

Annotated Bibliography Operating Room Team Performance and Use of Checklists to Prevent Wrong Site Surgery

Introduction

Surgery is a commonplace healthcare intervention to investigate, diagnose and/or treat a pathological condition, disease or injury. The invasive nature of surgery, with the increasing complexity of procedures, sets up an inherent risk to patient safety. Wrong site surgery is surgery conducted on the wrong person, the wrong organ, the wrong limb, the wrong side or the wrong location on a patient's body. The World Health Organization (WHO) estimates that in developed countries, major complications occur in 3 – 16% of inpatient surgical procedures,¹ although more modest estimates of wrong site surgery have been reported in the literature.² In addition, WHO estimates the incidence of permanent disability or death rates from wrong site surgery is approximately 0.4 – 0.8%.³ Although this is a relatively rare phenomenon, the outcome of a medical error from wrong site surgery could have catastrophic implications for the patient, the healthcare providers involved, and the healthcare system.

In July 2004, the Universal Protocol for Preventing Wrong Site, Wrong Procedure and Wrong Person Surgery™, became effective for all accredited hospitals, ambulatory care and office-based surgery facilities in the United States.⁴ As part of its National Patient Safety Goals, the original protocol was approved by The Joint Commission Board of Commissioners in 2003, and revised in 2010. The Universal Protocol emphasises pre-operative verification, site marking, and 'time-out' procedures. In June 2008, WHO launched the 'Surgical Safety Checklist', as part of the second Global Patient Safety Challenge, to reduce the number of surgical deaths worldwide.⁵ The Surgical Safety Checklist emphasises a set of safety checks that could be implemented a set of safety checks that could be performed in any operating room to reinforce safety practices and foster better communication and teamwork between clinical disciplines. Operating room departments around the world have adopted and incorporated the Surgical Safety Checklist as part of their own routine patient safety protocol, some influenced by state and national government-initiated directives.

Despite the nearly worldwide adoption of these key patient safety initiatives, the effectiveness of implementation of these safety measures in reducing wrong-site surgery, to date, is inconclusive.⁶ This document provides a brief annotated bibliography on the state of knowledge on the effectiveness of using a checklist to reduce wrong site surgery.

Utilising the PICO format, the key question guiding this annotated bibliography is *In surgical populations, does the use of checklists in the operating room compared to other strategies reduce the rate of wrong site surgery?* Since a systematic review of randomised controlled trials is considered the highest level of evidence for intervention questions, this annotated bibliography sought to identify systematic reviews, in the first instance, and then other studies in accordance with their level of evidence. Critical review of each paper was conducted using the Scottish Intercollegiate Guidelines Network (SIGN) Critical Appraisal Checklists.²

Included in the annotated bibliography is a critique on the one systematic review identified in the search. In addition, references and abstracts are provided for systematic review protocol and an additional 12 studies published between 2006 and 2011, with designs varying including literature reviews; prospective or retrospective observational and/or pre/post studies of team training, checklist use, or debriefings, alone or any combination of the three; cross sectional evaluation design or qualitative study design of checklist use.⁷

Bottom line: There is insufficient evidence to confirm effectiveness of checklists to reduce wrong site surgery. A systematic review is currently underway. Most studies involving checklists have been conducted with the aim of evaluating team training with or without the use of checklists, thus making it difficult to assess the effectiveness of the checklist in isolation as reducing wrong site surgery. More well designed are needed to determine effectiveness of checklists alone, whether used in isolation or as a component of a multicomponent intervention on reducing wrong site surgery.

¹ NHS National Patient Safety Agency (2009). Alert: NPSA/2009/PSA002/U1 WHO Surgical Safety Checklist Supporting information. Retrieved March 8, 2012 from <http://www.nrls.npsa.nhs.uk/resources/clinical-specialty/surgery/?entryid45=59860>.

² Kwaan, M.R., Studdert, D.M., Zimmer, M.J., & Gawande, A.A. (2006). Incidence, Patterns, and Prevention of Wrong-Site Surgery. *Archives of Surgery*, 141, 353-358.

³ NHS National Patient Safety Agency (2009). Alert: NPSA/2009/PSA002/U1 WHO Surgical Safety Checklist Supporting information. Retrieved March 8, 2012 from <http://www.nrls.npsa.nhs.uk/resources/clinical-specialty/surgery/?entryid45=59860>.

⁴ The Joint Commission. Facts About the Universal Protocol. Retrieved March 8, 2012 from http://www.jointcommission.org/standards_information/up.aspx.

