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Innovations in Simulation

Preventing Harm: Testing and Implementing Health Care Protocols Using Systems Integration and Learner-Focused Simulations: A Case Study of a New Postcardiac Surgery, Cardiac Arrest Protocol

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Abstract: Systems integration (SIS) simulation and system-focused debriefing is an approach to test new processes with health care teams to inform its design and utility and identify systems issues proactively. Learner-focused simulations support team training with a focus on individual knowledge and skills. These strategies combined provide a highly effective quality improvement approach to test and implement new processes. This article will describe how we used SIS followed by learner-focused simulations and debriefings to introduce, test, refine, and train our team on a new, locally adapted cardiac arrest protocol after cardiac surgery (early chest opening).

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Key Points

- Systems integration simulation (SIS) and system-focused debriefing (SFD), followed by learner-focused simulations, provide a highly effective quality improvement approach to test and implement new processes.
- This approach ensured safe testing and implementation of a revised European protocol, a significant change from our daily practice, and previously published postarrest algorithms of the American Heart Association (AHA), including both Basic Life Support (BLS) and ACLS.
- Teamwork was measured using the Mayo High Performance teamwork scale. Overall paired sampled *t*-tests of sessions demonstrated a statistically significant change in total team effectiveness behaviors ($p < .0001$). Statistical analysis showed that team behavior mean score for these questions on the MHPTS increased significantly from presession mean scores ($p < .0001$)

With increased standardization in health care comes an increase in the development and implementation of processes including patient care protocols and pathways (Wick et al., 2015). Often these processes are implemented using insufficient strategies such as email or in-services before use in the live patient care environment. When teams do not have opportunity to apply a new process in an immersive clinical environment before using with live patients, adverse risks can be introduced unknowingly. Many possible reasons exist for why processes are not tested, or first introduced to clinical teams before implementation, such as factors influencing economics, workload, and practice barriers (Rasmussen, 1997).

Rasmussen's framework (1997) on system dynamics describes how boundaries can be crossed unknowingly within our dynamic work environment as we adapt to change, such as new processes that occur across many subsystems in health care. This guides us on mitigating risk by taking proactive steps to prevent harm. Systems integration (SI), an engineering term, is defined as bringing many subsystems together into one better functioning system, which when applied to health care has much untapped potential to improve the safety and quality of care through re-engineering the process and systems in which we work (Lopreiato, 2016).

The Systems Engineering Initiative for Patient Safety (SEIPS) 2.0 model provides a framework for health care components and inter-relationships (Holden et al., 2013). Recently, the SEIPS 2.0 model has been applied to debriefing health care teams following system simulations focused on re-engineering process and systems (Dubé et al., 2019). The SEIPS 2.0 framework provides an easily adaptable means to thematically categorize systems issues from work system components such as equipment/tools/technology, environment, processes/tasks, and people as examples.

SIS followed by system-focused debriefing (SFD) is an approach that uses simulation and debriefing to test new processes with health care teams, with the aim to inform its design and utility and identify system issues proactively to prevent harm (Dubé et al., 2019; Dubé, Shultz, Barnes, Pascal, & Kaba, 2019a; Kaba & Barnes, 2019). Traditional learner-focused simulations support team training with a focus on individual knowledge and skills (Eppich & Cheng, 2015). These two strategies combined provide a unique and highly effective approach to test and then implement new processes.

Foundational to implementation science and quality improvement is the integration of evidence into health care practice. Implementation science examines the implementation of interventions within the controlled environment, testing its effectiveness and then piloting the specific intervention in a local context to test its efficacy (NIH, 2019). One approach to implementation science is the testing of a new process/clinical pathway in health care using SIS followed by SFD within continuous cycles of improvement. These iterative cycles of improvement are described as Plan, Do, Study, Act (PDSA) cycles. In quality improvement, PDSA cycles specifically target the highest risk (staff/patient safety threat) and impact (highest frequency of occurring) system issues (Donnelly & Kirk, 2015). PDSA cycles are a validated approach that focuses on testing new processes, making system improvements and determining if retesting is required before moving to team training simulations and implementation.

This article will describe the testing, refinement, and implementation of a new postcardiac surgery, cardiac arrest protocol termed "early chest opening (ECO)" for over 100 IP team members. The article outlines a scholarly approach to program evaluation that involves implementing new processes, specifically patient care pathways and protocols, using SIS and SFD, followed by learner-focused simulations.

