Vanderbilt University
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VentureWell DEBUT Grant Proposal

MULTI-SENSORY PRE-ALARM SYSTEM FOR PHYSICIANS

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ABSTRACT:

Current alarms in Intensive Care units are disruptive, unspecified, and often false. In response, a wearable, multisensory pre-alarm system was developed in order to be used in conjunction with current alarms. This system was intended to decrease the intense alarms in Intensive Care Units by providing physicians with more information about what the vitals of a particular patient are. In doing so, physicians can attend to patients earlier and with more precision, prior to alarms going off.The multisensory system is composed of two haptic actuators worn on the wrist and ankle and a wireless bone conduction headset. The headset plays music that corresponds to the patient vitals and changes given changes in vitals. The haptic actuators vibrate to further emphasize changes in particular vitals. A three-phase study was performed with 32 participants to first determine the music with which participants could most accurately determine the correct change in vital sign. Iterations 2 and 3 were significantly better that Iteration 1 of sounds, so Iteration 2 was used in the following two weeks of the study. The second and third phase tested the accuracy with which participants could correctly determine changes in vitals when using the system with only music, music and discrete haptics, and music and continuous haptics. It could not be determined that either haptic schema helped participants perform significantly better than without music.

DESCRIPTION OF THE PROBLEM:

Intensive Care Units have an overwhelming number and range of alarms that can distract and/or disturb both patients and physicians. This oversaturation of noise and visual stimulation has lead to the low positive predictive value (≥23%) associated with ICU alarms. Along with simply being distracting in the high stress environment, the high volume and frequency of alarm

signals also reduces the ability of the physician to differentiate between patient issues and causes desensitization to the alert stimuli. The current systems in place do not have much flexibility for physicians to track physiological parameters before they reach an alarming threshold, and can cause patients to develop PTSD or panic related psychological issues.

This project aimed to address the needs of physicians to track patients' vital signs before a threshold is met in a manner that is less obtrusive to the patient and care provider while improving positive predictive value of the associated alarms, and the final product is targeted towards the physicians in hospital Intensive Care Units. By providing this systems, physicians can increase the amount of personalized attention each patient receives, attend to patients faster and with more accuracy, and relieve some of the stress they may experience due to oversaturation of alarm noises in the ICU.

PROJECT OBJECTIVE STATEMENT:

This project aims to address the need of physicians to track patients' vital signs in a less intrusive manner before an alarm threshold is met through a device that transmits auditory and haptic signals to indicate what direction and how concerning a patient's vital signs are.

The principal components of the system are a bone conduction headset, soundscapes, wearable haptic actuators, and haptic signals. Each physiological parameter and direction (high/low) is associated with a sound, and haptics are incorporated to enhance the distinction between abnormal and concerning pre-alarm zones, in the form of either continuous or discrete vibrations felt on the wrist and the ankle. The team conducted efficacy studies that trained and tested subjects on multisensory combinations, and the results were analyzed to determine what composition resulted in the highest user accuracy, intuition, and comfort.

This design improves upon previous ones by comparing more multisensory combinations, by increasing precision, and by incorporating more qualitative analysis. The final study aimed to find a combination of signals that will make a pre-alarm monitoring system intuitive and comfortable enough for use in an ICU setting. In previous years, this project has explored whether one kind of haptic signal improved subject response time and accuracy to changes, and only tested direction of change. In this contribution to the project, two types of haptic signals were explored and the changes that could occur before a traditional ICU alarm went off were more defined and split into abnormal and concerning ranges.

DOCUMENTATION OF THE DESIGN:

The principal components of the system are a bone conduction headset, soundscapes, wearable haptic actuators, and haptic signals. Each physiological parameter and direction (high/low) is associated with a sound, and haptics are incorporated to enhance the distinction between abnormal and concerning pre-alarm zones. The team conducted efficacy studies that trained and tested subjects on multisensory combinations, and the results were analyzed to determine what composition resulted in the highest user accuracy, intuition, and comfort.

