Development Validation and Implementation of Customized Checklists for Safe Surgery

Atul Gawande, MD, MPH, Principal Investigator

Team Members:
Alex Arriaga, MD, MPH, ScD
Angela Bader, MD, MPH
William Berry, MD, MPH
Sascha Beutler, MD, PhD
Ruslan Baltaga, MD
Andrew Bond, MD
Ion Chesov, MD
Lizabeth Edmondson
Alex Hannenberg, MD
David Hepner, MD, MPH
Allen Ho, MD
Yelena Kuznets
Gifty Kwakye, MD, MPH
Morana Lasic, MD
Edward Laws, MD
Robert Lekowski, MD
Stuart Lipsitz, ScD
Andrew Miller, MD
Jennifer Misajet, BSN, MHA
Suliat Nurudeen, MD, MPH
Jaykar Panchmatia, MD, MPH
Charles Pozner, MD
Paul Preston, MD
James Sachetta, ALM
Douglas Smink, MD, MPH
Kristen Styer, MSN, RN
Judith Wong, MD
John Ziewacz, MD, MPH

Brigham and Women's Hospital
Harvard School of Public Health
Kaiser Permanente of Northern California
National Scientific and Practical Center of Emergency Medicine

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Project Officer: James Battles
Email: james.battles@ahrq.hhs.gov
Phone: 301.427.1332

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Structured Abstract

Purpose: To develop, validate, and implement customized checklists for surgical emergencies and specialty operations, to improve adherence to accepted safety processes and decrease the likelihood of serious harm.

Scope: We developed 12 crisis checklists for use in surgical emergencies and worked with three organizations to implement the checklists in the operating-room environment. Additionally we created customized versions of the WHO Surgical Safety Checklist for use in ambulatory, cardiac, and neurosurgery procedures.

Methods: The crisis checklists were tested in a randomized-controlled trial by operating room teams from three institutions. The primary outcome measure was failure to adhere to critical processes of care. The crisis checklists were later implemented in three sites. A perception survey was administered regarding crisis checklist implementation, training, and use. The neurosurgery procedure checklist was tested in two academic medical centers. The primary outcome measure was adherence to key processes before and after small-scale implementation. A survey regarding checklist utility was administered.

Results: Crisis checklist use resulted in a 75% reduction in failure to adhere to critical steps in management; 362 clinicians were trained across three study sites, and 91% of the trainees found the crisis checklists easy to use. Comparing pre-training and post-training impressions, there was a 26% increase in those who felt crisis checklists were helpful in a crisis scenario. In the neurosurgery procedure, checklist study process adherence increased from 71% to 82% ($p=.007$), primarily related to infection items. We found no significant difference in adherence to mechanical failure avoidance items between the baseline and post-implementation phases.

Key Words: surgery, checklists, crises, cognitive aids, crisis management

Purpose

This body of work aimed to develop, validate, and implement customized checklists for operating room emergencies and specialty operations in order to improve adherence to accepted safety processes and decrease the likelihood of serious harm. Such complications have been associated with failure to follow accepted process measures. The specific aims of our research were to:

1. Develop and study the utility of a set of crisis checklists in a high-fidelity surgical simulator.
2. Devise implementation strategies to put the crisis checklists into clinical use and study the implementation and training approaches in three diverse clinical settings, one US academic medical center, one US multi-hospital system, and a tertiary hospital in a lower-middle-income country setting.
3. Develop and study the use of a cerebrospinal fluid (CSF) shunt procedure-specific version of the WHO Surgical Safety Checklist.
4. Develop specialty-specific versions of the WHO Surgical Safety Checklist for ambulatory and cardiac surgery.

The operating room is a high-acuity patient care environment in which critical events occur more commonly than in many other patient care settings. It is now estimated that over 40 million operations are performed in the United States each year[1,2]. Studies in industrialized countries have estimated the risk of major complications from inpatient surgical procedures to be 3-17% [3,4]. Data suggest that at least half of all surgical complications are avoidable[3,4]. Studies have linked improved adherence to best practice (i.e., timing of antibiotics, objective airway examination prior to intubation, etc.) with decreases in surgical complications[5,6].

Checklists are tools that have been adopted by other high-stress, high-risk, high-reliance fields. 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[7–9]. In 2009, the concept of using checklists was brought to surgery to standardize and improve adherence to established clinical practices known to improve patient safety and outcomes, most notably with the introduction of the World Health Organization's Surgical Safety Checklist[10]. The WHO Checklist improved routine patient care and communication among the surgical team before induction of anesthesia, before skin incision, and before the patient leaves the room, resulting in a decrease in complications and mortality[10]. Since its release, we have been able to confirm that the WHO Checklist has been adopted in more than 122 countries[11], and it is now accepted as a global standard of care[12]. Following the testing and dissemination of the WHO Surgical Safety Checklist, two unmet needs subsequently emerged:

1. There was an opportunity to improve patient care and communication during operating room emergencies, and checklists could be a vehicle for that change.
2. Specialty- and procedure-specific versions of the WHO Checklist could further improve patient care and increase buy-in among surgical team members.

