The Surgical Safety Checklist: Lessons Learned During Implementation

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Procedural checklists may be useful for increasing the reliability of safety-critical processes because of their potential capacity to improve teamwork, situation awareness, and error catching. To test the hypothesized utility and adaptability of checklists to surgical teams, we performed a randomized controlled trial of procedural checklists to determine their capacity to increase the frequency of safety-critical behaviors during 47 laparoscopic cholecystectomies. Ten attending surgeons at an academic tertiary care center were randomized into two equal groups - half of these surgeons received basic team training and used a preprocedural checklist whereas the other half performed standard laparoscopic cholecystectomies. All procedures were videotaped and scored by trained reviewers for the presence of safety-critical behaviors. There were no differences detected in patient outcomes, case times, or technical proficiency between groups. Cases performed by surgeons in the intervention (checklist) group were significantly more likely to involve positive safety-related team behaviors such as case presentations, explicit discussions of roles and responsibilities, contingency planning, equipment checks, and postcase debriefings. Overall, situational awareness did not significantly differ between the intervention and control groups. Participants in the intervention (checklist) group consistently rated their cases as involving less satisfactory subjective levels of comfort, team efficiency, and communication compared with those performed by surgeons in the control group. Surgical procedural safety checklists have the capacity to increase the frequency of positive team behaviors in the operating room during laparoscopic surgery. Adapting to the use of a procedural checklist may be initially uncomfortable for participants.

OPERATING ROOMS are complex and highly technical environments where surgical teams are expected to synthesize, retain, and communicate large amounts of information. The risks for error in the surgical environment are considerable, with operative adverse events found to comprise 45 per cent to 66 per cent of all adverse events occurring within hospitals.[1, 2] In one study on medical errors, nearly 80 per cent of reported surgical adverse events occurred intraoperatively with almost a third resulting in permanent disability and 13 per cent in patient death.[3] Communication failures among personnel were cited as the second most common systems factor contributing to errors, only behind inexperience or lack of competence by the surgeon. Although the methodology of such retrospective-based investigations have been questioned, they represent some of the most comprehensive studies of medical errors to date in the medical literature.[4] Furthermore, a recent prospective study of surgical patients revealed complication rates 2 to 4 times higher than those identified in an Institute of Medicine report.[5, 6] Mortality rates from avoidable complications ranged from 19.0 per cent to 44.1 per cent depending on the surgical service. Together, these studies reveal substantial opportunity for improvement in operating room safety.

For many years, experts in high-risk domains other than surgery have used checklists to reduce the frequency of human error in the completion of complex, multistep tasks. Commercial pilots, for instance, use safety checklists during critical portions of flights to

This work was funded by a grant from The National Patient Safety Foundation, 268 Summer St., 6th Floor, Boston, MA 02210, http://www.npsf.org/.

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improve communication and ensure safe and standardized procedures, thereby minimizing error.[7] The opportunity for surgeons to implement similar measures in the operating room, however, thus far remains relatively unexplored and untested.[8–10] If intraoperative safety checklists can be similarly applied in a surgical setting, procedural variance and surgical errors may be reduced, as well as associated complication and mortality rates. The purpose of this study was to determine the feasibility of implementing the use of a checklist system within an intraoperative environment. This paper describes the first North American use of such a checklist by members of surgical teams performing laparoscopic cholecystectomy (LC) and reports its efficacy compared with teams performing the same procedure without the safety tool. In our analysis, we compare the frequency of safety-critical team behaviors during LC between groups as well as quantitative and qualitative responses from participants related to their *post hoc* recall of patient and case-specific details (situation awareness).

The purpose of this study was to evaluate the feasibility of implementing a perioperative safety checklist, and to gain an increased awareness of the challenges and solutions associated with such an effort. Our hypothesis was that implementation of a checklist would increase the frequency of safety-related behaviors, not adversely affect patient outcomes, and not be associated with significant decrement in participant satisfaction and comfort.