⁵ World Health Organization (2008). *Surgical safety checklist and implementation manual*. Retrieved March 8, 2012 at http://www.who.int/patientsafety/safesurgery/ss_checklist/en/index.html

⁶ Mahar, P., Wasiak, J., Batt,y L., Fowler, S., Cleland, H., & Gruen, R.L. (2011). Interventions for reducing wrong-site surgery (protocol). *Cochrane Database of Systematic Reviews (Protocol)*, Issue 11. Art. No.: CD009404. DOI: 10.1002/14651858.CD009404.

⁷ Scottish Intercollegiate Guidelines Network. Critical Appraisal Checklists. Retrieved March 8, 2012 at <http://www.sign.ac.uk/methodology/checklists.html>.

Devine, J., Chutkan, N., Norvell, D.C., & Dettori, J.R. (2010). Avoiding wrong site surgery: A systematic review. *Spine*, 35 (9 Suppl), S28-36.

ABSTRACT	
Background	From 1995 to 2005, the Joint Commission (JC) sentinel event statistics database ranked wrong site surgery as the second most frequently reported event (12.8%). Although the event seems to be rare, the incidence of these complications has been difficult to measure and quantify. The implications for wrong site surgery go beyond the effects to the patient. Such an event has profound medical, legal, social, and emotional implications.
Objective	The objectives of this study were to report (1) the incidence and (2) causes of wrong site surgery; and to (3) determine what preoperative measures are effective in preventing wrong site surgery.
Study Design	Systematic review
Population	Included patients undergoing spine surgery or other surgery
Intervention	Preventative measures to reduce wrong site surgery
Outcome	Wrong site, wrong side, wrong person, or wrong exposure surgery
Methods	A systematic review of the English language literature was undertaken for articles published between 1990 and December 2008. Electronic databases searched included Medline, EMBASE, the Cochrane Library, the Food and Drug Administration database, Joint Commission database; also reference lists of key articles were systematically checked. Two independent reviewers assessed the level of evidence quality using criteria set by The Journal of Bone and Joint Surgery, American Volume.
Findings	From 65 identified papers, 11 met the inclusion criteria. The estimated rate of wrong site surgery varies widely ranging from 0.09 to 4.5 per 10,000 surgeries performed. There is no literature to substantiate the effectiveness of the current JC Universal Protocol checklist, the North American Spine Surgery (NASS) checklist, or any other strategy in decreasing the rate of wrong site surgery.
Conclusion	Wrong site surgery may be preventable. The authors suggest that the North American Spine Society and JC checklists are insufficient on their own to minimize this complication. Therefore, in addition to these protocols, the authors recommend intraoperative imaging after exposure and marking of a fixed anatomic structure. This imaging should be compared with routine preoperative studies to determine the correct site for spine surgery.

CRITICAL REVIEW	
Introduction	Critical review was guided by five criteria questions adapted from the Scottish Intercollegiate Guidelines Network (SIGN) Critical Appraisal Checklists. The SIGN checklist assumes that a well conducted systematic review should each of the five criteria. The appraisal is a critique of the degree to which the criteria are met.
Criteria 1: The study addresses an appropriate and clearly focused question.	This criterion is not addressed well. The review addressed three simple questions - (1) what is the incidence of, (2) what are the causes of, and (3) what preoperative measures are effective in preventing wrong site surgery; however, the questions were not clearly focused. Firstly, the first two questions do not lend themselves to the specific research design of a systematic review of the literature. Secondly, asking the three questions in one review is inappropriate because the most suitable study design to answer each question is different and, as such, detracts from the focus of the review. The approach taken by the review authors may be in response to the limited empirical research on the state of science of preventing wrong site surgery, particularly in spine surgery.
Criteria 2: A description of the methodology used is included.	This criterion is adequately addressed in some areas and not addressed well in others. The review included a detailed, mostly adequate description of the systematic methods used to identify and evaluate individual studies, including the search strategy, inclusion and exclusion criteria, data extraction, quality assessment of included studies, and data analysis. Some areas that are not adequately described include types of studies to be included. This is a reflection of the inadequate focus of the review questions, allowing for a wide range of study types, such as cohort studies, case control studies and randomised controlled trials, either of which would be appropriate depending on the specific question addressed.
Criteria 3: The literature search is sufficiently rigorous to identify all the relevant studies.	This criterion is adequately addressed. The review authors searched the minimum expected databases, such as MEDLINE, EMBASE and the Cochrane Library from 1990 to 2008; as well as other sources such as the FDA and Joint Commission databases. Review authors reported following up reference lists of "key articles" but did not indicate if hand searching of key journals was undertaken. The search approach was described in detail, but key study type criteria were not explicitly stated (see above e.g. RCT, cohort, etc.). Description of the search strategy was provided but with no indication of key words searched – were there other terms for 'wrong site surgery' entered in the search? Article identification and retrieval was performed by two reviewers independently, with disagreements resolved by consensus.
Criteria 4: Study quality is assessed and taken into account.	Quality assessment processes were not clearly described in this paper, except review authors report using a documented approach based on the Journal of Bone and Joint Surgery. Review authors do, however, refer the reader to another previously published methodology paper that describes the quality assessment criteria used to delineate studies.

