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Hospital Ward Alarm Fatigue Reduction Through Integrated Medical Device and Hospital System Policy Instruction

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Hospital Ward Alarm Fatigue Reduction
Through
Integrated Medical Device and Hospital System Policy Instruction
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Special Acknowledgement goes to my wife, Robin, for endless support in the completion of this project.
Executive Summary
The objective of this project is to reduce alarm fatigue in American hospital systems and improve patient care. This objective will be addressed by providing a secure online knowledge base of proper settings for medical devices in conjunction with hospital-specific policy about alarm protocol, at the point of care, to instruct clinical staff with accuracy and consistency. Product is to be sold b2b.

Alarm Fatigue in American hospitals has been recognized by the Emergency Care Research Institute (ECRI) as one of the “Top 10 Health Technology Hazards” facing hospitals in regard to patient safety and rated the top concern for the last four years.

“In ECRI Institute’s experience, alarm-related adverse events—which can involve missed alarms or unrecognized alarm conditions—can often be traced to inappropriate alarm configuration practices. Thus, we encourage healthcare facilities to examine alarm configuration policies and practices in their alarm improvement efforts, if they have not done so already.”

Medical devices increasingly monitor patients in hospitals as part of daily care. Monitors may include electrocardiogram (ECG) devices, SpO2 devices (peripheral capillary oxygen saturation via pulse oximetry), blood pressure monitors, infusion pumps, ventilators and other devices. These monitoring devices often have audible alarm signals to alert clinicians about out-of-parameter conditions. Patients may be monitored by as many as 14 devices at a time.

Hundreds of alarm activations may occur per patient per day. In one recent study, University of California, San Francisco (UCSF) researchers tracked 5 Intensive Care Units (ICU) for 31 days involving 461 patients; which resulted in 2,557,760 audible and non-audible alarms. One patient alone generated 15,296 alarms signals. The average quantity of audible alarms for this study was 187 per patient/day.

Alarms may sound from patient movement, improperly set parameters, low battery signals, device malfunction, or temporary changing conditions (that automatically reset) and more. The resulting noise overload of medical device alarms, nurse call signals may contribute to clinicians missing important actionable alarms in a sea of non-actionable alarms. It is estimated in the UCSF study and others that 85-99% of alarm signals do not result in the need for clinical intervention or change in patient care.

The Emergency Care Research Institute (ECRI) “National Patient Safety Goal” focusing on alarm management has enacted two phases for accredited hospitals with the following goals, among others, (NPSG.06.01.01: Improve the safety of clinical alarm systems):
Phase I, January 2014
Hospitals to establish alarm safety as an organizational priority
Identify the most important alarms to manage based on their own conditions

Phase II, January 2016
Develop hospital-specific policies and procedures
Educate clinical staff about alarm management

Solutions to alarm fatigue are as numerous as patients, it seems. Some recommend creating central monitoring solutions that transmit alarm messages to monitoring teams or computer systems. Some suggest re-transmission of alarms to smartphones and mobile devices. Some recommend reduction of patients placed on monitoring devices altogether.

The Joint Commission recommends through its National Patient Safety Goal (NPSG.06.01.01) as an option, ongoing training to clinical teams about medical devices, settings and policy as a method of reducing non-actionable alarm events.

This project addresses alarm fatigue through the design and implementation of an online knowledge base, *The Alarm Signal Instruction Manual (ASIM)*, to integrate instructions for medical device alarm settings and hospital policy to improve the parameters being monitored, resulting in a reduction of false or non-clinically actionable alarms at the point of care.

This knowledge base will be created at the hospital-system level, relying on the hospital-specific device inventory. Each hospital or hospital system will require a unique installation. The knowledgebase will provide easy access to hospital policy regarding the following settings as appropriate and as desired by the hospital system:

- Method of accessing appropriate content from visual clue (QR Code, Bar Code, Model name, image recognition software)
- Clinically appropriate settings for alarm signals, per manufacturer device model
- Basic instructions for alarm settings per manufacturer device model
- Policy for When alarms can be disabled and by whom
- Policy for When alarm settings can be adjusted and by whom
- Policy for verifying alarm settings are correct prior to use by new patient
- Policy for How often alarm settings are inspected
- Policy for reporting of alarm setting changes to Electronic Medical Records (EMR)
- Updates to device inventory and training of settings
Project Objective

The objective of this project is to reduce alarm fatigue in American hospitals and improve patient care by providing an environment conducive to healing. This objective will be addressed by creating a secure online knowledge base of proper settings for medical devices in conjunction with hospital-specific policy about alarm protocol, at the point of care, to instruct clinical staff with accuracy and consistency, potentially resulting in a reduction of false or non-clinically actionable alarms. This knowledge base, The Alarm Signal Instruction Manual (ASIM), will be created at the hospital-system level, relying on the hospital-specific device inventory. The knowledge base will provide access to hospital policy regarding clinically appropriate settings for alarm signals, per device; when alarms can be disabled, adjusted and inspected and by whom. The system may be accessed by clinicians from smartphones, tablets or computers securely at the point of care for up-to-date accurate information.

