Redesigning Hospital Alarms for Patient Safety: Alarmed and Potentially Dangerous

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ABSTRACT

Alarm safety is one of healthcare's most high-profile and intractable problems. A phenomenon known as "alarm fatigue", including limited capacity to identify and prioritize alarm signals, has led to delayed or failed alarm responses and deliberate alarm de-activations. Alarm fatigue has been implicated in patient deaths, some highly publicized. There is a growing acknowledgement that this acoustical problem results in hundreds of identified patient deaths and thousands of injuries. The healthcare facilities industry, however, has been slow to recognize that "alarm fatigue" is in part a facility design issue.

Many factors contribute to alarm fatigue, but perhaps most significant is a false alarm rate as high as 83-85%; these large numbers of clinically irrelevant signals directly contribute to staff desensitization. In addition, high background noise levels in critical care and variable acuity units and in operating rooms contribute to alarm response failures by further increasing the cognitive load on staff, escalating distraction and irritability, and complicating discernment, attribution and communication. Noise levels in hospitals have been rising for decades and are far higher than guideline values established by the World Health Organization.

This paper identifies multiple levels of influence and opportunities for system intervention and innovation to facilitate timely alarm responses. These include addressing the broader acoustic context, clinician responsibility, deployment and teamwork training, threshold-setting guidelines, improved user interfaces, and algorithms balancing specificity and sensitivity.

Hospitals need a system-wide alarm policy and protocols that define the alarm management strategy for alarmed medical equipment, and delineate how caregivers/nurses respond to alarm conditions and signals. It is imperative to use a human factors approach based around the hospital's culture and engage architects, designers, acoustical engineers, facility engineering, staff and clinicians to address alarm fatigue and its implications on the physical built environment. Involving patients in the redesign of hospital acoustic environments may also improve patient experiences and satisfaction with their hospital care.

INTRODUCTION

> *Unnecessary noise, then, is the most cruel absence of care which can be inflicted either on sick or well.*
>
> *Florence Nightingale, 1859*

In the 150 years since Florence Nightingale wrote about the adverse effects of noise on hospital patients, others have noted the problem, but it is still not recognized as a major cause of harm. Noise control in U.S. healthcare environments grew as a priority after the publication of landmark papers in 2004, documenting the gradual and detrimental rise in worldwide healthcare noise levels since 1960 and the noise-related medical errors. Consequently, noise in healthcare environments is becoming recognized as a serious health issue, increasing staff stress and absenteeism, hindering patient healing, and causing patient injury and death (Chopra 2014).

CHARACTERISTICS OF SYSTEMS AND RISK MANAGEMENT FRAMEWORK

A healthcare system includes several sub-components. The foremost are the medical or clinical processes, which are undertaken. Another component is technology, medical and non-medical. This would include information systems, diagnostic systems, imaging systems as well as mundane technologies such as floor cleaning equipment, supply ordering and distribution technologies. Next there is organization, the administrative arrangement that includes policies, procedures, strategies and tactics, management tools, business plans, etc. Providers are another subsystem. They include professional, technical, administrative, management, patient, public, government and others. Finally, the designed, built environment is a subcomponent and includes a large number of characteristics (Amalberti 2005).

Charles Perrow studied major accidents and discovered that systems, rather than individuals, were often at fault (Perrow 1984). Perrow and James Reason re-defined how we should proceed to understand causes of accidents and fix problems (Reason 1997). One of Perrow's contributions was to describe how the components of systems relate. He defined two scales, complexity and coupling, which explained how components of systems react. There are many subcomponents, some characteristics of the system are hidden, and they require "operators" to use a great deal of short-term memory or computing power. Healthcare facility planning and designing are also tightly coupled in that there is no "wiggle room" in the connections. If one component fails, the adjoining components are immediately impacted, sometimes in unforeseen ways.

There has been an important reconceptualization in healthcare about clinical risk through emphasizing how upstream 'latent factors' enable, condition or exacerbate the potential for 'active errors' and patient harm. Understanding the characteristics of a safe, resilient and high-performing microsystem requires research to optimize the relationship between people, tasks and dynamic environments. The socio-technical approach suggests that adverse incidents can be examined from both an organizational perspective that incorporates the concept of latent conditions and the cascading nature of human error commencing with management decisions and actions. Organizational resilience is found in the responsiveness of delivery crews to an emerging hazard.

Noise engineers and medical personnel generally have been working separately on noise issues, with limited progress and implementation of their findings. With the new urgency for improvement, multidisciplinary teams have been formed to produce actionable research and evidence based design initiatives. This collaboration between medicine and engineering has produced data on physiological responses, healthcare outcomes, and economic impact, which all have more influence on policy making than the historic assumption that noise is nothing more than an annoyance.

