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Smart Alarms: Multivariate Medical Alarm Integration for Post CABG Surgery Patients

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Abstract

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Keywords

Comments

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ABSTRACT
In order to monitor patients in the Intensive Care Unit, healthcare practitioners set threshold alarms on each of many individual vital sign monitors. The current alarm algorithms elicit numerous false positive alarms producing an inefficient healthcare system, where nurses habitually ignore low level alarms due to their overabundance.

In this paper, we describe an algorithm that considers multiple vital signs when monitoring a post coronary artery bypass graft (post-CABG) surgery patient. The algorithm employs a Fuzzy Expert System to mimic the decision processes of nurses. In addition, it includes a Clinical Decision Support tool that uses Bayesian theory to display the possible CABG-related complications the patient might be undergoing at any point in time, as well as the most relevant risk factors. As a result, this multivariate approach decreases clinical alarms by an average of 59% with a standard deviation of 17% (Sample of 32 patients, 1,451 hours of vital sign data). Interviews comparing our proposed system with the approach currently used in hospitals have also confirmed the potential efficiency gains from this approach.

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General Terms
Experimentation, Human Factors,

Keywords
Clinical Data Integration, Clinical Decision Support, Vital Sign Monitor, Fuzzy Logic, Bayesian Theory

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[1]Andrew King wrote the Clinical Interview Tool used to test the efficacy of the Smart Alarm algorithm

1. INTRODUCTION
Currently, critical care professionals are inundated with alarms from a variety of medical devices. Most of these alarms are only based on the output of individual vital sign monitors and turn out to be false-positives. The purpose of this project is to devise an optimized algorithm for a smart alarm system that mimics the established decision processing of caregivers nationwide. Additionally, this system will prioritize important alarms for caregiver's immediate attention by combining the outputs of multiple monitors. We hope for our algorithm to be implemented in a Smart Alarm Manager within every patient room within the Intensive Care Unit.

The role of a nurse in an intensive care unit is vital to the monitoring of a recovering patient. After an invasive surgery, many unforeseen complications can arise requiring to nurse to intervene with a range of solutions. In order to simultaneously monitor multiple patients, these nurses routinely set threshold based alarms on individual vital sign monitors that will sound when any one of up to eight monitored vital signs leaves a predetermined range.

These simple threshold alarms produce many false positives. A study by the Penn E-lert eICU, which remotely monitors 80 ICU beds across four Penn sites, found that over a period of 12 hours, 2,100 alarms occurred through the monitors. Furthermore, only 10% of these alarms proved to be clinically relevant, requiring nurse intervention [1]. Nurses across the Penn Health System have validated this finding as a universal truth: alarms based on single vital sign variables are not efficient.

The Smart Alarms project is centered on an alarm algorithm that considers multiple vital signs, mimicking the routine thought process of a nurse. Instead of sounding an alarm as soon as single vital sign exceeds a threshold, the algorithm considers every relevant vital sign to determine both the clinical pertinence and the severity of the situation. The announcement of these alarms is similar in sound to the current three tiered alarm system in place in most hospitals. However, the Smart Alarms solution chooses the appropriate level using the same multivariate vital sign analysis and the requests of nurses. The Smart Alarms algorithm, in turn, reduces false positives and encourages a more efficient health system, where every alarm is clinically justified.

Clinical efficiency is also increased with the inclusion of the Clinical Decision Support subsystem. This tool outputs a list of possible complications as well as the significant risk factors for a patient every time a Smart Alarm is fired. This will decrease the time healthcare providers spend diagnosing the patient.

This algorithm focuses on patients coming out of coronary artery bypass graft surgery (CABG surgery). Additionally, most alarms are initiated by one of four vital signs: blood pressure, heart rate, respiration rate, oxygen saturation rate.

2. RELATED WORK

The problem of having multiple alarms in intensive care units has been acknowledged and discussed by health care professionals since the advent of widespread patient monitoring technologies in the late 1980s and early 1990s. The existing threshold-based alarms compromise the quality and safety of patient care due to the associated high rate of false positives. Excessive false positives lead nurses to turn off devices, set the thresholds for alarms unreasonably high or low, and become desensitized to the sounds. Moreover, the alarms do not always match the criticality of the patient's condition, hindering the nurses' ability to react rapidly with the appropriate clinical intervention [2]. Since then, a variety of statistical, artificial intelligence, and human-computer interface methods have been proposed to gain high specificity surrounding alarm detection and annunciation.

