



Identifying and categorising patient safety hazards in cardiovascular operating rooms using an interdisciplinary approach: a multisite study

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ABSTRACT

Background: Cardiac surgery is a complex, high-risk procedure with potential vulnerabilities for patient safety. The evidence base describing safety hazards in the cardiovascular operating room is underdeveloped but is essential to guide future safety improvement efforts.

Objective: To identify and categorise hazards (anything that has the potential to cause a preventable adverse patient safety event) in the cardiovascular operating room.

Methods: An interdisciplinary team of researchers used prospective methods, including direct observations, contextual inquiry and photographs to collect hazard data pertaining to the cardiac surgery perioperative period, which started immediately before the patient was transferred to the operating room and ended immediately after patient handoff to the post-anaesthesia/intensive care unit. Data were collected between February and September 2008 in five hospitals. An interdisciplinary approach that included a human factors and systems engineering framework was used to guide the study.

Results: Twenty cardiac surgeries including the corresponding handoff processes from operating room to post-anaesthesia/intensive care unit were observed. A total of 58 categories of hazards related to care providers (eg, practice variations), tasks (eg, high workload), tools and technologies (eg, poor usability), physical environment (eg, cluttered workspace), organisation (eg, hierarchical culture) and processes (eg, non-compliance with guidelines) were identified.

Discussion: Hazards in cardiac surgery services are ubiquitous, indicating numerous opportunities to improve safety. Future efforts should focus on creating a stronger culture of safety in the cardiovascular operating room, increasing compliance with evidence-based infection control practices, improving communication and teamwork, and developing

a partnership among all stakeholders to improve the design of tools and technologies.

INTRODUCTION

Cardiac surgery is a high-risk procedure despite significant reductions in associated morbidity and mortality over the past 30 years.¹ Each year, 28 000 of 357 000 patients undergoing a coronary artery bypass graft or valve procedure in the USA experience an adverse event,² approximately half of these are likely preventable.^{3 4} Furthermore, one-third of deaths following bypass graft surgery may be preventable.⁵

Patient safety efforts have seen little progress over the last decade towards safer care.^{6 7} Likely impediments are less rigorous or comprehensive methods to identify safety hazards and implement effective solutions.⁸ In the area of surgical safety, research is largely outcome driven and retrospective, limiting our understanding of structure and process variables that affect patient outcomes. To understand these variables in the cardiovascular operating room (COR), we must broaden our research methods and conduct prospective studies, including observational field studies.^{9 10}

Studies have identified specific safety hazards during cardiac surgery,^{11–14} but only few have used an interdisciplinary approach to compile these hazards.^{15 16} Yet, patient safety is inherently interdisciplinary and each discipline will ‘see’ different hazards in a care system. Collectively, researchers from various disciplines could provide a more

complete picture of hazards and opportunities to improve them.

The Locating Errors through Networked Surveillance (LENS) study was part of the Flawless Operative Cardiovascular Unified Systems initiative, and funded by the Society of Cardiovascular Anaesthesiologists Foundation. The LENS study was conducted by researchers from the Johns Hopkins Armstrong Institute for Patient Safety and Quality, and used multiple retrospective^{14 17} and prospective methods¹⁸ and an interdisciplinary team to identify patient safety hazards in cardiac surgery. This paper describes the categorisation of data prospectively collected in the LENS study to identify hazards in the COR.

METHODS

Study design

We used direct observations and contextual inquiry (researchers observing participating clinicians while they work and asking them questions to get information relevant to the study),¹⁹ complemented by on-site photographing, to prospectively identify hazards at five hospitals performing cardiac surgery and develop a classification scheme of these hazards. Sites were chosen using purposive sampling (based on cardiac surgery volume, teaching status, hospital size and geography)¹⁸ and included two academic medical centres, one non-teaching community hospital, and two community teaching hospitals. The interdisciplinary LENS research team included experts in health services research, clinical medicine, human factors engineering, organisational sociology, and industrial psychology. Our approach in using an interdisciplinary group of external technical experts that proactively identified hazards without fear of judgement or regulatory sanction was based on the peer-to-peer review program implemented by the World Association of Nuclear Operators. This approach played a significant role in improving safety and reliability in the nuclear industry.²⁰ The Systems Engineering Initiative for Patient Safety (SEIPS)²¹ model, which contends that safety hazards can emerge from the elements of a care system, was used for data analysis. The overall study was approved by the Johns Hopkins University Institutional Review Board (IRB) through expedited review with no consent required for the data collected for this analysis. Each hospital also obtained local IRB approval; details have been published.²²

Data collection and sample

Data for this study were collected during two 2.5-day visits to each site. Site visits were completed between February and September 2008. The direct observations

and contextual inquiries were conducted during the perioperative period; starting immediately before the patient was transferred from the pre-anaesthesia care unit to the COR and ending immediately after patient handoff to the intensive care unit (ICU)/post-anaesthesia care unit.

