Title of Project

- Development of a toolkit for dissemination and implementation of the OR crisis checklists

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Structured Abstract

Purpose: To understand the different implementation approaches and contextual factors that may determine the successful use of the crisis checklists/emergency manuals [CC/EM] at a mixed group of facilities, inpatient and ambulatory, across the United States and use that information to create a web/paper toolkit to support CC/EM implementation.
Scope: To use a pre-collected database of email addresses of downloaders of CC/EM to access a group of early adopters to gain insight into their implementation processes, facilitators, and barriers relative to a tool designed to improve care in emergencies in the operating room [OR]. These tools are built on experience gained in other high-hazard industries to support human performance in a crisis and have potential use in many healthcare settings.
Methods: A survey was designed, tested, and distributed to 12,722 email addresses of downloaders of CC/EM. Survey results were collected and analyzed. This was paired with a qualitative analysis of a smaller sample of 50 targeted, in-depth, structured interviews.
Results: Survey respondents were primarily anesthesiologists from facilities of mixed size. Implementation success was related to the number of implementation steps followed, smaller facility size, number of ways the tool was used beyond the OR, institutional support, and time to train staff. Implementation failure was associated with lack of a clinical champion, clinician resistance to use and the content of the tool, or the design of the tool being unsatisfactory. Clinician resistance is often grounded in fear of being seen incompetent if tools are used.
Key Words: crisis, checklists, emergency, manual, implementation, surgery, cognitive aids

Purpose (Objectives of Study)

The goal of this project was to understand the different implementation approaches and contextual factors that may determine the successful use of the crisis checklists/emergency manuals [CC/EM] at facilities across the United States. We took this knowledge and transformed it into a practical and effective toolkit that will accelerate uptake and adoption and ultimately improve the safety of individuals undergoing surgery across the diversity of institutions in the United States and other settings.

Specific Aim 1: Measure the current status of CC/EM implementation in the United States
Objective 1A: Assess the diversity of interest in CC/EM.
We analyzed the Harvard OR Crisis Checklists, Stanford Emergency Manual, and Emergency Manuals Implementation Collaborative (EMIC) databases to better understand institution type, geographic location, downloader characteristics, and other factors to comprehend the range of interest (defined as downloading the tool).

Objective 1B: Evaluate self-described stage of implementation and success or failure of deployment of CC/EM.
Through a short, internet-based survey sent to downloaders, we identified individuals who self-reported success or failure in institutional implementation of the tools and identified potential disparities, such as in large and small facilities or in teaching versus non-teaching institutions, where different barriers may exist.

Specific Aim 2: Identify implementation approaches, contextual factors, and local adaptation strategies associated with the success or failure of implementation of the CC/EM at a range of healthcare institutions in the United States
We conducted key informant interviews with a sample of geographically and institutionally diverse institutions that had self-reported either successful uptake of the CC/EM or attempted implementation with limited or no success. These interviews were designed to identify the process of implementation (e.g., who led the implementation, interprofessional engagement, how the tools were locally customized, how providers were trained, where the tools were located in the clinical environment, how organizations measured use). We also investigated contextual factors, which drive implementation decisions, the key factors associated with success, as well as implementation barriers and strategies to overcome them. The methods and domains were derived

from previous research and fieldwork on implementation strategies and facilitating factors for the WHO Surgical Safety Checklist.

Specific Aim 3: Create an implementation toolkit based on lessons learned from adopters to accelerate the effective implementation of the CC/EM as a component of patient safety work at institutions in the United States

To accelerate spread and bridge the implementation gap from knowledge of the tool to institutional adoption and effective use, practical tools that guide implementers through key elements were developed. We based this package on the field knowledge gathered from the key informant interviews and our team's experience implementing similar tools at a large scale, such as the WHO Surgical Safety Checklist. The cost-free toolkit provides guidance on issues such as local adaptation, training resources, critical steps such as leadership engagement, and potential solutions to frequently encountered challenges. The toolkit also draws on principles and lessons learned from the Agency for Healthcare Research and Quality's TeamSTEPPS program (2014). Toolkit materials were designed to specifically address barriers identified by institutions.

Overall impact

By understanding successful and failed implementation strategies and how institutions came to their approaches, we created new resources and annotated existing tools to create an implementation toolkit that will lower the threshold for starting implementation or accelerating implementation and will increase the probability of effective adoption, therefore enabling more patients to be protected by the proven tools.

Scope

Background

Remarkable gains have been made over the past century in the safety of anesthesia and surgical procedures performed in operating rooms. Despite these improvements, intra-operative emergencies like cardiac arrest and massive hemorrhage do occur. The infrequency of these emergencies challenges operating teams to work at their highest levels in situations that they rarely encounter. Particularly under stress, human memory is imperfect, and responses to crises can be compromised by the omission of key steps or failure to consider critical possibilities, resulting in threats to patient safety. Previous research, including AHRQ-funded work, has recently demonstrated that the use of crisis checklists and emergency manuals can dramatically improve team performance. Appropriate training in their use can provide critical direction during a crisis. There has been increasing effort in recent years to raise awareness and encourage the implementation of operating room crisis checklists and emergency manuals throughout the country. Tens of thousands of clinicians and their institutions have become aware of these tools, and thousands have downloaded them. Some of these adopters have gone on to implement the tools in their operating rooms with varying degrees of success. The aim of this project was to understand the current efforts that have gone into the implementation of crisis checklists/emergency manuals, to discover unique practices and approaches that will lead to the creation of an innovative toolkit to help others implement more easily and effectively.

Context

The operating room is a high-acuity patient care environment in which critical events occur more commonly than in many other patient care settings. Nonetheless, the experience of any single clinician in the management of relatively rare events is limited, and the capacity to reliably deliver optimal care for an unfamiliar problem is often compromised. Degradation of performance due to inaccessible knowledge and flawed communication is a well-demonstrated consequence of stress associated with high-risk situations (Staal, 2004). Furthermore, there are reports of major deviations from guidelines when working from memory alone (Kurrek, Devitt, & Cohen, 1998). Tools to improve management of critical operating room events offer the opportunity to produce a measurable impact on overall surgical mortality. In our group's previous work, we demonstrated significant improvement in the care provided in a simulated operating room by surgical teams when using crisis checklists. There was nearly a 75% reduction in failure to adhere to critical steps in management, with every team performing better when the checklists were available (Arriaga et al., 2013). The challenge that remains is in bringing crisis checklists to widespread clinical use through effective and efficient implementation approaches.