Project Approach

History

This project began in an ARTS 493 CoLab course at Virginia Commonwealth University (VCU) in the fall of 2013 as an exploration into the use of Google Glass as a communication device in the medical community. This was a continuation from the Spring 2013 CoLab course.

Proposals included the use of Google Glass wearable device by Emergency Technicians to document procedures and use of medical supplies as inventory management, risk management and training. Further exploratory uses included telemedicine and remote supervision of students by medical practitioners.

Further investigation suggested the use of Google Glass in the hospital environment as a tool for hands-free communication by doctors and nurses. The phenomenon of Alarm Fatigue was discovered as a significant challenge to clinical environments and the CoLab team investigated the use of Google Glass to mitigate alarm noise as an active part of an integrated system of alarm notification.

Challenges to the use of Google Glass in various public venues became a topic of news stories in 2013 because it was believed that the photo and video capturing capabilities of Google Glass was potentially seen as an invasion of privacy. The CoLab team saw this as a similar roadblock and discovered that such devices in a clinical environment were often prohibited and potentially illegal under HIPAA rules regarding “Full face photographic images and any comparable images.”

Alarm Fatigue was adopted as the topic for further investigation in the VCU course INNO 651 as an individual project. Google Glass or similar wearable devices were still considered as a component to a systems approach to alarm escalation but became
secondary to a new concept to mitigate alarm fatigue: to provide a method of alarm classification using sound recognition software and hardware to listen to, sort and deliver unique alarm signals to clinicians based on algorithms that would separate high-priority alarms to nurses on call and technical alarms such as low battery or “lead off” signals to medical technicians. (“lead off” refers to a condition where electrocardiogram (ECG) device electrodes adhered to a patient’s skin becomes detached). While this auditory methodology appeared to be an innovative application of interesting technology, it was abandoned as part of the INNO 652 research.

Alarms on medical devices were created as a form of loss prevention, helping clinicians by providing a way of monitoring patient conditions while a clinician was out of the room. Hospitals were happy to have new devices but it is important to note that the development occurred over many years and were not designed from a systems approach. Many medical devices are stand-alone and were not intended to communicate. Newer devices are developed to be integrated into central monitoring systems.  

Current Course Research
The research phase of the INNO 652 course revealed industry partners from medical device manufacturers to nurse and policy institutions recommending many technology solutions that created systems that:
- Unified all medical monitoring devices into a central system
- Repeated alarm signals through annunciators in remote locations and methods
- Escalated alarm signals from one tier of support to another
- Employed monitor watchers to monitor alarm signals manually and provide manual escalation

None of these solutions addressed the core problem of alarm fatigue: The quantity of alarms from medical device monitors and the fact that most of the alarm events were non-medically actionable or were false alarms. In other words, many alarm signal events either were momentary conditions that corrected themselves, or were not medically significant resulting in changes to medical care or treatment.

Key Question
INNO 652 research then looked at the following question: Why are there so many non-medically actionable alarms and how could they be reduced? Hospitals, medical device manufacturers and others were actively engaged in gathering research to try to answer this key question. Data gathering included interconnected systems of monitors and teams employed to gather and interpret data with direct feedback to patient conditions, monitoring conditions and information not contained within the data itself.

- For instance, Texas Children’s Hospital reported on a spike in patient alarm conditions due to the loud banging sound of a faulty trash can lid.  
- Another hospital reported on situations where training was needed in the application of ECG leads to improve adhesion.
• Texas Children’s Hospital reported that setting a delay of 4 seconds for SpO2 alarm signal reduced the quantity of alarms 64%.  
• Kaiser Foundation reported that by adjusting alarm parameter ranges to match patient specific conditions improved alarm quality by reducing false alarms that the default settings were generating.

These and many other examples lead to the insight that individual hospitals and hospital systems, patient wards and even patient populations have unique conditions that point to customized solutions instead of one-size-fits-all solutions.