The remaining portions of report describe the scope, methods, and results for the three aspects of this work that were designed as research studies:

1. Develop and study the utility of a set of crisis checklists in a high-fidelity surgical simulator.
2. Devise implementation strategies to put the crisis checklists into clinical use and study the implementation and training approaches in three diverse clinical settings, one US academic medical center, one US multi-hospital system, and a tertiary hospital in a lower-middle-income country setting.

3. Develop and study the use of a ventriculoperitoneal (VP) shunt procedure-specific version of the WHO Surgical Safety Checklist.

Develop and study the utility of a set of crisis checklists in a high-fidelity surgical simulator

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, intraoperative emergencies like cardiac arrest and massive hemorrhage do occur. The infrequency of these emergencies, though fortunate, challenges operating room teams to work at their highest levels in situations that they rarely encounter. Particularly under stress, human memory is imperfect and response to crises can be compromised by the omission of key steps or failure to consider critical possibilities, resulting in threats to patient safety and potential tragedy[13]. 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[14]. Furthermore, there are reports of major deviations from guidelines when working from memory alone[15]. Tools to improve management of critical operating room events offer the opportunity to produce a measurable impact on overall surgical mortality.

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[16]. 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. In the 1980s, modeled after such tools, Drs. David Gaba and Steve Howard, and colleagues at VA Palo Alto and Stanford University, began to develop protocols to help educate clinicians by condensing relevant literature and to help teams manage patients appropriately during operating room crises[17]. In 1994, they published a book, Crisis Management in Anesthesiology, with a recent 2nd edition, both containing many (80-90) of these protocols[18,19]. 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[20]. 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.

Setting

The operating room crisis checklists were studied in a high-fidelity surgical simulator at a US academic medical center.

Participants

Participants for the randomized control trial were recruited from three hospitals (one academic medical center and two community hospitals) in the Boston area over a 17-month period (August 2010 through December 2011). Teams consisted of anesthesia professionals (attending physicians, residents, and certified registered nurse anesthetists), operating room nurses, surgical technologists, and a mock surgeon participant. Staff and physicians were enrolled by means of sign-up sheets and random selection of staff members who were already scheduled to work on the study dates. Hospital administrators allowed staff and physicians to be scheduled to the simulator in lieu of a standard workday[21].

Methods
The crisis checklists consist of 12 common/life-threatening operating room emergencies addressing specific conditions (i.e., cardiac arrest) as well as two checklists for situations in which the diagnosis is unknown (unstable hypotension/hypoxia). After initial drafting and small-group vetting, two consultation meetings were held, including operating room directors, anesthesia professionals, nurses, surgical technologists, surgeons, and subject matter experts from 11 affiliate hospitals and other high-risk industries that utilize checklists. The checklists underwent several revisions over the course of the project, resulting in a final set of checklists that were designed by a graphic designer to ensure functionality and readability in high-stress environments. The final design of the checklists followed design principles from checklists in aviation, nuclear power, and other industries that utilize checklists for emergency management[21].

Study Design
The crisis checklists were tested in a randomized controlled simulator trial with 17 operating room teams from one academic and two community hospitals. Each team was exposed to simulated intraoperative crises (including air embolism, anaphylaxis, asystolic cardiac arrest, hemorrhage followed by ventricular fibrillation, malignant hyperthermia, unexplained hypotension and hypoxemia followed by unstable bradycardia, and unstable tachycardia). Each team was randomized to manage half the scenarios with a set of crisis checklists and the remaining scenarios from memory alone. The checklists were provided to participants at the anesthesia machine and nurse’s work area in the simulator. At the end of the simulation day, participants were given a survey to better understand their perceptions of the usefulness and clinical relevance of the crisis checklists[21].

Data Sources/Collection
All simulation sessions were recorded as multiscreen synchronized video, and three physician reviewers reviewed and scored the sessions. Reviewers scored teams on the completion of 47 key processes. These key processes were derived from evidence-based guidelines and scored in a binary fashion (yes or no). The primary outcome measure was failure to adhere to the life-saving processes of care for each emergency. Any case of disagreement or uncertainty among reviewers was decided by means of expert review by a physician who was an expert in the guidelines for advanced cardiac life support. A random 15% sample of the data was re-reviewed by an outside physician reviewer who was unaware of the study design and the hypothesis being tested[21].

Participants were asked to complete an end-of-day survey to assess their perceptions of the crisis checklists. A multidisciplinary team of operating room and implementation experts designed this survey. The survey used a 5-point Likert scale ranging from 1 (disagree strongly) to 5 (agree strongly)[21].

Limitations
The findings from this work should be interpreted in the context of the study design. The checklists were studied in a simulated operating room rather than in an actual operating room with patients. Additionally, there were few surgeons that participated in the simulator trial. However, we found no evidence that a surgeon’s presence changes the benefit that the crisis checklists had in the simulator[21].