2.1 Statistical Approaches

The Smart Alarms system will incorporate a data preprocessing step in order to filter noisy physiologic data into crisp values that can be used for further logical analysis. Below is a summary of some successful approaches that have been implemented to reduce noise in the monitoring devices and decrease the incidence of clinically irrelevant alarms.

2.1.1 Univariate Analysis

The application of median filters for data preprocessing was explored by Davies and Fried in their 2003 study of robust signal extraction for vital sign monitoring devices. They found that the application of a time-varying filter to noisy vital sign data could be further improved by eliminating the time delay associated with estimation [3]. This implied that increasingly fast algorithms for the computation of the repeated median could play a crucial role in effective alarm detection. [4]

Trend-based alarm algorithms have also been explored. In 1999, Schoeberg et al. described an algorithm in which trends were defined by a set of occurrences regarding specific variables, such as the percentage change in cardiac output or the absolute drop in mean arterial pressure. At regular intervals, each variable was evaluated against the predetermined set of criteria and a score was assigned depending on the extent to which trends deviated from the baseline. Alarms were then activated when the sum of these scores exceed a certain threshold. [5]

More recently, the results of another trend-based alarm system were published by Charbonnier and Gentil, researchers from the Automatic Control Laboratory of Grenoble. The proposed system required a vital sign input expected to remain stable, and used a series of three points in the data series to fit a straight line. The error of subsequent data points with respect to this line was then monitored at regular intervals. When the running tally of the errors passed a certain threshold, a new line was calculated and the trend direction was recorded. They found that the trend-based alarm system reduced false alarms significantly, while keeping the false negative rate of clinically relevant alarms in line with that achieved by traditional threshold alarms [6].

2.1.2 Multivariate Analysis

In 1997, Feldman, Ebrahim and Bar-Kana published their findings regarding the improvement of heart rate estimation using Robust Sensor Fusion, a method that entails combining data from multiple sensors with redundant data to improve the quality of alarm detection. The research team recorded heart rate data from the electrocardiogram, pulse oximeter and intra-arterial catheter and ran a sensor fusion algorithm based upon consensus between sensors, consistency with past estimates, and physiologic consistency (two other vital signs, blood pressure and oxygen saturation, were also recorded). The result was a fused estimate of heart rate that was consistently better than the estimates available from any individual sensor and that reduced the incidence of false positive alarms [7].

2.2 Artificial Intelligence Approaches

The primary value of the Smart Alarms system will be the integration of individual vital sign alarms into a single alarm management system. The Smart Alarm Manager (SAM), will contain expert medical knowledge regarding the detection and prioritization of critical states. A summary of the most prominent approaches for the introduction of artificial intelligence to clinical alarms is included below.

2.2.1 Knowledge-based systems

Expert systems are algorithms designed to mimic human reasoning through the use of a comprehensive knowledge base in the field of interest. In 1994, Koski et. al presented a knowledge-based alarm system for cardiac surgery patients that organized expert knowledge into an explicit decision tree [8]. The system improved the detection of critical events using a simple, deterministic approach; however, it did not result in a commercial application [9].

Subsequently, an expert system based on the integration of seven vital signs was developed in 1997 by researchers from the Department of Electrical Engineering and the School of Medicine of the Catholic University of Chile [10]. The expert system designed in this study employed fuzzy logic, which allows the modeling of imprecise concepts or dependencies. Fuzzy logic reverses the paradigm of binary logic by letting the algorithm estimate the "degree" to which an event occurs. For example, a patient does not have to be either hypertensive or not, but rather he or she can be "somewhat" hypertensive or "extremely" hypertensive. The Chilean researchers assigned the patients' vital sign readings to different "fuzzy" sets. They used the results as inputs to a series of if-then rules (the "knowledge base") that assigned the patient to one of several possible states and determined alarm activation. The resulting system improved alarm reliability and reduced the incidence of false alarms in patients undergoing cardiac surgery.

Another integrated systems methodology based on the principles of rule-based systems was presented during the 2006 [11]. Rules regarding vital sign thresholds and trends were developed by clinical experts, resulting in an alarm system that integrated vital signs data from multiple devices coupled with expert knowledge about the relevance of different events.