While progress has been made in the built-environment, changing healthcare worker behaviour and the healthcare culture has proven to be more challenging.

Hospital noise routinely exceeds international, WHO noise acceptable standards and is more than just an annoyance (Busch-Vishniac 2005). A growing body of research about the harmful effects of noise in the healthcare environment along with the new financial and regulatory incentives has advanced noise control in healthcare facilities to a top priority (Joseph 2007). The end goal is increasing patient outcomes, staff comfort and establishing a healthy environment for all.

This failure to provide patients with quiet rooms affects clinical outcomes through several mechanisms, including sleep deprivation, cardiovascular derangements (increased heart rate and blood pressure), poor wound healing, higher incidence of rehospitalisation, patient falls, pain, stress and dissatisfaction. Moreover, poor acoustic clinical environments are associated with excessive cognitive load on staff, and interference with speech and communication among healthcare professionals, both of which can increase risk of medical errors and patient harm.

HUMAN FACTORS AND SITUATION AWARENESS IN ALARM MANAGEMENT

Human factors research is of great relevance in designing healthcare facilities and in considering the impact of the many “performance shaping factors” that can degrade human capabilities (Table 1). One of the most important decision-making skills by healthcare teams is to decide what to devote attention to and what can wait. Where data overload is the rule and the patient’s status changes continually, the ability to recognize clinical cues quickly and completely, to detect patterns, and to set aside distracting or unimportant data can be lifesaving. Situation awareness (or situation assessment) is a comprehensive and coherent representation of the (patient’s) current state that is continuously updated based on repetitive assessment (Sarter 1991).

Situation awareness appears to be an essential prerequisite for the safe operation of any complex dynamic system. In the case of healthcare, establishing and maintaining a “mental model” of the acute patient and the associated care facilities, equipment, and personnel are essential to effective situational awareness. Successful team situational awareness requiring constant communication that enables members to converge around a shared mental model of the situation and course of action and quickly course correct as needed (Endsley 1995). Effective teams adapt to changes in task requirements, anticipate each other’s actions and needs, monitor the team’s ongoing performance, and offer constructive feedback to other team members. When team members share a common mental model of the team’s ongoing activities, each may “instinctively” know what each of their teammates will do next (and why) and often communicate their intentions and needs non-verbally (sometimes called implicit communication).

MEDICAL DEVICES

Monitoring devices that process complex data streams should produce clinically relevant alarm signals, in environments optimized for discernment and attribution, with user interfaces designed for timely interpretation, prioritization and prompt action. Addressing alarm fatigue requires regulators, manufacturers and clinical leaders to recognize the importance and context of human factors and staff behavior, with design and evaluation of devices accomplished through clinical simulations.

Medical device alarms are deliberately designed to alert attention (Graham 2010). Medical device alarms can make the difference between timely, life-saving interventions and serious injury or death. Physiologic monitors, ventilators, infusion pumps and many other devices generate clinical alarms to help caregivers keep patients safe (Rvherd 2008).

Table 1 Examples of performance shaping factors affecting alarm management.

Performance shaping factor	Example
Individual factors	Clinical knowledge, skills, and abilities Cognitive biases Risk preference State of health Fatigue (including sleep deprivation, circadian)
Task factors	Task distribution Task demands Workload Job burnout Shiftwork
Team/communication	Teamwork/team dynamics Interpersonal communication (clinician–clinician and clinician – patient) Interpersonal influence Groupthink
Environment of care	Noise Lighting Temperature and humidity Motion and vibration Physical constraints (e.g., crowding) Distractions
Equipment/tools	Device usability Alarms and warnings Automation Maintenance and obsolescence Protective gear
Organizational/cultural	Production pressure Culture of safety (vs. efficiency) Policies Procedures Documentation requirements Staffing Cross coverage Hierarchical structure Reimbursement policies Training programs

But most of the noises are false alarms or don't require action. The ventilator sounds a warning because a patient coughs. The infusion pump beeps after running out of a

medication the patient no longer needs. The blood pressure monitor goes off after a nurse adjusts a catheter in the patient's artery.

Conditions found in most hospitals produce an unintended consequence triggered by alarms called "alarm fatigue" that is not attributable to individually alarmed devices but rather to the aggregate conditions in which the alarms occur. "Alarm fatigue" a condition in which confusion and stress caused by loud and conflicting signals leads to dangerous, life-threatening behaviours (Blum 2010).