Context

Traditionally, patients experiencing a cardiac arrest early after cardiac surgery were managed with the same Advanced Cardiac Life Support (ACLS) protocol used in other, nonsurgical cohorts (Moretti et al., 2007). In 2015, the European Resuscitation Council developed new post-cardiac surgery arrest treatment guidelines, recognizing that use of generic ACLS resuscitative protocols commonly caused ventricular or graft injury, leading to adverse outcomes (Nikolaou et al., 2015). Our cardiovascular intensive care unit (CVICU), a major tertiary care center, performs 1,400 to 1,500 heart surgeries per year. The treatment guidelines developed in Europe were a significant change from our daily practice, and previously published postarrest algorithms of the American Heart Association, including both Basic Life Support and ACLS (Dunning et al., 2009).

The successful adoption of this new protocol that spanned a 17-month period resulted in paradigm shift in early postoperative management and significant changes in practice. Figure 1 outlines project timelines.

Our team consists of over 100 clinical IP staff including physicians, residents, registered nurses, registered respiratory therapists, cardiac surgeons, unit clerks, a clinical nurse educator, a clinical resource nurse, a clinical nurse specialist, and simulation specialist (i.e., a simulation educator who regularly designs and delivers simulation/debriefing for the purposes of learning and system improvements). Our implementation strategy included testing our refined protocol using SI simulation and SFD, implementing improvements and then training a large IP team using learner-focused simulation (Figure 2).

The project consisted of three phases including (a) planning, (b) SIS protocol testing, and (c) learner-focused simulations.

Methods

Phase 1: Planning

Fundamental project and change management approaches apply to the planning phase of any pathway or protocol including the engagement of key stakeholders and sponsorship. See Figure 2, an adaption of the Rasmussens' framework on system dynamics that highlights the initial planning phase for protocol development. To assist with the planning phase, Dubé et al. (2019) provide detailed description of considerations, recommendations, and the how-to strategies for developing and facilitating patient safety and system integration simulations (Dubé et al., 2019).

The ECO protocol was developed after review of the European Resuscitation Guidelines (Nikolaou et al., 2015) and modified our local practice and workflow. Protocol contextualization was led by the CVICU medical director, critical care fellow, and team members including an educator, clinical resource nurse, clinical nurse specialist, and the unit manager. Two activation protocols were developed to account for staffing level differences between days, nights, and weekends (i.e., no in-house cardiac surgeon coverage at night requiring OR on-call team). Significant changes to current practice were incorporated in our revised protocol including delayed chest compressions, three stacked defibrillations at 360 J, and adjusted epinephrine dosing.

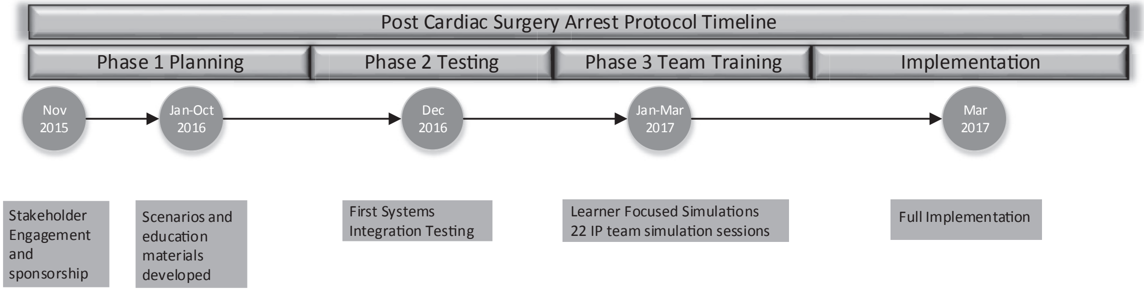

Figure 1 Project timeline.