<p>Criteria 5: There are enough similarities between the studies selected to make combining them reasonable.</p>	<p>Studies covered by a systematic review should be selected using clear inclusion criteria. Although the review authors attempt to identify inclusion and exclusion criteria, it is clear that the looseness of this description does not allow the reader to determine whether the studies would be comparable without returning to each individual study. The review authors appropriately report that it was not possible to calculate a pooled rate of wrong site surgery (Question 1) from the included studies due to the vast difference in study methods and definitions of wrong site surgery. This reflects the nature of the available literature. However, there is not discussion of appropriateness in combining studies to explore Question 3 (effectiveness of strategies to prevent wrong site surgery). This is again, most likely, a reflection of the lack of focus of the review. Data was summarised in tables and “qualitative analysis” was performed considering three domains: quality, quantity, and consistency of results.</p>
<p>Overall assessment of the review</p>	<p>The authors conclude that checklists are insufficient on their own to minimize wrong site surgery. Some of the criteria of a well-designed systematic review were not adequately fulfilled or described. Those criteria that were not fulfilled or not adequately described may alter the conclusions. Apart from focusing the review, widening the search parameters to include English language and unpublished studies may yield more studies for inclusion. Differences between included studies appropriately precluded pooling of data in a meta-analysis. The paper is entitled ‘systematic review,’ however in the first sentence of the discussion section the authors refer to the paper as ‘literature review,’ reflecting its true nature. Despite this, the recommendation for further research to estimate effect of wrong site surgery and establish causes is valid. Although the data support that the strength of the evidence that checklists prevents wrong site surgery is low, recommending intraoperative imaging after exposure and marking fixed anatomic structure is not supported.</p>

Mahar, P., Wasiak, J., Batty, L., Fowler, S., Cleland, H., & Gruen, R.L. (2011). Interventions for reducing wrong-site surgery. *Cochrane Database of Systematic Reviews (Protocol)*, Issue 11. Art. No.: CD009404.

Background	Over the last decade, much work has been done to determine which specific, and potentially modifiable, risk factors may contribute to wrong-site surgery, or, if modified, prevent it.
Objective	The objectives of this systematic review as per the published protocol are to determine the effectiveness of organisational and professional interventions for reducing wrong-site surgery.
Study Design	Systematic review including randomized controlled trials (RCTs), well-designed quasi-randomized controlled trials, controlled before and after studies (CBAs) that include at least two intervention and two control sites, and interrupted time series designs that meet the Cochrane Effective Practice and Organisation of Care (EPOC) Group inclusion criteria. The review will include studies involving healthcare professionals providing care to surgical patients; studies where patients are involved to avoid the incorrect procedures; or studies with interventions addressed to healthcare managers, administrators, stakeholders or health insurers
Population	All patients undergoing any type of surgery; nurses or clinicians involved in delivering surgical care; operating room technicians, healthcare managers or administrators and health insurers involved in delivering surgical care.
Intervention	Types of intervention may include interventions designed to address documentation, site, procedure and patient identification, communication amongst healthcare team members, patients and their caregivers.
Outcome	Primary outcomes will be the incidence of wrong-site surgery, including wrong-site, wrong-side, wrong-procedure and wrong-patient surgery. Secondary outcomes include mortality, health service resource consumption, healthcare professional behaviour and resource burden on healthcare providers in terms of additional time taken to undertake the intervention. Also included will be process measures (i.e. completion rate of checklists) where available.
Methods	Related systematic reviews and primary studies will be identified by searching the following databases, sources and other approaches: Database of Abstracts of Reviews of Effectiveness (DARE), Medline, Embase, The Cochrane Central Register of Controlled Trials, the EPOC Specialized Register, Dissertations and Theses, African Index Medicus (AIM), Latin American and Caribbean Health Sciences (LILACS) database, Pan American Health Organization (PAHO) database, WHO Library Information System (WHOLIS). Search strategies have been developed by the EPOC TSC in conjunction with the authors. There will be no language restrictions. Details describing data collection and analysis can be found in the paper.
Findings	Unable to comment
Conclusion	Unable to comment
Notes	<i>Unable to comment and critique this review as it is in protocol stage and review is ongoing.</i>

Allard, J., Bleakley A., Hobbs, A., & Coombes, L. (2011). Pre-surgery briefings and safety climate in the operating theatre. *BMJ Quality & Safety*, 20(8), 711-717.