However, it is possible to have too much of a good thing. Excessive numbers of alarms—particularly alarms for conditions that aren't clinically significant or that could be prevented from occurring in the first place—can lead to alarm fatigue, and ultimately patient harm. That is caregivers can become overwhelmed, unable to respond to all alarms or to distinguish among simultaneously sounding alarms. They can become distracted, with alarms diverting their attention from other important patient care activities. They can become desensitized, possibly missing an important alarm because too many previous alarms proved to be insignificant (Mahmood 2011).

Beyond alarm fatigue, patients could be put at risk if an alarm does not activate when it should, if the alarm signal is not successfully communicated to staff or does not include sufficient information about the alarm condition, or if the caregiver who receives the alarm signal is unable to respond or is unfamiliar with the proper response protocol. In short, any circumstance that results in the failure of staff (1) to be informed of a valid alarm condition in a timely manner or (2) to take appropriate action in response to the alarm can be considered a clinical alarm hazard.

In an April 2013 Sentinel Event Alert, the Joint Commission cited 98 alarm-related events over a three-and-a-half-year period, with 80 of those events resulting in death and 13 in permanent loss of function (www. jointcommission.org/sea_issue_50/). In June, the organization announced that alarm management would be established as a National Patient Safety Goal, with certain provisions taking effect during 2014.

Addressing clinical alarm hazards requires a comprehensive alarm management program involving stakeholders from throughout the organization. Goals for the program should include (1) minimizing the number of clinically insignificant or avoidable alarms so that the conditions that truly require attention can better be recognized and (2) optimizing alarm notification and response protocols so that the patient receives the appropriate care at the time it's needed.

Improving acoustic environments of hospitalized patients can decrease re-hospitalization rates, improve sympathetic arousal and raise patient satisfaction as compared with "ordinary" hospital environments. Reduced noise was the most common item reported by hospital executives to improve patient experiences. Almost 90% reported the primary driver was for patients to sleep better. Interestingly, other top reasons included patient reported outcome measures (PROM): help patients recover faster (75%), improve stress/anxiety (67%) (Wolf 2014).

ORGANIZATIONAL ENVIRONMENT-THE ROLE OF CLINICAL MICROSYSTEMS

Noise and alarms exist within the context of a technology, providers and patients—a system. A system is a set of interacting, interrelated, or independent elements that work together in a particular environment to perform the functions that are required to achieve a specific aim (Bertalanffy 1968). A clinical microsystem is a group of clinicians and staff working together with a shared clinical purpose to provide care for

a population of patients (Batalden 2003). The clinical purpose and its setting define the essential components of the microsystem, which include clinicians, patients, and support staff; information and alarm technology; and specific care processes and behaviours that are required to provide care. The best microsystems evolve over time, as they respond to the needs of their patients and providers, as well as to the external pressures such as regulatory requirements. They often coexist with other microsystems within a larger (macro) organization, such as a hospital (Mohr 2003).

The conceptual theory of the clinical microsystem is based on ideas developed by Deming (Deming 1986) and others. Deming applied systems thinking to organizational development, leadership, and improvement. The seminal idea for the clinical microsystem stems from the work of James Quinn (Quinn 1992). Quinn's work is based on analysing the world's best-of-best service organizations, such as FedEx, Mary Kay Cosmetics, McDonald's, and Nordstrom. Quinn focused on determining what these extraordinary organizations were doing to achieve consistent, high quality, explosive growth, high margins, and robust consumer loyalty. He found that these leading service organizations organized around, and continually engineered, the front-line relationships that connected the needs of customers with the organization's core competency. Quinn called this front-line activity that embedded the service delivery process the smallest replicable unit or the minimum replicable unit. This smallest replicable unit, or the microsystem, is the key to implementing a reliable, effective strategy to provide safe and consistent outcomes.

The microsystem also includes knowledge, equipment, and work tasks. The microsystem concept is based on an understanding of systems theory coupled with Quinn's theory of a smallest replicable unit. Nelson and his colleagues have described the essential elements of a microsystem as (1) a core team of health care professionals; (2) a defined population they care for; (3) an information environment to support the work of caregivers and patients; and (4) support staff, equipment, and work environment. Linking performance, technology and outcome data to the microsystem model provides a helpful way to identify potential areas for improvement that does not focus on the individual, but instead on the system that is producing the processes and outcomes of care.

In the late 1990s, Donaldson and Mohr investigated high-performing clinical microsystems. The research was based on a national search for the highest-quality clinical microsystems. The analysis of the interviews suggested that ten dimensions, shown in Table 2, were associated with effective and successful microsystems.

Table 2 Ten Dimensions of Clinical Microsystems.

