Factors Associated with Effective Implementation of a Surgical Safety Checklist

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Structured Abstract

Purpose: We aimed to describe Surgical Safety Checklist implementation among diverse hospitals, explore relationships between supportive implementation context and activities with implementation effectiveness, and test whether effective implementation results in improved teamwork.

Scope: We studied checklist implementation in 65 hospitals participating in Safe Surgery 2015 during 2011-2014.

Methods: We developed instruments to capture primary data from surgical team members about surgical safety culture; onsite observers' impressions of checklist implementation and surgical teamwork; and checklist implementation leaders about implementation objectives before, during, and following the implementation initiative. We are also exploring the impact of checklist implementation on clinical outcomes.

Results: Novel instruments demonstrated reliability and validity. Although most surgical staff reported positive surgical safety culture, many felt neutral or negative regarding readiness, teamwork, and safe surgical practice. These perceptions were related to feeling safe as a patient, and they improved among participating hospitals following implementation. Implementing checklists effectively (i.e., surgical teams always stopping at three critical points) correlated with feeling safe as a patient, averting complications, and perceived efficiency. Observations suggest that teams performed 80%+ of checklist items in about half of all cases. Teamwork and surgeons' buy-in related to checklist performance. Completing discrete procedural prompts was more frequent in more complex cases; completing communication checks, in cases involving stress. Implementation approaches varied; participating implementation leaders reported earning 61% of maximum achievable implementation objectives. In hospitals reporting more perceived improvement following checklist implementation, leaders also reported higher levels of implementation achievement, and staff reported that checklists were implemented more effectively. Analysis of surgical outcomes is ongoing.

Key Words: surgery, checklists, implementation, safety culture

In 2009, pilot testing of the World Health Organization Surgical Safety Checklist demonstrated marked reductions in mortality and other postoperative complications (Haynes et al., 2009). Since then, the checklist has been adopted by over 1800 hospitals in at least 122 countries, representing more than 90% of the world's population (World Health Organization, n.d.). Benefits of surgical checklists, however, depend on the ability of adopting hospitals to implement them effectively. Yet, we know very little about the processes and activities that hospitals use in implementing surgical checklists or about processes and activities that make checklist implementation effective and result in consistent use, adherence to process measures, and buy-in among surgical staff. Thus, the first two specific aims of our research were:

(1) To describe checklist implementation processes among a diverse group of hospitals.
(2) To relate supportive implementation context and activities to effective implementation.

Effective implementation is an important goal of implementing new innovations. Understanding the mechanisms through which effective implementation of an innovation leads to improvement in outcomes enhances the ability of adopting organizations to achieve its benefits. The WHO pilot study that demonstrated that strict adherence to the Surgical Safety Checklist could lead to marked reductions in morbidity and mortality, for example, did not explain why such reductions occurred in sites as diverse as rural Tanzania and a major academic medical center in Seattle (Haynes et al., 2009). Investigators believed that the checklist's effect was achieved through adherence to basic process measures (e.g., appropriate antibiotic administration, use of pulse oximetry, etc.) and improvements in teamwork. We also believed that effective implementation would be associated with measurable improvements in teamwork and other outcomes in addition to the reductions in morbidity and mortality noted previously. Thus, the third aim of the proposed study was:

(3) To test whether effective checklist implementation results in improved teamwork.

Scope (Background, Context, Settings, Participants, Incidence, Prevalence).

Background and Context

Need for additional information about what makes checklist implementation effective in achieving checklist use. Implementation has been defined as "planned efforts to mainstream" an intervention within an organization (Greenhalgh, Robert, Macfarlane, Bate, & Kyriakidou, 2004) that serves as "the critical gateway between an organizational decision to adopt an intervention and the routine use of that intervention" (Damschroder et al., 2009). Just as hospitals differ in location, patient population, and services offered, so too are they distinguished by the ways in which they implement new innovations. Several prior studies suggest factors that distinguish strong implementation processes and promote effective implementation (A. C. Edmondson, Bohmer, & Pisano, 2001; Klein, Conn, & Sorra, 2001; Tucker, Nembhard, & Edmondson, 2007). However, none had examined a single process innovation like the checklist. Past investigators had explored the relationship between supportive organizational context and implementation (A. C. Edmondson et al., 2001; Hackman, 1990) and suggested various activities that support innovation implementation (A. C. Edmondson, 2003; A. C. Edmondson et al., 2001) and lend to implementation effectiveness (Mukherjee, Lapre, & Van Wassenhove, 1998; Nutt, 1986; Rousseau, 1989; Tucker et al., 2007). Preliminary research by study investigators involving in-depth, qualitative interviews at five hospitals in Washington State that had implemented a modified form of the WHO Surgical Safety Checklist suggested that variation in checklist implementation effectiveness hinges on the ability of implementation leaders to persuasively explain why and adaptively show how to use the checklist (Conley, Singer, Edmondson, Berry, & Gawande, 2011).

*Relationship of checklist implementation and teamwork***.** Previous research suggests a variety of teamwork factors required for physicians, nurses, and other providers to function effectively in healthcare teams (Helmreich & Foushee, 1993; Holzman et al., 1995; Howard, Gaba, Fish, & et al, 1992; McIntyre, Salas, Morgan, & Glickman, 1989). Various terms have been used to describe these factors. Anesthesia Crisis Resource Management simulation developers refer to making inquiries and assertions, communicating, giving and receiving feedback, exerting leadership, maintaining a positive group climate, and re-evaluating actions in defining healthcare team performance (Gaba & et al, 1998; McIntyre et al., 1989). Healey et al., identified cooperation, leadership, coordination, awareness, and communication in surgical teams as key measurement domains in their Observational Teamwork Assessment for Surgery (OTAS) instrument to measure (Healey, Undre, & Vincent, 2004). Mazzocco and colleagues described 10 behavioral markers for teamwork in neonatal resuscitation (Mazzocco et al., 2009), whereas Flin and Maran identified nontechnical skill requirements for medical teams (Flin & Maran, 2004).