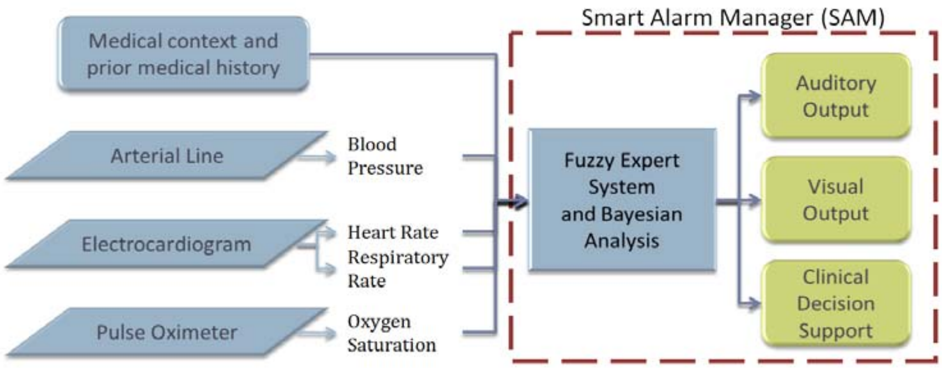

Figure 1. Smart Alarms System Block Diagram

2.2.2 Bayesian Networks

Bayes' theorem can be useful in critical care monitoring to calculate the probabilities of events of interest, such as cardiovascular complications or device measurement errors. Bayesian networks allow for continuous monitoring of these probabilities; that is, every time a new set of physiologic data is compiled, the event probabilities are recalculated and displayed to the user as a decision-support tool for diagnosis. The drawback to this approach is that a large amount of information regarding dependencies between physiologic variables and patient conditions is required [12]. An application of Bayesian networks for medical alarms was presented by Laursen in 1994, in which mean arterial pressure and central venous pressure were monitored and used for cardiovascular event detection [13]. The system proved useful for single-parameter event detection, but remained unable to detect long-term, slow changes in the patients' condition accurately.

2.2.3 Neural Networks

While other artificial intelligence approaches require the compilation and organization of expert knowledge prior to implementation, neural networks attempt to "learn" the relationship between combinations of vital signs and the consequent patient state from "training data sets" that contain sample entries of inputs (i.e., vital sign values) together with the corresponding outputs (i.e., high, medium or low priority alarms or no alarm at all) [14]. This approach has been used to develop alarm systems for specific clinical purposes, such as fault detection in anesthesia breathing circuits and vital signs monitoring in pediatric ICUs [15,16]. The main hindrance to widespread adoption of neural networks is the required training phase, difficulty in finding appropriate data sets to cover a wide range of clinical contexts, and the difficulty in determining the specific hypothesis the system has learnt.

2.2.4 Clinician-computer interaction

Behavioral studies about human responsiveness to alarms and their implications for medical devices have been identified as a promising path to achieve the principal objective of alarms: to communicate critical changes in a patient's condition early and reliably. In addition to making alarms more reliable, the Smart Alarm system will make them recognizable and identifiable. Some of the observed issues with the annunciation of existing clinical alarms include: alarms are manually turned off because they are too loud and irritating, there are too many going on at the same time for the user to determine which to address first, and there is little or no correlation between the degree of urgency of the patient's state and that implied by the alarm sound or light [17].

Edworthy and Hellier have proposed the use of auditory icons, or sounds which bear some relationship to the associated function, just like breathing sounds relate to ventilators [18]. The potential benefit of applying the principles of sonification (the science of turning data into sound) to medical alarms has also been discussed [19]. This application would likely result in an alarm system in which each vital sign is assigned to a different acoustic parameter (such as pitch, loudness, speed, harmonic content, among others). However, both fields of research are still in the early stages of development and we could not find studies that demonstrated quantifiable improvements in alarm responsiveness through the use of either method.

3. OUR APPROACH

3.1 Focus on CABG Surgery

CABG surgery is performed on patients with narrow or blocked heart arteries. The surgery involves grafting a larger vessel from another area of the body onto the heart and bypassing the blocked artery to optimize blood flow and oxygen to the heart. Post-operative management of the patient is challenging in that clinical changes and complications may develop rapidly. Continuous monitoring of physiologic data allows the clinician to detect early changes in the patient's condition and intervene in a timely manner to prevent complications. The primary post-operative goals are to restore adequate ventilation and hemodynamic stability. Blood pressure limits are maintained within a narrow range; high enough to ensure that enough oxygen is getting to the tissues but low enough to prevent bleeding or disruption of the graft. The heart rate and rhythm are continuously monitored for abnormal rhythms which may contribute to poor tissue oxygenation. Respiratory rate and pulse oximetry data are used to wean the patient from the mechanical ventilator and return to normal breathing patterns.