Methods

Setting

All adult nonemergent LC cases at our institution were screened for study eligibility from April 2001 to July 2002. Emergent procedures and those involving children, hospitalized patients, prison inmates, and the investigators' patients were excluded. Institutional Review Board approval was obtained, and a Certificate of Confidentiality was secured from the National Institutes of Health to further protect the confidentiality of participants. Permission to contact individuals was obtained from each patient's attending physician. Informed consent was also obtained both from patients and operative team members.

A total of 65 cases were randomized (by attending surgeon) to either proceed without modification or to have a preprocedure briefing and checklist followed by laparoscopic cholecystectomy. A total of 48 cases were subsequently videotaped, and 47 of these cases were eventually analyzed: 23 in the control group and 24 in the checklist group. Eighteen subjects/cases dropped out between randomization and analysis: two because the clinicians in the checklist group declined to use the checklist or requested that their case be withdrawn after videotaping, three cases were excluded due to conversion from laparoscopic to open procedures, procedure cancellations (unrelated to our protocol) occurred in four cases, and scheduling difficulties or mechanical problems precluded participation in the remaining nine dropouts (Fig. 1). Many of the scheduling problems and mechanical difficulties were attributable to the inevitable logistical problems associated with a single research team and a single set of recording/analysis equipment.

All accrued cases were recorded using an institutionally developed software program termed Remote Analysis of the Team Environment (the RATE tool)[11] (Fig. 2). The RATE software allows for a synchronized and integrated review of cases and provides the means to annotate, score, and index case information, including the frequency and timing of discrete behavioral elements such as team introductions and contingency planning (Table 1). Wireless microphones worn by participants captured communication between operative team members. Questionnaires developed by internal procedural and ergonomic experts were administered to case participants immediately after the operative case to evaluate their (situational) awareness to mission-critical patient and case-specific facts. The questionnaires also queried the respondents for their subjective experience of the case (Table 2). With the exception of the laparoscopic video view, all video and audio tapes were destroyed within 2 weeks of data acquisition.

Checklist

Ten general surgery attending physicians who agreed to participate in our study were randomly assigned to either an intervention (n = 5) or a control (n = 5) group. The intervention group made use of an intraoperative procedural checklist that reviewed critical steps of the LC procedure. The checklist was constructed from a review of current surgical practice literature and the consensus of two surgeons (RBA, JFC) from this research team and included preoperative, intraoperative, and postoperative components (Fig. 3). Preoperative steps included a briefing with introductions of all team members, review of the patient's history, laboratory, and radiographic studies, and discussion of any unusual case circumstances such as the need for an intraoperative cholangiogram.

Surgeons in the intervention group were provided instructions on the use of the checklist and reminded of the need to review the list before each case. In addition, a checklist copy was posted on the anesthesia monitor in the operating room during cases and participants