With a view toward improving teamwork, components of the WHO Surgical Safety Checklist modify surgical teams' workflow and tasks in the OR by requiring team members to introduce themselves, discuss critical events, and address contingencies pre-emptively. Specifically, surgical checklists instruct all team members to introduce themselves by name and role; the surgeon to discuss anticipated critical events; the anesthesia provider to note any patient-specific concerns; nurses to comment on equipment concerns; and everyone to note essential imaging, appropriate specimen labeling, and key concerns for recovery and postoperative management. In practice, many teams also incorporate a debriefing or informal feedback session into their discussion of postoperative management. All team members are invited to participate in such discussions. These components were included in the WHO Surgical Safety Checklist, with the intent of enhancing collaboration and coordination to achieve operation-specific goals as well as overarching goals of high-reliability and teamwork. As a surgeon in our preliminary study observed, "This sounds ridiculous, but a certain anesthesiologist used to go through the whole case without saying one word… [He] would raise the screen [between us] until it was six feet up off the ground. It is harder to do that now because he has to talk to us at the beginning of the case. That establishes that we are a team working together." Based on observations from the WHO pilot study and our own preliminary research, we expected teamwork to vary directly with the effectiveness of checklist implementation, including a preoperative briefing, adherence to process measures, and observable buy-in.

A theoretical model based on the literature and our preliminary studies directed the research conducted under this grant (see Diagram 1). Our model suggests that supportive context, supportive activities, and team factors will be associated with effective implementation of surgical checklists and improved teamwork. In turn, effective implementation and improved teamwork are expected to improve outcomes, as seen in the WHO pilot study. As this model implies, we hypothesized the following:

H1. Checklist implementation will be more effective in hospitals and surgical teams with more supportive context and team factors.

H2. Checklist implementation will be more effective in hospitals and surgical teams in which more supportive activities were employed in their implementation.

H3. Hospitals and surgical teams that experience more effective implementation will also exhibit better teamwork.

Though data limitations did not permit us to test the relationship between checklist implementation and improvement in teamwork, we also believed that an increase in the effectiveness of checklist implementation would be associated with an improvement in teamwork, suggestive of a virtuous cycle in which teamwork and effective checklist implementation reinforce one another.

H4. More effective implementation and improved teamwork are expected to improve checklist outcomes, as seen in the WHO pilot study.

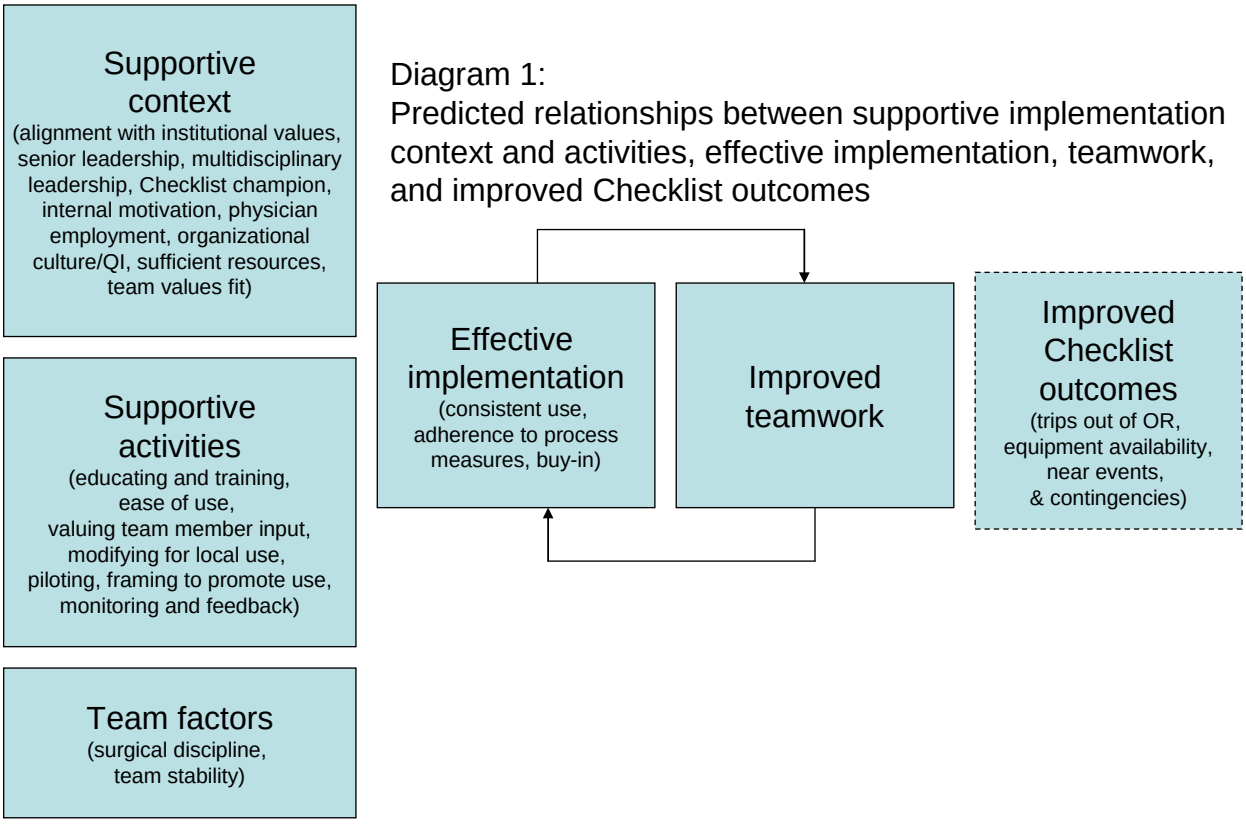

Diagram 1:
Predicted relationships between supportive implementation context and activities, effective implementation, teamwork, and improved Checklist outcomes

Setting

Safe Surgery 2015 is a global initiative to promote adoption and implementation of the Surgical Safety Checklist, composed of communication prompts and procedural checks meant to be used at three points before, during, and after all surgical procedures. As of mid-March 2011, all hospitals in South Carolina (n=65) had agreed to implement the Safe Surgery Checklist as part of an initiative entitled Safe Surgery 2015: South Carolina. Given this unique opportunity, we studied surgical checklist implementation primarily in hospitals in South Carolina. The Safe Surgery 2015: South Carolina intervention approach included a series of webinars, face-to-face learning sessions (including team training), and onsite coaching. We were able to work with the South Carolina Hospital Association (SCHA) and the Safe Surgery 2015: South Carolina initiative team to recruit South Carolina hospitals for this study. Partnering with organizations in South Carolina to conduct our study marked a departure from our original proposal, which had contemplated studying checklist implementation in hospitals that volunteered to participate in pockets of the US and Jordan.