Contextual inquiry involved researchers observing and probing clinicians in the context of their work (without an interview guide) to gather more information, come to a deeper understanding, and/or clarify what they just observed. When clinicians are interviewed in their work environment, the data obtained are typically richer and more realistic.¹⁹ The researchers used three strategies to collect data using the contextual inquiry method:

1. A clearly agreed upon research focus.
2. Active listening to clarify what was observed and described by repeating what the researcher heard back to the participant.
3. A master–apprentice model, wherein the researcher was the apprentice and the participant was the mentor. Hence, the researchers did not attempt to show participants better ways of doing their work during data collection.¹⁹

Photographs of the physical environment and tools and technologies complemented the other data collection methods. Patients and providers were not photographed. There were two LENS team observers per case (one clinician and one non-clinician), drawn from one cardiac anaesthesiologist, one nurse, one human factors engineer and one health services researcher. All handwritten notes from observations and contextual inquiries were typed into transcripts by each observer within 1 week of completing the site visit. Four researchers jointly reviewed the photographs, identified hazards and typed up a description of the hazards that were not already covered in the transcripts.

Data analysis

We conducted qualitative content analysis²³ to condense the raw data into categories of hazards. Each event or theme was treated as a single data point or segment and entered into NVIVO8© (QSR International Pty, Cambridge, Massachusetts, USA) to develop the classification scheme and code the qualitative data. We used deductive and inductive reasoning in our data analysis. The overall analysis, including the identification of the major (top-level) categories of hazards, was based on the SEIPS model. However, subcategories under each major category were developed inductively and allowed to emerge from the data based on a constant-comparison method. This combined approach allowed us to consider all of the different components of a work system and the interactions among them when identifying hazards (deductive), while at the same time, we

were able to capture hazards that may only occur in the COR environment (inductive).²⁴ Once the classification scheme was developed, the data were coded independently by two researchers (one clinician and one human factors engineer).

Development of the classification scheme

We developed the hazard classification scheme using an iterative approach and established three-tiered categorisation. The top level followed the SEIPS model and included care provider, tasks, tools/technologies, organisation, physical environment and processes.²¹ The second and third level categories were generated based on the data. The second level added detail to the top level category, and the third level defined specific hazard (s). Below is an example of a coding string:

<i>Top level:</i>	<i>Subcategory:</i>	<i>Hazards:</i>
Tools and technologies →	design characteristics →	poor usability, poor safety features

The second and third categories were developed using a constant comparison method through the following iterative process. First, one human factors engineer (AG) and one doctorally prepared nurse with a cardiac surgical ICU background (DT) read the same five transcripts (one from each site) and wrote marginal notes identifying key phrases and themes based on the data. Second, they convened, discussed their findings and developed an initial classification scheme, including definitions and subcategories. Third, the entire LENS team convened multiple times to review the initial schema, make suggestions and review the revised scheme. Fourth, the human factors engineer and the doctorally prepared nurse used this feedback to revise the classification scheme and coded five additional transcripts. Fifth, the revised classification scheme was shared with the entire team, with additional feedback requiring only minor changes, wherein the classification scheme was finalised.

Coding of the data

Two researchers (AG, DT) reviewed each transcript and independently coded the data using the final scheme. Data were coded at the most detailed subcategory level (specific hazard) of a given category. The inter-coder agreement was assessed using the kappa statistic, and scored 0.81, which is considered as 'almost perfect'.²⁵ The two coders and three non-coders (LB, GK, EM) convened to review any coding discrepancies and make decisions through group consensus.²⁶

Each data segment was coded under all the relevant subcategories in the classification scheme. This approach provided a clear map, capturing not only the hazards associated with or caused by the work system

components (SEIPS model) involved, but also the chain reaction of hazards that occurred after the interactions of these suboptimal systems. Below is an example of one data segment and how it was coded.

Many members of the surgical and anaesthesia team were observed not washing their hands (1). Alcohol hand cleaner is not placed for convenience (3). Two dispensers in the room, near both doors. One of the dispensers was empty for the entire case (2). When asked, the circulating nurse reported that having an empty dispenser occurs frequently (4).

This data segment was coded as follows:

1. Top category: processes; subcategory: care processes; hazard: non-compliance with the recommended guidelines and practices.
2. Top category: physical environment; subcategory: design/equipment; hazard: inappropriate positioning of equipment and supplies beyond reach of providers.
3. Top category: tools and technologies; subcategory: availability; hazard: insufficient quantity of tools and supplies.
4. Top category: processes; subcategory: other processes; hazard: ineffective supply chain management processes resulting in unavailability of supplies and equipment in a timely manner.

An expert panel of 20, including 4 cardiac surgeons, 7 cardiac anaesthesiology providers, 5 nurses, and 4 perfusionists reviewed the study design and data collection plan before the study was conducted, and the findings after data analysis was completed. All members were in agreement with the hazards identified and reported that the findings reflect accurately what they experience in the COR every day (face validity).

RESULTS

Twenty cardiac surgeries were observed, over approximately 160 h, and a total of 84 contextual inquiries were recorded. Fifty-nine hazard categories were identified; 54 related to the work system and 5 to processes. **Box 1** provides an abbreviated list of hazards. Online tables A and B provide the complete three-tiered classification scheme and coding of examples of hazards identified in the work system and processes, respectively.