The concept of using tools like crisis checklists and emergency manuals is not new to the operating room. In 1924, William Wayne Babcock, a prominent Philadelphia surgeon, published an article in Anesthesia and

Analgesia advocating for the use of a list of critical steps for managing a cardiac arrest to be displayed on a poster on the operating room wall (i.e., a checklist) accompanied by routine drilling of the operating room staff (Babcock, 1924). Cardiac arrest was all too common in operating rooms, and the surgeon and team were ill prepared to deal with the crisis, one that often led to the patient's death. In the next 60 years, Dr. Babcock's idea did not spread widely within medicine. However, in aviation and the nuclear power industries, sectors plagued by rare but deadly accidents, the use of checklists for routine and crisis situations rapidly became accepted practice (Burian, 2004, 2006; Degani & Wiener, 1993). In the 1980s, Drs. David Gaba, Steve Howard, and colleagues at VA Palo Alto and Stanford University began to develop protocols, modeled after such tools, to help educate clinicians by condensing relevant literature and to help teams manage patients appropriately during operating room crises (Goldhaber-Fiebert & Howard, 2013). In 1994, they published a book, Crisis Management in Anesthesiology, with a recent 2nd edition, both containing many (80-90) of these protocols (Gaba, Fish, & Howard, 1994; Gaba, Fish, Howard, & Burden, 2015). In the early 2000s, they led a team that worked with the VA's National Center for Patient Safety to bring the idea – now in the form of more usable binders – to VA operating rooms across the country (Neily et al., 2007). Throughout the 2000s, the group continuously engaged in user-centered design of these tools, improving them through ongoing simulation courses for anesthesiology, ICU, and code-team personnel.

In 2009, we began work at the Harvard T.H. Chan School of Public Health under an AHRQ grant [Grant R18HS018537], building on a campaign that we had led with the World Health Organization in developing the Surgical Safety Checklist. Using a collaborative process, we developed a group of 12 crisis checklists and validated them in a simulated operating room. The simulation-based testing was chosen because the rareness of the emergencies in the clinical setting made real-life testing infeasible. The results of the simulator testing showed a strong correlation between checklist use and better team performance of critical safety steps during a crisis (Arriaga et al., 2013). Simply put, the crisis checklists make good teams even better, at least in the simulator. In the time since that study was performed, we have continued to train operating room teams from Brigham and Women's Hospital, Kaiser Permanente of Northern California, and the National Scientific and Practical Center of Emergency Medicine in Chisinau, Moldova. After the training at Brigham and Women's Hospital, a survey was given that revealed highly variable awareness of the crisis checklists, dependent on role and specialty. Awareness appeared to be related to the effort that had been expended on a particular group. Anesthesiologists, who had proportionally received the most simulator training, were the most aware of the tools. Not surprisingly, surgeons, who had only been minimally involved in simulation, were the least aware. These early lessons from an implementation program provide a foundation for additional research. The most recent progress report that outlines the lessons from this work is included as an appendix (Berry, Gawande, Edmondson, & Nurudeen, 2014).

In parallel, the Stanford Anesthesia Cognitive Aid Group launched the Stanford Perioperative Emergency Manual in 2011, containing 23 protocols designed for real-time clinical use. This manual was iteratively tested in simulated crises and clinically implemented – along with dedicated familiarization and training -- with all operating room personnel (anesthesia, surgery, nursing, technicians) (Stanford Anesthesia Cognitive Aid Group, 2011). The framework used for clinical implementation of the emergency manual was based upon the published simulation, human factors, and psychology literature; examples from high-hazard fields, such as aviation; and their own extensive experience with such tools in simulation trainings and in early clinical implementation (Goldhaber-Fiebert & Howard, 2013).

In 2012, we brought these two parallel threads of work together to form the Emergency Manual Implementation Collaborative [EMIC]. This collaborative is designed to "foster the dissemination and effective use of emergency manuals to enhance our patients' safety…focus(ed) on perioperative crises" (Emergency Manuals Implementation Collaborative, 2012). For the past 5 years, EMIC members have been working together to better understand implementation of these types of tools. Through the efforts of EMIC, thousands of individuals have been exposed to the idea of using CC/EM (Emergency Manuals Implementation Collaborative, 2012). Today, the crisis checklists/emergency manuals and their associated implementation guides are accessible through three websites (Ariadne Labs, 2013; Emergency Manuals Implementation Collaborative, 2012; Stanford Anesthesia Cognitive Aid Group, 2011). For English versions, there have been more than 70,000 downloads of these types of tools in the past 5 years, with hundreds of thousands globally, including translated versions. Despite the availability of and interest in these tools and the founding of EMIC, implementation has

been slow or nonexistent in many facilities across the United States (Mills et al., 2004; Mulroy, 2013; Neily et al., 2007; Stiegler & Goldhaber-Fiebert, 2013).

Ideal use requires understanding and acceptance of the value of the CC/EM across the surgical team. Our current work with the CC/EM indicates that surgical team members, in general, are supportive of the concept of using memory aids during operating room crises. It is intuitive to many surgical team members that, in crisis situations, the increased levels of stress make vulnerability to error significantly higher and that the use of CC/EM will likely decrease that vulnerability. Despite that, when exposed to an emergency situation in the simulator, they sometimes fail to use the tool or only use it sparingly, apparently skipping steps (Goldhaber-Fiebert & Howard, 2013; Harrison, Manser, Howard, & Gaba, 2006). These observations make it clear that a better understanding of ideal training is needed. An implementation gap exists between current and ideal use, resulting in missed opportunities to protect patients and reduce preventable suffering and mortality (Bould et al., 2009; Burden, Carr, Staman, Littman, & Torjman, 2012; Nanji & Cooper, 2012; Nelson, Shilkofski, Haggerty, Saliski, & Hunt, 2008). This gap is a common challenge for new innovations in healthcare. In studies of similar interventions focused on improving quality and safety, both the contextual factors present prior to implementation (e.g., structural factors, patient safety culture, leadership, and training resources) and the nature of the intervention (e.g., relative advantage, complexity, cost) have been identified as common causes for the gap between awareness of and widespread use of these tools (Alidina, Schneider, Singer, & Rosenthal, 2014; Singer et al., 2009). Less is known about how the specific approach to implementation impacts success, although some critical decisions related to adaptation to local context as well as balancing this adaptation with fidelity can determine success in spread and effectiveness (Conley, Singer, Edmondson, Berry, & Gawande, 2011). Our group was deeply involved in the design, testing, and spread of the WHO Surgical Safety Checklist. We were principally responsible for the development of the initial implementation toolkit. Our group's experience with supporting implementation of the Surgical Safety Checklist suggests that a toolkit that outlines methods of building an implementation team, adapting the checklist to local culture and practice, engaging and training clinicians with subsequent coaching in the operating room can further improve checklist performance. Many of these principles were derived from the AHRQ TeamSTEPPS program (Agency for Healthcare Research and Quality, 2014). Many institutions have now adopted the WHO Surgical Safety Checklist using this approach. This widespread adoption has given us the opportunity to learn from thousands of implementation efforts. As an example, our team has been working with 67 hospitals in South Carolina to implement the WHO Surgical Safety Checklist. From this work, we learned the factors that must be considered and approaches that should be taken to lead to implementation success and have further refined materials to assist others with enhancing their use of the WHO Checklist (Safe Surgery 2015, 2011). The culmination of this learning has been integrated into a comprehensive toolkit to help additional institutions accelerate the implementation of the WHO Surgical Safety Checklist and other patient safety initiatives.