Results

Principle Findings and Outcomes

The following results were published in the 2013 New England Journal of Medicine article, "Simulation-Based Trial of Surgical-Crisis Checklists"[21]. Checklist use during operating room crises resulted in a 75% reduction in failure to adhere to critical steps in management. When checklists were available, 6% of the steps were missed, as opposed to 23% without the checklists available ($P<0.0001$). These results held up in a multivariate analysis that accounted for clustering within teams, with adjustment for institution, scenario, and simulation learning or fatigue effects (multivariate relative risk, 0.28; 95% confidence interval, 0.18 to 0.42; $P<0.0001$). The effect of checklist use remained the same when the results were stratified according to the scenario. Scenarios were grouped into three categories to provide samples large enough for analysis:

- scenarios that were directly related to algorithms for advanced cardiac life support (asystolic cardiac arrest, ventricular fibrillation, and unstable tachycardia),
- scenarios related to algorithms for advanced cardiac life support and preceded by a precode condition (hemorrhage followed by ventricular fibrillation or clinically significant hypoxemia and hypotension followed by unstable bradycardia),
- other crisis scenarios (malignant hyperthermia, anaphylaxis, hemorrhage, and air embolism).

In all strata, the failure rates were significantly lower in scenarios in which the crisis checklists were used. Bonferroni adjustment for the four main P values reported in this article remained significant at a P value of less than 0.05.

Overall, every team had a lower failure rate for adherence to key processes when the crisis checklists were available. Although there were not enough teams for us to definitively compare the teams according to whether a surgeon was present or absent, the relative-risk reduction in failure rates when a checklist was used was larger with a surgeon present (multivariate relative-risk reduction in failure rate, 0.15 for study sessions with a surgeon present and 0.30 for those with a surgeon absent; $P=0.34$ for the comparison of the two models). The effect of the checklist was significant ($P<0.001$) in all the secondary analyses, with no significant differences according to status with respect to the secondary variables[21].

Survey Responses

Participants felt that the checklists were easy to use, that the checklists helped them feel better prepared, and that they would use the checklists in their clinical practice if presented with an operative emergency. When asked, "If I were having an operation and experienced this intraoperative emergency, I would want the checklists to be used," a total of 97% of the participants agreed with this statement (gave a score of 4 or higher). All participants rated the overall quality of the session as above average or excellent (score of 4 or 5).

Discussion

The results of the trial showed a strong correlation between checklist use and better team performance of critical safety steps during a crisis. Simply put, the crisis checklists make good teams even better, at least in the simulator. Tools like the crisis checklists can be powerful tools to improve the care of patients in operating room emergencies. Although participants were supportive of the crisis checklists and wanted to use them in their clinical practice, incorporating the checklists into their workflow did not come easy to everyone. Some participants learned how to improve their use of the checklists over the simulation day; other participants began by using the checklists, but later put them down during the crisis. The inability to incorporate the checklists into their clinical workflow is not unique to the crisis checklists and has been observed when implementing with other types of cognitive aids[17,22]. These observations indicate that simply putting the checklists into operating rooms may not result in use and benefit to surgical patients. Participants raised other challenges about using the checklists:

- Who should read the checklists?
- How many copies of the checklist should be in an operating room?
- Who can call for the checklists?
- When should the checklists be used in an emergency? Should they be used at the first indication of an emergency or when the surgical team doesn't know what else to do?
- How do you use the checklists without interrupting the clinical workflow?
- Is a paper binder the best way to display the checklists?

Observations from the training and feedback from participants indicate that training programs need to be developed for surgical team members to learn how to use the checklists. The trial demonstrates that practice in a high-fidelity simulator is one mechanism for training clinicians. However, high-fidelity simulators are expensive, and a majority of hospitals and healthcare facilities do not have access to these facilities. Low-fidelity simulation options need to be developed so that any practitioner, despite their location and available resources, can be trained to use these tools.

Like other programs designed to improve patient care, there will likely be an implementation gap, resulting in missed opportunities to protect patients and reduce preventable suffering and mortality[23,24]. In order to avoid the gap that is experienced by other programs, more investigation needs to take place around implementing the checklists in a variety of environments.

<u>Devise implementation strategies to put the crisis checklists into clinical use and study the implementation and training approaches in three diverse clinical settings, one US academic medical center, one US multi-hospital system, and a tertiary hospital in a lower-middle-income country setting</u>

Scope

Background

Following the publication of the operating room crisis checklist trial in the New England Journal of Medicine article, "Simulation-based trial of surgical crisis checklists,"[21] the crisis checklists gained popularity in the surgical community, with thousands of organizations downloading the checklists. Although there was enthusiasm, there remained many unanswered questions about how to implement these tools effectively. Ideal use requires understanding and acceptance of the value of the crisis checklists across the surgical team. It is intuitive to many surgical team members that, in crisis situations, the increased levels of stress make vulnerability to error significantly higher and the use of the crisis checklists will likely decrease that vulnerability. Despite that, when exposed to an emergency situation in the simulator, surgical team members sometimes fail to use cognitive aids or only use them sparingly, apparently skipping steps[17,22]. An implementation gap exists between current and ideal use, resulting in missed opportunities to protect patients and reduce preventable suffering and mortality[25–27]. 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[23,24]. 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[28].

Setting
The crisis checklists were implemented in the operating rooms at three sites, a US academic medical center, a US multi-hospital system, and a tertiary medical center in a lower-middle-income country setting.