The initial phase of the study was designed to determine what combination of sounds was the most pleasant and discernable for subjects to differentiate between vital signs and directions. Three iterations of soundscapes were developed and the optimal one was selected based on which iteration resulted in subjects responding the most quickly and most accurately to changes. The second phase was dedicated to training subjects by introducing discrete or continuous haptics integrated with sounds in order to determine which combination resulted in the fastest response times and the most accurate identification of changes. The third phase was the

extinction portion of the study, and tested subjects on each type of multisensory combination to understand how well they were able to retain the training that was introduced in phase 2.

The options for multisensory combinations that were introduced in phase 2 were audio only, audio with discrete haptics, and audio with continuous haptics. Discrete haptics were transmitted as one vibration on the wrist when transitioning from normal (silent, and no haptics) to abnormal and two vibrations from abnormal to concerning in the high direction. In contrast, one vibration was transmitted to the ankle when going from normal to concerning, and two when going from concerning to abnormal in the decreasing direction. The continuous signals were transmitted through the wrist for one variable and through the ankle for the others, and the haptics were determined based on the sound in each zone.

This design was different from previous ones because it introduced the concept of multiple pre-alarm zones, varying haptic signals, and optimizing a soundscape before asking subjects to distinguish between zones.

PROTOTYPE OF THE FINAL DESIGN:

The bone conduction headset used was the Trekz Titanium by AfterShokz. The haptic actuator used was the Basslet by Lofelt. The two Basslets were worn with one on the non-dominant wrist and one on the opposite ankle.

PROOF THAT THE DESIGN IS FUNCTIONAL AND WILL SOLVE THE PROBLEM:

The design's effectiveness was determined through a three-phase study. In each phase of the study, qualitative and quantitative data was investigated to first determine the best set of sounds to represent the vitals, and second to determine the best haptic and audio combination.

In the first phase of the study, participants were introduced to the sound associations for three different vital signs: heart rate, blood pressure, and blood oxygenation. They then were quizzed on the associations. A particular sound would play, and the participant had to indicate the vital it was associated with. Their answer was confirmed. The participants were then presented with associations between sounds and direction of vital change. Again, they were quizzed. Finally, the subject listened to a four-minute long block with overlapping sound changes. They interacted with a touchscreen GUI where they clicked a button for the vital and direction they believe occurred in the block. This interface collected the timestamp the participant clicked, the vital sign they clicked, and the direction that they clicked. The accuracy of participants was based on their response time, whether they detected a change or not, if they detected the correct vital sign, and if they detected the correct direction of change. Qualitatively, the comfort and usability of the system was recorded for each participant using the NASA Task Load Index and System Usability Scale. Results from these quantitative and qualitative results were used to pick the best set of sounds to represent the vital signs.

In Phases two and three, the accuracy of participants was once again based on their response time, whether they detected a change or not, if they detected the correct vital sign, and if they detected the correct direction of change. In Phase two, participants were given the opportunity to play the sound and direction associations for up to five minutes in order to train themselves. They then were quizzed and tested in the same manner as Phase one, prior to being tested with the four-minute test block. In Phase three, the participants were simply presented with the associations, and then they jumped straight into completing the four-minute test. Phase two was performed to determine if participants, given extensive

training reflective of that they would receive in a hospital, could accurately detect vital sign changes with haptics and audio over just audio. The comfort and preference for each schema was also taken into consideration based on the same NASA Task Load Index and System Usability Scale which collected qualitative data.

The same data was collected in Phase three in order to determine if after extinction of training, participants could still accurately determine changes in vital signs. Qualitative data on comfort and perceived discernibility and task load was also collected in this phase.

RESULTS OF A PATENT SEARCH AND/OR SEARCH FOR PRIOR ART, ASSESSMENT, AND PATENTABILITY:

Despite the fact that the concept of alarm fatigue is increasingly being seen as a critical need to address within ICUs and greater healthcare systems in order to improve patient health outcomes and physician performance, the large majority of patient monitors in use today still have high false positive rates, which results in frequent, unnecessary alarms and low positive predictive value of patient health issues by physicians.