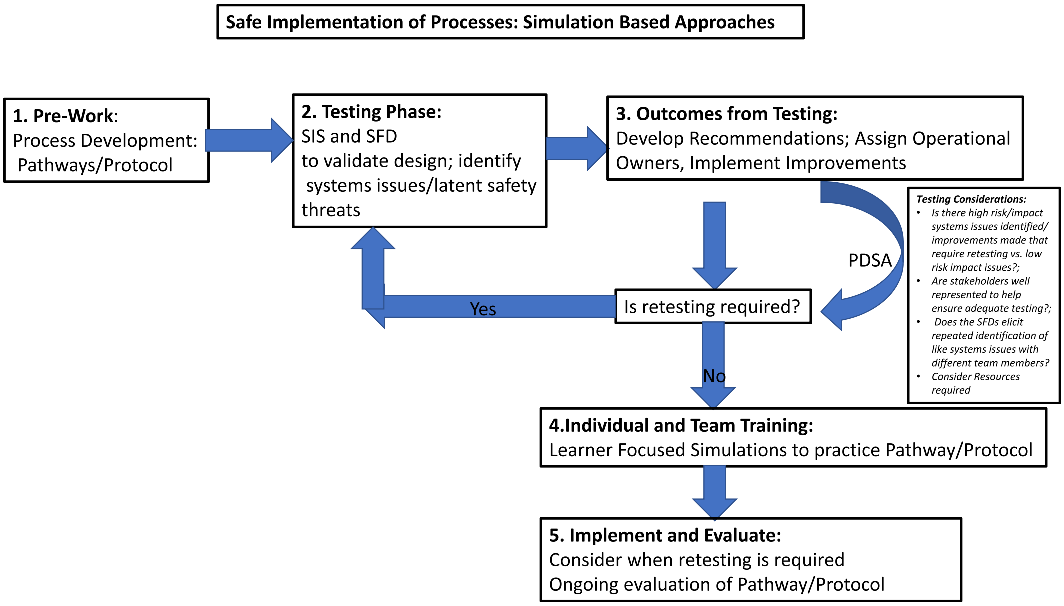

Figure 2 Safe implementation of processes: simulation-based approaches.

The European Guideline review process was intended to help better understand their protocol in relation to our local context. Their described workflows were somewhat different than our local practice that required some modifications to ensure they were effective (e.g., they had the same resources 24/7 on-call; we have different call teams and processes on nights and weekends).

Phase 2: Simulation for Systems Integration: Protocol Testing

Phase two of the project occurred in December 2016 (month 14; Figure 1). See Figure 2, an adaption of the Rasmussens' framework on system dynamics that highlights the testing phase and resulting outcomes for protocol development to validate the design and identify high-impact/high-risk system issues. The goal was to allow for a small cross-sectional number of IP team members to participate in SIS and SFD (Dubé et al., 2019) and provide feedback to the protocol including the identification of system issues including latent safety threats. The protocol was reviewed with the teams (30 minutes), a simulation prebriefing was provided highlighting system issue identification as the goal (15 minutes), followed by 20-minute simulations and 40-minute SFD after each one. Two full IP teams participated in one day of systems testing and included three scenarios with each team. Each participating team consisted of a physician, resident, three nurses, one respiratory therapist, 1 unit clerk, and a clinical resource nurse. Facilitators included a simulation specialist, two clinical nurse educators, one respiratory therapist, and a clinical nurse specialist.

This phase can include several PDSA cycles of testing and retesting as required to further refine the protocol and identify system issues (Figure 2). Considerations for the frequency or repetition of testing with new processes/protocols are dependent on many factors. Some of these factors include the identification of high-risk/-impact (staff/patient safety threat; highest frequency of occurring) system issues versus lower risk/impact. When higher risk/impact issues have been mitigated with improvement work, often retesting can validate the changes before moving to team training and implementation. Through multiple SFDs (i.e., testing the same scenario with different team members), hearing repeated identification of like system issues ensures thorough testing. Ensure all stakeholders who are impacted by the new process/protocol are well represented to ensure adequate testing and feedback. Considerations and support for resources required (i.e., time, cost, human resource, sponsorship etc.) for cycles of testing inevitably impact the approach. Organizational culture is another factor influencing system testing, although outside the scope of this article. For this project, we were able to facilitate 1 day of testing with two complete IP teams for our testing phase.

Some of the key system issues identified and mitigated through the SFD included the packaging of sterile personal protective equipment (PPE) for easier access (e.g., Two complete sets, aside from gloves, were placed in plastic bags); defining a clear process for date labelling on the patient ECO band in collaboration with human factors specialists; cognitive aids for emergency contacts developed, laminated, and posted on the bedside cart; improved process for switching from nonsterile to sterile cardiopulmonary resuscitation (CPR); improved workflow for draping patient and donning PPE; and standardization of CPR stool locations to name a few. Improvements were made and team training followed in phase 3. Cycles of improvement (i.e., PDSA cycles) on the highest risk/impact issues were made immediately between teams during testing day, right after the last team on testing day, and low-risk/low-impact improvements were made throughout the team training. (i.e., determining best location of cognitive aids once developed).

