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Patient Safety in the Cardiac Operating Room: Human Factors and Teamwork: A Scientific Study from the American Heart Association

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Patient Safety in the Cardiac Operating Room: Human Factors and Teamwork

A Scientific Statement From the American Heart Association

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The cardiac surgical operating room (OR) is a complex environment in which highly trained subspecialists interact with each other using sophisticated equipment to care for patients with severe cardiac disease and significant comorbidities. Thousands of patient lives have been saved or significantly improved with the advent of modern cardiac surgery. Indeed, both mortality and morbidity for coronary artery bypass surgery have decreased during the past decade (Figure 1).[1] Nonetheless, the highly skilled and dedicated personnel in cardiac ORs are human and will make errors. In 1991, Leape and colleagues[2,3] estimated that among the 2 million patients hospitalized in New York in 1984, there were 27 179 adverse events that involved negligence; other evidence suggests that up to 16% of hospital inpatients are harmed.[4] Gawande and associates[5] found that the incidence of surgical adverse events was 12% among cardiac surgery patients versus 3% in other surgical patients; 54% of the adverse events were considered preventable. Of the roughly 350 000 to 500 000 patients who undergo cardiac surgery each year, 28 000 will have an adverse event, and one third of deaths associated with coronary artery bypass graft (CABG) operations may be preventable.[6]

Refined techniques, advanced technologies, and enhanced coordination of care have led to significant improvements in cardiac surgery outcomes. However, more than 10 years after the Institute of Medicine report,[7] there is little evidence that much progress has been achieved in reducing or preventing errors.[8] The tools to measure potential risks and interventions to improve patient safety are still in the early stages of development and testing,[9] and funding for patient safety studies remains inadequate. Published studies provide only limited evidence of improved outcomes.[8,9] Furthermore, much of the existing research is, by necessity, qualitative and descriptive and thus does not lend itself to traditional quantitative statistical analysis. Therefore, many clinicians are not conversant with such research.

Preventable errors are often not related to failure of technical skill, training, or knowledge but represent cognitive, system, or teamwork failures (Figure 2).[10–14] Nontechnical skills such as communication, cooperation, coordination, and leadership are critical components of teamwork, but limited interpersonal skills often underlie adverse events and errors.[15–17] In a review of litigated surgical outcomes, communication

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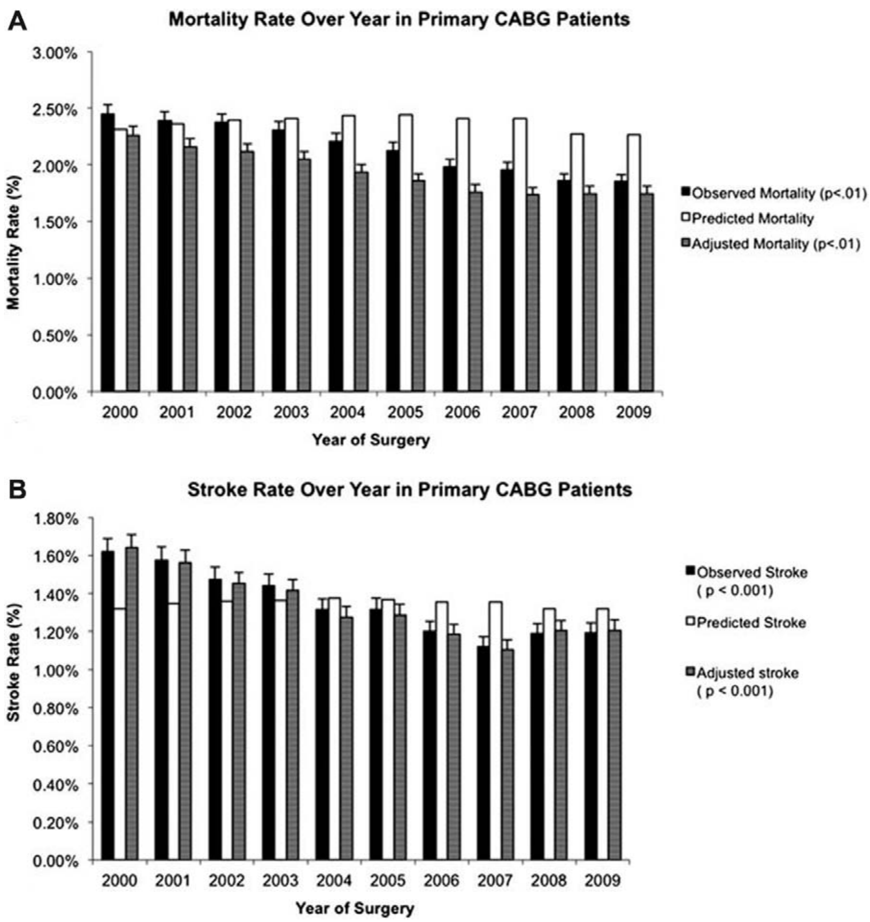


Figure 1. Change in mortality and stroke rates in patients undergoing isolated coronary artery bypass graft (CABG) surgery, 2000 to 2009. There was a 24.4% and 26.4% reduction in the unadjusted observed operative mortality (2.4% vs 1.9%) and stroke rates (1.6% vs 1.2%), respectively, during the course of the study period. Reprinted from ElBardissi et al[1] with permission from Elsevier. Copyright © 2012, The American Association for Thoracic Surgery.

failures accounted for 87% of the system failures that led to an indemnity payment.[18] The communication failures occurred primarily between caregivers, rather than between caregiver and patient.

Breakdowns in teamwork that lead to surgical flow or operative disruptions are exceedingly common, having been noted at a rate of 17.4 per hour in one cardiac surgery study[19] and at 11 per case in another.[20] Importantly, such disruptions add up, leading to technical errors and adverse patient outcomes.[21–23] The majority of flow disruptions are related to teamwork failures, and these disruptions have been shown to be strongly predictive of surgical errors.[20]

Even minor events in cardiac surgical procedures, that is, those not expected to affect outcome, reduce the team's ability

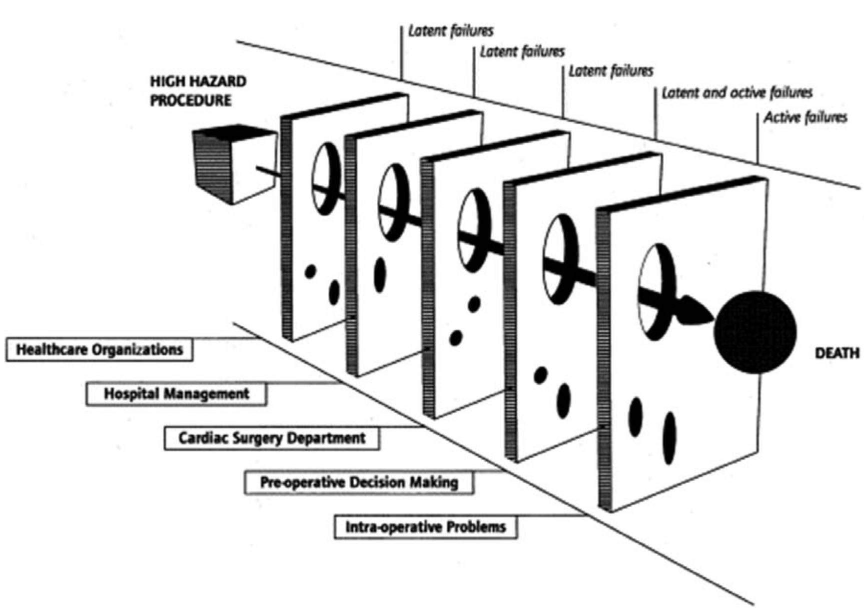


Figure 2. Accident model. Active and latent failures in healthcare organizations, hospital management, and individual human error can all contribute to adverse events during high-risk procedures. Reprinted from Carthey et al[13] with permission from Elsevier. Copyright © 2001, The Society of Thoracic Surgeons.

to recover from major events and appear significantly associated with both death and near misses.[22] In one study, for every 3 minor problems above the mean of 9.9 per case, intraoperative performance was measurably reduced and operative duration increased.[23] The accumulation of minor disruptions and events apparently reduced the ability of the cardiac team to compensate for major errors[24]; in short, "little things matter."[17,25]

Surgical team members vary in their awareness of their own and their colleagues' teamwork skills. In multiple studies, self-assessment of communication and teamwork skills by surgeons and anesthesiologists is disturbingly discordant with the opinions of their associated nursing and perfusion staff.[26,27] Surgeons rated the teamwork of other surgeons as high/very high 85% of the time, but nurses rated their collaboration with surgeons as high/very high only 48% of the time.[28] Objective assessment of teamwork skill reveals differences between skill level of team members and can indicate opportunity for education and training.[29]

The present scientific statement includes data regarding many teamwork skills but focuses on communication. Communication failures were the leading root cause of 65% of sentinel events reported by The Joint Commission between 2004 and 2012 and were a leading contributor to errors in medications, wrong-site procedures, and operative and postoperative events.[30] In one cardiac surgery study, teamwork failures occurred frequently (5.4 per case with familiar teams and 15.4 per case with unfamiliar teams); communication issues were the primary cause of these teamwork failures (89%).[21]

The American Heart Association commissioned this scientific statement to summarize the evidence regarding risks to patient safety and clarify interventions to reduce perioperative risks and human error in cardiac surgery. A comprehensive review of all potential risks to patient safety and tested interventions would be voluminous and could include wide-ranging topics such as surgical techniques (mammary arteries in CABG surgery), various cardiopulmonary bypass (CPB) strategies, or techniques to reduce infection or retained objects. We have chosen to focus primarily on those human, environmental, and cultural factors that affect teamwork, particularly how cardiac surgery teams communicate within the OR and with other unit teams. The statement is organized to describe current knowledge about communication within and between teams, the physical work environment and how it influences teamwork (space, equipment, and ergonomics), and the organizational culture (safety climate and quality improvement [QI]) of the cardiac OR.

Our process was to focus on studies in the cardiac surgical environment regarding teamwork, but we did draw on other literature as needed to present critical concepts that were specifically lacking in the cardiac surgical literature. Although many cardiac surgery studies identify communication as a significant source of error, discussion of the concepts that underlie effective or defective communication are found primarily in the cognitive psychology literature, and we have included these references in the "Communication and Teamwork" section. Similarly, although our focus is on cardiac surgery, we have included pertinent data from other surgical disciplines. We have attempted to identify the references specific to cardiac surgery, but the reader is encouraged to consult individual references for further information. Because of our focus, we excluded many dynamic areas of research that we hope will be summarized in other scientific statements or similar reviews. Finally, the present scientific statement aims to identify major knowledge gaps and potential areas for further research.

The present statement was coauthored by a writing committee composed of members of the American Heart Association's Council on Cardiovascular Surgery and Anesthesia, as well as collaborating members of the following nonprofit organizations: the Society of Cardiovascular Anesthesiologists and its FOCUS (Flawless Operative Cardiovascular Unified Systems) initiative (Society of Cardiovascular Anesthesiologists Foundation), the Society of Thoracic Surgeons, the Association of periOperative Registered Nurses, the Human Factors and Ergonomics Society, and the American Society of Extracorporeal Technology. We hope that these data and recommendations will motivate further research to address the challenges of reducing human error and improving patient safety in the cardiac OR. Such research should be widely applicable to all ORs, as well as to interventional cardiology and electrophysiology procedural settings. In particular, we hope that the present scientific statement will encourage similar reviews of patient safety in cardiology catheterization and electrophysiology laboratories, as well as in other interventional settings such as hybrid ORs designed for percutaneous management of valvular lesions, percutaneous assist devices, or stenting of aortic aneurysms.

Assessing Patient Safety

To understand how to improve patient safety, we must understand how researchers have assessed nontechnical skills and their impact. To begin with, we need a common vocabulary; terms for nontechnical skills must be defined to promote reliable comparison of studies and discussion. Second, the effect of specific nontechnical skills on the reduction of human error or on patient safety must be quantified. Third, interventions to improve individual and team nontechnical skills must be designed and tested for efficacy. Fourth, the effect of improved nontechnical skill(s) on error reduction and, hopefully, ultimately on patient outcomes must be studied to demonstrate progress.[31]

Technical skills can be measured objectively (eg, knots tied per minute), but nontechnical skills assessment requires observational and often seemingly subjective assessment by experts. Observational research, although new to many clinicians, has already identified the number, type, and severity of adverse events that occur in the OR.[13] Many team and individual behaviors that are precursors of adverse events, as well as the behaviors associated with surgical excellence, have been identified.[12,32] Observational research, however, has limitations: Valid results require trained observers, and not all trainees will become expert.[13,32,33] In one study, only 32% of all recorded events were captured by both observers, although events that were captured by both were rated equivalently.[34]

Teaching nontechnical skills is particularly challenging given the difficulty in assessing performance and providing feedback. Appropriate attention is paid to assessing the quality of technical skills, but nontechnical skills also require assessment for competency and to identify opportunities for education. As noted, observational assessment of nontechnical skills requires trained and experienced observers; to date, use of trained observers has primarily been applied in research, not in training or certification of clinical competence. During surgical simulations, a strong correlation is found between the expert's assessment and the resident surgeon's self-assessment of technical skills, but the same is not true for nontechnical skills.[35] Senior surgeons' self-assessments of technical skills highly correlate with that of an observer, but both junior and senior physician surgical trainees (resident and fellows), as well as surgical faculty, all rated themselves higher on their nontechnical skill level than did the expert observers.[36]

Objective observers are also necessary to accurately assess disruptions, errors, communication skills, and the impact of these factors on outcome. Unlike trained observers, OR personnel judged disruptions to affect their colleagues more than themselves; surgeons perceived fewer team disruptions than did other OR team members.[37] Nontechnical skills may need to be explicitly taught, because senior surgeons may or may not demonstrate better teamwork skills than those more junior, particularly in simulated crisis scenarios.[35,36,38]

Teamwork Measures

Many nontechnical skill measurement tools have been used (Table 1), but there is no single accepted instrument. Many are designed to measure nontechnical skills within a specific subteam (nurses, surgeons, anesthesiologists).[49] Behavior rating systems must be valid (measure what they purport to measure), reliable (have good intraobserver and interobserver correlation), sensitive (detect differences in behaviors when they exist), and feasible (be easy to implement and be cost-effective).

Five measurement tools, each with its own strengths and weaknesses, have been designed for surgical team and subteam skills[49]: the Observational Teamwork Assessment for Surgery (OTAS),[29,33,39–44,49] the Oxford Non-technical Skills (NOTECHS),[15,45–48] the Non-Technical Skills in Surgery (NOTSS),[50–52] the Anesthesia Non-Technical Skills (ANTS),[53,54] and the Scrub Practitioners' Non-technical Skills (SPLINTS).[54a,54b] Of these 5, NOTSS, ANTS, and SPLINT are designed to assess the individual nontechnical skills of surgeons, anesthesiologists, and scrub practitioners respectively, whereas OTAS and NOTECHS are specifically designed to assess team behaviors and skills.[55] The OTAS includes a task checklist and a team behaviors assessment. It has good construct validity (ie, it actually measures what it appears to measure) and strong reliability between expert observers but weak reliability between expert and novice observers, which indicates that training of observers is required.[41] The surgical NOTECHS was directly adapted from an aviation NOTECHS scale[45] and measures skills in 4 domains (cooperation/teamwork, leadership/management, situational awareness/vigilance, and problem solving/decision making); some research teams have added communication/team skills.[48] The NOTECHS has good reliability between expert and novice observers, has been used to show improvement in nontechnical skills after training, and has been used to show a significant inverse correlation between technical errors and nontechnical score.[15,47] There is good correlation between the NOTECHS and OTAS scores when used in parallel[47]; both the OTAS and the modified NOTECHS have been found to be construct valid.[47,56]

Table 1. Teamwork Assessment Tools

Tools to Assess Teamwork Skills Within Team	Definition
OTAS[29,33,39–44]	Procedural task checklist centered on patient, equipment, and communications tasks ratings • Communication • Cooperation • Coordination • Shared leadership • Shared monitoring
NOTECHS[15,45–48]	Adapted from the aviation NOTECHS scale used in Europe • Cooperation/teamwork • Leadership/management • Situational awareness • Problem solving/decision making • ± Communication/interaction

NOTECHS indicates Oxford Non-Technical Skills; and OTAS, Observational Teamwork Assessment for Surgery.

Surgical flow disruptions are correlated with adverse events in several studies but are defined differently in each study.[20,37,57] Two tools have been proposed, namely, the Surgical Flow Disruption Tool (SFDT)[57] and the Disruptions in Surgery Index (DiSI).[37] Both have strong interrater reliability but have not been tested by other researchers.

Outcome Measures

Poor teamwork and poor nontechnical skills have been shown to adversely affect patient outcomes. Morbidity and mortality are associated with system failures,[18] failures of coordination and communication,[58] reported levels of communication,[59] poor teamwork behaviors,[12] unfamiliarity among cardiac surgical team members,[21,60] and the number of minor events (disruptions) per case.[22] Other studies have linked teamwork quality and behaviors to surrogates such as increased length of operation,[23] number of technical errors in an operation,[46] number of major errors,[61] and stress levels of team members.[62]

The ultimate desired outcome for any safety intervention is reduction in morbidity and mortality. Mortality in cardiac surgery is quite rare; thus, studies have to be very large to achieve adequate power to discern improvement in this measure. Neily and colleagues[63] demonstrated a significant reduction in mortality with teamwork training but included 189 000 procedures at 108 Veterans Affairs hospitals to reveal a treatment effect.

Because the safety climate of an institution correlates with communication errors, several studies have used changes in attitude toward safety or changes in team "emotional climate" as a surrogate of outcome to measure impact; these studies show training in nontechnical skills to be effective.[64–70]

Summary

1. The nontechnical skills of individuals and teams affect patient safety.
2. OTAS and NOTECHS have proven construct validity and reliability. Training of observers who use these

instruments is strongly recommended for accurate results.

3. Proposed interventions to improve nontechnical skills should be tested for their efficacy in improving skill before being implemented.

Communication and Teamwork

Communication Within Teams

Communication

Communication is "the exchange of information between a sender and a receiver."[71] In the OR, multiple individuals communicate simultaneously. Unfortunately, communication skill has been measured as the worst of 5 aspects of teamwork behavior in the OR[29]; deficits in patient safety are frequently a product of breakdowns or delays in communication.[72,73] Miscommunication can occur when the sender inaccurately encodes a message (eg, by using vague or incomplete language), when the receiver decodes the sent information incorrectly, or when the information is given at the wrong time or received by the wrong individual.[72] Communication failures are common[72,74,75] and were the most common cause of problems in a host of studies.[16,21–23,58,76] Miscommunication has been implicated as the root cause of error and adverse outcomes in both general and cardiac surgery.[13,18,20–22,59,77–80] It is worse when teams are unfamiliar with each other.[21]

Communication failures in the OR are equally related to timing, content (erroneous or missing data), purpose, and audience (directed to or received by the wrong person).[72] Effective communication is open, adaptable, accurate, and concise, and it is more likely to occur in supportive and safe climates.[71] Open communication fosters seamless coordinated activities[81]; adaptable communication shows that team members are aware of and adapt to others' workloads, and concise communication promotes efficiency.[82]

The connection between effective communication and improved team performance/outcome has been shown in cockpit crews,[83] navy teams,[84] and surgical teams.[81] A recent meta-analysis provided definitive evidence of the criticality of information sharing for effective team performance.[85] Systematic literature reviews indicate that communication is a key feature of successful teams[86] and is essential for high-quality patient care.[87] Good communication enables and facilitates other fundamental team processes and states, such as coordination, cooperation, cognition, coaching, and conflict resolution.[88]

Cooperation

Cooperation is a critical element of teamwork as well and captures the feelings, attitudes, and beliefs that drive behavior. Attitudinal components began to be studied after several tragic aviation accidents were attributed to teamwork failures. Recognizing that the lack of teamwork skills (previously considered "nonessential") created severe consequences, the aviation industry developed and implemented CRM (ie, cockpit or crew resource management) programs to improve teamwork.[89]

Some of the most studied attitudes include collective efficacy (a collective sense of competence),[90,91] team orientation (a preference for and belief in teamwork),[92,93] cohesion (a commitment to the team, its task, or both),[94,95] and mutual trust (a shared belief that all will contribute to and protect the team).[96,97] Although data from cardiac surgical teams are lacking, other studies of dynamic, complex environments have shown that adaptive performance is critical. Psychological safety, team empowerment (the feeling that team members have the authority to control their work and environment), and safety climate are critical.[98–101] Empirical research has shown that when teams have high levels of collective efficacy, members exert more effort and take more strategic risks, which leads to better performance and higher satisfaction.[102,103] The level of trust within a team affects how much members monitor each other, how committed team members are to the organization, and performance.[104–111]

Coordination

Communication also enables the behavioral skills necessary for optimal coordination and team performance.[112] Coordination requires effective communication and is essential for successful team performance. It is, essentially, "orchestrating the sequence and timing of interdependent actions."[113] Coordination can be established explicitly with synchronization and awareness or implicitly with covert sequencing and communication.[71]

Implicit coordination entails a shared understanding of the task, the environment, and individual roles and responsibilities within the team. It allows members to anticipate each other's actions and needs without explicit communication, which enhances efficiency.[114–116]A mutual team understanding allows team members to provide assistance, information, and feedback,[71] which allows the team to modify structures and processes without detriment in performance.[117] The ability to foresee is imperative for effective teamwork and performance, especially in high-stress situations.[71] Without coordinated behaviors, team members cannot ensure that actions and tasks are performed in synchrony without wasted effort.[112]

For decades, research in the military and aviation has demonstrated that a team's mutual understanding facilitates coordination and performance.[114,115,120,121] Other studies show that teams with and without external pressures exhibit better performance when they have effective and efficient coordinating behaviors.[122,123] Within medical teams, explicitly stating the team's needs and goals or using team familiarity can build coordination skills and allow team members to develop clear expectations and understanding.[71] Training in coordination and adaptation, providing information updates, and distributing responsibilities improves coordinating behaviors.[115]

Cognition

Cognition is a shared understanding that arises from team interactions,[124] which improves with repeated interactions.[125] Cognition refers to the team's collective knowledge about the roles, responsibilities, and capabilities of each member.[82] The ability to anticipate team members' needs enhances coordination and communication.[126] A common understanding among team members enhances shared awareness of the surroundings, critical for problem solving in dynamic situations.[117] Teams lacking in shared understanding have reduced coordination, which leads to poor performance.[125,127]

Studies of team cognition in aviation and the military, as well as in laboratory studies with students, have shown that experienced teams and teams familiar with one another have better team cognition (eg, shared mental model) and better outcomes than inexperienced teams.[21,60,128–131] Shared knowledge affects team behaviors and performance (reviewed by Mathieu et al[132]). Shared cognition improves team communication,[133–136] learning and self-regulation,[126,137–140] and coordination.[125–127]

Within the medical domain, reflexivity training (ie, guided reflection of strategies used by the team),[131,140] cross-training (ie, training on the tasks and duties of other members),[126,141] and simulation-based team training[142,143] have been discussed as effective interventions to improve team cognition. Improving the understanding shared among team members enhances coordination and performance.

Conflict

Communication is pivotal for conflict resolution. Conflict, defined as discrepancies or incompatibilities among team members,[144] can center on tasks, relationships, or processes.[145,146] Conflict has been found to occur during the treatment of 50% to 75% of hospitalized patients,[147,148] and this may be even greater in the OR, where ostensibly equal physician teams share in the care of a single patient.

Conflict can have positive or negative implications.[149,150] Task-based conflict improves group performance in the evaluation of nonroutine problems and in group decision making,[144] but conflict also results in lower team member satisfaction, commitment,[151] cohesion, and effectiveness.[145] Unlike task-based conflict, relationship conflict has a profound negative effect on both performance and satisfaction and decreases members' willingness to remain part of the group.[151–153]

In the OR, conflicts are often poorly managed through avoidance, yielding, or competition, when collaboration and compromise would yield a better outcome.[154] Collaboration and compromise are particularly difficult when there is status asymmetry, whereby one member has greater power or seniority, such as physicians with nurses or an attending physician with residents.[147,155] Among OR personnel, 73% opined that disagreements in the OR are resolved appropriately, but 29% stated they would have trouble speaking up if they perceived a problem with patient care, and 41% felt unable to express disagreement.[156] Behaviors that physicians perceive as decisive and necessary to achieve task goals may be viewed as harsh and demeaning by subordinates.[157] Difficulty in seeing one's own behavior as others see it is pervasive throughout OR and intensive care unit (ICU) teams.[158,159] When watching videos of conflict scenarios, surgeons, anesthesiologists, and nurses rated the tension levels similarly but rated their own profession as having relatively less responsibility for creating or resolving the tension.[160,161]

There are well-known approaches to conflict resolution in the literature (eg, the 7-step model, principle-based conflict resolution, advocacy/inquiry).[144,146,162,163] Teaching conflict management to OR teams is important and possible.[157,163] Effective techniques for conflict resolution are an important component of most team-training methods.[63,164]

Coaching

Team coaching, defined as "direct interaction with a team intended to help members make coordinated and task-appropriate use of their collective resources in accomplishing the team's work,"[165] can be used to improve the performance of underperforming individuals and to enhance the skills of those who show promise as future high performers.[166] Coaching behaviors include identifying problems and leading consultations among the group members.[132]

Positive effects of coaching include better team member relationships, member satisfaction, team empowerment, and emotional security and safety.[132] A strong relationship exists between leadership and both personal and team empowerment (ie, the sense of personal or team control and motivation to complete a task), and team empowerment enhances team performance.[167] Within health care, coaching has been shown to increase nursing innovations[168] and reduce mortality.[63]

Leadership coaches can model desirable behaviors, provide constructive feedback to enhance team performance, and encourage open communication and speaking up.[86] Although cardiac surgeons are often viewed as the primary leaders in cardiac surgical teams, other team members can provide leadership and beneficial coaching to teammates. This intrateam coaching involves team members using constructive feedback to identify areas of poor performance and enhance task completion.[112] Intrateam coaching involves such behaviors as "providing advice, suggestions, guidance and instructions, calling attention to potential error, and confronting members who break norms."[112] These coaching behaviors are beneficial only when team members are receptive to suggestions and constructive criticisms.[112,169]

Interventions to Reduce Errors

Within the hospital and OR, interventions designed to improve teamwork are team training and structured tools and protocols; interventions often fit more than 1 of these categories.[170] These interventions lead to increased patient and staff satisfaction and reduced mortality.[171–175] Standardization of critical interactions by use of protocols (eg, handoffs) improves the content and structure of information and increases participation[21,77,176,177] but is often met with ambivalence at best and hostility at worst.[45,178] Physicians typically overrate their nontechnical skills; downplay the effects of stress, fatigue, and disruptions; and view the imposition of checklists or guidelines as limiting their ability to provide individualized patient care, or as an insult to their intelligence and skill.[26,44,46,62,156,179,180] The impact of nontechnical skill training, checklists, briefings, simulation training, and structured communication protocols on aviation safety is undeniable; the evidence that these interventions can improve surgical care is increasing.[181–185]

In surgery, as in aviation, even the best of protocols and teamwork efforts will not totally eliminate errors or accidents (errors that reach the patient). As postulated by Perrow,[186] accidents are the norm in high-risk industries and cannot be totally eliminated even by the best of teams; only the time interval between accidents can be increased or decreased. Vannucci and colleagues[187,188] described a series of 4 retained guidewires after central line insertion, 2 of which occurred after an extensive training program to eliminate retained guidewires; the operators who failed to remove the guidewires had successfully completed the training program. Therefore, continued review of adverse events will be required to identify not just teamwork issues but system issues that can improve safety. Review of all of those techniques (root cause analysis, sentinel event capture, competency review of clinicians, etc) is beyond the scope of this statement but is critical to patient safety.

