategic Direction and Structure

The meetings were detected 76 critical areas : These were collected into macro areas of where the most critical area : (Fig. 1)

- Medical record computerization areas , radiological and laboratory ( 17.1% ) ;
- Compilation of the STU ( 10.5 % ) ;
- Protocols of the operating unit ( 9.2% )
- Hospital pathways ( 9.2% ) ;
- Management of blood transfusion ( 6.5 % ) ,
- Conflicts between employees ( 6.5 % ) ;
- Patients transports ( 6.5 % ) .

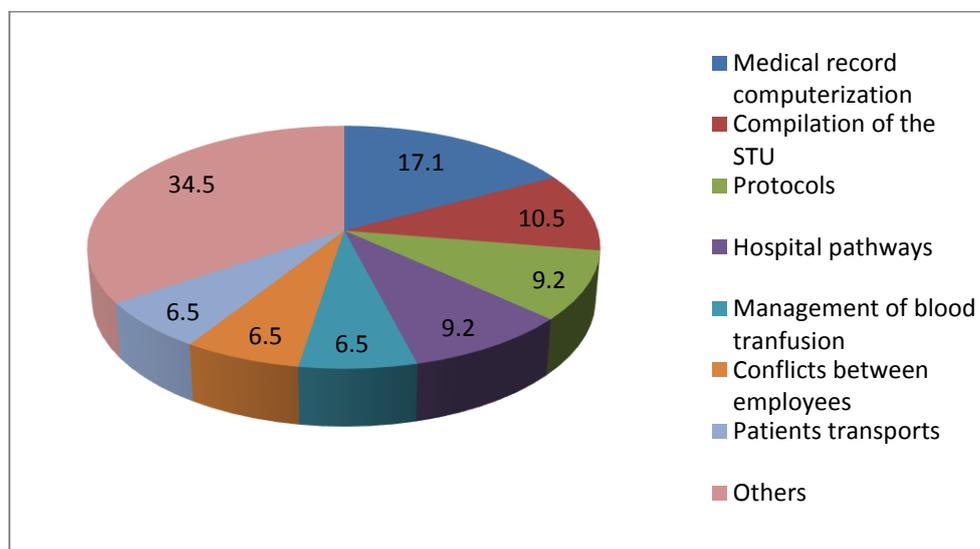


Figure 1. Percentage of most critical areas

#### 5. Conclusion & perspectives:

As a result of the findings they have been identified and shared with the hypothesis operators to improve organizational and training needed to resolve critical issues.

The fact that the greatest problems were identified in the computerization suggests that technological development applied to medical practice requires a reflection: the health staff must be properly trained to use the new equipment and above must be provided for the

professionals who assist healthcare professionals in the use of the same tools, now this aspect is unavoidable.

The other aspect that has been detected is the need for standardization in medical practice that should not be limited to the use of the guidelines but which must be contextualized to the realities of application; standardization and control of the systems does not have to be experienced by the medical staff as a mere bureaucratic aspect, but participated as an opportunity for shared improvement and patient safety.

**Keywords:** Safety Walk Around, checklist, clinical risk

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## Do physicians tailor their communication during medical consultations?

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### 1. Introduction and context

Research suggests that effective physician-patient communication is tailored to the patient's preferences for information and participation (Haskard Zolnierek & DiMatteo, 2009; Kiesler & Auerbach, 2006). The orthopaedic patient population is diverse and therefore in particular need of tailored approaches (van der Esch, Knoop, van der Leeden et al., 2015). Adequate physician-patient communication can increase patient activation, i.e. "an individual's propensity to engage in adaptive health behaviour". This results in better pain and disability relief after orthopaedic surgery (Andrawis, Akhavan, Chan et al., 2015; Skolasky, Mackenzie, Wegener et al., 2008, 2011; Street, Makoul, Arora et al., 2009).

Tailoring communication is a two-step process in which 1) information about the individual is assessed and 2) the communication's content and context is adapted accordingly (Hawkins, Kreuter, Resnicow et al., 2008). Our research explores whether physician-patient communication currently occurring in orthopedic consultations may be considered tailored. As a first step, this paper focusses on how physicians assess the patient.

### 2. State of the art

Tailoring may occur in consultations spontaneously, since interpersonal communication is considered the most advanced form of personalization (Kreuter, Farrell, Olevitch et al., 1999). Previous studies explored assessment of patient characteristics to support tailored physician-patient communication in breast cancer care by developing a questionnaire (Gorini, Mazzocco, Gandini et al., 2015; Kondylakis, Kazantzaki, Koumakis et al., 2014). However, both studies did not take into account potential spontaneous tailoring. This study adds to the research by specifically examining spontaneous tailoring.

### 3. Objectives and Methods

The aim of this paper is to examine if, and how, physicians assess individual patients during the medical consultation. A qualitative interview study with seven experienced orthopaedic surgeons was conducted subsequent to their outpatient consultations. A total of 80, 2- to 4-minutes, semi-structured interviews were conducted, audio-recorded and transcribed by the first author. Ecological momentary assessment (see Shiffman, Stone & Hufford, 2008; Stone & Shiffman, 1994) was used to account for recall bias associated with retrospective interviews. A conventional approach to qualitative content analysis guided interpretation of the transcripts (Hsieh & Shannon, 2005). In-vivo coding formed the initial classification scheme (Kondracki, Wellman & Amundson, 2002). During extensive discussions among the authors, final themes were checked for accuracy and saturation.

## 4. Results & Discussion

Surgeons characterize patients not by typology, but by narrative descriptions of typical features. For example, when prompted with the question, “What type of patient did you think this is?” surgeon 1 answered:

*“It remains difficult for me to classify the type, because I don’t have types in the back of my head. So I’ll just describe what kind of man this is. I think this is a realistic guy. An ex-worker, maybe a gardener from a village. Maasdijk. I’ll, um, call it a people’s man.”*

Across the seven surgeons, 103 different features were identified and on average 2.2 features were used to describe a patient. From this, the following clusters of features were established: “disease management success” and “communication role, style & effectiveness”.

### 4.1 Disease management success

Surgeons assessed the patient’s potential success in disease management. Realistic expectations, involvement and pain acceptance indicate successful disease management. Preoccupation with disease, insecurity and denial were deemed ‘red flags’ as illustrated by surgeon 3 classifying a 50-year old female patient:

*“No, no, they stay in their own world and they don’t accept that some things are what they are. Yes, they keep searching, searching, searching. Pain has to have a reason, right?”*

The assessment of disease management might be important to the surgeon because unrealistic expectations and pain catastrophizing can result in negative outcomes when not identified early in the care process (Flanigan, Everhart & Glassman, 2015; Palazzo, Jourdan, Descamps et al., 2014).

### 4.2 Communication role, style & effectiveness

How disease management factors are addressed by the surgeon during the consultation partially depends on the patient’s communication role and style, as well as the effectiveness in physician-patient communication. First, surgeons assess the role patients occupy in terms of hierarchy, and subsequently, what role to take themselves. Below is surgeon 6’s assessment of a ‘following’ patient:

*“This is a lady who is a little hesitant, who is staring at you, waiting what’s going to happen, and lets things develop.”*

The interaction is further shaped by the patient’s communication style, assessed here by surgeon 5:

*“She is funny, very amicable, that’s what you notice. [...] She’s direct in communication and amicable. In some patients that’s okay, so to say.”*

The finding that surgeons assess patients’ hierarchical role is consistent with Stewart and Roter’s (1989) typology of physician-patient relationships on high and low control exercised by patient and physician. Matching of the patient’s communication style may lead to increased patient satisfaction and trust (Farin, Gramm & Schmidt, 2012; Kiesler & Auerbach, 2006).

Finally, surgeons assess and account for potential difficulties and opportunities in communication. Difficulties that arose include language barriers, forgetfulness, and deafness, the latter reflected on by surgeon 5:

*“He had trouble hearing me correctly so I spoke a little slower and a bit clearer but at the same time you have to discuss something without creating immediate panic”*

Assessment of difficulties is not necessarily beneficial. Surgeons are inclined to pay more attention to behaviours of difficult patients, but this impairs their diagnostic performance (Mamede, Van Gog, Schuit et al., 2016).

## 5. Conclusion & perspectives

The present research explored spontaneous patient assessment in medical consultations to determine whether physician-patient communication currently occurring in orthopaedic practice can be considered tailored. The main finding is that surgeons do assess patients, specifically their potential disease management success and communication role, style, and effectiveness. The first step of tailoring communication, assessment of the individual patient, was taken by physicians in spite of the absence of formal assessment tools. These findings are consistent with the notion that interpersonal communication is tailored (Kreuter et al., 1999). Our future research will examine spontaneous tailored communication further by determining how assessment leads to adaptation of the communication's content and context and how this affects patient activation.

**Keywords:** personalized healthcare, tailoring, physician-patient communication, patient activation

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## Adaptive device for disease awareness and treatment adherence of asthma in children

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### 1. Introduction and context

In 2006, a national study revealed that there were 4,15 million of people with asthma in France, which represented 6,7% of the population (Afrite, Allonier, Com-Ruelle, & Le Guen, 2011). This chronic disease had generated 43 000 hospitalizations between 2005 and 2007 (Fuhrman et al., 2011). Nowadays, it is still responsible for 1000 death annually (Tual, Godard, Bousquet and Annesi-Maesano, 2008). Asthma is the first chronic disease in children: that concerns 10% of them (Darras & Demoly, 2006). This is a real public health issue, because its frequency and gravity increase since 2000's in this specific population (Delmas et al., 2014).

The main identified problem in asthma kids is the low rate of treatment adherence. Indeed, only 50% of them are taking their treatments as prescribed (duration, dosage...), and adopts healthy behaviors to avoid symptoms or crisis (de Blic, 2007). Moreover, 26% don't control their asthma, i.e. they can have crisis whenever (de Blic et al., 2009).

### 2. State of the art

To increase adherence rate, there is some strategies as therapeutic education programs (improve disease knowledge and management) (ANAES, 1998) and numerical technologies as serious games (Bronkie the Bronchiasaurus (Kato, 2010; Lieberman, 2001), ...) or mobile applications (My Asthma Pal (Abril, 2015), ...), but they all focus on short-term results. Furthermore, those learning systems are the same for all children, and it is proved that personalized program is more efficient than generic learning (Lopes, Clement, Roy, & Oudeyer, 2014).

### 3. Objectives and Methods

This thesis project, in collaboration with Inria Flowers Team, have the objective to create a personalized tool, named *KidBreath*, which is based on processes used in therapeutic education for children from 8 to 11 year old. Our easy to use solution is available on computers and tablets, and is design to allow children to use it autonomously.

*KidBreath* is composed by several interactive contents linked to asthma and displayed to different forms: learning activities with quiz, short games and videos. Asthma experts like health educators, pulmonologists, and pediatricians validated all the proposed content in the application.

The main goal of our project is to improve disease awareness. For this, we will care about three sub-components: usability, knowledge and motivation.

### 3.1. Usability

The interfaces are tailored to children. Indeed, they had been designed with iterative and user-centered methods such as:

- Participative workshops with children (Newell & Gregor, 2000),
- User tests (Daumal, 2012)
- Gamification features, for example: choose your own avatar (Fig.1) or visualize your performance evolution (Fig.2) (Mulletier, Bertholet, & Lang, 2014).



Figure1. Choice of avatar during inscription



Figure2. Visualization of what the child does on KidBreath (left : level reached; center : subjects seen today; right : time spent this week)

Because more the system is easy to use, more the objective will be reached with efficacy, efficiency and satisfaction (ISO 9241-11), we first checked the ergonomic criteria of Bastien & Scapin (Bastien & Scapin, 1993) and then we plan to evaluate *KidBreath's* usability with the System Usability Scale (Brooke et al., 1996).

### 3.2 Motivation & Knowledge

We add some features to increase asthma kids motivation to continue to make learning activities. To evaluate if the possibility of choosing activities (Fig.3) can maintain motivation and increase learning instead of non-possibility, first we will use the motivation questionnaire made by Cordova & Lepper (Cordova & Lepper, 1996). For the evaluation of knowledge about asthma, we will use a knowledge questionnaire in pre and post-test session (using the same questions encountered in the activities).

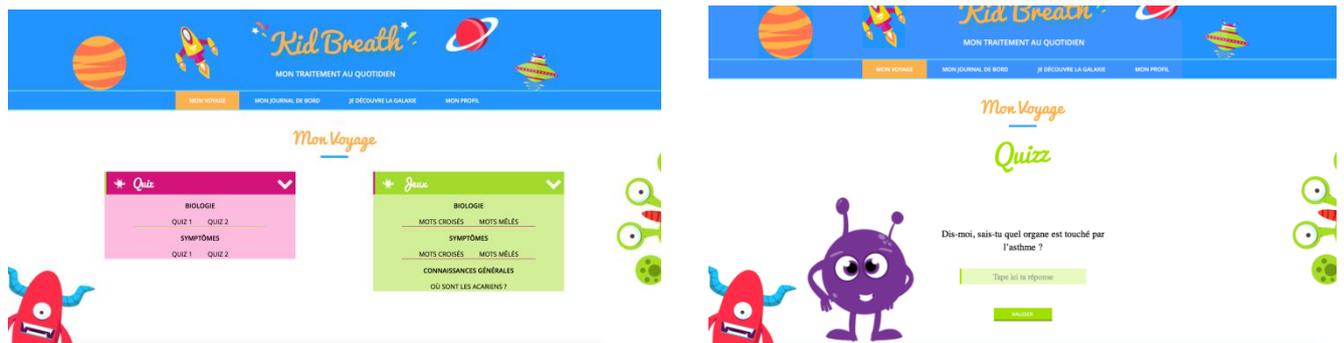


Figure 3. Learning activities interface in “choice” condition (left), and in “no-choice” condition (displayed in random) (right)

#### 4. Results & Discussion

First, we conducted a participative design workshop with forty kids aged 8 in order to iterate over the application interfaces. Then we realized a focus group with 5 asthma kids to validate the global comprehension of a part of the content. It revealed that children wanted more contents about the crisis treatment. Finally, we experimented two conditions in 40 control children, one giving the possibility of choosing activities like the child wants, and one not giving this choice (activities displayed in random). Results are in progress, but we hypothesized that *KidBreath* is easy to use, children acquire more knowledge and are more motivated using this system in the choice condition rather than no-choice condition.