We believe that our extensive experience with the WHO Surgical Safety Checklist together with the lessons we have learned in the development of the crisis checklists/emergency manuals has provided us a unique opportunity to continue to solve the problems that stand in the way of robust clinical adoption and use of the tools. Operating room crises occur across the United States every day, and critical steps in care continue to be missed, with lives altered as a result. The role of tools like the crisis checklists and emergency manuals is to close the gaps in care delivery by providing ready access to seldom-used information and, just as importantly, to give a framework to organize an improved, stepwise, and complete management approach to a critical event (Ramirez & Grantham, 2012; Ranganathan, Phillips, Attaallah, & Vallejo, 2014).

Settings

Our experience with the WHO Surgical Safety Checklist has taught us that dissemination of tools to providers and healthcare organizations and effective implementation of those tools at the frontline level are not equivalent. These tools do not implement themselves. In spite of extensive work and experience with training clinicians to use CC/EM, we continue to observe struggles, even in the simulation environment (Bould et al., 2009; Burden et al., 2012; Goldhaber-Fiebert & Howard, 2013; Harrison et al., 2006; Nanji & Cooper, 2012; Nelson et al., 2008). The struggles observed in simulation almost certainly also occur in the clinical setting, preventing optimal use (Mills et al., 2004). Describing and documenting the variability in implementation approaches and degree of adoption across many institutions helped us identify new ideas to support the creation of a package to facilitate broad implementation of these innovations. In a fashion similar

to the one that we used with the WHO Surgical Safety Checklist, we wanted to perform a structured investigation to better understand the methods that are currently being used to implement the CC/EM in institutions across the United States.

Participants
In total, 12,277 surveys were distributed by email, and 1796 responses were collected [response rate=14%]. In the smaller study sample of 368 (defined in the results section on page 9), 84.5% were anesthesiologists or nurse anesthetists, 3.5% were surgeons, and 6.5% were OR staff. In addition, 32.1% worked for a university or institution, 25.3% were in a physician owned practice, 13.9% were in a corporate practice, and 7.3% were in solo practice. Also, 8.4% had less than 5 years of experience, 10.9% had 5-10 years, 21.7% had 11-20 years, and 53.8% had >20 years. The respondents the facilities represented had 0-4 ORs (24.5%), 5-15 ORs (32.3%), 16-30 ORs (22.6%), or >30 ORs (20.1%). Thiry-seven implementers from 21 states were interviewed in the qualitative portion of the study.

Methods
Quantitative Study Design
The study used primary data and mixed methods to understand the adoption, implementation, and adaptation of the crisis checklists/emergency manuals [CC/EM], with a goal of creating a toolkit to accelerate their effective implementation in U.S. organizations. A mixed methods approach is uniquely suited to studying complex, non-linear, and nuanced processes, such as the implementation of innovations (Alidina, Rosenthal, E., & Singer, In press; Alidina et al., 2014; E. H. Bradley et al., 2010; L. Curry & Nunez-Smith, 2015; Singer, Hayes, Gray, & Kiang, 2014).

We used a four-phase approach to our work that aligns with our specific aims: 1) analysis of existing databases to develop a profile of those who have expressed an interest in the CC/EM (Objective 1A), 2) a survey to determine the extent of uptake of the CC/EM by those who accessed the instruments (Objective 1B), in-depth, qualitative interviews to understand the process and extent of implementation and adaptation as well as the related facilitators and barriers (Objective 2), and 4) development of a toolkit based on our findings from the first three steps and respondent validation to ensure that the toolkit contents reflect the feedback from participants (Objective 3).

Data Sources/Collection and Analysis

Study Sample and Recruitment
We used a purposive sampling approach to select participants who have knowledge about the CC/EM and were willing to discuss their experience. At the same time, we ensured that our sample was diverse in terms of characteristics such as hospital or private practice size, geographic location, teaching status (teaching vs. community), and how anesthesia professionals are paid (fee-for-service payment vs. salary). These features may be related to the use of CC/EM, and a sample that is diverse along these characteristics would also allow the results to be more generalizable to the broader U.S. hospital population (E. H. Bradley et al., 2009). Our initial sampling frame included U.S. organizations that had expressed an interest in the crisis checklists and emergency manuals. We used three information sources to generate a list of interested facilities: 1) members of Emergency Manuals Implementation Collaborative [EMIC] (approximately 200 members), 2) providers and institutions that have downloaded the CC/EM from Harvard and Stanford websites (approximately 13,000 downloads), and 3) other interested organizations identified through informal networks and key informants. To maximize participation, a letter outlining information on the study and its aims was sent from the PI with the survey, and we offered to share aggregated results with respondents.

Phase 1 (Objective 1A): Profile of those who have expressed an interest in the OR CC/EM
Data Collection
The first phase of our work was to develop a profile of those who are interested in the CC/EM (Objective 1A). We requested that survey participants provide information about their institutions [e.g., type of provider (hospital or ASC)], geographic location (state, zip code), size, and teaching status (teaching vs. non-teaching) to identify the diversity of organizational characteristics.

Data Analysis
To understand the profile of those who are interested in the CC/EM, we used descriptive statistics and GIS software to create maps that display information on the organization's characteristics (e.g., size, teaching vs. community). This information is available in Appendix 1.

Phase 2 (Objective 1B): Survey to determine the extent of CC/EM's uptake
Data Collection
The second phase of our study sought to understand the extent of the CC/EM's uptake (Objective 1B). To accomplish this, an online survey was sent to the group identified in Phase 1. The survey was adapted from related instruments as well as from input from members of the EMIC collaborative. The survey asked questions to understand what, if any, activities the organization has undertaken to implement the CC/EM. Examples of activities include:

- Reviewed CC/EM for adaptation to local context
- Modified CC/EM for local context
- Distributed CC/EM in all ORs
- Trained providers
- Measured uptake
- Coached providers
- Maintained use, after initial implementation

We collected respondent characteristics including clinician type, career stage (e.g., trainee vs. someone with 20 years of experience) and the type of leadership role they play within the organization. An expert in implementation science advised us on survey design. The survey was pilot tested prior to its use.