Team Training

The ample evidence that poor teamwork skills (communication, leadership, situational awareness) contribute to errors and adverse outcomes[16,17,21–23,58,61,75] suggests that teamwork training to improve nontechnical skills should reduce errors.[164,185] After the Institute of Medicine published "To Err Is Human,"[7] the Institute studied the successful use of CRM to reduce error in aviation and recommended that team-training programs be implemented in critical care areas of medicine. Implementation of these recommendations has taken time; the CRM principles had to be adapted for use in medicine, team-training methods had to be developed, and the results of team training had to be evaluated. Nonetheless, recent reviews have found that CRM-type strategies consistently increase desirable teamwork attitudes[170] and improve teamwork practices and outcomes (eg, complication rates).[189] Team perceptions of and attitudes toward patient safety are correlated with the quality of patient safety.[185]

An early report of the benefits of formal team training demonstrated a significant improvement in the quality of emergency department team behaviors and a reduction in clinical error rate from 31% to 4.4%.[190] Halverson et al reported that a team-training curriculum, with 4 hours of classroom work and in situ coaching, increased the use of preoperative briefings[191] and reduced communication errors by half.[74] Dedicated training sessions significantly improved communication composite scores in the OR.[192]

In a preintervention and postintervention observational study in vascular and general surgery, Oxford researchers implemented CRM-based teamwork training (9 hours of didactic and interactive teaching).[45,46] Teamwork scores and teamwork climate scores improved, and technical and procedural error rates were reduced.[46] A national prospective study of the Veteran's Administration Medical Team Training program based on CRM principles[193] showed an 18% reduction in annual mortality.[63] There was a dose-response relationship between Medical Team Training and mortality: For every quarter (3 months) of the team-training program, a reduction of 0.5 deaths per 1000 operations was observed.[63] Implementation of Medical Team Training program was also associated with a reduction in wrong-site surgery[194] and improved compliance with best practices.[195]

Another national team-training effort is TeamSTEPPS, an evidence-based, resource-rich, government-sponsored program (http://teamstepps.ahrq.gov/).[196] Although TeamSTEPPS has been implemented in hundreds of facilities, few empiric studies have examined its impact on patient outcome. One recent study verified that this program of team training significantly improved OR teamwork and communication scores, reduced surgical mortality and morbidity, increased OR efficiency, and improved patient satisfaction.[164] However, many of the initial gains were lost within 12 months, which indicates that sustained improvement may be difficult to achieve.[164]

Few data exist to define the components of effective team training. Training times range from a few hours[197] to several days,[45,46,63] program content is variable, and sustaining improvement may be difficult.[164] In one posttraining observational study, surgical teams that had undergone training were compliant with only 60% of the safety practices included in the program.[198] In another such study, communication and team skills improved immediately but extinguished after 3 months.[197] However, the calculated threat-to-outcome score improved immediately and remained significantly improved 3 months later.[197] From the data available, it appears that teams should be trained as teams, not as individuals[196]; that use of simulated scenarios is effective[196]; that both executive leadership and nurse managers are critical to effective implementation[199]; and that repetition, continued coaching, or both are required to strengthen and maintain benefits.[197,198]

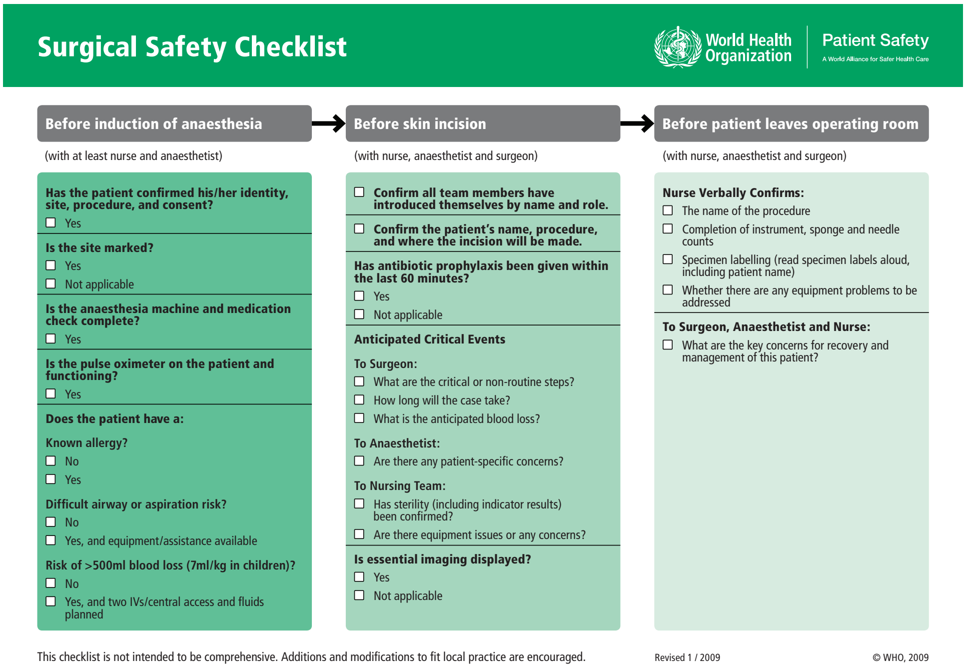
Time-outs, Checklists, Briefings, and Debriefings

Timeouts, checklists, and briefings can reduce errors in communication. Checklists and timeouts typically are close-ended, with specific information called out and verified, whereas briefings are quick discussions guided by a structured but open-ended checklist. Checklists are the same every time, covering the steps common to all procedures, whereas briefings should be different every time and focused on the unique aspects of the procedure. Briefings establish a dialogue and provide an opportunity for all OR personnel to "confirm details, exchange information, ask questions, and identify problems or concerns."[178] Debriefings are intended to facilitate sharing of what was learned after a complex task has been completed and often include the questions, "What went right today?" and "What can we do to make sure tomorrow goes more smoothly?"

Timeouts were first proposed, and then mandated by The Joint Commission in 2003, to reduce wrong-site procedures. The Joint Commission universal protocol requires verification of the patient's identity, marking of the operative site, and a "timeout" just before the operation or procedure.[200]

Checklists are simple cognitive tools that can improve the performance of both simple tasks (eg, shopping) and complex tasks (eg, flying an aircraft)[201] and can be effective as reminders of routine tasks that might otherwise be overlooked.[202] The World Health Organization (WHO) developed and strongly advocates universal implementation of the "Surgical Safety Checklist," a series of standardized timeouts at 3 times during an operation: (1) before induction of anesthesia, (2) before skin incision, and (3) before the patient leaves the OR.[171,203] It includes a comprehensive check of patient identity, site of surgery, use of antibiotics and pulse oximetry, and drug allergies; its use has been shown to reduce mortality (Figure 3).[171,204]

Checklists can be used to identify critical steps in a commonly performed procedure such as laparoscopic cholecystectomy,[205] or to provide direction in rare, crisis situations. Ziewacz and colleagues[206] identified 12 of the most frequently occurring OR crises and developed corresponding evidence-based metrics of essential care for each crisis scenario (failed intubation, pulseless electrical activity, air embolus, malignant hyperthermia, etc). The crisis checklist was studied initially by 2 surgical teams who managed 4 simulated crises with and without the checklist. Checklist use resulted in a


Surgical Safety Checklist

World Health Organization | Patient Safety
A World Alliance for Safer Health Care

Before induction of anaesthesia
(with at least nurse and anaesthetist)

Has the patient confirmed his/her identity, site, procedure, and consent?
☐ Yes

Is the site marked?
☐ Yes
☐ Not applicable

Is the anaesthesia machine and medication check complete?
☐ Yes

Is the pulse oximeter on the patient and functioning?
☐ Yes

Does the patient have a:

Known allergy?
☐ No
☐ Yes

Difficult airway or aspiration risk?
☐ No
☐ Yes, and equipment/assistance available

Risk of >500ml blood loss (7ml/kg in children)?
☐ No
☐ Yes, and two IVs/central access and fluids planned

Before skin incision
(with nurse, anaesthetist and surgeon)

☐ **Confirm all team members have introduced themselves by name and role.**

☐ **Confirm the patient's name, procedure, and where the incision will be made.**

Has antibiotic prophylaxis been given within the last 60 minutes?
☐ Yes
☐ Not applicable

Anticipated Critical Events

To Surgeon:
☐ What are the critical or non-routine steps?
☐ How long will the case take?
☐ What is the anticipated blood loss?

To Anaesthetist:
☐ Are there any patient-specific concerns?

To Nursing Team:
☐ Has sterility (including indicator results) been confirmed?
☐ Are there equipment issues or any concerns?

Is essential imaging displayed?
☐ Yes
☐ Not applicable

Before patient leaves operating room
(with nurse, anaesthetist and surgeon)

Nurse Verbally Confirms:
☐ The name of the procedure
☐ Completion of instrument, sponge and needle counts
☐ Specimen labelling (read specimen labels aloud, including patient name)
☐ Whether there are any equipment problems to be addressed

To Surgeon, Anaesthetist and Nurse:
☐ What are the key concerns for recovery and management of this patient?

This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged.

Revised 1 / 2009

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Figure 3. World Health Organization Surgical Safety Checklist.[201] IV indicates intravenous line. Reprinted from Reference 203 with permission of the publisher. Copyright © 2009, World Health Organization. All rights reserved.

6-fold reduction in failure of adherence to critical steps.[206] Arriaga and colleagues[207] recently studied management of simulated surgical crises with and without the checklist (17 surgical teams and 106 simulations) and found that failure to provide lifesaving steps was significantly reduced with use of the checklist (6% of steps missed with use of the checklist versus 23% of steps missed without its use.

Checklists can also be used to drive implementation of best practices and to reduce voluminous guidelines to a simple set of the most critical evidence-based practices.[208] Although checklists can improve outcomes, each must be simple, evidence based, and grounded in the realities of the workplace.[201] Implementation of checklists has been shown to reduce the rates of central line infection and ventilator-associated pneumonia, as well as mortality.[208–210]

However, experts argue that it is the adaptive work of the team that generates improvements in patient safety rather than the technology of a checklist.[211] If the checklist is imposed from above without a team-wide willingness to undergo the fundamental attitudinal change toward the behaviors outlined by the checklist, clinicians can feel that checklists undermine their authority, are infantilizing, and delay effective patient care.[212,213] In the Netherlands, where the Dutch Health Care Inspectorate mandated implementation of the WHO checklist by 2008, complete implementation of the checklist occurred in only 39% of 11 151 cases. Overall mortality decreased from 3.13% to 2.85%, but the reduction in mortality was strongly associated with checklist compliance.[204]

One of the most effective checklist implementation projects was the Michigan Keystone project to eliminate catheter-related bloodstream infections.[208] Analysis of that project ascribed its success more to creation of a "densely networked community" with a shared mission to improve practice and the use of hard data to create discipline, rather than the simple presentation of a checklist to be followed.[214]

Briefings allow teams to develop a shared mental model of the work ahead and have been widely used by the military, commercial aviators, and longshoremen. A preoperative briefing allows team members to share their knowledge and their particular concerns about the task ahead.[179,215] In aviation, the cockpit briefing is critical to verify technical details, but a key nontechnical role is establishing that a team member who sees anything of concern must speak up.[84] The pilot verbally affirms that all information regarding safety is welcome, even if it means questioning the pilot. In surgery, as was typical in pre-CRM aviation, a strict hierarchical framework can exist that inhibits lower-status team members from questioning someone with higher authority.[216] As noted above, many OR personnel report that they would have trouble speaking up or expressing disagreement.[156]

Before team training or formal implementation, few if any briefings occur.[217,218] Among the challenges in instituting briefings is the difference in opinion among caregivers as to what constitutes a briefing. Although 39% of surgeons in a United Kingdom practice survey stated they always perform briefings, only 4% of their nurses agreed.[179] This was also the case when efforts were made to institute briefings in cardiac surgery at Mayo Clinic (unpublished observation, T.M.S.). In the Safe Surgery Checklist study of 3733 cases, few included preoperative briefings.[171]

One checklist, the Surgical Patient Safety System (SURPASS) checklist, includes a briefing and debriefing.[182] A closed-claims review indicated that one third of the factors that contributed to adverse events could have been intercepted and nearly 40% of deaths might have been prevented by use of the SURPASS checklist with its imbedded briefings.[219] Implementation of SURPASS reduced complication rates from 27.3% to 16.7% and dropped in-hospital mortality from 1.5% to 0.8%.[183] Implementation of the WHO Surgical Safety Checklist, which contains many domains inherent in briefings, had nearly identical results, reducing mortality from 1.5% to 0.8% and complications from 11.0% to 7.0%.[171] This study included >3500 cases done at 8 institutions in 5 continents and included rudimentary to sophisticated procedures. In a recent study of 25 513 patients, van Klei and colleagues[204] showed that implementation of the WHO checklist, including a preoperative briefing, resulted in a reduction of in-hospital 30-day mortality from 3.15% to 2.85% (odds ratio, 0.85; 95% confidence interval, 0.73–0.98). The effect was driven by checklist compliance: The odds ratio for improved outcome with full checklist completion was 0.44 (95% confidence interval, 0.28–0.70), compared with 1.09 (95% confidence interval, 0.78–1.52) and 1.16 (95% confidence interval, 0.86–1.56) for partial compliance or noncompliance, respectively.

Recently, the use of briefings was mandated as part of a larger teamwork training intervention in the Veterans Health Administration; mortality decreased by 18% after team training was implemented.[63] In 2 other studies, compliance with antibiotic and deep venous thrombosis prophylaxis improved after the implementation of briefings and debriefings.[195,220] Briefings can reduce distractions and flow disruptions, which are a significant source of serious surgical error.[20] Gillespie and colleagues,[221] observing planned and unplanned surgeries, found an inverse correlation between the familiarity of a team and the number of miscommunications, as well as a positive correlation between number of interruptions in surgery and the number of miscommunications. Implementing a short, structured briefing halves the frequency of flow disruptions, lack of knowledge of the case, and miscommunications between staff even when instituted within a "familiar" team.[222] Nurses made fewer trips to the sterile core for supplies, and spent less time there, whereas wastage was decreased.[222] In another intervention study, preoperative briefings decreased unexpected delays in surgery by 31%.[68]

In addition to improving patient outcome, briefings enhance teamwork climate, behaviors, and performance. In one survey, respondents who said that briefings are common reported a better safety climate than respondents who reported no briefings.[218] Briefings are associated with perceptions of reduced risk and with enhanced collaboration.[66] In one study,[176] participants commented after the briefing, "Your opinions seem to matter. You feel more valued," and, "Now people are willing to say when they are not happy. They are not worried about backlash anymore." An Israeli study found that briefings reduced nonroutine events by 25% and that members "felt most valuable for their own work, the teamwork and patient safety."[217] In a United Kingdom study of briefings conducted over a 6-month period, staff members perceived that the team culture was improved, and potential problems were highlighted.[223] O'Neill[224] noted that leadership must create a culture wherein employees are treated with dignity and respect and that habitual excellence requires transparency and sharing of problems. Briefings and debriefings can provide the needed transparency and sharing.

Briefings do not prolong surgical procedures[225] but shorten them by decreasing interruptions and distractions.[222] In one study of >35 000 cases, the length of the briefing averaged 2.9 minutes (range, 1–5 minutes).[215]

Despite the strong evidence supporting briefings, there are organizational and psychological factors that "constrain safety in the OR."[212] The tendency of physicians to misperceive their nontechnical skills as better than they are may lead to the view that no improvement is needed.[26,178,213] Not all surgeons agree that briefings improve teamwork, although surgeons who have instituted briefings report greater efficiency and increased team morale.[179] Surgeons randomly assigned to a checklist intervention group performed more positive safety-related team behaviors than control surgeons but also reported lower levels of comfort, team efficiency, and communication, which indicates that adapting to checklists or briefings may be uncomfortable initially.[226] The role of facility and leadership and local champions is critical to effective implementation[227] but insufficient by itself, because a wide range of responses (from acceptance to resistance) to briefings and debriefings can hinder their implementation and must be understood before effective implementation of these practices can occur.[178,179,218]

Debriefings have been less well studied, although some outcome studies included debriefings, as did the large Veterans Health Administration study.[63] The debriefing allows members of the medical team to assess what went well and what did not, to coalesce as a team, and to improve their performance in their next case.[176] Debriefings provide teams the opportunity to formulate future plans, develop and implement system improvements, and address areas of communication weakness.[215] Debriefing methods and implementation processes have been described previously.[228–230]

In conclusion, a growing body of literature suggests that surgical briefings and debriefings can result in impressive reductions in morbidity and mortality. More research into impediments to implementation will be useful, but the evidence to date supports case-by-case structured briefing and debriefings in cardiac surgery.

Simulation

In aviation, simulation training is widespread and is used to train individual skills, assess the technical and nontechnical skills of individuals and teams, and study how errors occur and how they can be prevented.[89] Medicine has been slow to adopt simulation training, but the technical and educational tools and techniques that underpin high-fidelity simulation training in medicine are undergoing rapid evolution and development.[231,232] Simulators are emerging as a valuable tool for teaching procedural skills[233–235] and measurement of skills.[235] Such assessment is becoming part of the licensure process in some areas of medicine.[236,237]

Simulators show promise for assessing and training personnel in nontechnical skills.[36,128,238–240] Current patient simulators provide highly realistic physiological data with real clinical equipment, presenting accurate and believable clinical scenarios. This technology requires educators to design curricula and evaluation rubrics and to document the validity of the educational environment.[241–244] Although much of the initial research focused on technical skill training and assessment,[36,38] recent evidence supports simulation for team training and the development of nontechnical skills.[231,243,245,246]

Simulation also allows the scientific testing, without exposing a patient to risk, of the effect of human factors (eg, fatigue, stress) on technical skill,[43,247,248] communication patterns during crisis,[240] testing of educational methods,[249] and the relationship between technical and nontechnical skills[35,250] or between teamwork and clinical performance.[251]

High-fidelity simulation may provide an optimal learning environment. This can be especially effective in crisis situation training, enabling individuals and teams to experience the cognitive challenge, stress, and physical demands of emergencies without potential for patient injury. Catastrophic incidents require the delivery of a complex, coordinated response by the team under time pressure, but they occur rarely and cannot be practiced in the "real world."[252] In the simulated OR, team communication and tactical responses to challenging clinical problems can be practiced, evaluated accurately, and measurably improved. In a now famous study of learning in mice, Yerkes and Dodson[253] showed that learning was enhanced with moderate stimulation (arousal) but degraded with intense arousal.

Simulation is particularly suited for training in CPB emergencies and was first described in 1977.[254,255] Computer-controlled hydraulic models of the adult and pediatric human circulation exist for training in CPB and can be configured to simulate routine or crisis scenarios.[252,257] Virtually 100% of perfusionists surveyed in 2002 believed that such practice would be beneficial, but only 17% reported that such drills occur.[258] In a recent study of education of whole cardiac surgery teams in crisis management using high-fidelity simulation, participants reported 2 areas of highest priority and improvement: encouraging outspokenness about critical information and improved interprofessional communication by clearly defining the intended recipient (using the name of the person to whom communication is directed) and by attention to "closing the loop" in verbal communications.[259]

Structured Communication Protocols

Communication is improved by information exchange protocols that facilitate presentation and recall[260] and closed-loop communication to acknowledge receipt of information and verify content.[261] Closed-loop communication is particularly important in stressful contexts and when the intended recipient is not clear.[72,262] This style of communication ensures that the team has shared goals, expectations, situation awareness, and plan execution.[117]

Structured communication techniques, such as using words for letters (**a**lpha, **b**ravo, **c**harlie) or saying the individual digits of numbers ("one one" instead of "eleven," which sounds like "seven") can reduce ambiguity, enhance clarity, and specify the intended recipient. Read-backs, Situation-Background-Assessment-Recommendation (SBAR), critical assertions, and advocacy/inquiry have been used effectively for decades by the armed forces and aviation to standardize information transfer, reduce information loss, and facilitate communication to superiors. Few data exist about effectiveness in medical settings. Nevertheless, structured communication protocols are commonly part of the core curriculum of team-training programs that are effective in reducing errors and mortality.[63] Implementation of protocol-driven communication during CPB reduces surgeon/perfusion communication errors by nearly 40%.[263] Simulation-based studies of comprehensive team-training programs designed to measure communication skills have proved these interventions' content validity,[264] but rigorous studies of the effectiveness of communication training or structured communication protocols in cardiac surgery are lacking.

Communication Between Teams

The transfer of patients and patient information from one team to another, termed *handoff* or *handover*, is frequent in medicine. Handoff failures have been identified as a significant source of medical errors, both between and within teams.[78,265–269] The Joint Commission defines a handoff as a contemporaneous, interactive process of passing patient-specific information from one caregiver to another to ensure the continuity and safety of patient care; standardized handoff communications was a patient safety goal for 2006 (goal 2E).[270] Cardiac surgery patients are handed off many times: from cardiology (preprocedural testing, evaluation), to the surgeon and OR team, to the ICU team, to the ward team, and often back to the cardiology team for long-term follow-up and care.[271]

Gawande and colleagues analyzed surgical errors in closed claims at 4 malpractice insurance companies and provided results in 2 publications.[78,268] In the 258 surgical malpractice cases in which an error led to patient injury, 60 cases involved communication failures and resulted in injury to patients.[78,268] Forty-three percent of the communication failures occurred during a handoff between providers, and 19% of these communication failures occurred across departments (ie, between teams). The majority (92%) of communication failures were verbal, involved a single transmitter and a single receiver, and were caused by omission of critical information (49%) or incorrect interpretation of information (44%).[78,268]

Much of the original research of handoff failures focused on transfers of care within a team, such as residents cross-covering patients. In one survey conducted at Massachusetts General Hospital, 59% of responding residents reported that 1 or more patients had been harmed in their last rotation because of poor handoffs, and 12% reported that the harm was major.[269] Only a minority of the handoffs occurred in a quiet setting, and interruptions were frequent.[269] A similar study found that 31% of residents reported a patient event that involved their patient for which the handoff had not prepared them.[272] In one study of incidents involving transfer of patients from team to team, 29% involved no handoff procedure at all.[273]

It is not surprising that the majority of patient transfers involve communication failures, given the complexity of patient information, nuances of physiology difficult to objectively translate for the next team, and frequent distractions. The literature supports the perception that the handoff process is highly variable, unstructured, and fraught with environmental noise, distraction, and competing task priorities (eg, resetting monitors during the verbal transfer of information).[274] In an observational study of cardiac surgery handoff events, important content items were reported only 53% of the time; an average of 2.3 distractions occurred per minute of communication.[275]

Patient information transfer failures occur across the continuum of surgical care; the majority occur during the preprocedural and postoperative handoff phases.[266] Only 30% of surgical information was transmitted verbally, and often not by surgeons but by anesthesiology personnel. In a study from Great Britain, transfers of care between OR and recovery room were nonstandardized and varied depending on the staff involved.[276] Varying expectations of content and timing of the information transfer were held by anesthesiology and recovery personnel, and there was no standard point during the handoff when responsibility was transferred. In a study of a process that first rigorously defined, and then measured, critical information to be transmitted and tasks to be completed during an OR/recovery handoff,[265,277] nearly a third of critical facts were not transmitted (median of 9.1 omissions among 29 defined items), and a third of tasks (median 2.9 task errors of the 8 defined tasks) were not completed.[277] Critical members of the multidisciplinary team were often not present during the handoff process.[265]

The quality of the handoff information degrades across the continuum of care: Only 56% of essential information was transmitted from OR to recovery, and only 44% from recovery to the ward.[266] Seventy-five percent of observed patients had at least 1 clinical incident or adverse event attributable to such failures.[266]

Few studies have analyzed why communication failures occur during handoffs, or what information is essential. No study has tested the validity of what they designate as "essential information." Despite these limitations, virtually every intervention designed to improve handoff quality has shown positive effects. In a prospective study of congenital cardiac surgery handoffs from OR to ICU, implementation of a teamwork-driven process and protocol reduced errors from 6.24 per handoff to1.52 and reduced critical verbal information omissions from 6.33 to 2.38 per handoff.[77] Implementation of a protocol based on Formula 1 pit stops that specified the prehandoff preparation, tasks to be completed before information transfer, and specific information to be transferred reduced technical errors, reduced the number of information omissions, and shortened the handoff from 10.8 to 9.4 minutes.[278]

Another study found that implementation of a simple fill-in-the-blank, 1-page tool improved total handoff scores, as well as surgical intraoperative information subscores, but did not prolong handoff duration.[279] Craig and colleagues[280] echoed these results in their pediatric cardiac study of a different handoff tool; implementation resulted in a significant improvement in attentiveness, organization, and information flow and a reduction in interruptions. Finally, implementation of a standardized handoff protocol for cardiac patients between OR and ICU increased the presence of all critical personnel at the handoff from 0% to 68% of the time, decreased omitted information from 26% to 19%, and increased satisfaction scores from 61% to 81% among the ICU nurses.[281] However, the fact that the percentage of missed information remained at 19% after implementation indicates the scope of the problem.

The use of electronic technology in handoff protocols has been proposed, but few data exist. The framework of an automated protocol termed *MAGIC* (Multimedia Abstract Generation of Intensive Care) integrates cognitive and quantitative methods to create an electronic prompted briefing that provides a consistent set of handoff information.[282] The Association of periOperative Registered Nurses has developed resources with sample handoff documents and educational materials for clinicians.[283]

A less prescriptive protocol specifies only the type and order of basic topics to be covered, often using the mnemonic SBAR (situation-background-assessment-recommendation). The use of SBAR during handoffs has been suggested to facilitate more accurate communication of patient, anesthetic, and surgical information[284] and has been used by cardiac nurse practitioners to facilitate a patient's progress through the cardiac surgery continuum of care.[285] A curriculum that used videos and role playing to teach SBAR reduced the rate of order-entry errors.[286]

Communication between physically separated teams (referring cardiologist and cardiac surgeon) can be even more difficult. The use of a dedicated Internet connection between catheterization centers and a surgical center for electronic transmission of angiography data shortened the time between catheterization and surgical decision from 36 hours to 1 hour.[287] The time interval between diagnosis and emergent or urgent surgery decreased from 56 to 18 hours. No outcome or economic data were collected, but electronic transmission of essential patient data may well reduce errors and speed the delivery of care.

Several interventions have been tested across the continuum of care, which can involve multiple handoffs. One approach is to reduce handoff errors by minimizing the number of handoffs, primarily by using a universal bed. With this approach, a given patient can receive ICU, step-down, or ward level of care in a single physical location, with a single team of nurses and surgeons. Compared with national norms (Society of Thoracic Surgeons database, http://www.STS.org), universal bed patients had decreased ventilation time, ICU stay, and hospital stay and no sternal wound infections (0/610), with average cost savings between $6200 and $9500 per patient.[288]

Summary Statements

1. Communication skills have been measured as the worst aspect of teamwork behavior in the OR.
2. Multiple general and cardiac surgical studies have shown that communication failures are the most common root cause of errors and adverse outcomes.
3. The critical elements of teamwork can be summarized by 6 "C's": communication, cooperation, coordination, cognition (collective knowledge and shared understanding), conflict resolution, and coaching (team training).
4. Interventions to reduce human error include teamwork-training efforts. Studies such as the Veteran's Administration Medical Team Training (MTT) and the TeamSTEPPS program (government-sponsored by the Agency for Healthcare Research and Quality and the Department of Defense), have demonstrated significant improvements in OR teamwork and communication scores, as well as reductions in surgical mortality and morbidity; however, sustained improvement requires repetition and/or continued coaching.
5. Other interventions to reduce errors include checklists, such as the Surgical Safety Checklist (developed by WHO), and preoperative briefings and postoperative debriefings. Studies have demonstrated that the process

of adoption of checklists improves outcomes, including reduction in central line infections, ventilator-associated pneumonia, and mortality.

6. Other studies have demonstrated that briefings reduce distractions and flow disruptions, enhance team performance, and may reduce complications, although widespread implementation of these practices has been hindered by psychological and cultural impediments.
7. Simulation is a promising tool for assessing and training surgical personnel in nontechnical skills, including communication, cooperation, coordination, cognition, conflict resolution, and coaching, as well as the relationship between technical and nontechnical skills.
8. Transfer from one team to another occurs many times for patients undergoing cardiac surgery, and communication failures are common during these handoffs. Although few studies have analyzed why communication failures occur, or what information is truly essential, all studies of interventions designed to improve handoff quality have demonstrated improvements in omitted or misinterpreted information.

Physical Environment

Human Factors Issues

"Environment" is defined as "the circumstances, objects, or conditions by which one is surrounded."[289] In the OR, the environment comprises the physical space, the equipment, and the people (staff and patients). Ergonomics, defined as "an applied science concerned with designing and arranging things people use so that the people and things interact most efficiently and safely,"[289] has been suboptimal with respect to patient safety in the OR.[8,290–292] Improvements in OR design and space have lagged behind changes in surgical practices,[293,294] and the past 10 years have seen an enormous influx of new technologies, creating an overcrowded environment.[295] Many consider poor room and equipment ergonomics to be a major factor in the flow disruptions that contribute to technical errors; poor room and equipment ergonomics may be related to surgical-site infections.[20,294–296]

Space and Design

Both the size and layout of the OR can influence safety. In small ORs, equipment clutters the space and results in flow disruptions, whereas excessively large OR suites require staff to traverse longer distances. Brogmus and colleagues[297] reported that same-level slips, trips, and falls are the second-leading cause of workplace injury and cite 3 tripping hazards: cords and cables, low-profile equipment and supplies, and protective and absorptive mats. Cesarano and Piergeorge[298] described the "spaghetti syndrome," a phenomenon in which cluttered equipment and entangled lines obstruct clinicians from safely reaching the patient, endangering both patients and staff. Bringing power and equipment to the patient creates a significant challenge.[299]

Personnel and Traffic

The presence and flux of personnel in an OR are unavoidable but can be detrimental to OR safety, both because of the creation of distractions and the increased potential for infection. Approximately 20% of OR traffic is related to staff requests for information, 25% is related to staff breaks, and 20% is attributable to the delivery or retrieval of equipment.[300] Healey et al[19] correlated OR traffic with interference levels, such as shift changes that distract the operating surgeon, and concluded that these distractions are poor OR practices that can be improved.

Increased traffic implies a higher frequency of door openings, which has been shown to decrease the effectiveness of the ventilation system in clearing potential contaminants.[301] More door openings also may increase bacterial counts by permitting the mixing of OR air with corridor air.[302] In orthopedic and general surgery cases, the average number of door swings per hour ranges from 37 to 135 and approaches 1 every other minute.[300,303] In cardiac surgery, the mean rate of door openings is 19.2 per hour, and 22.8 per hour if prosthetic devices are involved.[304] This equates to an average period of 6.4 minutes per hour in which the door is open. Microbiological counts in unoccupied ORs increase significantly when a door is left open to the hallway.[305]

Additional personnel in the OR may contribute to infection risk. Having 5 additional OR personnel above the required minimum increased the microbiological counts >15-fold.[305] Another study of orthopedic trauma surgery found a strong positive correlation between the number of colony-forming units and the number of people in the operating room.[306] This relationship between the number of people in the OR and the incidence of surgical infection may be attributable to the number of people per se or to the greater amount of traffic into and around the room.[306,307]

Equipment

Although equipment and machines improve our lives and improve patient care, they can cause harm by injuring patients directly, by increasing errors related to poor design, and through poorly designed alarm systems that contribute to noise. Equipment-related problems account for ≈11% of flow disruptions in cardiac surgery.[20,75,308] In a review of hazards in cardiac surgery, Martinez and colleagues[8] noted numerous issues with equipment (eg, esophageal injury caused by transesophageal echocardiography probe insertion), CPB (eg, aortic dissection with onset of bypass), and surgical equipment (eg, air emboli caused by a blower-mister device). Machines and technology were identified to cause patient harm in 4 ways: (1) Misuse (poor training or negligence), (2) the inherent risks of using the device, (3) poor maintenance and upkeep, and (4) poor machine design. Poor training or lack of certification in the use of the device, improper risk balancing by clinicians, and failure to follow best practices in equipment maintenance can increase the risk.[8] In addition, a common theme among published reports of equipment-related adverse events is a failure to explore the contributing systematic errors.[8]

Much of modern equipment is designed with the focus on mechanical efficiency and biocompatibility, with little emphasis on how design can impact human error. Wiegmann and colleagues[309] studied CPB machines using a failure mode effect analysis and found that information displays suffered from problems with placement, legibility, and format. Components were poorly integrated into the machine, and the space-design and placement of the components was not ideal. Alarms were found to be too quiet or too loud or to have inappropriate tonality.