The SCHA has a unique relationship with their hospitals and was established as the primary convener, connector, and catalyst for collaborative work to improve the quality and safety of patient care across the state. SCHA sets themselves apart from many hospital associations by the leadership role that it plays with its member hospitals in improving the safety of South Carolinians in the healthcare environment. The SCHA has partnered with its member hospitals to implement over 50 quality improvement and patient safety programs, including the 100 Thousand and 5 Million Lives Campaigns, Hospital Engagement Network, Birth Outcomes Initiative, South Carolina Safe Care Commitment, Catheter-Associated Urinary Tract Infection (CAUTI), and Central Line-Associated Blood Stream Infection Programs.

Participants

Of the 65 hospitals performing surgery in South Carolina, 64 participated in at least one activity of the Safe Surgery 2015: South Carolina initiative over three waves, and 23 finished what they considered the "active period" for their implementation. The "active period" is the period in which hospital-based implementation teams were actively engaged in efforts prescribed by the Safe Surgery 2015 initiative to encourage checklist implementation in their facility. We invited all hospitals participating in the Safe Surgery initiative to participate in the research program sponsored by this grant. Among participating hospitals, 36 hospitals agreed to participate in one or more components of our research. Hospitals participating in the research are diverse in terms of location, teaching status, and size (ranging from 25-845 beds). Participating hospitals represent the majority (67%) of the state's surgical volume.

The data collection instruments used to collect primary data required input from different hospital representatives. For example, one or more individuals who participated as a member of the team responsible for conducting implementation activities within the hospital completed an "Implementation Leader Questionnaire" that inquired about specific processes used to introduce, encourage, and sustain checklist use in their hospital and contextual factors that may affect implementation. We invited all surgical team members to complete a "surgical safety culture survey" that sought their perceptions of contextual factors as well as surgical teamwork, adherence to safe practices, and checklist outcomes. Checklist and teamwork "coaching tools" used to observe surgical cases and evaluate implementation effectiveness, surgical teamwork, and additional factors required participation of two observers designated by the implementation team. Background and discipline of observers varied at the discretion of hospitals. (Additional information about participants for specific data sources is provided in the Data Sources and Collection section below.)

In addition to the hospitals in South Carolina, seven of 25 North Carolina hospitals participating in a Safe Surgery 2015 implementation initiative based entirely on South Carolina as a model also agreed to participate in this research.

Incidence/Prevalence

Not applicable.

Methods (Study Design, Data Sources/Collection, Interventions, Measures, Limitations).

Study Design and Intervention

We designed our study to explore theoretical constructs and their relationships and ,as data permitted, to test study hypotheses. Drawing on previously published climate surveys and observation tools, we developed novel instruments to capture primary data from checklist implementation leaders, surgical team members, and onsite observers before, during, and following the Safe Surgery 2015: South Carolina implementation initiative as well as capture supporting materials to enhance the usability and reliability of these tools. All the tools and supporting documentation, as well as information about the Safe Surgery Initiative, are accessible through the Safe Surgery 2015 website at www.safesurgery2015.org. We are also working with the SCHA and Safe Surgery initiative investigators to explore the impact of the Safe Surgery 2015 initiative and checklist implementation on clinical outcomes.

Data Sources and Collection

Our study obtained and analyzed data and provided feedback to participating hospitals about the implementation of the Surgical Safety Checklist through multiple primary sources, including surveys of implementation leaders, surgeons, and surgical team members, and observations of checklist implementation and surgical teamwork. The inclusion of a surgical team member survey represented a departure from our proposal, enabling us to obtain more

robust information about surgical teamwork and other domains in our theoretical model. Through our partnership with the SCHA, we have access to the South Carolina all payer claims database maintained by the State Revenue and Fiscal Affairs Office. This database contains all claims for surgical care, inpatient hospitalization, and emergency room visits and is linkable on a patient level through an encrypted ID as well as on a hospital level. Through the Safe Surgery 2015: South Carolina initiative, we have provided feedback to participating hospitals reflecting data received in the form of benchmarked reports, presentations, and in-person and online seminars, highlighting strengths and opportunities implied by our findings. These reports have received the attention of all levels of hospital personnel, including hospital boards.

Surgical Safety Culture Survey. We developed the "**Surgical Safety Culture Survey**" to be administered to all surgical team members at least twice, before and following checklist implementation. A "pre-intervention" version of this survey measures readiness (a contextual dimension), five dimensions of teamwork, adherence to safe surgical practices, and consequences of safe surgery (e.g., how safe would team members feel being treated as patients in their own operating rooms). A post-intervention version of the survey omits the readiness items and adds measures of implementation process and effectiveness. For both pre- and post-intervention surveys, we developed two versions, a "long" version including all items and a "short" version, abridged based on preliminary psychometric analysis to encourage response among physicians and CRNAs. Thus, the long and short versions of the pre-intervention survey included 35 and 12 items, respectively. The long and short versions of the post-intervention survey included 31 and 15 items, respectively. In general, survey items offered a seven-point Likert response scale, with one item included in the post-intervention survey, "In the ORs where I work, problems or complications have been averted by the checklist," using a yes/no response. The survey also included demographic items and an open response section, inviting free-form comments from respondents.

At each participating hospital, our target sample was 100% of surgical team members, including clinical staff and clinical and administrative managers. Using online and paper-based surveys, we collected pre-intervention data from 36 hospitals. We received 2062 pre-test responses. The overall response rate for the pre-test was 43%. We collected post-intervention data from 16 hospitals (one from a hospital that did not provide pre-test data). Though fewer in number, these still represent more than half of the state's surgical volume. We received 857 post-intervention responses. The overall response rate for the post-test was 44%.