Recommendations
Recommendations of the ECRI National Patient Safety Goal support the idea that more training for clinical staff in regards to medical device settings and configuration in regards to alarm settings is one of many solutions to reducing alarm signal events. Additionally, the National Patient Safety Goal also suggests that hospital systems create policy about alarm settings to include:

- Clinically appropriate settings for alarm signals, per device
- When alarms can be disabled and by whom
- When alarm settings can be adjusted and by whom
- How often alarm settings are inspected
- Reporting of alarm setting changes to Electronic Medical Records (EMR)
- Updates to device inventory and training of settings

The combination of these two requirements of the National Patient Safety Goal in combination of supporting research is the basis of this INNO 652 project.

Possible Solutions
There are several methods of achieving the combined goals of clinical training and policy education to include:

- Onboarding training courses
- Online continuing education
- Classroom continuing education
- Printed training manual

While the above methods of content delivery are important and have value, this project has identified that a solution that includes an online and mobile component may prove to be a valuable addition if not a replacement to traditional methods.

Recommended Solution - The Alarm Signal Instruction Manual (ASIM)
ASIM is a knowledge base with the following technology and components:

- Responsive design - web-based delivery viewable and scalable to fit smart-phones, tablets and computer displays
- Secure with usernames and passwords
- Search system to identify desired device by device manufacturer, model number, device type
● Hospital-system specific database of medical devices regularly maintained and updated
● Hospital-system specific policy for alarm settings, adjustment of alarms and reporting of alarm changes.
● Help system with methodology to contact health technical management support

Example of Intended Use
A nurse practitioner enters a patient room and desires to check and adjust if necessary a device that monitors patient conditions, for example a pulse oximetry monitor that measures oxygen levels in the blood.

She cannot recall the exact settings needed for the device. She uses her hospital approved wireless device (smart-phone, tablet, etc..) and starts the ASIM website. She signs-in to the ASIM and looks for identifying marks on the pulse oximetry device.

She enters the model number of the device and a photograph of the device displays on the screen along with the full manufacturer, model number and make. The nurse confirms that this is the device in question and continues. She has the option to view the settings screens for the device, the hospital policy or the ability to ask for help. She chooses the setting screen chooses the age group for her patient (patient population). She is reminded that the medical device is set to pre-approved operating parameters for alarm high and low conditions, and according to policy, settings are routinely verified.

Policy indicates that if she desires to set the device to parameters outside the pre-approved range, she should get approval from the Nurse Manager.

The nurse verifies that her settings are in the correct range on the medical device.

ASIM indicates that she should verify that the alarm annunciator icon on the medical device matches the picture on her mobile device. She confirms that the medical device is set properly. Optionally she may see a message that to silence or suspend the alarm annunciator sounds that she must follow hospital policy.

The nurse can feel confident that the medical device is set to the intended parameters and that she is acting according to the policy of her hospital. She knows that if she can easily contact technical support with any questions.

Results

Research
Alarm Fatigue is a multi-headed beast with many factors contributing to the problem. Initial expectations for this project led to the belief that a technological solution was best for managing existing alarms events. This project began with the premise that, if alarm sounds from devices in each patient room could be captured and analyzed, that
algorithms could be built to recognize alarm sounds by their auditory signal (much like a bird call,) and this analysis could then send high-priority alarms to some staff and send medium and low priority alarms to technical staff. This was certainly a technologically feasible solution. While researching for similar existing products, this concept appeared a unique application in the medical environment, but it did not address the quantity of alarm signal events.

**Activities by Others**

It became apparent through research that there were many companies already working on taming the alarm beast in a variety of ways:

- **Central Monitoring** - This concept gathers existing alarm signals, aggregates them and displays them in central stations (on or off site) with “alarm watchers”... people paid to sit and watch alarm events and then act on them.
- **Alarm Transferring** - Copying the alarm signals and transferring them to digital displays, hallway annunciators or even transferring them to mobile devices. These systems are often called “middleware”.
- **Alarm Escalation** - Gathering alarm signals, transmitting them to first tier nurses and if the alarm is not responded in time, escalate the alarm to second tier responders, etc.

Each of the above systems does nothing to address the quantity, the type or the underlying cause of alarm event.