As the patient moves from the operating room to the ICU, the nurse connects the patient and the invasive lines to the monitoring equipment. Many false alarms are generated at this time, mainly due to manipulation or disconnection of the monitoring leads. The nurse then sets each of the vital sign alarm parameters (heart rate, blood pressure, respirations and pulse oximetry) individually. Each parameter that falls outside of the pre-set limit will generate an alarm. A patient's heart rate may drop one number below the limit and an alarm will generate, even though all other parameters remain the same and within range. This alarm would be classified as a "false" alarm, as it does not represent a

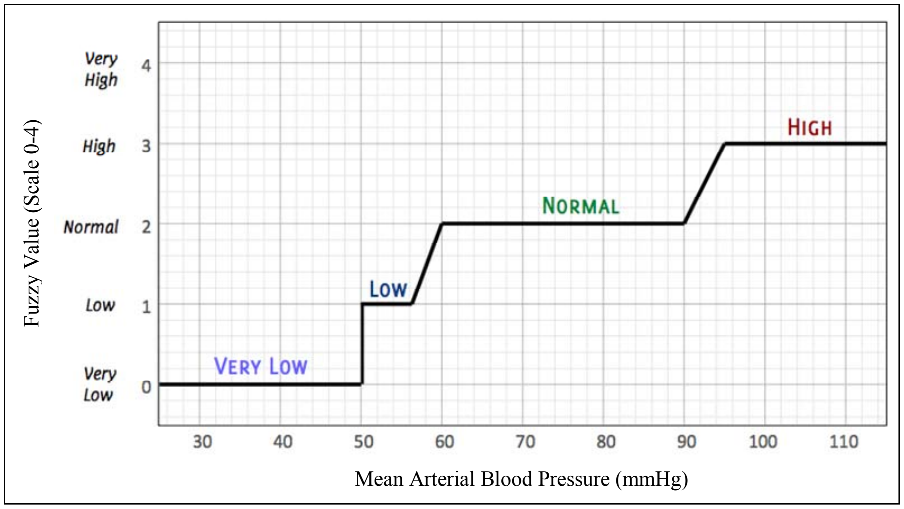

Figure 2. Illustrative Fuzzy Value Graphic Definition

change in the condition. In the intensive care unit, the majority of alarms (85%) are false or are of limited utility [20]. The high number of false alarms leads to "alarm fatigue": the number of alarms overwhelms clinicians, possibly leading to alarms being disabled, silenced, or ignored [21].

3.2 System Block Diagram

The diagram above is a high level view of the Smart Alarm System. The system initially takes in four parameters from the electrocardiogram, the arterial line and the pulse oximeter. These four vital signs are already collected from the respective devices and presented in a unified display screen by most patient monitors.

The algorithm does not only take in the four vital signs, but also includes contextual patient data such as age, weight, fitness level, and medical history. It uses fuzzy logic to activate alarms only when needed and to differentiate the urgency of the alarms through a visual and auditory output. Bayesian theories were also used in the algorithm to output a Clinical Decision Support for nurses' decision-making. The Clinical Decision Support was designed to assist nurses' decision process and to improve their response time in critical situations. This tool, however, was not intended to replace human reasoning and insight in the care of critical patients.

3.3 Fuzzy logic and expert system

The Smart Alarm algorithm performs a multivariate analysis that determines whether an alarm should be activated and the associated urgency of the event. Its inputs are four different parameters from bedside monitors: heart rate, blood pressure, respiration rate, and oxygen saturation rate (SpO2). These parameters were selected based on their clinical relevance discussed in "Caring for a patient after coronary artery surgery" [22]. These vital signs are used to diagnose the most severe complications that could arise after a coronary artery bypass graft, such as cardiac tamponade, atrial fibrillation, and respiratory impairment.

Fuzzy logic was implemented to deal with imprecise concepts that are associated with monitoring patients in the ICU. Fuzzy logic uses multi-valued reasoning to address complex issues that cannot be discretely defined. Unlike classical reasoning where a statement is determined to be either true or false, fuzzy logic assigns partial membership to a value. The degree of membership ranges from 0 to 1 and is used to measure the extent to which something is found to be true. For example, consider a patient with a blood pressure of 135/89 mmHg, implying he is 80% hypertensive as he is nearing the hypertensive threshold levels of 140/90 mmHg [23]. This example depicts a typical scenario where there is no concrete answer and fuzzy logic should be applied. In fuzzy logic, non-numerical values called linguistic variables are used to explain the situation. Each variable is assigned one or more descriptive values. In the example above, blood pressure is the variable and hypertension or hypotension would be the values assigned to it.