Coaching tools. To provide a framework for coaching surgical teams, we developed a pair of observational tools that could be distributed widely and used by designated coaches with limited training to assess and guide discussion about checklist performance and surgical teamwork. These tools were also designed to measure the impact of the Safe Surgery 2015 initiative on teamwork and implementation effectiveness, and checklist outcomes.

The **Checklist Coaching Tool** measures the key behaviors and processes contained on the Surgical Safety Checklist template developed in collaboration with participating South Carolina hospitals. It also includes several that assess whether surgical team members follow checklist best practices (e.g., reading all checklist items aloud without reliance on memory) and exhibit "buy-in" while performing the checklist. In order to measure checklist outcomes for the observed cases, we also incorporated items measuring operating room efficiency, the avoidance of errors, and adherence to existing surgical standards of care (e.g., antibiotic re-dosing for operations >2 hours in duration). The checklist coaching tool includes 25 items total, divided into sections (processes of care, 3 items, briefing, 8 items, debriefing, 3 items, buy-in, 5 items, and "additional data" reflecting checklist outcomes, 5 items). Items use two-, four-, and five-point response scales. For certain processes, which are not applicable in every case (e.g., antibiotic prophylaxis, compression boots), we also allowed observers to indicate if they were not applicable to the case. We recommended that circulating nurses conduct checklist observations.

The companion **Surgical Teamwork Coaching Tool** measures teamwork among surgical team members in the operating room, following the conceptual model derived through psychometric assessment of the *Surgical Safety Culture Surve*y. The tool includes 19 items, which describe what is considered an optimal teamwork behavior (e.g., "Discussions took place in a calm, learning-oriented fashion") and use a five-point frequency scale to indicate whether the behavior never occurred (1), occurred about 25% of the time (2), occurred about half of the time (3), occurred 75% of the time (4), or always occurred during the case (5). A "N/A" option was provided for four items that referenced behaviors unlikely to occur in every case. The last item on the tool asked for an overall rating of surgical teamwork during the procedure on a scale of one to five, with a five indicating excellent surgical teamwork. We recommended that a nurse manager or patient safety coordinator conduct the teamwork observations.

Common to both tools is a section capturing case demographics (patient age and gender, surgeon's specialty, and procedure performed) and observer information (age, gender, role, and tenure). This information enables users to match observations from the two tools for the same case in order to examine associations between checklist implementation and teamwork. We also included more detailed case characteristic information, such as case duration, measured as time of incision to surgical end time; whether the case was urgent/emergent or delayed; and patient disposition, in order to study the relationship between these characteristics, checklist performance, and teamwork.

In addition to paper-based instructions, we developed a web-based training module for observers, available at http://safesurgery.teamtraining.sgizmo.com/s3/. For each of the five teamwork domains, the training module provides a definition, list of the related items from the observation instrument, and two short, videotaped vignettes. The videos depict simulated scenarios, carefully designed to demonstrate positive and negative forms of each behavior we ask the observers to rate. At the end of the training, observers receive feedback about how well they rated the scenarios.

We requested that each participating hospital electronically send five to 10 completed coaching tools each quarter. However, compliance with this request was poor and highly variable. For a test of inter-rater reliability, two observers conducted both types of observations in 50 surgical cases from November 2012 to January 2013. In addition, throughout the duration of the Safe Surgery 2015 initiative, we received 242 checklist coaching tools and 213 teamwork coaching tools (207 from the same surgical cases) for research purposes.

Implementation Leader Questionnaire. The **Implementation Leader Questionnaire** was a 59-item questionnaire, developed with reference to existing research and frameworks describing determinants of effective implementation in healthcare delivery (Damschroder et al., 2009; Greenhalgh et al., 2004; Kitson, Harvey, & McCormack, 1998; Rycroft-Malone et al., 2002), our preliminary qualitative research on checklist implementation (Conley et al., 2011), and Safe Surgery 2015 initiative recommendations. Items addressed nine topics related to team characteristics, contextual factors, supportive activities, and self-reported outcomes: the checklist implementation team; hospital in which the checklist was being implemented; surgical specialties in which the checklist was being implemented; motivation for implementation; conditions for implementation, planning and preparation, pilot testing, promoting, and ensuring checklist use; and impressions of surgical teams' experience with checklist use. Most questions were closed-ended. Two-, four- and five-point response scales varied according to items, with a higher score corresponding to more of a recommended condition or activity.

We administered questionnaires online and on paper between 2012 and 2014 as each hospital completed its active period, defined as the time during which they engaged with the Hospital Association's initiative activities in pursuit of checklist implementation. We received 25 implementation leader questionnaires from South Carolina hospitals indicating that implementation leaders had felt they had completed (at least for now) the active period for their implementation.

Safe Surgery 2015: South Carolina. The Safe Surgery 2015 initiative team kept records of points of contact with implementation teams at each institution, including participation in webinars and in-person meetings, site visits, and other implementation activities. Data on inpatient operations were obtained through the state all payer claims database and linked to readmissions and ER visits. The data were also linked to the state vital statistics registry to ascertain deaths that may have occurred outside of the hospital.

Measures

Surgical safety culture. Based on exploratory and confirmatory psychometric analysis, we derived a set of factors underlying the teamwork dimension of the surgical safety culture survey: communication, coordination, respect, assertiveness, and clinical leadership. We calculated scores for each factor as the unweighted average of factor items. We also summarized the teamwork dimension by averaging factor scores. In addition, we calculated unweighted average scores for the contextual (readiness in the pre-test; supportive activities in the post-test), practical (adherence), and implementation effectiveness (post-test only) dimensions, treating these as simple indices, and for the three items measuring perceived checklist outcomes. We also treated these three items as individual outcome measures. Given the skew of responses toward the higher end of the response scale, we focus on the percentage of neutral or negative responses (1-4) after reverse-scoring negatively worded items. Combining neutral and negative responses assumes neutral responses may imply a weak climate (Singer et al., 2003). We also calculated the percentage of positive and strongly positive response. For the dimensions and factors, average scores <4.5 were classified as negative/neutral. We analyzed responses to individual items and dimensions/factors overall, by respondent hospital, and by professional discipline. We confirmed that aggregation to the hospital level was appropriate by calculating intraclass correlation coefficients (ICC).