#### 5. Conclusion & perspectives

Until now, therapeutic observance was used to define the patient behavior when he takes his medication as prescribed and adopts healthy behavior. Nowadays, this term is pejoratively used and tends to mean there is bad observant and good observant. It is progressively replaced by the term therapeutic adherence, which precise that the change of behavior must involve an evolution of the psychological view. This paradigm explains our approach: if we want to change disease awareness and consequently healthy behavior (decrease of accidents by iatrogenic effects), we have to improve factors which influence it: usability (ergonomic approach), knowledge (cognitive approach) and motivation (psychological approach).

In the next version, we will implement an Intelligent Tutorial System composed to learning optimization algorithms. These algorithms, implemented first for the KidLearn Project (Clement, Roy, Oudeyer, & Lopes, 2013), use child success rate and the Zone of Proximal Development (Lopes et al., 2014), which is the “zone” where learning activities are neither too easy (to avoid child boredom), nor too difficult (to avoid abandonment). In this way, the activities proposed fit to each child learning style (memory capacity, initial knowledge, information perceptions). To evaluate if a personalized system improves disease knowledge more efficiently than a generic learning system, we will use the same knowledge questionnaire described above.

Finally we will evaluate the impact of *KidBreath* on perception of asthma with the Illness Perception Questionnaire adapted to the target population (Broadbent, Petrie, Main, & Weinman, 2006; Chateaux & Spitz, 2006), and the behavior (Parent’s observations, treatments dose counting, reduction of doctor’s appointment).

**Keywords:** adherence, asthma, therapeutic education, Intelligent Tutoring System

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- School and actors associated who permitted me to test first version of *KidBreath* in control children.
- Inria Flowers Team, who helped me to implement processes for the test of this first version.

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## **The impact of operators' profession and experience and informational uncertainty during an advert event occurring in a surgical operation: A combined evaluation of situation awareness using SAGAT and eye tracking**

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### **1. Context**

Risk of adverse events occurring in relationship with patients' safety during surgery in operating rooms had been the preoccupation of many health care surveys. These events are reported to be mainly due to communication malfunction (WHO, 2009). Following these reports, our research aims to understand how the different operating room actors seek and share information.

### **2. Objectives**

The main objective of this study was to compare the situation awareness among team members of the operating room during an adverse event (here, a hemorrhagic shock). Using a computerized simulation of a patient undergoing a generic operation, we measured the information behaviors related to situation awareness for four types of operators (surgeons, anesthetists, operating room nurses (CNOR) and nurse anesthetists (CNRA)) each with three different levels of experience (less than five years, from five to ten years and more than ten years of experience). We also manipulated the ambiguity of the situation by delivering either precise or uncertain information through the scenario.

### **3. Methods**

We based our methodology on the theory of Situation Awareness (Endsley, 1995). We used the Situation Awareness Global Assessment Technique (SAGAT, Endsley & Garland, 2000) to measure the quality of the situation awareness for each members of the surgical team. This theory supports three levels of situation awareness: a perception level, a comprehension level

and a projection level (meaning the anticipation of the situation future states). Therefore, SAGAT used three types of questions, one type for each level.

According to McCloskey (1996), the lack of information is the main source of ambiguity. We created two similar scenarios, one delivering precise information and clear outcome (e.g. the evolution of vital signs was obviously leading to a hemorrhagic shock), and one with a lack of precision and unclear outcome (e.g. the drop of vital signs was slower and could be explain by the patient antecedents). SAGAT questions (ex: What is the patient's heart rate?) remained the same for both scenarios.

The Script Concordance Test (SCT) was used to assess clinical reasoning in ambiguous or uncertain situations (Fournier, Demeester, & Charlin, 2007) and through the process evaluate the level of expertise (Lubrasky, Charlin, Cook, Chalk, & Van der Vleuten, 2011). We compared the score of our participants to the score of a selection of experts chosen by Faure (2014) to objectively measure their level of expertise but the results were inconclusive. We chose to pursue our analysis with the experience factor.

Finally, as suggested by Schulz, Endsley, Kochs, Gelb and Wagner (2013), we coupled the evaluation of the participants' situation awareness measured by the SAGAT with measures of the participants' visual fixations, using an eye tracking device in order to have complementary results.

We conducted this experiment with 53 participants: 25% of them were CNRA (nurses), 40.4% were CNOR (nurses), 9.6% were surgeons and 25% were Anesthetists. 59.6% had less than five years of experience (the Exp group 1), 17.3% between 5 and 10 years of experience (the Exp group 2) and 23.1% more than ten years of experience (the Exp group 3).

The participants were presented 3 SCT questions, then a training phase to get use to the computerized interface. The scenario was cut into four parts with no going back possibility and with 3 SAGAT questions at the end of the three first parts. At the end of the fourth, the participants had to give a final diagnosis on the patient' state.

We measured the SAGAT score made up by the number of correct answers to the observation question, the number of references to each protagonist's action of the scenario for the comprehension questions and the number diagnosis produced for the projection question. We also measured the number of fixation on each information.

#### 4. Main results

Results regarding the first level of perception showed an effect of the ambiguity of the situation,  $F(1, 47)=5.41$ ,  $p=0.024$ , ;  $\eta_p^2= 0.103$ . Participants performed better with the normal scenario ( $m=3.30$ ;  $sd=0.21$ ) than with the ambiguous one ( $m=2.57$ ;  $sd=0.23$ ).

Results regarding the second level of comprehension did not show any effect of the type of operator. A Fisher's LSD test showed that, in the ambiguous condition and with all type of operators considered, the Exp group 3 ( $m=14.69$ ;  $sd=6.49$ ), referred more to the actions of the CNOR than the Exp group2 ( $m=1.92$ ;  $sd=1.92$ ),  $p= 0.04$  and the Exp group 1 ( $m=4.14$ ;  $sd=1.66$ ),  $p=0.02$ . Those results were backed by an analysis (planned comparison) on the outcome of the eye tracking measures. The Exp group 3 ( $m=45.75$ ;  $sd=8.95$ ) fixed longer their gaze on the avatars representing the CNOR than the Exp group 2 ( $m=17.96$ ;  $sd=5.81$ ),  $F(1, 32)=7.25$ ,  $p=0.01$  and the Exp group 1 ( $m=32.43$  ;  $sd=5.91$ ),  $F(1, 32)=6.67$ ,  $p=0.01$ .

Finally, results regarding the third level of projection showed an interaction effect between the level of ambiguity and the years of experience  $F(2, 47)=11.11$ ,  $p=0.001$ ;  $\eta_p^2= 0.132$ . The Exp group 1 ( $m=3.83$ ;  $sd=0.29$ ), in the ambiguous situation, produce more diagnosis than the

Exp group 2 ( $m=1.75$ ;  $sd=0.83$ )  $F(1, 47)=6.40$ ,  $p=0.01$  and more than the Exp group 3, ( $m=1.40$ ;  $sd=0.74$ ),  $F(1, 47)=19.99$ ,  $p<0.001$ .

## 5. Discussion and perspectives

Our main results, regarding the evaluation of the situation awareness, resulted from the experience factor and the ambiguity of the situation. At the first level, the lack of certainty led the participants to complete their mental model with elements from previous situations (Endsley & Jones, 2011). At the second level, our results pointed out the importance of the CNOR for the more experienced participants, having acquired a better sense of teamwork they extend their clues for building their situation awareness to other teammates hence reducing the risks in operating theatres (Salas, Rosen, Burke, & Goodwin, 2007). We also had a matching result between SAGAT and eye tracking analysis so, in the manner of Shultz et al. (2013), we recommend more experiments combining both methods. At the third level, our results fall within the Recognition Primed Decision model (Klein, 1993) and the pattern matching mechanism. With experience, operators can recognize a situation and match it with a previous one, thus faster emit a relevant diagnosis.

**Keywords:** operating room, situation awareness, eye tracking, risk management, human information behaviors

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## Mapping Emergency Responders' Current Procedures in the Event of a CBRNe Incident

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### 1. Introduction and Context

When a Chemical, Biological, Radiological, Nuclear or explosive (CBRNe) event occurs a time and safety critical environment instantly exists. In order for emergency services to most efficiently complete their primary task of saving lives it is essential to have effective and well-rehearsed procedures in place. This environment requires many different services to interact with one another including: Fire, Police, Health and Military personnel. Therefore, it is important that each service understand not only their role but also that of the other emergency services (JESIP, 2013). In such a scenario every second can make a difference, with tasks such as triaging, treating and decontaminating casualties all heavily reliant on a swift response. However, this has to be balanced with offering maximal health and safety conditions for the emergency service personnel (NARU, 2015). Emergency personnel from other geographical locations may also be recruited to provide further support, so having a nationally recognised standard procedure for each emergency service is essential to allow smooth interaction between regional emergency crews (NATO, 2014).

By taking a Human Factors/ Ergonomics approach to the problem it is essential to first understand what is required of each actor in the system. There are many different methods that can be used to capture a system such as that described above. One example is an Accident Map (AcciMap) (Rasmussen, 1997) - this allows for the different layers in the system to be identified, the lines and methods of communication to be shown as well as any interactions within a system to be acknowledged.

With this in mind the aim of a work package within the European Commission (EC) funded TOXI-Triage project (Toxi-Triage, 2016) was to establish procedures in the event of a CBRNe incident for different emergency service providers across a number of EU countries.

### 2. Objectives and Method

The objectives are to identify, and then display in diagrammatic form, the current procedures for emergency responders' during a CBRNe incident. It should allow for comparison across both emergency service providers e.g. Ambulance compared to Police, and across countries e.g. The UK's procedures compared to Greece's.

Existing documentation for standards and guidelines on emergency service response in the event of a CBRNe incident were obtained, read and then interpreted in the form of an AcciMap- a 'Tactical' level excerpt is shown in Figure 1. The UK's 'National Ambulance Resilience Unit's National Ambulance Service Command Control Guidance' (NARU, 2015)

was used. Interviews with experts who are trained and employed to act as Strategic, Tactical, Operational and ground level responders were then conducted. These interviews involved showing the responders the AcciMap produced based on the documentation in order to validate the diagram from their perspective and give further insight into how actual behaviour might differ from those in guidelines.

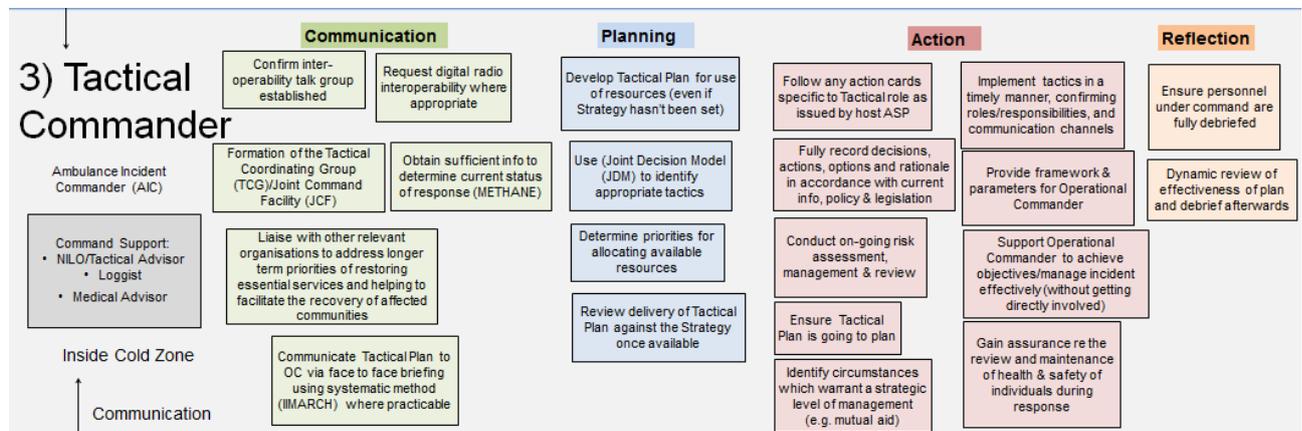


Figure 1. NARU Silver Command 'Tactical' level AcciMap extract

These procedures were then repeated for the 'NATO Guidelines for First Response to a CBRN Incident' (NATO, 2014) to create an AcciMap, followed by interviews with Strategic and Tactical commanders from the Greek Military. The same NATO AcciMap was also presented to a Finnish Fire Service (FFS) 'Strategic' level representative, followed by an interview to identify where the AcciMap needed modifying to accurately represent their procedures and system. This approach of creating uniform visual representations of the systems, in the form of AcciMaps, enabled high level comparisons across systems to be made.

### 3. Results and Discussion

The 3 AcciMaps have been compared and many similarities between the different nations' planned response to CBRNe incidents were found. All nations used the same structure of command ranging from top level Gold (also termed Strategic), Silver (Tactical) and Bronze (Operational). For NATO and NARU this was followed by two further levels of Bronze 1b (specialist responders) and Bronze 1a (initial responders). Similarities found between tasks carried out at each level are shown below:

- **Gold:** Outwards facing, dealing with 'the big picture', communicating messages to the general public and considering long terms plans for evacuation, infrastructure/ economic recovery etc.
- **Silver:** Funnels information up and down the structure, so that both Gold and Bronze levels do not become inundated with unnecessary information. They also make tactical decisions based on the information they receive from above and below and pass these down to Bronze.
- **Bronze:** Formulating Operational plans deciding what people who are actually on scene should be doing as well as managing resources to ensure the tasks can be conducted safely and efficiently.
- **Bronze 1b:** The specialist 'on the ground' tasks including: triage; detecting, identifying and monitoring the agent; casualty decontamination etc.
- **Bronze 1a:** Recognise the scene they have arrived at may be a CBRNe event and pass as much information as possible on to control rooms so relevant specialists can be dispatched to the scene.

FFS differed slightly whereby Bronze 1b and 1a would be conducted by the same personnel, with additional backup teams called in if necessary.

#### **4. Conclusions and Perspectives**

The systems and procedures in place to deal with CBRNe events across 3 nations (UK, Greece and Finland) and 3 services (Paramedics, Military and Fire) were found to very similar when being viewed from a high level perspective. Furthermore, visually representing the systems in the form of AcciMaps proved an effective way to allow these complex systems to be captured and then compared.

**Keywords:** Chemical, Biological, Radiological, Nuclear, explosive (CBRNe) event, AcciMap, Human Factors/ Ergonomics, emergency response procedures, National Ambulance Resilience Unit (NARU)

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## How medical staff is trained to manage critical situations?

### Exploratory work on the mobilization of non technical dimension of skills in simulation-based medical training

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#### 1. Context: the MacCoy Critical projet

This work is part of a larger project called MacCoy Critical, that aims to: 1) enhance knowledge, i) on the so-called “non technical skills” (NTS) in two safety-critical domains with high challenges of education in medicine and car driving; ii) on combination of situations and indicators to allow follow-up the development of these skills by the trainees and the trainers or a computer system ; 2) offer innovative pedagogic tools by the means of virtual reality and simulation for training.