1. Leadership
2. Organizational support of clinicians
3. Staff focus
4. Education and training
5. Interdependence of team members
6. Patient focus
7. Community and market focus
8. Performance results
9. Process improvement
10. Medical devices and information technology

NEW PROCESS FOR HEALTHCARE DESIGN AND PROCUREMENT

Rather than trying to improve a process, which has demonstrably yielded inadequate results, we suggest that a new process be created. The proposed design process for patient safety should include three goals:

- Reduce the enterprise and patient risk of health care associated (caused by treatment including noise) injury to patients and health care providers.
- Remove or minimize hazards including ambient noise, which increase risk of health care associated injury to patients.
- Educate the design team in systems and human factors thinking, and in the complexity of designing health care settings for safe outcomes.

The strategy that we advocate for achieving these goals incorporates the following concepts:

- Treat the creation of safety as part of a process that addresses the safety and integration of all system components, i.e., as part of the culture.
- The “creation of safety processes” involves users and stakeholders at all levels of the institution including the patients and the community in which the facility will reside.
- A complete array of disciplines and knowledge is necessary at the start of the project.
- Use a wide range of risk management tools including: Failure Modes Effect Analysis (FMEA), Root Cause Analysis (RCA), mock-ups, simulation, testing, data modeling, etc.
- Create and require team education about the patient safety problem, about the process of building design, and about the process of collaboration with others to derive effective and efficient solutions.
- Gain appreciation that designing for safety is an iterative and emerging process.

These strategies apply to the planning and design of all areas of health care facilities. The building codes and regulations need to be modified to allow these changes to occur (Dickerman 2005). Regarding the built-environment, the 2014 edition of the Guidelines for the Design and Construction of Health Care Facilities, a document used or referenced in 42 American states and in 60 countries, has a greatly expanded acoustics section covering a wide range of topics from acoustical finishes and sound isolation to paging systems and noise-related safety risk reduction (Facility Guidelines Institute 2014). Furthermore, sustainable building design initiatives, which have become increasingly popular in the U.S., have included acoustics as a design consideration since 2009.

The weaknesses of the present planning and procurement process are exactly the opposite of its strengths. Because of the rigid structure, disciplines that would benefit by cross-pollination and collaboration rarely have the ability or headroom to have that opportunity. For instance, a decision about a medical process might be made before all available technologies and equipment are considered. Opportunities to improve process to achieve greater efficiency and quality are artificially limited. Rarely in these instances have we seen adequate research. Because the design/bid/build process is led by a representative of either the architect or the owner, there is little incentive to engage specialized consultants including behavioral scientists that can

help understand how best to design spaces that engage and respect the clinicians who will occupy these spaces.

One example of this is in the area of human factors, or ergonomics research. Although health care buildings contain hundreds of workstations, many of which are used day and night, the extent of design research typically involves asking a few users in a nonscientific manner how high the counter should be and what distractions and noises support or undermine health workers. That same counter is typically designed without specific knowledge of the monitor and computer or other devices to be installed into it and to be used by staff members. It is also designed without consideration of the physical characteristics of the staff who will use it. Engaging human factors engineers, acousticians and other specialists at the outset of the project where they would have a chance to be effective and would disrupt the rigid structure of the conventional project delivery system.

Effective hazard reduction and risk management in healthcare facility planning will require meaningful efforts to address the trust gap that has undermined the success of many projects (Jorm 2012). It will require reframing patient care from one that is task oriented at the level of the practitioner, to a systems based, team based patient-centred model that looks to the actual relationships within the socio-technical microsystems in which care is actually delivered (Barach 2006). At the most basic level, this will involve a re-conceptualization of the patient from the passive object of medical intervention to an active ‘consumer’ or ‘user’ of health services who co-produces and “owns” their own health. Healthcare services are currently too fragmented for effective application of this patient centred model of quality improvement.

ADVOCATING FOR CHANGE TO IMPROVE ALARM MANAGEMENT (FIGURE 1)

Addressing alarm fatigue will require changes in how individuals and teams address noise measures and must be grounded in team theory, account for individual and team-level performance, processes and outcomes, adhere to standards for reliability and validity, and address barriers to measurement. A recent summit (Priority Issues from the Medical 2011) addressed alarm fatigue and in considering the pragmatic aspects of conducting a training program, offered a number of recommendations for research in the clinical setting where alarms must function to help teams delivery safe care (Otero 2009).

Training Recommendations

- Undertake risk analysis of patient populations within acute care facilities to develop standards for monitor assignment and continuation.
- Examine indicators of patient deterioration such as respiration rate, pulse rate/heart rate, systolic blood pressure, pulse oximetry, to determine which indicators should be monitored.
- Design simulation scenarios from reported harm or near misses with trigger events that link alarm fatigue and teamwork skills to training objectives and specific competencies.
- Design a parallel set of scenarios that can be used to evaluate the effectiveness of training these specific competencies.
- Develop and apply measures of success in alarm management.