In fact, one of the most troublesome contributors to OR distractions is alarms generated by machinery.[310–312] Alarms are designed to make the operator aware of conditions outside of predetermined norms and can identify dangerous conditions. A typical cardiothoracic OR, however, has ≈18 different alarms with a mix of visual and audio alerts.[313] Schmid et al[314] reported that 359 alarms occurred per cardiac surgery procedure, at 1.2 per minute. Unfortunately, up to 90% of all alarms are false-positives,[315] which desensitizes OR personnel to true alarms. One study analyzed 731 warnings during cardiac surgery by linking them to the response of the anesthesiologist: only 7% were useful, whereas 13% followed a planned intervention and could have been predicted and eliminated.[313]

Noise

As noted above, the OR traffic, conversations, alarms, and, in some cases, music can lead to a deafening noise level in the OR[316] that exceeds both Occupational Safety and Health Administration and National Institute for Occupational Safety and Health standards.[317] This noise level can be dangerous to the hearing of both patients and physicians and can affect patient outcomes.[318,319] In one study, abdominal surgery patients who subsequently developed a surgical-site infection had operative environments with significantly higher sound levels.[319] Conversations about non–surgery-related topics were associated with significantly higher sound levels.[319]

An observational study conducted by Moorthy et al[250] concluded that OR noise reaching 80 dB was associated with a significant increase in medical errors during in situ laparoscopic procedures. Clinical impairment may be compounded by inexperience; a randomized controlled trial found that music had a detrimental effect on the surgical performance of novice laparoscopic surgeons.[320] Some research, however, suggests that the appropriate use of music in the OR can reduce stress and improve the performance of some OR staff.[290] Nevertheless, 25% of surveyed anesthesiologists stated that OR music impaired their ability to effectively communicate with other staff.[321] Music that is pleasing and helpful to one practitioner might be distracting to other OR personnel.[322] Compounding this issue is that each subteam in the OR has a different cognitive workload at different times during a case (Figure 4),[263] potentially leading to casual conversation just when another team member needs absolute quiet.

The Optimal OR

There is a paucity of scientific literature regarding optimal OR design and layout, with many editorial suggestions but few studies showing better outcomes. Two studies have linked improvements in the physical environment to (1) reduction in staff stress and fatigue, which increases effectiveness in delivering care; (2) improvement in patient safety; (3) improvement in outcomes; and (4) improvement in overall healthcare quality.[323,324] Optimal size may reduce adverse patient events and mitigate OR staff injuries,[297] which has led to recommendations that rooms for cardiovascular procedures be ≥600 sq ft.[325] The guiding principles for optimal OR design, as summarized by Killen,[322] are as follows: (1) Standardize the location of the head of the table and the handedness of the room; (2) provide adequate space for staff to move around and for equipment; (3) maintain focus on the patient; (4) ensure that all staff have a line of sight to the patient at all times; and (5) use technology to help workflow. Novel ideas such as rounded room corners, walls shaped to transition to doors, and floor patterns that provide additional visual guides have been proposed.[297]

Optimal room flow requires avoiding unnecessary congestion, with equipment positioned to maintain open corridors and to keep the floor clear and free of hazards, such as avoiding cords across walking paths.[297] Ceiling-mounted booms can reduce the number of cords and cables across high-traffic areas.[291,326] The setup of equipment should be consistent, with dedicated space for the sterile field, OR table, Mayo stands, anesthesia equipment, and perfusion setup.[326] Sterile core and patient-entry doors should be positioned away from swinging equipment booms and stationary machines. OR doors should be situated to protect the sterile surgical field from work zone traffic.[325]

Restricting the number of people in the OR and regulating OR traffic may reduce the movement of airborne contaminants shed by people and objects.[305,306] The most recent Association of periOperative Registered Nurses "Standards and Recommended Practices" present best practices for traffic patterns.[302]

There is a lack of published literature regarding the optimal physical location of materials and supplies for a cardiac OR, but guidelines specify a minimum of 50 sq ft of storage space per OR.[325] Common sense would suggest that storing supplies inside the OR suite would improve workflow and mitigate door openings, but virtually no data on this practice exist. Regardless, preoperative briefings reduce trips to the core.[222]

Regarding noise in the operating room, no studies have yet demonstrated improved outcome with noise reduction efforts. Some have suggested that a sterile cockpit approach should be adopted.[327] However, as Wadhera and colleagues[263] have illustrated, each team has a different cognitive workload at different times during a case (Figure 4). These investigators propose having structured conversations at key parts in the operation (eg, heparin administration, cannulation, initiation of CPB, separation from CPB), but this intervention has not been tested for its impact on reducing errors.

Integration of the sheer volume of auditory and visual information available during any case is challenging. Monitors and charting systems should be positioned to allow clinicians to face the sterile field and remain attentive to the surgical procedure.[326] In 2006, Egan[328] described the Massachusetts General Hospital's "operating room of the future." By integrating information from various monitors, computers, and equipment through wall panels with unobstructed views, personnel were kept abreast of the surgical procedure. The simplification of information transfer reduced the amount of equipment surrounding the patient and possibly improved communication.[328] Finally, real-time imaging of the surgical procedure can be shared with team members off-site, which would facilitate handoffs.[329,330]

Integration of electronic medical records with anesthetic and surgical interventions can curtail alarm fatigue and alarm-related distractions. Kruger and Tremper[313] proposed 3 key areas for future research: (1) Design of these systems to bridge

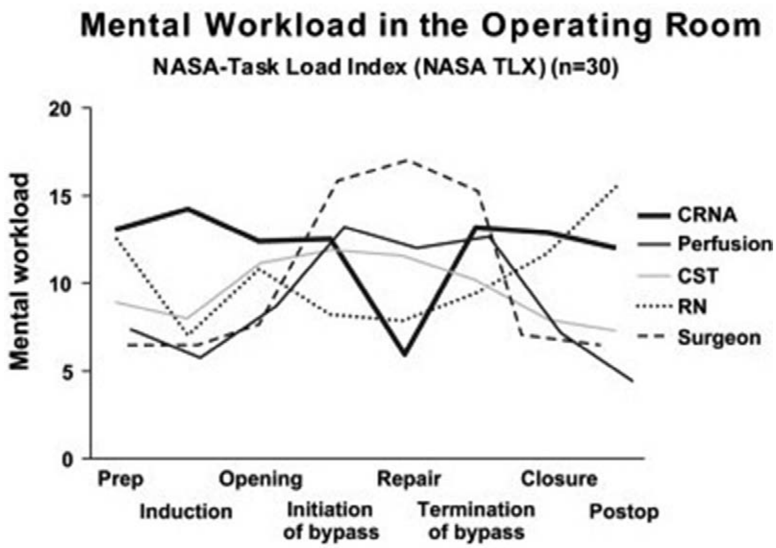

Figure 4. Mental workload in the cardiac surgery operating room varies across the cardiac surgery procedure for individual providers depending on task complexity and responsibilities. CRNA indicates certified registered nurse anesthetist; CST, certified surgical technologist; NASA, National Aeronautics and Space Administration; Postop, postoperative; Prep, surgical preparation; RN, registered nurse; and TLX, Task Load Index. Reprinted from Wadhera et al[263] with permission from Elsevier. Copyright © 2010, The American Association for Thoracic Surgery.

the gap between academic prototypes and integration into clinical practice; (2) integration of various types of medical domain knowledge into comprehensive physiologic and disease models and (3) advanced algorithms to use this domain knowledge for high-sensitivity and -specificity alerts.

Finally, high-fidelity simulation laboratories can be used to investigate where the human-machine interface can be improved, providing insight into how industry can make the next generation of machines safer.[331] Simulation laboratories can also permit testing of optimal room design and layout without putting patients at risk.

Summary Statements

1. Poor OR ergonomics (size and layout) contribute to human error and safety hazards, including procedure-flow disruptions, technical errors, and surgical-site infection, as well as workplace injuries for surgical personnel.
2. Optimal OR design ensures standardization of the location of the head of the patient bed and surgical table, adequate space for equipment and staff movement, maintenance of focus on the patient, and use of technology to help workflow.
3. Reduction of traffic in the OR may reduce patient risk (procedure-flow disruption and surgical-site infection).
4. Noise levels in the OR, caused by equipment alarms, conversations, and music, present hazards for patients (surgical performance, surgical-site infections) and surgical personnel (hearing loss).

Safety Culture

Organizational Culture

Deficits in safety culture have been implicated in adverse outcomes after cardiac surgery.[8] A climate of teamwork and collaboration, along with safety-minded work processes and communication styles that focus on error prevention, is ideal, allowing those in high-risk clinical environments such as cardiac surgery to identify and prevent patient harm.[332–334]

Many cardiac surgery safety studies have been retrospective studies, with the goal to identify trends.[8,13,16–18,78,292] Few have been prospective studies, and fewer have tested interventions designed to improve safety. Nevertheless, they indicate where improvements can be made. For example, underdeveloped quality assurance programs contributed to unexpectedly high mortality rates in pediatric cardiac hospitals in Bristol, United Kingdom,[335,336] and Winnipeg, Canada.[337–339] Providers at the Bristol Infirmary had raised concerns about poor outcomes that went unheeded, attributable in large part to the absence of a central quality assurance department to identify and address problems. In Winnipeg, the low volume of cases exacerbated a troubled quality assurance program that was inadequate to detect and respond to sentinel events. Both cases illustrate the dual danger of a culture reluctant to acknowledge issues, even when raised internally, and poorly responsive quality assurance systems.

In this section, we review organizational culture in health care, identify behaviors that undermine safety, and explore organizational contributors to safety attitudes, including the sparse literature specific to cardiac surgery.

Organizational Culture in the Healthcare Environment

An institution's organizational culture, that is, its aggregate beliefs, assumptions, and value systems, greatly influences the attitude manifested by its personnel toward keeping patients safe. Seemingly similar institutions can have quite different cultures and subcultures. Most hospital personnel are unaware of how they contribute to and shape the safety culture in their own environment. The current hierarchical structure of health care has evolved over many years, but organizational cultures that emphasize deference and power differences between healthcare workers may be unsafe, given the increasing complexity and technological sophistication, particularly in cardiac surgery. Increasing data on the impact of culture on patient safety highlight the need for a reevaluation of the current educational and training paradigm toward more collaborative and interdisciplinary approaches.[339–342]

Safety Culture Versus Safety Climate

An organization's *safety culture* refers to those collective behaviors and values that influence its ability to identify and mitigate hazards and systemic conditions that contribute to error. Safety culture has been stated to be "the product of individual and group values, attitudes, perceptions, competencies and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization's health and safety management."[343] Although senior leadership is critical in establishing a safety-oriented culture, it is the frontline providers who must be fully engaged in creating a climate of QI and safety.

In contrast, *organizational climate* refers to the commitment with which individuals or groups carry out an organization's vision and to what degree they adhere to established policies and procedures. Zohar[344] refers to *safety climate* as "… shared perceptions with regard to safety policies, procedures, and practices." Climate is often defined as "the way we do business around here." Safety culture tends to be more ethereal, whereas safety climate is more conducive to measurement, particularly within a functional unit.

Although safety culture and climate are typically a function of the larger organization, small functional units such as the OR often have a unique culture and climate that are distinct from, albeit influenced by, the larger organization. In the OR environment, assessments of safety culture and climate using a variety of instruments such as questionnaires and surveys have raised a number of interesting and potentially actionable observations.[69,156,197,345,346] One study in a non–cardiac surgery setting identified marked differences between surgeons and nurses in the degree of familiarity with other team members, a factor known to impact patient safety.[21,28,60] In another study, nurses expressed more negative responses than physicians concerning their work unit's support of and attention to safety.[346] It is important to recognize that such findings may not be generalizable and that culture measurement tools have inherent limitations and applicability.

Although a strong safety culture is thought to save lives, the relationship between culture and clinical performance is complex and nuanced. Acting on findings from attitude surveys, combined with team-skills training sessions, has improved indices of emotional climate, teamwork, and threats to patient outcomes.[69] Some authors have argued, however, that safety culture and actual performance are conceptually and practically different.[341] Moreover, although measurable improvements in safety attitudes can be elicited after interventions, it is unclear whether these effects are sustainable or translate into better patient outcomes.

In the area of cardiac surgery, only a few observational studies have assessed the impact of organizational characteristics on potential outcomes.[8] Fleming and colleagues[80] used a questionnaire to assess leadership, organizational structure, and safety climate, in addition to confidence assertion, information sharing, stress and fatigue, teamwork, work values, and error and procedural compliance. Respondents reported that established procedures and protocols frequently were not followed, and only 43% of the respondents reported feeling comfortable speaking up. Similar results have been reported in pediatric cardiac surgery.[156] The unique milieu of the cardiac OR includes heavy reliance on technology, with the added dimension of CPB and perfusionists. This highly complex environment is ideal for the study and design of interventions to improve team culture.[347]

Behaviors That Undermine a Culture of Safety

Rigid Hierarchical Culture

Organizations with a predominantly hierarchical culture are generally oriented toward and place a high premium on stability.[348] These organizations are characterized by uniformity, rigid coordination, internal efficiency, and a close adherence to rules and regulations.[348] These characteristics are not inherently bad; in surgery, as in the military, a close adherence to rules and regulation and clear lines of authority are critical to effective performance. However, when these characteristics lead to significant power distance, status asymmetry, and disruptive behavior, safety will be compromised, with team members reluctant to challenge authority or to speak up when errors are recognized.[156,158,345] A centralized approach to management often results in frontline providers feeling less empowered to speak up or take action when confronted with safety issues.[349,350] Hospitals and surgical teams with a rigid hierarchical culture have been shown to have inferior scores on performance measures[351–356] and safety climate measures.[349] Targeted interventions, as highlighted by Singer and colleagues,[349] include team training that emphasizes the collective shunning of unprofessional behavior and a commitment to continuous QI.

Professionalism and Disruptive Behaviors

High-quality and safe patient care depends on teamwork, communication, and a collaborative work environment. Professionalism is maintained through the interplay of individual behavior and organizational structure.[357] The culture of health care has historically tolerated disruptive and intimidating behaviors in exchange for a high level of skills and expertise.[358] As the delivery of health services shifts from individual practitioners to team-based and multidisciplinary approaches, organizations that do not embrace interprofessional training and communication and that fail to eliminate maladaptive behaviors will be incapable of achieving highly reliable levels of safety and sustained outcomes.[359–363]

Surgical errors must be understood in the context of the culture of the surgical team.[364] In a study of surgical teams, Mazzocco et al[12] found that teams that exhibited fewer teamwork behaviors, particularly information sharing during the intraoperative phase and debriefing during the handoff phase, were at higher risk for patient death and complications. Another study found that teamwork factors alone accounted for ≈45% of the variance in the technical errors committed by cardiac surgeons.[20] Finally, Nurok et al[69] found an association between a perturbed emotional climate and poorer thoracic surgical team performance.

The literature continues to link disruptive behaviors to errors and even to mortality. In a study of the effects of workplace intimidation on medication practices, 7% of respondents reported being involved in a medication error in which intimidation played a role.[365] In cardiac surgery, data are scarce, but Rosenstein and O'Daniel[366] indicated that there was a "high predilection for disruptive behaviors to occur in high-stress areas with a greater potential for patient harm." In a survey of 4530 hospital physicians and nurses, 77% reported witnessing disruptive behavior among physicians and 65% reported witnessing disruptive behavior among nurses at their hospitals.[367]

Respondents reported that general surgery was the specialty in which disruptive events occurred most often (28%), with cardiovascular surgery at 13%. This behavior cuts across all disciplines. In a perioperative study, 75% of respondents reported having witnessed disruptive behaviors in attending surgeons, 64% in anesthesiologists, 59% in nurses, 43% in surgical residents, and 35% in anesthesiology residents.[368] Additionally, 46% of respondents claimed they were aware of potential adverse events that could have occurred from disruptive behavior, and 19% reported that they had specifically witnessed an adverse event caused by disruptive behavior. More than 80% of the perioperative personnel reported loss of concentration, reduced communication/collaboration, and impaired relationships with other team members as a result of disruptive behavior. Finally, investigators have reported that frontline staff believes that these behaviors affect patient safety and outcomes.[367,369,370]

In 2009, The Joint Commission implemented leadership standards that required the "creation and maintenance of a culture of safety and quality throughout the hospital," including having a disruptive behavior policy in place and a formal process to manage unacceptable behaviors.[371,372] These disruptive behaviors are specifically defined: "Intimidating and disruptive behaviors include overt actions such as verbal outbursts and physical threats, as well as passive activities such as refusing to perform assigned tasks or quietly exhibiting uncooperative attitudes during routine activities…. Such behaviors include reluctance or refusal to answer questions or return phone calls or pages; condescending language or voice intonation; and impatience with questions. Overt and passive behaviors undermine team effectiveness and can compromise the safety of patients." Recently, The Joint Commission has revised the definitions to "behaviors that undermine a culture of safety."[373]

There is considerable overlap between disruptive behaviors and workplace bullying. In one view, bullying is seen as the most extreme example of disruptive behavior. The Workplace Institute[374] defines bullying as "repeated, health-harming mistreatment that takes 1 or more of the following forms: a) verbal abuse; b) offensive conduct/behaviors (including nonverbal) which are threatening, humiliating, or intimidating; and c) work interference—sabotage—which prevents work from getting done."

As a high-stress, high-intensity, complex environment, the perioperative setting is particularly susceptible to the insidious introduction of disruptive or bullying behavior. The environment is tense, procedures do (and must) move quickly, and precision is expected. In particular, the bullying of nurses and other personnel in the OR may be caused in part by the inherent stress of performing surgery, high patient acuity, shortage of perioperative professionals, overtime, on-call demands, and the fact that any one surgical subspecialty can be quite isolated.[375] Disruptive behaviors are perpetuated by a physician-dominated hierarchical culture and a perceived "code of silence."[376] The inability to speak up for fear of retribution creates an environment in which small errors may accumulate to contribute to a major event. Bullying behavior erodes teamwork and the development of a safety culture.

The reluctance by healthcare organizations to address disruptive behaviors may stem from multiple factors. Rosenstein[376] recommends a 10-step process (Table 2) to help organizations succeed in promoting a culture of patient safety. Recognition of an existing problem is the first step, with leadership committed to assessing the professional environment through validated tools to identify the prevalence of disruptive behavior. Collaborative leadership efforts can raise the level of awareness and accountability by providing education and training. Agreed-upon policies and procedures must include safe, nonpunitive mechanisms for reporting disruptive behaviors. Thus, organizations and their individual employees can better commit to patient safety and quality.[376]

For more than a decade, the Vanderbilt Medical Center has focused on promoting professionalism through identifying, measuring, and addressing unprofessional behaviors.[360,377] These efforts include 6 core principles: (1) Dedicated leadership, (2) a model or framework for guiding intervention, (3) institutional policies, (4) surveillance tools, (5) training, and (6) accountability.[360] Positive results included reduced malpractice claims, improved patient safety and quality, better team communications, reduced reinforcement of negative behaviors, and behavior change among physicians.[377] No studies specifically speak to the impact of such programs in cardiac surgery.

The "Hero Culture" as a Vulnerability

Further complicating the hierarchical structure that allows unchallenged disruptive behavior, the "hero culture" of the exhausted surgical team is revered in the media, where the self-sacrificing surgeon and team members go beyond the point of exhaustion to serve patient needs. This image belies the impact of fatigue on performance. Although the studies were performed in noncardiac units, 2 separate reports documented the effect of prolonged working hours and associated sleep deprivation on attention failures[378] and the incidence of serious medical errors committed by interns working in ICUs.[379] Subsequently, other investigators showed that sleep

Table 2. The 10-Step Process to Promoting a Culture of Safety[376]

1. Organizational culture
   a. Leadership commitment, assessment, structure
2. Clinical champions
3. Recognition and awareness
   a. Education
4. Structured education/training
   a. Diversity, sensitivity, stress management
   b. Conflict management, assertiveness
5. Collaboration/communication tools
6. Relationship building
7. Policies and procedures
8. Reporting mechanisms
9. Intervention
   a. Pre: assess safety culture before implementation of intervention
   b. Current: assess safety culture during implementation of intervention
   c. Post: assess safety culture after implementation of intervention
10. Reinforcement of patient safety initiatives

deprivation increases the risk of accidental self-inflicted injuries[380,381] and the risk of medical residents (trainees) having car accidents during their daily commute.[382] Growing concern that fatigue and extended working hours can contribute to poor performance and outcomes has led to regulatory efforts in resident training in an attempt to improve patient safety.[383]

Of the 3 studies that specifically focused on the role of fatigue and sleep deprivation in cardiac surgery, none demonstrated an association between sleep deprivation and major complications or mortality.[384–386] However, the studies did not measure intermediate outcomes such as incidence of errors or of error capture and recovery, and the results may speak more to team resiliency in recovering from errors than to lack of an effect. A survey of perfusionists found that 15% were performing CPB after being awake for up to 36 hours, and 50% described experiencing microsleep during bypass.[387] Two of 3 reported committing fatigue-related minor errors, and 6.7% admitted to serious perfusion-related accidents ascribed to fatigue.[387]

Cultivating a Culture of Safety

A great deal of the literature regarding changing an organization's culture is reported at the hospital level, not the cardiac OR level.[346,349,388] Interventions to improve quality and safety in the OR are still in their infancy; convincing data demonstrating that these interventions result in sustained improvements in the safety climate of these high-hazard environments are still lacking. As described previously, interventions to improve communication in the cardiac ORs, such as checklists, briefings, and teamwork training, are typically associated with improvements in safety attitudes of OR personnel, as well as patient safety.* Attempts to impact an entire organization's safety attitudes underscore the vexing nature and intractability of the culture problem.

Functional units have been shown to be amenable to structural, if not strategic, interventions. The Comprehensive Unit-Based Safety Program (CUSP) is a safety culture program that has been tested, albeit in ICUs, not the OR.[390] CUSP was the safety culture improvement intervention in the Keystone project, an improvement collaborative to reduce catheter-based infection in 100 ICUs.[208] CUSP is a 5-step iterative process that includes educating staff on the science of safety, identifying defects, involving senior executives to work with staff to prioritize safety hazards and provide resources, learning from 1 defect per month, and implementing teamwork and improvement tools with intermittent quantitative assessments of culture. CUSP is integrated into the organization's strategic plan but defers to frontline workers, giving them autonomy to identify and rectify safety hazards. Use of the CUSP approach together with specific checklists resulted in a virtual elimination of catheter infections,[208] a significant decrease in ventilator-associated pneumonia,[210] and significant improvements in teamwork climates.[390]

Benefits of Organizational Focus on Quality

The experiences at Bristol and Winnipeg that led to the deaths of several pediatric cardiac surgery patients highlight the need for robust QI and quality assurance programs.[335–339] In both cases, the institutions were inadequately equipped to either identify or address problems, and warnings went unheeded. The investigating authorities recommended radical changes, such as institutional prioritization of quality control systems, incorporation of feedback from all stakeholders (including patients and families), and establishment of a culture that encourages all clinicians to speak up and be heard. The authors noted that such an effort should be led by a centralized quality department to detect issues and monitor progress after interventions.[335,339]

Single-Center Improvements

As a result of the tight coupling that exists along the continuum of care, most QI initiatives in cardiac surgery are not focused exclusively on the OR. Comprehensive approaches used in the management of cardiac surgery patients include Total Quality Management,[391,392] Institute for Healthcare Improvement Breakthrough Collaboratives,[393] ProvenCare,[394] Operational Excellence,[395] and others.[396,397] The success of these efforts depends on the extent to which each model fulfills the elements of team trust, data integrity, clinical leadership, institutional commitment, and infrastructure for QI.[398]

Doran and colleagues[393,394] observed the use of the rapid-cycle improvement model (ie, Institute for Healthcare Improvement Breakthrough Series) in a community adult cardiac surgery program. They found significant improvements in hospital length of stay, time on the ventilator, patient satisfaction, and cost. Stanford and colleagues[391] published results of a Total Quality Management System, including surgeon-led implementation of perioperative checklists, nursing supervision to track progress, mortality and morbidity conferences focused on "fix the problem, not the blame," and mandated multidisciplinary consultation. These interventions significantly reduced the operative mortality of CABG patients.[392]

A single-center QI program (ProvenCare; Geisenger Health System, Danville, PA)[394] asked cardiac surgeons to develop a 40-element care bundle for elective CABG patients. Care elements were evidence based and hard-wired into the care process to ensure consistent implementation. The care process was continually altered to improve implementation. Blood product use, ICU readmissions, and hospital readmissions decreased. Although the ProvenCare model has received considerable interest in controlling costs for health plans, its effectiveness and consistency also provide a model for continuous quality management with profound implications for safety culture.[394]

A process-oriented multidisciplinary approach (POMA) at a cardiac surgery program in Leeds, England, brought all care providers together preoperatively to evaluate and prepare the patient for CABG surgery.[396] In a comparison of patients who underwent CABG before (n=262) and after (n=248) POMA was implemented, improvements in average length of stay, median procedural cost, and the incidences of atrial fibrillation and respiratory infections were noted.[396]

Uhlig et al[397] described the implementation of formal multidisciplinary daily rounds on heart surgery patients that involved patients, family members, pharmacy personnel, nurses, social workers, physician assistants, and cardiac surgeons. This program markedly improved patient satisfaction and decreased mortality among CABG patients.

Finally, Culig et al[395] described an "operational excellence" method derived from the Toyota Production System used in a

*References 44, 63, 158, 164, 171, 183, 278, 389.

new community cardiac surgery program. Shifting of the culture from a strict, hierarchical, "defects are punished" mentality to a collaborative "problems are blessings" mentality was accomplished through disciplined 10-minute daily meetings, which included a formal problem-solving process. The display of relevant, real-time data on public boards was used to track ongoing progress.[395] Over 2 years, the risk-adjusted CABG complication rate was 60% less than that observed for the regional population.[395]

A culture of safety and trust is a cornerstone of effective quality and safety improvements.[399] Rather than a punitive culture of "blame and shame," a "just culture" mentality provides conditions and behaviors necessary to develop trust.[400,401] Clinical leaders with training in the science of improvement can strengthen workplace trust with consistent behavior in identifying and working to resolve work defects.[402] Such leadership behavior demonstrates an institutional commitment to QI and provides a QI infrastructure.

Multicenter Collaborative Improvements

Over the years, multicenter collaborative efforts in cardiac surgery have improved quality and safety in cardiac surgery in large part by sharing of site-specific and surgeon-specific data and best practices. This model in cardiac surgery originated in 1987 with the formation of the Northern New England Cardiovascular Disease Study Group.[403–406] Five hospitals and their cardiovascular teams started collecting and sharing patient demographic, process, and outcome data and developed risk-adjustment methodology for creation of predictive models. Site visits between hospitals and frequent face-to-face meetings focused on standardization, ongoing improvement, and shared learning.[407] Use of this model has led to improvements in overall mortality,[408] mortality in women,[409] and reexploration for bleeding.[410]

On the basis of this success, other multicenter collaborative efforts have developed. In 1996, a group of cardiac surgeons initiated the Virginia Cardiac Surgery Quality Initiative,[411] which encompasses 17 hospitals and 10 cardiology and thoracic surgery groups. Focused projects resulted in statewide reductions in the incidence of perioperative atrial fibrillation, improved glycemic control, and decreased blood transfusion.[412] The Michigan Society of Thoracic and Cardiovascular Surgeons formed a quality initiative with the goal of decreasing variation around best practices.[413] Now funded by a health plan, their focus on interventions and data sharing has increased use of the left internal mammary artery in CABG surgery, and decreased the incidence of prolonged controlled ventilation.[414,415] Other collaborative efforts in adult CABG patients include the Alabama Coronary Artery Bypass Grafting Project, Washington Clinical Outcomes Program, California Local/Regional Cardiac Surgery Database, and Minnesota Local/Regional Cardiac Surgery Database.[398]

Some studies have questioned the general effectiveness of QI collaboration.[416,417] Lack of funding, data fatigue, and the competitive pressures among surgeons may limit collaborations to a finite lifespan. Future research to examine the usefulness of external data sharing and interorganizational learning may identify those properties and characteristics that maximize performance among all participants. The extensive availability of information technologies and quality control tools with refinements designed for the healthcare environment will aid groups in deploying interventions that will result in continuous outcomes improvement.

Future Research

Multidisciplinary prospective studies regarding predisposition to error may be the next phase in the evolution of understanding of human error in the cardiac surgical setting.[347,418,419] This human factors research includes study of the larger organization, the workspace, the necessary clinical and technical processes, human interaction with equipment, and particularly human interaction with one another (communication and teamwork). Investigators with clinical expertise (surgeons, nurses, anesthesiologists, and perfusionists) and nonclinical expertise (human factors engineers and systems analysts) must collaborate to perform this research[420] To gain a better understanding of safety and performance in the cardiac OR, Catchpole and Weigmann[347] recommend future emphasis on study design, a systems approach to improvement, and measurement of impact on outcomes. This methodology generates observations and analyses regarding what really happens, rather than what "should" happen, and goes beyond incident reporting of near-misses and adverse events.[347]

Summary Statements

1. Most studies of patient safety in cardiac surgery are reactive (retrospective studies that seek to identify trends) rather than prospective studies to test interventions to reduce human error or improve safety.
2. The Joint Commission has implemented standards requiring "creation and maintenance of a culture of safety and quality throughout the hospital," including having a disruptive behavior policy in place and a formal process to manage unacceptable behaviors.
3. Poor teamwork behaviors and a tense emotional climate are linked to surgical team errors and patient outcomes.
4. Local and regional QI initiatives in cardiac surgical settings specifically have resulted in improvements in blood product use, time on the ventilator, hospital length of stay, ICU readmissions, hospital readmissions, mortality, patient satisfaction, and cost.
5. Multicenter collaborative QI efforts in cardiac surgery specifically to share demographic, process, and outcomes data, as well as site visits between hospitals, have resulted in regional standardization of best practices and improvements in overall mortality, mortality in women, use of blood transfusions, prolonged ventilator support, glycemic control, and increased use of internal mammary arteries.