**Further Research**

Seeing the already crowded field of middleware and systems approach for post-alarm processing, further research indicated that there were ways of reducing the quantity and types of alarms based on proper configuration settings of medical devices. Hospitals (Boston Medical ⁹, Johns Hopkins and others) were gathering data to determine the scope of the problem and the types of alarms most often occurring. Alarm signal event reductions were achieved in several using several methods but the most promising solutions seemed to point to changes in medically appropriate settings on monitoring devices:

- Adding delays to some alarm thresholds that would wait a period of time before audible alarms, allowing conditions to reset on their own
- Adjusting sensing thresholds to measurements that better represent either the patient-population range or to a more specific individual patient’s range
- Reviewing parameters in general, some of which may be set on decades-old data

It was found that when nurse-teams were given permission (with proper authority and checks and balances) to adjust parameters, fewer alarm conditions resulted, allowing for a quieter ward and more attention paid patient care overall.

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National Patient Safety Goal
The ECRI, Joint Commission has identified patient safety goals to address the problem of alarm fatigue by recommending in Elements of Performance for NPSG.06.01.01:

1. As of July 1, 2014, hospital systems should recognize alarm hazards as a priority

2. During 2014, hospitals should establish guidelines for which are the most important alarm signals to address based on staff input, published guidelines, review of equipment and risk to patients.

3. As of January 1, 2016, hospital systems should establish policy to manage medical devices with alarm capacity to specify who may change, disable or alter alarm settings and when, how often alarm devices should be inspected and default settings.

4. As of January 1, 2016, hospitals should educate staff about policy and proper use of alarm settings and equipment parameters.

These National Patient Safety Goals provided the insight to the focus of this project:

How best to reduce the quantity of alarm signal events, thereby reducing alarm fatigue?

- Provide education to the clinical staff about adjusting parameters along with other hospital-tested techniques AT THE SAME TIME as providing the hospital-specific policy about alarm settings.
- Where best to provide this service? At the point-of-care; empowering nurses to make the correct choices about settings while being guided by hospital policy.
- How to deliver this content? A web application accessible from mobile devices and computers such as smartphones, tablets and laptop computers.
- Who should have access? All clinicians within a hospital system, with username and password authentication.

Commercial Opportunities
Providing timely and relevant device and policy information to clinical caregivers at the point of care could reduce false or non-actionable alarm signals and improve the quality of care and the environment of the ward. A secondary benefit would be to reduce the effects of alarm fatigue on clinicians that may in turn reduce the potential for indirect medical mistakes.
This project needs further testing to determine the rollout for individual hospital systems. As it is designed, content would be customized per hospital system to include the following components:

- Medical device inventory, limited to bed-side monitors with alarm capabilities
- Hospital Policy pertaining to medical device settings and authority

Sales efforts would include identifying potential hospital systems, coordinating with alarm committees or task forces within the hospital to identify content and schedules. The American Hospital Association indicates there are close to 6,000 registered hospitals representing over 900,000 beds. These facilities and potentially others including nursing homes may prove to be a basis for a scalable product.

Some hospitals are grouped into systems and sub-systems including wards or divisions. The quantity of medical devices included in the inventory for this project will vary dramatically from one hospital system to the next. The product could be designed to sort devices by sub-system, ward or division as desired. A per-bed pricing structure may prove to be the model to utilize, as the patient to caregiver ratio varies from 1:1 to 1:6. This would determine the quantity of clinicians, accounts needed and complexity of the end product.

Cost Structure:

- Initial consultation, inventory assessment and policy assessment
- Knowledgebase build
- Annual Subscription (hosting, user management)
- Change orders Policy and Inventory updates
Several existing software platforms were tested for database creation and compatibility with various device platforms and screen resolutions. It is a conclusion that there are
existing software products that could be adapted to this market. Criteria for product functionality include:

- Responsive design - viewable on all mobile devices with web browsers
- Article creation - being able to add articles with any desired content
- Tagging - the ability to tag articles by:
  - Topic
  - Title
  - Manufacturer
  - Model number
  - Device type
  - Patient population
- Customization - providing hyperlinks, popups, custom pages, etc.
- Security - providing user management, local or web delivery (intranet or internet)

Conclusions and Recommendations

One finding from this project is the fact that it takes an enormous amount of research to learn about a new field of study. There are layers of complexities, factors from outside influences and interested parties that bring new insights to the onion-like layers as a field is uncovered.

My wife often commented that I had no “permission” delving into the medical environment. She said that I had no first-hand interest or connection with the field. I wrestled with this concept of “permission” for the last 18 months, trying to understand where permission comes from and who grants them. The second finding is that permission is something you earn, through the act of acquiring knowledge about a topic or endeavor. I agreed with her then and still do now, but I know that I have learned enough about alarm fatigue and medical device alarms in general that permission is hard-fought and must continue to be fought for, to remain current and effective.