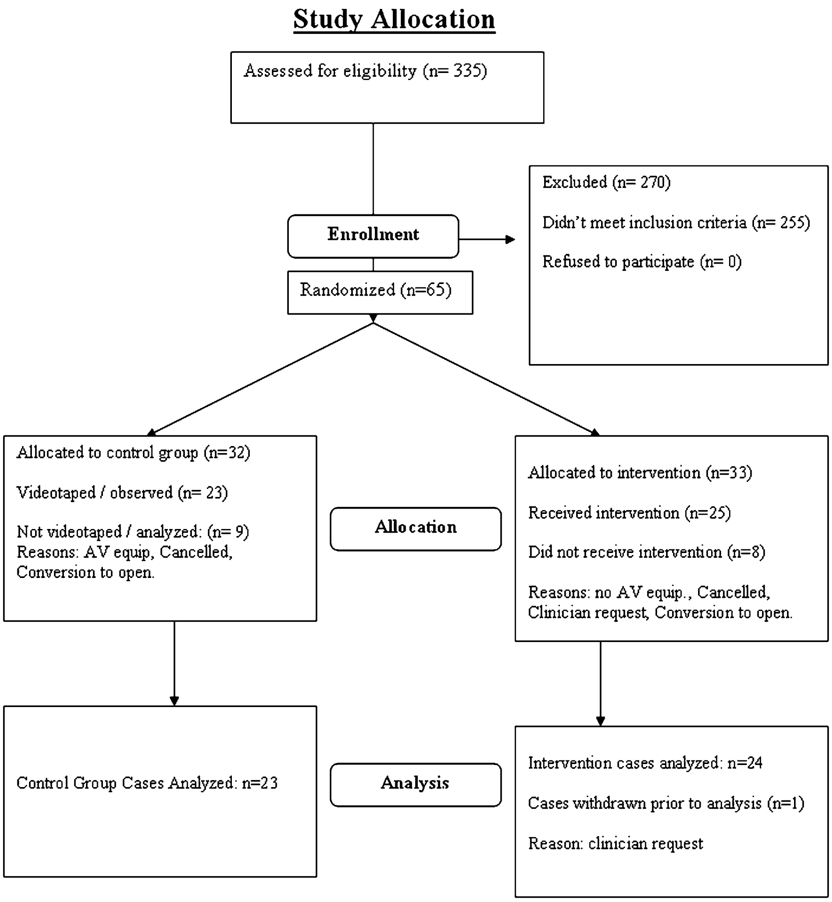

FIG. 1. The allocation tool accounts for assignment of research subjects to randomization and analysis groups. SCD, sequential compression device; LFT, liver function tests; AST, aspartate aminotransferase; ALT, alanine aminotransferase; CBD, common bile duct; NG, nasogastric; SQ, subcutaneous.

were instructed to use a call-and-repeat method to ensure critical steps from the checklist were neither omitted nor performed suboptimally. Attending surgeons and operating teams in the control group performed the LC procedure in their normal fashion without any formalized checklist or prebriefing.

Scoring

Team communication and coordination during the preoperative phase were evaluated by nonblinded members of the research team using a *post hoc* three-point scale for five different elements. These elements included role introductions, case presentation, roles and responsibility review, contingency planning, and an equipment check.

The intraoperative component of the checklist items was scored by a nonblinded external reviewer to assess compliance with directives for patient positioning, placement of proper appliances (*e.g.,* nasogastric tube, Foley catheter), and appropriate administration of antibiotics, heparin, and/or sequential compression devices. Also included in the scoring schema were assessments of scorer assessments of accurate identification of anatomic structures during the procedure with verification of clip placement and hemostasis along with a 360 degree inspection of the abdomen before removal of the gall bladder. A 24-item postcase questionnaire captured team members' demographics, knowledge of case events, and subjective measures on a five-point Likert scale.

Statistical Analysis

The Mann-Whitney *U*/Wilcoxon W analysis was used to test for the presence of significant checklist-control group differences. Asymptotic Wald Z statistics with p-values ≤ 0.05 indicated significant group differences. The statistical software packages SAS (Version 8.2, SAS, Cary, NC) and SPSS (Version 18, SPSS, Inc., Somers, NY) were used for all analyses.

Results

In the final data set that was analyzed, there were 23 cases in the control group and 24 in the checklist group. Table 3 highlights case demographics. Length of operation, discharge status, and readmission rates as indications of case outcome showed no statistical differences between groups. Favorable team behavior, defined as discrete, objective, observable shared