Participants
Surgical teams working in the organizations listed above were actively involved in the implementation of the operating room crisis checklists.

Methods
Each site was provided with the generic checklist template and was asked to build an implementation team that consisted of at least one administrator, an anesthesia professional, a nurse, a surgeon, and a surgical technologist. The implementation team worked in collaboration with a graphic designer and crisis checklist experts to modify the set of checklists to meet the organization's unique needs. Each site customized the checklists to match their existing protocols, emergency numbers, and patient populations. Multiple revisions were made to the checklists at each site and each revision was tested using tabletop simulation to ensure that the modifications didn't interfere with clinical practice. Once the checklists were finalized for each site, checklists were printed in the form of booklets or binders, depending on the sites' preferences. Each site was surveyed to better understand where checklists should be placed in the operating room environment. All the sites chose to have two copies of the checklists in the OR, one near/in the anesthesia cart and a second copy located at the nursing station.

Training programs were developed for each of the sites to train a subset of their surgical staff and physicians to use the crisis checklists. Lessons from the randomized control trial were incorporated into the development of the training scenarios. Each site chose to use simulation to expose their staff to the crisis checklists and executed the following training:

- *Scenario One* – Simulated crisis without the use of the checklists
- *Scenario One Debriefing*
- *Introduction to the checklists and background about the project*
- *Scenario Two* – Simulated crisis with the checklists available in the simulator
- *Scenario Two Debriefing*
- *Optional Scenario Three* – Simulated crisis with the checklists available in the simulator
- *Optional Scenario Three Debriefing*

At the end of each training session, participants were asked to complete a survey about the training and their perceptions of the crisis checklists. In addition to training staff and physicians, each site was encouraged to publicize the checklists through departmental and staff meetings, newsletters, and any other means available to them. Six to 9 months after the checklists were distributed to the operating rooms, a survey was administered to all operating room personnel to better understand their perceptions of the implementation of the checklists and use of the checklists in a clinical setting.

Data Sources/Collection
Trainees were given a short survey at the conclusion of the training session to better understand their perceptions of crisis checklists and the utility of the crisis checklists.

The training day survey was created using a modified Delphi approach with subject matter experts in the field of crisis management, cognitive aids, and team training, following a technique described by Kelley Skeff in the article, “Evaluation of a Medical Faculty Development Program: A Comparison of Traditional Pre/Post and Retrospective Pre/Post Self-Assessment Ratings[29]. This 13-item survey sought to assess trainees’ awareness of the crisis checklists, perceptions of use, mechanics of use, quality of training, barriers to checklist use, and demographics. Surveys were administered to trainees as part of the training sessions on paper. The data were then inputted into the Research Electronic Data Capture (REDCap) survey system and analyzed by the research team.

Six to 9 months following the organizations’ deployment of the crisis checklists, the research team surveyed operating room personnel about their perceptions of the crisis checklist implementation efforts and their use of the checklists clinically at the two domestic implementation sites. This survey was developed with a team of subject matter experts. The 16-question survey sought to understand if and how the checklists were being used in the clinical environment, how operating room personnel were exposed to the checklists, and perceived barriers to checklist use.

Limitations
The implementation of the checklists was conducted at three sites and, therefore, may not be representative of hospitals in general. The 16-question post-implementation survey was given by email and had a low response rate, so it may be subject to bias.

Results
Training Day Survey Principle Findings
In total, 362 clinicians were trained across the three study sites (one US academic medical center, one US multi-hospital system, and one lower-middle-income country tertiary medical center). The following table shows the professional role breakdown of trainees:

Professional Role	Number of Participants (N)	Percentage Trained (%)
Anesthesia Professionals		
Anesthesia attending	56	15%
Anesthesia resident	51	14%
Certified Registered Nurse Anesthetist (CRNA)	40	11%
Registered nurse	122	34%
Surgical technician	37	10%
Surgeons		
Surgical attending	25	7%
Surgical resident	17	5%
Other	6	2%
Declined to answer	8	15%
Total	**362**	

Overall, the training improved perceptions of the crisis checklists; 91% of the trainees found the crisis checklists easy to use. When commparing pre-training and post-training impressions, there was a 26% increase in those who felt that crisis checklists were helpful in a crisis scenario and a 19% increase in those who would want to use a checklist during an operating room critical event. Following the training, 91% of individuals would be comfortable reading the steps in the checklist, whereas only 64% of individuals were comfortable reading the checklist prior to the training session. The training also raised awareness among participants about other ways that the crisis checklists can be utilized. When participants were asked their opinion of the statement, "I would use the emergency checklist for myself for pre-crisis education review," only 69% agreed prior to the training versus 94% agreement following the training session. The changes observed were all found to be statistically significant (P=<0.0001).