Care providers

Hazards observed among providers in the COR were inadequate knowledge and skills, poor professionalism, and practice variations (**Box 1** and online table A). An observation of inadequate knowledge and skills was an anaesthesiologist who had difficulty operating

Box 1 A sample list of hazards. Please refer to tables A and B (available online) for a complete list of hazards and specific examples from the cardiac surgeries observed

- Care provider
 - Inadequate/insufficient knowledge or skills.
 - Inadequate/lack of professionalism such as not respecting other providers.
 - Non-standardised approach to care delivery and/or task performance due to habits, preferences, education and previous experiences of individual care providers that may not be based on the current evidence.
- Task
 - Avoidable time pressure and unexpected changes.
 - Ambiguities due to different preferences of care providers.
 - Non-value adding tasks.
- Tools and technologies
 - Poor usability (eg, non-intuitive interface design, inconsistency in design, poor visibility of system status).
 - Poor fit or misalignment of safety features with users' needs or work as intended (eg, too many alarms without prioritisation).
 - Use of tools, technologies, and supplies with different design characteristics and brands across different sectors of the work environment (eg, operating rooms and ICUs).
 - Delay in tool and technology availability at the point and time of need (such as surgical equipment not sterilized in a timely manner).
- Physical environment
 - Poor planning and design of work area in relation to other parts of the operating room suite and the hospital (proximity of operating room suites to each other, to the storage areas and laboratories, and to the ICU).
 - Insufficiency of size and poor layout design of the operating rooms.
 - Non-standardisation of workspace designs across different operating rooms.
 - Poor configuration of workspaces leading to clutter, inadequate storage and poor organization of tools, equipment, furniture and cables.
- Organization
 - Focus on productivity in expense of patient safety.
 - Lack of or poorly organized policies and protocols for care and other processes.
 - Inadequate discussion, training and dissemination of protocol and policy changes.
 - Exclusion of front-line providers' input to purchasing decisions that can potentially affect safety of care.
 - Lack of or insufficient reinforcement of policies and protocols.
- Care processes
 - Non-compliance with the recommended guidelines and practices.
 - Lack of standardisation in care processes.
- Other processes
 - Ineffective supply chain management processes resulting in unavailability of supplies and equipment in a timely manner.

a defibrillator. Common examples of unprofessional conduct included being absent from the COR when needed, playing music loudly, making inappropriate comments, and talking to others in a raised voice or a condescending tone.

Many practice variations were observed among care providers within the same institution that were not based on evidence-based recommendations, patient risk or a research hypothesis. Variations were observed in the types and doses of medications administered, the supplies and equipment used (eg, ultrasound to place central lines), and the performance of tasks and procedures (eg, femoral site used for central line insertion because physician assistant lacked experience with other sites). We observed confusion among staff because of these practice variations, which increased the complexity of care and workload, and led to workarounds. For example, COR nurses were found to have assembled a folder that listed the supplies and equipment that each surgeon preferred for a particular type of surgery.

Tasks

Task-related hazards identified in the COR were high job demands/workload, non-value adding tasks, ineffective preparation and planning, and interruptions (Box 1 and online table A). Workspace design characteristics of some of the CORs added unnecessarily to the clinician workload (an example of interactions among work system components in the SEIPS model) such as in the following case:

The cell saver was located far away from the perfusionist, making him walk around the [cardiopulmonary bypass] CPB circuit to attend to it. This increased the perfusionist's workload and could lead to losing situational awareness.

We observed various types of non-value adding tasks. For example, four of five sites were using different brands of intravenous pumps in their CORs compared with their ICUs/post-anaesthesia care units, requiring a changeover of medications to another pump during handoffs between the COR and ICU providers. Through

contextual inquiry, we learned that top management at the four sites approved the purchase of a more expensive brand of intravenous pump for the operating room (OR) and an inexpensive brand for the ICU to save money. This finding illustrates how the interactions of different components in a work system (in this case task and organisation) affect processes of care such as handoffs, as described by the SEIPS model.

Tools and technologies

Three types of hazards were observed for tools and technologies (online table A): design and implementation related problems, hardware and software issues and timely availability of tools and technologies. Design problems of COR tools and technologies were ubiquitous. In all five sites, for example, we saw three different brands of infusion pumps in the cardiovascular perioperative area and all three had numerous design risks. All three pump types were described as not intuitive, hard to use and prone to errors during use. These design-related hazards led to workarounds, as exemplified by the following observation:

The name of the medication being administered can be stored in the intravenous pump machine and appears as a digital read-out on the screen. However, the name scrolls across the screen, causing a delay before the full medication name is seen again. Because the anaesthesiologists need to see the name of the medication immediately, they work around this design problem by taping the hand-written names of medications on pumps.

Hazards related to hardware and software included poor use of their safety features, and their unreliable functioning. At one site, for example, management did not purchase the drug library and Guardrails software for the intravenous pumps, which significantly reduced the extent of the use of safety measures designed into this technology (SEIPS system components interaction between an organisational decision and tools and technologies).

When examining unreliable functioning of tools and technologies, we found that poor user interface was also an underlying factor. In 12 of 20 cases observed, care providers spent 11 min or more trying to operate the transport monitors. In 8 of 12 cases, providers had the monitor fully functional after a delay, and in 4 cases only a subset of monitor features were functioning (eg, only blood pressure). Finally, we routinely observed unavailable equipment and inadequate (re)stocking of necessary supplies in the COR (the third sub-category of hazards under the tools and technologies component).

