When a Checklist is Not Enough: How to Improve Them and What Else is Needed

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Ultra-mini abstract: Time-outs have become an important tool in patient safety in the operating room. Despite the improvements though, patients are still harmed. We utilized a novel accident analysis technique to identify time-out improvements and systemic changes to promote safety in cardiac surgery.

Objectives: Checklists are being introduced to enhance patient safety, but the results have been mixed. The goal of this research is to understand why time-outs and checklists are sometimes not effective in preventing surgical adverse events and to identify additional measures needed to reduce these events.

Methodology: 380 consecutive patients underwent complex cardiac surgery over a 24-month period between Nov, 2011 & Nov, 2013 at an academic medical center, out of a total of 529 cardiac cases. Elective isolated Aortic Valve Replacements, Mitral Valve Repairs & CABG surgical procedures (N=149) were excluded. A time-out was conducted in a standard fashion in all patients in accordance with the WHO surgical checklist protocol. Adverse events were classified as anything that resulted in an operative delay, non-availability of equipment, failure of drug administration, or unexpected adverse clinical outcome. These events and their details were collected every week and analyzed using a systemic causal analysis technique using a technique called CAST (Causal Analysis based on Systems Theory). This analytic technique evaluated the socio-technical system to identify the set of causal factors involved in the adverse events, and the causal factors explored to identify reasons. Recommendations were made for the improvement of checklists and the use of system design changes that could prevent such events in the future.

Results: Thirty events were identified. The causal analysis of these 30 adverse events were carried out and actionable events classified. There were important limitations in the use of standard checklists as a standalone patient safety measure in the operating room setting, due to multiple factors. Major categories included miscommunication between staff, medication errors, missing instrumentation, missing implants, and improper handling of equipment or instruments. There were an average of 3.9 recommendations generated for each adverse event scenario.

Conclusions: Time-outs and checklists can prevent some types of adverse events, but they need to be carefully designed. Additional interventions aimed at improving safety controls in the system design are

needed to augment the use of checklists. Customization of checklists for specialized surgical procedures may reduce adverse events.

Background

Checklists have been promoted as a way to improve healthcare outcomes and safety. Studies of the results have been mixed. Some researchers have found impressive decreases in mortality by instituting simple checklists before surgical procedures. For example, Haynes et al. showed an impressive 35 percent decrease in mortality by instituting a simple checklist before every surgical procedure [1]. The SURPASS checklist also demonstrated greatly improved surgical outcomes.[2]

As checklist usage became more widespread, however, results have not always been as impressive, and results have been mixed or inconclusive.[3] Recently mandated implementation of the WHO Safe Surgery Checklist[1] at all hospitals in Ontario, Canada, failed to show a decline in mortality and morbidity rates.[4] Studies began to show that even where 100% compliance with the checklist was documented, in reality checklists were completed less than 10% of the time when OR staff were actually observed.[5] A recent report by Urbach and colleagues reported results of the implementation of the WHO surgical checklist in the entire province of Ontario, Canada.[4] We evaluated the effects and use of a standard WHO surgical checklist mandated by the institution, in the setting of complex cardiac surgery. Causal effects of adverse events were also studied, using systems theory.

Methods

Data were collected on 380 consecutive complex cardiac surgery cases over a 24-month period, between Nov 1, 2011 and Nov 1, 2013 at Rush University Medical Center, a large academic medical center in inner city Chicago. During this period, a total of 529 cardiac surgery cases were performed and the complex cases numbering 380 accounted for 71.8% of the total caseload. For purposes of uniformity, elective Coronary Artery Bypass Graft (CABG) procedures (n=77), elective simple mitral valve

repairs (n=22) and uncomplicated aortic valve replacements (n=55) were excluded. Checklist compliance, effectiveness, utilization and outcomes were evaluated in patients undergoing complex heart surgery. These included emergencies, urgent CABG, multiple valve procedures, combined valve & CABG procedures, aortic surgery, LV reconstruction, VAD implants, heart transplants. During this period, heart transplantation and VAD implants were restarted as part of heart failure surgery in this institution. All patient and procedure details were made available through the STS database maintained by our database manager. This was a retrospective review of cases, approved by the Rush Institutional Review Board.