Conclusions

Cardiac surgery is a high-risk endeavor that requires an intense focus on patient safety, but sustainability requires a culture of safety. The research in this area is nascent but informative. Hospitals and research groups are testing interventions designed to improve teamwork and communication and other interventions intended to reduce disruptive behaviors and fatigue. Placing patient safety first will ultimately lead to greater patient satisfaction and better clinical outcomes.

Table 3. Applying Classification of Recommendations and Level of Evidence

SIZE OF TREATMENT EFFECT

ESTIMATE OF CERTAINTY (PRECISION) OF TREATMENT EFFECT	**CLASS I** *Benefit >>> Risk* Procedure/Treatment **SHOULD** be performed/ administered	**CLASS IIa** *Benefit >> Risk* *Additional studies with focused objectives needed* **IT IS REASONABLE** to perform procedure/administer treatment	**CLASS IIb** *Benefit ≥ Risk* *Additional studies with broad objectives needed; additional registry data would be helpful* Procedure/Treatment **MAY BE CONSIDERED**	**CLASS III** *No Benefit* or **CLASS III** *Harm* (Procedure/Test / Treatment) COR III: No benefit — Not Helpful / No Proven Benefit COR III: Harm — Excess Cost w/o Benefit or Harmful / Harmful to Patients
LEVEL A Multiple populations evaluated* Data derived from multiple randomized clinical trials or meta-analyses	■ Recommendation that procedure or treatment is useful/effective ■ Sufficient evidence from multiple randomized trials or meta-analyses	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Sufficient evidence from multiple randomized trials or meta-analyses
LEVEL B Limited populations evaluated* Data derived from a single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is useful/effective ■ Evidence from single randomized trial or nonrandomized studies	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Evidence from single randomized trial or nonrandomized studies
LEVEL C Very limited populations evaluated* Only consensus opinion of experts, case studies, or standard of care	■ Recommendation that procedure or treatment is useful/effective ■ Only expert opinion, case studies, or standard of care	■ Recommendation in favor of treatment or procedure being useful/effective ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation's usefulness/efficacy less well established ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Only expert opinion, case studies, or standard of care
Suggested phrases for writing recommendations	should is recommended is indicated is useful/effective/beneficial	is reasonable can be useful/effective/beneficial is probably recommended or indicated	may/might be considered may/might be reasonable usefulness/effectiveness is unknown/unclear/uncertain or not well established	COR III: No Benefit — is not recommended; is not indicated; should not be performed/ administered/ other; is not useful/ beneficial/ effective COR III: Harm — potentially harmful; causes harm; associated with excess morbidity/mortality; should not be performed/ administered/ other
Comparative effectiveness phrases†	treatment/strategy A is recommended/indicated in preference to treatment B treatment A should be chosen over treatment B	treatment/strategy A is probably recommended/indicated in preference to treatment B it is reasonable to choose treatment A over treatment B		

A recommendation with Level of Evidence B or C does not imply that the recommendation is weak. Many important clinical questions addressed in the guidelines do not lend themselves to clinical trials. Although randomized trials are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

*Data available from clinical trials or registries about the usefulness/efficacy in different subpopulations, such as sex, age, history of diabetes, history of prior MI, history of heart failure, and prior aspirin use.

†For comparative effectiveness recommendations (Class I and IIa; Level of Evidence A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

Recommendations for Future Action and Research: A "Call to Action" for Patient Safety

WHO has made the reduction of surgical errors one of its primary goals. WHO published guidelines in 2008 that identified multiple recommended practices to ensure the safety of surgical patients.[421] However, errors persist. Traditional approaches to reducing human error, typically driven by hospital or professional society quality assurance committees, have established precedents that make significant improvements in patient safety difficult. A few interventions are supported by currently available, albeit limited evidence, as noted in each topic area above. Priority for implementation of these interventions would almost certainly improve patient safety. Furthermore, a concerted effort to expand the scientific study of human error as a unique area of clinical research could provide opportunities to improve patient safety in the cardiac OR, as well as other surgical and interventional settings (eg, the cardiac catheterization suite). Specific areas of study would certainly include (1) research to better understand communication failures and breakdowns in teamwork; (2) the best way to implement and reinforce interventions to improve communication and teamwork (eg, teamwork training, briefings and debriefings, and simulation); (3) interventions to promote professionalism and safety culture; and (4) OR ergonomics, including ideal space and layout to minimize flow disruptions and personnel traffic. Ideally, both provider outcomes such as behavior change and communication skills and patient outcomes such as morbidity (eg, infections) and costs would be measured.

Opportunities to Facilitate Translation of Current Knowledge Regarding Communication and Teamwork Into Clinical Practice

Table 3 displays the American College of Cardiology Foundation and American Heart Association scheme for the classification of recommendations and level of evidence. The writing group's conclusions and recommendations using this classification scheme are listed below.

Communication failures are common and have been implicated as a cause of error and adverse outcomes in both general and cardiac surgery.† Research in aviation and the military has demonstrated that team training can facilitate improved coordination and enhanced performance. Substantial data do exist in surgical settings regarding the impact of training in nontechnical communication skills; for example, checklists, briefings and debriefings, other structured communication tools and protocols, team training, and simulation training.‡ However, except for the standardized time-out process, which is required by The Joint Commission, widespread adoption of standardized critical interaction by use of protocols has not occurred in cardiac or other ORs. Furthermore, in a few longer-term studies of team training, it appears that improvements are not easily sustained.[164,197,198]

Recommendations

1. **Checklists and/or briefings should be implemented in every cardiac surgery case, and postoperative debriefings should be encouraged by leadership in cardiac ORs *(Class I; Level of Evidence B)*.**
2. **Team training to improve communication, leadership, and situational awareness should be implemented in cardiac ORs and should involve all members of the cardiac operative team *(Class I; Level of Evidence B)*.**
3. **Formal handoff protocols should be implemented during transfer of the care of cardiac surgical patients to new medical personnel *(Class I; Level of Evidence B)*.**
4. **It is reasonable to conduct event scenario training for significant and rare nonroutine events (ie, emergency oxygenator change out) on a regular basis that involves the complete cardiac surgery team *(Class IIa; Level of Evidence C)*.**
5. **It is reasonable to conduct future studies of teamwork and communication that (a) investigate optimal communication models (eg, briefings and structured communication protocols in the cardiac surgical OR); (b) investigate team-training models to determine the "best product" for use in the cardiac OR; (c) investigate impediments to implementation of formal training in teamwork and communication skills; (d) include long-term studies of the sustained impact of such training on provider outcomes (eg, attitudes regarding safety, compliance with best practices, and communication skills); (e) investigate efficacy of formal training in teamwork and communication skills in improving patient outcomes (eg, satisfaction, blood product use, infections, ICU readmissions, mortality, and costs); and (f) include establishment of an anonymous national multidisciplinary event-reporting system to obtain data about events and near-misses *(Class IIa; Level of Evidence C)*.**

Physical Environment Research Opportunities

Poor OR ergonomics are present in many, if not most, cardiac ORs. Hazards for both patients and staff exist, including infection in patients related to personnel traffic and airflow,[305,307] risk of injury to staff caused by tripping over cords and equipment,[297,298] and hazardous noise levels for everyone in the room because of alarms, music, and multiple simultaneous conversations.§ Optimal OR design to maintain efficient flow and restriction of the number of personnel may reduce hazards. Integration of information from various monitors and reduction of noise and alarm fatigue, by design of high-sensitivity and -specificity alerts, may improve patient safety.[313,328]

Recommendations

1. **It is reasonable to investigate the optimal design and testing of information systems in the OR to reduce alarm-related distractions and improve clinicians' ability to integrate knowledge from multiple sources *(Class IIa; Level of Evidence C)*.**
2. **It may be reasonable to test optimal room design and layout, both in real-time and in simulation laboratories, as an innovative area of future research, which may avoid expensive design errors *(Class IIb; Level of Evidence C)*.**

Safety Culture: Implementation of Policies Regarding Professionalism and Quality

In 2009, The Joint Commission implemented standards requiring the creation and maintenance of a culture of safety, including having a disruptive behavior policy in place and a formal process to manage unacceptable behaviors.[371,372] Subspecialty units, including the cardiac operating team, may develop a unique culture with both positive and negative aspects.

Recommendations

1. **Local institutional policies that define disruptive behavior in medical professionals in all hospital settings should be implemented immediately, with transparent and formal procedures for addressing unacceptable behaviors and interventions to eliminate such behaviors *(Class I; Level of Evidence C)*.**
2. **We recommend that every institution commit to a culture of safety by establishing a robust quality assurance and QI program to (a) continuously identify system, unit, and individual safety hazards; (b) provide leadership and resources to eliminate identified hazards; and (c) encourage and value the input of all members of the cardiac surgery team in a nonpunitive atmosphere *(Class I; Level of Evidence C)*.**

Safety Culture: Research Opportunities

Only a few studies have assessed the impact of organizational culture on provider or patient outcomes.[394,395,397] Currently available data provide limited evidence that patient outcomes (eg, satisfaction, blood product use, infections, ICU readmissions, mortality, and costs) may be improved with patient safety and QI initiatives. It is unknown whether improvements in safety-oriented provider attitudes and organizational culture are sustainable.

†References 13, 16, 18, 20–23, 58, 59, 72, 76–80.

‡References 44, 45, 63, 66, 68, 162, 164, 170–173, 176, 178, 182–184, 190–192, 195, 197, 198, 204, 208, 210, 215, 217–220, 222, 223, 422, 423.

§References 296, 304, 310, 311, 314, 316, 317, 321.

Recommendations

1. **Scientific testing of interventions in the complex technology-oriented setting of the cardiac OR is reasonable, including interventions that (a) test existing tools and develop new tools designed to improve safety culture and climate; (b) provide ongoing assessment after intervention(s), to measure sustainability of improvements in safety culture; and (c) lead to establishment of multi-institutional large clinical trials to assess the efficacy of improvements in safety culture in reducing selected adverse patient outcomes *(Class IIb; Level of Evidence C)*.**
2. **Design and funding of multidisciplinary prospective studies of human and systems factors that predispose to error in the cardiac OR is reasonable *(Class IIb; Level of Evidence C)*.**

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*Modest.

†Significant.

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*Modest.

†Significant.

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Circulation

Patient Safety in the Cardiac Operating Room: Human Factors and Teamwork: A Scientific Statement From the American Heart Association

Joyce A. Wahr, Richard L. Prager, J.H. Abernathy III, Elizabeth A. Martinez, Eduardo Salas, Patricia C. Seifert, Robert C. Groom, Bruce D. Spiess, Bruce E. Searles, Thoral M. Sundt III, Juan A. Sanchez, Scott A. Shappell, Michael H. Culig, Elizabeth H. Lazzara, David C. Fitzgerald, Vinod H. Thourani, Pirooz Eghtesady, John S. Ikonomidis, Michael R. England, Frank W. Sellke and Nancy A. Nussmeier

on behalf of the American Heart Association Council on Cardiovascular Surgery and Anesthesia, Council on Cardiovascular and Stroke Nursing, and Council on Quality of Care and Outcomes Research

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Correction

In the article by Wahr et al, “Patient Safety in the Cardiac Operating Room: Human Factors and Teamwork: A Scientific Statement From the American Heart Association,” which published online August 5, 2013, and appeared in the September 3, 2013, issue of the journal (*Circulation*. 2013;128:1139–1169), a correction was needed.

On page 1139, in the author byline, Bruce E. Searles’ degrees were listed incorrectly as “MSN, CCP.” They have been changed to read, “Bruce E. Searles, MS, CCP.” The authors regret the error.

This correction has been made to the print version and to the current online version of the article, which is available at http://circ.ahajournals.org/content/128/10/1139.

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American Heart Association®

心臓手術室の医療安全：ヒューマンファクターとチームワーク：
米国心臓協会（**American Heart Association**）からの科学ステートメント

Patient Safety in the Cardiac Operating Room:
Human Factors and Teamwork:
A Scientific Statement from the American Heart Association

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AHA Scientific Statement

心臓手術室の医療安全：ヒューマンファクターとチームワーク：米国心臓協会（American Heart Association）からの科学ステートメント

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on behalf of the American Heart Association Council on Cardiovascular Surgery and Anesthesia, Council on Cardiovascular and Stroke Nursing, and Council on Quality of Care and Outcomes Research

心臓手術室は，複雑な医療行為が行われる場であり，重度の心疾患と重大な合併症に苦しむ患者を治療するべく，高度な訓練を受けた医師およびメディカルスタッフが精巧な器具を用いてチームとして治療に取り組む場所である．近年の心臓手術の進歩により，何千もの患者の命が救われ，その予後も著しく改善された．実際，冠動脈バイパス術の手術死亡率と合併症発生率は，過去 10 年間にわたり低下を続けている（図 1）[1]．だが，高い技術を有し献身的に仕事に励む心臓手術室のスタッフであっても，人間である以上はエラーを起こす．1991 年に出された Leape らの報告[2,3] によると，1984 年にニューヨークで入院した計 200 万人の患者のなかで（不注意によるものを含めて）27 179 件の有害事象が発生していたとの推計が発表された．他の報告でも，入院患者の最大 16% が実際に被害を被ったことを示唆するエビデンスもあるという[4]．Gawande ら[5] は，外科における有害事象の発生率が心臓外科の患者では 12% であるのに対し，他の領域の外科患者では 3% であったことを報告し，有害事象の 54% は防止できると主張した．現在，心臓手術を受ける年間約 35～50 万人の患者のうち，有害事象は 28 000 名に発生し，冠動脈バイパス術に関連する死亡の 3 分の 1 は予防可能であると考えられている[6]．

洗練された医療技術，先進的なテクノロジー，医療チーム内での連携の推進により，心臓手術の成績は著しく改善された．しかしながら，米国医学院（Institute of Medicine）の報告書[7] が出されて 10 年以上が経過した現在においても，エラーの減少や防止が大いに進んだというエビデンスはほとんど得られていない[8]．潜在的なリスクを測

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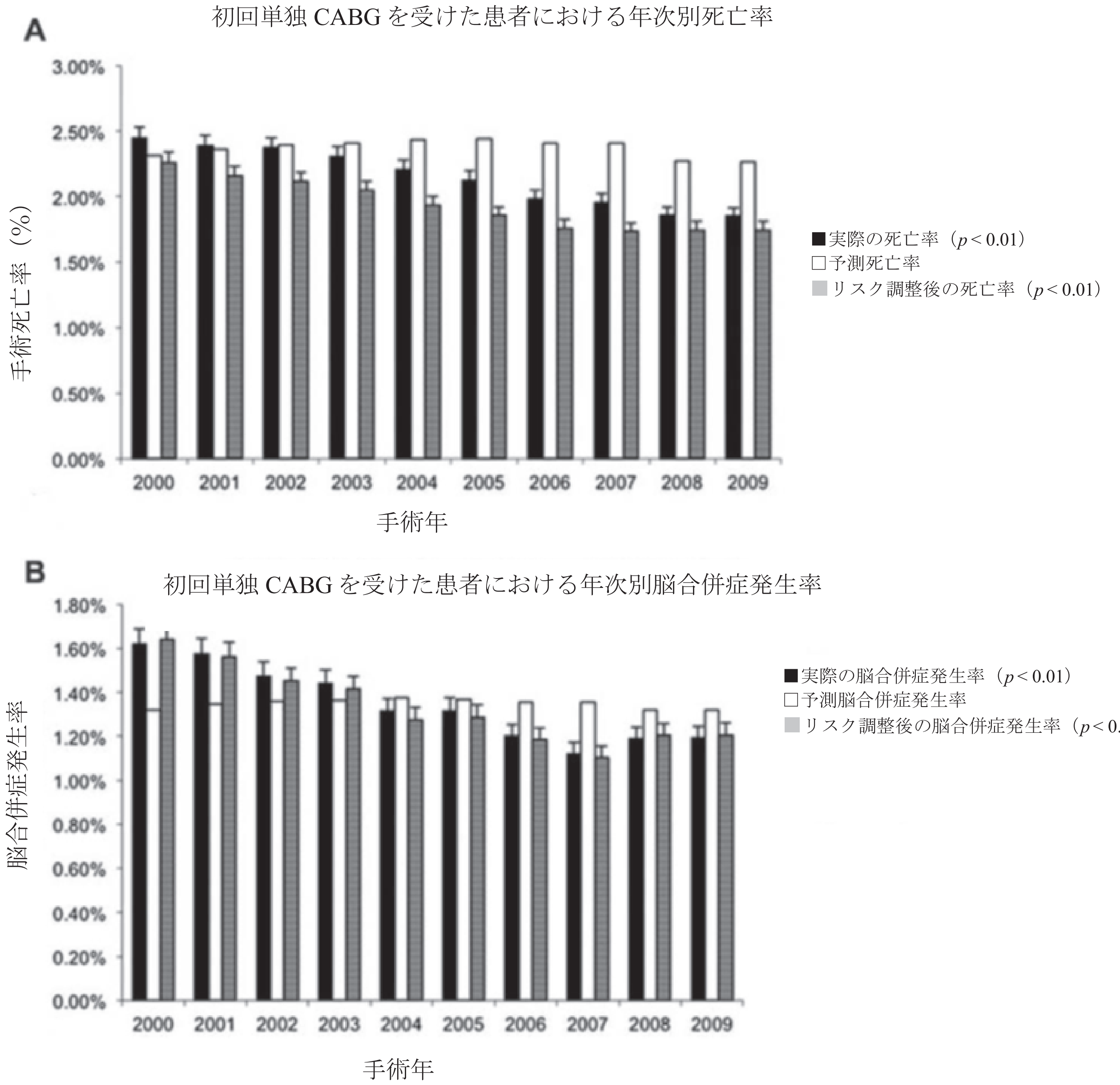


図 1　単独冠動脈バイパス術（CABG）患者における手術死亡率と脳合併症発生率の推移（2000〜2009 年）．調査期間中，実際の手術死亡率は 24.4%（2.4% から 1.9% へ）低下し，実際の脳合併症発生率は 26.4%（1.6% から 1.2% へ）低下した．Elsevier の許可を得て ElBardissi ら[1] から転載．©2012 American Association for Thoracic Surgery

定するツールや医療安全を改善するための方策は，いまだ開発とテストの初期段階にあり[9]，医療安全研究のための資金投入も不十分なままである．既報の文献からは医療安全対策の成果が表れたというエビデンスは限られたものしか得られていない[8,9]．さらに，既存研究の大部分はその性格上，質的あるいは記述的な研究であり，従来型の定量的な統計解析には利用できない．そのため，このような研究に精通した臨床医は少ないのが現状である．

防止できるエラーの多くは，医療技術や訓練，知識などに関係したものではなく，認識，システム，チームワークの欠如を反映している（図 2）[10-14]．コミュニケーションや協力，共同作業，リーダーシップなどのノンテクニカルスキルは，チームワークの重要な構成要素であり，こうした対人技能の欠如はしばしば有害事象やエラーの誘因となる[15-17]．訴訟に発展した手術症例を対象としたレビューでは，賠償に至ったシステムとしての失敗の 87% をコミュニケーションの失敗が占めていた[18]．そして，それらのコミュニケーションの失敗は，医療従事者と患者の間ではなく，主として医療従事者の間で発生していた．

手術手順の妨げや手術の停滞につながるチームワークの失敗は，ことのほか頻繁に起こっており，心臓手術を対象とした研究[19] によると 1 時間当たり 17.4 回，他の研究[20]

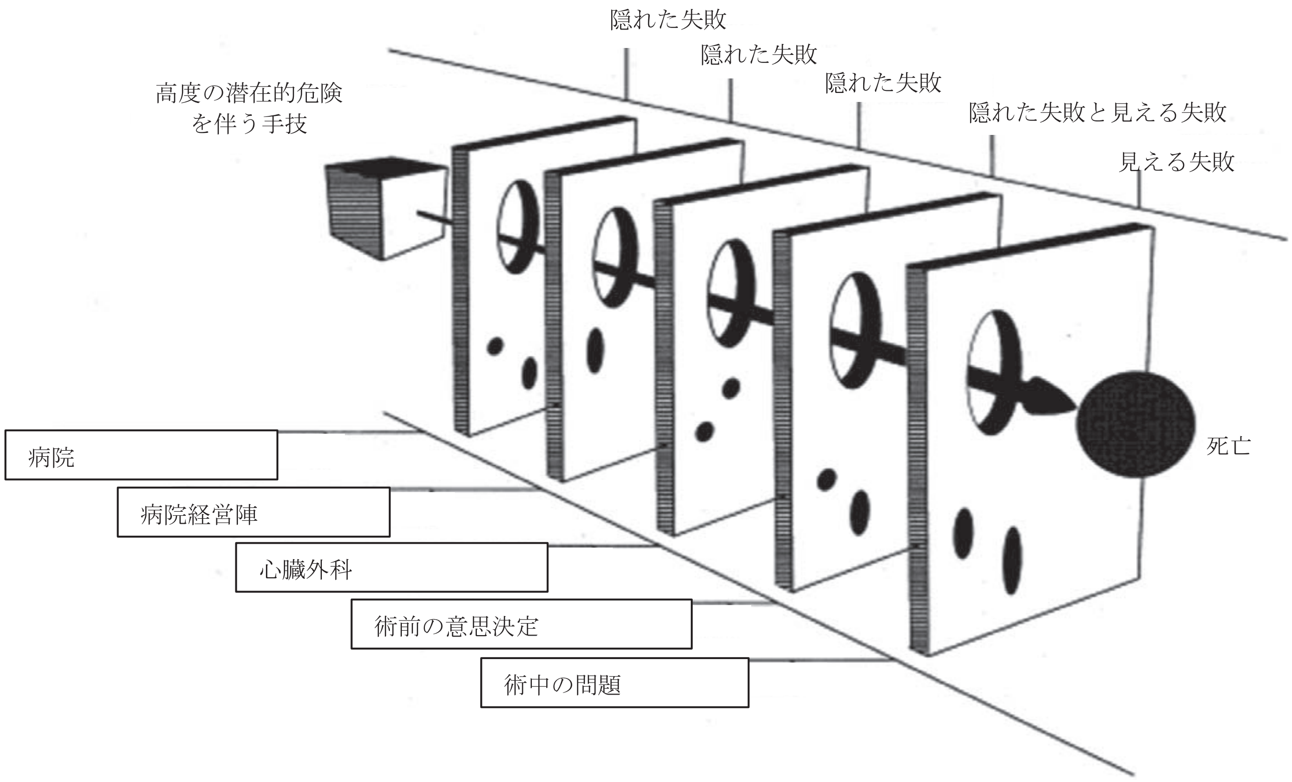


図 2　事故モデル．高度の潜在的危険を伴う手技においては，病院，病院経営陣および個人のヒューマンエラーに起因した見える失敗と隠れた失敗が重なると，有害事象の発生につながる場合がある．Elsevier の許可を得て Carthey ら[13] から転載．©2001 American Association for Thoracic Surgery

では 1 時間当たり 11 回の頻度と報告されている．ここで重要なことは，このように手術の停滞が重なってくると，技術的なエラーの発生から有害な結果を招くということである[21-23]．このような停滞の原因の多くはチームワークの欠如に関連したものであり，こうした停滞は手術エラーにつながることが多いことが示されている[20]．

軽微なイベント，すなわち患者の手術結果には影響を及ぼさないと考えられるイベントですら，チームが重大なイベントから立ち直る能力を損なうことにより，死亡とニアミスの双方と有意に関連する[22]．ある研究では，1 件の手術で発生する軽微な問題の件数は平均 9.9 回であり，この平均を 3 回上回る毎に，術中のパフォーマンスが目に見えて落ち，手術時間が延長していた[23]．軽微な停滞とイベントの発生が蓄積してくると，重大なエラーに対処する心臓手術チームの能力が損なわれるものと考えられる[24]．要するに，「ちりも積もれば山となる」のである[17,25]．

手術チームの各メンバーがもつ自身や同僚のチームワークスキルに関する認識はメンバーごとに異なる．複数の研究でなされた検討では，コミュニケーションスキルとチームワークスキルに関する外科医と麻酔科医の自己評価は，同じチーム内の看護師や体外循環技士の見解とは大きく異なる[26,27]．外科医は他の外科医とのチームワークについて，85% が「高い/非常に高い」と評価したが，看護師は自身と外科医の連携について「良い/非常に良い」と評価したのは 48% にとどまったのである[28]．チームワークスキルを客観的に評価できれば，メンバー間の技能水準の差を明らかにして，教育と訓練の機会につないでいくことができる[29]．

本文書で示す科学ステートメントには，チームワークスキルに関する多くのデータを盛り込んでいるが，重点はコミュニケーションに置いている．米国医療機関認定合同委員会（Joint Commission on Accreditation of Healthcare Organizations）の報告によると，コミュニケーションの失敗は 2004〜2012 年に報告された警鐘イベント（sentinel event）の根本原因のうち，65% と最大の割合を占めており，投薬ミス，手術部位の取り違え，術中および術後イベントの主要な発生要因であった[30]．また，心臓手術ではチームワークの不具合が頻繁に起きていること（慣れたチームでも手術 1 件当たり 5.4 回，不慣れなチームでは手術 1 件当たり 15.4 回）を示した研究もあり，それらのチームワークの不具合をもたらした主な原因（89%）はコミュニケーション不足によるものであった[21]．

米国心臓協会（American Heart Association）は，今回この科学ステートメントの作成にあたり，医療安全上のリスクに関するエビデンスを要約するとともに，心臓手術における周術期リスクとヒューマンエラーを低減するための対策を明確化するように努めた．医療安全に対するすべての潜在的リスクとそれに対する対策を網羅した包括的レ

ビューは膨大な分量に及んだが，そこでは手術手技（冠動脈バイパス術での内胸動脈の使用など），さまざまな人工心肺手技，感染や体内への器材の置き忘れを減らすための手法といった多岐にわたるトピックがあげられた．そこでわれわれは，チームワーク（特に心臓手術チームが手術室内や他の医療チームとの間で情報をやりとりする方法）に影響を及ぼすヒューマンファクター，環境要因および文化的要因に焦点を合わせることとした．本ステートメントでは，チーム内およびチーム間のコミュニケーション，物理的な業務環境（空間，設備および人間工学）とそれらがチームワークに与える影響，ならびに心臓手術室の組織文化（安全文化と医療の質改善）について，最新の知見を系統立てて記載している．

当初は心臓手術の環境におけるチームワークについて検討した研究を重視する予定であったが，必要に応じてそれ以外の文献も引用して，心臓手術の文献に特に不足している重要な概念を提示した．心臓手術に関する研究の多くが，エラーの重大な原因としてコミュニケーション不足をあげているが，有効なコミュニケーションと不完全なコミュニケーションの基礎をなす概念について検討を行っているのは，主に認識心理学の文献であったため，「コミュニケーションとチームワーク」の項ではこれらの参考文献も引用した．同様に，本ステートメントでは心臓手術に焦点を当てながらも，他の外科領域から得られた関連データも含めている．心臓外科に限定された参考文献の特定を試みたが，さらに詳細な情報を求める読者は個々の参考文献を参照されたい．今回は心臓手術に焦点を絞っているために，活発に研究が行われている領域でも，対象範囲外であったことから除外した価値の高い文献も多数あり，これらについては，他の科学ステートメントや同様のレビューで要約されることを期待する．最後になるが，この科学ステートメントは，重大な知識の欠落と更なる研究が待たれる領域の特定を目的としている．

本ステートメントは，米国心臓協会（AHA）の American Heart Association's Council on Cardiovascular Surgery and Anesthesia の委員で構成される執筆委員会と以下の非営利団体の協力会員が共同執筆したものである．参加非営利団体：心血管麻酔学会[Society of Cardiovascular Anesthesiologists] とその FOCUS 構想 [Flawless Operative Cardiovascular Unified Systems]，胸部外科医学会［Society of Thoracic Surgeon，STS］，周術期管理看護師協会［Association of Perioperative Registered Nurses，AORN］，ヒューマンファクター・人間工学会［Human Factors and Ergonomics Society，HFES］，米国体外循環技術学会［American Society of Extra-corporeal Technology］．われわれは，本ステートメントで提示したデータと推奨策が，心臓手術室におけるヒューマンエラーを減らし医療安全を改善するという難題に対処するための更なる研究を促進する原動力となることを望んでいる．そのような研究は，すべての手術室に加えて，血管内治療や電気生理学的検査の実施環境にも広く適用されるべきである．特に心臓カテーテル法と電気生理学検査，さらには弁膜疾患の経皮的治療や経皮的循環補助装置，大動脈瘤に対するステントグラフト治療などのために設計されたハイブリッド手術室を始めとする他の治療環境についても，この科学ステートメントによって医療安全に関する同様の検討の実施が促進されることを期待している．

医療安全の評価

医療安全を改善する方法を理解するには，これまでに研究者たちがノンテクニカルスキルとその影響をどのように評価してきたかを理解する必要がある．そのために第 1 に必要となるのは共通の語彙であり，「ノンテクニカルスキル（nontechnical skill）」という用語を定義して，研究の比較と議論を信頼に足るものとしなければならない．第 2 には，ヒューマンエラー（human error）の減少，あるいは医療安全に関する特定のノンテクニカルスキルの影響を定量化する必要がある．第 3 に，個人およびチームのノンテクニカルスキルを改善するための対策を立て，その有効性を検証する必要がある．そして第 4 に，ノンテクニカルスキルの改善がエラーの減少と（望むらくは）最終的な患者の転帰に与える影響を研究し，その進歩を実証しなければならない[31]．

テクニカルスキルは客観的に測定可能（たとえば 1 分間に作れる結び目の数など）であるが，ノンテクニカルスキルを測定するには，専門家による観察評価や一見すると主観的な評価が必要となる場合が多い．こうした観察調査は大半の臨床医にとって馴染みがないが，この方法により，手術室で発生する有害事象の件数，種類，重症度がすでに特定されており[13]，有害事象発生の誘因となるチームおよび個人の多くの行動と，優れた手術でよくみられる行動も明らかにされている[12,32]．しかしながら，この観察調査にも限界がある．それは，有効な結果を得るには観察者を訓練する必要があり，訓練しても全員が調査の専門家になれるわけではないということである[13,32,33]．ある調査では，2 名の観察者がともに捉えた事象の評価は一致したものの，両者が一致して捉えた事象は，全体の事象のわずか 32% にすぎなかった[34]．

パフォーマンスを評価して，フィードバックを返す難しさを思えば，ノンテクニカルスキルを教えるのは非常に骨が折れる．テクニカルスキルの質の評価にばかり関心を払うのではなく，ノンテクニカルスキルについても，能力を評価し，教育の機会を特定する必要がある．前述のように，ノンテクニカルスキルの観察調査には，訓練をされた経験豊かな観察者が必要である．しかし，今日まで，訓練をされた観察者が研究の一翼を担うことはあっても，臨床能力の訓練または検証に関与することはなかった．手術シミュレーションにおいて，テクニカルスキルに関する専門家の評価と外科レジデントの自己評価の間には強い相関を認めるが，ノンテクニカルスキルについては事情が異なる[35]．上級外科医によるテクニカルスキルの自己評価は観察者による評価と高い相関を示すものの，ノンテクニカルスキルに関しては，若手のレジデントと上級の外科フェロー，ならびに外科常勤医による自己評価は，すべて，専

門知識を有する観察者による評価より高かった[36].