Three simulation scenarios (see Supplementary Material 1A, 1B, and 1C) were developed using a standardized scenario template. SIMMan3G, a high-fidelity simulation manikin, was used for all simulations. Taking place in an unoccupied and routinely empty CVICU bed (i.e., in situ) provided optimal systems testing. Each scenario had a similar standardized structure: objectives, scenario stem, clear transitions, and the ability to test the different components of the protocol.

Phase 3: Team Training: Learner-Focused Simulations

Participants

Phase 3 consisted of 22 IP team simulation sessions (January 2017 to March 2017; month 15—month 17; Figure 1), involving 85 RNs, 17 RRTs, nine intensivists, and seven residents and bedside physicians. Figure 2, an adaption of the Rasmussens' framework on system dynamics, highlights phase 3 that includes individual and team training to practice the protocol and support implementation. The entire IP team ($n = 118$) participated over 11 days. Each session included a standardized prebriefing to include major protocol/process improvements that had been made, and debriefing (Eppich & Cheng, 2015), and took a total of 2 hours and 45 minutes to complete. Each learner-focused debriefing targeted the individual and team learning needs related to the new protocol use, its design, and improved team performance (Table 1). The teams that had opportunity to participate in phase 2 returned to participate in the learner-focused simulations and were validated knowing the improvements that had been made between phases 2 and 3. At the end of each learner-focused debriefing, the teams were asked if they had any other process or system improvements they could offer with all those that were realized in phase 2. Low-risk and -impact feedback allowed for fine tuning of improvements such as placement of CPR stools and cognitive aids. Facilitators for the learner-focused simulations were the same as the SFD. All faculty had been trained in a foundational 2-day simulation course for the provincial program, had been mentored in learner- and system-focused simulation and debriefing previously, and were supported throughout by the simulation specialist.

The simulation session was cancelled once in the early months because of unit acuity and staffing needs. To rectify this in subsequent simulations, staff were replaced at the bedside to ensure their uninterrupted participation, and no further cancellations were required.

Scenario one was focused on the team's ability to identify if a patient was on the "ECO" or not and become familiar with delaying chest compressions while defibrillating with three stacked shocks. Scenario two was focused on the use of the ECO algorithm including delayed chest compressions, three stacked shocks, and preparing for ECO. The final scenario allowed for continued practice of the ECO protocol using different cardiac rhythms.

Results

Data were collected and analyzed from phase 2 "systems integration testing" and phase 3 "team training: learner-focused simulations" as described in Methods section. This testing phase led to several system and team improvements before and after simulations in which the results are summarized in Tables 1 and 2 with supporting qualitative narrative quotes and thematically categorized based on SEIPS 2.0 systems issues categories. Some of the salient changes included donning and doffing techniques, as well as review of, and modifications to, the chest opening cart contents.

Table 1 summarizes the teamwork improvements before and after the project and is supported by qualitative narrative quotes from participants.

Table 2 summarizes the system and process improvements before and after the SISs and is supported by qualitative narrative quotes from participants.

Team Improvements Before and After Project Phases 2 and 3

We measured teamwork using the Mayo High Performance teamwork scale (MHPTS) (Malec et al., 2007). Participants and facilitators completed the forms in real time after the first and third simulations, before debriefing. As these data were collected as part of program evaluation and quality improvement, no rater training was completed for the MHPTS for participants and facilitators. Overall paired sampled t-tests of all sessions demonstrated a statistically significant change in total team effectiveness behaviors ($p < .0001$), as measured by self-reported ratings from participants and facilitators on the MHPTS. The teamwork constructs evaluated by the MHPTS were associated with statistically significant higher scores after session. These items (1, 3, 4, 5, 6, 8) on the MHPTS measure constructs specific to team behaviors: leadership, role clarity, situational awareness, and closed loop communication. Statistical analysis showed that team behavior mean score for these questions on the MHPTS increased significantly from presession mean scores ($p < .0001$).

ECO Quantitative Metrics

Timing metrics (Table 3) were captured on several of our simulation days for the purpose of quality improvement

