

Using human factors engineering to improve patient safety in the cardiovascular operating room

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Abstract. Despite significant medical advances, cardiac surgery remains a high risk procedure. Sub-optimal work system design characteristics can contribute to the risks associated with cardiac surgery. However, hazards due to work system characteristics have not been identified in the cardiovascular operating room (CVOR) in sufficient detail to guide improvement efforts. The purpose of this study was to identify and categorize hazards (anything that has the potential to cause a preventable adverse patient safety event) in the CVOR. An interdisciplinary research team used prospective hazard identification methods including direct observations, contextual inquiry, and photographing to collect data in 5 hospitals for a total 22 cardiac surgeries. We performed thematic analysis of the qualitative data guided by a work system model. 60 categories of hazards such as practice variations, high workload, non-compliance with evidence-based guidelines, not including clinicians' in medical device purchasing decisions were found. Results indicated that hazards are common in cardiac surgery and should be eliminated or mitigated to improve patient safety. To improve patient safety in the CVOR, efforts should focus on creating a culture of safety, increasing compliance with evidence based infection control practices, improving communication and teamwork, and designing better tools and technologies through partnership among all stakeholders.

Keywords: Safety, Cardiac surgery, Medical error, Human factors

1. Introduction

Despite significant advancements in medical technology and surgical techniques, cardiac surgery is still a high risk procedure. [1-6] For example, it is estimated that 14,000 of the 357,000 patients who will have a coronary artery bypass graft (CABG) or valve procedure in US annually will experience a preventable adverse event.[3;4;7] Based on the UK's National Reporting and Learning System (NRLS),

one of the largest adverse event reporting systems in the world, 21% of the cardiac surgery related medical errors occurred in the operating room, which constitutes approximately only 4% of patient's length of stay in the hospital.[6]

*A human factors engineering approach that uses a proactive hazard analysis may be beneficial to iden-

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tify safety hazards and improve the safety in the cardiovascular operating room (CVOR). The purpose of this study was to identify and categorize safety hazards (anything that has the potential to cause a preventable adverse patient safety event) in the CVOR using an interdisciplinary approach including human factors engineering in addition to medicine, nursing, and health services research. We conducted a qualitative study in five hospitals to uncover and classify potential hazards to patient safety and used the Systems Engineering Initiative for Patient Safety (SEIPS)[8] model to guide our research. The SEIPS model focuses on how the design characteristics of different elements in a care system (provider, physical environment, tools-technologies, tasks, organization) and their interactions affect processes and outcomes (e.g., patient outcomes) in a care system. Safety hazards in a system may occur as a result of inappropriate design of any of the five elements and/or interactions between these elements. The SEIPS model does not focus only on one element of the work system, rather takes into account the complexities of a work system and emphasizes the interactions between different elements. Hence, using this model ensured that we covered all elements of a work system and interactions between them while identifying hazards. This paper reports findings from a larger, multi-site, and interdisciplinary study called LENS. The LENS study was conducted by the Johns Hopkins Quality and Safety Research Group as part of an initiative sponsored by the Society of Cardiac Anesthesiologists to achieve harm-free cardiac surgery called the FOCUS project.[9]

2. Methods

We used direct observations, complemented by contextual inquiry and photographing, to prospectively identify and classify safety hazards in the CVOR in a multi-site study. An interdisciplinary research team including one human factors engineer, one cardiac anesthesiologist, one nurse, and one health services researcher collected data during the 2.5 day site visits to 5 US hospitals. Twenty on-pump cardiac surgeries were observed (total observation time=over 160 hours), contextual inquiries with 84

care providers were conducted, and 327 pictures were taken.

During observations, each researcher independently took handwritten notes of any single or multiple related hazard(s), which were typed within a week of each site visit. Each picture was reviewed and a description of the hazard(s) illustrated was written. Each focused event or information from observations, contextual inquiries and photographing were treated as a single data point, known as stanzas in qualitative research.[10] An iterative approach was used in developing the 3-level classification scheme and the actual data coding using NVivo 8©. The top level of categories was based on the SEIPS model and included provider, tasks, tools/technologies, organization, physical environment, and processes.