Coaching tools. For the checklist tool, we calculated scores for each item and section of the survey (i.e., processes of care, briefing, debriefing, buy in, and checklist outcomes). In addition, we calculated performance of a set of seven items considered communication-based "prompts" (e.g., Before the incision, did the surgeon discuss the operative plan?) and five discrete procedural "checks" (e.g., Was an antibiotic given within 1 hour of incision?) by averaging across these sets. For the teamwork tool, we calculated scores for each item and teamwork domain (communication, coordination, respect, assertiveness, and clinical leadership), focusing on the percent of observations indicating excellent teamwork or that desired teamwork behaviors occurred at least 75% of the time (i.e., top box responses). Using procedure and observer information captured on both tools, we also created variables indicating case duration (a continuous variable), observer gender, patient age (a proxy for case complexity), and "stress," which we defined as a case described by the observer as urgent or emergent (requiring same day completion), involving significant nonclinical disruptions, and/or delayed more than 30 minutes. In measuring inter-rater reliability, we measured percent absolute agreement between raters as well as weighted kappa coefficients for each section, generating an overall kappa coefficient for each tool by averaging the kappa scores of each section.

Implementation Leader Questionnaire. Given a small number of responses relative to the number of items on the implementation leader questionnaire, traditional methods for identifying a factor structure were considered unreliable (DeVellis, 2012). Thus, after preliminary data cleaning, we used three complementary techniques to identify a set of latent variables underlying the implementation leader questionnaire data: principal components analysis, correlation analysis, conceptual grouping. Triangulating results, we identified a coherent set of factors, including mutually exclusive sets of items, each of which demonstrated satisfactory or near-satisfactory reliability and discriminant validity. This approach resulted in six domains, which we describe as "implementation objectives": (1) establish supportive processes, which captures the extent to which implementation teams employed recommended processes and

personnel to support checklist implementation; (2) anticipate and resolve obstacles, which addresses the extent to which implementation teams face obstacles and overcome them; (3) use a relational approach, which represents the extent to which implementation teams create opportunities to connect personally with individuals and groups in order to spread checklist use; (4) ensure shared responsibility, which describes the extent to which responsibility for implementing and championing the checklist was shared among surgical disciplines; (5) provide motivation and quality improvement infrastructure, which measures a hospital's preparedness with QI personnel, salaried doctors, financial resources, patient demand, and monitoring capability for checklist implementation; and (6) demonstrate senior management engagement, which addresses the extent to which senior managers and board member expectations motivate implementation and the level of engagement of senior managers with the implementation process. These objectives included 46 of the 59 items in the survey. The questionnaire also included four items that we considered as self-reported checklist outcomes, including implementation team leaders' assessments of checklist use (i.e., stopping at three points with every or almost every surgical procedure) and the impact of checklist implementation on surgical procedure efficiency, teamwork, and systemic changes. We considered the remaining nine items as orphan items.

We scaled each variable in the questionnaire so that responses equaled some score between 0 and 1, with 1 representing that a hospital had achieved the desired condition or activity for that variable, based on recommendations from the Safe Surgery 2015: South Carolina Education Series (www.safesurgery2015.org). Next, we determined objective achievement scores by calculating the average of item scores within each objective. To calculate an overall implementation achievement score for each hospital, we summed the six objective scores. We also computed the percentage of hospitals that achieved the criterion for each variable, objective, and overall.

Surgical complications and mortality. We are stratifying hospitals by their degree and timing of engagement with checklist implementation and evaluating changes in postoperative mortality during the study period. We are using a propensity score adjusted analysis to account for hospital and patient characteristics that may impact outcomes as well as the clinical classification software system produced by the Agency for Healthcare Research and Quality to account for differences in case mix.

Limitations

Although our surgical safety culture survey and coaching tools proved reliable based on rigorous analysis, the implementation leader questionnaire did not lend itself to standard psychometric assessment, given the small number respondents relative to the number of items included in the questionnaire. Therefore, we employed a combination of techniques, including qualitative and quantitative, theoretical, and empirically driven approaches, and triangulated findings to identify a coherent set of empirically supported measures. Our teamwork coaching tool elicited consistently high marks, suggesting that observers may have missed or were reluctant to report nonoptimal behavior among surgical teams in their own hospital. Alternatively, the observers' presence may have influenced the behaviors of surgical teams. Additional training or use of calibration to lower scoring for the observers may be required to expand the range of teamwork scores reported. In addition, and most important, we were limited in our ability to test our hypotheses by the limited response of participating hospitals to requests that they contribute data for our research. Rather than lack of willingness or interest in measurement, we believe this reflects the hospitals' need to prioritize implementation over measurement, given significant production pressure and limited bandwidth.

Results (principal findings, outcomes, discussion, conclusions, significance, implications)

Through a series of analyses, we have deepened our understanding of factors associated with successful implementation of surgical checklists, the relationship of teamwork

and checklist use, and the relationship of checklist use with checklist outcomes. Analysis of changes in clinical outcomes is still ongoing, as the lag associated with feedback of data has prevented study of the program until now. Our analyses have been organized around specific questions; we thus report them accordingly.

Principal Findings and Outcomes

Surgical safety culture and association of culture change with checklist implementation and checklist outcomes. Using cross-sectional analysis, we assessed staff perceptions of readiness, teamwork, and adherence to and consequences of safe surgical practice at baseline in 36 South Carolina hospitals participating in the Safe Surgery 2015: South Carolina initiative. This analysis enabled us to verify that the surgical safety culture instrument provides a valid and reliable measure to inform implementation of surgical checklists. At baseline, perceptions of surgical safety culture were mostly positive, but responses within and among hospitals varied, and opportunity to improve surgical safety remained. We found that, overall, 78% of responses were positive. However, 40%, 17%, 25%, and 16% of responses regarding safe surgical practice, readiness, teamwork, and consequences, respectively, were neutral/negative. Respondents not reporting they feel safe in their operating rooms varied from 0% to 57% among hospitals. Surgeons responded more positively than nonsurgeons, particularly with regard to items about clinical leadership and respect—two dimensions of teamwork. Readiness, teamwork, and adherence related to perceived consequences of safe practice ($p<0.001$).