The cases were observed for completion of the preoperative timeout and the presence of any adverse events. The preoperative checklist used was a modification of the WHO Surgical Safety Checklist and covered the items seen in Table 1. This Surgical Safety Checklist was mandated by the institution and had no specific customization for various specialties. We chose to study outcomes related to the use of the checklists, as a mechanism of process and quality improvement.

Adverse events were defined as anything that resulted in an operative delay, non-availability of equipment, failure of drug administration, or unexpected adverse clinical outcome. Incidents were identified via direct observation, weekly case reviews or chart analysis after an "Unexpected Occurrence Report" was filed by the care team. Additionally, weekly meetings were held by the surgical team to uncover adverse events, in an effort to track them and streamline peri-operative processes. In terms of the heart transplant procedures, additional investigations were made into processes used for immunosuppression management, organ retrieval and peri-operative protocols. Lines of communication between different Intensive Care Units and Clinical Services were also assessed.

Adverse events were then analyzed using a system engineering technique called Causal Analysis based on Systems Theory (CAST)[6] . CAST, grounded in systems theory, is a more powerful and inclusive analysis technique than the typical root cause analysis used to investigate adverse events. CAST goes

beyond individual error and examines the contextual, social, and organizational influences on human behavior. The philosophy behind CAST is that human behavior is influenced by the environment in which it occurs. Assigning blame to doctors, nurses, and technicians will not prevent future incidents unless the environmental determinants of the behavior, the systemic factors, involved are identified and corrected.

CAST (and systems theory in general) is based on the system-theoretic principle that accidents are not just the result of individual system component failures or errors but more generally result from inadequate enforcement of constraints on the behavior of the system components. Examples of safety constraints are that pre-emptive immunosuppression must be administered to patients before receiving a heart transplant or that all required equipment must be available during cardiac surgery.

The safety constraints are enforced by controls. Controls include such things as physical and logical design to reduce or eliminate common errors, checklists, performance audits, altering the order of steps in a procedure to reduce the risk of skipping some, and changing incentive structures (i.e., aligning individual incentives with system-level goals). In general, controls may be physical, procedural, or social. Losses result when the controls are inadequate and flaws in the overall system design and in the interactions among the system components violate the safety constraints. Safety is treated not as a human reliability problem but as a control problem where the system design should prevent (control) unsafe behavior.

The basic philosophy in CAST is that identifying the mistakes people make and going no further, which is often the result of root cause analysis performed on adverse events in hospitals, does not provide the information needed to prevent future losses. Most people want to do a good job. While in hindsight their behavior may appear to involve "mistakes," at the time they were trying to do the right thing[6]. To get the information necessary to change the work context to one that increases safe behavior, we must

understand *why* it made sense to those involved to act the way they did when the behavior, in hindsight, turns out to be unsafe.

People's behavior is affected by the context in which it occurs. Therefore the first step in identifying why particular behavior occurred is to identify the contextual influences that determined or influenced it. Then, to change behavior, we change the context. That is the "systems" approach to accident reduction.

Behavior is also affected by our mental models of the state of the process being controlled. Figure 1 shows a simple feedback control loop. The controller, perhaps the surgeon or nurse, executes control actions that may be instructions or actual physical actions on the controlled process. Decisions about what to do are affected by the model the controller has of the current state of the controlled process. If the model of the controlled process becomes inconsistent with the real state of the process (perhaps because of missing or incorrect feedback) then mistaken and perhaps unsafe behavior will result. For example, the nurse or physician believes that an immunosuppressant has already been given when it actually has not and therefore did not administer it themselves.