The survey was administered electronically to the downloaders of the CC/EM using Qualtrics online survey software. Participation was voluntary, and no financial incentives were offered. We sent all potential respondents up to three reminders with a link to the survey at approximately 2-week intervals.

Data Analysis
To understand the characteristics of the adopters and the extent of implementation, we calculated the mean and range for the responses to each survey item. We stratified the data by those who self-reported lower levels of implementation versus those who reported higher levels of implementation to understand the differences. To understand how the extent of implementation differs by organizational characteristics, we analyzed the data by comparing the degree of implementation with healthcare organizational characteristics, including teaching/non-teaching, size, and geo-location.

Phase 3 (Objective 2): In-depth interviews to identify implementation and adaptation processes including related facilitators and barriers

Qualitative Study Design

<u>Methods</u>
Study Design
This qualitative phase of the study involved semi-structured interviews conducted with clinicians in the U.S. who had implemented the OR Crisis Checklist or OR Emergency Manual in their health facility. We used a positive-deviance framework with high success implementers as the positive deviants and low success implementers as the comparison group (Baxter et al. 2016).

Participants
Clinicians were selected from among those who had completed the OR Crisis Checklist/Perioperative Emergency Manual Implementation Survey, indicated on the survey that we could contact them for an interview, and provided contact information. Our intent was to include as much diversity as possible in order to sample a broad spectrum of experiences. Consequently, we developed a sampling grid based on facility size [i.e., number of operating rooms (ASCs and small hospitals: 1-4 ORs, medium hospitals: 5-29 ORs, large hospitals: 30+ ORs)], geography (by state), and academic/non-academic facility. We aimed to include 15 higher-success implementers and 15 lower-success implementers, with each strata of participants being

sampled from across the diversity characteristics. To measure implementation success, we used the following survey item: “At my facility, the tool is used regularly during applicable clinical events,” which was measured on a five-point scale from “strongly disagree” to “strongly agree.” Facilities defined as having less successful implementation were those who indicated that they either disagreed or strongly disagreed with the survey item, and facilities defined as having higher success implementation were those who indicated that they either agreed or strongly agreed. Respondents who “neither agreed nor disagreed” as well as those who did not answer were excluded from the study sample. To further inform specific implementation activities, we also conducted 10 key informant interviews with individuals who were identified as having expertise and/or knowledge in a particular area related to successful implementation of emergency checklists. Given their reputation for excellence in implementation, we present the findings from their interviews with those of the higher-success strata. Overall, we aimed for a sample size of 40 participants based on the general rule of thumb that saturation (i.e., no longer obtaining new, meaningful insights (Glaser and Anselm 1967)) is typically achieved with a sample of approximately 30 people (Mason 2010) but that saturation can take longer as diversity of the sample increases (Ritchie et al. 2003).

The interview guide

The interview guide was designed to explore the implementation steps included in the OR Crisis Checklist/Perioperative Emergency Manual Implementation Survey and to gain insights into *how* the steps were implemented as well as barriers and facilitators to implementing each step. We also asked questions about any other activities that were conducted as part of the implementation, how the checklist/manual was used, the perceived value and drawbacks of use, and advice for future implementers. The guide was pilot tested with three implementers who were excluded from the sample pool because they neither agreed nor disagreed with the item measuring implementation success. The piloting was used to assess clarity and appropriateness of interview questions and minor changes were made based on their feedback.

Data collection

Interviews were conducted over the phone and led by four team members. Interviews lasted 45-60 minutes and were audio recorded. One interviewer who might have been known to participants and had less experience conducting interviews was trained by a qualitative expert on how to conduct a semi-structured interview, avoid leading questions, and minimize his potential influence over interviewee answers. Interviewees did not receive any remuneration for their time.

All interviews were transcribed verbatim and reviewed for quality by members of the study team, and any transcripts with discrepancies with significant errors were sent back to be edited. As a final quality check, coders referred back to the original audio recording if there remained any parts of the transcript that needed clarification. Names of individuals and institutions were removed from all transcripts, and transcripts were stored on a secure computer drive.

Data analysis

Data analysis of the interview transcripts was completed in four steps:

1. Coding

   Study team members, including the interviewers, co-investigators, and principal investigator, created a deductive list of themes based on evidence in the literature and the interview guide. Initial interviews were coded by three study team members trained in qualitative methods, and any inconsistencies in themes were discussed until a consensus was reached. After consistent inter-coder agreement was met, a qualitative expert reviewed every interview to ensure quality and appropriate assignment of themes. In addition to coding agreement, theme definitions were clarified as necessary to ensure a shared understanding of when the themes should be applied. Coding was conducted in NVivo (Version 11.4.2. for Mac, Australia for Mac), the qualitative analysis software.
2. Identifying patterns within and across strata

   The coded transcripts were thematically analyzed by two of the team members who conducted and coded the interviews. The analyses explored implementation steps as well as facilitators and barriers to implementation**.** Each theme was stratified by both facility size (large/medium and small/ASC) and performance (high vs. low), and we looked for similarities and differences within and across each strata. Key findings were summarized for each theme.

3. Discussion with study team

   After this first phase of analysis, the analysts met with an expert implementer and anesthesiologist from our team to help determine which key findings were most important. An implementation step, facilitator, or barrier was considered to be important based on the number of times it was mentioned either within or across all strata. As a final step, the entire study team discussed the relevance and potential implications of these findings.

This study was reviewed by the Partners HealthCare and Stanford University School of Medicine Institutional Review Boards and determined to be exempt. Participants were contacted via email to participate in the study, and active consent was obtained before the start of every interview.

Results

Principal Findings:

Quantitative Survey Study

In total, 12,722 surveys were distributed to potential respondents identified in the merged database. Responses were obtained from 1796. After removing partially completed surveys, 1700 remained for analysis. After removing international respondents and parsing the sample based on the level of implementation success perceived by the respondent, 368 facilities were represented in the sample (65.5% successful, 34.5% unsuccessful).