また，客観的な観察者は，手術の停滞，エラー，コミュニケーションスキル，そしてこれらの要素が転帰に与える影響を正確に評価できることが必要である．訓練された観察者とは異なり，手術室現場のスタッフは，チーム連携の不具合について，他の同僚メンバーへの影響は大きく，自分への影響は少ないと感じる傾向にある．そのため外科医は（看護師や麻酔医などのチームの他メンバーと違って）チーム連携の不具合に気づきにくい[37]．特にシミュレーションされた危機的状況においては，上級外科医が若手の外科医より優れたチームワークスキルを示すとは限らないので，ノンテクニカルスキルについて明確に教えておく必要があるかもしれない[35, 36, 38].

チームワークの測定

ノンテクニカルスキルの測定ツールは数多く使われてきた（表 1）が，広く認められた単一のツールは存在しない．多くのものは，特定のサブチーム（看護師，外科医，麻酔科医）内でノンテクニカルスキルを測定するように設計されている[49]．これらの行動評価システムは有効で（測定すべきものを測定できる），再現性があり（観察者内および観察者間の評価が十分相関する），感度が高く（行動の違いがあれば検出できる），実行可能で（実践が容易で費用対効果がよい）なければならない.

手術チームとサブチーム（外科医，麻酔科医，手術室看護師などの職種別）のスキルに関しては以下の 5 つの測定ツールが設計されており，それぞれ長所と短所がある[49]．Observational Teamwork Assessment for Surgery（OTAS）[29, 33, 39-44, 49]，Oxford Non-Technical Skills（NOTECHS）[15, 45-48]，Non-Technical Skills in Surgery（NOTSS）[50-52]，Anesthesia Non-Technical Skills（ANTS）[53, 54]，Scrub Practitioners' Non-Technical Skills（SPLINTS）[54a-54b] の 5 つである．このうち NOTSS，ANTS，SPLINTS は，それぞれ外科医，麻酔科医，手術室看護師の個々のノンテクニカルスキルを，OTAS と NOTECHS は特にチームの行動と技能を評価するよう設計されている[55]．OTAS は業務のチェックリストと，チームの行動評価からなり，評価指標としての妥当性（すなわち，測定対象と思われるものを実際に測定しているか）が高く，専門知識を有する観察者による評価者間の再現性が高いが，経験を積んだ観察者と，経験が浅くまだまだ訓練が必要な観察者による評価の間には大きな違いが表れる[41]．手術のための NOTECHS は，航空業界の NOTECHS 尺度[45] をそのまま適用したもので，4 つの領域（協力/チームワーク，リーダーシップ/管理，状況認識/警戒，問題解決/意思決定）のスキルを測定する．一部の研究チームは，ここにコミュニケーション/チームスキルを加えている[48]．NOTECHS は専門知識を有する観察者と経験の浅い観察者による評価の間に高い相関があり，訓練後のノンテクニカルスキルの改善，ならびに技術的なエラーと非技術的スコアの有意な逆相関を示すために使われてきた[15, 47]．NOTECHS と OTAS を並行して使用すると，両者のスコアはよく相関する[47]．また，OTAS と修正 NOTECHS の双方が評価指標としての妥当性を有することがわかっている[47, 56].

表 1　チームワーク評価ツール

チーム内のチームワークスキル評価ツール	定義
OTAS[29, 33, 39-44]	患者，機器，コミュニケーション評価に目を向けた，業務手順チェックリスト ・コミュニケーション ・協力 ・共同作業 ・共通のリーダーシップ ・共通の監視
NOTECHS[15, 45-48]	欧州で使用されている航空業界の NOTECHS 尺度を適用 ・協力/チームワーク ・リーダーシップ/管理 ・状況認識 ・問題解決/意思決定 ・±コミュニケーション/相互作用

NOTECHS は「Oxford Non-Technical Skills」，OTAS は「Observational Teamwork Assessment for Surgery」を指す.

いくつかの研究では，手術の流れの停滞が有害事象と相関しているが，その定義は研究ごとに異なる[20, 37, 57]．これについては 2 つのツール，すなわち Surgical Flow Disruption Tool（SFDT）[57] と Disruptions in Surgery Index（DiSI）[37] が提案されている．どちらも強い評価者間再現性を示すが，他の研究者による再検証はなされていない.

転帰の測定

チームワークとノンテクニカルスキルが不十分であると，患者の転帰に悪影響が及ぶことが示されている．合併症発生率と手術死亡率は，システムの機能不全[18]，共同作業とコミュニケーションの失敗[58]，報告されたコミュニケーションのレベル[59]，不十分なチームワーク行動[12]，心臓手術チームのメンバー同士の馴染みのなさ[21, 60]，そして，手術 1 件当たりの小さな事象（手術の停滞）の発生件数[22] と関連している．また，チームワークの質と，その指標となる事象に対する行動を関連付けた研究もある．このような指標の例としては，手術時間の延長[23]，手術当たりの技術的なエラーの発生件数[46]，重大なエラーの発生件数[61]，チームメンバーのストレスの程度[62] があげられる.

安全な対策すべてに関して，最高に望ましい転帰は合併症発生率と手術死亡率の減少である．最近の心臓手術の死亡率は非常に低いので，きわめて大規模な研究を実施して，測定法の改善を認識できるようにする必要がある．たとえば，チームワーク訓練を実施して死亡率を劇的に減少させた Neily ら[63] は，対策の効果を明らかにするために 108 の退役軍人省病院（Veterans Affairs hospitals）で

行われた18万9000件の手術を対象に研究を行っている．

病院の安全風土はコミュニケーションエラーと相関するので，安全もしくはチームの「感情的な風土（emotional climate)」に対する態度の変化を結果の指標として利用し，その影響を測定した研究もある．これらの研究は，ノンテクニカルスキルの訓練が医療安全の改善に有効であることを示している[64–70]．

要　約

1．個人およびチームのノンテクニカルスキルは医療安全に影響を及ぼす．

2．OTASおよびNOTECHSは，評価指標としての妥当性と信頼性が高いことが証明されている．これらのツールから正確な結果を得るには，使用する観察者の訓練が非常に重要である．

3．ノンテクニカルスキルを改善するために提唱された対策については，実施に先だって検証し，実際にスキルを改善することを確認する必要がある．

コミュニケーションとチームワーク

チーム内のコミュニケーション

コミュニケーション（Communication）

コミュニケーションとは，「送り手と受け手との情報交換」であり[71]，手術室においては，複数の個人が同時に情報をやりとりする．しかし残念なことに，コミュニケーションスキルは手術室でのチームワーク行動のうち，最も不十分な5項目の1つである[29]．医療安全の欠如は，コミュニケーションの失敗または遅延に起因することが多い[72,73]．コミュニケーションに齟齬が起きるのは，情報の送り手がメッセージをきちんと伝達しなかった場合（曖昧な表現や不十分な表現など），受け手が情報を不正確に理解した場合，情報が送られるタイミングや相手が間違っている場合などである[72]．コミュニケーションの失敗は一般的にみられる現象で[72,74,75]，多数の研究において問題の主たる原因とされている[16,21–23,58,76]．一般外科と心臓外科のどちらの手術においても，コミュニケーションの齟齬はエラーと有害転帰の根本原因であると指摘されており[13,18,20–22,59,77–80]，チームのメンバーが互いのことをよく知らないと状況がさらに悪くなる[21]．

手術室内のコミュニケーションの失敗は，情報の授受のタイミング，内容（間違った，もしくは不十分なデータ)，目的，受け手（間違った人に指示したり伝達したりする）の誤りによる[72]．有効なコミュニケーションはオープンであり，順応性があり，正確で，簡潔であり，それは医療安全の促進を支援する風土で育まれる可能性がある[71]．このうち，オープンなコニュニケーションは切れ目のない活動を生み[81]，順応性のあるコミュニケーションはチームのメンバーが同僚の作業負荷を認識して配慮する効果を生み，簡潔なコミュニケーションは仕事の効率を高める[82]．

有効なコミュニケーションがチームパフォーマンスや結果の改善と結びつくことは，航空機のコックピットとクルー[83]，海軍のチーム[84]，そして手術チーム[81]において示されている．最近実施されたメタ分析では，チームのパフォーマンスを最大にするためには，情報共有が最も重要であるという明確なエビデンスが提示された[85]．系統的レビューでは，コミュニケーションはチームとしての成功の鍵であり[86]，質の高い医療に不可欠である[87]ことが示されている．良好なコミュニケーションが確立されていれば，それ以外の基本的なチームプロセスや共同作業，協力，認識，コーチング，対立解決などが可能になり，業務が円滑化される[88]．

協力（Cooperation）

協力もまた，チームワークの重要な要素であり，行動を駆り立てる感情や態度および信念につながる．態度（attitude）の要素に関する研究が始まったのは，チームワークの欠如に起因するものとされた何件かの悲劇的な航空機事故がきっかけであった．航空業界は，チームワークスキル（以前は「重要ではない」とみなされていた）の欠陥が重大な結果を招くことを認識し，チームワークを改善するべく乗務員人材マネジメント（crew resource management：CRM）プログラムを開発して導入した[89]．

最もよく研究されている態度としては，チームとしての能力に対する自信（collective efficacy：集団として能力があるという感覚）[90,91]，チームの方向性（team orientation：チームワークを信じて優先する傾向）[92,93]，結束（Cohesion：チームや業務への献身）[94,95]，そして相互信頼（mutual trust：全員がチームに貢献してチームを守るという共通の信念）[96,97]などがある．心臓手術チームについては十分なデータは得られていないが，動的で複雑な環境について実施された他の研究では，適応可能な実践現場で実践可能な対策が重要であることが示されており，特に重要とされるのが，チーム内での安心感（psychological safety），チーム権限の強化（team empowerment：チームのメンバーには業務と環境を制御する権限があるという感覚），そして安全風土（safety climate）である[98–101]．経験的研究によれば，チームとしての能力に対する自信が高ければ，メンバーが一層努力し，戦略的なリスクをそれまで以上にとるようになり，その結果，より良いパフォーマンスと高い満足感が得られることが示されている[102,103]．チーム内の信頼のレベルは，メンバーがどのくらい互いをモニタリングするか，組織への献身の程度がどの程度かに影響し，結果としてチームのパフォーマンスに影響を与える[104–111]．

共同作業（Coordination）

コミュニケーションはまた，最良な共同作業とチームパフォーマンスに必要な行動がとれるようにしてくれる[112]．共同作業にはコミュニケーションが有効に機能していることが必要であり，高いチームパフォーマンスを得るには共同作業が不可欠である．共同作業とは，本質的には「相互に依存した活動が行われる順序とタイミングを統制すること」を意味し[113]，同期化と認識によって言葉に出して，あるいは順位付けとコミュニケーションによって、暗黙のうちに阿吽の呼吸により，確立することができる[71]．

暗黙の共同作業には，業務と環境，そしてチーム内の個々の役割と責任に関する共通の理解が必要である．これがあれば，明確なコミュニケーションがなくてもメンバーは互いの実行と必要とするものを予想でき，これにより効率が高まる[114-116]．また，相互理解があれば，メンバーが支援，情報，フィードバックを提供し合うことができるため[71]，チームはパフォーマンスを損なうことなく構造とプロセスを修正することが可能になる[117]．特に，強いストレスに曝される状況において，有効なチームワークとパフォーマンスのために絶対に欠かせないのは，事態を予見する能力である[71]．共同作業行動がなければ，チームのメンバーは同調して行動と業務を行うことができず，労力が無駄になってしまう[112]．

軍隊と航空産業を対象にした研究が何十年にもわたって続けられており，チームの相互理解が共同作業とパフォーマンスを円滑化することが実証されている[114,115,120,121]．また，有効かつ効率よく共同作業を行っているチームは，外部からの圧力の有無を問わず，良好なパフォーマンスを発揮すること示した研究もある[122,123]．医療チーム内では，チームのニーズと目標を明確に述べる，またはメンバー間の親しさを利用することにより，メンバーに共同作業スキルを習得させ，事態の予見と理解を明確に確立することが可能となる[71]．そして共同作業と順応の訓練を通じて最新の情報を提供し，責任を割り当てれば，共同作業行動をより良いものにすることができる[115]．

認識（Cognition）

認識とはチーム内の相互作用から生まれる共通の理解[124]を指し，これは相互作用を繰り返すことで改善可能である[125]．また認識は，各メンバーの役割，責任，能力に関するチームの集合的な知識を意味し[82]，メンバーが必要としていることを推し測る能力があれば，共同作業とコミュニケーションを強化できる[126]．メンバーの共通理解は状況の共通認識を高めるため，また時々刻々変化する状況における問題解決にきわめて重要である[117]．これが不十分であると，チームが十分な共同作業を行うことができなくなり，パフォーマンスが低下するという事態を招く[125,127]．

航空産業と軍隊におけるチーム内の認識に関する研究，ならびに学生を対象にした実験的な研究では，経験豊かでメンバーが互いをよく知っているチームは，経験の浅いチームと比較して，より良いチーム認識（共通のメンタルモデルなど）ならびに良好な転帰を達成することを示している[21,60,128-131]．チーム内で共有された知識はチームの行動とパフォーマンスに良い影響を及ぼし（Mathieuら[132]のレビューを参照のこと），共有された認識はチームのコミュニケーション[133-136]，学習と自律[126,137-140]，そして共同作業[125-127]を改善する．

医学領域においてチームの認識を向上させる有効な対策として検討されてきたのは，常に振り返る訓練（チームが採用した戦略に対する振り返り）[131,140]，クロス訓練（cross-training：他のメンバーの業務や職務を代わりに行う訓練）[126,141]，そしてシミュレーションを利用したチーム訓練[142,143]である．チームメンバーの共通の理解を深めれば，共同作業とパフォーマンスを強化できる．

対立（Conflict）

コミュニケーションは対立の解決にきわめて重要である．対立は，メンバー間の見解の不一致ないし不適合と定義され[144]，業務，人間関係またはプロセスに関連して発生する[145,146]．入院患者の治療過程では50〜75%の症例で何らかの対立が起きることが報告されているが[147,148]，建前上は対等の医療従事者のチームが1人の患者の診療を分担する手術中では，より高い頻度で発生している可能性がある．

対立は正の効果を及ぼすこともあれば，負の効果を及ぼすこともある[149,150]．業務に関する対立は，通常は発生しない問題の評価やチーム内の意思決定における集団としてのパフォーマンスを改善するが[144]，同時にメンバーの満足，献身[151]，結束，有効感[145]を低下させることもある．これに対して，人間関係に基づく対立は，パフォーマンスと満足感の双方に重大な負の影響を及ぼし，チームの一員でいたいというメンバーの意欲を減退させる[151-153]．

手術室では，対立の管理が回避，屈服，競い合いのために十分に解消されないことが多いが，実際は協力と譲り合いを用いたほうがより良い結果につながる[154]．しかしながら，医師と看護師の関係や指導医とレジデントの関係のように，一方のメンバーが相対的に大きな力をもっていたり，年長者であったりするなどして職務上の地位が同等でない場合は，協力と譲り合いは特に困難となる[147,155]．手術室スタッフの73%は，手術室で生じた意見の相違は適切に解決されていると考えているが，29%は患者の診療に問題があることに気付いても声を上げるのは難しいと感じ，41%は異議を唱えることはできないと回答した[156]．医師が職務上の目標を達成するのに重要かつ必要と考える行動が，医師以外の医療従事者には厳しく，屈辱的と感じられることがある[157]．他者の身になって自身の行動を客観的に眺めることができていないという状況は，手術室と集中治療室のチームでよくみられる[158,159]．対立状況を描いたビデオを見せると，外科医，麻酔科医，看護師は現場の緊張の程度を同じように評価したが，それぞれが，それを招いた責任は自身の職種にはあまりなく，緊張を解決する責任も相対的に自分達には小さいと考えていた[160,161]．

対立解決のアプローチについては，よく知られたものがいくつか文献に登場する（7ステップモデル［7-step model］，原理に基づく対立解決［principle-based conflict resolution］，擁護/調査［advocacy/inquiry］）[144,146,162,163]．手術室チームに対立管理を教えるのは重要なことで，またそれを実際に教えることは可能である[157,163]．対立解決のための有効な手段は，大部分のチーム訓練法の重要なものの1つである[63,164]．

コーチング（Coaching）

チームにおけるコーチングとは，「チームに課された業務を遂行するにあたって，メンバーが共同作業を行って全体の情報と素材を業務に見合った形で活用できるよう支援することを目的とする，チーム内での直接の働きかけ」[165]

と定義され，期待を下回るパフォーマンスしか示していない個人のパフォーマンスを向上させたり，優れたパフォーマンスを発揮する見込みのある個人の技能を強化したりする方法として用いることができる[166]．コーチングの行動としては，チームにおける問題の特定やメンバー間で協議が行われるように誘導することなどがある[132]．

コーチングの効果としては，メンバー間の人間関係改善，メンバーの満足度向上，チーム力の強化，心理的安心感と安全の向上などがあげられる[132]．リーダーシップという概念と個人およびチーム双方の実力の向上（すなわち，個人またはチームを制御しているという感覚と，作業を完遂しようとの意欲）は強く結びついており，チームの実力の向上はチームのパフォーマンス自体を向上させる[167]．医療においては，コーチングにより看護の改革を促進し[168]，死亡率を減少させられる[63]ことが示されている．

リーダーシップのコーチングは，望ましい行動のひな型を示し，チームのパフォーマンスを強化する建設的なフィードバックを提供して，オープンなコミュニケーションと率直な発言を促す効果がある[86]．心臓手術チームの第一のリーダーは心臓外科医と考えられることが多いが，他のメンバーもリーダーシップを発揮して，他のメンバーに有益なコーチングを行うことができる．このチーム内のコーチングには，メンバーが建設的なフィードバックを使用して，実践が不十分な領域を特定し，業務の完遂を促すことも含まれ[112]，「助言や示唆，手引き，指示を与えて，起こり得るエラーに対する注意を促し，必要に応じて決まり事を破るメンバーと厳しく向き合う」などの行動が求められる[112]．しかし，これらのコーチング行動が有益なのは，チームのメンバーが提案と建設的批評を受け入れるだけの精神的素地を持っている場合だけである[112,169]．

エラーを減らすための対策

病院と手術室内でのチームワークを改善すべく設計された対策としては，チーム訓練とマニュアル，プロトコルなどがあり，対策はこれらの分類のいずれかあるいは複数に関連することが多い[170]．これらの対策は患者とスタッフの満足を高め，死亡率を低下させる[171-175]．プロトコルを使用して重要な連携作業（引き継ぎなど）を標準化すると，情報の内容とその整理を改善し，スタッフの参加者を増やすことができる[21,77,176,177]が，よくて心理的葛藤，悪くするとメンバー間の敵対心を増してしまうことも多い[45,178]．医師は，概して自身のノンテクニカルスキルを過大評価して，ストレス，疲労，停滞の影響を軽視する．また，チェックリストやマニュアルの使用を強制されると，個々の患者に合った医療を実施する能力が制約されると考えたり，自身の知性とスキルへの侮辱と感じたりもする[26,44,46,62,156,179,180]．しかし，ノンテクニカルスキルの訓練，チェックリスト，ブリーフィング，シミュレーション訓練，よく練られたコミュニケーションの手順が航空安全に果たした役割は否定できない．そして実際に，これらの対策が外科的ケアの質を改善するというエビデンスが増えている[181-185]．

手術においては，航空産業と同様に，プロトコルの活用とチームワークが最善の形で行われたとしても，エラーまたは事故（患者に害が及ぶエラー）を根絶することはできない．Perrow[186]が仮定したように，事故は高リスク産業にはつきものであり，最高のチームでさえゼロに抑えることはできない．変えられるのは，次の事故が発生する間隔が長いか短いかだけである．Vannucci ら[187,188]は，中心静脈ラインの留置後にガイドワイヤーの抜去を忘れた 4 件の事象のうち，2 件はガイドワイヤーの抜き忘れをなくすための集中的な訓練プログラムの実施後に発生したと記載している．ガイドワイヤーを抜き忘れた術者も，その訓練プログラムを適切に修了していた．したがって，チームワークの問題だけでなく，システムの問題を特定して安全を改善するには，有害事象の継続的なレビューが必要になるであろう．この作業（根本原因分析，警鐘事象の検出，臨床医の能力の検証など）は本ステートメントの目的ではないが，医療安全にとってはきわめて重要である．

チーム訓練

不十分なチームワークスキル（コミュニケーション，リーダーシップ，状況認識）がエラーや有害な結果の誘因となることについては，豊富なエビデンスが得られている[16,17,21-23,58,61,75]．これが示しているのは，ノンテクニカルスキルを改善するためのチームワーク訓練を実施すれば，エラーを減らせるはずだということである[164,185]．米国医学院は，「To Err Is Human」[7]と題した報告書を公表した後，航空産業における CRM の利用を通じたエラー削減の成功例を研究し，重症患者管理でのチーム訓練プログラムの導入を推奨した．しかし，そのためには CRM の原則を医療用に改変し，チーム訓練法を開発して，その結果を評価せねばならないので，これらの推奨事項の実践は進んでいない．しかしながら，最近行われたレビューにより，CRM 型の戦略がチームワークの改善に一貫して寄与し[170]，チームのパフォーマンスと患者の転帰（合併症の発生率など）を改善することが明らかになった[189]．また，医療安全に対するチームの認識と取組みは医療安全の質と大いに関連している[185]．

正規のチーム訓練の利点に関する報告は，緊急医療チームの行動の質が著しく改善し，臨床上のエラーの発生率が 31% から 4.4% まで減少したことを示している[190]．Halverson らは，4 時間の座学と現場でのコーチングからなるチーム訓練カリキュラムにより，術前のブリーフィングの導入が増加し[191]，コミュニケーションエラーが半減した[74]と報告した．このように，集中的な訓練セッションは，手術室でのコミュニケーションを有意に改善する[192]．

血管手術と一般手術において対策の前後を観察した研究で，Oxford 大学の研究者らが CRM に基づくチームワーク訓練（9 時間にわたる通常の講義と双方向的討論型の教育）を実施したところ[45,46]，チームワークのスコアとチームワーク風土のスコアが改善し，技術的なエラーと手順のエラーの発生率も低下した[46]．CRM の原則[193]に基づく退役軍人病院（Veteran's Administration）の Medical

Team Training program による全国規模の前向き研究では，年間死亡率が 18% 低下し[63]，このプログラムを推進すればするほど死亡率が低下するという量的関係も認められた．このチームトレーニングプログラムを四半期（3 カ月間）実施するごとに，手術 1 000 件当たり死亡者数が 0.5 人減少したのである[63]．このプログラムの実施は，手術部位の取り違えの減少[194]，ならびにベストプラクティスの遵守率の向上[195] という成果も生んだ．

もう 1 つの TeamSTEPPS は，エビデンスに基づき，しかも経済的裏付けがしっかりしている政府の出資による全国規模のチーム訓練プログラムである（http://teamstepps.ahrq.gov/）[196]．これは数百の施設で実施されたが，患者の転帰への影響を調べる経験的研究はほとんど行われていない．最近行われた研究は，このチーム訓練プログラムが，手術室でのチームワークとコミュニケーションスコアを有意に改善し，手術による死亡率と合併症発生率を低下させて，手術室での効率を改善し，患者の満足を高めることを証明した[164]．しかしながら，当初みられた改善の大部分は 12 カ月以内に失われ，改善を維持することの難しさも示された[164]．

チーム訓練の構成要素を定義する中で何が有効であったかを示すデータはほとんど存在せず，訓練期間も数時間[197] から数日[45,46,63] まで多岐にわたり，プログラムの内容もさまざまであった．これが，持続的な改善が困難な場合がある原因かもしれない[164]．また，安全措置を含む訓練を手術チームに受けさせ，訓練後に観察研究を行ったところ，この安全措置の遵守率はわずか 60% であり[198]，同様の他の研究では，ただちに改善されたコミュニケーションとチームのスキルが 3 カ月後には元に戻っていた[197]．しかし，同じくただちに改善された「安全措置が患者の転帰に直接的に関与するという意識」（threat-to-outcome score）は，3 カ月たっても有意な向上を維持していた[197]．利用可能なデータが示唆しているのは，チームは個人としてではなくチームとして訓練する必要があり[196]，シナリオを用いたシミュレーションの使用が効果的で[196]，有効な実施には経営陣と看護管理者のリーダーシップがきわめて重要であり[199]，さらには，訓練効果を高めて維持するには，コーチングの反復や継続が必要であるということである[197,198]．

タイムアウト，チェックリスト，ブリーフィング，デブリーフィング

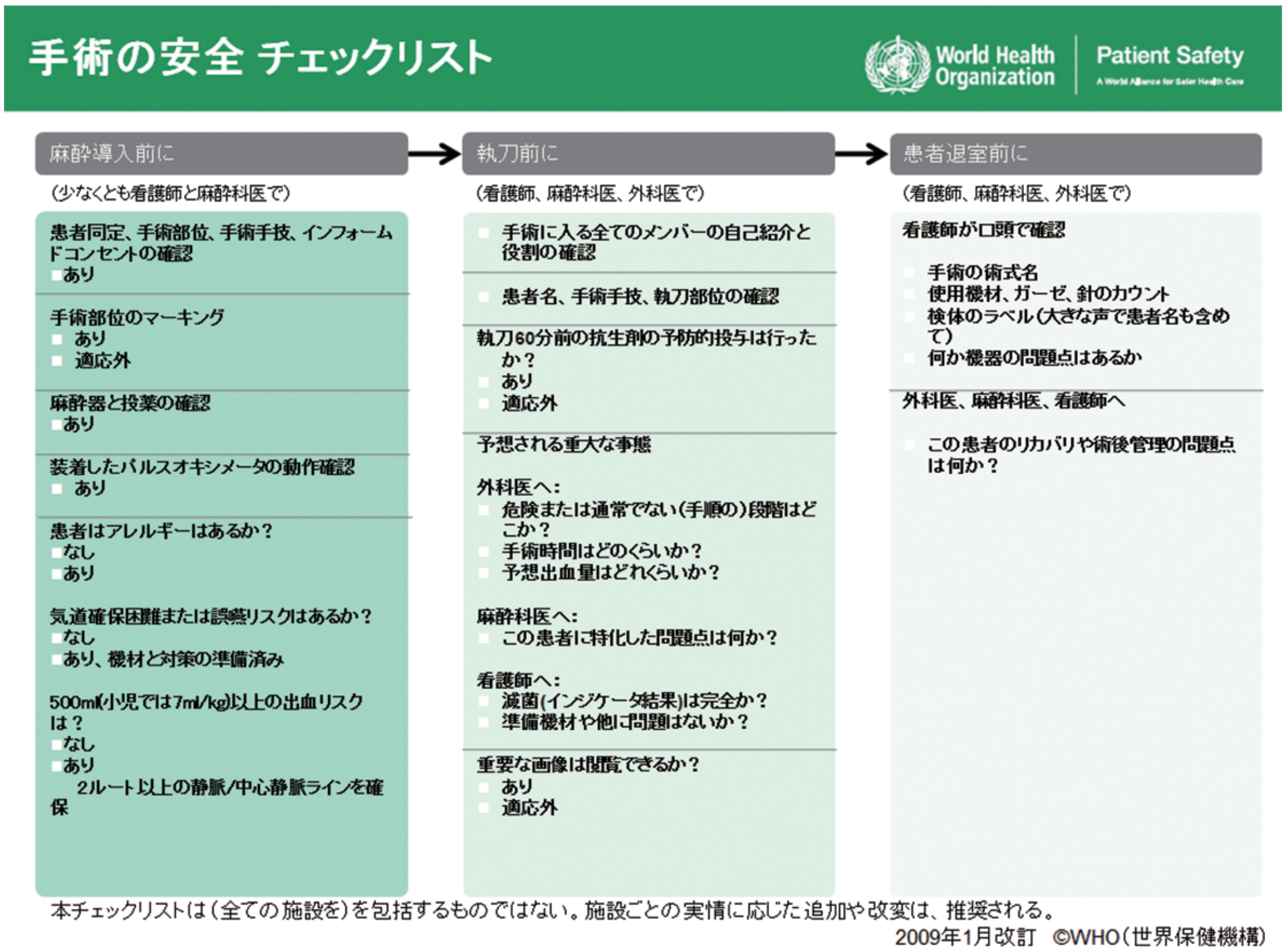
タイムアウト（timeout），チェックリスト（checklist），ブリーフィング（briefing）により，コミュニケーションエラーを減らすことができる．チェックリストとタイムアウトは概して回答が決まっており，特定の情報を声に出して確認する．これに対して，ブリーフィングは短時間の議論であり，手順化されてはいるが自由回答式のチェックリストに従って実施する．チェックリストは内容が毎回同じで，すべての処置に共通する手順をカバーしているのに対し，ブリーフィングの内容は毎回異なり，処置の異なる側面に焦点を当てている．ブリーフィングでは会話が行われ，手術室のスタッフ全員に「詳細を確認し，情報を交換し，疑問を尋ね，問題や懸念を特定する」機会を提供する[178]．デブリーフィング（debriefing）は，複雑な作業が完了した後に，そこで学んだ内容の共有を促進することを目的として行われ，たいていは「今日は何が上手く行ったか」および「明日もっと円滑に行えるようにするために何ができるか」などの質問が出される．