This exploratory work aims to address the first goal by analyzing real training situation in medical sector.

#### 2. State of the art

In high-risk or critical situations, as they could be encountered in medicine, an empirical model of skills had been introduced few years ago in the training area. These skills were called “NTS” and was transferred directly from the aviation field. They are mainly based on empirical evidences from accidents or incidents analysis (Flin, O'Connor & Crichton, 2008). This type of skills was defined to be able to enhance human performance in critical situations where and when procedural and craft skills were not enough to manage them. Training programs were developed (as Crew Resource Management in aviation domain or Crisis Resource Management in medical domain) for the purpose of developing NTS, while other trainings were supposed to develop Technical Skills (TS). Nevertheless, it was not very clear what NTS were, because they were mainly described by what they were not “NT”. It was not very clear how they differed from TS, for example the know-how of “communication” is defined as part of NTS but some previous works showed that communication was undoubtedly “technical” (Austin, 1962).

#### 3. Objective and methods

Our intention was to address those questions in regards to previous works on skills and team interactions realized under the theoretical framework of “activity” (Daniellou & Rabardel, 2005) developed in ergonomics approach (Karsenty & Lacoste, 2004; Largier, Delgoulet & De La Garza, 2008; Ouellet & Vézina, 2008; Delgoulet & Vidal-Gomel, 2015). The aim is also to understand how the non technical dimension of skills were used, by trainers and trainees, in actual simulated-based medical training.

The assumption is that the segregation between NTS and TS is neither theoretically relevant nor operationally efficient. NTS and TS are two dimensions of craft skills that are embedded in real training situation. They have to be trained at the same time to enable medical teams to manage critical situations or crises.

In an activity analysis approach and a constructive ergonomics perspective (Falzon, 2015), two kinds of investigations are conducted.

- 1) Two trainers and 12 trainees were observed in a real simulation-based medical trainings for medical staff. The training session lasted 3 days. It consisted of classroom courses, 7 simulated critical cases (5 scenarios of critical interventions and 2 scenarios of announcement of bad news) and 7 debriefings.
- 2) Semi-structured interviews with 7 trainers complemented the observations to understand how trainers used simulated situation to train skills of medical staff.

Data analyses will be both qualitative (e.g. thematic analyses of debriefings or interviews) and quantitative (e.g. the frequency, duration and arrangement of training's sequences).

#### 4. Results

The thematic analysis of debriefings showed that discussions were organized around 8 principal topics (affects, technical concepts, allocation of tasks, decision making, communication in team, experience sharing, leadership and goals). Beyond the procedural and technical know-how, the mobilization of craft skills combined organizational, collective and individual dimensions and were multifunctional.

Analysis of the trainers' interviews confirmed the multipurpose character of skills. Objectives of medical simulations were to train together and to develop the various dimensions of skills, even if technical and procedural dimensions were paramount. The trainers considered that the current challenge was to propose medical simulations which make it possible to learn in interprofessional trainings.

#### 5. Conclusion & perspectives

The results are helpful to discuss NTS framework (interest - limits) and to propose another way to understand what is mobilized when medical staff are facing critical cases and how they should be trained.

**Keywords:** skills, non technical skills, medical training, simulation, activity analysis

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## Patient falls in hospitals: from best knowledge to better prevention

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### Abstract

*Context:* Adverse events (AEs) are common in healthcare. There are many consequences as for instance patient falls with fracture, and other injuries. Other important psychological consequences may arise, namely fear of falling, anxiety, and depression that also may lead to disability.

*Objectives:* Estimate the incidence, impact and preventability of AEs in Portuguese hospitals. From those AEs collected identifying the hospital falls and their consequences for patients and for the organizations.

*Methods:* A retrospective cohort study was carried out at twelve acute care hospitals/Trusts in Portugal. The identification of AEs and their impact was done using a two-stage structured retrospective medical records review based on 18 screening criteria. A random sample of 4.225 medical records (representative of 176.461 hospital admissions) for the year 2012 was analyzed.

*Results:* We found incidence rates of 12.5% AEs, and 39.5% were considered preventable. AEs were more related with hospital acquired infections (HAI) (39.7%); surgical procedures (26.7%), drug errors (9.8%). From the total of AEs, 7.5% were falls. Those falls happened more on week days (66%) and in morning shifts (51%). Most of AEs (67.4%) resulted in minimal or no physical impairment or disability, and 12.5% were associated to death.

*Conclusions:* This study suggests that AEs in Portuguese hospitals affect more than one in ten patients and results in considerable avoidable suffering and economic costs. AEs, as patient falls, should be seen in an integrated and systemic approach but with local evidence of the size and nature of the problem, staff has the information needed to act, preventing adverse events. The knowledge of the incidence and the real causes of AEs should be seen as a first step towards the improvement of knowledge on healthcare systems performance and quality and safety in health care.

**Keywords:** adverse event, patient falls, patient safety, ergonomics, healthcare quality

### 1. Introduction

Adverse events (AEs) occur with worrying frequency in healthcare. These AEs represent significant losses from a clinical, economic and social perspective (Thomas & Petersen, 2003; de Vries et al., 2008; Landrigan et al., 2012). To learn from these events and improve safety, they must be identified, measured and their causes found. Healthcare providers and researchers are searching for an accurate, reliable and low cost method to identify and measure AEs in hospital and other settings (Sousa et al., 2014).

Patient falls are sudden, unintentional, and frequent events in hospitals (when causing harm to the patient are considered as adverse events) that are frequently related with a changing in patient position, usually from a high position to a lower one.

## **2. State of the art**

The growing emphasis on quality is a relatively recent phenomenon in health systems. In fact, it is a subject that has become particularly important in agendas and policies of many European Countries (such as Portugal), the United States of America and Australia. This is linked to and derived from the development of new political orientations, centered on the principle of accountability and strategies for quality improvement, on concerns about the risk management, and on a growing interest in evaluating the degree of patient satisfaction and the outcomes attained.

Health care quality can be viewed by different perspective, and thereby assume different definitions. Joint Commission on Accreditation of Healthcare Organizations (JCAHO) defines health care quality as the “the degree to which health services, with the current professional knowledge, increase the likelihood of desired health outcomes and decrease unwanted outcomes” (Batalden & Stoltz, 1993).

Patient safety is currently recognized as an extremely important component of health care quality. Nowadays there is a substantial body of evidence about the consequences of deficiency of patient safety in health organizations and in its staff. The absence of patient safety can result in: (i) lost of confidence in health organizations and its professionals, deteriorating professional and patient’s relationship; (ii) increase of economic and social costs; and (iii) reduction in the probability of achieving expected outcomes. These consequences will also have a direct impact on the quality of health care delivered.

The World Health Organization (WHO) estimates that up to one in ten patients are harmed by adverse events in hospitals not directly related to their clinical care (WHO, 2008).

Patient falls frequently occur in hospitals. They can seriously reduce patients’ quality of life and increment healthcare costs. Among hospitalized patients aged over 65 years, the number of falls suffered during the previous year is a significant predictor of functional impairment, with a negative impact on the performance of basic activities of daily life (Huang et al., 2013).

Patient falls causes are complex and the hospitalized elderly are particularly vulnerable to falling due to their personal condition, which may include psychological perturbations as delirium, or other disease as cardiac, neurological or musculoskeletal disorders. Adverse effects of medication or problems with balance, strength or mobility are also important factors for falls. Over 400 risk factors for falls have been identified (Oliver et al., 2004). The majority of falls, particularly by the elderly, are multifactorial. The causes of falls in hospitals have usually been analyzed by retrospectively examining a scenario in which they may occur, trying to identify the circumstances involved in order to isolate the most prevalent risk factors. These risk factors are classified into intrinsic and extrinsic; the first group includes individual risk factors as advanced age, agitation, confusion or disorientation, generalized muscle and/or lower limb weakness, unstable gait, urinary incontinence, previous falls, visual deficit, and the use of certain medications (Evans et al., 2001; Perell et al., 2001; Hitcho et al., 2004; Oliver et al., 2004); the second group, extrinsic risk factors, include environmental and organizational conditions as the presence/absence of bed rails, the height and stability of any type of seat (including the toilet), obstacles presented by medical equipment and fittings, and insufficient human resources (Connell, 1996).

A better understanding of the circumstances of falls in a specific environment, and the predisposing factors, will allow healthcare professionals to take decisions, and establish programs for improvement, thus achieving a better approach to prevent patient falls. According to Joint Commission International falls are one of the most frequently adverse events among hospitalized patients (JCI, 2013).

### 3. Objectives and Methods

The main purpose of this study is to estimate the incidence, impact and preventability (i.e. organizational, environmental) of adverse events in Portuguese hospitals. From those AEs collected we want (i) to identify the hospital falls, (ii) to determine the characteristics of hospitalized patients who suffer falls, (iii) to analyze the distribution of falls and the profile of patients who suffer them, and (iv) to analyze the risk factors to the falls with consequences.

The study was carried out in twelve acute care hospitals in Portugal, following a retrospective cohort study design. The methods were based on the protocol used in the Harvard Medical Practice Study (Leape et al., 1991; Davis et al., 2002; Wilson et al., 2012) with modifications introduced in subsequent studies undertaken in the United Kingdom, New Zealand, Canada, the Netherlands, Sweden, and Brazil.

The identification of AEs and their impact was done using a two-stage structured retrospective medical records review based on 18 screening criteria (Table 1). A random sample of 4.225 medical records (representative of 176.461 hospital admissions) for the year 2012 was analyzed.

In the first stage, a group of nurses (two from each hospital, with a minimum of five years' experience in clinical audits) assessed the medical records, looking for the presence of, at least, one of the 18 criteria for the presence of a potential adverse event. In stage two, physicians (with a minimum of five years' experience in clinical codes and in clinical audits) reviewed each positive record of the first evaluation in order to confirm the presence of an adverse event, to estimate its impact and determine its preventability.

Hospital-incurred patient injury (e.g. pressure ulcers; patient falls)
Unplanned readmission after discharge from index admission (12 months)
Unplanned admission related to previous healthcare management
Hospital-acquired infection or sepsis
Adverse drug reaction
Unplanned return to the operating room
Any other undesirable outcomes not covered in this list of criteria
Unexpected death
Unplanned transfer from general care to intensive care
Other patient complications
Cardiac or respiratory arrest
Unplanned removal, injury or repair of an organ during surgery
Unplanned transfer to another acute care hospital
Development of neurological deficit not present on admission
Inappropriate discharge to home
Dissatisfaction or correspondence indicating litigation
Injury related to abortion or delivery
Dissatisfaction with care documented in the patient's medical record

**Table 1.** Screening criteria

#### 4. Results & Discussion

We found AEs incidence rates of 12.5%, and 39.5% were considered preventable. AEs were majority related with hospital acquired infections (HAI) (39.7%); surgical procedures (26.7%), and drug errors (9.8%).

Most of AEs (67.4%) resulted in minimal or no physical impairment or disability, but 12.5% were associated to death.

There were 60 registered patient falls in this study (Table 2 and 3). From the total of falls only 41 (68,3%) were considered as AEs (7.5% of all adverse events).

Those falls happened more on week days (66%) and in morning shifts (51%).

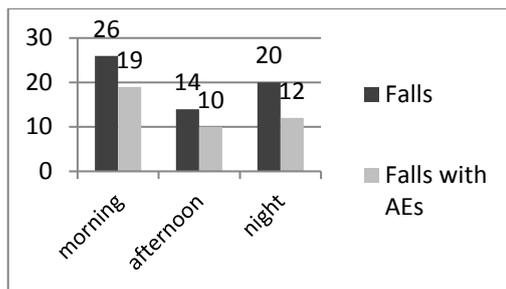


Table 2 – Day AEs distribution

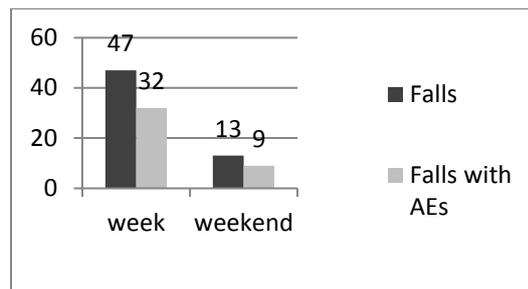


Table 3 – AEs (week and weekend)

The majority of these falls (40/60) were also registered in the notification system of the hospitals. Five patients had fall repetitions register and there were a previously fall risk assessment procedure in 33 patients. From these, 16 were classified has moderate or high risk. Most of patients were classified with physical impairment (n=21) and mental perturbations (n=19).

From identified falls with AEs 12 were falls from the bed, one from the wheelchair and two from the chair. Most of them haven't health adverse consequences but there were two head traumatism, 11 contusions, two bone fractures and eight hematomas.

Retrospective reviews of medical records aim to assess the nature, incidence, and clinical and/or economic impact of adverse events and to provide some information on their causes. A major issue is the assessment of preventability. That should indicate the potential gains to be achieved by improvements. For this reason, analysis of each patient medical record case requires careful to decide prevention strategies. On the other hand, the classification of preventable AEs, while still using a clear criteria and standard, still involves a subjective element and may vary with the expertise, practical experience of the physician and the way the data is registered in the medical record. Some authors argue that knowing the outcome and its severity, for instance due to a patient fall, may influence the judgment of causation and preventability and that the bias element is likely to be in the direction of overestimation of the rate of "preventable" AEs. Falls are one of the major bias for deciding "preventability" because if they do not harm the patient most of the times they are not even registered and they can't also be preventable.

#### 5. Conclusions & perspectives

In Portugal, there is an overall awareness and a growing concern about patient safety issues. This study suggests that AEs in Portuguese hospitals affect more than one in ten patients and results in considerable avoidable suffering and economic costs. With local evidence of the size of the problem, staff and administration are more motivated to act, especially if effective interventions to reduce adverse events can be selected and implemented to target those AEs

that are prioritized, namely those resulting from surgical procedures, drug errors, patient falls, and health-acquired infections.

The falls identified in this study were mostly considered preventable and cost-effective interventions can be implemented to avoid these type of occurrences. Healthcare managers and policy makers may begin to view patient falls prevention as an investment rather than an expense. This can also speed changes in hospital incentives so as to reward local patient falls prevention and quality. Local evidence of the size and nature of the problem and its clinical and cost impact is one of the first steps toward prevention that should be done in a systematic and integrated approach.