Physical environment

Three types of hazards were observed in the physical environment: physical layout, workspace design and

ambient environment (online table A). Small, crowded ORs, and inadequate physical space in other areas of the OR suite were observed across multiple sites. For example:

Very narrow corridors in the surgical suite area that are crowded with different equipment and supplies due to lack of storage space. When they were transferring the patient to the ICU after surgery, the patient's intravenous pump hit the equipment stored in the corridor twice.

Physical distance between the ORs and the ICU or post-anaesthesia care unit, and the ORs and the laboratories/supply storage area was a problem. At one site, transport time for a postoperative patient from the OR, five flights up by way of an elevator that was not designated for postoperative patient transports, to the ICU was 20 min.

Workspace design hazards included poor configuration (ie, inadequate horizontal space, 'unreachable' supplies and equipment) and non-standardised OR workspace design. Inadequate horizontal space made care providers stack supplies, medications, equipment and papers in a disordered pile, making it harder for providers to find the necessary items, frequently causing items to fall on the floor. In one case, we observed an unsterile garbage can being placed against the sterile field, creating an infection risk. At four of five sites, we observed bloody sponges thrown on the floor and left there until the end of the operation. In several cases, supplies and equipment were inappropriately positioned beyond the reach of providers, requiring care providers to step away from patient view and monitoring of their clinical status.

In summary, cluttered and congested workspaces due to poor organisation and placement of equipment, inadequate storage areas, tangled wires, tubes and lines were ubiquitous in the COR.

Organisation

We identified six types of organisation-related hazards: safety culture, education and training, policies and protocols, delivery of ancillary services, purchasing decisions and team factors (online table A). Safety culture in the COR was commonly evidenced by hierarchical and demeaning interactions among team members. For example, attending surgeons often did not use names when giving orders, causing confusion between anaesthesia and perfusion teams regarding the intended receiver of the order. Systematic efforts to identify and mitigate patient safety risks were very limited in all participating sites. Through contextual inquiry, participants reported that care providers were hesitant to report patient safety incidents because of

possible retaliation or the belief that nothing would come from reporting the incident.

Financial constraints, coupled with not seeking the input of frontline providers, led to suboptimal purchasing decisions and inadequate technology training for staff. Ineffective, poorly developed, or lack of policies and protocols for intraoperative tasks and processes posed safety hazards by causing confusion among care providers and increasing workloads. In one case, we observed clinicians discussing how to provide care given recent changes in policies, protocols and practices. We also observed numerous cases of non-compliance that may be due to lack of knowledge of the policy and protocol, inadequate training or inadequate enforcement and reinforcement of these by the organisation. For example, attending surgeons were observed entering the COR with their white coats on at one site (which is against the infection prevention and control policy), while at another site, outside technicians were observed entering and repairing equipment in the COR without scrubs or appropriate sterile garments.

Teamwork-related hazards were ubiquitous in the COR. For example, we observed poor situational awareness and insufficiently shared mental models (online table A) among team members, some of which led to unnecessary delays in care and unsafe care. The poor situational awareness we observed usually stemmed from ineffective team communication, poor teamwork skills, distractions and poor design, configuration or use of tools and technologies (eg, not using the whiteboard effectively), especially when coupled with high workload and fatigue (SEIPS system components of physical environment, tools and technologies, provider and organisation).

Communication-related hazards were prevalent. In the majority of cases, briefings/time-outs and debriefings were either not performed or incompletely performed. Only one of the 20 cases observed completed the time-out appropriately (eg, all team members were involved, all the recommended issues were addressed). Team members frequently used abbreviations during discussions that other team members did not understand, and the recommended communication practices (repeat backs, call-outs, confirmation, structured communication techniques) were rarely followed. Delays or ambiguity of the information shared and unnecessary information transfer were common and frequently caused apparent confusion and frustration among team members, and in some instances suboptimal care and errors.

Processes

Hazards related to both care processes and other processes were observed (online table B). Non-compli-

ance with evidence-based practices was common. Of the 20 cases observed, none followed all the recommended practices for central line insertion. In at least one case at all five sites, skin preparation was done incorrectly. For example, most of the procedures involving skin antisepsis (eg, arterial line placements, saphenous vein site and mediastinal chest preparation) failed to completely or correctly follow evidence-based infection control practices. Each discipline working in 'silos' eliminated the team's ability to comply with the evidence-based practices:

During central line placement by the anaesthesiologist, a full barrier drape was unrolled only to mid-chest, instead of covering the entire patient's body [which is the recommended practice by Centers for Disease Control and Prevention], to allow the circulating nurse to perform skin antisepsis simultaneously.

In all five hospitals, we observed hand hygiene violations across all disciplines: no hand washing, glove wearing or glove changing between tasks.

We also observed several hazards in the medication administration process, such as administering the prophylactic antibiotics too early (eg, vancomycin started at 5:00 on floor and incision was at 8:30, although the recommended guideline is to administer vancomycin intravenously slowly over a 1-h period, with completion of the administration within no more than 1 h of the surgical incision²⁷) and use of unsafe administration methods (eg, potassium not being administered via intravenous pump, which can cause significant safety problems).