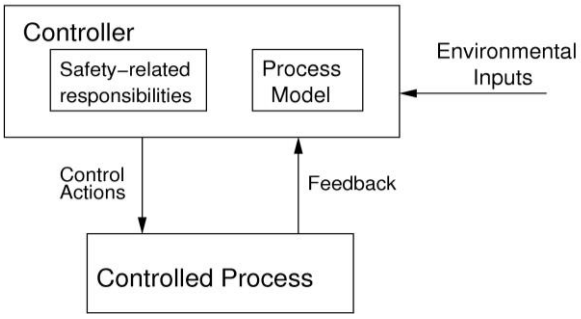
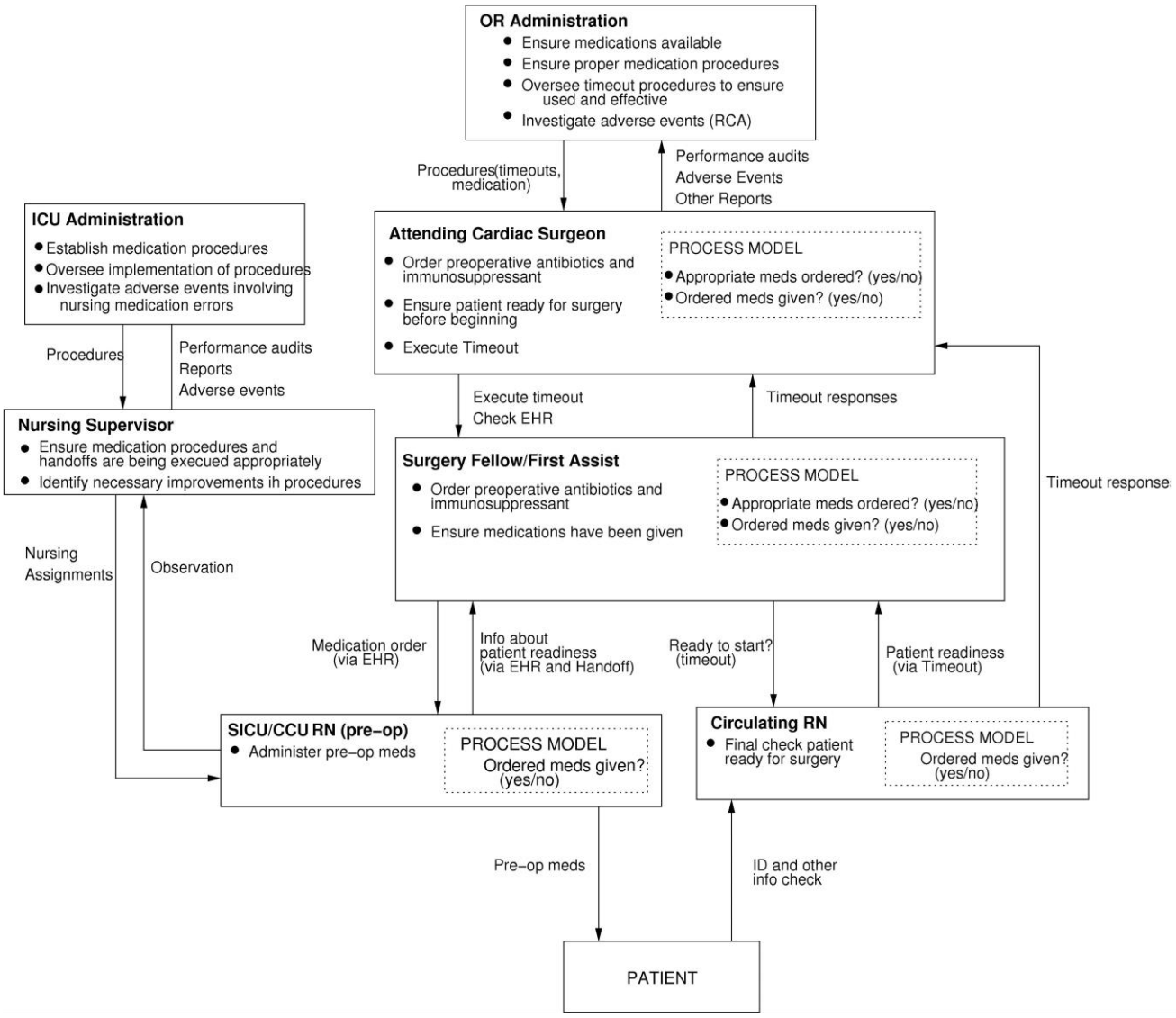


Figure 1: A general safety-control structure

The individual feedback control loops are part of a larger hierarchical control structure. Figure 2 shows a model of the control system (feedback and communication loops) used to control surgical medication errors at the hospital where the adverse events occurred. The model shows the system as it

158 is assumed to work under ideal conditions. It will differ for each hospital, depending on the particular
159 processes used. Accidents and incidents occur when the control structure (i.e., the designed controls)
160 does not enforce the safety constraints on the system operation, assuming that the controller did not
161 intentionally harm the patient.