The survey was returned primarily by anesthesiologists (84%) with more than 20 years of experience (54%). The facilities ranged in size from one to more than 30 operating rooms, and most were larger than four ORs. The respondents were employed in all major employment models. The facilities represented significant geographic dispersion (see maps included). The analysis of the sample revealed the following findings:

Successful facilities reported implementation was associated with:

1. Following more implementation steps
2. A supportive leadership
3. More dedicated time to train staff
4. A smaller facility sizes
5. Prior Quality Improvement experience

Lack of implementation success was associated with:

1. Lack of an identified champion
2. Resistant providers
3. Unsatisfactory content or design of the checklists

Other significant findings:

1. Overall, 90% of respondents, irrespective of their facility's reported implementation status, agreed or strongly agreed with the statement, "If I were having an operation that had an intraoperative emergency, I would want this tool to be used."
2. "Use begets Use": Facilities reporting implementation success also reported more use of the tools apart from real-time management of critical events.
3. Nearly 60% of respondents from successful sites reported that the implementation process had improved team performance in critical event management.

Qualitative Interview Results:

Participant characteristics

Due to a low response rate, we used a convenience sample and were unable to capture the full range of intended diversity. Implementers for small hospitals and ASCs were under-represented, as were higher-success implementers from non-academic facilities. Part of the over-representation of higher-success implementers stems from including the 10 hand-selected key informants in this stratum. Overall, a total of 37 implementers participated in the study from 21 states.

Implementation strategies

The interviews revealed that there are five steps typically conducted in implementing the checklist/manual. Although there is consistency in the category of steps, there is variation in how each of the steps is implemented. In general, the variation did not appear to correlate with level of implementation success, although there was a small number of activities that were done most commonly or exclusively in either higher- or lower-success sites. Table 1 identifies the most common implementation steps, examples of how these steps were implemented, and illustrative quotes describing the experience of implementing the step. Variation associated with a specific level of success is described following the table. It is important to note that an absence of an implementation strategy does not mean that none of the sites used it but rather that none of them reported using it during their interview. Similarly, for strategies that we identify as only being used in either higher- or lower-success sites, it is possible that there are exceptions to this finding but that they were not mentioned in the interview. Consequently, the results provide a sense of the range of variation in implementation of the OR Crisis Checklist and OR Emergency Manual and identify what appear to be patterns of differences between higher- and lower-success sites.

Table 1. Primary Implementation Steps

Implementation Step	**Examples of how the step was implemented**	**Illustrative quotes**
Buy-in	Ways to get buy-in ● Use in simulations and/or drills ● Present at meetings ● Present to leadership ● Have 1:1 conversations with resistors Target audience ● OR director or executive committee ● Residents ● Surgeons	people are like “Wow! That was so much easier with this manual in place. It really helped me through the treatment process.” ... - the best way to do it is when people have these experiences with and without manuals and see how different it was.” “It has to be a casual conversation. I truly believe in that. You know, there’s a difference between educating people in a rigorous matter and there’s a difference in educating people in an informal matter. I truly believe in that and when you’re trying to get them to buy-in something, sometimes it’s better to just be one-on-one informally, you know, talk at lunch. You sit down, I’ll be at lunch and I’m like, ‘Oh, you know, we have this manual that we’re going to be putting in the OR. Do me a favor, next time you are in the OR, ask the CRNA to look at it. Stuff like that.’”
Training	Methods ● Low-tech training ● High-tech training ● Debrief after training ● Provide ongoing training Participants ● Nurses ● Anesthesia ● Residents ● Surgeons ● Technicians ● Administrative staff Other ● During simulations, participants can also work on teamwork and communication skills	“I think ...as I’ve evolved as a simulation person, I started out, you know, everything had to be high fidelity and it’s close to real life as possible and then now all the time I feel like you can actually get a lot more done if you just kind of keep it simple.” “And then in the simulations themselves, if they’re not using the manual, we’ll often have a, we’ll throw in some prompts. I asked them, ‘Do you want to use the manual,’ or if they’re struggling with coming up with particular medications and they say, ‘Well, I think that medication is in the manual.’... It just goes to show that it is valuable and that it sort of jogs their memory to use it.”

Place checklist	Location ● Drawer on cart or machine ● Side of machine ● Electronic version Advice for sites ● Have multiple copies in the OR ● Make sure it is easily accessible and visible ● Put in a 3-ring binder ● Laminate pages ● Attach with a lax chain or cable	"...whoever needs to implement those need to really spend a lot of time with their anesthesia machine on which side they want to put it. Significant factors being, you do not want the chain too long, you do not want the chain too short, and you need to make sure that, that the location is such that the book doesn't keep getting dirty or sloshed on all the time." "I've made all the books as accessible as possible so nobody has an excuse to not use the books because in the OR they are everywhere."
Present checklist	How to present the checklist ● Meetings such as grand rounds, department meetings, in-service time ● Email ● 1:1 conversations Target audience ● Anesthesiologists ● Nurses ● Surgeons ● Residents Content ● Explain the purpose of the checklist	"We had a staff meeting...it was our administrative office staff to our nurses to - it was everybody. Doctors, nurses, everybody across the board." "...can be done by, you know, in service, one-to-one in the operating room, discussions, time, things of that nature...definitely formal and informal."
Customize	● Added or subtracted protocols to fit facility ● Added local phone numbers ● Laminated pages ● Have multiple people help with customization to increase buy-in	"I think it helped with the success of the checklist because the people that worked on either the customizations or owned that little part felt that they were the content expert. They really, we felt, local buy-in so the checklists are branded like our institutions. They are customized with phone numbers. They are customized with workflow and then we've even further customized not just our main campus but our satellite site that is six blocks away that has a little bit of a different workflow or different phone numbers or different patterns of doing things so it makes it a workable checklist that really, in a local environment, is helpful." "So I think the first thing I would say is, absolutely locally customize, absolutely know your own culture and think about what will work in your place and adapt. Don't just cookie cutter, you know, ah, take something, print and plunk and expect it to be used."

Certain ways of implementing the steps were (almost) only done at lower-success sites. These include the "print and plunk" method of implementation (i.e., printing the checklist and placing it in operating rooms without any presentation of, or training on, the materials), presenting the checklist without explaining the rationale for using it, and presenting the checklist but not providing training on how to use it. Lower-success sites were also the only sites that limited training to low-tech simulation, such as tabletop exercises, unlike higher-success

sites, which used either high-tech simulations or a combination of high- and low-tech simulations. Given the apparent association between these implementation strategies and lower success, it is plausible that these approaches are suboptimal, although larger sample sizes are needed to verify this. It is important to note that not all lower-success sites implemented with the approaches and that many of the lower-success sites used many of the same implementation strategies as the higher-success sites.
Unlike lower-success sites, higher-success sites tended to discuss the value of checklists/cognitive aids when presenting the checklist or manual. Although not all higher-success sites discussed the rationale, none of the lower-success sites reported presenting this. Presenting the rationale is likely a good implementation practice.