Finally, ineffective supply chain management processes, inadequate and/or low quality maintenance, repair, and technical support processes, and delays in completion of housekeeping services were observed.

DISCUSSION

This study used an innovative approach, an interdisciplinary peer-to-peer review methodology, to prospectively identify and categorise patient safety hazards in the COR and postoperative transfer period. This approach allowed us to undertake a more in-depth and comprehensive evaluation of cardiac surgery services, providing a detailed analysis of risks and opportunities to improve safety that would not be possible through retrospective hazard identification methods.

The participating sites were large medical centres with solid reputations for providing good cardiac surgery services. Given that we identified numerous types of cardiac surgery related hazards in these five sites, it is likely that hazards and preventable harm to patients in US CORs are at concerning levels. Although this study was

not designed to quantify the magnitude of adverse events and harm to patients in the COR, our findings demonstrate common and substantial risks to patient safety.

Many types of hazards emerged from our analysis, including practice variations among care providers, poor teamwork and hierarchical cultures in the COR, violations of guidelines and protocols, and cramped and cluttered workspaces. Most of these hazards have been found in other studies^{28–30} and have been associated with errors^{10 15} and negative surgical outcomes.^{16 31} For example, Wiegmann and colleagues¹¹ associated surgical errors with teamwork and communication failures in the COR. An observational study of paediatric cardiac and orthopaedic surgeries by Catchpole *et al* found that minor problems (ie, undesirable events that did not have a direct impact on the surgical flow) during the surgery significantly reduced intraoperative performance (ie, proportion of key tasks not disrupted by problems during surgery) and increased the surgery duration.¹⁵ An earlier study that focused on a series of 243 neonatal arterial switch operations performed by 21 different surgeons revealed that increased number or severity of human failures, which is similar to the construct of ‘hazards’ in our study, were significantly related to increased number of postoperative hospital deaths and/or major postoperative complications (eg, postoperative cardiac arrest, mediastinitis).¹⁶

Several of the hazards were commonly identified among all five sites and provide significant opportunities to improve care. One such hazard was the care providers’ non-compliance in practicing evidence-based medicine. During every case, we observed some deviation from the recommended infection prevention practices while inserting central lines.³² We also observed at least one case at each site where providers failed to follow the recommended guidelines for safe surgical skin preparation.³³ This important finding corroborates McGlynn’s study of nearly a decade ago,³⁴ describing inadequacies in the quality of care patients receive.

Tool and technology-related hazards were found to be ubiquitous in all the participating CORs. This finding provided support for the previous literature that echoed the need for designing safer tools and technologies, providing adequate training and information to clinicians before introducing new tools and technologies to the CORs, and having more reliable tools and technologies management in the hospitals to ensure timely availability of these resources.^{15 35} There were usability problems in almost all of the major tools and technologies, including the anaesthesia, perfusion and echocardiogram machines, transport monitors, intravenous pumps, and intravenous poles. Health information technologies were not integrated across the continuum of care, making it harder for care providers to access

information necessary for providing safe care. The switching out of intravenous pumps and malfunctioning transport monitors occurred repeatedly during patient handoffs from the OR to the ICU or post-anaesthesia care unit team at all sites. These findings support the SEIPS framework, showing how other components of the care system, such as an organisation’s purchasing decision, plus device design and reliability, can impact patient safety. Hence, efforts to improve handoffs should focus on the entire transition of care, not just improving communication during the handoff report.

We found that clinicians commonly established workarounds such as creating preferences lists for surgeons, using the corridors to store extra equipment, or having residents restart the COR computers every morning to ensure the clock kept accurate time for electronic charting. These workarounds were done because the current work system, including technologies, organisational policies, physical environment design, for example, did not meet clinicians’ needs.^{36 37} Unfortunately, workarounds can impart hazards by introducing further complexity and unintended consequences into the system, thereby impeding organisational learning.^{38 39} Better and more informed systems (re)designs are required to reduce the need for these potentially unsafe and inefficient workarounds and other hazards. **Box 2**

Box 2 Sample practical solutions for the identified hazards

- Standardise care (at the minimum) within the same institution to reduce or eliminate workarounds by reaching consensus among care providers.
- Coordinate purchasing of tools and technologies across different units of hospitals.
- Purchase tools and technologies with input from frontline care providers and human factors and usability experts (human factors and proactive risk assessment informed technology procurement).
- Train cardiovascular operating room care providers in teamwork skills, such as being assertive, inquiring when necessary, effectively sharing pertinent information and mental models, etc.
- Consistently use the recommended communication practices (eg, repeat backs, callouts, confirmations).
- Use cognitive aids such as checklists to support these communication mechanisms—conduct audits and provide individualised feedback to ensure that briefings/timeouts, debriefings and handoff reports are completed as recommended.
- Proactively assess prototypes and plans before building a new cardiovascular operating room using methods such as proactive risk assessment, simulation etc. Incorporate frontline care providers’ input into decisions regarding physical environment design.
- Use multi-dimensional interventions such as the Comprehensive Unit Safety Plan (CUSP)^{40 41} to improve compliance with infection control guidelines and improve outcomes.

provides a list of potential solutions that are practical and relatively easy to implement to eliminate or mitigate some of the hazards identified in this study.