Table 1 Teamwork Improvements Realized Before and After Project

Teamwork Change	Systems Issue Category (SEIPS 2.0) • Equipment/tools/technology • Environment/room layout • System processes/tasks • People/staffing/roles/ responsibilities	Before Simulations	After Simulations	Qualitative Narrative
Challenges anticipated early	People/staffing/roles/ responsibilities	Chest opening rarely occurred before ECO	As soon as ECO identified, chest opening cart brought to bedside	*"Now we know if we need to run for the chest opening cart right away instead of waiting."* *RN*
Team members cross-monitoring with PPE donning	People/staffing/roles/ responsibilities	Staff were not required to don PPE in emergency arrest situations	When team lead and one RN donning sterile PPE, remainder of team maintaining situational awareness	*"So good to practice … I feel like an OR nurse now."* *RN*
Role clarification during code	People/staffing/roles/ responsibilities	Staff assuming roles without announcing, and at times assuming more than one role	Early identification and announcement of roles	*"This has helped so much to make us function better as a team in codes."* *CVICU MD*
Early identification of code recorder role	People/staffing/roles/ responsibilities	Unaware of importance of the role and not delegating it to another person	Aware of the importance and maintaining one individual assigned to task throughout code	*"I really recognize the importance of the recorder role—especially when the physician is getting sterile wear on"* *CVICU fellow*
Improved closed loop communication	People/staffing/roles/ responsibilities	Observed lack of consistent closed loop communication during cardiac arrest	Much improved use and awareness of closed loop communication after simulations specific to epinephrine medication administration and ask or announce	*"It's very helpful to hear back, so we know if we are going to chest opening or not."* *RRT*
Improved team communication when calling for help.	Equipment/tools/ technology	Not all staff aware of who to call during an emergency chest opening	Each bedside has laminated sheet that provides a list of phone numbers and a cognitive aide on what to say to activate the OR team	*"I had no idea before who to call."* *RN*
Improved resource utilization: development of cognitive aid for OR activation	Equipment/tools/ technology	Single contact number for the OR at main CVICU desk	Development of cognitive aid for calling OR at each bedside table	*"As a clinician I like that now I am not the only one who knows where to find the OR number."* *CVICU Clinician*
Shared mental model of eligibility for ECO during code	System processes/tasks	No ECO pathway	Team uses "ask or announce" to make all team members aware of ECO code pathway, that is, whether ECO or no ECO	*"It is very helpful now to know up front if we might be opening the chest to be able to plan ahead."* *CVICU educator*

Note. CVICU = cardiovascular intensive care unit; ECO = early chest opening.

Table 2 System and Process Improvements Realized Pre and Post System Integration Simulations

System/Process Change	Systems Issue Category (SEIPS 2.0) • Equipment/tools/technology • Environment/room layout • System processes/tasks • People/staffing/roles/ responsibilities	Before Simulations	After Simulations	Qualitative Narrative *(Quotes from participants)*
Identification of "ECO" versus non-ECO patients	System processes/tasks	Did not exist prior to simulations	Patients now identified on CVICU admission with a blue arm band.	*"It's so easy now to identify which patients we need to open the chest on without looking it up in the chart."* *RRT*
CPR Stool	Environment/room layout	No designated locations	Designated locations throughout unit with signage	*"So glad I know where to find that darn stool now!"* *RN*
Routine Crash Cart Check	People/staffing/roles responsibilities	Standard hospital check done daily by charge nurse only	Developed new comprehensive daily checklist done by rotating staff nurses	*"I feel more familiar with the ins and outs of the defibrillator."* *RN*
Emergency chest opening cart PPE mask	Equipment/tools	2 pieces: mask and goggles	One-piece mask with shield	*"This is so much faster and easier."* *RN*
Personal protective equipment	Equipment/tools	Separate PPE items	Pre-packaged bundled together (except gloves)	*"Way more efficient this way."* *CVICU MD*
Defibrillation Pad Access	System processes/tasks	Located on crash cart	Time decreased to access pads by adding defib pads to every bedside storage cart	*"These really help speed things up while someone goes to the get crash cart."* *RN*
Chest opening pan	Equipment/tools/technology	Large sterile cardiac surgery instrument pan	Modified smaller instrument pan	*"Really like the smaller tray, that big tray was overwhelming with all the OR instruments."* *RN*
Process of sterile draping of the patient before chest opening	People/staffing/roles/ responsibilities	No knowledge in applying universal split pack (sterile drape)	Practical experience in applying universal split pack	*"Practicing was so helpful, with such a big drape."* *RN*
Implementation of IP simulation program	System processes/tasks	No standardized simulation program for postcardiac surgery—cardiac arrest patients	Standardized IP Simulation program for all new staff and ongoing for current staff	*"Sim has been so helpful to make me feel more comfortable in code situations!"* *RN/CVICU fellow*
Cognitive aid development for OR activation	Equipment/tools/technology resources	Single number at main desk	Each bedside has laminated sheet that provides a list of phone numbers and a cognitive aide on what to say to activate the OR team	*"I find it really helpful to have this phone number in more than one place!"* *CVICU Nurse Clinician*

Note. ECO = early chest opening.

