SEIPS 3.0: Multisensory approach to reduce Post-ICU Syndrome

Section I: Background information

Submitted by:

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Section II:

Role of the ergonomists/human factors experts in the project: (Project leader, ergonomist in multidisciplinary team, please describe)

Joseph J Schlesinger, MD, FCCM was the principal investigator of this project. Dr. Schlesinger is part of a human factors research team at Vanderbilt University Medical Center, the Center for Research and Innovation in Systems Safety (criss.app.vumc.org), led by Matt Weinger, MD, MS. We had multidisciplinary research meetings in that group to conceptualize the approach. Through that, we used focus groups as developed in the Human Factors literature (Acher 2015) to form our clinical question and conceptualize our design.

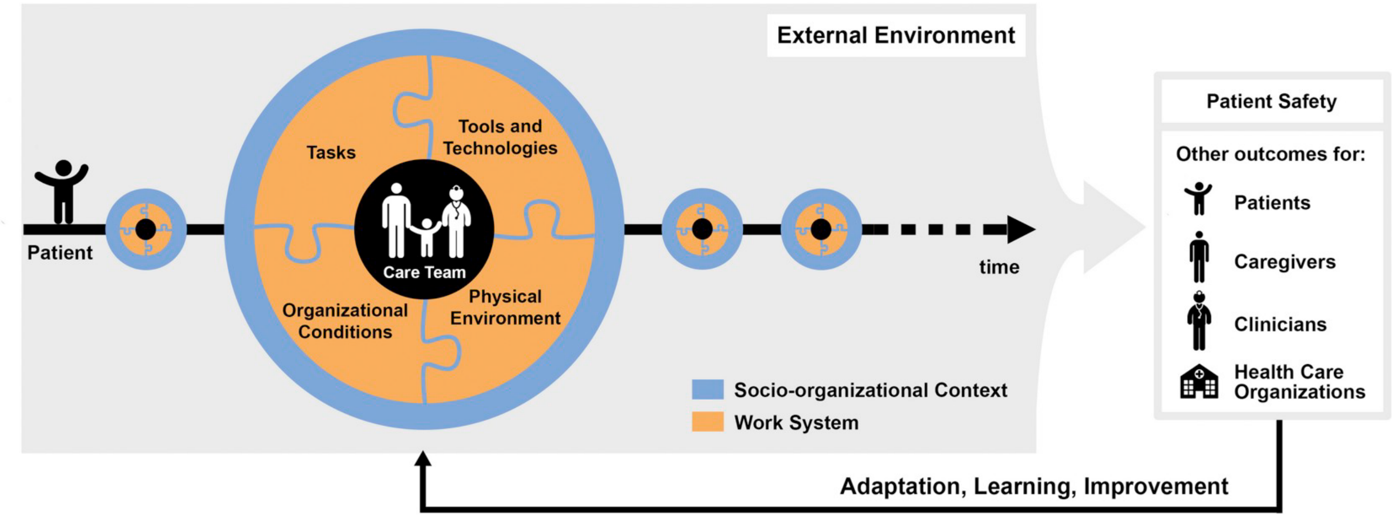
Main area(s) of intervention: (physical, cognitive, organizational ergonomics or mix)

This intervention was focused on minimizing the cognitive impact of alarms on patients in the intensive care unit (ICU). The auditory environment of the ICU is saturated with constant alarms that are mostly clinically insignificant (Cvach 2012), yet result in disruption for recovering patients, and the later development of Post-Intensive Care Syndrome (PICS). By reducing the alarm burden of the ICU by using alarms that are multisensory and “smart”, meaning they provide more information to the user, patient disruption may be reduced, which may decrease the incidence of PICS.

This new approach to alarms could evolve into a “smart” design for understanding and possibly predicting patient physiology. For example, a patient in rate-controlled atrial fibrillation with premature ventricular contractions (PVCs) could wear a device that not only alerts the patient to a potentially dangerous rhythm, but can learn the specific patients’ trends and adapt new alarm thresholds that are tailored to their own physiology. In the end, a device could notify the patient when they have reached a critical point, but also when they are trending toward this critical point, giving more time to intervene and prevent. Additionally, this informative and multisensory monitor can "travel" with the patient from ICU to normal hospital room, to a long-term acute care facility or skilled nursing facility. By redesigning the alarm, we have the capacity to create a novel long-term, patient-centered multisensory alarm that is both proactive and reactive with information-rich alarms.

Keywords (max 5): Post-Intensive Care Syndrome, alarm fatigue, SEIPS 3.0, human factors, multisensory

What was the aim of this patient safety project (Please tie into the SEIPS 3.0 model)?