The classification scheme developed in this study can be used to develop practical tools healthcare organisations can use to collect data during local peer-to-peer assessments, to analyse the data relatively quickly, and to provide useful feedback regarding where to focus quality improvement efforts. These tools are needed at the frontlines to spread and incorporate the principles of the science of safety to clinicians to improve care at the bedside.

This study has several limitations. First, we focused on identifying and classifying patient safety hazards and cannot estimate what percentage of hazards actually resulted in harm. Nevertheless, some of these hazards have been described as significant threats to patient safety and associated with harm in the COR.¹² Moreover, hazards rather than harms likely provide direct information regarding where to focus safety improvement efforts. Second, our classification scheme may have misclassified some hazards. Third, our sample size was relatively small and determined prior to data collection based on our available resources. Therefore, we cannot claim that theoretical saturation was reached or that our results are comprehensive or generalisable. Nonetheless, the sample of hospitals was selected to try and represent various common hospital types in the USA. Fourth, the existence of observers in the COR may have influenced providers' behaviours and practices (Hawthorne effect). Such an effect may have reduced the number and types of hazards we observed. Despite the high potential for a Hawthorne effect, we observed many types of hazards, including those that are clearly susceptible to care provider behaviour modification (eg, consistent non-compliance with central line insertion guidelines across all cases observed). Furthermore, we waited for the clinicians to complete the task at hand before asking them any questions using contextual inquiry. Fifth, we did not collect any patient-level data and cannot judge the relationship or interaction of safety hazards with patient-specific factors. Sixth, this study was not designed to identify the common issues (eg, safety culture, accountability etc) that may be underlying many of the safety hazards in the COR. Our focus was on identifying hazards that were actionable, relatively easy to fix and clinically relevant (eg, non-compliance with central line insertion guidelines).

In summary, this study used an innovative, in-depth, and interdisciplinary approach to classify patient safety hazards identified in CORs at five hospitals. We identified many hazards and opportunities to improve patient safety. Broad application of the peer-to-peer assessment model used in this study could substantially improve patient safety in cardiac surgery care.

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Online Table A: Classification of Hazards Identified in Cardiac Surgery Work Systems

SEIPS Categories	Subcategories	Hazards	Specific Examples from Cases
Care Provider	<u>Knowledge and skills:</u> The fit between an individual’s qualification, training, education, and/or skills with respect to a particular task.	(1) Inadequate/ insufficient knowledge or skills for a task due to lack of education, experience or training.	A surgeon asked a technician for a piece of equipment with which the technician was unfamiliar. This unfamiliarity delayed the progression of the surgery. Anurse stated that this piece of equipment was newly purchased and did not look like the old one, and that neither the nurses nor the technicians had beeninserviced on it.
	<u>Professionalism:</u> Any behavior by a cardiovascular operating room team member that can affect the safety of care directly or indirectly (by affecting the professional relationship between care providers or between care providers and patients).	(2) Inadequate/ lack of professionalism such as not respecting other providers. May include a hierarchical culture where offenders do not expect to be disciplined.	A surgical team waited for the attending surgeon to come to the operating room and initiate the time-out. The circulating nurse had called to notify him 18 minutes earlier. The anesthesia attending physician (who was covering multiple rooms) checked repeatedly to see if the surgeon arrived and finally said he was going to call him. The surgeon had been in his office doing paperwork. This behavior caused unnecessary exposure of patient to anesthesia. 2: An anesthesiologist took multiple personal calls during a case and was observed to administer a dose of midazolam to the patient without putting the phone down.
	<u>Individual practice variations:</u> Differences among individual care providers within the same institution in performing tasks and procedures in ways that are not supported by evidence, specific patient needs or research; rather driven by authority, habits, experience or preferences of individual care providers.	(3) Non-standardized approach to care delivery and/or task performance due to habits, preferences, education, and previous experiences of individual care providers that may not be based on the current evidence.	1: Despite the availability of national evidence-based recommendations, each surgeon within an institution has an individual algorithm for heparin reversal, leading to variations in protamine dosing. This results in confusion among staff.
Task	<u>Job demands/ workload:</u> The burden or cost incurred by an individual in performing direct and indirect	(4) Unexpected fluctuations in demands (eg non-emergency case added to the OR schedule) (5) Unnecessarily increased	A new casewas added to the schedule in the morning. This unexpected change in plans had a negative impact on the cardiac surgery team’s ability to review