Post-Implementation Survey Principle Findings
Six to 9 months after the crisis checklists were placed in the operating rooms at the study sites in the United States (one academic medical center and one multi-hospital system), the research team conducted a survey to better understand the perceptions of all operating room personnel. The survey was offered to everyone who worked in the operating rooms at each of the study sites and was administered electronically and on paper; 645 individuals responded to the survey, yielding a 19% response rate. The following table shows the professional role breakdown of respondents across the two study sites:

Professional Role	**Number of Respondents (N)**	**Percentage Respondents (%)**
Anesthesia Professionals		
Anesthesia attending	90	14%
Anesthesia resident	94	15%
Certified Registered Nurse Anesthetist (CRNA)	4	1%
Nursing Staff		
Registered nurse	131	20%
Surgical technician	15	2%
Surgeons		
Surgical attending	135	21%
Surgical resident	83	13%
Nurse Practitioner/Physician Assistant	93	14%
Total	**645**	

Overall, respondents were aware of the crisis checklist project, with 83% of respondents reporting that they were aware that the checklists are available in the operating room; 64% of respondents had reviewed the crisis checklists, and 110 respondents (17%) reported that they had been involved in one or more cases in which they used the crisis checklists. In these cases, the crisis checklists were used in multiple ways: 83% of respondents utilized the checklists for intraoperative crises; 58%, for education use/review; 20%, for preoperative planning; and 11%, for postoperative planning. Furthermore, 91% of individuals who used the crisis checklists reported that the checklists did not interfere with delivering care.

Discussion
Training plays a vital role in the implementation of the crisis checklists. Although training is critical to clinicians being able to use the checklists, finding the time to train operating room personnel is difficult. Our study sites were not able to train everyone who works in their operating rooms due to time constraints and costs. Many of our sites were able to conduct the trainings by repurposing time set aside for other reasons; for example, the academic medical center repurposed the 2-hour block of time when the operating rooms were closed to deliver

grand rounds presentations. Due to the lack of time available for such trainings, we created a training program that could be delivered in 2 hours yet still be effective at teaching the skills necessary to use the crisis checklists clinically. The results from the training day survey demonstrate that the 2-hour training sessions were powerful in increasing buy-in and familiarizing staff and physicians with how to use the checklists clinically. Though participants felt generally more comfortable with the crisis checklists, 9% of trainees didn't feel comfortable reading and following the steps on the checklists.

Simply going through the process of putting the crisis checklists into place (even if it does not result in regular checklist use) improves the system. The domestic sites reported identifying equipment availability and process issues when they tested the checklists in their institutions. Additionally, this program helped them improve their systems for delivering care in emergency situations. For example, one of the US sites refined their systems by implementing a paging program for specific emergencies; when an emergency was recognized, they could send one page to get the necessary clinical help and equipment in the room at one time. One of the implementation leads said, "Even if we never put the checklist into place, the fringe benefit of having to think about our systems has been beneficial." The lower-middle-income country site leveraged this program to advocate for the equipment and medications that are required to treat the emergencies included in the OR Crisis Checklist manual. This program helped this site acquire additional code carts, equipment, and training so that their operating room teams could adequately treat operating room emergencies.

Develop and study the use of a cerebrospinal fluid (CSF) shunt procedure-specific version of the WHO Surgical Safety Checklist

Scope

Background

The WHO Surgical Safety Checklist aims to improve patient care for all surgical patients by ensuring that surgical teams perform key processes and communicate critical information before the induction of anesthesia, before skin incision, and before the patient leaves the room. The WHO Checklist Template is designed for all environments, from academic medical centers in the United States to rural hospitals in Tanzania[10]. Although the checklist is designed for use across all settings, modification is recommended to ensure that the checklist matches a facility's workflow, culture, and patient population[30]. The checklist was initially tested in an eight-center pilot study, in which the checklist use led to a greater than one third reduction in major perioperative complications and death[10]. Subsequent trials have shown similar reductions in complications and mortality[31–36]. Following the release of the WHO Checklist, many organizations began to implement the checklist but faced opposition from surgical team members. One of the primary complaints was that procedure-specific checklists were needed, because the general template did not address the needs of specific surgical procedures, in particular for neurosurgery. A literature review was conducted to identify the major adverse events in principle areas of neurosurgery (open cerebrovascular, endovascular, tumor, spine, and shunt). Upon review of the major categories of neurosurgical procedures, cerebrospinal fluid (CSF) shunt surgery appeared to be the most amenable to checklist intervention due to its relatively high frequency, high infection rate, and incidence of mechanical failure[37].

Setting

The cerebrospinal fluid (CSF) shunt checklist was tested at an adult academic medical center and a children's academic medical center in the United States.

Participants
Participants in this study were surgical teams that performed cerebrospinal fluid (CSF) shunt procedures.

Methods
A multidisciplinary panel consisting of neurosurgeons, neuronurses, and neuroanesthesiologists from across the United States was convened to develop the Cerebrospinal Fluid (CSF) Shunt Checklist. This panel reviewed literature and evidence regarding this procedure and compiled a list of known best practices from their field. An initial draft of the checklist was developed based on the committee's recommendations. Simultaneously, the operating room workflow was studied in the two pilot hospitals that would later test the checklist. The checklist content, structure, format, and delivery were refined multiple times with the help of a communications and graphic design specialist and subject matter experts until a stable checklist was created that the panel agreed to test in the two sites. The research team and panel concluded that the CSF shunt checklist should be structured as an adjunct to the WHO Safe Surgery Checklist to preserve the integrity of the WHO Checklist that each institution had previously implemented.