3. Results

We identified 55 types of hazards related to the five components of the CVOR work system. A shortened list of these hazard categories and some of the corresponding qualitative data samples are included in Table 1.

4. Discussion

Hazards to patient safety were nearly ubiquitous in CVOR, which is probably not surprising given the complexity of the cardiac surgery procedures and the limited research conducted on improving patient safety in the CVOR using a human factors engineering approach. The extent of non-compliance with evidence based guidelines, usability problems of tools and technologies, practice variations among care providers within the same institution, poor teamwork, and hierarchical nature of the organizational culture were some of the hazards that were common across sites. Future research and quality improvement efforts should focus on creating a culture of safety in the CVOR, increasing compliance with evidence-based infection control practices, improving communication and teamwork among care providers, and developing a partnership among all stakeholders to improve design of tools and technologies.

Table 1
Classification of immediate perioperative cardiac surgery hazards

Work-system components	Hazards	Specific examples/ Cases
Provider	<ul style="list-style-type: none"> - Inadequate/ lack of knowledge or skills due to lack of education, experience or training. - Inadequate/ lack of professionalism - A non-standardized approach to care delivery due to habits, preferences, education, and previous experiences of individual care providers. 	<p><i>Surgeon asked for a Kelly clamp mid procedure. Scrub nurse thought he meant someone in the room named "Kelly." Surgeon exasperated: "Kelly, that is different from those. No, not Kelly the girl, have you ever heard of a Kelly clamp?"</i></p>
Task	<ul style="list-style-type: none"> - Unexpected fluctuations in demand (e.g. adding a new non-emergency case to the OR schedule), unnecessarily increased workload - Production pressures - Non-value adding tasks - Complexities and ambiguities due to the individual care provider preferences - Interruptions 	<p><i>Perfusionists use paper-based forms during the surgery for documentation. After each case is completed, they enter the same information into the computer in the perfusion room</i></p>
Tools and Technologies	<ul style="list-style-type: none"> - Poor usability - Inadequate safety features - Safety features/ measures not fitting to users' needs or work as intended - Size (too large, bulky) - Use of tools /technologies /supplies with different design characteristics across operating rooms and ICUs. - Information technology not being integrated across the peri-operative area and the ICU. - Hardware/software issues except those related to design/usability of the software - A tool/technology not being at hand when needed. 	<p><i>The timer on the perfusion machine does not start automatically when cardioplegia gets started to be administered. Perfusionists need to start the timer for keeping an eye on the duration of cardioplegia administration themselves.</i></p>
Physical environment	<ul style="list-style-type: none"> - Layout problems due to the long distance of OR suites to ICU and central supplies/lab area (e.g., no point of care labs), size and layout of the operating room - Non-standardization of workspace designs across different operating rooms - Equipment and supplies beyond reach of care providers - Cluttered workspace due to poor configuration, inadequate storage and poor organization of tools, equipment, furniture, and cables - High noise levels, sub-optimal room temperature, illumination-related issues 	<p><i>Very narrow space between door by scrub sinks and getting in the room. High risk for bumping something.</i></p>
Organization	<ul style="list-style-type: none"> - Culture related factors such as focus on productivity in expense of patient safety, hierarchical culture etc. - Inadequacy or lack of necessary education/training and experience of staff. - Unavailability of good policies and protocols - Inadequate or lack of reinforcement of policy and protocols - Absence of ancillary service in the operating room area and/or inadequate staffing - Not considering front-line care providers' input in purchasing decisions - Management's poor resource allocation policies and approaches - Team members lacking non-technical skills - Care system design not supporting teamwork - Inadequate mechanisms to hold individual team members accountable 	<p><i>The hospital had purchased a new type of cautery gun but failed to train OR staff and surgery staff on the use of the gun. Later discussion revealed that this was not a first-time occurrence and was likely due to cost saving methods resulting from decreases in revenue.</i></p>

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