Fuzzy expert systems use if-then statements and operators of Boolean logic, such as AND, OR, NOT to define the reasoning involved in assigning membership to one or more sets. Fuzzy logic is the ideal method of medical reasoning because it is difficult to discretely define a specific number to be the limit of whether a patient is treated or not, especially since each patient varies in context and has dissimilar reactions. It is additionally a good representation of human behavior since it takes into account both quantitative and qualitative values, and thus is relevant for critical decision making, specifically when deciding whether an alarm should go off and its urgency. [24]

In contrast to the current medical alarms which are based on exact thresholds, the Smart Alarm Manager creates fuzzy sets, or membership value ranges for each of the four inputs. An illustrative example of the fuzzy sets for blood pressure is included above in Figure 2. This graph displays the partial membership function, mapping the range of Mean Arterial Blood Pressure to an appropriate Fuzzy Value ranging from Very Low to High.

Partial membership functions can also be expressed by piecewise equations. The output of the equation is a real number between 0 and 1 which describes the degree of membership of a particular value of blood pressure to the fuzzy sets named Low (corresponding to hypotension), Normal, and High (corresponding to hypertension).

The vital signs knowledge used to generate the actual fuzzy sets for the Smart Alarm Manager was attained through interviews with medical doctors and nurses at the Penn Presbyterian Medical

Table 1. Rule Samples

Blood Pressure (mABP)	Heart Rate	SpO_2	Respiratory Rate	Alarm
Normal	**Low**	Normal	**NOT Very Low**	None
Low OR High	Normal	Normal	Normal	Level 1
Normal	Normal	**Very Low**	**High**	Level 2
Low	Normal	**Low**	**Very Low**	Level 3

Center and from a textbook widely used in the field of critical care called Monitoring the Critically Ill Patient [25].

A sample of the rules that will be incorporated into the Smart Alarm Manager's knowledge base are included in Table 1.

The clinicians we interviewed at the Penn Presbyterian Medical Center and the Penn eICU supplied the expert knowledge necessary for understanding the care of patients that have undergone coronary artery bypass graft surgery. This knowledge has come in the form of acceptable and un-acceptable threshold levels for each of the four vital signs and the corresponding medical conclusions whenever one or more vital signs exceed their thresholds. This information was used in the Smart Alarm algorithm to assess the extent to which a patient's condition merits an alarm. The algorithm implements typical nurses' decisions--whether to react or ignore an alarm—through the use of if-then rules that integrate patient information from all four vital signs. For example, whenever a patient is determined to be over 50% tachycardic, the algorithm checks the patient's degree of membership in the hypotensive set and the low oxygen saturation set in order to assess the criticality of the patient's state.

In addition to fuzzy reasoning, the Smart Alarm Manager uses the patient's clinical context to evaluate the relevance of alarms. Although all of the patients simulated in our system are post-CABG surgery patients, they have different age, weight, body mass index, and medical history. A patient's clinical context is important because it plays a critical role in the correct detection of alarms. For example, since children tend to have higher heart rates than adults, when evaluating their heart rate, the degrees of membership should be higher and different from that of adults [26].

3.4 Clinical Decision Support Tool

Once it has been determined that an alarm must be activated, the algorithm will additionally output a list of possible complications the patient might be undergoing. The Smart Alarm algorithm focuses on the eleven most relevant complications that arise in CABG patients in the immediate post-operative period. For the purposes of this study, the immediate post-op period refers to the average ICU stay for any given patient, 48-60 hours [27]. Additionally, the complications included are only those that can be pinpointed by these four vital signs and do not require additional information, for example sepsis. In order to determine what complications are possible based on the vital sign behavior, extensive interviews with three nurses in the ICU were conducted.

Table 2 shows when complications are relevant according to the relevant fuzzy levels.

After the algorithm compiles the list of possible complications based on the vital signs, the list will be shown in decreasing order

Table 2. Sample CDS Complications Rules

Complication	Blood Pressure (mABP)	Heart Rate	SpO_2	Respiratory Rate
Pain	Above Normal	Above Normal	Less than High	Above Normal
Hypertension	Above Normal	NOT Normal	Any	Any

of likelihood. In order to do so, the Smart Alarm algorithm applies Bayesian network principles that represent probabilistic relationships between random variables [28].

Once the list of possible complications has been determined and sorted, the algorithm will also crosscheck the medical record of the patient to find the key risk factors significant for each complication that are present in the patient. The list of specific risk factors considered for each complication was compiled through research of several medical journals. A sample list of risk factors for the same two complications are shown in order of significance in Table 3.