Study Design
This pre-post study consisted of three phases: pre-implementation data collection, small-scale implementation and rapid-cycle testing of the checklist, and post-implementation data collection. Cases were included regardless of time of day or level of urgency. Cases were only excluded in the case of additional concurrent procedure(s), if the surgery involved removal of shunt hardware only, or on the rare occasion that the operating room team felt that it would be disruptive to the case. Urgent cases were defined as those needing to start within 4 hours, whereas emergent cases required less than 1 hour. The data collectors observed the first three cases together to ensure agreement on interpretation of process adherence. The case data was reviewed weekly to ensure consistency.

Small-scale implementation and rapid-cycle testing took place over 2 months. The purpose of rapid-cycle testing was to introduce the checklist on a small scale and garner feedback to improve checklist fidelity. During this phase, researchers introduced the checklist prototypes to OR staff members on a per case basis, instructed the OR staff on how the checklist intervention would be operationalized within the OR flow, corrected user error, and answered end-user questions. Feedback was solicited to improve the content and mode of delivery. The graphic design specialist aided in the revision process. In line with the goals of a usability study, rapid-cycle testing was considered complete when no additional modifications to the checklist were made. This iterative process resulted in a finalized checklist prototype that incorporated feedback from all members of the operative team.

Following rapid-cycle testing of the checklist, the intraoperative observers collected data in consecutive shunt surgeries on the same key processes, following the same methods as in the pre-implementation phase.

Data Sources/Collection
We identified key processes based on the sites' customized versions of the WHO Surgical Safety Checklists as well as the CSF shunt checklist prototype. Prior to the introduction of the CSF shunt checklist into the operating rooms, specially trained data collectors observed consecutive shunt surgeries for adherence to these key processes. A standardized data collection form was used, and specific criteria were defined for achievement of each key process. The key processes were divided into items related to the WHO Checklist and those of

the CSF shunt checklist, which were also classified according to infection control and mechanical failure avoidance. The primary outcome was adherence to key processes. Proportions were used to characterize categorical case characteristics (e.g., urgency of procedure) and process measures (e.g., antibiotics administered within 60 minutes of skin incision); means were used to characterize continuous (e.g., case length) and ordered categorical (e.g., number of OR personnel at the time of incision) variables. Rao-Scott chi-squared tests[38] (1 below), accounting for clustering of cases performed by the same surgeon, were used to compare categorical variables at pre versus post times. Wilcoxon rank-sum (two-sample) tests[39], accounting for clustering of cases performed by the same surgeon (2 below), were used to compare continuous or ordered categorical variables at pre versus post times. Because case characteristics were balanced, confounding was considered not significant, and results of the bivariate analyses (Rao-Scott and Wilcoxon) are presented.

Following small-scale implementation and data collection, OR personnel, including neurosurgeons, neuroanesthesiologists, and neuronurses, were surveyed to better understand their experience using the checklist. The surveys were administered electronically using the Research Electronic Data Capture (REDCap) survey system.

Limitations

Our findings should be interpreted in the context of the study design. Because we intended to evaluate the process of checklist development and subsequent behavior change, we structured the data collection to focus on process adherence. We were not powered to detect any differences in postoperative complications, such as infection. The data collectors often relied on staff-led notification of emergent cases. Perhaps this introduced bias, as those more likely to notify the research team of a pending case may be more invested in checklist research and therefore more likely to perform better. Despite best attempts to minimize our data collectors' presence in the operating room, we cannot exclude a Hawthorne effect, though this effect was likely the same for both the pre- and post-implementation study phases.

Results

Principle Findings

Seventeen cases were collected prior to rapid-cycle testing, 12 cases contributed to checklist development through rapid-cycle testing, and 16 cases were collected following rapid-cycle testing and implementation of the checklist. There were no significant differences in the number of procedures performed at each institution, the urgency of the procedures, or the type of procedure between the pre- and post-rapid-cycle testing groups. Overall adherence to the shunt checklist-specific processes increased from 71.4% to 82.4% (p=.007), driven by steps related to infection control (59% to 74%, p=.0056). Key drivers to the improvement in infection avoidance were the discussion to minimize OR personnel (6% to 25%, p=.026), the discussion or use of antibiotic impregnated catheters (38% to 94%, p=.0004), and double gloving (59% to 94%, p=.0017). There was no observable difference in adherence to the mechanical failure avoidance items between the baseline and post-rapid-cycle testing phases. We found no change in adherence to WHO Checklist items.

In the 16 cases in which the checklist was piloted, every checklist item was addressed in nine of the cases. In the seven cases in which one or more items were missed, the majority of the missed items were from the *Before Closing* or *Before Patient Leaves the OR* sections of the checklist, or a combination of the two. In 14 of the 16 cases, the circulator initiated its use alone or in coordination with a surgeon, surgical resident, or scrub technician. The surgeon or surgical resident initiated or helped to initiate its use two times.