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## Finnish Ergonomic patient handling card® -education scheme

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### 1. Introduction and context

Work-related musculoskeletal disorders (MSDs) in nursing persist as the leading and most costly occupational health problem in Europe and the USA (Nelson et al. 2009). The cumulative effect of repeated manual patient handling activities and static awkward postures in care work are the main cause of MSDs. Little progress has been made in the prevention of MSDs (Hignett et al. 2013). MSDs studies show that especially low back symptoms are common already among student nurses (Videman et al. 1989; 2005) Pre-eminent reason: insufficiently taught safe patient handling in vocational education. In the USA, in 2005, a safe patient handling curriculum module has been piloted (Iakovou 2008; Waters et al. 2009). Nursing schools in most European countries remain deficient in their ergonomic instruction in patient handling competencies (Hermann et al. 2014).

A survey in Finland revealed wide variations in patient handling training among schools (Rantsi 2005). The legal requirement to ensure competence & safely was not fulfilled. To achieving improvements, nationwide quantity & quality guidelines for patient handling, extended studying cycles training, a requirement for teachers to update their knowledge and better co-operation between schools and trainee placements are crucial (Tamminen-Peter 2007).

### 2. State of the art

Training on patient handling has but a moderate impact on working practice or injury rates according to the systematic reviews of patient handling interventions (Hignett et al. 2003, Amick et al. 2006, Martimo et al. 2008). The reviews do not carefully consider the principles for safe and smooth patient handling, i.e. no lifting avoidance-training, based on easiest human body movement and the best way to support patients to move.

### 3. Objectives and Methods

The aim of the *Ergonomic patient handling card®* -education scheme (hereafter called *Card*): define the competencies, skills, and knowledge levels for safe patient transfers; ensure legislative compliance, improve: patient safety and quality of care, caregivers' abilities to assess and avoid risks and thus enhances overall safety, by lowering the physical load and decreasing work-related musculoskeletal injuries, exam to enable caregivers to prove their competence.

The Finnish *Card* was developed in 2007-2009 based on the earlier project and on research evidence (Tamminen-Peter 2007, Nelson et al. 2009). The *Card* -scheme was developed in cooperation with national experts for FIOH, supported by Ministry of Social Affairs and Health. Content test: pilot courses, in an old people's home, a university hospital and a nursing college. A focus group discussed results, a pedagogical e-learning advisor added an e-

learning frame, for feedback three pilot courses for the experienced teachers and physiotherapists and. two for the *Card* -instructors were held.

## 4. Results & Discussion

### 4.1 Content of the *Card*

The *Card*, standardized and registered in Finland since 2009 is intended for all social & healthcare professionals and students, it consists of 1) E-learning and exam 1, 2) Practical evidence-based principals training 3) Application of evidence-based methods at the workplace, and 4) Repetition and exam 2 (Figure 1). *Card* validity five years then 1-day refresher training.



Figure 1. *Card* -education scheme

E-learning: The online platform comprises the theoretical fundamentals for online study: exercises, tests, and a discussion forum to be completed in two months:

1. Ergonomics in patient handling to improve safety at work and prevent MSDs
2. Implementing body awareness and body control for optimal working methods during patient handling
3. Principles of biomechanics, assistive devices and hoists during patient handling
4. Responsibilities and obligations from Occupational Safety and Health act

16 hours practical training: (1) Assessment of patient's functional capacity, activation and promotion of patients' own resources, moving abilities and optimal independence, (2) Principles of normal human movement and free workspace for optimal patient handling (3) Knowledge and skills to apply safe ergonomic handling principles. (4) Students practice taught methods (5) Documentation of patient's functional capacity, chosen method to assist and required aids. Dealing with unpredictability like patient falls. Application phase: One-month skills deepening phase at their workplace. Exam: one manually and one hoist-transfer filmed and evaluated by two qualified *Card* -instructors.

### 4.2 Changes in the curriculums of the vocation education

To date, over 5 700 people in Finland have passed the *Card* -exam, 317 underwent the instructor training of whom 100 are actively training. 46/140 Finnish vocational schools have a *Card* -scheme -instructor. The *Card* -training is most commonly an optional or supplementary course. For the practical nurses training is in seven collages compulsory, for the registered nurses and physiotherapists, in four organizations compulsory.

### 4.3 Effectiveness of the card training

In the workplaces, the benefits of the *Card* are evident. The long-term care unit in the Rovaniemi municipality started the *Card* -training in 2009. Their 2009-2012 statistics, revealed a 600 days' sick leave reduction, for this, the Wellbeing Prize was awarded in 2012. Nowadays their wards and home care have eight *Card* -instructors.

Similar trend has been documented in the areas where there has been extensive training e.g. Ylöjärvi, Salo and Kouvola show similar results. In Kouvola municipality, the sickness absences due to MSDs have been decreased 15%.

## 5. Conclusion & perspectives

Patient handling activities, consisting of physical risk factors for MSDs, is one of the core competencies of health care workers. Slow progress is made in Finland in the development of safe and ergonomics working methods in the workplaces and in vocational education. Further research is needed on how training interventions and vocational ergonomics education affect working methods and the prevalence of MSDs and sickness absences throughout the whole working career. The future demographic changes in the population will cause a labour force shortage, requiring a system approach with ergonomic solutions to promote caregivers' health and safety (Tamminen-Peter et al. 2011, ISO/TR 12296. 2012).

**Keywords:** ergonomics, safe patient handling, ergonomic patient handling card®, education, training

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## **An original methodological tool to guide health facilities in developing structured action plans after the analysis of adverse events**

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### **1. Introduction and context**

Since patient safety has become a major concern for healthcare systems, health facilities have been asked to implement various approaches aimed at learning from adverse events (AE) in order to avoid the reoccurrence of such events, and to alleviate their consequences; for instance, mandatory and voluntary reporting systems, near-miss event assessments, morbidity and mortality conferences, and experience feedback committees. Whatever the approach, the effective management of an AE is a multi-step process that includes reporting, objective description, causal analysis, the development of a structured action plan (SAP), and finally, the monitoring of the implementation and effectiveness of the SAP.

### **2. State of the art**

The current conceptual frameworks and methodological tools that have been developed to provide guidance for the management of AEs focus mainly on reporting and analysis. For instance, healthcare facilities can rely on guidelines to implement an effective AE reporting system (WHO, 2005) and use proven methods to identify root causes (Vincent, Taylor-Adams, Chapman, *et al.*, 2000). However, these methodological tools put less emphasis on the development of a SAP, and this may contribute to reduce the effectiveness of the overall process (Pham, Kim, Natterman, *et al.*, 2010; Wu, Lipshutz, Pronovost, 2008).

### **3. Objectives & Methods**

The goal of this communication is to present a methodological tool designed to guide healthcare facilities in the development of a SAP following the analysis of an AE, and to propose to healthcare facilities that operate without an AE database, one containing the essential elements needed for effective AE management.

The project involved three phases. In the first phase, a paper-and-pencil prototype was designed, the goal of which was allow users to formulate, for each cause identified beforehand, one or more remedial action within one or more categories of actions. The framework used for the categorization of remedial actions was devised by the University Hospitals of Geneva under the name *CARECAT*®. This framework is a modified version of the conceptual framework 'DEPOSE', which describes the components of any sociotechnical system (Perrow, 1999), adapted to healthcare systems. For each formulated action, the methodological tool provides a set of criteria to help in the specification and prioritization of the action.

In the second phase, the prototype was assessed in a randomized study involving 56 volunteer participants working as risk managers in a hospital (Vacher, El Mhamdi, D'Hollander, *et al.*, 2016). Participants were asked to identify causes, and to formulate a SAP, for two adverse drug event scenarios. In a first measure, all participants were asked to use habitual methodological tools. In a second measure, a control-group used habitual methodological tools while a test group used the paper-and-pencil prototype. The main outcome was the mean number of actions that were identical to a referential established by eight AE-analysis experts.

In the third phase, a software version of the methodological tool, *EXPLICIT ACTIONS*®, was developed. This software development was entrusted to a company specialized in the design of information-technology systems for public health (*EPICONCEPT*, Paris, France). Five hospital risk managers were involved. They provided feedback to the designers throughout the software-development process, and they assessed the perceived usefulness and user-friendliness of the tool during interviews.

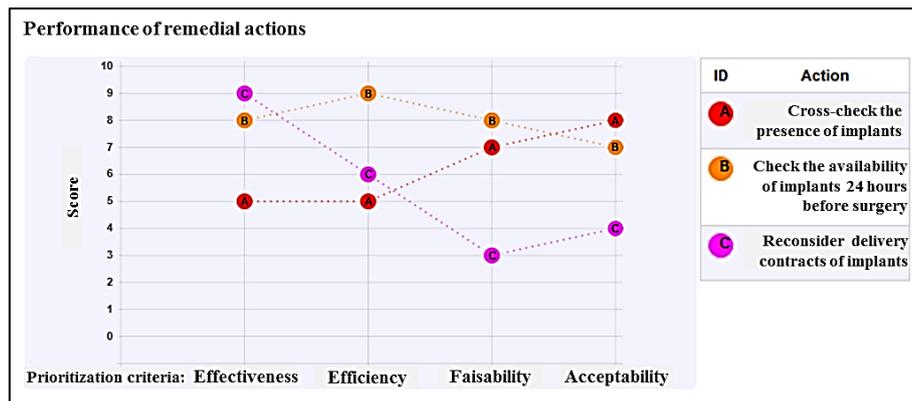
## **4. Results & Discussion**

### **4.1 Assessment of the effectiveness of the paper-and-pencil prototype**

For the first measure, the mean number of relevant actions was not statistically significantly different for the control group ( $M = 3.00$ ,  $SD = 1.8$ ) and the test group ( $M = 3.07$ ,  $SD = 1.9$ ,  $t(53) = 0.213$ ,  $p = .83$ ). For the second measure, the mean number of identified actions was statistically lower in the control group ( $M = 2.8$ ,  $SD = 1.2$ ) than in the test group ( $M = 4.6$ ,  $SD = 1.7$ ,  $t(53) = 4.35$ ,  $p < .001$ ). Moreover, the mean difference in the number of relevant actions identified by participants between the two measures (measure 2 – measure 1) was statistically significant between the control group ( $M = -0.6$ ,  $SD = 2.2$ ) and the intervention group ( $M = 1.3$ ,  $SD = 2.2$ ),  $t(53) = 2.96$ ,  $p < .01$ ).

### **4.2 Presentation of the software**

The software guides healthcare risk managers in elaborating their SAP after AE cause analysis and guides decision-makers in prioritizing remedial actions using an explicit set of criteria, presented graphically in a synthetic form (Figure 1). In addition, the software allows healthcare facilities to create a database containing AE descriptions (e.g. circumstance of reporting, type of AE, consequences, avoidability), a list of its root causes, and the associated SAP. Finally, the software proposes simple elements for monitoring the implementation of remedial actions and a query tool permits the realization of specific requests in the database (e.g. audit, demands of safety authorities).



**Figure 1.** Translated screenshot of the graphical summary provided by *EXPLICIT ACTIONS*® for the prioritization of remedial actions formulated after a surgical AE (implant lens missing during a cataract surgery). Each prioritization criterion is scored on a ten-point numerical scale by the hospital risk manager.

## 5. Conclusion & perspectives

The paper-and-pencil prototype seems to have proved its effectiveness in the two AE scenarios studied, with more appropriate remedial actions formulated in the group that used it. Furthermore, the software version may be useful in helping healthcare facilities manage AEs, especially for the development of SAPs and for the prioritization of remedial actions based upon explicit criteria.

However, a few limitations of this study must be acknowledged. Firstly, the two AE scenarios that were tested both involved adverse drug events. The effectiveness of the methodological tool should be tested for other types of AE. Secondly, the study was concerned specifically with SAPs developed in response to an AE, and not with SAPs produced by healthcare facilities on other occasions.

In the future, the database could be used to study the characteristics of the remedial actions formulated by healthcare facilities in response to AEs. In addition, the relevance of the methodological tool could be considered for the management of AEs encountered in other contexts than healthcare facilities (e.g. medico-social establishments).

**Keywords:** patient safety, adverse event, action plan, systemic analysis

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## **Legal information**

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The *WHO Taxonomy for incident types*, from p.32-p.46 of the World Health Organization was reproduced with the permission of the World Health Organization. © WHO, 2009. *WHO/IER/PSP/2010.2. Conceptual Framework for the International Classification for Patient Safety. Version 1.1. Final Technical Report:1-154*. Report available at: [http://www.who.int/patientsafety/taxonomy/icps\\_full\\_report.pdf](http://www.who.int/patientsafety/taxonomy/icps_full_report.pdf)



## Exploring children and young people's experience of care in a mental health and physical health setting

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### 1. Introduction and context

Over the past decade, there has been a growing focus on service-user experience as part of the monitoring and evaluation of health services. Both the National Health Service (NHS) and Care Quality Commission (CQC) use patient experience data as part of the evaluation and delivery of quality care. (Department of Health, 2008; Raleigh et al, 2015). Patient experience provides important information about care quality additional to clinical outcomes and encompasses feedback on elements of care, such as physical environment, and practitioner-patient communication (Sanders, Ben Omar, & Webster, 2015). It can also serve as an indicator of the extent to which service-users feel they have been listened to and included in their care. In the case of children and young people, it may be especially salient to capture experience, as they may be less likely to be involved in their care than adults (Davies & Randall, 2015).

### 2. State of the art

Service-user experience in adult mental and physical health settings has been found to be positive overall (Ford, Bryant & Kim, 2012; Raleigh et al., 2015), while available research on experiences of children and young people accessing health services mirrors positive results seen in adult literature (Barber, Tischler & Healy, 2006; Bradley, 2013; Brown, Ford, Deighton & Wolpert, 2014), there are fewer studies of care experience in children's health services, highlighting a need to include their voices and better understand how they experience care across healthcare settings. In particular, there is a paucity of research comparing children's experiences across physical and mental health settings. Exploring children's experience of care, and how it may differ across physical and mental health settings will increase the understanding of the range of children's experiences of care, and help inform future efforts to improve care across different settings.

### 3. Objectives and Methods

The objective of the current research is to compare experience of care for parents and children who have accessed help from child and adolescent mental health services (CAMHS) to those who have accessed help from pediatric hospital settings in sites across the UK.

Experience of care was assessed using selected items from the Experience of Service Questionnaire (ESQ) (Attride-Stirling, 2002), a standardized measure developed to capture patient experience in child health settings. It is composed of 12 items derived from focus groups with children and parents on factors important for positive care experience, rated on a

3 point scale. The ESQ is available in child or parent-report, with item phrasing varying between versions.