As of September 2014, 13 hospitals participating in the Safe Surgery 2015 initiative in South Carolina had repeated the culture survey and provided data to the investigator team. Among these 13 hospitals, responses to questions about teamwork and adherence to and consequences of safe surgical practice consistently improved. After adjusting for individual characteristics, responses in each domain were significantly better in the post-test than at baseline. Overall, improvement averaged 0.33 points (on a scale of 1-7) across all items in the survey, a 6% increase in teamwork. However, not every hospital experienced improvement; in one hospital, responses became less positive; in another hospital, staff reported feeling less safe in their operating rooms than at baseline. In addition, when asked about checklist use, only 55% of physicians and 58% of nonphysicians overall reported that their entire surgical team always stops at three critical points during the procedure to read the checklist. Yet, 75% of physicians and 80% of nonphysicians agreed that checklist use has averted problems or complications in surgery; 77% of staff felt using the checklist "helps my cases run more smoothly," and 80% agreed that patient safety has improved as a result of using the checklist. Differences in perceptions between surgeons and nonsurgeons regarding clinical leadership and respect persisted but at a somewhat reduced level.

According to data from the surgical safety culture survey, effective checklist implementation correlated with checklist outcomes. Specifically, the percentage of staff who reported they stop at all three critical points during a procedure to review the checklist correlated significantly with their feeling safe as a patient, their reporting that problems or complications had been averted by the checklist, and that their cases run more smoothly. In addition, changes in staff members' perceptions of teamwork were correlated significantly with changes in the percentage of staff members who reported feeling safe being treated as a patient.

Inter-rater reliability of coaching tools. Through an independent test of the coaching tools, focused in one hospital with two observers who independently rated 50 surgical procedures, we found 93% agreement and a kappa of 0.74 for the checklist coaching tool and 86% agreement and 0.84 kappa for the surgical teamwork tool, suggesting that both tools achieved satisfactory inter-rater reliability. Percent agreement and kappa scores did not change significantly between the first 10 and last 10 cases observed, indicating that use of the tools required limited training.

Checklist use, teamwork, and their association. In cross-sectional analysis comparing checklist and teamwork observations of 207 surgical cases from 10 South Carolina hospitals that used both coaching tools and shared the data with investigators, observers rated surgical

teamwork during procedures as excellent (5 on 5-point scale) in 74% of cases. They also indicated that desired team-oriented behaviors occurred at least 75% of time (5 on 5-point scale) in 76% of cases on average. Observers reported that coordination and communication behaviors occurred most frequently: in 83% and 82% of cases, respectively, they occurred at least 75% of the time. Respectful behaviors occurred least frequently: in 67% of cases, they occurred at least 75% of the time. According to observations using the checklist coaching tool, surgical teams performed all 12 checklist items documented on the tool in 13% of cases. They performed at least 80% of items in 47% of cases. Surgical teams were more likely to complete checks than prompts.

Based on multiple regression analysis, all five teamwork domains and the rating for overall teamwork related significantly to performance of at least 80% of checklist items ($p<0.05$). Surgeon's buy-in also related significantly to completing at least 80% of the checklist ($p<0.01$). Clinical leadership, coordination, and the overall teamwork rating were significantly associated with completing the items considered to be communication-based prompts ($p<0.01$); respect was also marginally associated with communication. Prompts were also more likely to be completed in more complex cases (i.e., those involving older patients). Clinical leadership, communication, coordination, overall teamwork, and marginal respect were also associated with completing discrete procedural checks. In contrast to prompts, however, checks were more likely to be completed in cases involving stress.

Variation in implementation and association of implementation objectives with successful checklist implementation. Among implementation teams from 32 hospitals (25 in South Carolina, and seven in North Carolina that had participated in a Safe Surgery 2015 implementation initiative based entirely on South Carolina as a model), responses indicated substantial variation in implementation approach, despite clear guidance regarding activities measured. No implementation team leaders reported conducting all recommended activities; however, all took part to some degree, and many reported achieving most of the desired conditions and activities. All implementation team leaders reported instructing nurses or surgical techs to initiate the checklist if surgeons did not. Fewer implementation team leaders reported that they had achieved the desired state for other items. The lowest percentage of implementation teams accomplishing any item was 24% regarding their ability to find time without difficulty for hospital staff and physicians to work on quality improvement projects for their operating rooms. With regard to perceived checklist outcomes, 72%, 72%, and 56% of implementation team leaders indicated positive changes in efficiency, teamwork, and systems change, respectively, and 63% of implementation team leaders indicated all or most surgical teams were using the Surgical Safety Checklist in every or almost every surgical procedure at each of three stopping points.

Out of the maximum achievable implementation objective score of 1 for each implementation objective (establish supportive processes, anticipate and resolve obstacles, use a relational approach, ensure shared responsibility, provide motivation and quality improvement infrastructure, and demonstrate senior management engagement), the average achievement score among the six implementation objectives was 0.61, ranging from 0.44 for senior management engagement to 0.73 for obstacles and efforts to resolve them. In hospitals where the implementation team leaders reported more improvement in efficiency, teamwork, and systemic change ("higher-performing hospitals") following checklist implementation, implementation team leaders also reported higher levels of implementation achievement ($p<0.001$). On average across implementation objectives, higher-performing hospitals achieved 0.77 of the maximum achievable implementation objective score compared with 0.48 for lower-performing hospitals. Senior management engagement was the implementation objective that most differentiated higher-performing from lower-performing hospitals ($p<0.05$). In addition, when we compared achievement of implementation objectives versus staff reports of checklist use at three stopping points in 13 hospitals for which both measures were available, these measures were also significantly positively correlated.

Change in surgical complications and mortality before and following checklist implementation. Analysis is ongoing due to lag in return of clinical data. However, preliminary analysis suggests a decrease in postoperative mortality among certain groups of hospitals. We currently have data for the full calendar year of 2013 and are performing analyses with these data.

Discussion

Our study of checklist implementation among diverse hospitals contributes insight about level and variation in surgical safety culture, checklist implementation, and change in culture and checklist outcomes following checklist implementation. Notably, we find improvement in team climate, safe practice, and perceived outcomes following active participation in the Safe Surgery 2015: South Carolina. Our research also establishes connections between the achievement of implementation objectives, teamwork, safe surgical practice, and checklist outcomes, using survey, questionnaire, and observation data.