Given that the Smart Alarm algorithm will output the list of possible complications with the corresponding risk factors, the CDS can improve healthcare providers' efficiency. Nurses can consider complications they might otherwise forget as well as identify the most important contextual information. Although there are many other factors that come into play in patient diagnosis, the Smart Alarm algorithm can increase the response time of caregivers by extracting their thought process and displaying it on a screen. Inexperienced nurses that might need some time to connect relationships between vital signs and complications could benefit from this feature. Similarly, nurses who care for multiple patients at a time will not need to memorize or look up the patients' contextual information and can gain from the CDS as well.

3.5 Alarm Interface

The final step in the Smart Alarm Algorithm is the clear and effective annunciation of alarms to the nurses. For this purpose, some of the principles of human computer interface were be implemented, including the use of colors in the patient monitor and graduated alarm sounds to convey the urgency and nature of the patient's critical condition. A model for alarm differentiation that was developed at the Hospital of the University of Pennsylvania (HUP) classifies all alarms in the clinical area as level I, II, or III [29]. Following a similar methodology, the Smart Alarm Manager outputs three different levels of alarms according to whether they command an intervention, a rapid intervention, or an immediate retention. Given the system's ability to analyze information from four different physiologic parameters, the Smart Alarm evaluates the need for clinical intervention more accurately than existing individual monitors.

Table 3. Sample CDS Risk Factors

Complication	Risk Factors
Pain	Less than 60 years old, Male, Previous Myocardial Infarction
Hypertension	Hypertensive, Smoker

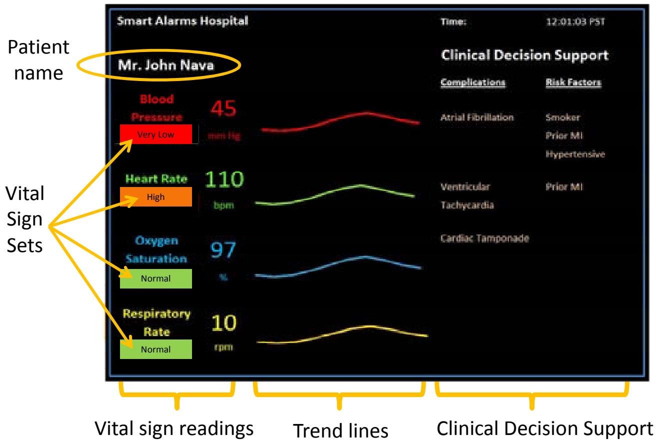

Figure 3. Screenshot of the "Hospital View" tab firing two Threshold Alarms

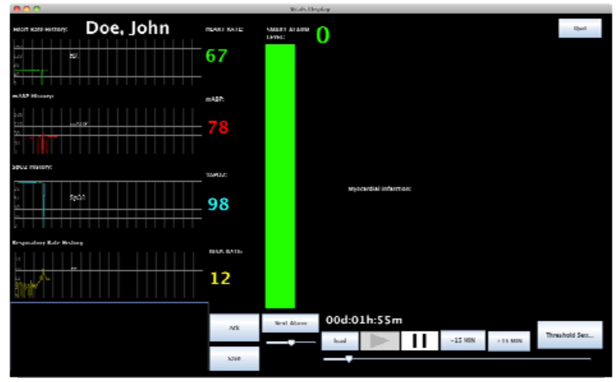

Figure 4: Java Implementation of the Smart Alarms App

The alarm sounds used in the demonstration of our system are different from the ones currently used in hospitals so that the immediate clinical severity of each alarm is accurately communicated. In 2003, the International Electrotechnical Commission (IEC) published standards for the safety of Medical Electrical Equipment, which contained a section about Alarm Systems (See section IEC 60601-1-8 in [30]). The IEC advocates the use of different combinations of musical notes to denote the category of the alarm (e.g., cardiovascular, temperature, drug delivery, etc) and the use of speed and repetition to denote the urgency level of the alarm. The Smart Alarm Algorithm uses these IEC-compliant sounds.

Currently, many clinically irrelevant alarms are triggered by nurse's interactions with patients, like when blood is drawn from the arterial line for lab tests. While nurses tend to ignore them with ease, these alarms may cause great anxiety to the patients and their family if they do not know the sound was produced by an intervention. For this reason, most nurses silence the alarms temporarily when they walk into the patient's room for some procedure. When implemented in hospitals, the Smart Alarm Manager will therefore keep the function found in existing vital sign monitors that allows nurses to temporarily silence alarms with a single command.