Data from predominately outpatient CAMHS settings was obtained from the Child Outcomes Research Consortium (CORC), a learning collaboration of child and adolescent mental health services. Routinely collected outcome data is submitted to CORC by members for bespoke analysis and research. Data from inpatient paediatric wards was collected from hospitals across the UK participating in the Situation Awareness for Everyone (S.A.F.E.) project. Guidance for mental health settings recommended the ESQ be administered 6 months after initial contact (or case closure if sooner) and guidance for physical health settings recommended the questionnaire be administered at discharge.

Data from 5 ESQ items was assessed for 577 parents and children on pediatric wards, and 4300 parents and children accessing CAMH services who completed the ESQ between January 2015 and March 2016. Age distribution for both samples is displayed in table 1. The 5 items were totaled and compared across physical and mental health settings for parent-reported and child-reported questionnaires using a Mann-Whitney U Test.

Respondent	Mental Health Setting			Physical Health Setting		
	N	Range	Mean(SD)	N	Range	Mean(SD)
<i>Child-Reported</i>	77	9-15	12.3 (2.7)	2238	9-18	13.7 (2.8)
<i>Parent-Reported</i>	500	0-15	4.7 (4.9)	2062	0-18	10.8 (4.0)

Table 1. Age range, mean and standard deviation for parent and child-reported samples

#### 4. Results & Discussion

A Mann-Whitney test indicated the distribution of total child-reported ESQ scores was more positive for children and young people accessing help from a physical health setting than a mental health setting,  $U=61886$ ,  $p<.001$ ,  $r=.10$  while the distribution of parent-reported ESQ scores did not significantly differ between the groups,  $U=508973$ ,  $p=.577$ ,  $r=.00$ . The percentage of responses in the most positive category for individual items of the child-reported ESQ, as shown in figure 1, was less positive for all 5 items for those children who had accessed CAMHS.



Figure 1. Item level responses for child-reported ESQ across mental health, and physical health settings

## 5. Conclusion & perspectives

In keeping with previous research (Barber et al, 2006; Bradley, 2010; Brown et al, 2014), care experience results for both settings were positive; however, there was variation between respondents and settings. Total experience scores for children and young people were more positive for those receiving care on pediatric wards than from CAMHS, suggesting a possible imbalance in perceived quality of care between these settings for services whose data was used in this research. Discrepancies in scores were also visible on an item level, the proportion of children and young people answering “certainly true” was less positive for CAMHS settings on each of the 5 ESQ items analyzed, in particular items, “given enough explanation”, and “know how to help”. Significant differences were not observed in parent-reported scores, suggesting children and young people may experience care differently from parents. These differences could be explained by a range of factors, including differences in sample size, impact of individual’s conditions on their daily lives, and differences in the nature of pediatric inpatient and predominately outpatient CAMHS settings. Each of these factors is a potential area for further exploration into how children and young people experience care across different settings and how their experience may be influenced by the severity and type of their condition.

Data used in the present study provided an opportunity to explore how children and young people experience care in different settings, comparing a predominately physical health inpatient setting to a predominately mental health, outpatient setting. While it is limited due to the opportunistic nature of the analysis, it is valuable in the questions it raises for further investigation.

**Keywords:** mental health, pediatrics, experience of care

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# **ROUND TABLES AND SYMPOSIUMS**



## **Exploring all the benefits of Safe Patient Handling interventions in health and community care**

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### **1. Description of the topic**

The evidence to support the implementation of Safe Patient Handling (SPH) programs is growing. In particular there is a widening collection of evidence quantifying the musculoskeletal loads for caregivers and the links to injury and musculoskeletal conditions. The use of assistive technologies and mechanical devices is shown to reduce the exposures to hazardous handling in controlled laboratory based studies. Some evidence has shown the translation of these findings into the practice seen in the wide range of healthcare settings and the benefits to patients, caregivers and health delivery organizations.

### **2. Organization of the debate**

This round-table event will provide a series of summary presentations outlining various findings and questions around the level of understanding of the biomechanical loads and implementation of best practice into the range of health care settings. Each presenter will briefly describe key facts about the different risk factors that are present in patient handling tasks and the various risk assessment methods that have been used to collect evidence about those specific risks. This review of the methods used will lead to information about how some

of the advances in equipment, training, safety behavior and environmental improvements have been shown to reduce the musculoskeletal risks for healthcare workers.

The presentations will review the following areas of current knowledge and understanding:

- The work relatedness of cumulative manual handling - Matthias Jaeger.  
A series of studies have investigated and supported the inclusion of healthcare handling as a route to occupationally recognized musculoskeletal injury. This has supported the health insurance claims process for German nurses.
- The risk assessment of various healthcare settings by the MAPO method – Marco Tasso.  
The MAPO method has been used in a many investigations to identify the risk factors related to the provision of healthcare. This assessment method reviews environmental conditions, training, space and equipment provision to develop a series of changes to improve performance.
- The advantages of using assistive devices in reducing biomechanical loads – Arun Garg.  
The use of biomechanical evaluation as part of a wider ergonomics assessment has been used to collect data on the more hazardous physical activities. The measurement of physical load has a strong legacy as a route to change in the patient handling field.
- Training and learning in the development of skills and competency for patient handling – Leena Tamminen-Peter.  
Whatever systems, designs or equipment solutions are delivered there is always a human behavior element to the effectiveness of the intervention. The evidence is mixed about the effectiveness of training in the reduction of risk but the delivery of education is still a focus for SPH practitioners worldwide.
- The wider influence of safe patient handling practice on healthcare workers, patient safety and healthcare organisations – Sue Hignett.  
More recently research surrounding the delivery of healthcare is exploring a different range of benefits and outcomes. Measures that can add to the clinical, financial or workforce efficiencies are all valued by health care managers. There is some evidence to link the management of patient handling risks to other outcomes such as falls, pressure care, treatment or rehabilitation goals etc.

The discussion section of this round table session will review the progress of the science that supports the implementation of SPH programmes. In particular the group will explore the gaps in evidence and the requirements for future research and evidence to support the wider benefits of SPH programmes.

There are some evidence sources that could be used to aid the investment in future developments these could include:

- Patient outcomes including length of hospital stay, improvements in tissue viability, measures of quality of care, improvements in function through rehabilitation, patient comfort or satisfaction.
- Organisational efficiencies including the number of carers required, cost benefits of various interventions, the financial gains of reduced sickness absence etc.
- Alternative benefits for healthcare workers including improved psychological demand, better well-being, reduced fatigue, etc.

It is hoped that the discussion can assist the transition from a focus on the biomechanical loading of healthcare workers to the clinical and organizational benefits that anecdotally are suggested with the adoption of high quality healthcare practice. This evidence could be used

to support future spending on improving the implementation of SPH programmes more widely in healthcare.



## **eHealth in Home Healthcare - Dystopia or Utopia**

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### **Introduction**

The symposium proposes a working group session (workshop format) which aligns with the conference theme of healthcare in society, providing a mechanism for understanding the current state of eHealth science in the EU and the role of Human Factors/ Ergonomics (HFE) in the development, implementation and understanding of the impact of eHealth in home healthcare. The content of the workshop takes a multicultural perspective to home based eHealth and how it is currently implemented by health service providers within different EU countries, utilizing the experiences of experts from the UK, Sweden, France and Catalonia,

Spain to set the scene and engage participants in discussion. It will address topics such as the role of digital technologies in healthcare provision and also the emergence of patients as partners in healthcare and advocates/ voices in improving the quality, safety and experience of healthcare provision. The planning of the symposium capitalizes on the conference opportunity to engage HFE experts in the topic of eHealth and participate in an interactive conference session. This symposium will facilitate learning from current good practice and HFE application in this domain whilst also providing a forum for discussion about the more challenging aspects of eHealth implementation, user experience and long term use.

Due to a range of issues associated with ageing populations, healthcare service provision is moving from hospital care into peoples' homes and the community (Gaikwad & Warren 2009). Technical solutions are sought to solve problems like shortages of staff, communication, monitoring, measuring health conditions, managing information and so forth (Barakat et al. 2013). This of course raises a lot of questions about the user requirements of such complex systems and their integration into the home environment, whereby there is still a relatively poor understanding of the human factors/ ergonomics of these interventions. The home as an environment for healthcare provision provides a context of work and user behavior in environments within which there is little control and standardization with regards to the physical components, mental models of use and affective elements (Swedberg 2014). As such there are many potential HFE challenges to be considered.

Additionally, eHealth represents very different things for different user groups; patients, healthcare professionals and informal carers who may be present in the home environment. The utilities experienced by these user groups can also be seen in the light of pros and cons, whereby an advantage or opportunity of these systems for one user group might subsequently pose a challenge to another group of users.

The exploration of eHealth by ergonomics and human factors is not new. However the development of systems, processes and current practice in countries and even regional areas differs greatly (Genet et al. 2011). As such this workshop offers the opportunity to explore these issues in a cross-cultural forum, learning from the application, experiences and knowledge of human factors/ ergonomics of eHealth in different places.

Whilst there are many different understandings and definitions of eHealth (Oh et al. 2005) this symposium utilizes the definition of eHealth as described by the World Health Organisation (WHO 2016). "E-health is the transfer of health resources and health care by electronic means. It encompasses three main areas:

- The delivery of health information, for health professionals and health consumers, through the Internet and telecommunications.
- Using the power of IT and e-commerce to improve public health services, e.g. through the education and training of health workers.
- The use of e-commerce and e-business practices in health systems management."

The working symposium aims to examine a range of HFE challenges, this will be achieved through consideration and discussion of the user and organizational needs of those systems and will be explored through the enquiries outlined below.

- explore the role of eHealth in home care,
- examine the ergonomics challenges associated with eHealth in home care,
- discuss the opportunities for empowering patients and healthcare staff,
- understand the potential conflicts that arise from the needs of these two distinct user groups (healthcare staff and patients) and how human factors can mediate these different needs,

- explore the varying practices of eHealth in different countries and see if there is opportunity for knowledge transfer.

The development of the symposium plan and content for the day is the production of a multidisciplinary group (HFE, Design, Business, Public Health, Virtual Reality for healthcare) representing the state of eHealth science in the UK, Sweden, France and Catalonia, Spain. This will provide the symposium with a broad view of the utilization of eHealth in different countries and offers the basis for discussion and forum for learning about the opportunities and challenges faced within different countries.

## **Working Symposium Plan**

### *Introduction and Group Discussion 1(30 min)*

Symposium facilitators set the scene for the symposium. This provides a brief presentation outlining the rationale and shift towards eHealth (including but not limited to, the ageing population, the increase in multiple and complex health conditions, technical solutions as a way to address this challenge). The presentation proceeds to detail the focus of the working symposium, what the aims and goals are and what is expected of the attendees.

This includes consideration of,

- How home care is organized in different countries – what do the participants from different countries mean by home care? Examples taken from facilitators countries.
- Which technical solutions are used or could be used?
- For what purposes?
- What is the impact of eHealth on patients and their lives?
- What is the impact of eHealth on healthcare professionals and their working practices?
- To what extent will the technical solutions be an aid in meeting the needs in home care?

Group Discussion 1 - Symposium attendees are invited to exchange their experience about home care in the represented countries from a HFE perspective. – How is it organized? How is it developing? What are the challenges? These discussions will be captured by the individual groups or if one large group by the facilitators. Participants will draw on their knowledge of eHealth systems in their own countries and be asked to consider the contextual, cultural, ethical and social differences experienced in use and research of these complex socio-technical systems. They will be encouraged to discuss technical solutions that are used or could be used to benefit the current use and management of eHealth by a range of users. The discussions will aim to work towards themes which provide a framework for good practice and also provide insight into the most significant HFE challenges of use and implementation of these systems.

### *Group discussion 2 (or one big group depending on number of participants) (40 min)*

Attendees will then look at these issues in further detail and try to harmonise the needs from the users being considered. Groups will try to discern where the needs of patients and healthcare providers correlate and where they might pose a challenge due to differing or opposing requirements. This will be explored through the discussion of a utopi/dystopi of eHealth. Workshop participants will be split into groups to consider the dystopian (worst case) and utopian (best case) views of eHealth in practice for both patients and healthcare providers. This will be achieved through the use of several exemplar healthcare case studies that will be established prior to the workshop – they may include examples of monitoring chronic conditions such as COPD, a mental health example such as dementia or depression, the access and use of medical records from the home, robots and/or sensor based eHealth

systems for the elderly etc. (10minutes will be spent introducing the case studies at the start of this discussion session). Groups will work with the provided case studies and be asked to explore the various human factors challenges and opportunities for the user groups identified. Individual groups will present the opportunities and challenges for each case study and their outputs of the group discussions to the wider group of workshop participants. These will be captured and recorded by the workshop facilitators to help inform the Summary session. This session will use the combined expertise from attendees to provide commentary on ways in which ergonomics/ human factors can improve the use of eHealth by healthcare providers and patients (approx. 30minutes discussion).

#### *Summary and Planning (20 min)*

Symposium facilitators will summarize the themes from the group discussions and then support a discussion about how to progress the exploration of HFE in eHealth in a systematic and strategic way. The workshop as a whole will consider the themes and requirements captured throughout the symposium. Attendees will reflect on these and discuss the short, medium and long term support that human factors/ ergonomics can provide; to patients, eHealth developers and to healthcare service providers, where challenges to good practice are identified and where there is opportunity for sharing eHealth best practice stories to the wider community.

This discussion will evolve to consider these issues in regard to research proposals and relevant funding streams. Identifying areas where HFE can collaborate with eHealth experts to improve the understanding of these technologies and how they impact the lives of patients and working practices of healthcare professionals.

#### **Conclusion & perspectives**

The outputs of this working symposium will include but are not limited to the following;

- 1) Identify how home care is performed using eHealth systems in different countries.
- 2) Present current understanding of the human factors/ ergonomics issues for users of eHealth, both healthcare providers and patients across a range of European states.
- 3) Formation of network for eHealth within HEPS/ IEA community.
- 4) Identification of future collaborations and funding opportunities, directly derived from cross cultural workshop.
- 5) Produce a list of potential healthcare industry stakeholders who are instrumental and required for changes in practice and research proposals – with a view to making contact for future workshop or funding applications.

**Keywords:** eHealth, home care, community, patients, healthcare professionals,

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## **Usability-related Regulation for Medical Devices: Challenges to achieving patient safety**

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### **Introduction**

This symposium deals with the Human Factors/Usability Engineering Process (HFE/UE Process) required by the international usability/human factors engineering IEC 62366 to ensure at least the development of a medical product that is safe to use and does not provide any unacceptable risk for the patient, the user or third parties being involved. The contributors will present the process and the corresponding regulation, illustrate the most important difficulties encountered by all stakeholders engaged in the process and, finally propose some solutions to improve the current situation.