162

163 **Figure 2:** The safety control structure to protect against pre-operative medication errors

164 Each "controller" in the system has specific responsibilities with respect to safety. Each also has a
165 model of the process being controlled (not all shown in Figure 2) that will impact how well the safety-

related responsibilities are carried out. Note that the attending cardiac surgeon and the surgery fellow both have responsibility for ordering medications, which could potentially lead to confusion and omission of required actions.

This kind of CAST analysis was conducted on every one of the 30 cases identified by the MIT systems engineering specialists (ALS & NL).

Results

Out of 380 consecutive complex cardiac surgeries, 30 adverse events occurred. Patient outcomes in those adverse events ranged from patient death to prolonged anesthetic time with no clinically observable consequences; outcomes are tabulated in Table 2. In all of these cases, 100% checklist compliance was documented by the nursing staff.

Incidents fell into several different categories, collated in Table 3. The CAST analyses on these incidents identified ways to improve the checklists. It also identified additional protection needed to prevent events that cannot be consistently prevented by using a checklist. While the "symptoms", e.g., specific adverse events, differed greatly among the categories, the systemic causal factors were very similar, therefore demonstrating that fixing a few systemic factors can potentially reduce whole categories of adverse events.

Missing Medications

There were four instances of missing medications: three cases of missing immunosuppression preoperatively and one case of a delay in heparin dosing. In the cases of missing immunosuppression, all of the patients had orders written for immunosuppression but somehow never received it before entering the operating room. A major driver of these incidents was a lack of feedback specifically related to the electronic health record (EHR) and the timeout. The immunosuppression was ordered the night before surgery as part of a preoperative order set. This order set includes a combination of orders to be

given at different times and by different people. Some orders are meant to be carried out by the intensive care nurse an hour before the patient goes, and others, such as antibiotics, are meant to be carried out by the anesthesiologist in the operating room. Usually this ambiguity is not a problem because the teams are used to carrying out these orders. Complicating these scenarios was that cardiac transplants were relatively infrequent until a recent change in leadership. The intensive care nurses had not given immunosuppression before and likely did not realize that this was their responsibility. Additionally, these were performed after-hours, when the pharmacy dispensing medications was at a remote location.

Compounding the lack of feedback is the difficulty in seeing whether an order has been carried out in the EHR. To see this, one has to compare the orders to the Medication Administration Record (MAR), which is on an entirely separate screen. There was no obvious signal to the surgical team that an order has been placed but not filled. These gaps were identified a few months later, after detailed searching of the EMR by the bio-informatics expert (MO), focusing on the actual times when the immunosuppressive medications were truly administered.

Missing Equipment and Missing Implants

Out of the 30 incidents, eight involved missing equipment and an additional three involved missing implants. Typically, missing equipment cases involved less common procedures where the setup was missing a specialized piece of equipment. Cases involving missing implants were all valve replacement cases where the surgical team could not obtain a properly sized valve. Cases arising from missing equipment typically shared similar proximal events with a wide variety of contributing factors. The proximal events were that the physician either requested the wrong equipment or the nurse did not retrieve all of the equipment or the correct equipment for the case.

Relieving Nurse Unaware of Cardiac Procedures

There were four incidents where the relieving circulating nurse did not have the skill set necessary to work in the cardiac surgery operating room. They did not know where to find or how to use specialized cardiac equipment.

Improperly Handled Equipment

There were nine instances of mishandled equipment. The OR staff frequently incorrectly believed that the equipment was broken, when in reality it was set up improperly. It is easy here to say that the nurse was responsible, but the biomedical engineer and the surgeon also believed the equipment to be broken. In most of these cases, it was not until after the procedure when the team met with the company representative that they realized the device was just set up incorrectly. These incidents raise the question of device design and training.

Analysis of Recommendations

In analyzing these incidents, we came up with recommendations for preventing future accidents based off of the identified causal factors. There was an average of 3.9 recommendations generated for each accident scenario. We further analyzed these recommendations by coding them using the VA Action Hierarchy[7]. The VA Action Hierarchy is a set of guidelines to categorize preventative actions as stronger, intermediate, or weaker actions. Stronger actions include forcing functions and active leadership engagement and action, while weaker actions include double checks and training. 35% of recommendations generated from these analyses were stronger actions, 27.5% intermediate, and 37.5% weaker actions.