The area of greatest growth in me from the VCU daVinci Center program was the compartmentalization of the concept of “idea.” Prior to the program, “idea” was God, and “idea” was complete unto itself. Now, an idea without testing is not worth much. Testing of an idea holds it up to various measurements: validity; place; appropriateness; value; marketability; manufacturability, and more. Now, an idea is just a seed; a tiny component of a greater system that, if provided the correct circumstances, would flourish. The environment that ideas must confront is harsh, exacting and fickle, but not impossible.

If I were to continue this project and move into product development, the project would need a team of medical advisors; nurses, hospital administrators and web developers to
fast-track prototyping into the hands of pilot hospital sites for measured data gathering before during and after rollout. A sales team would have to be assembled to hit the market quickly, to sell the product in advance of the January 2016 National Product Safety Goal.
# Innovation Canvas

<table>
<thead>
<tr>
<th>Cost/Price</th>
<th>Feasibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design, implement, and launch the prototype. The launch is quick.</td>
<td>Defined with clear expectations. Responsibilities are assigned to each team member.</td>
</tr>
<tr>
<td>Estimated cost of stock purchase for inventory assessment, policy, etc.</td>
<td>Determined with a focus on cost efficiency and inventory management.</td>
</tr>
</tbody>
</table>

**Disadvantages**
- Cost and feasibility challenges.
- New components and software may require extensive training.
- The technology may be in its early stages, affecting its reliability.
- Privacy concerns and data security.

**Features**
- 3D printing technology.
- Internet of Things (IoT).
- Mobile app development.
- Cloud storage solutions.
- Blockchain for secure transactions.

**Timeline**
- **Q3 2014**
- **OC 2014**

**Team**
- Jim Robb
- Project Lead/Team

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**Notes**
- The project timeline is flexible, allowing for adjustments as needed.
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Appendices

Key Terms

**Alarm Fatigue** – The condition of stress, inattentiveness or error as a result of overabundance of alarm signals, both audible and visual

**ASIM** - The Alarm Signal Instruction Manual

**Bar Code** – machine-readable code for identification

**ECRI** - Emergency Care Research Institute

**ECG** – Electrocardiogram

**EMR** - Electronic Medical Records

**ICU** - Intensive Care Unit

**Lead Off** - refers to a condition where electrocardiogram (ECG) device electrodes adhered to a patient’s skin becomes detached

**Middleware** – software and hardware systems situated between medical devices and central monitoring stations or communication networks

**QRCode** – machine-readable code for identification. Often used with smartphones

**SpO2** - peripheral capillary oxygen saturation via pulse oximetry

**VCU daVinci Center** – sub-department of the Virginia Commonwealth University School of Business

Biography

Specializing in innovative solutions to solve complex problems, Jim combines years of creative experiences together to bring positive change to organizations.

Jim recently completed his Masters of Product Innovation degree at Virginia Commonwealth University's daVinci Center, bridging art, business and engineering.

Teaching 3D computer design courses since 1999, Jim recently completed co-teaching Technology Principles for Product Innovation at the VCU daVinci Center. This teaching opportunity expands Jim’s teaching offerings this year to include a 3D Modeling and Rendering course at Reynolds Community College and a STEM course at St. Catherine's School. Jim has used 3D printing technologies in his courses since 2005.

As Associate Director of Marketing for St. Catherine’s School, Jim is a passionate change agent, managing the online environment including the website, the student information system database and multimedia content while looking to the future for what is coming next. He creates dynamic and compelling photos and videos for St. Catherine’s.
In addition Jim is a 3D content provider at design4today. Since 1992, Jim has specialized in retail, interior, architecture and museum visualization, bridging AutoCAD Architecture, REVIT, 3ds Max, VIZ and Sketchup to bring interesting solutions to complex projects. Jim has worked with Kendall Buster, Sculptor and VCU professor for 7 years providing 3D design services to enhance design workflow.

In the 1990's he was founding president of the Central Virginia Electric Auto Association, a chapter of the EAA national organization. Jim's group helped individuals convert cars and trucks to electric power. Jim's own 1973 VW bug conversion was featured in many Earth Day and electric car shows. The group sponsored a member's electric car in the 1996 American Tour de Sol event which traveled from New York City to Washington DC.

Proposed Site Map of Knowledge Base application
https://sites.google.com/a/mymail.vcu.edu/seh/
Site map indicates example data in the SpO2 category for two example patient monitors.