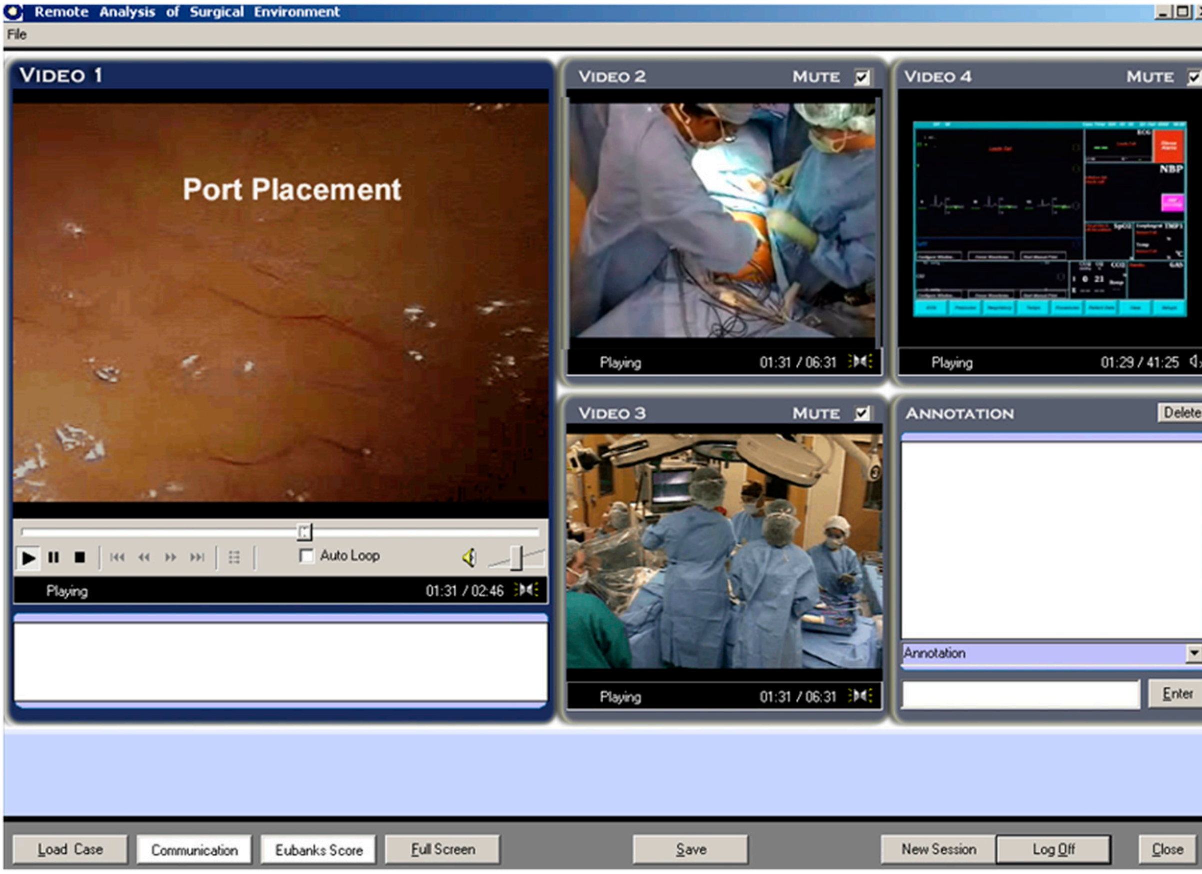

FIG. 2. The Remote Analysis of the Surgical Environment Tool (RATE) was used to record, analyze, and score cases.

TABLE 1. *Team Communication and Coordination*

		Control (n = 23)	Intervention (n = 24)	*P* value
Pre-procedure phase*	Introductions	1.11	2.77	<0.001
	Patient case presentation	1.39	2.92	<0.001
	Role and responsibilities	1.07	2.49	<0.001
	Contingency planning	1.42	2.82	<0.001
	Equipment and personnel check	2.25	2.78	0.06
Post-procedure phase*	Performance review	1.61	2.10	<0.05

* Scale for both components: 1, not done; 2, partially completed; 3, completed successfully.

TABLE 2. *Postcase Questions*

	Control (n = 142) Median (Mode)	Checklist (n = 139) Median (Mode)	*P* value
Difficulty of case*	2 (2)	2 (3)	0.0065
Comfort during case†	1 (1)	2 (1)	0.0335
Surgical outcome‡	1 (1)	1 (1)	0.1225
Team efficiency‡	1 (1)	2 (1)	0.0002
Team communication‡	1 (1)	1 (1)	0.0370

* Scale: 1, easy to 5, hard.
† Scale: 1, at ease to 5, uncomfortable.
‡ Scale: 1, very satisfied to 5, not at all satisfied.
P–values reported based on an asymptotic *Z* statistic.