Care for individual patients and global healthcare alike are strongly affected by innovations in medical technologies and devices. New technology has the potential to provide better, more effective and sometimes even less expensive care. However, a good idea does not make a revolutionary medical device (MD). There is a process that must be followed before the idea becomes a device in the hands of healthcare professionals or patients to ensure that it poses a risk that is as low as possible to those who use it and on whom it is to be used. In Europe, health authorities require that MDs demonstrate their reliability and safety before they are authorized to be put on the market (CE marking).

Concerns of national and European health authorities over "use errors" with health technologies and MDs have recently led the European Commission to reinforce the ergonomic essential requirement for CE marking. The EU revised Medical Device Directive (MDD; European Parliament and the Council, 2007) enforced in 2010 explicitly requires a safety oriented usability engineering process to be integrated in the design and development lifecycle of MD. The corresponding harmonized standards IEC 62366 and IEC 60601-1-6 (International Electrotechnical Commission, 2007) require manufacturers to "achieve

*reasonable usability, which in turn is intended to minimize use errors and to minimize use-associated risks"* (p. 6, IEC 62366). This safety-oriented process introduces the HFE/UE Process which aims to prevent harm to patients, users and other affected persons by eliminating flaws in the MD – user interface. To identify such potential usability problems, hazards that could arise from the use of and failures by the device need to be identified. Unfortunately too many examples of use errors that have led to patient harm or death have been reported, such as the radiation treatment overdose at the Epinal hospital (Ash, 2007). Dangerous use errors also happen with much simpler devices used by patients, such as pen injectors (Grissinger, 2010) or orthopedic implants (Fakler et al., 2007). In all of these examples, usability flaws of the human-machine interface have been identified, among others, as root causes of the errors.

The HFE/UE process works to stop these dangerous usability defects before the product is released on the market. The HFE/UE process addresses user interaction with the MD according to the application specifications (e.g., intended medical indication, intended users, intended conditions of use) along with the identification of hazards and hazardous situations related to usability. The design of the MD needs to rely on user interface risk control measures that prevent, to the greatest extent possible, hazards and hazardous situations. Usability specifications are then to be developed to provide testable requirements of the user interface associated with the risk control measures, including criteria for determining the adequacy of risk control achieved by the usability engineering process. The manufacturer has to develop and maintain a usability evaluation process including formative and summative evaluations. Formative evaluations aim at providing inputs to the design process and verify the implementation of the MD user interface design against the requirements of the usability specifications. Summative evaluations (i.e. usability validation) aim at testing the achievement of the acceptance criteria for risk control.

When the acceptance criteria are met, the usability engineering file (where the entire usability engineering process is documented) is ready to be included in the global CE marking file (usability is only one of the essential requirements). The manufacturer then can claim that the product meets the essential requirement of the relevant European MDD. Depending on the path to obtaining a CE mark, a Notified Body conducts a conformity assessment of the relevant sections of the applicable Directive. The conformity assessment usually involves an audit of the manufacturer's quality system and, depending upon the particular classification of the device, a review of the relevant technical documentation provided by the manufacturer in support of the safety and performance claims for the device. Concerning usability, the main goal of a notified body is to control that the HFE/UE process has been correctly implemented. The main objective is to ensure that the MD released on the market presents no threatening risk of use errors induced by usability flaws of the human-machine interface. It is critical in delivering to patients and healthcare professionals easy to use and safe medical technologies.

Since the HFE/UE process has become a requirement for the CE approval that manufacturers need in order to launch their products in Europe, interest in this topic has increased, especially as difficulties are encountered by the various stakeholders. These challenges include:

- Differences between this specifically safety-oriented HFE/UE process and the well known Human-Centered Design approach usually adopted to implement a common usability engineering process.
- The fact that implementing the HFE/UE process requires multidisciplinary expertise, covering: (i) knowledge of healthcare work situations and of the medical domain targeted by the medical device or medical device software, (ii) human factors and usability expertise, and (iii) knowledge of regulatory affairs, especially risk management.

- Properly implementing the HFE/UE process requires a minimum level of usability maturity from the manufacturers.
- The last step of usability validation/usability summative evaluation is critical in ensuring that the device to be released presents no threatening usability flaws that could engender use errors and ultimately lead to patient harm or death. This final usability validation stage presents its own unique methodological challenges.

This symposium will be organized in two parts. First, Torsten Gruchmann, one of the members of the International Human Factors Standardization Committee, will present an elucidation of the regulatory demands – what they are and how manufacturers can establish a usability engineering process for CE certification – and the importance of this regulation for patient safety – what are common usability problems and how can a UE process uncover and eliminate these. Second, Pierre-Marie Lacroix, certification project leader of the French notified body, and Sylvia Pelayo, usability specialist, will discuss the difficulties raised by this usability regulation for the different stakeholders. By covering these aspects, this symposium will provide room for a well-rounded discussion of the HFE/UE process and its implications.

### **Usability is the key to increasing patient safety**

Torsten Gruchmann

Torsten Gruchmann will describe how usability relates to patient safety. Worldwide several studies are talking about the large number of people who die due to medical mistakes (Kohn et al., 2000; Langrigan et al., 2010; Pham et al., 2012). Most recently, an article was published in the Journal of Patient Safety estimating that as many as 440 000 people may die from preventable medical mistakes in US hospitals. This is more than 1 000 people per day and makes medical mistakes the 3<sup>rd</sup> leading cause of death in the United States. Similar studies have been published in other countries. Several incidents are based on use errors triggered by design shortcomings of medical products. Often user needs are not considered sufficiently during the product development process. The result is a product that does not fulfill the user's expectations and is not easy and safe to use. Considering the huge variety of medical products in a hospital, the divergence of the user interfaces they provide to the user and the increasing complexity of these technical devices, it is not surprising that some users struggle with how to use the device. One should also not forget that the users are very often healthcare professionals with an educational background in nursing but not in medical device technique. This is reason enough to motivate manufacturers to implement usability engineering activities in their product design and development process to improve the ease and safety of use.

A usability/human factors engineering process is required by the international usability/human factors engineering IEC 62366 to ensure at least the development of a medical product that is safe to use and does not provide any unacceptable risk for the patient, the user or third parties being involved.

In 2015 the second edition, IEC 62366-1:2015, of this standard was published in the USA. It is a more streamlined and updated version of the predecessor IEC 62366:2007. Some terminology has been changed to improve the readability and understandability. Furthermore it has a closer relation to the risk management process defined in ISO 14971 and is based on hazard related use scenarios that need to be specified by the manufacturer. Additional information for manufacturers who want to sell their product on the US market was published by the FDA in a guidance paper titled "Applying human factors and usability engineering to medical devices" in February 2016. In April the technical report IEC TR 62366-2:2016 was published as the informative part of IEC 62366-1:2015 and includes guidance on how to

successfully establish the normative requirements. This technical report provides medical device manufacturers with guidance on how to integrate usability engineering principles and user interface design practices into their overall medical device development processes. It goes beyond safety and also describes how to ensure user satisfaction and efficiency which can enhance a medical device's commercial success.

## **Main challenges of Usability Engineering Process for various applications in the Medical Devices field**

Pierre-Marie Lacroix

Medical Devices covers a large range of devices from simple infusion syringe to complex imaging equipment by passing through surgical implant, wound dressing or ophthalmic rinsing dose. Consequently, user interface can be a complex interactive interface (display, data entry, complex command) or a simple interface such as gripping or handling. Users and use environments are also very different between devices used in hospitals or health care facilities by well competent and trained people (imaging equipment, monitoring devices, surgical implants) and devices used at home by non-professional users such as wound dressing, ophthalmic rinsing dose, insulin pump.

Even if Usability Engineering Process described in the standard IEC 62366 is a very understandable concept applicable at all medical device, its implementation leads some concerns for medical device manufacturers or notified bodies particularly in case of specific user interface or specific design situations (device change, historical interface design).

The first difficulty for manufacturers is the integration of Usability Engineering Process into existing design process. For instance, if characteristics and hazard situations related to users and use environments are not identified precisely at the beginning of the design process, there is a risk that user specifications will not be exhaustive or relevant, and the designed interface will be not efficient. Concerning the evaluation of interface, usability tests and methods linked are not always well known and managed by medical devices manufacturers. Indeed, medical device manufacturers are historically experts in technologies directly linked to the design of device (mechanics, electronic, software, etc), usability is a recent concern and availability of specific competence (internal or external to company) is not always sufficient to support the process.

The second concern is the application of the Usability Engineering Process to devices without interactive interface. Today, there is few data, method or guideline dedicated to the implementation of process for implants, invasive devices and associated ancillaries. One of the main problems for this type of device is the simulation of the use during summative evaluation. Moreover, the clinical investigation cannot be performed with use scenario including a risk for patient.

The last main challenge is to tailor Usability Engineering Process to specific cases, for instance device change, not complex interface or not innovative interface. The revision 2015 of the IEC 62366 is more precise concerning criteria to take into account nevertheless the decision of tailoring the process is subject to different interpretation between manufacturers and authorities. Post-market surveillance data can be helpful to confirm the level of risk with the condition that methodologies used are relevant to support conclusions.

## **Challenges raised by the final usability validation stage (summative evaluation)**

Sylvia Pelayo

Dr Sylvia Pelayo will discuss the methodological challenges raised by the last step of the usability validation / summative evaluation. This step is supposed to dramatically reduce the

use-related risks, given that it is properly designed, run and analyzed. Unfortunately it is far from being the case. Dr Sylvia Pelayo will present the main challenges of this last step and will propose some solutions to improve the current situation. The main methodological challenges are:

- The usability validation requires carrying out usability tests in simulated environments based on “worst-case scenarios”. The principal benefit of this procedure is scientific reproducibility. However, this comes with the downside of poor ecological validity. The challenge for usability validation of medical devices is to make sure that risks of use errors identified during usability tests are effectively representative of risks of use errors when the device is used in the real clinical setting.
- The usability validation stage requires an appropriate number of participants. This is a key factor that may introduce large cost variances and may impact the validity of the results. Scientific debate over the appropriate number of participants in usability tests needed to catch as many usability flaws as possible are not new in the ergonomics and usability community. But this question is even more crucial for safety-oriented usability validation of medical devices.
- Currently, the uncertainty about usability validation methods and protocols prevents the vast majority of manufacturers to efficiently plan usability validation and to properly anticipate on related costs. This results in weak usability validation, delays in CE marking or rejection of the CE marking file by certification bodies, therefore slowing down the overall time-to-market. To our knowledge no scientific study of methodological choices or protocols regarding usability validation of medical device (including ecologic validity and number of participants) have also performed an economic evaluation of these protocols. This type of evaluation will lead to explicit the tradeoff between costs and effectiveness and to better support and guide the manufacturer in the planning and application.

**Keywords:** regulation, Human Factors, usability, patient safety

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## Risk assessment tools for manual handling in healthcare sector

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### Introduction, PATE, BIPP Transfer Evaluation, OWAS, REBA, Other tools

Deepak Sharan

International statistics state that healthcare workers are among those at highest risk for musculoskeletal disorders (MSD), especially of the low back and shoulder. Whilst the methods used to evaluate risk and preventive capabilities differ widely throughout the world, there is general agreement over the need for an approach that begins by assessing risk, and then envisages an integrated process for analysing work organisation, environment, aids and training, and ultimately assesses effectiveness.

The methods used for assessing patient handling risk can be categorised as follows:

1. Individual Patient Handling Risk Assessments and Plans, e.g., safe system of work (SSOW)
2. Physical Environment Risk Assessments
  - i. Criteria Based Assessments, e.g., Lite Workplace Profile, Hoist Identification Tool, Quick Scan
  - ii. Residual Risk Scores/Evaluations, e.g., MAPO tool, Lift/Care Thermometer, Patient Transfer Assessment Instrument (PTAI)
3. Individual observational tools for specific handling tasks
  - i. Postural Analysis Tools, e.g., REBA, OWAS, People Environment Risk tool
  - ii. Biomechanical Assessment Tools, e.g., The Dortmund Approach
  - iii. Exposure Measures: self-reported exposure methods
  - iv. Subjective Appraisal Measures, e.g., Borg scales for the rate of perceived exertion, likert scales for comfort and ease of use for equipment
  - v. Methodological Observation Tools, e.g., PATE, DINO

In the Dortmund approach (Theilmeyer A, et al, 2010), the lumbar load is determined by simulation calculations using a comprehensive biomechanical model ('The Dortmund').

PATE is a video observation instrument for description and assessment of nursing personnel's work technique in patient transfer tasks with regard to musculoskeletal health and safety. The instrument consists of 24 items arranged in three phases of a transfer: the preparation phase, the starting position and the actual performance (Kjellberg K, et al, 2000).

Kaiser Permanente Northwest Region developed a Back Injury Prevention Project (BIPP) to try to reduce the back injury rate among healthcare professionals. An instrument called the BIPP Transfer Evaluation was developed to evaluate patient-handling tasks. The BIPP Transfer Evaluation is an inexpensive way to get early, objective information about the quality of an intervention to reduce back injuries among nurses, nursing aides, and orderlies. (Feldstein A, et al, 1990).

The aim of this symposium is to discuss various commonly used risk assessment methods that may help in estimating the risk involved in patient handling for healthcare professionals and may eventually help in modification of risk of developing MSD.

### **DINO, PTAI and Til Thermometer**

Leena Tamminen-Peter \*

#### *Introduction*

Manual patient handling can induce high loads to the musculoskeletal system of the caregiver, and static overload is a risk when patient handling is being undertaken. General risk assessment methods really can identify the problems in such detail that it helps to solve them. Several more detailed methods for patient handling have been developed.

#### *Objectives*

To introduce three practical risk assessments tools DINO (Johnson et al. 2004), PTAI (Karhula, Rönholm & Sjögren 2007) and Care Thermometer. Care Thermometer is derivation of a Dutch model TilThermometer (Knibbe H and Knibbe N. 2005).

#### *Methods*

The PTAI (Patient Transfer Assessing Instrument) is a practical tool that occupational safety and occupational health professionals can use to evaluate the risk of patient transfers in the unit. Total 15 factors are observed and interviewed. The criteria allow classifying the risk by 3-zone model (green, yellow and red). The first nine factors are filled in by the evaluator on the basis of observing the work environment and the nurse performing the patient transfer as usual. The patient is guided and helping devices are used in the normal manner. A load index can be calculated on the basis of the results of observations and the interview.

The TilThermometer is an instrument to assess exposure for physical overload for nurses who carrying out basic care and assess compliance with Guidelines for Practice. It was developed in an excel format and the results will be calculated automatically and afterwards the results can be aggregated from ward level to facility level. The TilThermometer has been further developed into the Care Thermometer (Kinbbe et al. 2011).