Of the 13 neurosurgical attendings who trialed the shunt checklist, seven completed the usability survey (54% response rate); 100% of responders found the checklist easy to use. One surgical attending and one nurse felt that the checklist did not fit well into the OR workflow. The majority responded positively to the checklist overall, and all except three responders answered that they would want the checklist used if they were undergoing a shunt procedure themselves.

Discussion
Using our defined methodology for checklist development[40], we successfully designed and pilot-tested an institutional procedure-specific preoperative checklist. Using this tool, we helped increase overall adherence to shunt-related key process measures from 71% to 82%. Though this trend was statistically significant, it was largely driven by the discussion to minimize OR personnel, discussion of antibiotic-impregnated catheters, and double gloving. We feel the latter two steps to be straightforward, simple ways to improve process. Minimization of OR personnel, however, is more difficult in execution. The change in this step, though significant, still resulted in only 25% post-implementation adherence, well below a goal of perfect adherence. Credit was given for this action point if the team had the discussion. However, the actual number of OR personnel present during shunt procedures did not change, even with a sign posted on the door to minimize unnecessary entry. This fact highlights the difficulty in changing behavior even with a simple tool such as a checklist, and it underscores the key role of good implementation when instituting changes to workflow involving multiple clinical teams.
We found no detectable improvement in adherence to mechanical failure items, but baseline adherence to these items was already nearly 100%. We postulate that the inclusion of these items still add value by minimizing the potential for serious, but rare, events.

There was no statistically significant change in adherence to the WHO Safe Surgery Checklist items after the rapid-cycle testing of our specialty checklist. However, we did observe a small reduction. Although it is difficult to know exactly what may have caused this change, the concern is that use of the shunt checklist may have distracted from appropriate use of the WHO Checklist. For this reason, we made every effort to minimize the number of additional action items when designing and introducing this specialty checklist to avoid checklist fatigue and distraction. This highlights the need to carefully choose areas for safety intervention and limit the number of checklists or interventions to those that would be used most effectively.

Only about half of the piloted cases acknowledged all items on the checklist. This lack of adherence suggests that there is opportunity for greater investment in end-user implementation training. The Before Closing and Before Patient Leaves the OR sections had particularly low adherence. This phenomenon was also observed with the final pause point of the WHO Safe Surgery Checklist[41]. The Before Patient Leaves the OR Section is a particular difficult portion of the WHO Checklist to execute. There is no clear time to stop at the end of the case and initiate this portion of the checklist[41]. The same hypothesis could certainly apply to this shunt checklist. The final components of the checklist therefore may need greater implementation guidance or be better assigned to a natural pause point that triggers its use.

Development of Specialty-Specific Versions of the WHO Surgical Safety Checklist
The following section describes the development of specialty checklists. This section doesn’t follow the scope, methods, and results format, because the development of these checklists was not designed as a formal research study.

As part of this grant, the research team also developed two specialty-specific versions of the WHO Surgical Safety Checklist for ambulatory and cardiac surgery. These specific types of surgery represent the extremes in terms of simplicity and complexity of surgical operations. The specialty checklist templates were created by subject matter experts from each of the specialties, including anesthesia professionals, nurses, perfusionists, and surgeons.

The ambulatory surgery checklist was created with the input of seven ambulatory surgery centers that performed a variety of surgical procedures. These centers tested and refined the checklist over a 6-month period and came to a consensus to create one ambulatory surgery center checklist template that could be customized based on the center's culture, workflow, and patient population. Items that were not applicable to ambulatory procedures, like estimated blood loss, were removed from the checklist template; in addition, items were added to the before skin incision section for their patient population. This checklist template was later incorporated into AHRQ's National Program for Ambulatory Surgery as one of the key tools to improve patient outcomes, teamwork, and communication in the outpatient surgical setting. Through the efforts of this program, the checklist template has been refined and has been spread to over 600 ambulatory surgery centers in the United States to date.

The cardiac surgery checklist was modified and tested at two academic medical centers in the United States. Subject matter experts at these sites felt that the checklist needed to be expanded beyond the three pause points on the original WHO Checklist to include additional pauses to communicate critical information before bypass, before wean from bypass, and before protamine is given. The content was also heavily refined to ensure that the team discussed critical information specific to cardiac procedures before induction, before skin incision, and before the patient leaves the operating room.

Eight of the nine sites that tested the ambulatory and cardiac surgery checklists maintained their use of the checklist. The ambulatory and cardiac surgery checklists were easier to implement than the procedure-specific checklist was because of the environment of these specialties. Ambulatory and cardiac surgery procedures are performed in rooms that are dedicated to those specialties, thus eliminating the complexity of ensuring that the correct checklist was present for the correct case. Additionally, the specialty-specific checklists were designed to replace the WHO Checklist instead of serving as an adjunct to the original checklist. We believe that having one unified checklist for the specialty led to ease of use and increased buy-in from surgical team members.