タイムアウトを初めて提唱し，その後 2003 年に実施を義務付けたのは米国医療機関認定合同委員会（Joint Commission on Accreditation of Healthcare Organizations）であり，その目的は手術部位の取り違えを減少させることであった．同委員会が作成した汎用プロトコル（universal protocol）では，手術部位に印を付けて患者を同定するとともに，手術または処置の直前に「タイムアウト」を行うよう求めている[200]．

チェックリストは単純な認識ツールであり，単純作業（買い物など）と複雑な作業（航空機を飛ばすなど）の両方を改善でき[201]，見落としがちなルーチン業務を思い出させる上で有効である[202]．世界保健機関（World Health Organization：WHO）は「手術安全チェックリスト（Surgical Safety Checklist）」を開発し，世界中で導入するように強く推奨している．これは，手術中に（1）麻酔導入の前，（2）皮膚切開の前，そして（3）患者を退室させる前のタイミングで，標準化されたタイムアウトを計 3 回行うというものである[171,203]．これらのタイムアウトでは，患者確認，手術部位，抗生物質とパルスオキシメトリーの使用，薬物アレルギーの有無など広範囲にわたる情報が確認される．これの導入により死亡率が低下することが示されている（図 3）[171,204]．

チェックリストは，腹腔鏡下胆嚢摘出術のような一般的な手術において重要な手順を確認したり[205]，発生率の低い危機的状況が起こった場合の指示を与えたりする方法としても使用できる．Ziewacz ら[206] は，手術室で最も発生頻度が高かった危機的シナリオを 12 種類（挿管失敗，無脈性電気活動，空気塞栓，悪性高熱など）を同定し，それぞれに特有かつ不可欠な処置を評価する指標を科学的根拠に基づいて開発した．初期の研究では，危機管理チェックリストがある場合とない場合のそれぞれについて，2 つの手術チームに 4 つの危機的状況をシミュレーションさせたところ，チェックリストを使用したほうが重要な手順の不遵守が 1/6 に減少することが判明した[206]．また，チェックリストがある場合とない場合で手術時の危機対応シミュレーション（17 の手術チームが計 106 のシミュレーションを実施）を行った Arriaga ら[207] による最近の研究では，チェックリストの使用により，救命のための手順が適切に行われなかった事例が有意に減少した（手順忘れの発生頻度はチェックリスト使用時では 6%，非使用時では 23% であった）．

チェックリストを使用すれば，ベストプラクティスの実践を促進したり，膨大な量に及ぶガイドラインを簡略化して最も重要でエビデンスに基づく一連の業務だけをまとめたりすることも可能である[208]．さらに，チェックリストによって患者の転帰の改善を図ることもできるが，そのた



手術の安全 チェックリスト

World Health Organization | Patient Safety
A World Alliance for Safer Health Care

麻酔導入前に

（少なくとも看護師と麻酔科医で）

患者同定、手術部位、手術手技、インフォームドコンセントの確認
- ありあり

手術部位のマーキング
- あり
- 適応外

麻酔器と投薬の確認
- あり

装着したパルスオキシメータの動作確認
- あり

患者はアレルギーはあるか？
- なし
- あり

気道確保困難または誤嚥リスクはあるか？
- なし
- あり、機材と対策の準備済み

500ml(小児では7ml/kg)以上の出血リスクは？
- なし
- あり
  2ルート以上の静脈/中心静脈ラインを確保

執刀前に

（看護師、麻酔科医、外科医で）

- 手術に入る全てのメンバーの自己紹介と役割の確認

- 患者名、手術手技、執刀部位の確認

執刀60分前の抗生剤の予防的投与は行ったか？
- あり
- 適応外

予想される重大な事態

外科医へ：
- 危険または通常でない（手順の）段階はどこか？
- 手術時間はどのくらいか？
- 予想出血量はどれくらいか？

麻酔科医へ：
- この患者に特化した問題点は何か？

看護師へ：
- 滅菌(インジケータ結果)は完全か？
- 準備機材や他に問題はないか？

重要な画像は閲覧できるか？
- あり
- 適応外

患者退室前に

（看護師、麻酔科医、外科医で）

看護師が口頭で確認

- 手術の術式名
- 使用機材、ガーゼ、針のカウント
- 検体のラベル(大きな声で患者名も含めて)
- 何か機器の問題点はあるか

外科医、麻酔科医、看護師へ

- この患者のリカバリや術後管理の問題点は何か？

本チェックリストは（全ての施設を）を包括するものではない。施設ごとの実情に応じた追加や改変は、推奨される。

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図 3　世界保健機関の手術安全チェックリスト（World Health Organization Surgical Safety Checklist）[201]．IV は静脈ラインを示す．出版者の許可を得て参考文献 203 から転載．©2009 World Health Organization．無断転載を禁止する．

めには，チェックする個々の項目が単純で，エビデンスに基づき，職場の実状に合っている必要がある[201]．チェックリストを導入することで，中心静脈ラインの感染と人工呼吸器関連肺炎の発生率，さらに死亡率を低減できることが示されている[208-210]．

しかしながら，医療安全を向上させるのはチェックリストを実現する技術ではなく，チーム全体の適応努力であると専門家らは主張している[211]．チェックリストに書かれた行動を目標として抜本的に自身の行動を変えようというチームをあげての意欲がない状態で，ただ上層部がチェックリスト導入を強制するようなことがあれば，臨床医はむしろ，チェックリストによって自身の権威が損なわれ，子ども扱いされ，患者に対する有効な診療が遅れると感じる恐れもある[212,213]．オランダでは，Dutch Health Care Inspectorate によって 2008 年までに WHO チェックリストの使用が義務付けられたが，完全な形で実践したのは全症例 11 151 件中わずか 39% であった．しかし，総死亡率は 3.13% から 2.85% に低下し，この死亡率の低下にはチェックリストの遵守との関連が強く認められた[204]．

チェックリスト導入プロジェクトで最も大きな効果を収めたものの 1 つに，カテーテル関連感染の根絶を目的とした Michigan Keystone Project がある[208]．このプロジェクトが成功したのは，単にチェックリストを提供して使用するよう命じるのではなく，実務と確かなデータの使用を改善してルール作りを進めるという共通の使命で結ばれた「緊密なネットワーク」を作り上げたからであると分析されている[214]．

ブリーフィングを行えば，チームがこれから行う業務に関して共通のイメージを確立することができる．そのため，軍隊，パイロット，港湾労働者らは，このブリーフィングという方法を広く用いてきた．術前にブリーフィングを実施すれば，チームのメンバーはこれから行う手術に関する知識と起こりうるイベントの知識を共有できる[179,215]．航空産業では，コックピットでのブリーフィングは細大漏らさず技術的な検証を行う上で重要とされるが，ここで重要となるもう 1 つの要素は，チームのメンバーが自身が感じている懸念を何であれ率直に述べなければならないことを明確にすることである[84]．すなわち，パイロットは，安全に関わる情報はすべて伝えてほしい，そのためには自分に異議を唱えることになっても構わない，とはっきり言

葉にして伝える必要がある．外科手術では，CRM を導入する前の航空産業に普通にみられたのと同様に，厳しい上下関係が存在し，医師以外のメンバーは医師に異議を唱えるのは困難である[216]．前述のように，手術室スタッフの多くが，意見を率直に述べたり，意義を唱えたりするのは難しいと報告している[156]．

ブリーフィング自体は，チーム訓練や正式導入の以前は，ほとんど実施されていない[217,218]．ブリーフィングの導入にあたっての課題の 1 つは，ブリーフィングの構成要素に関する医療従事者間の見解の相違である．英国で実施された調査では，外科医の 39% がブリーフィングを毎回実施すると回答したが，同じように答えた看護師はわずか 4% であった[179]．同様の現象は，Mayo Clinic の心臓外科でブリーフィングを導入しようとした際にも認められた（未発表データ，T. M. S.）．また，3 733 例を対象とした Safe Surgery Checklist Study においても，術前にブリーフィングを実施している例はほとんどみられなかった[171]．

Surgical Patient Safety System（SURPASS）のチェックリストには，ブリーフィングとデブリーフィングが含まれており[182]，確定した賠償請求を調査した研究では，ブリーフィングを含む SURPASS チェックリストを使用していれば，有害事象の誘因の 3 分の 1 を排除し，死亡例の約 40% を予防できていた可能性[219]が示されている．そして SURPASS の導入により，合併症の発生率が 27.3% から 16.7% に，院内死亡率が 1.5% から 0.8% に低下した[183]．WHO 手術安全チェックリストにもブリーフィングに関する多くの領域が含まれており，その導入により死亡率が 1.5% から 0.8% まで，合併症の発生率が 11.0% から 7.0% まで低下し，ほぼ同様の結果が得られた[171]．この研究は，5 大陸の 8 病院で 3 500 件を超える症例を対象として実施されたもので，基本的なものから高度なものまで，あらゆる手技が用いられていた．さらに，25 513 名の患者を対象にした最近の研究において，van Klei ら[204]は，術前のブリーフィングを含む WHO チェックリストの導入により，入院 30 日間当たりの死亡率が 3.15% から 2.85% まで減少したことを示している（オッズ比：0.85，95% 信頼区間：0.73–0.98）．この効果は，チェックリストの遵守によりさらに確かなものとなった．チェックリストを完全に遵守した場合のオッズ比は 0.44（95% 信頼区間：0.28–0.70）で，これに対して部分的に遵守した場合とまったく遵守しなかった場合は，それぞれ 1.09（95% 信頼区間：0.78–1.52）と 1.16（95% 信頼区間：0.86–1.56）であった．

近年，退役軍人健康管理局（Veterans Health Administration）は，大規模なチームワーク訓練対策の一環としてブリーフィングの実施を義務付けた．すると，チーム訓練実施後に死亡率が 18% 減少した[63]．さらに，他の 2 件の研究では，ブリーフィングとデブリーフィングの導入後に抗生物質と深部静脈血栓予防薬に関する投薬遵守率が上昇した[195,220]．注意散漫と手術の流れの停滞は，深刻な手術エラーの大きな原因であるが，ブリーフィングはこの両者を減少させる[20]．Gillespie ら[221]は待機手術と緊急手術を観察し，チームのメンバーが互いに相手をよく知っていることとコミュニケーションの齟齬の発生数に逆相関があり，手術の停滞回数とコミュニケーションの齟齬の発生数に順相関があることを見出した．組織立った短時間のブリーフィングの導入により，手術の停滞回数，症例に関する知識の欠如，スタッフ間のコミュニケーションの齟齬が半減する[222]．この結果は，もともと「メンバー同士が互いによく知っている」チームに導入した場合も同様であった．また，看護師が必要な補給品を取りに滅菌室に移動する回数および滅菌室での滞在時間が減り，廃棄物の量も減少した[222]．さらに，別の介入研究では，術前のブリーフィングにより手術の予期せぬ遅れが 31% 減少した[68]．

ブリーフィングは患者の転帰を改善するだけでなく，チームワークの風土，行動，パフォーマンスを強化する．ある調査では，ブリーフィングを日常的に実施していると述べた回答者は，ブリーフィングを実施していないとした回答者と比べて，良好な安全風土を持っていると報告した[218]．ブリーフィングは，リスクの減少と強化された協働の認識と関連する[66]．また別の研究[176]では，ブリーフィングの後で参加者が，「その意見は重要なようだ．自信を持ってほしい」とか，「みな，納得できない時は口に出して言おうと考えるようになりました．もう，しっぺ返しの心配をしなくていいですから」とコメントした．さらに，イスラエルで実施された研究では，ブリーフィングにより，まれにしか発生しない事象が 25% 減少し，メンバーが「自身の業務，チームワークおよび医療安全を高く評価するようになった」ことが判明した[217]．そして，英国で 6 カ月間にわたって行われたブリーフィングに関する研究では，スタッフが，チーム文化が改善され，潜在的な問題が浮き彫りになったと認識していることが明らかになっている[223]．O'Neill[224]は，リーダーシップはスタッフを尊厳と敬意をもって扱うような文化を生み出すものでなければならず，日常的に優れた医療を実施するには，透明性と問題共有が必要であると記載している．そして，この透明性と問題共有をもたらすのがブリーフィングとデブリーフィングなのである．

ブリーフィングにより手術時間が延長することはなく[225]，手術の中断と注意散漫を減少させることで，むしろ手術時間を短縮できる[222]．35 000 件を超える症例を対象に実施された研究では，ブリーフィングの長さは平均 2.9 分（分布：1～5 分）であった[215]．

ブリーフィングの効果を支持する確固たるエビデンスがあるにもかかわらず，「ブリーフィングは手術室の安全のために強制されるもの」という考え方がある[212]．その背景には，医療従事者らが自身のノンテクニカルスキルを実際より過大評価する傾向があり，これが，これ以上の改善は必要ないという見方を招いている恐れがある[26,178,213]．外科医の中には，ブリーフィングがチームワークを改善することに同意しない者もいるが，実際にブリーフィングを導入した外科医らは，効率が上がり，チームの勤労意欲が高まったと報告している[179]．チェックリスト介入群に無

作為に割り付けられた外科医らは，対照群と比較して，安全に関するチーム行動を積極的に実践していた．しかし，その一方で，快適さ，チーム効率，コミュニケーションについては低い評価を付けており，これは，チェックリストまたはブリーフィングの使用に慣れるまで居心地悪く感じることがある可能性を示している[226]．有効に導入するには施設とリーダーの役割ならびに現場の協力が重要であるが[227]，それだけでは不十分である．それは，ブリーフィングとデブリーフィングに対するさまざまな反応（受容から抵抗まで）により導入が阻害されるためであり，これらの方法を有効に導入するには，この点について理解しておく必要がある[178,179,218]．

デブリーフィングについてはあまり研究されていないが，退役軍人健康管理局による大規模研究である Veteran's Health Administration Study[63] を始めとするアウトカム研究で，デブリーフィングが検討されている．それによると，デブリーフィングを実施すると，医療チームのメンバーは何が上手くいき，何が上手くいなかったかを評価できるようになり，チームの結束を強め，次回のパフォーマンスを改善することができる[176]．また，今後の計画を作成するとともに，システムの改善を検討して実施し，コミュニケーションが不十分な部分に対処する機会も得られる[215]．デブリーフィングの方法と実践プロセスについては既刊の文献を参照のこと[228-230]．

結論としては，手術時のブリーフィングとデブリーフィングが合併症発生率と死亡率を著明に低下させることを示唆した文献が増えている．導入に対する障害に関する研究も有用であろうが，今日までに示されたエビデンスが支持しているのは，心臓手術においては症例ごとに組織立ったブリーフィングとデブリーフィングを行うのが有効であるということである．

シミュレーション

航空産業ではシミュレーション訓練が普及しており，個人の技能訓練や個人およびチームのテクニカルおよびノンテクニカルスキルの評価のほか，エラーの発生機序とその防止を検討する研究にも利用されている[89]．これに対して医療分野では，シミュレーション訓練の導入が遅かったが，技術的および教育的ツール，そして医療現場に則したシミュレーション訓練を支える技術が急速に進化し，発展している[231,232]．シミュレータは，技能の教育[233-235] とその技能の評価[235] に有効なツールとして登場した．シミュレータを使ったこれらの技能の評価が専門医認定プロセスに組み込まれている医学領域もある[236,237]．

シミュレータは，スタッフのノンテクニカルスキルの評価と訓練手段としても有望である[36,128,238-240]．現在の患者シミュレータは正確で信頼できる臨床シナリオを用いて，本物の臨床機器を用い，きわめて現実的な患者データを提供する．この技術を利用するには，教育者はカリキュラムと評価項目を策定して，教育環境の妥当性を実証する必要がある[241-244]．初期の研究の多くは，テクニカルスキル訓練とその評価に焦点をあてている[36,38] が，最近のエビデンスからは，チーム訓練とノンテクニカルスキルの開発にシミュレーションを用いるのが有効であることが示されている[231,243,245,246]．

シミュレーションを利用すれば，患者をリスクにさらすことなく，ヒューマンファクター（疲労，ストレスなど）がテクニカルスキル[43,247,248]，危機におけるコミュニケーション様式[240]，教育法の研究[249]，テクニカルスキルとノンテクニカルスキルの関係[35,250]，およびチームワークと臨床でのパフォーマンスの関係[251] などに与える影響を科学的に検討することも可能である．

医療現場に則したシミュレーションでは，最適な学習環境を提供できる可能性がある．これが特に有効となるのは危機的状況に関する訓練であり，患者に害を及ぼす恐れなしに，個人とチームに緊急事態における認識課題，ストレス，身体的要求などを体験させることができる．たとえば，致死的なインシデントが発生すると，チームは時間的なプレッシャーの下で共同作業を要する複雑な対応を迫られる．しかし，このようなインシデントは滅多に起きないため，「実際の診療現場」では訓練できない[252]．これに対して手術シミュレーションであれば，チームのコミュニケーションと困難な臨床的問題への周到な対応を練習し，正確に評価し，明確に改善させることが可能である．Yerkes と Dodson[253] は，今日では有名なマウスの学習に関する研究を行い，学習は適度な刺激（興奮）により強化され，過度の興奮により退化することを示している．

シミュレーションが特に適しているのは，人工心肺の緊急事態に関する訓練で，これが初めて文献に記載されたのは 1977 年のことであった[254,255]．この訓練では，成人および小児患者の循環を模したコンピュータ制御の油圧モデルを利用し，通常の状態と危機的状況をシミュレーションできる[252,257]．2002 年の調査では，臨床工学技士のほぼ全員が，このシミュレーション訓練は有用であろうと回答したが，実際に訓練を受けたことがあるのはわずか 17% であった[258]．臨床現場に則したシミュレーションを用いた，手術チーム全体の危機管理に関する教育については，最近研究が実施され，参加者は最も重要で，高い改善がみられたとして以下の 2 つの領域をあげた．1 つはきわめて重要な情報を率直に伝えるよう促すこと，もう 1 つは異なる職種の間のコミュニケーションの改善で，これには，意図する受け手を明確に定め（情報を伝える相手の名前を呼ぶ），口頭でのやりとりにおいては必ず復唱することが重要である[259]．

組織立ったコミュニケーション手順

コミュニケーションを改善するのは，情報の提示と想起を円滑化する情報交換手順[260] と，受けた情報を認識して内容を検証する閉じたコミュニケーション（closed-loop communication）である[261]．閉じたコミュニケーションは，ストレスに満ちた状況と，意図された受け手が明瞭でない場合に特に重要になる[72,262]．この形式のコミュニケーションにより，チームが目的，予想，状況認識，計画遂行を確実に共有できる[117]．

構造化コミュニケーション技術には，その文字を含む単語の使用（アルファの a，ブラボーの b，チャーリーの c

など）や 1 桁の数字を使った数の表現（eleven は seven と紛らわしいため「one one」と言う，【翻訳者追記：thirteen は thirty と紛らわしいので one three と言う】など）があり，曖昧さを排して明瞭さを高め，受け手に確実に伝えることができる．数十年前から軍隊と航空産業で使用されてきたものに，復唱，SBAR（状況・背景・評価・提案：Situation-Background-Assessment-Recommendation），批評的主張，擁護/調査があり，情報伝達を標準化し，情報の喪失を減らし，上司とのコミュニケーションを容易にするのに有効である．医療現場での有効性に関するデータはほとんど得られていないが，それでも組織立ったコミュニケーションという手法は，一般にエラーの減少と死亡率の低下に有効な方法として，チーム訓練プログラムのコアカリキュラムの一部とされている[63]．人工心肺を用いる手術の際に手順に基づくコミュニケーションを実践すれば，外科医/臨床工学技士のコミュニケーションエラーを 40% 近く減らすことができる[263]．コミュニケーションスキルの測定を目的に実施された，包括的なチーム訓練プログラムに関するシミュレーションを利用した研究は，これらの対策が有効であることを証明した[264]．しかし，心臓手術に関するコミュニケーション訓練の有効性，または組織立ったコミュニケーション手順に関する厳密な研究は不足している．

チーム間のコミュニケーション

チーム間で患者とその患者情報を受け渡すことを，引き継ぎ（handover）あるいは受け渡し（handoff）と言い，医療では頻繁に行われる．そしてチーム間とチーム内の引き継ぎの機能不全が，医療上のエラーの大きな原因と特定されている[78,265–269]．米国医療機関認定合同委員会では，引き継ぎを，患者固有の情報を医療従事者間で授受して患者が受ける医療の連続性と安全を確保するための同時発生的な対話型プロセスと定義している．引き継ぎに関する標準化されたコミュニケーションは，2006 年の医療安全の目標（目標 2E）に定められた[270]．心臓手術を受ける患者の場合は，循環器科外来（術前の検査と評価）から，外科医と手術室チーム，集中治療室チーム，病棟チーム，そして多くの場合，長期にわたる経過観察と加療のために再び循環器科外来へと何度も引き継ぎが行われる[271]．

Gawande らは，医療過誤保険を扱う 4 つの保険会社を対象として事例研究を実施し，手術エラーの分析を行って，その結果を 2 報の文献にまとめた[78,268]．これによると，エラーが患者の傷害に至った 258 件の手術事故事例のうち，60 件にコミュニケーションの失敗が関与し，結果として患者に傷害が及んでいた[78,268]．そしてコミュニケーションの失敗の 43% が医療従事者間の引き継ぎの際に，全体の 19% が部門間（チーム間）の引き継ぎの際に起きており，その大半（92%）が，口頭による送り手と受け手が 1 対 1 の情報伝達であった．また，これらの機能不全は，重要な情報の省略（49%）または情報の不正確な解釈（44%）に起因していた[78,268]．

引き継ぎの失敗に関する初期の研究の多くが，患者の診療をレジデント同士で引き継ぐなどのチーム内の引き継ぎに注目していた．Massachusetts 総合病院（Massachusetts General Hospital）で実施された調査によると，回答したレジデントの 59% が，前回の実地研修の間に引き継ぎの失敗により 1 名以上の患者に害を与え，12% が重大な害を与えたと報告した[269]．また，落ち着いた状況で引継ぎが行われることは滅多になく，業務の中断が頻繁に起きていた[269]．同様の調査では，レジデントの 31% が，自身の患者の引き継ぎの準備が整っていなかったことで発生した事象を報告していた[272]．チーム間の患者の移送に起因するインシデントに関する研究では，29% の事例で，引き継ぎ自体がまったく行われていなかった[273]．

患者情報の複雑さ，次のチームに微妙な生体情報を客観的に伝える困難さ，頻繁に発生する注意散漫を考えれば，患者の移送の大多数でコミュニケーションの失敗が起きるのは驚くようなことではない．文献は，引き継ぎプロセスが非常に多様で，組織立っておらず，環境騒音や注意散漫を伴い，他の業務と優先順位が競合する（情報を口頭で伝えながら，監視装置をリセットする，など）という現場認識を支持している[274]．心臓手術患者の引き継ぎに関する観察研究によると，重要な内容を報告していたのは 53% にすぎず，コミュニケーション 1 分当たり注意散漫が平均 2.3 回起きていた[275]．

患者情報伝達の不具合は，外科的処置のどの段階でも発生し，その大多数は，術前術後の引き継ぎの際に発生する[266]．口頭で伝えられた手術情報は 30% だけで，多くの場合，外科医ではなく麻酔科スタッフが伝えていた．英国で実施された調査は，手術室から回復室への患者ケアの引き継ぎが標準化されておらず，関与するスタッフ次第で変わることを示している[276]．伝達する情報の内容と伝達のタイミングについての考えはばらばらで，これを麻酔科と回復室のスタッフが担い，引き継ぎを通じてどの時点で責任が移るのかが標準化されていなかった．プロセスの研究では，手術室/回復室の間の引き継ぎで伝達すべき重要な情報と，完了すべき業務を厳格に定義した上で，これを評価した[265,277]．すると，重要な事実のほぼ 3 分の 1 が伝達されず（29 個の定義済み項目のうち中央値で 9.1 個が省略された），業務の 3 分の 1（8 個の定義済み項目のうち，中央値で 2.9 個で職務上のエラーが発生した）が完了されていなかった[277]．また，多職種チームの重要なメンバーが引き継ぎプロセスに参加しないことがよくあった[265]．

引き継ぎ情報の質の低下は医療の連続性全体で発生する．非常に重要な情報の伝達率は，手術室から回復室への引き継ぎでは 56%，回復室から病棟への移送では，わずか 44% であった[266]．そして，観察した患者の 75% に，このような引き継ぎの失敗に起因する臨床上のインシデントまたは有害事象が 1 件以上発生していた[266]．

引き継ぎの際にコミュニケーションの失敗が起きる原因，または，伝えるべき重要な情報を分析した研究はほとんどなく，さらには「必須の伝達情報」もそれが本当に妥当であるのかまったく検証されていない．このような制約

はあるものの，引き継ぎの質を高めるよう設計された対策は，ほぼすべてが有効なことが示されている．先天性心疾患手術後の手術室から集中治療室への移送の引き継ぎに関する前向き研究では，チームワークに基づくプロセスと手順の実施により，引き継ぎ 1 回に発生するエラーの数が 6.24 回から 1.52 回に，口頭でのコミュニケーションにおける必須情報の省略が引き継ぎ 1 回当たり 6.33 回から 2.38 回までそれぞれ低下した[77]．また，自動車レースの最高峰である F1 のピットストップでの作業手順に基づくプロトコルを作成して実施したところ，引き継ぎ前の準備，情報伝達の前に完了しておくべき業務，伝達すべき情報を特定でき，これにより技術的なエラーと情報の省略の発生頻度を下げ，引き継ぎにかかる時間を 10.8 分から 9.4 分まで短縮することができた[278]．

別の研究では，1 ページの単純な穴埋め式シートの導入により，引き継ぎスコアの合計点と手術中の情報サブスコアが改善し，引き継ぎの所要時間の延長もみられなかった[279]．Craig ら[280] は，異なる引き継ぎシートを用いた小児循環器分野の研究で同様の結果を得ている．このシートの導入により，注意深さ，系統化，情報の流れが著しく改善し，業務の中断が減少した．最後に，心疾患患者を手術室から集中治療室に移送する際に標準化された引き継ぎ手順を実践したところ，重要なスタッフ全員の引き継ぎへの参加が 0% から当時は 68% まで増加して，情報の省略が 26% から 19% まで減少し，集中治療室の看護師の満足度スコアが 61% から 81% まで上昇した[281]．しかし，シート導入後も欠落した情報の割合が 19% のままであったことは，問題の深刻さを示している．

電子技術を用いた引き継ぎ手順が提案されているが，データはほとんど存在しない．MAGIC（Multimedia Abstract Generation of Intensive Care）という自動化手順の枠組みは状況認識的手法と量的手法を統合したもので，電子的技術に基づき，ブリーフィングでの引き継ぎ情報一式の提供を可能にする[282]．また，周術期管理看護師協会は，引き継ぎ書類の見本と医療従事者のための教材を含む教育プログラムを開発した[283]．

自由度の高い引き継ぎ手順は，基本的なトピックの種類と順序だけを示し，記憶を助ける SBAR（状況・背景・評価・提案）を使用することが多い．この SBAR を引き継ぎの際に用いると，患者，麻酔，手術に関する情報のより正確な伝達が容易になることが示唆されている[284]．また，心臓手術に関わる看護師も，これを利用して心臓手術における医療の連続性を通じた患者の移送を円滑に行っている[285]．さらに，ビデオとロールプレイを用いて SBAR を教えるカリキュラムにより，指示入力の際のエラーの発生率が低下した[286]．

物理的に離れた場所にいるチーム（患者を紹介した循環器専門医と心臓外科医）の間のコミュニケーションは一層困難である．しかし，心臓カテーテル病院と心臓手術を行う病院の間の専用のインターネット回線を通じて血管造影データを電子的に送受信することで，心臓カテーテル検査を実施してから手術を決断するまでの時間が 36 時間から 1 時間まで短縮され[287]，診断から緊急手術までの時間も，56 時間から 18 時間になった．患者の転帰や経済学的側面に関するデータは得られていないが，必須の患者データの電子送信によりエラーを大きく減らし，医療を迅速に提供できる可能性がある．

複数回の引き継ぎを含む医療の連続性を検証した対策がいくつか存在する．1 つのアプローチは，主として 1 つのベッドを多目的に使うことで引き継ぎ回数を最小限にし，引き継ぎのエラーを減らそうというものである．このアプローチでは，1 人の患者が，同じ看護師と外科医のチームによる集中治療，ハイケアユニット治療，病棟レベルの治療を同じ場所同じベッドで受ける．全国基準（胸部外科医学会データベース（Society of Thoracic Surgeons Database）http://www.STS.org）と比べて，1 つのベッドを多目的に使用すると，人工呼吸器使用日数と集中治療室への収容，入院日数が減少し，胸骨創傷感染が発生せず（0/610），患者 1 人当たり平均 6 200～9 500 ドル削減できた[288]．

要　約

1. コミュニケーションスキルは，手術室におけるチームワーク行動のうち，現状では最も不十分な項目の一つである．
2. 一般外科と心臓外科双方の手術を対象とした複数の研究により，エラーと有害な結果の根本原因で最も多いものがコミュニケーションの失敗であると指摘されている．
3. チームワークの重要要素は 6 つの C，すなわちコミュニケーション（Communication），協力（Cooperation），共同作業（Coordination），認識（Cognition）（集合的な知識と共通の理解），対立解決（Conflict resolution），コーチング（Coaching）（チーム訓練）で要約することができる．
4. ヒューマンエラーを減らすための対策の一種に，チームワーク訓練プログラムがある．退役軍人病院の Medical Team Training（MTT）や TeamSTEPPS プログラム（米国医療研究品質庁［Healthcare Research and Quality］と国防総省［Department of Defense］による政府出資のプログラム）などの研究では，手術室でのチームワークとコミュニケーションスコアの有意な改善と手術患者の死亡率および合併症発生率の低減が証明された．しかしながら，こうした改善を持続していくためには，コーチングの反復や継続が必要である．
5. エラーの減少を目的とする他の対策には，WHO が開発した手術安全チェックリストなどのチェックリスト，術前のブリーフィングと術後のデブリーフィングなどがある．チェックリスト適用プロセスにより患者の転帰が改善し，中心静脈ライン感染，人工呼吸器関連肺炎，そして死亡率が低下することが研究から明らかになっている．
6. 他の研究は，ブリーフィングが注意散漫と流れの停滞の発生回数を減らして，チームのパフォーマンスを強化するとともに，合併症を減らす可能性があることを証明した．しかしながら，これらのツールの導入は心理学的障害