Discussion

In this research, we examined 30 adverse events that occurred during cardiac surgery on 380 consecutive patients over a 24-month period in a large American academic medical center. A timeout was conducted in a standard fashion for all patients in accordance with the WHO surgical checklist

protocol. Compliance in performing the timeout was established by direct observation during the surgeries. We then used a sophisticated causal analysis method[6] to identify why the checklist did not prevent the adverse events and what else is needed to substantially reduce adverse events. Stopping the analysis at the proximal event, however, provides no useful information to prevent this from happening again. When we further explored why the local actors performed the wrong actions, a far more nuanced picture became clear. The surgeons' pick lists, where they list their preferred equipment for each surgery, are frequently outdated. Furthermore many physicians are unaware that they are outdated and unaware of how to change them, suggesting that the surgical leadership team needs to enforce the updating of pick lists. Additionally, there were potentially problems with incomplete equipment kits—an issue that should be addressed by further investigating the entire equipment inventory and sterilization process, as opposed to blaming the nurses for not getting all of the required equipment.

Analyzing these accidents with CAST not only provided insight not only into the limitations of checklists and how they need to be supplemented to prevent more adverse events, but also, fundamentally, into the limitations of defense-in-depth thinking for modeling and controlling healthcare risks. As one example, the government of Ontario, Canada, recently mandated implementation of surgical safety checklists at all hospitals in an effort to improve patient safety, as the insertion of an additional layer of defense against adverse events. In this diverse population, the WHO surgical checklist failed to reduce mortality and morbidity in a wide range of surgical patients[4]. This study raises the question of how much of the early positive results were the result of the Hawthorne[a] effect and other systemic changes that accompanied the introduction of checklists, rather than the checklist itself.

[a] The Hawthorne Effect is a phenomenon that occurs where the subjects of a study alter their behavior as a response to being observed.

Some of the arguments for checklists come from their use in aviation and their supposed influence on the low accident rate in that industry. However, the role and impact of checklists on aviation safety have been exaggerated. In fact, the misuse and nonuse of checklists by flight crews, aircraft maintenance workers, and operators in nuclear power plants (another industry that uses checklists) has actually been a major contributor to accidents or serious incidents[8]. Typical pilot errors in using checklists include skipping items, often with the intention of coming back to them; interruptions and distractions; misperception (where the pilots see the checklist item in an improper status but perceive it as having the correct status); time constraints and production pressures; incomplete compliance, and others[9].

While checklists and standardized procedures do play a role in aviation safety, their use is a small part of the reason for the low accident rate in flying today. For example, aircraft are designed using a "fail-safe" principle so that failures of physical components, human errors, or flaws in implementing operational procedures (including checklists) will not, by themselves, lead to an accident. The success of checklists in aviation depends on the careful analysis and design that goes into the entire system design, as well as on human ingenuity in selecting and applying and even modifying standard procedures and checklists. That is, checklists are only effective in commercial aviation because the larger system is engineered to protect against human fallibility. Attributing the success of aviation safety to the use of checklists or placing too much reliance on them for healthcare safety would be a tremendous mistake.

The overuse of checklists without making system changes is beginning to be recognized in healthcare too. Drs. Stock and Sundt recently published an editorial arguing that more than just checklists are needed to prevent accidents[10]. Additionally, there is a need to show that checklists actually help avoid major adverse events, otherwise surgical teams may just view them as wasteful impositions[11]. Accidents are not only caused by lapses in memory, so a tool that is designed to serve as a memory aid will not protect patients throughout their hospital stay.

As it relates to missing equipment, it might be best to ask about specific equipment that is different than what is used in more routine cases. The specific question on the timeout is phrased as "Do we require any equipment, implants, radiology films, or are there any special requirements for this patient?" The question is too general to serve as a memory aid by highlighting any particular piece of missing equipment. Additionally, it is a stacked question, meaning that one question is actually asking for multiple answers. Human factors studies show that stacked questions like this one make it more likely that respondents will miss specific parts of the general question[11].