Post-Intensive Care Syndrome (PICS) affects up to 70% of intensive care unit (ICU) patients, making it a significant cause of morbidity in the ICU (Myers 2019; Burdick PICS 2019; Burdick & Callahan 2020). By the World Health Organization's (WHO) International Classification of Functioning, Disability, and Health framework, patients suffering from PICS have significant impairments to multiple daily function domains, even one year after their ICU stay (Ohtake 2018). This indicates that PICS is both an acute and chronic challenge for patients. While PICS is likely caused by a myriad of factors, the constant interruption of sleep from alarms and providers in the ICU is a significant contributor (Shigeta 2001).

The reduction of false alarms and auditory burden on patients is one step to reducing PICS. The patient is the main focus of the hospital, specifically the ICU setting, which is why constant monitoring and vital sign checks are so important and frequent. Ironically, these alarms can complicate the recovery process. Currently, 80-99% of medical alarms are false or clinically insignificant, usually resulting in the provider carelessly silencing it (Cvach 2012). Alarm fatigue is the phenomenon where providers who are chronically surrounded by constant alarms ignore alarms due to high frequency and rate of false alarm (Sendelbach 2012). However, for patients who are new to the clinical environment, these alarms are disruptive and unnerving. For the overall benefit to both healthcare providers and patients, there needs to be a decrease in the volume, frequency, and false alarm rate of medical alarms.

The Systems Engineering Initiative for Patient Safety, or SEIPS, model offers a way to understand, evaluate, and ultimately re-design complex healthcare settings, such as that of the ICU, to improve patient outcomes across the patient journey (Carayon 2006). By breaking down the healthcare work system into components, e.g. *people* who do certain *tasks* using *tools and technology* in a *physical* and *organizational* environment, and the interactions between those components, the SEIPS model can elucidate barriers to providing high quality care (Carayon 2007). In the ICU this is exemplified by the tension between needing to provide clinicians critical and urgent information (via alarms) and providing patients the acoustic environment they need to rest and recover. Designing an ICU environment that achieves both of these goals is essential to reducing PICS and alarm fatigue, alike. While we cannot safely decrease patient monitoring, we can attempt to change the alarm environment, minimize unnecessary patient interruption, and maximize patient recovery and long-term well-being.

Alarms that are smart and communicate more to the healthcare provider may improve the sound environment of the ICU. Yu et al, led by Dr. Hallbeck's Human Factors Engineering Lab at Mayo Clinic, found that the clinical environment is cognitively demanding, specifically in the perioperative setting (Yu 2016). By communicating more information (ex. downward trend of oxygen saturation) through each alarm, we can optimize attention allocation while also providing information to providers so they can intervene before a patient reaches an alarm-worthy vital sign. Through a reduction of unnerving and false alarms, there may possibly be a decline in alarm fatigue development. The increase in alarm information can be achieved by restructuring the alarm sound and sensory stream modality.

Multisensory alarms may be a way to increase the information available for users. Alarms that incorporate more than one sensory stimuli (ex. tactile and auditory) communicate important information without decreasing demanding task performance (Katzman 2019), as well as increase cognitive processing speed and attentional capacity (Hecht 2006). The integration of multisensory alarms in the ICU should also benefit the patient with fewer alarms interrupting their crucial sleep and lowered incidence of delirium and PICS.

Industry or sector: Health Care and Patient Safety

Section III.

Description of HOW the work was done and the OUTCOME (may contain photos, diagrams or tables). Please state the methods used and what was achieved (the result).

To increase the overall efficiency of medical alarm design, we combined auditory and tactile stimuli to create a multisensory alarm, SAVIOR ICU (Burdick JCMC 2019). Analysis compared the unisensory trials to the multisensory trials based on the percentage of correctly identified point of change, direction of change and identity of three physiological parameters (indicated by different instruments): heart rate (drums), blood pressure (piano), blood oxygenation (guitar). Responses were tested while participants performed a cognitively demanding visual task, which was meant to simulate the ICU. The participants' performances, based on the accuracy of alarm identification, were compared to their performance using unisensory auditory input.

The integration of tactile and auditory stimuli into a multisensory alarm improved the accuracy of alarm responses by participants, compared to the traditional unisensory alarm. Specifically, the multisensory group had better performance in correctly identifying physiological parameter (ex. blood pressure; $p < 0.05$) and point of change ($p < 0.05$) compared to unisensory.

Ultimately, the successful integration of multisensory alarms may help ensure that ICUs and other medical settings do not experience an excessive burden and reliance on their auditory system, enabling clinicians to multitask well and provide optimal patient care. Furthermore, the reduced auditory burden may relieve significant disruption and anxiety that recovering patients suffer from, ultimately reducing the incidence of PICS.

Was the outcome evaluated following implementation? If so, how and with what result:

SAVIOR ICU has not yet been implemented in the clinical setting, as there are ongoing studies using this technology in high-fidelity medical simulation, a necessary precursor step to clinical implementation. However, there are qualifiable results from end-users using the System Usability Scale which shows promising results (Lewis 2018).

Was a cost-benefit analysis done? If so, please briefly describe the results:

No, a cost-benef$300, so a cost-benefit analysis would likely support its development and implementation. Overall, it is beneficial for patients, providers, and the hospital as a whole to use alarm innovation such as our multisensory design to optimize patient monitoring recovery, and safety.