	activities of care that reflect the combined effects of demands imposed by the cardiovascular operating room environment.	workload due to sub-optimal design of other elements of the work system (6) Production pressures	patient's full history. It also negatively affected nursing preparation time as indicated by several nurses. Multiple care providers noted that in this organization there is significant amount of pressure from surgeons to work fast, to finish cases quickly, and to get the next case started.
	<u>Non-value adding tasks</u> : Any instance where the cost of performing a task outweighs the benefit, for example, if a task is performed in an inefficient manner or resources are misallocated.	(7) Poor tool/technology design issues (8) Hardware/software problems (9) Suboptimal purchasing decisions and resource availability (10) Differences or non-alignments in practice between OR and ICU/post-anesthesia care unit	1: Anesthesiologists prepare most of their drug doses rather than having them come prepared from the pharmacy. 2: Perfusionists use paper-based forms during the surgery for documentation and enter the information into the computer in the perfusion room after the case is over.
	<u>Ineffective planning and preparation</u> : Not being ready in a timely manner for performing the tasks and procedures required.	(11) Avoidable time pressure and unexpected changes (12) Ambiguities due to different preferences of surgeons and other care providers (13) Inadequate coordination across units, departments and care providers	The surgeon asked for aortic cannula and then told the perfusionist to heparinize it. The perfusion lines were not ready and should have been prepared in advance in case they need to go on bypass urgently.
	<u>Interruptions</u> : Disruptions not directly related to patient care or to the task at hand.	(14) Someone paging, calling, or entering the OR in reference to another patient (15) Care providers talking about unrelated subjects during surgery	A junior cardiologist came into the OR to discuss another patient with the surgeon. There was a lot of back and forth conversation between the two physicians while the surgeon was starting the operation.
Tools and Technologies	<u>Design and implementation</u> : Any issues due to design characteristics of tools and technologies and/or their deployment in the work system	(16) Poor usability (eg, tangled or kinked lines, non-intuitive interface design, inconsistency in design, poor visibility of system status, difficulties in correcting user errors, user has to rely on memory rather than options and instructions being visible) (17) Inadequate safety features (eg, no redundant checks, no alarms when necessary) (18) Poor fit or misalignment of	1: The IV pump repeatedly alarmed. It was not clear what the cause was to the provider at first. Eventually corrected it. 2: In this hospital they have only one type of perfusion machine that is extremely old and lacks most of the software and other features that are critical for safety. Furthermore, since the perfusion machine is too big, it causes too much hemodilution.

		<p>safety features with users' needs or work as intended (eg too many alarms without prioritization)</p> <p>(19) Size mismatch (too large, bulky)</p> <p>(20) Use of tools, technologies, or supplies with different design characteristics and brands across different sectors of the work environment (operating rooms and ICUs)</p> <p>(21) Lack of integration or interoperability in tools and technologies, causing inadequate support of critical tasks across the hospital</p>	
	<p><u>Hardware/ software:</u> Any equipment and programming issues except those related to software usability</p>	<p>(22) Unreliability of hardware and software performance in a given task</p> <p>(23) Misuse or inadequate use of hardware and software features because they are missing, not installed, hard to use or training about them not adequately provided</p>	<p>1: Oxygen sensors on a perfusion machine may fall from the machine, causing it to shut down without warning at any time. In one case, this required the perfusionist to restart the perfusion machine.</p>
	<p><u>Availability:</u> The degree to which tools, technologies, supplies and information are readily available when needed</p>	<p>(24) Insufficient quantity of tools and supplies (either in the area where needed or in the hospital)</p> <p>(25) Delay in tool and technology availability at the point and time of need due to, for example, surgical equipment not being sterilized in a timely manner</p> <p>(26) Necessary information not being available due to issues related to tools and technologies</p>	<p>1: Equipment needs to be borrowed from another location. In one case a Doppler was obtained from another operating room during a case, with the nurse telling the surgeon that they did not know how long they would be able to have it: "There is only one Doppler today, we don't know why."</p>
<p>Physical environment</p>	<p><u>Layout:</u> Workplace allocation and design characteristics of the large scale environment in the operating room suite</p>	<p>(27) Poor planning and design of work area in relation to other parts of the operating room suite and the hospital (proximity of operating rooms to each other, to the storage areas and laboratories, and to the ICU)</p> <p>(28) Insufficiency of size and poor layout design of the operating rooms</p>	<p>1: A technician was called into the room for assistance with placement of airway. The OR is quite small and the anesthesia team did not have very much room to work when placing the airway.</p>

		(29) Poor or inadequate renovation of operating room suite	
	<u>Workspace design:</u> Design characteristics of the immediate work area of individual care providers.	(30) Non-standardization of workspace designs across different operating rooms (31) Inappropriate positioning of equipment and supplies beyond reach of providers (32) Poor configuration of workspaces leading to clutter, inadequate storage and poor organization of tools, equipment, furniture, and cables.	1: In several of the cases observed, medicines in the anesthesia medicine drawer did not seem to be in any order, presenting a potential for wasting time in searching for something or selecting the wrong drug. 2: Medications kept in a Pyxis machine that are not directly accessible to the anesthesiologists' work area require them to lose sight of the infusion pumps and monitors while getting drugs. 3: Corridors used as receptacles for equipment that should be stored elsewhere
	<u>Ambient environment:</u> Characteristics of the cardiovascular operating room related to human sensory perceptions including noise, lighting levels and temperature.	(33) Noise or loud background music may impair hearing and communication (34) Extremes in room temperature may distract workers (35) Poor lighting may reduce visibility and vigilance	1: In one case, the operating room temperature was never turned back up despite multiple people recognizing that it took a long time to warm the patient.
Organization	<u>Safety culture:</u> The collective (as opposed to individual) approach taken to safety and risk by the organization.	(36) Focus on productivity in expense of patient safety (37) Hierarchical/ top-down culture (38) Limited efforts to identify and mitigate patient safety risks	One anesthesiologist noted: <i>"This hospital encourages an adversarial relationship among staff, often using RN/managers to spy on physicians for the benefit of hospital administration. This destroys any possibility of a team effort for patient care and safety. The administration's motto is "divide and conquer."</i>
	<u>Education and training:</u> Local policies and practice of preparing front-line and support staff to perform their duties well.	(39) Inadequacy or lack of appropriate structured education and training programs	Surgeon was handed a new brand of cautery gun and was confused: <i>"Wait a second; does this thing have a special attachment? It's not doing any energy. What am I looking at?"</i> Nurse stated that it was the first time this brand had been used. The equipment did not work. Further inquiry revealed that the hospital had purchased a new