There were instances where cross covering nurses were not familiar with cardiac procedures. It is easy to say that the nurses were inadequately trained and that it was a problem of just a few inadequately trained personnel. However, the same incident happened four times with four different nurses and saying that it was simply a matter of poorly trained nurses will not prevent this from happening a fifth time or more. These incidents were reported to the nursing hierarchy and assurances obtained about avoiding repetitions. Adequate training and competency verification of staff in complex cardiac surgery suites falls to the institutional clinical educational department with monthly review to keep staff properly trained.

Identifying the systemic factors involved and fixing these factors requires moving to higher levels of control in the system. Why were these nurses, who were not trained in cardiac surgery, working in the cardiac surgery operating rooms? Analysis of the managerial levels highlights that there is a policy against non-cardiac nurses being assigned to the cardiac rooms, even as relieving nurses. However, this policy is balanced by budgetary and staffing constraints. There is a constant message from upper level management that making staff work overtime breaks the budget and hurts the organization. How then is the nurse manager supposed to keep the operating room staffed with appropriately trained staff? These conflicting system goals— safety through using appropriately trained staff and financial constraints limiting overtime payment— need to be discussed and prioritized at the highest levels of

hospital leadership before this problem will truly be prevented in the future. In terms of missing equipment such as valve implants, these were related to recent use of the sized implants. Alternate implants were used made by a different manufacturer. Feedback was provided to the nursing hierarchy and the supply chain management group in each instance. Additional redundancy measures were introduced, such as immediate re-ordering of the valve implant by the circulating nurse and cross-checking of all implants prior to commencement of cases.

Medical devices are notoriously designed with little thought given to the usability and their integration into the existing workflow. Equipment should have as simple a design as possible, with clear labels and diagrams. Solutions that focus on making the equipment less error prone would prevent just such incidents in the future. Why, then, is medical equipment not designed using knowledge of human factors and error proneness? Medical device companies have little incentive to change the design if health systems buy the devices regardless of the design. The companies may not even know about the incidents raised by their equipment without this type of feedback. Doctors and hospitals need to start pushing for better designs and stop settling for products that they know have design flaws regardless of the time and budget pressure placed on these purchases.

The checklist and timeout are designed to be a communication tool common to all operating rooms. Therefore, at this medical center, every operating room uses the same timeout checklist, a modified WHO Surgical Safety Checklist. However, because this is a general checklist, there is no question specifically asking about immunosuppression. The timeout is not an effective tool for catching this type of error the way that it is currently designed.

One lesson that can be learned is that checklists need to be tailored to the specific task being performed, in this case cardiac surgery. Questions about deep vein thrombosis prophylaxis may have limited relevance, for example. The rote use of stock questions may take up time and decrease the likelihood that key OR personnel will be fully attentive to the entire checklist. Additional questions that

are relevant, such as in some of these cases, preoperative immunosuppression, need to be added. Adding questions though is a difficult task. There is a compromise between adding questions to cover more content and making the checklist so long, such that the user does not complete it entirely. Finally, there need to be changes to the format of the checklist to increase its usability. These changes include separating stacked questions and creating more close-ended questions.

However, making these changes to the checklist would not have prevented all the adverse events. The CAST analysis discovered systemic causes at both the local level as well as at higher levels of the system safety control structure. For example, management of change procedures need to be instituted and used when changes are made in standard practices, such as, in this case, an increase in cardiac transplant surgery. Risks of changes should be evaluated and proper design of procedures and instruction provided to ensure that new risks are not introduced by the change.

Other recommended changes are listed in Table 4. Many of the higher control level recommendations would prevent accidents of many different types. For example, implementing a strong incident reporting system with formal investigations may have prevented the repetitive incidents. The UO (Unexpected Occurrence) forms were infrequently filled out in these 30 adverse events, suggesting that the mechanisms set in place by the administration were not being utilized properly. Would unsafe staffing levels be a problem if safety took priority over cost in all managerial decision making? Additionally, many of the identified changes with these analyses fell into the “stronger actions” categorization, suggesting that they would be more effective at preventing these accidents in the future than merely training or reminding staff of how to properly perform their jobs. Until these changes at all levels of the system are made to eliminate the systemic factors in adverse events, we will continue to see problems at the lower levels with unsafe staffing, inadequate training, insufficient stock, poor design of equipment and computer records, and blood banks located a block away from where blood is most needed.