The Surgeon's Checklist

Laparoscopic Cholecystectomy

Patient Label Here

Time (Begun)	Checkpoints	Document	ABN (√)	Specify or List Exception(s)
______	**Study review (LFT's & radiology: Before Skin Prep**			
	AST……………………………………	______		
	ALT……………………………………	______		
	Conj. bilirubin…………………………	______		
	Total bilirubin…………………………	______		
	CBD diameter (from film) ………….	______mm		
	Stones ?………………………………	Yes / No		
	Cholangiogram indicated?	No		
______	**(Functioning) Appliances: Before Draping**			
	NG tube ………………………………	______		
	Foley Catheter……………………….	______		
	SCD's………………………………….	______		
______	**Administer antibiotics and SQ Heparin: Before Incision**			
	Antibiotic(s) Name(s) (Generic)……	______		
	Dose…………………………………….	______		
	Route……………………………………	______		
	Re-Dose…………………………………	______		
	Heparin 5000u SQ	Yes		
______	**360 Degree & Trochar Check: Before Cautery Turned On**			
	Bleeding………………………………	No		
	Other Pathology……………………..	No		
______	**Identify cystic artery and cystic duct: Before Insertion of Clip Applier**			
	Inflammation…………………………	None / Mild		
	Cystic Artery…………………………	Well Identified		
	Cystic Duct…………………………..	Well Identified		
______	**Verify clips: cystic artery & cystic duct: Before Completion of Fundal Dissection**			
	(2) Clips verified on cystic artery..….	Yes		
	(2) Clips verified cystic duct ………..	Yes		
______	**Check gallbladder hemostasis & bile leaks: Before Removal of GB from Abdomen**			
	Gall bladder bed bleeding………….	No		
	Collateral Injury……………………..	No		

______ Case Finish Time

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FIG. 3. The Surgeon's Checklist for Laparoscopic Cholecystectomy. A modified version of this checklist was posted for operating room members during each intervention case and included individual role responsibilities. For example, tasks for the surgery resident included chart and radiology review, patient positioning and preparation, and sequential compression device placement if heparin was not administered.

communication behaviors that promote safety, on the other hand, occurred with significantly greater frequency in the checklist group (Table 1) as compared with control cases. Participants in the checklist cohort were significantly more likely to perform introductions of team members, case presentations, assignment of team roles, contingency planning, and postcase performance reviews. Five of the six criteria team coordination and communication elements in the pre and postoperative phases differed significantly between control and checklist groups (Table 1).

Table 2 demonstrates that case participants found the cases in the checklist cohort more technically challenging, and, surprisingly, they also described them

TABLE 3. *Case Demographics (n = 48)*

Characteristic	Control, n = 23	Checklist, n = 24
Length of case*	85.8 ± 38.0	89.1 ± 34.3
Discharge status†		
Same day	16 (69.6%)	17 (70.8%)
Next day	7 (30.4%)	5 (20.8%)
2–7 days later	0 (0%)	2 (8.3%)
Readmission status		
Not readmitted	22 (95.7%)	21 (87.5%)
Readmission within 30 days related to surgery	0 (0%)	1 (4.2%)
Eubanks score‡	69.4 ± 28.3	61.4 ± 33.5

* From skin incision to skin closure, in minutes.
† Numbers may not add to unity because of rounding.
‡ Score reported as a percentage.

perceptually as subjectively "harder" in terms of, comfort level, team communication, and team efficiency processes. This signifies that implementation of procedural checklists for surgery will be challenging to the extent to which clinician's will be asked to modify their behavior and adopt explicit attention to safety.