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Table 3 Timed Improvements During ECO Simulations

5 Simulation Sessions (10 Simulations):	Cardiac Arrest to 1st Defibrillation (Average Time in Minutes)	Cardiac Arrest to Chest Opening (Draping of Patient Chest) (Average Time in Minutes)
Simulation Scenario 2	1:45	7:50
Simulation Scenario 3	:49	5:30
Average Improvement	53% (or:56 seconds)	70% (or 1:46)

checks. Not every simulation included the collection of timing metrics as this was not the primary focus of the project and required the recruitment of additional faculty which was not feasible at the time of the project. In particular, the authors wanted to know whether the timing from cardiac arrest to the first defibrillation and from arrest to the preparation of ‘‘ECO’’ (noted by draping the chest) would improve after the SIS and SFD. We have included an example of debriefing data collection form (see Supplementary Material 2). The results were based on average times calculated from five representative simulation sessions during phases 2 and 3 of the project and demonstrate positive improvements through the use of simulation-based approaches.

Discussion

Our CVICU used SI and learner-focused simulations and debriefings to introduce, test, refine, and train our team on a new and locally adapted cardiac arrest protocol after cardiac surgery (ECO). The implementation of this protocol was met with multiple challenges. For over 25 years, our unit had been training staff to follow the generic ACLS protocol. We were faced with some local realities: our unit is not staffed with in-house 24/7 cardiac surgeon coverage which forced us to amend the recommendations made by the European resuscitation council. This new protocol addressed a high-risk, low-frequency event. The proposed changes required a sustainability plan for ongoing training and skill maintenance and an effective implementation strategy.

During our SIS testing phase, the IP team provided feedback through debriefing on system issues (i.e., tools, technology, tasks, environment, people, organization, processes) (Dubé et al., 2019) and the resulting improvement work was completed.

Improvements included the addition of cognitive aids for calling for OR help, revising the location and layout of the chest opening tray to improve usability, relocating CPR stools for easier access, greater efficiency in garbing PPE, improved role clarity among team members, and enhanced communication strategies for most immediate and accurate assessment of patient ECO candidacy. Limitations of this phase included time constraints and a lack of evidence suggesting the amount of testing required; we adopted 1 day of testing with two IP teams and were able to include the timing metrics for five simulation sessions (10 scenarios). Future work is needed to define criteria for the amount of testing required for new processes; for example, expanding on those listed in Figure 2 such as ensuring most of the highest risk/impact system issues have been identified through the SFD.

Introducing a new policy addressing a high-risk, low-frequency event is associated with multiple challenges including lack of skill maintenance (Ferlie & Shortell, 2001). Through training using learning-focused simulations, our staff were able to effectively apply the ECO algorithm before implementation. Qualitative results from the debriefings demonstrate our staff gained sufficient comfort and confidence in the new ECO protocol.

This project highlights a unique approach to implementation science through the testing of a new clinical protocol through the application of SIS followed by SFD within continuous cycles of improvement. This quality improvement approach ensured a safe and reliable implementation of a high-risk, low-frequency protocol which allowed us to pre-emptively identify, and mitigate, potential threats to patient safety (Bold, 2011; Braithwaite, Wears, & Hollnagel, 2015). Had we not used this implementation science approach (NHI, 2019), patients may have been exposed to adverse outcomes as a result of this significant practice change. PDSA cycles ground this work in a validated method to test processes, make system improvements, and determine if retesting is required before moving to team training simulations and implementation (Donnelly & Kirk, 2015) (Figure 2). Rasmussen’s framework (1997) on system dynamics describes how invisible and unsafe boundaries can be crossed unknowingly within our dynamic work environment as we adapt to change, such as new processes that occur across many subsystems in health care. Our approach was successful to reduce unintended harm with the implementation of a new process. This is evidenced by the system, process, and team work improvements including qualitative quotes stated by the participants (Tables 1 and 2).

In a learning organization, adoption of system level change and developing a safety culture requires strategies such as simulation that can proactively identify and mitigate patient risk while improving the systems in which we work (Auerbach, Kessler, & Patterson, 2015; Geis, Pio, Pendergrass, Moyer, & Patterson, 2011; Parry,et al., 2013).

As our team was large and diverse, this approach allowed for IP systems learning, problem solving, and system improvements.

Although this project highlights one case, this approach has the potential to be generalizable to other large-scale quality improvement practice changes and clinical protocol implementations.

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Supplementary Data

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