<u>References</u>

Acher AW, LeCaire TJ, Hundt AS, et al. Using Human Factors and Systems Engineering to Evaluate Readmission after Complex Surgery. J Am Coll Surg. 2015;221(4):810-820. doi:10.1016/j.jamcollsurg.2015.06.014

Burdick, K.J.; Callahan, C.J. Sleeping Soundlessly in the Intensive Care Unit. *Multimodal Technol. Interact.* 2020, *4*, 6. https://doi.org/10.3390/mti4010006

Burdick, K.; Courtney, M.C.; Schlesinger, J.J. Post-Intensive Care Syndrome (PICS): Behavioral Therapies. In Lessons from the ICU; Ridolfi, A., Ed.; Springer: Berlin/Heidelberg, Germany, 2019.

Burdick KJ, Jorgensen SK, Combs TN, Holmberg MO, Kultgen SP, Schlesinger JJ. SAVIOR ICU: sonification and vibrotactile interface for the operating room and intensive care unit. J Clin Monit Comput. 2020;34(4):787-796. doi:10.1007/s10877-019-00381-1

Carayon P, Schoofs Hundt A, Karsh BT, Gurses AP, Alvarado CJ, Smith M, Flatley Brennan P. Work system design for patient safety: the SEIPS model. Qual Saf Health Care. 2006 Dec;15 Suppl 1(Suppl 1):i50-8. doi: 10.1136/qshc.2005.015842. PMID: 17142610; PMCID: PMC2464868.

Carayon P, Alvarado CJ; Systems Engineering Initiative for Patient Safety. Workload and patient safety among critical care nurses. Crit Care Nurs Clin North Am. 2007 Jun;19(2):121-9. doi: 10.1016/j.ccell.2007.02.001. PMID: 17512468.

Cvach M. Monitor alarm fatigue: an integrative review. Biomed Instrum Technol. 2012 Jul-Aug;46(4):268-77. doi: 10.2345/0899-8205-46.4.268. PMID: 22839984.

FDA Patient Safety News: Show #106, January 2011. FDA. 2011. URL: https://www.webcitation.org/6bFBLdWA5

Holden RJ, Carayon PSEIPS 101 and seven simple SEIPS toolsBMJ Quality & Safety Published Online First: 26 May 2021. doi: 10.1136/bmjqs-2020-012538

Hecht, David & Reiner, Miriam & Halevy, Gad. (2006). Multimodal Virtual Environments: Response Times, Attention, and Presence. Presence. 15. 515-523. 10.1162/pres.15.5.515.

The Joint Commision. Medical device alarm safety in hospitals. Sentinel Event Alert. 2013. http://www.jointcommission.org/assets/1/18/SEA_50_alarms_4_5_13_FINAL1.PDF

Katzman N, Gellert M, Schlesinger JJ, Oron-Gilad T, Cooperstock JR, Bitan Y. Evaluation of tactile cues for simulated patients' status under high and low workload. Proceedings of the Human Factors and Ergonomics Society Annual Meeting. 2019;63(1):658-662. doi:10.1177/1071181319631285

Myers EA, Smith DA, Allen SR, Kaplan LJ. Post-ICU syndrome: rescuing the undiagnosed. JAAPA 2016; 29: 34–37. doi: 10.1097/01.JAA.0000481401.21841.32.

James R. Lewis (2018) The System Usability Scale: Past, Present, and Future, International Journal of Human–Computer Interaction, 34:7, 577-590, DOI: 10.1080/10447318.2018.1455307

Ohtake PJ, Lee AC, Scott JC, Hinman RS, Ali NA, Hinkson CR, Needham DM, Shutter L, Smith-Gabai H, Spires MC, Thiele A, Wiencek C, Smith JM. Physical Impairments Associated With Post-Intensive Care Syndrome: Systematic Review Based on the World Health Organization's International Classification of Functioning, Disability and Health Framework. Phys Ther. 2018 Aug 1;98(8):631-645. doi: 10.1093/ptj/pzy059. PMID: 29961847.

Sendelbach S. Alarm fatigue. Nurs Clin North Am. 2012 Sep;47(3):375-82. doi: 10.1016/j.cnur.2012.05.009. Epub 2012 Jul 4. PMID: 22920428.

Shigeta, H.; Yasui, A.; Nimura, Y.; Machida, N.; Kageyama, M.-O.; Miura, M.; Menjo, M.; Ikeda, K. Postoperative delirium and melatonin levels in elderly patients. Am. J. Surg. 2001, 182, 449–454.

Yu, D., Lowndes, B., Thiels, C. et al. Quantifying Intraoperative Workloads Across the Surgical Team Roles: Room for Better Balance?. World J Surg 40, 1565–1574 (2016). https://doi.org/10.1007/s00268-016-3449-6