The visual interface of the Smart Alarm Monitor maintains the standards currently expected by nurses—black background and bright colors for each vital sign—and adds two new features: color-coded descriptive boxes for each vital sign and a list of potential complications in order of likelihood (the clinical decision support subsystem). Inclusion of the first feature is supported by research on human-computer interfaces from the chemical industry (in nuclear and petrochemical plants) and from the aviation industry (in pilot dashboards), which has shown that individuals process colors more rapidly than numbers or words. Inclusion of the second feature was validated by our medical experts as a tool that can help nurses respond faster to potential complications by extracting relevant portions of a patient's medical chart and displaying them on-screen in real time.

3.6 Smart Alarm Manager

In order to test and validate our algorithm, the Smart Alarm Manager was programmed using Microsoft Excel and Visual Basic. The program was designed to mimic a similar system at the patient's bedside, both in the algorithm employed and visual output. There are three iterative versions of the Smart Alarm ICU Program. The first version of the program processes a single patient's time in the hospital and displays an output made to resemble a standard Vital Sign Monitor already in use, the second adds the ability to view three "checked in" patients simultaneously, and the third version was created to efficiently process vital sign data from multiple patients through a batch process. This program has been used to demonstrate and test the Smart Alarm Manager algorithm with previously recorded data.

Additionally, in order to facilitate validation experiments, we implemented a version of the smart alarm as a Java application for a tablet computer. The Java version 1) emulates the visual appearance of a standard multi-variate vital signs monitor, 2) exploits the tablet's touch capabilities to emulate the interactivity of a standard vital signs monitor 3) can replay recorded clinical scenarios and 4) automatically records how clinicians interact with the program (*i.e.*, acknowledge alarms).

4. EVALUATION

4.1 PhysioNet Data

PhysioNet data was used to validate our model. Since the data obtained from this databank contained vital sign data and contextual factors, it was only used to validate the reduction of total alarms. The total number of alarms that would have sounded for each patient using the current system and the Smart Alarm system was measured and compared.

The current system uses threshold levels that are typically inputted manually by nurses. The threshold levels used for validation purposes were those deemed "standard" for CABG patients by the nurses of the Penn Presbyterian SICU. For the current threshold-based system, any time a single vital sign surpassed one of these thresholds, the alarm count was incremented by one. Since there are different levels of alarms in the Smart Alarm algorithm, the counting mechanism was more complex: In the cases where a vital sign transitioned from "high" to "very high" or from "low" to "very low", the count was only incremented once, although the alarm sound might have fluctuated through 1 or 2 urgency levels. This methodology ensured that the alarm counts of the current system and of our Smart Alarm algorithm were truly comparable.

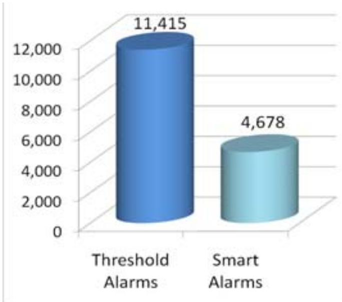

Figure 5: Comparison of Total Number of Alarms under both systems (n = 32 patients, 87,061 min)

From the total number of alarms for each patient, we then computed the decrease in alarms as a percentage of the initial total number. The average and standard deviation of this percentage reduction was computed for the entire population of PhysioNet patients. From a total of 1,451 hours of actual data comprising 32 patients, the Smart Alarm algorithm was found to have reduced total alarms by 57.13% with a standard deviation of 17.57%.

4.2 Presbyterian Medical Center Data

While PhysioNet data provided a valuable source of data to validate our reduction in the total number of alarms, it was only through live data collection that we could validate that the foregone alarms had been false positives. After obtaining expedited approval from the Internal Review Board of the Penn Presbyterian Medical Center, we gained access to vital sign data and annotated clinical interventions in real time for 4 different post-CABG patients in the Presbyterian SICU, resulting in 7 hours of annotated data. The data was annotated for clinical interventions in real time during 2-hours shifts using the worksheet in Appendix 7.