Some recent patents have sought to address the issue of alarm fatigue directly by decreasing the frequency of alarms from these machines through various methods. In particular, one system (U.S. Patent No. 10,255,994) attempts to alleviate this need through the use of an adjustable delay between when the alarm condition is detected and when the alarm notification actually sounds in the hope that the system may correct a false positive prior to the alarm sounding; however, this leaves room for error in situations in which such a delay could cause a healthcare provider to not respond in an adequate time period to a health crisis. Another system (U.S. Patent No. 10,123,729) has attempted to address the issue of alarm fatigue by incorporating filters into an alarm monitoring tool to assess the likelihood of a true positive in the event of an alarm condition, but this solution also poses related risk.

Given that the proposed system for this project primarily focuses on detecting the possibility of an alarm condition within the "pre-alarm" space (prior to a vital sign exceeding the alarm condition threshold) through predictive real-time analysis of patient health trends, this system aims to reduce alarm fatigue by addressing patient health concerns prior to the point of crisis and is novel in that regard. In addition, the multisensory use of the aforementioned haptic and auditory icons within this system also appears to be novel and poses additional possible benefits in reducing patient and physician alarm fatigue.

ANTICIPATED REGULATORY PATHWAY (510(k) VS. PMA):

As this system is not substantially equivalent to a legally marketed device and would therefore not qualify for the 510(k) approval process, it would require a pre-market approval (PMA) from the FDA in order for it to enter the U.S. markets. In particular, since this device functions to assess and alert healthcare providers to possibly declining patient health trends within the pre-alarm space and the normal patient monitor alarms are still functioning as a fail-safe, the system poses minimal risk to the patient and would most likely be classified as a Class I device.

REIMBURSEMENT:

Given that this system is intended to improve upon alarm systems associated with patient monitors that are currently used in the ICU, the patient will not interact with the system and its use would be standard for all patients being monitored there. As a result, the device is not expected to be reimbursable by Medicare/Medicaid since the physician or primary healthcare provider will be the individual directly interacting with it and costs for its purchase and use would not be billed to the patient.

ESTIMATED MANUFACTURING COSTS:

A single unit of the system requires two Lofelt Basslet subwoofers at $100 each, an Aftershokz™ Trekz Titanium bone conduction headset at $100 dollars, and a $50 software design and development cost. Assuming a larger scale manufacturing plan would eventually be developed, it is likely that bulk orders could be supplied at lower costs, ultimately reducing the total cost of the design. Furthermore,

in-house production capabilities would also greatly mark down the price. The brand of the headset and haptic actuators is irrelevant, assuming that audio and haptic signals can be delivered effectively to the user. It is assumed that assembling the components, packaging the set, and enforcing a strict quality assurance plan would add approximately $30 to the manufacturing cost of each unit. These costs sum to the total manufacturing cost of $380 per unit, before any volume discounts or expansion of production facilities to allow for in-house manufacturing.

POTENTIAL MARKET AND IMPACT:

In the United States, annually, 5.7 million patients are admitted to intensive care units for intensive monitoring, airway support, breathing assistance, stabilization of life-threatening issues, and management of illness or injury. These patients require constant oversight via a wide array of sensors and monitors. The prevalence of alarm fatigue and false alarm rates as high as 95% indicate the need for improvement on the current ICU alarm systems. Although the patients that require critical care in an ICU setting validate the need for this multisensory integration pre-alarm system, they are not the end users or target market. It is the hospital management teams and the care providers that must decide if they wish to implement this system into their facilities.

The American Hospital Association's annual survey from 2014 estimated that the U.S. has 5,686 hospitals. Of these, all of the acute care hospitals have at least one ICU and together care for approximately 55,000 patients per day. In 2010, it was calculated that the number of critical care beds in the U.S. is 77,809. Assuming that primary caregivers, specifically the ICU nurses, are typically responsible for two patients, there are 38,904 nurses that could use this system. Physicians oversee approximately seven individuals, for a total of 11,115 physicians that would benefit from this pre-alarm system. This sums to an estimated 50,019 total potential users. If each set was sold for $500, assuming no volume discounts, this yields a potential market value of more than $25 million. Although the clinicians are the end users, the hospital administrators are the customers. These administrators heavily consult

physicians in their decisions to purchase new technologies. Because the pre-alarm system improves the working environment for the staff, as well as improves the quality of care for 5.7 million patients each year, the physicians will play a critical role in the distribution and sales of the product.

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