			type of cautery but failed to inform or train care providers in its use.
	<p><u>Policies and protocols:</u> Availability, dissemination and shared awareness of structured rules and contingency plans for cardiovascular operating room providers and staff. Includes adequacy of reinforcement and maintenance of quality of rules and plans.</p>	<p>(40) Lack of or poorly organized policies and protocols for care and other processes</p> <p>(41) Inadequate discussion, training and dissemination of protocol and policy changes</p> <p>(42) Poorly developed or reviewed policies and protocols</p> <p>(43) Lack of or insufficient reinforcement of policies and protocols</p>	<p>1: In one hospital, insulin administration was not protocolized, requiring individual doses to be prepared for every patient by a provider with an opportunity for error.</p> <p>2: In one case, there was a discrepancy regarding when to place ETT fastener devices: whether this should occur in the OR at the beginning of the case or in the ICU just after the surgery is completed. The policy had been changed and not everyone had been informed, leaving the vulnerability for the device to be left off completely.</p>
	<p><u>Service provision by ancillary services (blood bank, pharmacy, etc.):</u> The quality and timeliness of tasks performed by departments and agencies outside of the cardiovascular operating room and ICU.</p>	<p>(44) Suboptimal performance</p> <p>(45) Delays in services</p> <p>(46) Absence of an ancillary service in the OR suite (eg, no pharmacy in the OR suite)</p> <p>(47) Inadequate ancillary service staff.</p>	<p>1: Surgeon complained that the blood bank lost blood samples for type and matching, requiring intraoperative re-sampling and testing, thus slowing down the case.</p>
	<p><u>Purchasing decisions:</u> Hospital management's purchasing policies, protocols and behaviors that may impact the delivery of services</p>	<p>(48) Exclusion of front-line providers' input to purchasing decisions that can potentially affect safety of care</p> <p>(49) Poor allocation and management of resources</p>	<p>In one hospital, the brand of infusion pumps used in the OR (Pump A) are different than the brand of infusion pumps used in the rest of the hospital (Pump B). This requires a complete changeover from the intra-operative pump when the patient is transferred to ICU from OR, (i.e., transferring all IV medications and tubing to a new IV pump), a practice which is extremely high risk for giving an inadvertent bolus of a medication or interrupting a vital agent. The decision of buying two different brands of infusion pumps was based totally on costs [Pump B is cheaper but less user-friendly than Pump A] without consultation with providers on the impact of the purchase on care delivery.</p>
	<p><u>Team factors:</u> Any aspect of the cardiovascular</p>	<p>(50) Team members may not be assertive, may not ask questions</p>	<p>1: Anesthesia: "Did you drain the left chest (asked after the</p>

	<p>operating room group work that have the potential to affect patient safety.</p>	<p>when necessary, may not share pertinent information or know when to ask for help, may not be situationally aware or know how to stay focused on tasks by using distraction management strategies effectively</p> <p>(51) Team members may not have an adequately shared mental model (defined as the degree to which team members share a common understanding of roles and functions of each team member, task requirements and the coordination activities required for providing safe care)</p> <p>(52) Team members not helping to each other adequately (even though they could)</p> <p>(53) Lack of support for teamwork (eg, physical layout having a negative effect on situational awareness of team members)</p> <p>(54) Inadequate mechanisms to hold individual team members accountable</p>	<p>chest was closed)?” Surgeon: “No, is there something wrong?” Anesthesia had seen pleural effusion on the Echo, which could have been addressed but they did not share the information with the surgeon earlier.</p> <p>2: There was a delay because they did not have the right size aortic cannula and realized this after the incision was already in aorta. This should have been discussed during the briefing.</p>
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Online Table B: Classification of Hazards Identified in Cardiac Surgery Processes

Process subcategories	Definitions	Hazards	Specific Examples/ Cases
Care processes	Processes that are used to provide and manage clinical care to patients.	(55) Non-compliance with the recommended guidelines and practices (56) Lack of standardization in care processes	1: Tinted chlorhexidine was used as the skin prep but applied incorrectly. Rather than applying it with friction in a back and forth motion, nurses just painted it on patient's skin. 2: Insulin administration was not protocolized in this hospital, hence the attending anesthesiologist made up a dose.
Other processes	Processes that do not directly related to patient care but support the delivery of the care processes (eg, housekeeping)	(57) Ineffective supply chain management processes resulting in unavailability of supplies and equipment in a timely manner (58) Inadequate or low quality maintenance, repair, and technical support processes (59) Delays in completion of housekeeping services	"I experience at least several instances every week that the supplies or equipment are not available in a timely manner. I think one reason for this is that supply departments have a lack of understanding of clinical needs-urgency and importance are not understood. I cannot do my job if I don't have my supplies and patient will die."