と文化的障害のためあまり進んでいない．

7.　シミュレーションは，手術室のスタッフのコミュニケーション，協力，共同作業，認識，対立解決，コーチングを含むノンテクニカルスキル，ならびにテクニカルスキルとノンテクニカルスキルの関係を評価でき，訓練するための有望なツールである．

8.　心臓手術を受ける患者はチームからチームに何度も移送され，その引き継ぎの際にはコミュニケーションの失敗が日常的に発生する．この原因や，本当に必要な情報は何かを分析した研究はほとんどないが，引き継ぎの質を改善すべく設計された対策に関する研究はすべて，情報の欠落または誤解が減少することを実証している．

物理的環境

ヒューマンファクターの問題

「環境」の定義は，「人間を取り巻く状況，物体または状態」である[289]．手術室の環境は，物理的空間，機器，人間（スタッフと患者）からなり，人間工学は「人間が使用する物の設計および手配に関係する応用科学で，人間と物の最も効率的かつ安全な相互作用を生むことを目的とする」[289]と定義される．しかし，手術室での人間工学は，医療安全という観点からいうと最適状態にあるとはいえない[8, 290–292]．過去 10 年間に外科的処置に関する新技術が大量に導入されたのに伴い手術室が過密状態になっている一方[295]，手術室の設計と空間の改善がこの変化に追い付いていないのである[293, 294]．このように手術室や機器の設計が人間工学的に不適切であることは，手術の流れの停滞につながる大きな要因となり，結果として技術的なエラーを招くと広く考えられており，また，手術部位感染との関連も報告されている[20, 294–296]．

空間と設計

手術室の広さとレイアウトの双方が安全に影響する．小さな手術室では，機器が空間を塞ぐことで手術の流れが停滞し，逆に過度に広い手術室では，スタッフが長い動線を移動しなければならない．Brogmus ら[297]は，労働災害の 2 番目に多い原因が，段差のないところで足を滑らせる，つまずく，転倒する事故であったと報告し，つまずく原因として，コードとケーブル，目立たない機器や備品，保護マットと粘着マットの 3 つをあげた．また Cesarano と Piergeorge[298]は，散らかった機器とからまったコードが邪魔をして医療従事者が安全に医療行為を行うことができず，患者とスタッフの双方を危険にさらす現象を「スパゲッティ症候群（spaghetti syndrome）」と記載した．このような環境では，患者の近くに電源と機器を持ち込むこと自体が非常に困難になる[299]．

スタッフと移動

手術室内にスタッフが動き回ることは避けようがないが，その結果としてスタッフの注意がそらされたり，感染リスクが高まったりすることで，手術室の安全が損なわれる場合がある．手術室内をスタッフが移動する目的の約 20% が情報の獲得，25% が休息，そして，20% が機器の調達と除去である[300]．Healey ら[19]は，手術室内の移動と手術中の外科医の注意をそらすスタッフの交替といった干渉の程度を関連付けて，これらの注意散漫は手術室での不具合の要因の 1 例であるが，これは改善できると結論付けた．

スタッフの移動の増加はドアの開閉頻度が高まることを意味し，これにより汚染源となりうる物質を除去する換気システムの効果が低下することが示されている[301]．また，手術室の空気と廊下の空気が混じることで細菌数が増加する可能性もある[302]．整形外科と一般外科の事例では，1 時間当たりのドアの平均開閉回数は 37 回から 135 回にわたり，1 分間に約 1 回であった[300, 303]．心臓手術においては，ドアの平均開閉回数は 1 時間に 19.2 回で，人工材料を使用する場合は 22.8 回であった[304]．これは，1 時間当たり平均 6.4 分間ドアが開いている計算になる．また，使用していない手術室のドアが廊下に向かって開いたままになっていると，室内の微生物数が大きく増加する[305]．

手術中にスタッフが新たに手術室に入ると，感染リスクが高まる恐れがある．必要な最低人数より 5 人余分に手術室に入った場合は，微生物数が 15 倍を超える[305]．整形外科領域の外傷手術に関する他の研究は，コロニー形成数と，手術室内の人数の間にはっきりした正の相関があることを明らかにしている[306]．この手術室内の人数と手術感染の発生率との関係は，人数が多いことそのものか，または手術室の出入りや手術室内での移動が増加することに起因する可能性がある[306, 307]．

機　器

機器や機械は人の生活や患者が受ける医療を改善するが，その一方で患者に直接損傷を与えたり，完成度の低い製品に関連するエラーを増加させたり，現場のニーズに合わない雑音を発する警報システムを通じて患者に害を及ぼすことがある．実際，機器に関連する問題は，心臓手術の流れを停滞させる原因の約 11% を占めている[20, 75, 308]．Martinez ら[8]は，心臓手術に伴う潜在的危険についてレビューを行い，機器（経食道心エコーのプローブ挿入による食道損傷など），人工心肺（体外循環開始に伴う大動脈解離など），手術器具（OPCAB のブロアーに起因する空気塞栓など）に関する問題を多数記載した．この中で，機械と技術が患者に害を及ぼす機序として，以下の 4 つが同定されている．（1）誤使用（不十分な訓練または不注意），（2）装置の使用による固有の危険，（3）不十分なメンテナンス，そして，（4）機械の完成度の低さ．不十分な訓練，または使用認可を受けていない装置の使用，医療従事者の不適切なリスク認識，機器の管理におけるベストプラクティスの不遵守がリスクを高める[8]．これに加えて，機器に関連する有害事象に関して報告されているものに共通する事項は，誘因となる組織的なエラーを探求できていないということである[8]．

現代の機器の大半が機械効率と生体適合性に焦点をあてて設計されており，設計がヒューマンエラーに影響を及ぼすか否か，という観点はほとんど重視されていない．Wiegmann ら[309]は，不具合モード解析を使用して人工心肺装置を研究し，情報ディスプレイの位置，読みやすさ，

書式に問題があることを見出した．部品は機器にしっかり組み込まれておらず，空間設計と部品の設置も理想的でなかった．そして，警報音の音量が小さすぎたり大きすぎたりし，音の調律も不適切であった．

実際，手術室での注意散漫の最大の原因の 1 つは，機器が発する警報音である[310-312]．警報は事前に設定した基準から外れたことを術者に知らせるよう設計されているため，術者が危険な状態を確認できる．しかし，典型的な心臓手術室には，視覚または聴覚に訴えかける警報を発する約 18 もの異なる機器が設置されている[313]．Schmid ら[314]は，心臓手術 1 件の間に警報が 359 回発生することを報告した．これは 1 分間に 1.2 回の割合である．残念なことに，警報全体の 90% もが誤検出であり[315]，この結果，手術室のスタッフは本当の警報に対しても鈍感になっていた．また，心臓手術中に発生した警報を麻酔科医の反応と結びつけて分析した研究によると，731 回の警報のうち有用であったのは 7% にすぎず，13% は鳴ることが予測でき，止めておくことが可能であった[313]．

雑　音

上述のように，手術室内の移動，会話，警報，時には音楽のせいで，室内の騒音が職業安全衛生管理局（Occupational Safety and Health Administration）と国立職業保安・健康協会（National Institute for Occupational Safety and Health）の基準[317]を超えるレベルに達することがある[316]．こうなると患者と医療従事者双方の聴覚を妨げ，患者の転帰に影響を及ぼす危険がある[318,319]．ある研究によると，腹部手術後で SSI（手術部位感染）が起きた患者の手術環境では，雑音のレベルが有意に高かった[319]．また，手術内容と無関係の会話は，雑音レベルの著しい上昇と同等に認識される[319]．

Moorthy ら[250]は観察研究を実施して，通常の腹腔鏡手術の際に手術室の雑音が 80 dB になると，医療上のエラーの著しい増加につながると結論付けた．また，スタッフの経験が浅い場合は，臨床上の障害が増悪することがあり，ランダム化比較試験により，経験の浅い外科医の腹腔鏡手術の実践に，音楽が有害な影響を与えることが明らかになっている[320]．その一方で，手術室での音楽の適切な使用により，ストレスを減らし，一部の手術室スタッフのパフォーマンスを改善できることを示唆した研究もある[290]．しかしながら，調査した麻酔科医の 25% が，手術室に音楽が流れていると他のスタッフと有効に情報交換するのに妨げになると回答している[321]．言い換えると，あるスタッフにとって心地よく有用な音楽が，他のスタッフの注意散漫を招く恐れがあるということである[322]．この問題がさらに厄介なのは，手術中に情報伝達の負荷がかかるタイミングがチーム内の担当ごとに異なるという事実であり（図 4）[263]，そのため，チーム内の他の担当メンバーが絶対的な静寂を求めているときに何気ない会話をしてしまうことがある．

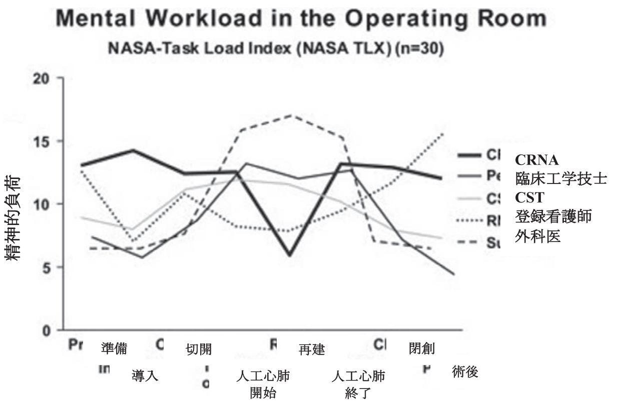

図 4　心臓手術室における精神的負荷は，個々の医療従事者が担う業務の複雑さと責任に応じて手術の過程全体を通じて変化する．NASA の業務負荷指数（NASA TLX：NASA-Task Load Index）（*n*=30）

CRNA：認定看護麻酔師，CST：認定外科技術士，NASA：米国航空宇宙局．Elsevier の許可を得て Wadhera ら[263]から転載．©2010 American Association for Thoracic Surgery

最適な手術室

手術室の最適な設計とレイアウトについては，論評で示唆されることはよくあるが，科学的な文献は不足し，良好な結果を示す研究はほとんどない．その中で，2 つの研究が物理的環境の改善を以下の要素と関連づけている．それは，（1）スタッフのストレスと疲労の軽減，これにより医療の実施の有効性が高まる，（2）医療安全の改善，（3）患者の転帰の改善，そして（4）医療の質全体の改善[323,324]の 4 つで，手術室の広さが最適であれば，患者への有害事象と，手術室のスタッフ自身のトラブルが減少する可能性があることから[297]，心臓血管手術室を 600 平方フィート（55.7 m^2）以上にするようにとの勧告が出された[325]．Killen[322]は，最適な手術室を設計するための指針を以下のように要約した．（1）手術台の頭部の位置と手術室内の左右の位置関係を標準化する．（2）スタッフが移動し，機器を設置するのに十分な空間を確保する．（3）患者に注意を向け続ける．（4）スタッフ全員が常に患者を確実に目視できるようにする．（5）作業の流れの改善に役立つ技術を使用する．これに関連して，部屋の角を丸くする，壁とドアが同一面になる設計にする，床に視覚的な誘導路を描くなどの新たな提案がなされている[297]．

手術室の動線を最適化するには，不必要な過密状態を避ける必要がある．通路を確保できるように機器を配置し，コードが通路を横切らないようにするなどの工夫により，床に物がなく，潜在的危険がない状態にしなければならない[297]．天井にケーブルカバーを取り付けてコードとケーブルを通せば，頻繁に使う通路を横切る配線を減らすことができる[291,326]．また，機器の設置は，無菌野，手術台，メイヨー台，麻酔機器，人工心肺装置との位置関係を考慮されていなければならず[326]，無菌室のドアと患者が出入りするドアの近くには，可動アームのある機器や定置用の機器を配置しないようにする．手術室のドアは，作業領域内を移動しても無菌領域に立ち入ることがないような場所に設置される必要がある[325]．

手術室内の人数を制限して，室内の移動を調整することで，スタッフと物品から落下する空中浮遊汚染物質を減らせる可能性がある[305,306]．ごく最近，周術期管理看護師協会の「Standards and Recommended Practices」は，手術室内の移動のベストプラクティスを提示した[302]．

心臓手術室内の物品や消耗品の最適な位置関係に関する文献はまだないが，指針は，手術室には最低50平方フィート（4.64 m^2）の収納場所が必要であるとしている[325]．常識的に考えれば，消耗品を手術室内に保管すれば，作業の流れが改善し，ドアの開閉回数が減るように思われる．しかしこれに関するデータはない．いずれにせよ，術前にブリーフィングすると保管庫に行き来する回数が減少する[222]．

手術室内の雑音については，雑音の抑制により予後が改善することを明らかにした研究は現時点では存在しない．なかには，航空機のコックピットでの『滅菌』概念（sterile cockpit）の採用を推奨する文献もあるが[327]，Wadheraら[263]は，手術の経過の中でチームの認識負荷が変化することを実証し（図4），手術の重要な部分（ヘパリン投与，カニューレ挿入，人工心肺の開始，人工心肺からの離脱など）では組織立った会話をするよう提案した．しかし，この対策が実際にエラーを減らすかどうかは検証されていない．

どのような症例であっても，手術中に利用できる莫大な量の聴覚および視覚情報を統合するのは容易ではない．モニターと記録システムは，スタッフが術野に顔を向けて手術に集中したまま参照できるように設置されるべきである[326]．2006年，Egan[328]は，Massachusetts総合病院の「未来の手術室」を記載した．さまざまなモニター，コンピュータ，機器が視界を遮らないように壁のパネルに取り付けられ，これにより，スタッフは情報を統合しながら手術を進められる．情報伝達の単純化は，患者を囲む機器を減らし，おそらくはコミュニケーションを改善する[328]．また，現場にいないチームのメンバーと外科的手技のリアルタイム画像を共有できることから，引き継ぎが容易になる[329,330]．

麻酔科的対策と外科的対策を電子カルテ上で統合できれば，警報による疲れと，警報に関連する注意散漫を軽減できる．Kruger と Tremper[313]は，将来の研究課題として以下にあげる３つの主要な領域を提案した．（1）これらのシステムを設計し，理論上の雛形と，その臨床診療への統合の橋渡しをする，（2）医学領域のさまざまな種類の知識を，包括的な生理的モデルおよび疾病モデルに統合する，（3）この領域の知識を利用して，感度と特異度の高いアラームシステムを製作するための高度なアルゴリズムを開発する．

最後に，臨床現場に則したシミュレーション環境は，人間と機械のインタフェースの改善点を精査するのに使用でき，次世代の安全な機器を生み出す方法について医工業界にヒントを与えてくれる[331]．また，患者を危険にさらすことなく，最適な手術室の設計とレイアウトを検討することができる．

要　　約

1. 手術室の人間工学的な配慮（広さとレイアウト）が不十分であると，手術の流れの停滞，技術的なエラー，SSI（手術部位感染），スタッフの労働災害など，ヒューマンエラーの発生や潜在的危険につながる．
2. 最適な手術室の設計には，患者のベッドと手術台の頭部の位置の標準化，機器とスタッフの移動に十分な空間，患者への注意の持続，作業の流れを支える技術の使用を確実に盛り込む．
3. 手術室内の移動を減らせば，患者のリスク（手術の流れの停滞とSSI）を減少させられる可能性がある．
4. 手術室内には，機器の警報音，会話，音楽などによる雑音があり，そのレベルが高いと患者（手術の遂行，手術部位感染）と手術室のスタッフ（聴きにくさ）に危険が及ぶ．

安 全 文 化

組 織 文 化

安全文化の欠落は，心臓手術後の良くない結果につながることが指摘されている[8]．チームワークと協力の風土は，エラー防止に留意する安全に主眼を置いた作業プロセスやコミュニケーション方法とともに理想的なものであり，これがあれば，心臓手術に代表される高リスク臨床環境においても患者への有害事象を認識し，防止できる[332–334]．

心臓手術の安全に関する研究は大部分が後ろ向き研究で，全体の傾向をつかむ目的で実施されてきた[8,13,16–18,78,292]．前向き研究はわずかしかなく，安全を改善するよう設計された対策をテストしたものはさらに少ない．しかしながら，これらの研究により改善可能な領域が指摘されている．たとえば，英国のブリストル[335,336]とカナダのウィニペグ[337–339]にある小児心臓病院では，完成度の低い質保証プログラムが異常に高い死亡率の誘因になっていた．ブリストル病院（Bristol Infirmary）の医療従事者は患者の転帰が不良であることに懸念を抱いていたが，それらの意見は取り上げられることはなかった．これは主として，問題を特定して対処する病院管理部門の「医療の質保証部門」が存在しなかったからである．ウィニペグでは症例数が少なかったために，問題のある医療の質保証プログラムがさらに不十分なものになり，警鐘事象を検出したり，それに対処したりできなくなっていた．この双方の事例が示しているのは，内部から懸念の声が上がっても問題を認識したがらない文化と対応が不十分な医療の質保証システムによる二重の危険性である．

本項では，医療における組織文化についてレビューし，安全を揺るがす行動を特定するとともに，心臓手術に限定して記載された少数の文献を含めて，医療安全を目指す態度の素地となる組織的要因を検討する．

医療環境における組織文化

病院における組織文化，すなわち院内で培われてきた信条，思い込み，価値体系は，患者を安全に保つことに対してスタッフが示す態度に多大な影響を与える．一見よく似た病院が，まったく異なる文化とサブカルチャーを有する

ことがあり，病院スタッフの大部分が，自身の環境の安全文化に貢献して，これを創造する方法を知らずにいる．医療における現在の階層構造は長い年月をかけて進化してきた．しかしながら，特に心臓外科領域でみられるように，複雑さと技術的洗練度が高まっていることを考えると，医療従事者間の違いと力の差を重視する組織文化は安全でないことがある，組織文化が医療安全に与える影響に関しては，現在の教育および訓練パラダイムを再評価して，より協力的で職種を超えたアプローチを重視することの必要性を強調するデータが増えている[339-342]．

安全文化 対 安全風土

組織の安全文化は，危険を特定して減少させる能力と，エラーの誘因になるシステムの状況に影響するチームとしての行動と価値観を意味し，安全文化は「個人とグループの価値観，態度，認識，能力，そして組織の健全性と安全管理に決意を持って取り組む行動パターン，その様式，そして熟達」であるといわれる[343]．安全指向の文化を確立するにはリーダーシップがきわめて重要であるが，質改善と安全の風土を作るべく，全力で打ちこまなければならないのは最前線の医療従事者である．

これとは対照的に，組織風土は，個人またはグループが組織の構想を真摯に実施し，策定された方針と手順を遵守する度合いを意味する．Zohar[344]は，安全風土は「安全に関する方針，手順，実務に関する共通の認識」であると述べた．風土は「その部署で実務を行う方法」と定義されることが多い．安全文化には，より微妙なものである傾向があるのに対し，安全風土は測定につながりやすく，特に機能するユニット内での測定に有用である．

安全文化と安全風土は，通常は比較的大きな組織の機能であり，手術室などの小さな機能単位には，より大きな組織の影響を受けるとはいえ，それとは異なる独自の文化と風土があるのが普通である．手術室の環境で質問表や調査などのさまざまなツールを用いて安全文化と安全風土を評価すると，興味深く，潜在的に実用性のある観察が多数得られる[69,156,197,345,346]．心臓以外の領域の手術環境に関する研究により，外科医と看護師ではチームの他のメンバーとの親しさの程度が著しく異なることがわかった．この，メンバー間の親しさは，医療安全に影響する要素として知られている[21,28,60]．また，実務を行う部署による医療安全への支援と認識について行われた別の研究では，看護師は医師と比較して否定的な回答を多く寄せた[346]．しかし，このような知見は必ずしも一般化できず，文化の測定ツールにはそのツール本来の限界と適用の方法にもよることを認識する必要がある．

強い安全文化が生命を救うと考えられてはいるが，文化と臨床行為の関係は複雑で微妙である．態度に関する調査から得られた知見とチームワークスキルの訓練セッションを結び付け，これに基づいて行動すれば，感情的な風土，チームワーク，患者の転帰への脅威に関する指数を改善できる[69]．しかし研究者の一部は，安全文化と実際の実践は概念的にも，実際にも異なると主張している[341]．さらに，対策によって医療安全に対する態度が大幅に改善されるものの，これらの効果が持続するかどうか，また，より良好な患者の転帰に帰するかどうかは不明である．

心臓手術領域では，組織の特徴が潜在的な転帰に与える影響を評価した観察研究はわずかしかない[8]．Fleming ら[80]は，自信に基づく主張，情報の共有，ストレスと疲労，チームワーク，業務上の価値観，エラー，手順の遵守に加えて，リーダーシップ，組織構造，安全風土について，質問表を用いて評価した．回答者らは確立された処置と手順の不遵守が頻繁に起きると述べ，それに対して安心して率直に声を上げられると回答したのはわずか 43% であった．類似の結果が小児心臓手術についても報告されている[156]，心臓手術では人工心肺法が用いられ臨床工学技士が加わることから，心臓手術室には技術を重視する独特の環境がある．チーム文化を改善するための対策を研究，設計する上で，この非常に複雑な環境は理想的である[347]．

安全文化を揺るがす行動

硬直した上下関係の厳しい文化

上下関係の厳しい文化が優勢な組織は，総じて安定性を志向し，これを非常に重視する[348]．これらの組織の特徴は，画一性と融通の利かない共同作業であると同時に，内部統制が良く効いており，そして規則と規制の厳格な遵守がなされていることである[348]．このような特性は本質的に悪いことではない．手術においては，軍隊と同様に，規則と規制を厳格に遵守し，権限の境界を明瞭にすることが，有効な実践にきわめて重要だからである．しかし，これが力の著しい乖離，職位の不平等，破壊的行動（disruptive behavior）につながるなら，チームのメンバーはエラーを認識した場合ですら権威あるメンバーに異議を唱えたり，率直に話したりするのをためらうようになり，安全が損なわれる[156,158,345]．管理者に中央集権化したアプローチは，安全の問題に直面した最前線の医療従事者が，率直に話し，対策を講ずることができない状況を招きがちである[349,350]．硬直した上下関係の厳しい文化をもつ病院と外科チームは，実践測定スコア[351-356]と安全風土測定スコア[349]が低いことが示されている．Singer ら[349]が強調しているように，目標をしぼった対策に必要なのは，プロフェッショナリズムに反する行動を集団として慎むことと，継続的な質改善への決意に力点をおいたチーム訓練をすることである．

プロフェッショナリズムと破壊的行動

質が高く安全な医療は，チームワーク，コミュニケーション，チームとしての業務環境に左右され，プロフェッショナリズムは，個人の行動と，組織構造の相互作用を通じて維持される[357]．医療の文化は，高いレベルの技術および専門知識と引きかえに，破壊的で脅迫的な行動を許容してきた歴史がある[358]．しかし，医療サービスの提供が医師個人による診療から，多職種からなるチーム中心のアプローチに移行する中で，専門家間の訓練とコミュニケーションを大切にせず，不適応行動を排除しない組織は，信頼できるレベルの医療安全と良い患者の転帰を達成し続けることはできないであろう[359-363]．

手術エラーは手術チームの文化を踏まえて理解しなければならない[364]．Mazzocco ら[12] は手術チームの研究を通じ，チームワーク行動，特に手術中と，引き継ぎの際のデブリーフィングで情報の共有があまりみられないチームは，患者の死亡と合併症の発生リスクが高いことを明らかにした．また，心臓外科医による技術的なエラーの発生頻度の違いは，その約 45% がチームワークの要素だけに起因することを示す研究もある[20]．そして Nurok ら[69] は，スタッフを混乱（ピリピリ）させるような手術室のムードと，胸部外科チームの低いパフォーマンスが関連することを見出した．

破壊的行動（disruptive behavior）とエラー，さらには死亡率を関連付ける文献が増えている．職場での脅迫的な行動が医療現場に与える影響に関する研究は，脅迫的な行動のために誤投薬に至ったことがあると回答した参加者が 7% いたと報告している[365]．心臓手術については，データは少ないながら，Rosenstein と O'Daniel[366] が，「強いストレス下では破壊的行動が起きやすく，患者に害が及ぶ恐れが高まる」ことを示した．また，4 530 名の病院勤務医と看護師を対象にした調査は，医師による破壊的行動を自身の病院内で目撃した回答者が 77% に上り，看護師による同様の行動を目撃した回答者も 65% いたことを報告している[367]．

この回答者らによると，破壊的行動が最も起きやすいのは一般外科（28%）で，心臓血管外科では 13% であった．この行動はすべての専門領域で認められた．また，周術期に関する研究では，回答者の 75% が病院外科医による破壊的行動を目撃し，麻酔科医によるものは 64% が，看護師によるものは 59% が，外科レジデントについては 43% が，そして麻酔科レジデントによるものは 35% が目撃したと報告した[368]．さらに，回答者の 46% が，これらの破壊的行動が有害事象を招く可能性を認識していると述べるとともに，19% が破壊的行動に起因する有害事象をはっきり目撃したと報告した．また，周術期医療に関わるスタッフの 80% 以上が，破壊的行動による集中力の低下，コミュニケーション/協力機能の低下，そしてチームの他のメンバーとの関係悪化を報告している．研究者らは，最前線のスタッフが，これらの行動が医療安全と患者の転帰に影響を与えると考えていると指摘した[367,369,370]．

米国医療機関認定合同委員会は，2009 年に「病院全体での安全と質の文化の創造と維持」を義務付けるリーダーシップ基準を導入しており，そこには破壊的行動に対する対処方針の策定と，容認できない行動を管理する正式なプロセスが含まれている[371,372]．これらの破壊的行動の具体的な定義は以下のとおりである．「脅迫的で破壊的な行動としては，言葉の爆発，身体的威嚇などの目に見える行為に加えて，与えられた任務の実行を拒否したり，通常の活動中に非協力的態度を示したりすることも含まれる．また，質問への回答や電話またはポケットベルへの対応を渋ったり拒否したりする行為，見下したような言葉，声色，イントネーションの使用，質問に対する苛立ちもこれに該当する．明白な行為も消極的な行為もチームの有効性を蝕み，患者の安全を損なう」．そして近年，米国医療機関認定合同委員会はこの定義を「安全文化を揺るがす行動（behaviors that undermine a culture of safety）」に変更した[373]．

破壊的行動と職場いじめには共通する部分がかなりあり，いじめは破壊的行動が極端になった例という見方もできる．Workplace Institute[374] は，いじめをこのように定義している．「健康を害する虐待で，以下のいずれかに該当するものが反復される状態．a）暴言，b）威嚇的，屈辱的，または強迫的で，攻撃的な行為/行動（非言語的なものを含む），そして，c）業務の完了を妨げる干渉または妨害」．

周術期の医療環境は，強いストレスに曝され，高い集中を要し，複雑であるため，破壊的行動もしくはいじめが潜行性に起こりやすい．状況は緊張し，手順は迅速に実施され（そうでなければならない），正確さが求められる．特に，手術室での看護師と他のスタッフに対するいじめは，手術の実施それ自体にあるストレス，患者の重症度の高さ，周術期医療専門家の不足，超過勤務，昼も夜もない待機状態，そして個々のスタッフの専門分野がそれぞれ異なり，その意味で孤独であるという事実からある程度起こっている可能性がある[375]．破壊的行動は，医師を頂点とする階層的な文化と，スタッフが感じている「沈黙のおきて」により永続化し[376]，報復を恐れて率直に口にできないことが，小さなエラーが積み重なって大きな事象を招く環境を生む．つまり，いじめはチームワークと，安全文化の醸成を損なうのである．

破壊的行動に対して病院の腰が重いのは，複合的な原因による可能性がある．Rosenstein[376] は，組織が医療安全の文化を成功裏に推進するための 10 段階のプロセス（表 2）を推奨した．第 1 段階では，リーダーシップを発揮し，破壊的行動の発生率を特定するとされるツールを用いて職場環境を真摯に評価することで，既存の問題を認識する．調整能力を発揮できるリーダーシップは，教育と訓練の提供を通じて，認識レベルと責任レベルを押し上げる．決められた方針と手順には，破壊的行動を報告するための，安全で，非懲罰的な仕組みを組み込む必要がある．このようにすれば，組織と，その個々のスタッフが，医療安全と質に一層取り組めるようになる[376]．

Vanderbilt Medical Center では，10 年以上にわたって，プロフェッショナルとは呼べない行動を特定して測定し，それに対処することでプロフェッショナリズムの推進に力を入れてきた[360,377]．ここには中核となる 6 つの原則がある．それは，（1）リーダーの熱意，（2）対策を導くためのモデルまたは枠組み，（3）組織の方針，（4）監視ツール，（5）訓練，そして（6）説明責任[360] である．この取組みは有効で，医療事故に対する請求件数が減少し，医療安全と質が向上し，チームのコミュニケーションが改善され，否定的な行動に突き進むことが減り，医療従事者らの行動が変化した[377]．しかし，このようなプログラムが心臓手術に与える影響に特に言及した研究はない．

表 2　安全文化を推進するための 10 段階のプロセス[376]

1．組織文化
　a．リーダーシップの表明，評価，構造
2．安全な臨床医療の擁護
3．認識と意識
　a．教育
4．組織立った教育・訓練
　a．多様性，感受性，ストレス管理
　b．対立管理，主張
5．協力/コミュニケーションツール
6．関係構築
7．方針と手順
8．報告の仕組み
9．対策
　a．術前：対策を実践する前に安全文化を評価する
　b．術中：対策を実践しながら安全文化を評価する
　c．術後：対策を実践した後に安全文化を評価する
10．医療安全構想の強化