Surgical safety culture and association of culture change with checklist implementation and checklist outcomes.

Our study of surgical safety culture, including measures of readiness, team climate, safe practice, and perceived outcomes in 36 South Carolina hospitals, found that staff perceptions were mostly positive at baseline, albeit varied and with room for improvement. Variation among hospitals suggests that most hospitals could benefit from innovations like surgical checklists, designed to promote safe surgical practice. It also implies that strong teamwork and safe practice are possible and that many facilities could benefit from collaborations that provide opportunities for cross-institutional learning. Our results highlight differences in attitudes and perceptions among professional disciplines, particularly that physicians were more positive than nonphysicians. Given physicians' critical role in achieving teamwork, hospitals are unlikely to make significant progress without physicians' willing and active participation. Psychometric results support the reliability of a five-factor interpersonal dimensions of communication, coordination, clinical leadership, respect, and assertiveness. Strong relationships between measures of readiness, teamwork, and adherence to safe practice with perceived consequences of safe practice also suggest criterion validity for the survey.

Repeated measurement of team climate, safe practice, and perceived outcomes following active participation in the Safe Surgery 2015: South Carolina suggested improvement in all domains, indicating that the effort to promote implementation of surgical checklists successfully achieved its improvement aims. However, though consistently true across domains, improvement—as measured to our surgical safety culture survey—was small and not evident for all hospitals, and substantial room for improvement remained, including in reducing perceptual differences between surgeons and nonsurgeons. Moreover, that just 13 of the 64 hospitals that have participated in the Safe Surgery 2015 initiative to date (and of the 36 that conducted a baseline survey) have elected to administer a follow-up survey and provide their data to investigators suggests that implementation leaders feel they would like to accomplish more before evaluating their achievements; several have said as much to the Safe Surgery: South Carolina intervention team. This may indicate an increased awareness of required change, which in itself may be considered a positive outcome. Although staff who responded to our survey reported inconsistent use of the checklist following their hospital's implementation initiative, most staff felt that checklist use had benefited their patients by averting problems or complications, making cases run more smoothly, and improving patient safety. Checklist use also correlated with these outcomes, as well as with staff feeling safe as a patient. These positive associations with checklist use suggest the effort to implement surgical checklists can be worthwhile. However, checklist implementation is a journey, requiring long-term commitment, substantial resources, and the ability to overcome obstacles along the way. Recognizing and

providing for such dedication may increase the likelihood of successful implementation initiatives.

Inter-rater reliability of coaching tools. We developed, pilot tested, and evaluated the inter-rater reliability of a pair of novel coaching tools for measuring Surgical Safety Checklist performance and teamwork in the OR. In what we believe was the first test of checklist and teamwork observation tools conducted in a "real-world" setting, two observers with minimal training and no previous OR experience achieved IRR scores meeting standard statistical criteria. In the authors' opinion, a debriefing to resolve observers' questions was important for creating an opportunity for observers to discuss between themselves how they would apply the tools. Lack of significant change in IRR between the first and last 10 cases suggests that there is a minimal learning curve for using the instruments. The ability to use the tool almost immediately is important, as most participating hospitals do not have the resources to train observers. Also, many hospitals want to observe cases periodically to ensure consistent checklist performance. An easy-to-use tool with high IRR ensures that these observations are comparable and useful.

Checklist use, teamwork, and their association. Analysis of observations of surgical teams suggests numerous opportunities for improvement in checklist performance, with certain checklist items being performed in fewer than half of observed cases. For example, more surgeons relied on memory than read the checklist aloud. Surgeons also often failed to discuss the operative plan, expected duration, or expected blood loss. Whether these omissions were conscious is unclear. However, the tendency to rely on memory suggests that educating surgeons to read from a printed checklist could lead to improved checklist performance.

Our findings suggest that high-quality surgical teamwork, characterized by shared clinical leadership, communication, coordination, assertiveness, and respect, is associated with checklist completion. Patient age, a possible proxy for case complexity, is related to more communication about the case. In stressful situations, staff appear to rely on the checklist as a reminder of safe practices. Teamwork demonstrates a positive relationship with checklist completion, despite observer ratings that suggest surgical team members almost always demonstrate teamwork-related behaviors. These findings highlight the importance of high-quality and consistent teamwork to safe surgery.

Variation in implementation and association of implementation objectives with successful checklist implementation. Implementation varied substantially across hospitals according to implementation team leaders responding to our request for information, despite participation in a collaborative initiative that gave clear and consistent direction regarding implementation. We may have detected even greater variation had we had information about all hospitals participating in the Safe Surgery 2015: South Carolina initiative. We identified six key objectives for implementing surgical checklists: (1) establish supportive processes, (2) anticipate and resolve obstacles, (3) use a relational approach, (4) ensure shared responsibility, (5) provide motivation and quality improvement infrastructure, and (6) demonstrate senior management engagement. Framing checklist implementation in terms of objectives, rather than activities or processes, may be helpful, because it implies flexibility in the strategies for achieving them.

On average, hospitals accomplished about 60% of key implementation objectives, testifying to how difficult it is to conduct an effective implementation initiative. They achieved less than half of the desired activities related to senior management engagement. A key factor for successful implementation of many interventions (Damschroder et al., 2009), difficulty with demonstrating support and engagement is a challenge that hospital senior managers seeking to implement surgical checklists will need to overcome.

Most implementation teams reported some improvement in checklist compliance and checklist outcomes, including case efficiency, teamwork, and systemic change. Higher levels of implementation achievement were associated with both higher levels of these self-reported outcomes as well as higher levels of staff-reported checklist use. Hospitals that reported more

improvement in checklist outcomes also described higher levels of senior management engagement. These results suggest that following a rigorous initiative to implement surgical checklists can result in greater checklist use.