We have good evidence to show that process improvement measures initiated by team members, even at the level of a fellow or trainee, may have great implications in improving peri-operative outcomes[12]. Focusing on reducing preventable adverse events may by itself not be as important as working through the processes to improve peri-operative outcomes[13]. Finally, when the adverse events do occur, there should be adequate mechanisms in place to rescue these patients from complications, since measuring failure to rescue may be a better metric than looking at adverse events alone[14].

From our experience with this CAST approach, we made some changes in our practice –

1. Customized time-out & checklist for complex cardiac surgery with separate set of questions for transplants & VADs
2. Cross checking the administration/delivery of pre-operative medications in all cardiac surgery procedures.
3. A pre-operative check with the nurses about possible range of implants being used for the case
4. Ensuring availability of specialized equipment, prior to the case

It is our plan to repeat this study to evaluate effects of these changes, over a 2-year period.

Conclusions

Timeouts and checklists can play a role in patient safety. Their use in these cases, however, did not prevent the adverse events that occurred. The fact that accidents happen despite having implemented a preoperative checklist goes beyond merely an issue with checklist compliance or even checklist design. Part of the solution is to improve the checklists, as suggested in this paper and others. But an improved checklist will not prevent most of the causal factors identified in this research and may not be the best way to solve them even if it could. Solutions need to move beyond the local level where the checklist acts and into the overall system design and controls to truly be effective. These changes would have the added benefit of improving care throughout the entire health system and not just surgical care.

A checklist is only one of the tools in our arsenal for improving patient safety. Identifying the systemic factors in adverse events and correcting them could have a major impact on patient safety.

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Table 1. Preoperative timeout checklist

What patient do we have?
What procedure are we doing?
What side/site/level is to be done?
Is the site marked?
Do we require any equipment, implants, radiology films, or are there any special requirements for this patient?
Are antibiotics required?
Is DVT prophylaxis (anticoagulation) indicated?
Are there any precautions based on patient status or medications?
Suction Pre-use Checklist completed?
“If anyone has any concerns about this patient at any point during the procedure, I expect you to speak up.”

439 Table 2. Adverse Event Outcomes and Incidences

Patient Outcomes	Number (%)
Death	2 (7.7)
Prolonged Hospitalization	1 (3.8)
Prolonged "on-pump" time	3 (11.5)
Prolonged anesthetic (off-pump)	16 (61.5)
Aborted Procedure	2 (7.7)
No clinical or sub-clinical consequences	2 (7.7)

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441

442 Table 3. Adverse Event Categories and Incidence

Incident Category	Number (%)
Miscommunication during staff handoff throughout the procedure	4 (13.3)
Missing medication prior to incision	4 (13.3)
Missing instrumentation leading to intra-operative delay	8 (26.7)
Missing implants leading to delays and sub-optimal implants being used	3 (10.0)
Broken and/or improperly handled specialized instruments	9 (30.0)
Miscellaneous incidents	2 (13.3)

443

444 Table 4. Select recommendations to supplement checklists coded by the VA Action Hierarchy

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Local Levels	Higher Control Levels
Change the EHR format to provide more feedback on order status (intermediate)	Implement an incident reporting system and formal event analysis program (stronger)
Institute a formal pre-operative patient handoff from SICU to the surgical team (intermediate)	Implement and enforce a policy requiring pick lists to be reviewed and updated yearly (weaker)
Change the format of the pick list for surgeons' equipment preferences (intermediate)	Institute yearly competency measures to evaluate staff training needs (weaker)
Standardize equipment names to facilitate communication (intermediate)	Implement weekly meetings with nursing and surgical management (and surgical and medical management) to facilitate interprofessional communication (intermediate)
Maintain a stock of blood products in the ICU for emergencies (stronger)	Create consistent national reporting guidelines for medical device incidents (weaker)
Standardize consult procedures (stronger)	Push medical device vendors to create more usable and safer equipment (stronger)
Implement novel surgical volume prediction tools to better match needed staffing levels (intermediate)	Make safety a top priority for the health system from the highest levels of management down (stronger)

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