「ヒーロー文化」のもろさ

破壊的行動を問題視しない厳しい上下関係構造をさらに複雑化するのは，疲弊した手術チームの「ヒーロー文化」をメディアがもてはやすということである．外科医と手術チームのメンバーが自らを犠牲にして，疲労困憊をものともせず患者のニーズを満たすというイメージは，疲労がパフォーマンスに及ぼす影響を正確に反映していない．心臓領域以外の手術チームについて行われた研究のうち，長時間にわたる勤務時間とそれに伴う睡眠不足が注意力不足[378]ならびに集中治療室に勤務するレジデントによる重大な医療上のエラーの発生率[379]に及ぼす影響を記載したものが 2 件ある．また，他の研究者らは，睡眠不足が偶発的な針刺し事故のリスク[380,381]と，レジデントの通勤時の自動車事故のリスク[382]を上昇させることを示した．このように，疲労と長時間勤務が低いパフォーマンスと悪い患者の転帰を招く懸念が高まったことで，医療安全を改善しようとの努力の一環として，レジデントの勤務時間に規制がかけられることになった[383]．

特に疲労と睡眠不足が心臓手術に与える影響に焦点をあてた研究は 3 件あるが，いずれも，睡眠不足と重大な合併症または死亡率との関連については実証していない[384–386]．しかし，これらの研究は，エラー自体，またはエラーの認識と修正の発生率などの中間転帰を測定していないため，この結果は疲労と睡眠不足が影響しないということではなく，エラーが起きても修正するチームの回復力を反映している可能性がある．臨床工学技士を対象にした調査では，15% が起きてから最長で 36 時間後に人工心肺操作を担当し，50% が人工心肺運転中にウトウトとした経験があると述べた[387]．さらに，3 名中 2 名の割で疲労に関連する小さなエラーを報告し，6.7% が疲労のせいで人工心肺に関連する重大な事故を起こしたことを認めている[387]．

安全文化の醸成

組織文化の変化に関する文献のほとんどが，心臓手術レベルではなく，病院レベルでの報告である[346,349,388]．手術室での質と安全を改善するための対策は，まだ萌芽期にあり，これらの対策が，心臓手術などの危険性の高い環境の安全風土を持続的に改善できることを証明する説得力のあるデータは不足している．前述のように，チェックリスト，ブリーフィング，チームワーク訓練といった心臓手術室でのコミュニケーションを改善するための対策を導入すると，通常は手術室スタッフの安全に対する態度の改善，さらには医療安全の改善が認められる*．しかし，安全に対する組織全体の取組みを変えていこうとする試みは，組織文化というもの自体の難しい性格とそれを変えることの困難さを浮き彫りにする．

一方でチーム単位で対策を行うとすると，それが周到に練られたものでないとしても，その対策を受け入れやすいことが示されている．部署を単位とする包括的プログラムである Comprehensive Unit-Based Safety Program（CUSP）は，安全文化の構築を目指したプログラムであり，手術室ではなく集中治療室で検討されてきた[390]．この CUSP は，Michigan Keystone Project の一環として安全文化の改善を目指す対策であり，カテーテル関連感染の減少を目的として，100 施設の集中治療室が共同で取り組んでいる[208]．これは，チームワークと改善ツールを導入するための，5 段階から成る反復するプロセスであり，まず安全科学についてスタッフを教育し，問題を特定する．その上で，経営陣がスタッフと共同で安全に対する潜在的危険に優先的に対処しつつ必要な情報と資金を提供し，毎月 1 件の問題から教訓を得て，文化を断続的かつ定量的に評価するというものである．このプログラムは組織の周到に練られた計画に組み込むことができるが，安全に対する危険を特定し，これを正す決定権は最前線のスタッフに与えてその裁量に任せている．CUSP アプローチを特定のチェックリストと併用すれば，カテーテル関連感染の事実上の根絶[208]，人工呼吸器関連肺炎の有意な減少[210]，ならびにチームワーク風土の著明な改善[390]を達成できる．

組織による質の重視がもたらす有益性

小児心臓手術患者が多数死亡したブリストルとウィニペグの経験は，確固たる医療の質改善と質保証プログラムの必要性を強調する[335–339]．この双方で，病院が問題を特定して対処する能力が不十分で，発せられた警告が顧みられなかった．調査委員会は，組織として医療の質管理システムを優先し，あらゆる関係者（患者と家族を含む）からのフィードバックを取り込み，医療従事者全員が率直に声を上げ，それに耳を傾けるよう奨励する文化を確立するなどの抜本的な改革を推奨した．そして，病院全体の医療の質を管理する部局がこれらの努力を先導して，問題を検出し，対策の実施後の進捗を監視すべきであると記載している[335,339]．

*References 44, 63, 158, 164, 171, 183, 278, 389.

単一病院が実施した改善

個々の医療行為は医療の連続性を通じて緊密に結びついているため，心臓手術における医療の質改善構想の大部分は，手術室だけに焦点を当てているわけではない．心臓手術患者の管理に用いる包括的なアプローチには，Total Quality Management[391, 392]，Institute for Healthcare Improvement Breakthrough Collaboratives[393]，ProvenCare[394]，Operational Excellence[395] などがある[396, 397]．これらの取組みが奏効するか否かは，各モデルがどの程度，チームの信頼，データの統合，臨床上のリーダーシップ，組織の関与，質改善のための基盤からなる要素を満たしているかで決まる[398]．

Doran ら[393, 394] は，地域の成人心臓手術プログラムにおける迅速サイクル改善モデル（米国医療の質改善研究所の Breakthrough Series）使用の結果を観察し，入院期間，人工呼吸器使用期間，患者満足度，費用が有意に改善することを見出した．また Stanford ら[391] は，Total Quality Management システムの効果を発表した．このシステムは，外科医主導による周術期チェックリストの導入，看護師による進捗の監視，「誰かを咎めるのではなく問題解決を重視する」M & M カンファレンス（mortality and morbidity conference）の実施，そして多職種チームによる協議の義務化からなり，冠動脈バイパス術を受けた患者の手術死亡率を有意に低下させた[392]．

ProvenCare は，病院が単独で推進する医療の質改善プログラム（Geisenger Health System，米国ペンシルバニア州ダンビル）[394] で，待機的冠動脈バイパス術患者に対する 40 の要素からなる医療指針であり，これは心臓外科医に依頼して開発された．これらの要素はエビデンスに基づくもので，一貫して実践できるよう医療プロセスに組み込まれており，この医療プロセスはパフォーマンスを改善するため繰り返し修正された．その結果，血液製剤の使用量，集中治療室への再収容，ならびに再入院が減少した．ProvenCare モデルは健康保険のための予算を削減できるとして大いに注目されたが，それにとどまらず，その有効性と一貫性により，継続的な質管理と，安全文化を目的とする重要な実践のためのモデルを提供している[394]．

プロセスを重視する多職種アプローチ（process-oriented multidisciplinary approach : POMA）は，イングランド　リーズの心臓手術プログラムの一環で，冠動脈バイパス術を受ける患者を医療従事者全員で術前に評価し，準備するよう求めている[396]．POMA 実施以前（$n=262$）と実施以後（$n=248$）に冠動脈バイパス術を受けた患者を比較すると，平均入院期間，手技の費用の中央値，そして心房細動と呼吸器感染の発生率の改善が認められた[396]．

また，Uhlig ら[397] は，冠動脈バイパス術を受ける患者を多職種チームが毎日決まって回診する試みについて記載した．この回診には，患者，患者の家族，薬剤師，看護師，ソーシャルワーカー，医師助手，心臓外科医が参加する．その結果，患者満足度が大いに上がり，死亡率も低下した．

最後に，Culig ら[395] は，トヨタ自動車の生産システム（Toyota Production System）から着想を得た「Operational Excellence」の効果を調査した．これは，地域で使用する新たな心臓手術外科プログラムで，正式な問題解決プロセスを含む 1 日 10 分間のきちんとした会議を実施したところ，厳格で，上下関係が厳しく，「問題は罰するべきである」と考える文化を，協力的で「問題が見つかるのは良いことだ」と考える文化に転換できた．そして，自治体の担当部局が持つデータで進捗状況を 2 年間にわたって追跡した[395] ところ，冠動脈バイパス術合併症のリスク調整済み発生率が，対照として用いた地域住民で観察された数値の 60% に低下した[395]．

医療の安全と信頼の文化は，質と安全を有効に改善する第一歩である[399]．「非難と恥」の懲罰的な文化より，「公正な文化」のほうが，信頼構築に必要なムードと行動を生む[400, 401]．改善の科学の訓練を受けた臨床分野のリーダーは，職場の問題を特定し，その解決を図るための一貫した行動を通じて職場の信頼を強化できる[402]．このようなリーダーシップ行動は，医療の質改善を目指す組織の決意を示すとともに，質改善のための基盤を提供することになる．

複数の病院が共同で実施した改善

多施設が長年にわたり共同で取り組むことで，心臓手術の質と安全の改善が得られている．これが成功した理由の大部分は，心臓手術に関する各施設・各外科医のデータとベストプラクティスを共有したことにある．心臓外科におけるこのモデルは，1987 年に Northern New England Cardiovascular Disease Study Group の設立に伴って始められた[403-406]．5 つの病院とそれぞれの循環器チームが，患者の人口統計学的データとプロセスおよび結果に関するデータの収集と共有を開始し，予測可能なモデルを構築するためのリスク調整法を開発するとともに，標準化，実践による改善，学習の共有などを重視しながら，互いの施設にサイトビジットを行い，頻繁に顔を合わせて会議を行った[407]．このモデルの実用化により，総死亡率[408]，女性患者の死亡率[409]，出血再開胸止血[410] などのデータが改善された．

この成功を基礎として，他の多施設共同プログラムも開発されている．1996 年には，心臓外科医のグループにより，17 の病院と 10 の循環器および胸部外科グループが参加する Virginia Cardiac Surgery Quality Initiative[411] が設立された．この焦点を絞ったプロジェクトは，米国バージニア州全域で周術期の心房細動の発生率を低下させ，血糖管理を改善し，輸血の頻度を低下させた[412]．またミシガン胸部・心血管外科学会（Michigan Society of Thoracic and Cardiovascular Surgeons）は，ベストプラクティスからの逸脱を減らすことを目的とした質に関する構想を策定した[413]．現在，この構想は健康保険からの資金投入を受けており，対策とデータの共有に力点を置くことで，冠動脈バイパス術における左内胸動脈の使用を増加させ，長期間の人工呼吸器使用率を低下させた[414, 415]．成人の冠動脈バイパス術患者を対象とした上記以外の共同プロ

グラムとしては，Alabama Coronary Artery Bypass Grafting Project，Washington Clinical Outcomes Program，California Local/Regional Cardiac Surgery Database，Minnesota Local/Regional Cardiac Surgery Database[398] などがある．

一方で，医療の質改善を目的とした共同プログラムの全般的な有効性に疑問を呈した研究もある[416, 417]．資金不足，データの脆弱性，外科医にかかる競合的プレッシャーにより，共同プログラムは長続きしない可能性があるという主張である．今後は，外部データを共有したり，組織を超えて学習しあうことの有用性を検討することで，どのようなプログラムが参加者全員のパフォーマンスを最大化するのかを見出せる可能性がある．また，医療環境での使用を想定して改良された情報技術と質管理ツールが広く利用可能になれば，持続的なアウトカムの改善をもたらす対策の開発に役立つであろう．

将来の研究

心臓手術環境でのヒューマンエラーの理解を深める上で，次の段階として行うべきは，エラーの原因となる因子に関する多職種を対象にした前向き研究であるかもしれない[347, 418, 419]．このヒューマンファクター研究では，より大きな組織，作業空間，必要な臨床的・技術的プロセス，機器と人間の相互作用，そしてとりわけ人間同士の相互作用（コミュニケーションとチームワーク）について検討する必要がある．また，臨床的な専門知識を有する研究者（外科医，看護師，麻酔科医，臨床工学技士）と，臨床以外の専門知識を有する研究者（ヒューマンファクター専門家，システム分析の専門家）が共同して実施するものでなければならない[420]．Catchpole と Weigmann[347] は，心臓手術室での安全とパフォーマンスをより深く理解するべく，将来の研究では，研究デザイン，改善のためのシステム改革，そして転帰に及ぼす影響の測定を重視するよう推奨している．この方法論に基づいて「起きるはず」の事象ではなく，実際に起きた事象の観察と分析を行えば，有害でなかったインシデントと有害事象について，インシデント報告を超える情報が得られるであろう[347]．

要　　約

1. 心臓手術の医療安全に関する研究の大半は，現状の傾向を確認するための後ろ向き研究であり，ヒューマンエラーの減少や安全の改善を目的とした対策をテストするための前向き研究ではない．

2. 米国医療機関認定合同委員会は「病院全体での安全と質の文化の創造と維持」を義務付ける基準を導入しており，破壊的行動に対する対処方針の策定と，容認できない行動を管理する正式なプロセスが含まれる．

3. 不十分なチームワーク行動とピリピリした風土は，手術チームのエラーと患者の悪い転帰につながる．

4. 心臓手術環境における地域および地方レベルの医療の質改善構想は，とりわけ血液製剤の使用量，人工呼吸器使用時間，入院期間，集中治療室への再入室，再入院，死亡率，患者満足度，ならびに費用を改善させた．

5. 心臓手術に関する多施設共同の医療の質改善プログラムは，具体的には，患者の人口統計学的データとプロセスおよび結果に関するデータを共有して互いの病院をサイトビジットし合うことで，ベストプラクティスの地域における標準化と，総死亡率，女性の死亡率，血液製剤の使用量，長期にわたる人工呼吸器の使用，ならびに血糖管理を改善し，内胸動脈の使用率を増加させた．

結　　論

心臓手術はリスクの高い医療行為であることから，医療安全に大きな注意を向ける必要があるが，それを持続するには安全文化が不可欠である．この領域の研究はまだ萌芽期ではあるものの，価値ある情報が得られている．現在も病院や研究グループによって，チームワークとコミュニケーションを改善するべく設計された対策や，破壊的行動と疲労の減少を目的とする他の対策の検討が行われている．医療安全を最優先すれば，最終的には患者満足度の大幅な向上と臨床での転帰改善につながるはずである．

将来の対応と研究に関する推奨事項：医療安全のための「実施要請」

WHO の主な目標の 1 つは手術エラーの減少である．そのため，2008 年にガイドラインを公表し，手術を受ける患者の安全を確保するための実務を複数特定し，推奨した[421]．それでもエラーはなくならない．しかし，ヒューマンエラーを減らすための従来のアプローチは，通常は病院または専門学会の医療の質管理委員会が主導したもので，医療安全における問題点を著しく改善する先例を確立してきた．上記の各トピックに記載したように，現在までに得られているエビデンスは限られているが，いくつかの対策を支持しており，これらの対策の実施を優先すれば，ほぼ確実に医療安全を改善できる．さらに，共同で行う努力を通じて臨床研究の独自の領域であるヒューマンエラーに関する科学的研究を拡大することで，心臓手術室ならびに他の手術環境と治療環境（心臓カテーテル実施施設など）での医療安全を改善する機会を提供できる可能性がある．具体的な研究領域には，以下の内容が確実に含まれている必要がある．（1）コミュニケーションの失敗とチームワークの崩壊に関する理解の深化，（2）コミュニケーションとチームワークを改善する対策（チームワーク訓練，ブリーフィングとデブリーフィング，シミュレーションなど）を実践し，強化する最善の方法，（3）プロフェッショナリズムと安全文化を推進する対策，そして，（4）理想的な空間とレイアウトを含み，流れの停滞とスタッフの移動を最小限にする手術室の人間工学．さらには，行動の変化とコミュニケーションスキルなどの医療従事者の側の改善と，合併症発生率（感染など）と費用などの患者側の転帰を測定するのが理想である．

コミュニケーションとチームワークに関する最新知識の臨床現場への応用を容易にする機会

表 3 に，米国心臓病学会財団と米国心臓協会が取り決

表 3　推奨事項の分類とエビデンスレベル

治療の有効性の大きさ（横軸）／治療の有効性の確実性（正確さ）の推定（縦軸）

	クラス I 有益性 >>> リスク 処置/治療を実施/施行するべきである．	**クラス IIa** 有益性 >> リスク 目的を限定した更なる研究が必要である． 処置/治療の施行が妥当である．	**クラス IIb** 有益性 ≥ リスク 幅広い目標を有する更なる研究が必要．追加のレジストリデータがあるのが望ましい． 処置/治療を考慮してもよい．	**クラス III** 有益でない **クラス III** 有害である （処置/検査／治療） COR III: 有益でない：有用でない／有益性が証明されていない COR III: 有害である：多大な費用がかかる ± 有益でないか有害／患者に有害である
レベル A 複数の集団での評価* 複数のランダム化比較試験またはメタアナリシスから得られたデータ	■処置または治療が有用/有効であるとする推奨事項 ■複数のランダム化試験またはメタアナリシスから十分なエビデンスが得られている．	■処置または治療が有用/有効であることを支持する推奨事項 ■複数のランダム化試験またはメタアナリシスから相反するエビデンスが得られている．	■有用性/有効性があまり確立されていない推奨事項 ■複数のランダム化試験またはメタアナリシスから相反するエビデンスが多く得られている．	■処置または治療が有用/有効でなく，有害となりうるとする勧告 ■複数のランダム化試験またはメタアナリシスから十分なエビデンスが得られている．
レベル B 限定された集団での評価* 1 件のランダム化試験または非ランダム化研究から得られたデータ	■処置または治療が有用/有効であるとする推奨事項 ■1 件のランダム化試験または非ランダム化研究からエビデンスが得られている．	■処置または治療が有用/有効であることを支持する推奨事項 ■1 件のランダム化試験または非ランダム化研究から相反するエビデンスが得られている．	■有用性/有効性があまり確立されていない推奨事項 ■1 件のランダム化試験または非ランダム化研究から相反するエビデンスが多く得られている．	■処置または治療が有用/有効でなく，有害となりうるとする勧告 ■1 件のランダム化試験または非ランダム化研究からエビデンスが得られている．
レベル C 非常に限定された集団での評価* 専門家，症例研究または標準治療にみられる意見の一致のみ	■処置または治療が有用/有効であるとする推奨事項 ■専門家の意見，症例研究または標準治療しか存在しない．	■処置または治療が有用/有効であることを支持する推奨事項 ■専門家の意見，症例研究または標準治療しか存在せず，異論もある．	■有用性/有効性があまり確立されていない推奨事項 ■専門家の意見，症例研究または標準治療しか存在せず，異論もある．	■処置または治療が有用/有効でなく，有害となりうるとする勧告 ■専門家の意見，症例研究または標準治療しか存在しない
推奨事項の記載に勧められる文言	べきである 推奨される 適応となる 有用/有効/有益である	妥当である 有用/有効/有益となりうる おそらく推奨されるか，適応となる	考慮してもよい/考慮してもよいであろう 妥当である可能性がある 有用性/有効性は不明/不明確/不確定である，もしくは確立されていない	COR III: 有益でない：推奨されない／適応とならない／実施/施行すべきでない/その他／有用/有効/有益でない COR III: 有害である：有害である可能性がある／害を引き起こす／合併症発生率/死亡率の増加と関連する／実施/施行すべきでない/その他
有効性を比較する場合の文言†	治療/戦略 A は，治療/戦略 B に優先して推奨される/適応となる 治療/戦略 B ではなく，治療/戦略 A を選択するべきである	治療/戦略 A は，おそらく治療/戦略 B に優先して推奨される/適応となる 治療/戦略 B ではなく，治療/戦略 A を選択するのが妥当である		

エビデンスレベル B または C の推奨事項であっても，それだけで推奨の度合いが弱いことを意味するわけではない．ガイドラインで扱われる重要な臨床上の問題の多くは，それ自体は臨床試験で検討されず，またランダム化試験が実施できなくても，特定の検査または治療が有用または有効であるという非常に明確なコンセンサスが得られる場合もあるからである．

*臨床試験またはレジストリから入手可能な，異なる部分集団（性別，年齢，糖尿病の既往歴，心筋梗塞の既往歴，心不全の既往歴，アスピリン使用歴など）での有用性/有効性に関するデータ．

†推奨事項の有効性の比較（クラス I と IIa，エビデンスレベル A と B のみ）については，比較動詞を用いて説明する研究は，評価対象の治療または戦略同士を直接比較するものでなければならない．

めた推奨事項の分類とエビデンスのレベルを示す．さらに，執筆者グループが下した結論と，この分類方式を適用した推奨事項の一覧を以下に示す．

コミュニケーションの失敗は，よくみられる現象であり，一般外科と心臓外科の双方において，エラーと有害な転帰をもたらす原因の 1 つと指摘されている†．航空産業と軍隊で実施されてきた研究により，チーム訓練を行うことで共同作業の改善とパフォーマンスの強化を促進できることが実証されている．コミュニケーションに関するノンテクニカルスキルの訓練については，手術環境で生じる影響に関するデータがかなり得られており，具体的な方法としては，チェックリスト，ブリーフィングとデブリーフィング，その他の組織立ったコミュニケーションツールとプロトコル，チーム訓練，シミュレーション訓練などがある‡．しかしながら，米国医療機関認定合同委員会が求めている標準化されたタイムアウトを除けば，プロトコルを

† References 13, 16, 18, 20–23, 58, 59, 72, 76–80.
‡ References 44, 45, 63, 66, 68, 162, 164, 170–173, 176, 178, 182–184, 190–192, 195, 197, 198, 204, 208, 210, 215, 217–220, 222, 223, 422, 423.

利用する標準化された重要な相互的な対策は，心臓手術室でも他の手術室でも広く導入されてはいない．さらに，チーム訓練に関する長期研究によると，改善の維持が容易でないことが示唆されている[164, 197, 198]．

推 奨 事 項

1．心臓手術症例では必ずチェックリスト，ブリーフィングまたはその両方を実践するべきであり，心臓手術室のリーダーは術後のデブリーフィングを奨励すべきである（*クラス I，エビデンスレベル B*）．

2．心臓手術室では，コミュニケーション，リーダーシップ，状況認識を改善するためのチーム訓練を実施すべきであり，その対象には心臓手術チームのメンバー全員を含めるべきである（*クラス I，エビデンスレベル B*）．

3．心臓手術患者を他の医療従事者に引き継ぐ際には，正式な引き継ぎ手順を実践すべきである（*クラス I，エビデンスレベル B*）．

4．重大であるがまれにしか起こらない事象（人工肺の緊急交換）を想定したシナリオ訓練を，心臓手術チームのメンバー全員を対象として定期的に実施するのが妥当である（*クラス IIa，エビデンスレベル C*）．

5．チームワークとコミュニケーションに関して以下のような研究を今後実施していくのが妥当である．（a）最適なコミュニケーションモデル（心臓手術室でのブリーフィングと構造化されたコミュニケーション手順など）を検討する研究．（b）心臓手術室での使用に「最善の成果」を判断するためのチーム訓練モデルを検討する研究．（c）チームワークとコミュニケーションスキルの正式な訓練を実践する上での障害を調査する．（d）このような訓練が医療従事者の成果（安全に対する態度，ベストプラクティスの遵守，コミュニケーションスキルなど）に与える持続的な影響に関する長期的な研究．（e）チームワークとコミュニケーションスキルの正式な訓練について，患者のアウトカム（満足度，血液製剤の使用量，感染率，ICU への再収容，死亡率，費用など）の改善における有効性を調査する研究．（f）有害事象および有害でなかったインシデントに関するデータを得るための多職種を対象とした全国的な匿名の事象報告制度を確立する研究（*クラス IIa，エビデンスレベル C*）．

物理的環境の研究機会

心臓手術室への人間工学の応用は，大部分とまではいえないまでも，多くの手術室で不十分である．患者とスタッフ双方に対してさまざまな潜在的危険が存在しており，例をあげれば，スタッフの移動と気流による患者の感染[305, 307]，コードや機器へのつまずきによるスタッフの転倒リスク[297, 298]，警報音，音楽，あちこちで同時に行われる会話などに起因する室内の全員にとって危険な水準の雑音などがある[§]．しかしながら，効果的な作業の流れとスタッフの人数制限を設ける最適な手術室を設計すれば，これらの潜在的危険を低減できる可能性がある．さらに，感度と特異度の高いアラームシステムを設計することによっても，さまざまな監視装置からの情報を統合し，雑音やアラームによる疲れを軽減することで，医療安全を改善できる可能性がある[313, 328]．

推 奨 事 項

1．アラームに関連した注意散漫を減らし，複数の情報源から得た情報を統合する医療従事者の能力を向上させるべく，手術室における最適な設計と情報システムの試験を検討するのが妥当である（*クラス IIa，エビデンスレベル C*）．

2．今後の研究における革新的な領域として，手術室の最適な設計とレイアウトを現場とシミュレーション環境の双方で検討していく手法は妥当であり，それにより，費用のかさむ設計エラーを回避できる可能性がある（*クラス IIb，エビデンスレベル C*）．

安全文化：プロフェッショナリズムと質に関する方針の実践

2009 年，米国医療機関認定合同委員会は，安全文化の醸成と維持を義務付ける基準を導入した．そこには，破壊的行動に対する対処方針の策定と，容認できない行動を管理するための正式なプロセスが含まれる[371, 372]．心臓手術チームを含む各専門分野の部署は，正の側面と負の側面を兼ね備えた独自の文化を築くことがある．

推 奨 事 項

1．あらゆる病院環境での医療専門職による破壊的行動を定義した病院ごとの方針を，容認できない行動に対処するための透明性ある正式な手順と，そのような行動を根絶するための対策とともに，ただちに実施すべきである（*クラス I，エビデンスレベル C*）．

2．われわれは，すべての病院が医療の質保証と質改善を目的としたしっかりとしたプログラムを確立し，以下の活動を通じて真摯に安全文化の構築に努めることを推奨する．（a）システム，部署，個人レベルの安全に対する潜在的危険の特定を継続的に試みていく．（b）特定した潜在的危険を除去するためのリーダーシップと情報および費用を提供する．（c）心臓手術チームのメンバー全員が懲罰的でない風土の醸成に協力するよう促し，それを尊重する（*クラス I，エビデンスレベル C*）．

安全文化の研究機会

組織文化が医療従事者または患者の転帰に及ぼす影響を評価した研究はわずかしかない[394, 395, 397]．現在利用できるデータからは，医療安全と医療の質改善構想が患者アウトカム（満足度，血液製剤の使用量，感染率，ICU への再収容，死亡率，費用など）を改善する可能性について限定的なエビデンスしか得られておらず，安全重視に向けた医療従事者の態度と組織文化の改善が持続可能かどうかも分かっていない．

[§] References 296, 304, 310, 311, 314, 316, 317, 321.

推 奨 事 項

1. 技術志向で複雑な心臓手術室の環境での対策に対して科学的な検討を行うことが妥当であり，具体的には（a）安全文化と安全風土を改善するべく設計された既存のツールをテストし新たなツールを開発すること，（b）対策後に継続的な評価を実施して安全文化の持続的改善を測定すること，（c）選択した有害な転帰を減少させるか否か，安全文化の改善における有効性を評価する大規模な多施設共同臨床試験の確立につなげること，などがあげられる（*クラス IIb，エビデンスレベル C*）．

2. 心臓手術室でのエラー発生の素地となるヒューマンファクターとシステム要因を検討する多職種を対象とした前向き研究の計画と，それに対する資金投入は妥当である（*クラス IIb，エビデンスレベル C*）．

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利益相反の開示

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David C. Fitzgerald	Inova Heart and Vascular Institute	None	None	None	None	None	None	None
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Bruce E. Searles	SUNY Upstate Medical University	Transonic Systems†; Circulatory Technologies†	None	None	Expert witness for defense in 2010 and 2011 for standards of care for perfusion practice†	None	None	None

(*Continued*)

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This table represents the relationships of writing group members that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all members of the writing group are required to complete and submit. A relationship is considered to be "significant" if (1) the person receives $10 000 or more during any 12-month period, or 5% or more of the person's gross income; or (2) the person owns 5% or more of the voting stock or share of the entity, or owns $10 000 or more of the fair market value of the entity. A relationship is considered to be "modest" if it is less than "significant" under the preceding definition.

*Modest.

†Significant.

Reviewer Disclosures

Reviewer	Employment	Research Grant	Other Research Support	Speakers' Bureau/ Honoraria	Expert Witness	Ownership Interest	Consultant/ Advisory Board	Other
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Jeffrey Riley	Mayo Clinic, Rochester	None	None	None	None	None	None	None
Marc Ruel	University of Ottawa Heart Institute	None	None	None	None	None	None	None
Doug Wiegmann	University of Wisconsin–Madison	US Department of Defense†	None	Grand rounds talk*	None	None	American College of Surgeons (unpaid)*	None

This table represents the relationships of reviewers that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all reviewers are required to complete and submit. A relationship is considered to be "significant" if (1) the person receives $10 000 or more during any 12-month period, or 5% or more of the person's gross income; or (2) the person owns 5% or more of the voting stock or share of the entity, or owns $10 000 or more of the fair market value of the entity. A relationship is considered to be "modest" if it is less than "significant" under the preceding definition.

*Modest.

†Significant.

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KEY WORDS: AHA Scientific Statements ■ briefing ■ communication ■ handoff ■ patient care team ■ patient-centered care ■ patient safety ■ safety culture ■ simulation

Correction

In the article by Wahr et al, "Patient Safety in the Cardiac Operating Room: Human Factors and Teamwork: A Scientific Statement From the American Heart Association," which published online August 5, 2013, and appeared in the September 3, 2013, issue of the journal (Circulation. 2013;128:1139–1169), a correction was needed.

On page 1139, in the author byline, Bruce E. Searles' degrees were listed incorrectly as "MSN, CCP." They have been changed to read, "Bruce E. Searles, MS, CCP." The authors regret the error. This correction has been made to the print version and to the current online version of the article, which is available at http://circ.ahajournals.org/content/128/10/1139.

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