Conclusions

Surgical safety culture and association of culture change with checklist implementation and checklist outcomes. We developed and evaluated novel surveys for describing the status of factors likely to influence or be influenced by effective checklist implementation at baseline and following an initial effort to implement surgical checklists. Our approach reflects a belief that measures that are tailored for patient safety innovations can help make a compelling case for supporting active participation. Findings suggest opportunities to improve current practice through patient safety innovations like surgical checklists and suggest that strategies for improving implementation effectiveness might especially benefit from efforts to engage surgeons, whose perceptions of surgical teamwork tend to be more favorable than nonsurgeons. Improvement in measures of safety culture following implementation of a surgical checklist underscores the value of checklists for improving safety culture, safe practice, checklist outcomes, and---ultimately---patient safety.

Inter-rater reliability of coaching tools. The coaching tools used by observers as part of the Safe Surgery 2015 initiative appear reliable. These tools provide an example of how observational tools can be integrated into large-scale implementation and research efforts. The tools and training materials are publicly available and in use by other hospitals.

Checklist use, teamwork, and their association. Even in hospitals that are implementing surgical checklists, variation in checklist use remains. Encouraging consistent use, rather than use only when patient complexity or case-related stress warrants heightened attention, should be a key message when coaching teams. Surgical teams that exhibit better teamwork also experience more effective checklist implementation.

Variation in implementation and association of implementation objectives with successful checklist implementation. Wide variation also exists in hospitals' implementation efforts, and few hospitals can achieve rigorous implementation objectives. In particular, opportunity exists for senior managers to engage and demonstrate their support for checklist implementation. Achieving implementation objectives appears associated with improvement in checklist outcomes. Creatively thinking about how implementation objectives may be accomplished could enhance hospitals' abilities to successfully implement.

Significance and Implications

Riskin and colleagues described three broad categories of innovation in surgical care: simple tool modifications (e.g., Kocher clamp), revolutionizing tools (e.g., Fogarty catheter, video laparoscopy), and revolutionizing technologies or science (e.g., anesthesia, cardiopulmonary bypass) (Riskin, Longaker, Gertner, & Krummel, 2006). The last category is reserved for innovations that change the face of surgical care. One such innovation is aseptic technique. In 1847, Ignaz Semmelweis noted that expectant mothers who delivered by midwives had much lower infection rates than those whose deliveries were attended by physicians. He also noticed that the physicians shuttled between autopsies and deliveries without washing their hands and hypothesized that puerperal fever was being transmitted during vaginal examinations. After instituting a strict handwashing protocol in his institution, the maternal mortality rate decreased 95%, from 20% to 1% (Cooper & O'Leary, 1999). Like the checklist, handwashing had the potential to make dramatic, global improvements in surgical morbidity and mortality. But Semmelweis' failed to implement effectively. By shouting to affect change, he alienated would-be supporters and strengthened detractors' resolve. It was not until 20 years later, when Joseph Lister published a clear, persuasive plea, that aseptic technique began to gain acceptance (Gawande, 2007). Today, organizations continue to struggle to implement hand hygiene protocols.

Implementation science remains a rudimentary field in healthcare delivery. Through this research, we sought a better understanding of what facilitates effective implementation in order to facilitate thorough, consistent, and widespread use of the Surgical Safety Checklist. This study is one of the largest and most rigorous to date. It improves our level of sophistication about implementation in theoretical, methodological, and practical ways. Theoretically, the checklist is distinguished from previously studied technological innovations (Weiser et al., 2008) or improvement programs (Tucker et al., 2007) by the fact that it does not require novel surgical skills, equipment, or personnel. Unlike minimally invasive cardiac surgery, for example, the checklist can be used halfheartedly or not at all. The effectiveness of its implementation is therefore directly reflected by consistency of use, adherence to process measures, and surgical team member buy-in. This study enhances our understanding of how implementation contexts and activities can lead to effective implementation for such nontechnical innovations and how effective implementation improves teamwork and sustains clinical gains.

Methodologically, we developed and tested a new data collection instruments to evaluate implementation processes and surgical safety culture as well as new observation tools to gage implementation effectiveness, teamwork, and measures of checklist outcomes. We developed simulation-based training materials for surgical staff to support their consistent use. Both the instruments and training materials could be packaged with the checklist to increase the likelihood of effective implementation in hospitals globally. They could also be applied to study implementation of other innovations like the checklist.

Practically, lessons learned from effective implementers will inform the implementation process for those considering checklist use. This is essential in a world where 234 million operations occur each year (Weiser et al., 2008). In 2002, the World Bank reported that 164 million disability-adjusted life-years (11% of the global burden of disease) were caused by surgically treatable conditions (Debas, Gosselin, McCord, & Thind, 2006). As surgical capacity increases to meet this need, so will the potential for surgical complications. Yet, we know that the checklist is capable of substantially reducing 30-day mortality, from 1.5% to 0.8% ($p=0.003$), and overall complications, from 11% to 7% ($p<0.001$), under optimal conditions (Haynes et al., 2009). Real-world conditions may not yield comparable benefits, even with best-practice recommendations for implementation. However, if only half the benefit were realized, over 800,000 lives might be saved and 4.6 million complications avoided.

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

Websites:

Website	
Safe Surgery 2015	http://www.safesurgery2015.org/
Safe Surgery 2015: South Carolina	http://www.safesurgery2015.org/safe-surgery-2015-south-carolina.html
Checklist Monitoring Program Resources	http://www.safesurgery2015.org/south-carolina-monitoring-program.html
Checklist Observation Training Program	http://safesurgery.teamtraining.sgizmo.com/s3/

Data Collection Instruments:

Title
Pre-test Implementation Climate Survey—short version
Pre-test Implementation Climate Survey—long version
Post-test Implementation Climate Survey—short version
Post-test Implementation Climate Survey—long version
Surgical Checklist Coaching Tool
Surgical Teamwork Coaching Tool
Implementation Team Leader Survey

To request use of any of these checklist program monitoring instruments, please contact us at safesurgery2015@hsph.harvard.edu.

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Singer SJ, Kiang MV, Conley D, Edmondson L, Sachetta J, and Berry WR, "Innovations in Health Surveys: Application to Research in Action," 2011 AcademyHealth Annual Research Meeting, June 14, 2011.

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Huang LC, Kiang MV, Jiang W, Edmondson LA, Gawande AA, Berry WR, and Singer SJ, "Are surgeons less likely to perceive problems with teamwork in the operating room?" Harvard Medical School Surgery Research Day, May 2012.

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