DINO (Direct Nurse Observation instrument) was developed based on the Pate instrument (Kjellberg et al. 2000). The aim of the instrument is to assess the work technique of nursing personnel during patient transfers, and to relate this to health and safety in the musculoskeletal system. DINO consists of 16 items, divided into three phases of a transfer: the preparation

phase, the performance phase and the result phase. All items are used to calculate the overall score of the instrument.

<b>Method</b>	<b>DINO</b>	<b>PTAI</b>	<b>CareThermometer</b>
Main determinant risk factor	Compliance with safe patient transfer technique with 16 items, divided into three phases of a transfer: the preparation, performance and the result phase	15 factors: environment, availability and use of aids, physical load on different body parts, transfer skill and received guidance, frequency of patient handling.	Compliance with national guidelines to use of lifting devices, beds in basic care task
How collected?	Direct observation	Interview and observation + video	Interview the nurse who knows the patient's care
Quantified factors	Scoring system 0-1, depending on the level of musculoskeletal health and safety.	Frequency of observed and experienced patient transfers, criteria to classification into three categories	Any patients not managed in the stipulated in the guidelines score as a residual risk. These risks are provided in tables and in different graphs, in red, yellow or green.
Repeatability and usability	The validity and reliability tests done	Done in two pilot studies	Done in four countries.
Benefits	Assess if the used technique is the risk factor for musculoskeletal problems	Gives reliable overview of the situation – relative fast (30-60 min/unit)	
Availability	In paper version.	In internet in Finnish and English	Web-based tool in 11 tongues
Limitations		A video shot is recommended; the calculation of overall load index is manual.	It is not specific enough for individual assessments.
Type of use	evaluating training results	It can be used for risk analysis in hospital units and nursing homes, also in the home care. It used a lot in Finland	For national monitoring studies in Holland but also very much used in Europe.

Table 1. The comparison of the risk assessment tools

### *Discussion/perspectives*

All these tools are practical and reliable but one must choose the tool which fits one's need. PTAI covers the most extensively risk factors connected to patient handling situations in the unit. Tiltthemer tool looks and patients' functional ability and what is needed to take care it safety and it gives the unit level task outcome. DINO –tool gives staff level outcome and can be used as an individual risk assessment.

### **Patient handling in the Healthcare Sector: risk management with MAPO Methodology**

Marco Tasso

International statistics comparable to Italian figures state that healthcare workers are among those at highest risk for musculoskeletal disorders, especially of the low back and shoulder.

Therefore, the problem is tackled in many countries, albeit using different approaches.

Our research group has benefited, in the effort to compare these various approaches, from the creation in 2005 of the spontaneously formed European task force named EPPHE (European Panel on Patient Handling Ergonomics) as well as from our direct participation in the drafting of ISO and CEN Technical Reports (TR ISO/CD 12296 - Manual handling of people in the healthcare sector) published by ISO on 1 June 2012 and approved by CEN in August 2013.

Whilst the methods used to evaluate risk and preventive capabilities differ widely, there is extensive agreement over the need for an approach that begins by assessing risk, and then envisages an integrated process for analysing work organization, environment, aids and training, and ultimately assesses effectiveness.

The MAPO method fully complies with the mentioned approach not only because it entails a step-wise risk assessment process (i.e. hazard identification, MAPO screening and analytical risk assessment), but also because it covers every aspect pertaining to risk management. It was validated with two cross-sectional studies carried out in 1999 and 2003 on 440 different types of wards in hospital and residential care facilities, and for 6400 nurses exposed to manual patient handling.

The MAPO methodology is aimed at providing a parametric index representing the risk level of the unit considered, hence it is not addressed to analyzing the single movement but to the whole of the determinants, negatively or positively contributing to defining the risk level for unit operators.

A preliminary review of the most reliable literature on the subject singles out the following principal factors which, all together, characterize risk exposure in this specific setting:

- number of dependent (or non-cooperative) patients
- type of routine, total or partial, of patient lifting tasks and degree of effort required
- structural aspects of work and care environments
- availability and actual utilization of mechanical lifting devices
- training of staff on the specific topic

A numeric value is assigned to each of these factors, which is used to calculate the index.

The risk analysis process involves two steps: an interview with the head of the ward to gather information about work organization in the ward, and an on-site facility assessment to gather additional details, mainly concerning the equipment on hand and the environment itself. The on-site inspection also allows to check the validity of the information provided during the interview.

This initial stage assesses the “care load” in terms of patient handling, and largely to estimate the frequency with which an operator performs patient handling activities. To overcome the problem of choosing which information to collect and how to collect it, a special Data Collection Sheet has been drawn up. The ward staff involved in “patient handling activities” and thus potentially exposed to MPH risk is broken down into job categories, described and quantified in order to assess whether the shifts are properly designed.

The next step is to define how many operators performing MPH activities are working on each shift (morning, afternoon and night, both full and partial shifts), the sum total of which represents the OP factor, and if they generally handle patients alone or in pairs.

It is necessary to know the average number of disabled patients present in the unit. Disabled patients (D) are further classified, on the basis of residual mobility and current illness, into "totally non-cooperative (NC)" and "partially cooperative (PC)". By totally non-cooperative (NC) we intend a patient who is unable to use the upper and lower limbs and, therefore, has to be fully lifted in transfer operations. By partially cooperative (PC) we intend a patient who has residual motorial capacity and who is therefore only partially lifted.

Operator training is also an important factor, both in terms of the process of educating (i.e. transmitting knowledge and skills) and of delivering training proper (i.e. teaching how to use equipment). The following information must be obtained during the interview:

- type of training delivered;
- duration of training course;
- number of operators currently on the staff involved in training;
- time elapsed between training course and current risk evaluation process;
- assessment of training effectiveness.

Patient handling tasks need also to be defined, with a distinction made between tasks requiring total patient lifting (TL) and tasks requiring partial moving or lifting of the patient (PL). The purpose is twofold: if the facility plans on purchasing lifting devices, these data may help decide which ones best suit the needs of each specific ward and objectively calculate the percentage of patient handling operations requiring mechanical devices.

Other important aspects that need to be analysed are the following:

- patient handling devices (hoists, stretchers, ergonomic beds and minor aids)
- wheelchairs
- environmental assessment (bathrooms & toilets, patient rooms)

All the elements discussed above are to be found in the following formula:

$$(NC / OP \times LF) + (PC / OP \times AF) \times WF \times EF \times TF$$

where NC and PC represent the number of non-cooperative and partially cooperative patients; OP is the number of operators working over three shifts; LF is the lifting devices factor; AF is the minor aids factor; WF is the wheelchairs factor; EF is the environment factor and TF is the training factor.

The results of the relationship between MAPO exposure index and acute low back pain in the previous 12 months show that the crude odds ratio for exposure levels (MAPO Index) above 1.5 were all positive and statistically significant with respect to  $MAPO \leq 1.5$ . Moreover, for the second and third exposure classes, the trend was upward and tended to decline or stabilise at the highest exposure level ( $MAPO > 10$ ).

The odds ratios, adjusted for the confounding factors gender, age and total job seniority, were not significantly different.

**Keywords:** patient handling, healthcare sector, risk analysis, measurement tools, musculoskeletal disorders

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**The role of Human Factors in fighting against Sepsis:  
an organizational and safety perspective**

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**Introduction**

Sepsis is a common clinical condition, difficult to manage, associated with a very high mortality when it is connected to organ failure (sepsis, 20-25%) or to a state of shock, (40-70%). Sepsis and septic shock represent a medical emergency. The incidence is still increasing, in parallel to the average age of the population and the chronicity of many diseases resulting in immunosuppression and immune paralysis and more invasive diagnostic and therapeutic procedures. In the European Union 1.4 million cases of sepsis are estimated per year with a variable mortality rate between 28% and 50%. The Global Sepsis Alliance (<http://www.world-sepsis-day.org>) has set the goal of 25% reduction in mortality from sepsis by 2020. The revision in last years of the recommendations contained in the three editions of international guidelines (1) led to the definition of sets of resuscitation bundle to be implemented in the first 3 and 6 hours of recognition of Sepsis and septic shock.

In Europe the number of patients with sepsis - septic shock who are hospitalized in the intensive care coming from a medical ward is significantly higher than in the US ( 51.5 % vs. 25.4 % ) , with a higher mortality rate (2) . Sepsis is defined as a life-threatening organ dysfunction caused by a dysregulated host response to infection. At present, it can be identified by a constellation of clinical signs and symptoms in a patient with suspected infection (3). Sepsis is a time dependent syndrome and every hour spent outside of a safe and validated clinical pathway increases patient mortality of 8%. As far as we know everyone can

develop organ dysfunction in consequence of an infection. Therefore risk stratification is not straightforward as for other time-framed pathologies such as AMI and stroke. Nevertheless Sepsis outperforms stroke four times and it is the first cause of inpatient mortality. Because no gold standard diagnostic test exists sepsis identifications requires expertise and training. The diagnosis of Sepsis is one of the emergency department pitfalls and accounts for the 9.4% diagnostic errors (4). Moreover after the identification has occurred only a timely, coordinated and seamless care process can guarantee the 18% reduction of mortality (5).

The experience gained has allowed health care professionals to raise attention to the issue of sepsis even outside the critical area, through greater involvement of health personnel of inpatient facilities and Emergency department is needed. The guidelines of the Surviving Sepsis Campaign collect the points that enable the early identification of patients at risk of sepsis and indicate the necessary diagnostic and therapeutic procedures to be implemented. The timely identification of sepsis and septic shock, can significantly reduce the hospital mortality. Despite these conditions, there are still some problems in both the early identification of the disease and in the application of guidelines these problems are attributable to:

- Healthcare personnel skills need to promptly recognize sepsis as a clinical entity
- Need to know the recommendations of the guidelines of the SCC -Surviving Sepsis Campaign
- Need to define specific responsibility matrix and organizational procedures designed to ensure the activation of a clinically effective response (timely implementation of the essential points of the treatment regardless of the place of hospitalization and activation of professional skills involved)

For this reason Sepsis is without any doubts a medical and organizational challenge.

“Ergonomics (or human factors) is the scientific discipline concerned with the understanding of interactions among humans and other elements of a system” (www.iea.cc). It is acknowledge by the WHO as the theoretical framework for patient safety and training of health care professionals (6). This symposium aims to provide insights on how human factors principles can underpin health care organization improvements in reducing the burden of sepsis.

### **The barriers to change – Lessons learned from a multi-center QI improvement project in Germany**

Konrad Reinhart

Despite the fact that Quality Improvement (QI) teams are widespread tools for improving performance in medical settings, little is known about what makes teams effective and successful (9). The goal of this study was to identify barriers and supportive conditions for QI teams to implement an effective and successful QI project to improve quality of care. Multicenter expert interviews with 17 team leaders were conducted in a cluster randomized trial. Interviews were based on a semi structured interview guide and were recorded and transcribed. Qualitative analysis was performed according to the principles of grounded theory. The major findings of our study can be summarized in a framework of conditions that support the implementation of changes by QI teams. This framework can be divided into 5 core categories: the availability of external support, an interdisciplinary QI team, staff characteristics such as dedicated employees who are aware and experienced, and generally supportive structural circumstances. Furthermore, the interviewees reported that changes should be disseminated through, for example, repeating key elements or addressing employees directly. Using a grounded theory–based qualitative approach, we identified a

framework of conditions supportive of QI-related change, which can help project initiators to create environments that are supportive of change.

### **Introduce sepsis guidelines in a pediatric hospital: benefits, pitfalls and possible solutions**

Niranjan Kissoon

Clinical practice guidelines are useful in improving quality of care and outcomes, reducing inappropriate variation in practice, promoting efficient use of resources, informing and empowering patients and informing public policy. However, difficulties arise when guidelines are poorly introduced into routine daily practice and, as a consequence, many patients do not receive the care

intended or receive harmful or unnecessary care. Many guidelines have been formulated for the treatment of sepsis in children and adults. These guidelines emphasize early recognition and aggressive treatment of the patient with sepsis in order to improve outcomes. However, the context in which a guideline is to be used is important and to a large extent determines whether it will be implemented successfully. Thus, in an attempt to make sepsis guidelines relevant

in both resource-poor and resource-rich environments, the level of resources in various settings have been taken into account and guidelines have been formulated to suit both resource rich and poor regions of the world (7-8). Sepsis guidelines for children have also been designed to accommodate both resource and skill sets for countries with varying under-five mortality rates and to accommodate resources for monitoring and treatment from district clinics to tertiary care facilities, while guidelines for sepsis management of both adults and children have been proposed by the Global Intensive Care Working Group of the European Society of Intensive Care Medicine. In addition, tremendous effort has been expended in revising the Surviving Sepsis Campaign guidelines to include new evidence since its previous iteration in 2008. Although these efforts are laudable, adherence to these guidelines has met with mixed results in both resource poor and rich regions. Therefore, while resources to implement guidelines are important, other factors beyond resources may also mitigate against successful adoption.

These guidelines emphasize early recognition and aggressive treatment of the patient with sepsis in order to improve outcomes. However, the context in which a guideline is to be used is important and to a large extent determines whether it will be implemented successfully. Thus, in an attempt to make sepsis guidelines relevant in both resource-poor and resource-rich environments, the level of resources in various settings have been taken into account and guidelines have been formulated to suit both resource rich and poor regions of the world.

Guidelines are useful in improving the quality of care and outcomes, reducing inappropriate variation in practice and promoting efficient use of resources. However, the benefits are hampered by poor adoption in both resource-rich and resource-poor environments. Adoption and adherence to guidelines is hampered by many factors, including the very nature of the process used in preparing the guidelines, as well as clinicians' skepticism, cultural aversion to guidelines and resource limitations that preclude implementation. In order to circumvent these issues it is suggested that a uniform and transparent inclusive process be used to craft the guidelines. Such process tools also include systems to allow evaluation of resources needed and outcome measures as well as opportunities for revising the guideline. The guidelines should also be crafted with a

knowledge of the context they would be employed. An environmental scan to identify the possible barriers to implementation in any setting is important. The most common barriers are lack of personnel and resources for carrying out the steps required for guideline adherence.

These barriers should be addressed early in the implementation stage for guideline adoption to be successful. Rigorous attention should be paid to outcome measures to determine adherence to guidelines as well as relevance to patient care. Many of the barriers to guideline adherence can be overcome by close adherence to the culture of the environment in which the guideline will be adopted. Developing a community of practice in which all clinicians are involved in the development and promotion of the guidelines may ensure their success. Ensuring that a guideline is successfully adopted requires a tremendous investment of resources and effort. However, the favorable outcomes associated with guideline adherence far outweigh the effort that is needed for

successful implementation. This presentation will address some of these issues. It will outline the benefits of compliance with sepsis guidelines, the published experience with compliance, possible reasons for poor compliance and offer some possible solutions to improve compliance and ultimately patient outcomes.