Post-case questionnaires comprised 24 items assessing case specific data as a measure of situation awareness. A composite score was calculated for each surgical team role based on 298 questionnaire responses. Figure 4 exhibits scores for those participants categorized by team role. Though scores were generally higher for each team role in checklist cases compared with control cases, these differences were not statistically significant.

Discussion

To our knowledge, the preceding data, from November of 2001, represent the first investigational use of procedural or safety checklists in the operative environment in the United States. Our data confirm other reports in the literature that it is possible to modify the behavior of surgical teams using a procedural safety checklist. Our study was designed to test such a safety checklist for elective LC procedures. Observer ratings of positive team behaviors that evaluated preoperational and postoperational team coordination, communication, and team efficiency elements were significantly higher in the checklist groups. These elements included such practices as patient case presentations and contingency planning before a case as well as a performance review at the end of each case. Team performance among a team of seven or more individuals is extremely complex, and communication may vary greatly between teams. The knowledge base, role, personality, and experience of each team member are just several factors that might affect team performance in the operative environment, some more difficult than others to measure.

The barriers and challenges to implementing procedural checklists and high bandwidth/high fidelity capture of audio-visual data are not trivial. To date, surgeons have had few external procedural mandates imposed upon them, least of all the expectation that they explicitly and unequivocally establish an environment of safety with themselves as the team leader, briefing participants and informing them as to what will be expected from them during the case. In this study, neither the surgeons, the anesthesia providers, the residents, nor the staff could be described as "comfortable" as they were wired with microphones and the cameras were trained upon them, though, eventually, most became somewhat accustomed to the presence of the research team in the operating room.

Even as uncomfortable with the conduct of this research as the health care providers were, gaining the endorsement and participation of the hospital administrative

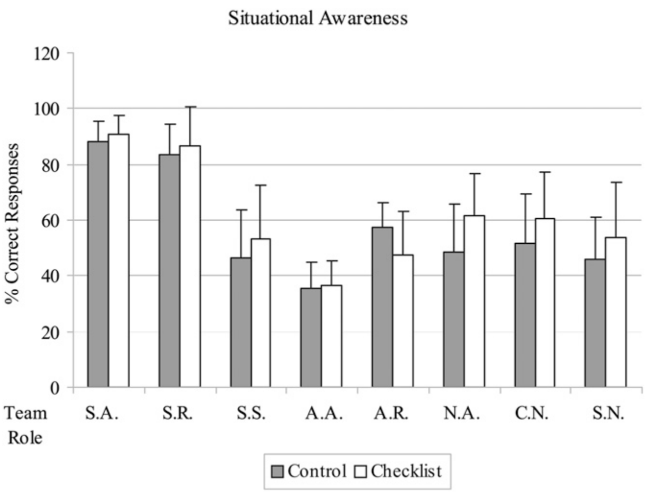

FIG. 4. Situational awareness scores evaluating participant's knowledge of critical patient information and team events. The "Anesthesia Resident" category included both anesthesiology residents and nurse anesthetists. The "Nurse" category includes circulating and scrub nurses. Every attending anesthesiologist in the analysis indicated they were present intermittently or for "critical" portions of each case. SA, surgery attending; SR, surgery resident; SS, surgery student; AA, anesthesia attending; AR, anesthesia resident; NA, nurse anesthetist; CN, circulating nurse; SN, scrub nurse.

staff, Human Investigation Committee, and legal counsel was yet even more challenging, despite the fact that the schema for destroying all audiovisual data within 2 weeks of acquisition would seem to completely eliminate the chance that any such data could be acquired for use in a disciplinary or legal process. Patients and their families, on the other hand, subjectively seemed not the least bit concerned by the protocol. Words can hardly describe the anxiety experienced by all the healthcare providers at the specter of their conduct analyzed *post hoc* by peers, supervisors, or worst of all, lawyers seeking remuneration for a safety slip-up. It remains possible that at least briefly, during the early phases of accrual, that the safety of the environment was actually decreased by the disrupted comfort of the environment by the presence of the research team. Subjectively, the environment induced by the presence of the black box recorder seemed to promote a quieter environment, with fewer extraneous conversations, though there may be some advantage in this, increasing the discomfort that some individuals have with speaking up when they are uncomfortable may not be helpful in some circumstances.