Program Conclusions

Crisis Checklists

Checklists for operating room emergencies can lead to dramatic improvements in patient care. Our study shows that in a simulated environment their use resulted in a 75% reduction in failure to adhere to critical steps in management[21]. Since the release of the checklists, more than 3,000 individuals downloaded them. Additionally, the release of the crisis checklists sparked other groups to develop and release similar tools. The creators of these tools came together to spread the idea of using cognitive aids, like the checklists, by building the Emergency Manual Implementation Collaborative. The goal of this collaborative is to spread the use of these tools and to develop and disseminate implementation strategies to put these tools into clinical practice. This collaborative has touched thousands of clinicians globally over the last 3 years and has created a website, www.emergencymanuals.org to post all the publicly available resources.

In our experience, 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 the use of crisis checklists 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[22,42]. It is important to develop implementation and training resources to help accelerate the implementation of tools like the crisis checklists so that patients and care providers can benefit from their use.

Simply putting the checklists into the operating room does not equate to use. Hospitals need to create robust implementation and training programs to ensure that the checklists are used clinically. Although it is difficult to find the time and money to pay for these types of training programs, the programs are critical to the use of tools, like the crisis checklists. A project, like the operating room checklist, also provides organizations with the unique opportunity to train operating room personnel together as teams. Currently, the majority of training that takes place in the surgical environment is single disciplinary[43,44]. The crisis checklist training program not only provided a venue for multidisciplinary team training but also provided a platform to reinforce key communication and teamwork skills that are needed to optimize patient care. Low-cost, multidisciplinary training programs need to be developed to ensure that surgical teams are equipped to handle emergencies and use cognitive aids.

The process that is required to implement the checklists (building a multidisciplinary team, customizing the checklists, and training surgical teams) improves patient safety and care on its own. The implementation sites reported that, even if the checklists do not get optimally used in the clinical environment, their systems and process have been improved because of this project.

Specialty Checklists

The Shunt Procedural Checklist improved overall adherence to processes from 71.4% to 82.4%. Although the checklist helped improve adherence to critical processes that are known to reduce infection, the study sites did not sustain the use of the checklists beyond the study. Even though there has been wide adoption of the WHO Checklist, effective use of checklists remains variable[28,45,46]. Furthermore, the introduction of procedure-specific checklists requires organizations to ensure that the correct checklist is used for the right patient. Most healthcare facilities do not have the technology or systems in place to ensure reliably that the correct checklist is available for the correct patient.

Program Implications and Significance

Cognitive aids in the form of checklists have been found to significantly improve operating room safety. We followed evidence-based methods to produce effective tools for significantly improving surgical safety practices both for crisis checklists and specialized fields of surgery, and we demonstrated marked improvements in performance, in particular with a manual of crisis checklists. The crisis checklists were demonstrated to reduce life-threatening errors by 75% in a simulator trial published in a high-impact journal[21], followed by wide adoption of the tools worldwide. Following the publication of the trial, we established methods for effective implementation of the crisis checklists in diverse settings.

The surgical environment is still embracing checklists and learning how to use them effectively. Since the initial adoption of the WHO Checklist, there has been pressure to create customized checklists, particularly for surgeries that represent the extremes in terms of simplicity and complexity. Most institutions do not yet have the capacity to implement and effectively use multiple specialty checklists at this time. Additional research and implementation work are required to ensure that checklists become proven standards of care.

List of Publications and Products
Publications

1. Ziewacz JE, Arriaga AF, Bader AM, et al. Crisis checklists for the operating room: development and pilot testing. J Am Coll Surg 2011 Aug;213(2):212–7.e10. PMID 21658974.

2. Wong JM, Panchmatia JR, Ziewacz JE, et al. Patterns in neurosurgical adverse events: intracranial neoplasm surgery. Neurosurg Focus 2012 Nov;33(5):E16. PMID 23116096.

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8. Arriaga AF, Bader AM, Wong JM, et al. Simulation-based trial of surgical-crisis checklists. N Engl J Med. 2013;368(3):246-253. PMID:23323901.

Product name	URL/Email Address
Emergency/Specialty/Procedural Checklists	
Operating Room Crisis Checklists	http://www.projectcheck.org/crisis
Ambulatory Surgical Safety Checklist	http://www.safesurgery2015.org/templates.html
Cardiac Surgical Safety Checklist	http://www.safesurgery2015.org/templates.html
Cerebrospinal Fluid (CSF) Shunt Surgical Safety Checklist	Available upon request by emailing: Available upon request by emailing: safesurgery@ariadnelabs.org
Videos	
OR Crisis Checklist Use During an Emergency	http://www.projectcheck.org/videos.html
OR Crisis Checklists as a Tool to Prepare for a high-risk case	http://www.projectcheck.org/videos.html
Emergency without the OR Crisis Checklists	http://www.projectcheck.org/videos.html
Reflections on a Day of Using the Crisis Checklists	http://www.projectcheck.org/videos.html
Overcoming Implementation Barriers	http://www.projectcheck.org/videos.html
Dealing with Skeptical Colleagues	http://www.projectcheck.org/videos.html
OR Crisis Checklist Implementation Guide	http://www.projectcheck.org/crisis.html
Survey Instruments	All survey instruments are available upon request by emailing safesurgery@ariadnelabs.org
OR Crisis Checklist Training Day Survey	
OR Crisis Checklist Post-Implementation Survey	
Cerebrospinal Fluid (CSF) Shunt Usability Survey	

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