### **The role of Human Factors in fighting against Sepsis: a patient safety perspective**

Giulio Toccafondi

Sepsis is defined as a life-threatening organ dysfunction caused by a dysregulated host response to infection. At present, it can be identified by a constellation of clinical signs and symptoms in a patient with suspected infection. There are three main challenges connected to the fighting of sepsis and septic shock and all of them are related to the capability of the health care organization and of its members to promptly respond to sepsis. Sepsis is difficult to diagnose, it can be identified by a constellation of clinical signs and symptoms in a patient with suspected infection. Because no gold standard diagnostic test exists sepsis identifications requires expertise and training.

Everyone can become severely septic in every sector of the hospital; there is not a specific medical discipline in charge for organizing the pathway against sepsis; all disciplines are involved and teamwork is a crucial factor for success. Moreover sepsis is time dependent, patient mortality increases of 8% for every hour spent outside of a safe and validated clinical pathway.

To respond to this dynamic challenge the healthcare system should enhance resilience and develop expertise in sepsis management. In order to defeat sepsis a human factors approach could become extremely useful in empowering the health care system and diffuse knowledge regarding sepsis in every sector of the hospital.

The main focus of Human Factors and Ergonomics (HFE) is the interactions between humans and the elements of a systems. HFE is fundamentally endowed with a contextual approach which turns to be useful for integrating the endeavors and empower the interactions of several disciplines such emergency medicine, critical care medicine, surgery, pediatrics, obstetrics, maternal and infant care diagnostic services, microbiology and infectious diseases which are all involved in the sepsis pathway. Sepsis is a metaphor: the factors that make possible an effective answer to sepsis are the same that make the healthcare system more resilient and safer. Likewise, in sepsis the focus is on the systemic response to the disease rather than the disease itself. Since implementation is unique to local context, by using an HFE approach, human limitations and system criticalities should be preventively analyzed in order to mitigate human frailties, enhance human performance and address system deficiencies.

Through a HFE approach it is important to optimize human performance through better understanding the behavior of individuals, their interactions with each other and with their environment. Which are the assets that could enhance the system response to sepsis? The knowledge regarding sepsis cannot be taken for granted and this issue must be considered in order to create an organized response to sepsis. We need develop two important interdependent elements. Firstly constructing a common ground on sepsis identification, management and treatment which should be condensed into shared and participated guidelines in which the functions and roles of every professionals are accounted for and made explicit. Secondly the guidelines needs to be contextualized and scaled up to the operational level of each single hospital in order to guarantee the back- up for every single steps of the pathways and guarantee adherence to the sepsis bundle in sustainable ways. The level of resources in various settings needs to be taken into account in order to contextualize the application of the sepsis pathway to suit local capacity. In Italy the national clinical risk management and patient safety committee proposed a clinical pathways based on the international guidelines of the surviving sepsis campaign for sepsis. The pathway was initially applied in Lombardy region and then proposed in Tuscany. This presentation will focus on how in the Tuscan health care system the clinical pathway was then transformed into a training program in which the professionals of the different disciplines were represented. The training was designed as a two steps process. The first steps aimed at training the trainers and in the second step the trainers (one from each specialty) will scale up to the local context the sepsis pathways with the support of the clinical risk management units. In order to measure the adherence to the bundle a set of ICD 9 codes for the diagnosis of sepsis have been identified and have been proposed to healthcare professionals in order to quantify the sepsis burden and the efficacy of the implementation activity. The data collected will then foster proactive audit in order assess the overall process outcomes.

### **The role of Educational and Organizational Intervention for enhancing adherence to the sepsis guidelines**

Gianpaola Monti

Sepsis is widespread (1.8 million cases annually worldwide) and accounts for a very high mortality: 20-25% of all sepsis, 40-70% of all septic shock. The Surviving Sepsis Campaign (SSC) recommends a first 6 hours "resuscitative bundle" to improve patient's outcome. Despite this, the bundle is poorly performed, because of a superficial knowledge of the guidelines and several difficulties in their clinical implementation. In recognition of this, a "sepsis six" bundle is designed to facilitate early intervention with just three diagnostic and three therapeutic steps to be delivered by staff within 1 h. The aim of our study is to evaluate if an Educational and Organizational Intervention (EOI) could improve septic patient's outcome in no Critical Care Units. The second endpoint is to evaluate if the compliance to the "sepsis six" bundle could improve after this sort of intervention.

**Keywords:** sepsis, Human Factors, improvement, organization, training

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**Using Human Factors and Ergonomics to improve care coordination  
during transitions of care across health care boundaries:**

**Current and Future Directions**

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**Description of the topic**

Effective care coordination is essential to the safety and efficiency of transitions of care, especially given that health care is currently fragmented and episodic (Arbaje, Kansagara et al. 2014). Each patient movement from one health care setting to another requires the complex management of multiple pieces of information, typically from a variety of sources, including health care professionals, informal (nonprofessional, unpaid, typically a family member or friend) caregivers, and technologies (Arbaje, Kansagara et al. 2014). The Agency for Healthcare Research and Quality defines care coordination as “deliberately organizing patient care activities and sharing information among all of the participants concerned with a patient's care to achieve safer and more effective care.” However, during transitions of care, the burden of care coordination often falls on the patient and informal caregivers, who may not always have the skills or capacity to facilitate successful transitions (Wolff, Meadow et al. 2008). The outlook does not necessarily improve when health care providers are tasked with care coordination that occurs, as they must often rely on suboptimal processes and technology design as well as challenges with accessing the information they need to effectively coordinate the transition of care (Schoenborn, Arbaje, Eubank, Maynor, & Carrese, 2013; Nasarwanji et al., 2015).

The panel members in this session will present examples from their areas of research focused on exploring various aspects of care coordination during transitions of care. The purpose of this panel is to improve our understanding of how care coordination affects transitions of care in terms of both the quality and safety of the care delivered, as well as to discuss and identify methods to improve care coordination across health care boundaries.

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Pascale Carayon and Peter Hoonakker will present the results of their study on the implementation of care managers in different settings (hospital, primary care and call centers). The goal of this study was to examine how the different types of care management could improve medication reconciliations and follow-up after hospitalizations and to examine the impact on hospital re-admissions.

Patrick Waterson and Ken Eason will present the results of a set of studies covering the use of electronic and people (role-based) systems to manage care transitions across a variety of healthcare boundaries including primary/secondary care and social services. One part of the presentation will focus on recent work, the aim of which is to improve handover across the community and acute care boundaries.

Nicole Werner will be presenting results from a set of studies that identified cross-cutting sociotechnical system barriers to coordinating transitions of care across health care settings including transitions from the hospital to home care, from the hospital to the skilled nursing facility, and from the emergency department to the home.

### **Integrator Roles in the Provision of Coordinated Health and Social Care**

Ken Eason and Patrick Waterson

There is widespread agreement in the UK that we need to do more to care for the elderly and people with multiple long-term conditions at home and that to do so we need to share information between many health and social care professions to coordinate the care that is given. But widespread agreement has not led to rapid progress in the effective sharing of information. There are many reasons why not.

First, there are the practical issues of how to do it. The people providing care may be many and various, from many different agencies, trained and untrained. And the patients/clients may be different in each case, depending on the conditions being treated, the location etc. And the health and social care staff dealing with a particular patient/client are unlikely to meet together where they can share information face-to-face. We have to find ways of sharing information within unstable, 'boundaryless', virtual groups within which, in all probability, everybody is keeping information in their own systems. Secondly, even supposing we find the means of sharing information, there are the reasons why we might choose not to. Patient and client information is confidential and should we share it with all the people providing care or just with some of them or may be just some of the information? There will also be status and professional differences between care givers leading to role conflicts and ambiguities, all of which may inhibit the extent of information sharing. Finally what part does the patient/client have in the information sharing? Autonomy and self-management of medical conditions are important goals and being fully informed would seem to be a necessary condition but does that mean access to all information or some of it? We can look for solutions to these problems in process solutions (what needs to happen when), organisational solutions (for example,

using case managers as coordinators) or technological solutions (for example, ‘virtual wards’ and telehealth) but in practice we need to be looking for sociotechnical solutions that embrace all three.

In the UK there has been relatively slow progress in integrating all the agencies that provide care and the organisational solution in many places has been to create integrator roles (care managers, community matrons etc) who attempt to coordinate care so that it is ‘person-centred’. One such programme is the Primary Care Navigator (PCN) programme in West London which locates PCNs in General Practitioner clinics and whose function is to help patients over 65 years of age locate and access the many agencies in the locality who can help them with social, financial, housing, transport and other issues that may be impacting on their health. We undertook a quantitative assessment of the patients referred to the PCNs and looked at a range of outcomes, e.g. referrals to Accident and Emergency Departments. We also undertook a qualitative study of a range of stakeholders (the PCNs, the patients, GP staff and service providers both statutory and voluntary. The results revealed positive quantitative outcomes e.g. less A&E visits, fewer GP visits etc and very strong positive feedback from patients and GP staff about the value of the PCN role. There were however organisational and systems issues about implementing a new service of this kind, e.g. getting it recognized across all stakeholders and creating shared information records. The PCNs, for example, had no information system of their own but ‘borrowed’ the patient systems of the GPs and the ‘client’ records of service providers. Although the service was proving effective it worked because of the perseverance of the navigators in dealing with the existing health and social care system rather than being a new integrated system solution.

### **Care coordination for patients with chronic conditions – Benefits and challenges of a care management program**

Pascale Carayon and Peter Hoonaker

Patients with chronic conditions such as CHF and COPD can benefit from interacting with care managers who coordinate various care processes, such as ensuring and organizing follow-up appointments with the primary care provider and coordinating other services (Carayon et al., 2015). We examined the implementation of a care management program aimed at reducing readmissions and ED visits of CHF and COPD patients in a five-county region of Central Pennsylvania, USA. The program created positions of nurse care managers located in 18 outpatient primary care clinics, 4 hospitals and a transition-of-care call (TOC) center. We first report the benefits of the program by recording care gaps identified and addressed by the care managers. We then describe the range of health information technologies used by care managers in their daily activities.

Care managers document patient data and their own activities in a case management system. Whenever they identify a care gap, they record it along with the strategies they use to address the gap. We analyzed data collected for 4,002 patients between November’2011 and March’2013. Inpatient care managers identified care gaps in 52% of their assessments; outpatient care managers in 44% of their assessment and TOC care managers in 47% of their assessments. In the hospital setting, the most frequently identified care gaps were follow-up appointment not scheduled (35%), whereas in the outpatient setting, medication errors were most frequently identified (23%-TOC care managers; 16%-outpatient care managers). Inpatient care managers often took care of scheduling follow-up appointments for patients or refer the scheduling of the appointment(s) to the TOC or outpatient care manager. The TOC and outpatient care managers often communicated with the primary care providers in order to address care gaps.

Care managers use a variety of health information technologies to support their coordination activities. These technologies allow them access to patient-related information that is often scattered across multiple systems and healthcare organizations. This creates a range of challenges as revealed in a survey of care managers. For instance, two-thirds of the care managers reported the major barrier of having to log in multiple systems, which can impede timely access to information (reported by 54% of the care managers). Because not all hospitals and clinics share patient-related information electronically, 61% of the care managers describe as a major barrier the need to obtain the information in a different manner (e.g., fax); which can have a significant negative impact on their efficiency and can create frustration.

Care managers play a critical role in coordinating care for patients with chronic conditions; they identify multiple problems in the care of these patients and help to solve them. However, their work system, in particular the health information technologies available, are not designed to fully support their work. Additional effort is necessary to continue to understand care coordination as a sociotechnical system that spreads across multiple organizational boundaries.

### **The Professional and Nonprofessional Work of Care Coordination**

Nicole E. Werner

A fundamental shift in healthcare that has occurred over recent decades is the shift from a focus on the acute treatment of disease to a focus on the long-term management of chronic illness. As a result, much of healthcare can no longer be thought of as a response to a one-time episode, but as an ongoing process that is part of a “patient journey.” The patient journey, in turn, requires a new conceptualization of health care providers as including family members and even friends (i.e., informal caregivers) in addition to formal health care providers. In fact, care coordination has become the responsibility of patients and their informal caregivers. The patient journey also requires a new conceptualization of healthcare environments as a continuum of both formal and informal healthcare settings. In the face of this new focus, a key question for Human Factors and Ergonomics is: How can we conceptualize and improve patient safety in the context of the patient journey approach to health care?

Transitions of care occur across sociotechnical boundaries, including the hospital (acute care), rehabilitation, skilled nursing, long-term care, assisted living, ambulatory care, primary care, and home. As a confluence of the factors described above (and possibly other challenges), patients who transition across these health care settings experience risks to their health and safety (Jencks, Williams et al. 2009, Arbaje, Kansagara et al. 2014). The complexity of care coordination across these boundaries lends itself to a Human Factors and Ergonomics approach such that a comprehensive, in-depth, and context-driven investigation of barriers and facilitators to care coordination can lead to the creation of effective, usable, and sustainable interventions to improve coordination during transitions of care (Carayon 2010). One challenge to system alignment across the patient journey is that these risks cross sociotechnical system boundaries from professional work systems to non professional work systems (e.g., the hospital to home). Non professional or patient and informal caregiving work occurs under vastly different sociotechnical conditions than that of professional work. For example, consider the patient and informal caregiving dyad (i.e., team). Patient and informal caregiving teams do not have assigned roles or externally imposed operational guidelines, team membership and/or roles may change at any time, and team members may not even be aware that they are part of a team. In addition, there are emotional, motivational, as well as

other psychosocial aspects to being a patient and informal caregiver that differ from professional work.

Despite these differences, coordination of care must span these sociotechnical boundaries of professional and nonprofessional work systems. Often, the solution that is implemented is a coordination role. However, if this role is not designed and implemented as a way to align the professional and nonprofessional work systems, it can lead to unanticipated challenges.

Through the study of care coordination across 3 different types of healthcare transitions from professional to nonprofessional work systems, we have found that the complex processes that span those settings provide a unit of analysis for studying sociotechnical interactions across those boundaries. Studying processes specific processes limits the number of interactions for focused study (i.e., configuration), and allows for the observation of emergent properties across systems (Holden et. al., 2015).

**Keywords:** transitions of care, care coordination, work system boundaries, sociotechnical systems

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