Although the sample size was admittedly small, this data was crucial to the validation of our system, because it provided confirmation that no false negatives (i.e., missed true alarms) were generated. The alarm counting methodology was the same as the one used for the PhysioNet patient data. After running the 7 hours of vital sign data through our Smart Alarm Manager and comparing it to the current system, the following results were obtained:

- Reduction in total alarms: 49.2% on average, 26.2% standard deviation
- Reduction in false positives: 52.1% on average, 26.6% standard deviation
- Zero false negatives (no true alarms were missed)

4.3 Clinical Interviews

In order to begin testing the accuracy of our Smart Alarms rule table, we also built a small testing applet to conduct interviews. This applet would have each ICU clinician input their preferred fuzzy set values ('Low,' 'High,' etc) for each vital sign given the medical context information of the current patient. Then, the applet would randomly select real Vital Sign value combinations from previously recorded data, displayed them on screen with the recent waveforms, and asked the clinician to designate an appropriate level of alarm ranging from no alarm to a Level 3 alarm.

We ran this initial interview with ten ICU clinicians over a week long period. While the small sample size was not enough to lead to any conclusive results, the survey did help define our future direction. First, more than 95% of the time, each clinician proposed the alarm level that our rule database would have fired. Also, the clinicians always agreed with the certain scenarios that would have led to no alarm in our new system, but leads to a normal alarm with threshold alarm system in place today.

This initial validation in our system not only came from accurate rules, but also the clinician's ability to set their appropriate 'fuzzy values' for the patient. We found that clinicians who had worked within the ICU environment for more than 15 years often set more extreme bounds for 'Low' and 'High' values of each vital sign, while clinicians who had worked for less than 5 years set more stringent alarms with tighter bounds for the 'normal' range. This difference in fuzzy values occasionally led the lower alarm levels for the more senior clinicians, which they repeatedly requested in the survey.

This initial survey has also aided in the development of our Java Applet that we will use to conduct a full clinical study, comparing the efficacy of clinicians responding to alarms from both the threshold system and our Smart Alarms system using previously recorded medical data.

5. CONCLUSION AND FURTHER RESEARCH

The Smart Alarm project met the stated goals of creating a multivariate alarm algorithm reducing alarms by at least 25% accompanied by a 3-level alarm priority system. The algorithm, called the Smart Alarm Manager, was tested using 1,451 hours of actual vital sign data from 32 post-CABG patients obtained from the clinical database PhysioNet, resulting in an impressive 57% average reduction in the total number of alarms (standard deviation of 17%). The Smart Alarm Manager was further tested with 7 hours of vital sign data (annotated in real time for clinical interventions) from 4 post-CABG patients in the SICU of Penn Presbyterian Medical Center, resulting in an average reduction of 52% in false positive alarms (standard deviation of 27%) and no increase in the number of false negatives, or missed alarms.

The Smart Alarm Manager is an Expert System that uses both Fuzzy and Bayesian reasoning to evaluate a patient's condition at every point in time. The process that led to its design, that is, the extensive nurse interviews and research into the medical literature, produced the following key insights:

- *Alarm overabundance:* The inordinate number of clinically irrelevant alarms in ICUs presents several issues relating to patient safety, patient satisfaction and efficiency in care.
- *Patient Safety:* To avoid excessive alarms, nurses may set overly wide alarm thresholds in the vital sign monitors manually. While this approach reduces alarms, it compromises patient safety because it leaves the door open for missing true alarms. Alternatively, nurses may keep standard alarm thresholds, but become desensitized to the sounds, such that their response times to critical events grow longer, again compromising patient safety. The Smart Alarm Manager decreases the number of alarms without compromising patient safety by looking at the instantaneous vital sign values, the vital sign trends, and the medical history holistically.
- *Patient Satisfaction*: According to our medical experts, noise is one of the chief complaints of ICU patients and their families. Investing in a system that reduces alarms,

one of the main sources of noise, would increase the level of patient satisfaction.

- *Efficiency:* In our interviews with nurses, we found varying degrees of dissatisfaction with the current alarm system. Most nurses agreed that a reduction in the number of false positive alarm s would improve their working conditions. They also agreed with our hypothesis that the integration of the patient's m edical history with the vital sign monitor would save time and help train new nurses.

The Smart Alarm Manager can be further improved in several ways:

- The knowledge base of vital sign rules and potential complications can be improved by incorporating insights from a larger number of medical experts.
- The system can be expanded to cover other clinical scenarios besides the CABG postoperative period.
- We are currently continuing to investigate into the clinical accuracy of the alarms outputted in with s ystem. Using the Java Applet, we are collecting information on: (1) the clinical relevance of the alarms that were generated by the system and (2) the com plications that were experienced by the patient during that tim e. This data m ay be able to be used to generate training sets for improved alarm systems based on machine learning approaches.

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