- Embed training in alarm management into multidisciplinary teams so members train in the context in which they will work.

Figure 1. Alarm Management Program (adapted from ECRI) (Health Devices Nov. 2013)

GUIDING PRINCIPLES IN ALARM MANAGEMENT

The environment has a significant impact on the ability of clinicians to build trusting, therapeutic relationships. The building must support the model of care with appropriate physical, social and symbolic environments. The design process for health care environments needs to be radically changed to address community needs and financial drivers. We are moving from a decade of highly structured top down programs to local ownership and more transparent community partnerships. Engagement strategies need to include (Weick 2009): 1) get clinicians 'moving and experimenting' with their own systems; 2) provide permission, space and time for clinicians to find purpose and set their own direction in partnership with their patients and consumers; 3) direct attention through hyper transparent measuring, collating and sharing of data about ‘what is happening' at the service delivery level; and, 4) 'facilitate respectful interaction' between clinicians and managers.

In making these recommendations our guiding principles are:

- The organizational complexity of healthcare must be recognised.
- Patient-centred health services means that the patient’s perspective and acoustic well-being must be central to all healthcare policy, planning and procurement decision making.
- Quality healthcare includes all aspects of service delivery: clinical and non-clinical.
- Patient safety must be the foundation of acoustic decisions regarding alarm management.
- Systems of care, and facilities, as well as individuals, affect the quality of healthcare.

- Learning from error, rather than seeking someone to blame, must be the priority of health policy makers in order to improve safety and quality.
- Openness and transparency are crucial to the development of trust between health facility procurement and healthcare professionals, patients and consumers, and the wider public.

Creating an environment where a culture of patient safety can flourish is a daunting challenge. Innovation will not happen if participants in the process are not invited or unwilling to think outside the constraints of convention and if they are unwilling to challenge the risk averse nature which characterizes the cultural and intellectual development of so many of our professional and commercial institutions.

CONCLUSIONS

The U.S. FDA, National Patient Safety Foundation and the Joint Commission designated “alarm fatigue” the “#1 priority in healthcare technology. The Joint Commission, an industry-supported organization, that inspects health care facilities and holds them to standards, has made alarm safety a national patient safety goal starting in 2014, signalling that hospitals must give it top priority (Medical device alarm safety in hospitals 2013). By January 2016, hospitals must have plans in place to better manage alarms, including deciding whether specific alarms are needed or unnecessarily contribute to safety concerns, when alarms can be disabled, and who has authority to disable them

Hospitals need a system-wide alarm policy and protocols that define the alarm management strategy for alarmed medical equipment, and delineate how caregivers/nurses respond to alarm conditions and signals. These conditions produce an “acoustic feedback loop" in which noise inevitably and rapidly escalates to intolerable levels and interfere with behaviour. It is imperative to use a human factors approach based around the hospital’s culture and engage architects, designers, acoustical engineers, facility engineering, staff and clinicians to address alarm fatigue and its implications on the physical built environment. Involving patients in the redesign of hospital acoustic environments may also improve patient experiences and satisfaction with their hospital care.

System analysis identifies multiple causes with parallel points for intervention. Chief among these are the high background noise levels in hospital units and ORs, the sheer number of alarms, and the large proportion of these alarms that are redundant or carry no clinical relevance; these alarms raise staff cognitive load and reinforce their desensitization. Improved acoustic environments will deliver a better signal-to-noise ratios and support enhanced alarm discernment with more accurate attribution at lower sound levels. Sufficient staff-to-patient ratios, together with adequate training in configuration and threshold setting, enhanced team coordination and better designed user device interfaces will contribute additional human factor benefits.

Development of more advanced device algorithms is needed to balance the sensitivity and specificity of triggering alarm signals, to block artefacts, and to produce clinically relevant alarms. Real time trend analyses must be conveyed so care can be delivered before full patient rescue is required.

Monitoring devices that process complex data streams should produce clinically relevant alarm signals in environments that are optimized for alarm discernment and attribution, with user interfaces designed for timely interpretation, prioritization and prompt action. Addressing the alarm fatigue crisis will require recognition of hospital

context and the human factors as critical to implementing improved monitoring technology (Borowski 2011).

There is also a compelling role for industry cooperation that would facilitate device linkages to limit alarm redundancy, standardize and scale alarm signals to convey urgency, develop alternative modalities and sensory channels, and enhance options for central oversight.

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