Facilitators and barriers to implementation
The facilitators and barriers described by participants cross-cut lower- and higher-success sites with no noticeable differences by level of implementation success. Table 2 outlines typical implementation facilitators and barriers.

Table 2.

Facilitators and Challenges in All Sites	
Facilitators	● General support from colleagues ● Having a budget for implementation ● Having dedicated time for training ● Having a culture of patient safety and accepting of cognitive aids ● Younger physicians because they are more accepting of cognitive aids ● Surgeon checklist champion ● Implementer autonomy
Challenges	● Even with training, people might not use it/remember to use it ● Hard to know where to best place the manuals ● Training ○ Difficult to coordinate multidisciplinary teams for training ○ Hard to find time for training ○ Conveying the importance of training ● Cost (can be difficult to get a budget) ● Copyright concerns relating to customization ● General resistance ○ Anesthesiologists feel that everything should be memorized ○ Sign of weakness to use a cognitive aid ○ Older physicians are more resistant ● Implementation is a long process ● Do not know how to monitor use ● Lack of staff and resources to effectively implement

Phase 4 (Objective 3): Develop implementation toolkit
The focus of our fourth phase of work was the development of a toolkit based on the findings from Phases 1 to 3 to accelerate effective implementation and uptake of the CC/EM. It include tools such as a web platform that facilitates access to training packages and approaches, implementation strategies, and improvement strategies to address common challenges. The toolkit aims to answer the following questions:

1. What are the specific types of resources that are required to effectively implement the CC/EM?
2. What is the core of the CC/EM?
3. How to build an interdisciplinary team to support your effort?
4. What steps should be taken to gain support and buy-in across your organization?
5. What should be adapted locally and how can this adaptation be facilitated more easily?
6. What is the best way to provide training for CC/EM, particularly for those institutions that don't have simulation facilities?
7. How can training be sustained given that crises are rare events?

8. What is the difference between the training needs of novice vs. experienced clinicians and individuals vs. teams?
9. What are the best ways to have clinicians and teams use the CC/EM and integrate them into the workflow of care for a patient in a crisis?

In developing the toolkit, we worked with a web design firm with particular expertise in transforming complex information into compelling stories through clear, accessible graphics and organization. They provided advice on layout of the many resources in the toolkit to maximize users ability to find information relevant for their needs. We conducted respondent validation with a subgroup of EMIC members.

Difficulties and Limitations:
The ability to carry out the proposed research was limited by the current spread of the CC/EM. Though the idea of using training and checklists to improve performance is not new, the efforts to spread the idea more widely and to develop robust training programs are relatively recent. The CC/EM materials have been widely downloaded; however, the level of actual implementation is unknown.

A second concern is ensuring the rigor of qualitative data. To do this, we used methods recommended by experts, including having telephone interviews conducted by researchers who have experience and expertise in this area, using an interdisciplinary team to code the transcript data to minimize researcher bias and to generate insights from different perspectives, examining any deviant cases for possible reasons for why they are different, and maintaining an audit trail of all our coding and analytical decisions (L. A. Curry et al., 2009). Another concern with qualitative research is the small sample size. To improve generalizability, we recruited a range of organization types (e.g., teaching and community, public and private, system owned or not, and how the anesthesia professionals are paid [fee-for-service payment or salaried]) in our sample.

Outcomes:
The mixed methods approach to this project enabled the collection of a series of findings that were then incorporated into an implementation toolkit. The high-level information gathered through the web-based survey allowed the development of an interview guide and subsequent interviews that provided the detail needed to create the toolkit.

Discussion:
Our mixed methods study of downloaders of CC/EM enabled us to better understand the implementation process, barriers, and facilitators to implementation of an innovation from outside healthcare into the healthcare environment. The unique collection of email address gave us ready access to a group of early adopters that would have otherwise been inaccessible. Even though the overall response rate of the web-based survey was 14%, we were able to gather sufficient data to reasonably inform the qualitative interviews that followed. The importance of following steps in an implementation process was demonstrated, as was the need to have leadership support and a clinical champion confirming findings from much prior research (Damschroder). The qualitative interviews added rich contextual detail and additional insight that further informed the design and creation of a web-based implementation toolkit. Our hypothesis that more frequent use of these tools takes place beyond sole use in the operating room was confirmed. Use begets more use. Using these types of tools in more than a single context is likely critical to sustaining use over time, because emergencies in the operating room are relatively rare, making the intervals between use variable and long. Giving users the opportunity to read, handle, and understand the tools repeatedly away from the patient is not done enough in the healthcare setting.

The principle barrier to implementation of the tools was clinician resistance to use, which took several forms. There were those who felt that they did not need the tools, that the care provided in emergency situations could not be improved by having a memory aid. Those clinicians can often be swayed through simulation training, in which the gaps in their care can be readily identified. In a previous study (Arriaga), we showed that, after being exposed to these tools in a simulated crisis, more than 90% of participants thought the tools were useful to them. A separate group of clinicians described a fear of being judged incompetent or weak if they were seen using the tools. To remove that barrier, the culture of a facility would have to change to a place in which use of cognitive aids is encouraged and, in some way, expected. The third resistance barrier had to do

with clinician opinions about the form and content of the tools, a barrier that could be addressed by encouraging and supporting facility-level adaptation of the tools. Each of these concerns has been addressed in some way in the toolkit that was developed.

Conclusions:
The project allowed us to develop an understanding of different implementation approaches and contextual factors using a mixed methods approach that may determine the successful use of the crisis checklists/emergency manuals [CC/EM] at facilities, inpatient and ambulatory, across the United States. We took this knowledge and transformed it into a practical toolkit that will accelerate uptake and adoption and ultimately improve the safety of individuals undergoing surgery across the diversity of institutions in the United States and other settings. In the first 90 days since launching the online toolkit, we have had more than 3000 individuals access the site. With continued promotion and disemination, we plan to reach many more.

Significance/Implications:
Cognitive aids for the operating room represent some of the first team performance and safety tools to be successfully imported from other industries into healthcare. Although there is a long history of the use of these tools in critical events in multiple industries, there has been little cross-industry spread. These tools in other settings have been used for decades now and have been built into a system that not only makes the tools available but supports them with team training [CRM] and electronic decision support. The operating room cognitive aid is in the “paper” phase, akin to the period when pilots wore emergency manuals strapped to their thighs. This project has generated implementation lessons that have now been built into a toolkit to enable wide adoption of the tools into the clinical setting. This eventual adoption will make future research in this area easier by allowing future investigations into the ways the tools are further refined and adopted in the field. Cognitive aids are being widely adopted across the healthcare environment and lessons from this project can be used for further improvement of those tools as well.