Study Limitations

Theoretically, the checklist can only prompt the surgeon to complete the major steps in the case and should not directly affect a surgeon's technical skill. There exists the possibility that residents and other staff participated in both intervention and control cases and this contaminated our results. The attending surgeon was the only team member who was clearly assigned to a control or intervention group. Moreover, surgeons in the checklist group performed a variable number of procedures, with one surgeon performing just one recorded LC for this study whereas another surgeon performed eight such cases. This occurred in the control group as well. Finally, the checklist was not always implemented as rigorously as intended, particularly by those surgeons who performed fewer checklist cases. Reeducating participants on the checklist midway through the study may have proved beneficial to maintain intervention group competency with the tool.

The necessity to entirely exclude two checklist-group cases from all subsequent analysis after randomization and accrual (due to protocol violations or clinician request) may have skewed the results of the Team Communication and Coordination Analysis (Table 1) so as to overestimate the capacity of a checklist to make favorable team behaviors occur more reliably. However, the exclusions were necessary because of confidentiality agreements put in place by our human investigation committee—any participants were guaranteed the right to pull their cases from the study at any time for any reason, particularly with the right to have all data referent to the case destroyed. Likewise, the two post video case dropouts in the checklist group may have also had the effect of causing underestimation of the magnitude of the discomfort (Table 2) induced by introducing a rigorous (and novel) communication scheme.

Conclusions

Surgical procedural safety checklists have the capacity to increase the frequency of positive team behaviors in the operating room during laparoscopic surgery. It is likely that they can be implemented in a wide range of other medical and procedural settings with similar results. Adapting to the use of a procedural checklist additionally represents a cultural shift that may be initially uncomfortable for participants.

REFERENCES

1. Gawande AA, Thomas EJ, Zinner MJ, Brennan TA. The incidence and nature of surgical adverse events in Colorado and Utah in 1992. Surgery 1999;26:66–75.
2. Thomas EJ, Studdert DM, Burstin HR, et al. Incidence and types of adverse events and negligent care in Utah and Colorado. Med Care 2000;38:261–71.
3. Gawande AA, Zinner MJ, Studdert DM, Brennan TA. Analysis of errors reported by surgeons at three teaching hospitals. Surgery 2003;33:614–21.
4. Hayward RA, Hofer TP. Estimating hospital deaths due to medical errors: preventability is in the eye of the reviewer. JAMA 2001;286:415–20.
5. Healey MA, Shackford SR, Osler TM, et al. Complications in surgical patients. Arch Surg 2002;137:611–8.
6. Kohn LT, Corrigan JM, Donaldson MS. To err is human: building a safer health system. Washington, D.C.: National Academy Press, 2000, pp xxi, 287.
7. Degani A, Wiener E. On the Design of Flight Deck Procedures. Nasa Ames Research Center: Contractor Report, 1994, pp 1–73.
8. Awad SS, Fagan SP, Bellows C, et al. Bridging the communication gap in the operating room with medical team training. Am J Surg 2005;190:770–4.
9. Lingard L, Regehr G, Orser B, et al. Evaluation of a preoperative checklist and team briefing among surgeons, nurses, and anesthesiologists to reduce failures in communication. Arch Surg 2008;143:12–8.
10. Lingard L, Espin S, Rubin B, et al. Getting teams to talk: development and pilot implementation of a checklist to promote interprofessional communication in the OR. Qual Saf Health Care 2005;14:340–6.
11. Guerlain S, Adams RB, Turrentine FB, et al. Assessing team performance in the operating room: development and use of a "black-box" recorder and other tools for the intraoperative environment. J Am Coll Surg 2005;200:29–37.