List of Publications and Products (Bibliography of Published Works and Electronic Resources from Study)

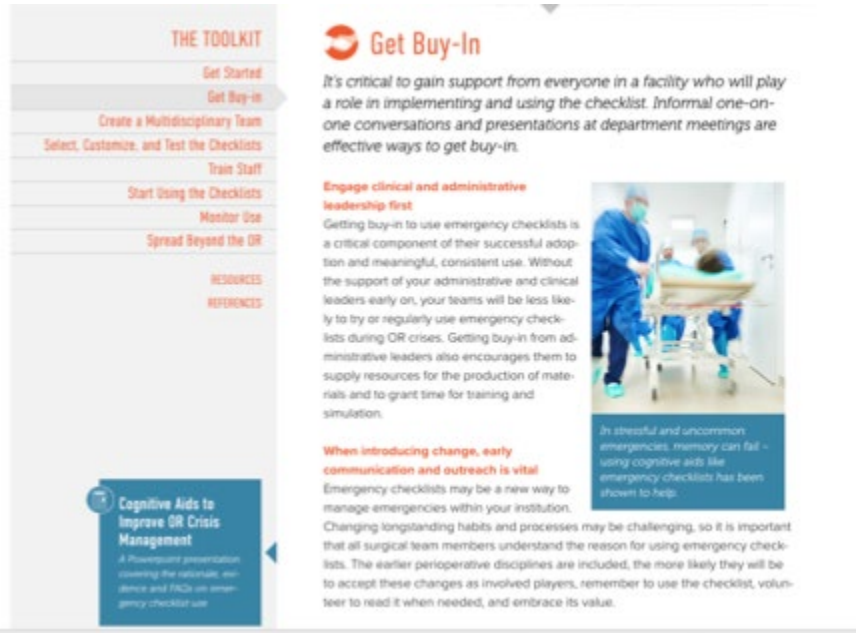
The Operating Room Emergency Checklist Implementation Toolkit (https://www.implementingemergencychecklists.org). The purpose of the toolkit is to facilitate effective implementation and use of the checklists and lower the burden of a successful implementation process. Our synthesis of the key needs of emergency checklist implementers identified in our surveys and interviews was further vetted by the key national leaders in development and dissemination of OR emergency checklists, especially the steering committee of the Emergency Manuals Implementation Collaborative [www.emergencymanuals.org]. These individuals both helped refine the text and identified numerous resources to which we have provided access from the toolkit.

The toolkit is a dynamic, web-based tool with an organization that roughly tracks the key implementation tactics identified in our surveys and interviews. Each of the “chapters” of the toolkit contains narrative text that shares insights and strategies pertinent to that activity. The chapters are:

- Get Started
- Get Buy-In
- Create a Multidisciplinary Team
- Select, Customize, and Test the Checklists
- Train Staff
- Start Using the Checklists
- Monitor Use
- Spread Beyond the OR

Because these activities are not distinct and separate, each chapter provides a clickable link to all the other chapters. Furthermore, the resources and references from every section of the toolkit are grouped together for easy access. These features are intended to accommodate different styles of learning among our users. Through clickable links attached to the narrative text, the toolkit provides extensive resources for use by the implementers. For example, the “Get Buy-In” chapter, in which checklist champions are supported in their work

to gain institutional and colleague support for adoption of the checklists, contains prepared slide decks, discussion outlines, and videos for use in this effort.



The “Train Staff” discussion is accompanied by multiple resources to facilitate the use of simulation and team training as tools to introduce clinicians to the checklists. Trigger videos, instructor discussion guides, simulation center directories, as well as educational resources focused on debriefing skills, are all available as links from the “Train Staff” discussion. Separating these resources from the narrative text allows the discussion to flow easily and be approachable and digestible by busy clinicians while at the same time making the resources immediately accessible to the user when desired, especially in the context of the topic discussion. The narrative text addresses barriers to implementation and shares solutions derived from our surveys and interviews.

Publications:

1. Article reporting the results of the web-based survey is submitted and under review.
2. Article reporting the analysis of the qualitative interviews in draft.

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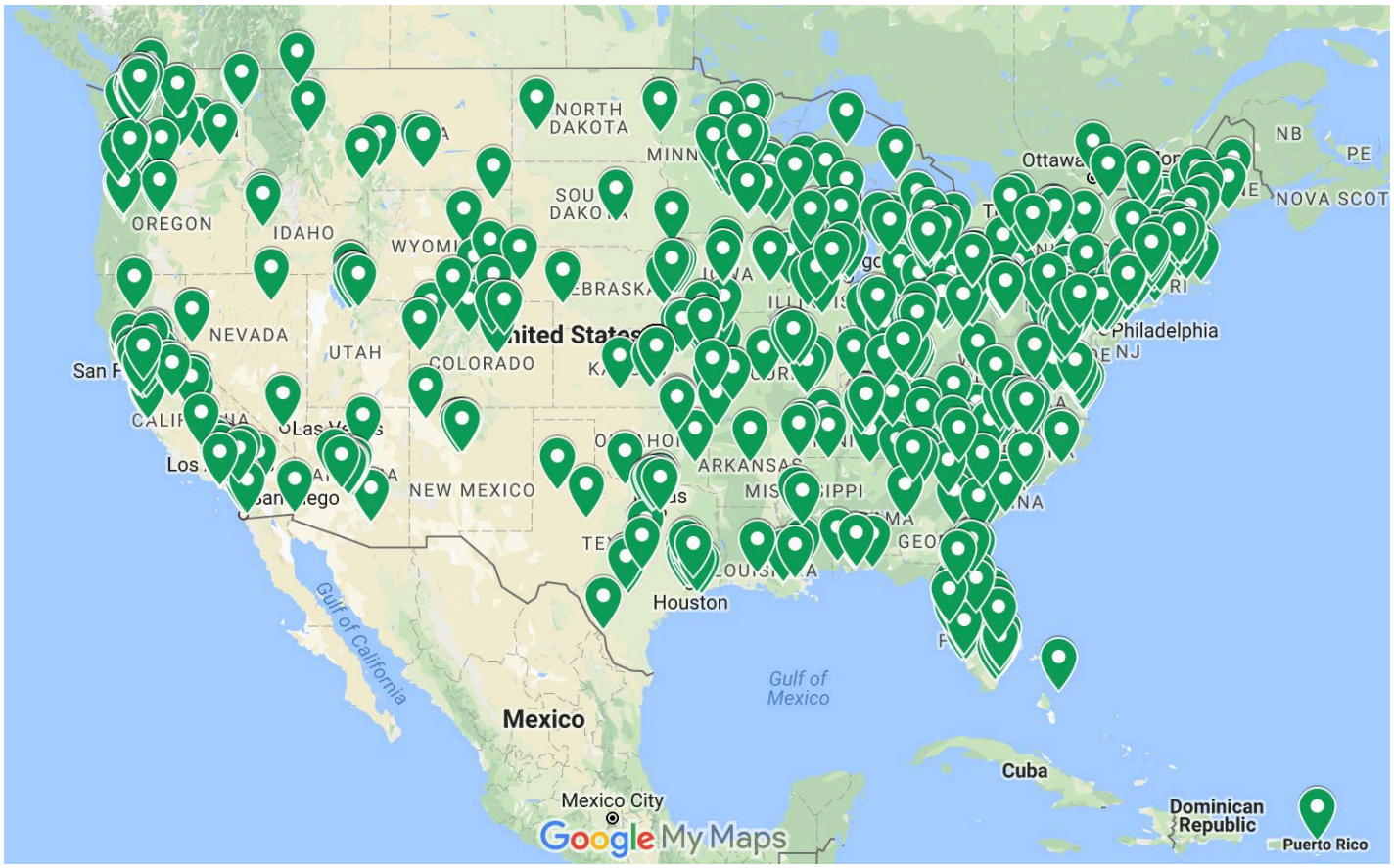
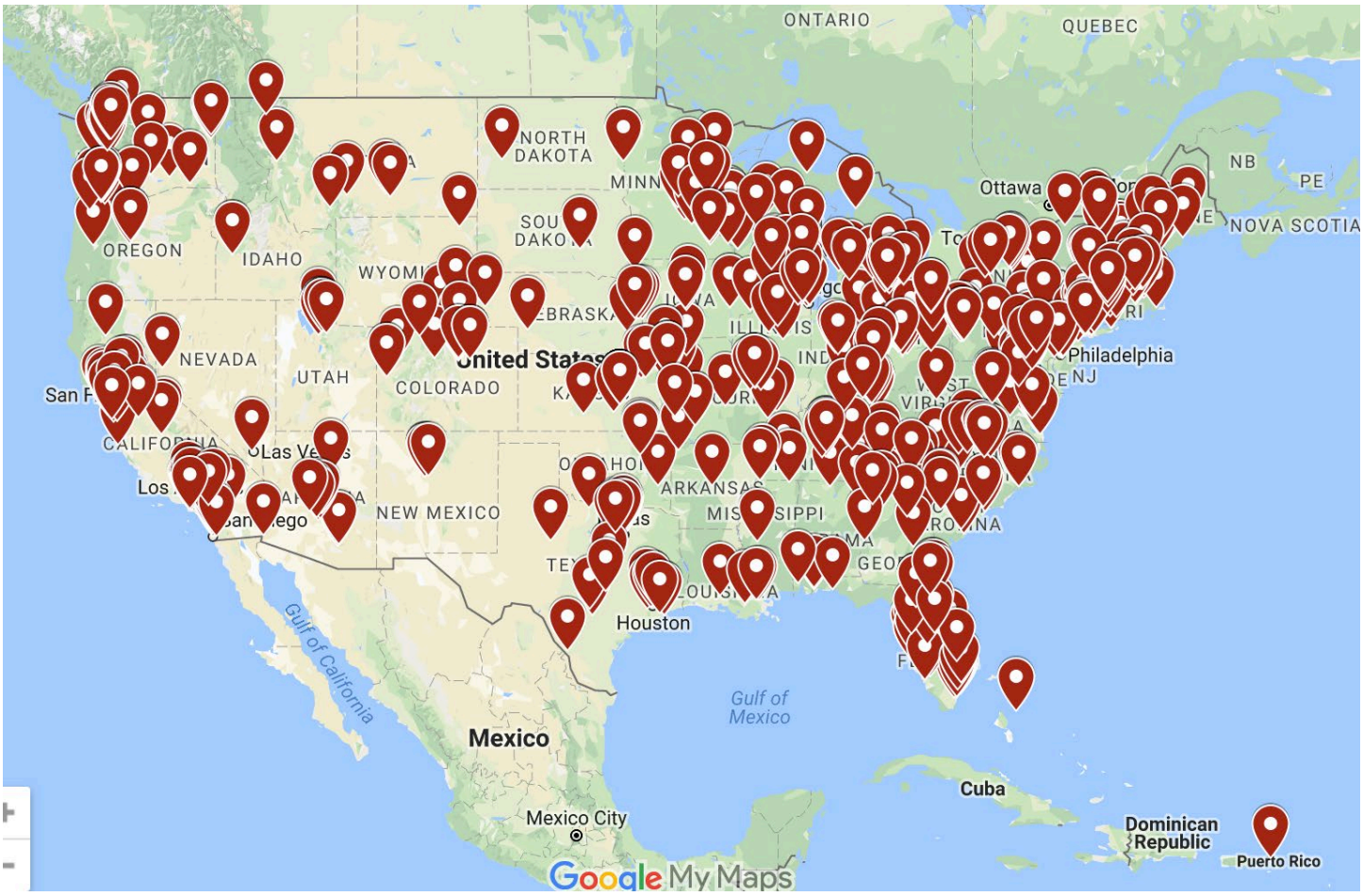
Appendix 1: Mapped Characteristics of Survey Participants

Survey Participants – Total U.S. Distribution



Survey Participants by Facility Type – Hospital



Survey Participants by Facility Type - Ambulatory Surgery Center (ASC)

Survey Participant Institutional Teaching Status

Survey Participant Institutional Size

Appendix 2: Cumulative Inclusion Enrollment Report
Development of a toolkit for dissemination and implementation of the OR crisis checklists

This data is self-reported by respondents to the OR Crisis Checklists/Perioperative Emergency Manual Implementation Survey

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/Not Reported	Female	Male	Unknown/Not Reported	Female	Male	Unknown/Not Reported	
American Indian/Alaska Native	1	1	0	0	0	0	0	0	0	**2**
Asian	63	88	0	0	0	0	0	0	0	**151**
Native Hawaiian or Other Pacific Islander	0	1	0	0	0	0	0	0	0	**1**
Black or African American	9	5	0	0	0	0	0	0	0	**14**
White	439	693	1	0	0	0	0	0	0	**1,133**
More than one race	15	24	0	0	0	0	0	0	0	**39**
Unknown or Not Reported	30	63	92	27	57	0	0	0	0	**269**
Total	**557**	**875**	**93**	**27**	**57**	**0**	**0**	**0**	**0**	**1,609**