Background	In 2008, the WHO produced a surgical safety checklist against a background of a poor patient safety record in operating theatres. Formal team briefings are now standard practice in high-risk settings such as the aviation industry and improve safety, but are resisted in surgery. Research evidence is needed to persuade the surgical workforce to adopt safety procedures such as briefings.
Objective	To investigate whether exposure to pre-surgery briefings is related to perception of safety climate.
Study Design	Complex, longitudinal prospective collaborative inquiry
Population	Contexts include operating room ad hoc teams, teams with more or less continuity, and with different kinds of surgical foci.
Intervention	Theatre Team Resource Management using principles associated with crew resource management. This study focused on one component, briefings. Briefings included a formal checklist ; 'informal corridor' and 'coffee room', 'horizon' (the night before), cumulative (such as 'whiteboard' briefs) and were introduced in conjunction with debriefing.
Outcome	Outcome measures drawn from the 'safety climate' domain of the Safety Attitude Questionnaire (SAQ).
Methods	Three SAQs, completed by operating theatre staff in 2003, 2004 and 2006, were used to evaluate the effects of an educational intervention introducing pre-surgery briefings.
Findings	Individual practitioners who agree with the statement 'briefings are common in the operating theatre' also report a better 'safety climate' in operating theatres.
Conclusion	The study reports a powerful link between briefing practices and attitudes towards safety. Findings build on previous work by reporting on the relationship between briefings and safety climate within a 4-year period. Briefings, however, remain difficult to establish in local contexts without appropriate team-based patient safety education. Success in establishing a safety culture, with associated practices, may depend on first establishing unidirectional, positive change in attitudes to create a safety climate.
Notes	<i>Although use of checklists was a component of the intervention, it is not possible to isolate the effect of the checklist on reduction of wrong site surgery.</i>

Young-Xu, Y., Neily, J., Mills, P.D., Carney, B.T., West P, Berger, D.H., ... Bagian, J.P. (2011). Association between implementation of a medical team training program and surgical morbidity. Archives of Surgery, 146(12), 1368-1373.

Background	Considerable efforts to reduce risk associated with surgery have been promoted over the past decade.
Objective	To determine whether there is an association between the Veterans Health Administration Medical Team Training (MTT) program and surgical morbidity.
Study Design	A retrospective health services cohort study using a contemporaneous control group
Population	Data collected from VHA Surgical Quality Improvement Program (VASQIP) annual surgical morbidity rates from 74 facilities for 3 fiscal years (2006, 2007, and 2008) for major non-cardiac operations.
Intervention	Medical Team Training (MTT) program based on crew resource management theory from aviation. MTT included checklist-guided preoperative briefings and postoperative briefings. MTT program began with 2 months of preparation and planning at the facility followed by a 1-day learning session held on site. This was followed up with 4 quarterly follow-up telephone interviews conducted with the team. Everyone in the OR is trained to work as a team. Detailed program description is provided in the paper.
Outcome	Observed and risk-adjusted 30 day morbidity rates; aggregated morbidity rates at the facility level;
Methods	The MTT program was implemented in 42 facilities and 32 facilities served as the contemporaneous control group. Before and after analyses were performed for the MTT two groups and the changes in the two groups compared. Outcome data were obtained from the Veterans Health Administration Surgical Quality Improvement Program. The analysis included aggregated measures representing 119,383 sampled procedures from 74 Veterans Health Administration facilities that provide care to veterans. The primary outcome measure was the rate of change in annual surgical morbidity rate 1 year after facilities enrolled in the MTT program as compared with 1 year before and compared with the non-MTT program sites.
Findings	Facilities in the MTT program (n = 42) had a significant decrease of 17% in observed annual surgical morbidity rate (rate ratio, 0.83; 95% CI, 0.79-0.88; P = .01). Facilities not trained (n = 32) had an insignificant decrease of 6% in observed morbidity (rate ratio, 0.94; 95% CI, 0.86-1.05; P = .11). After adjusting for surgical risk, we found a decrease of 15% in morbidity rate for facilities in the MTT program and a decrease of 10% for those not yet in the program. The risk-adjusted annual surgical morbidity rate declined in both groups, and the decline was 20% steeper in the MTT program group (P = .001) after propensity-score matching. The steeper decline in annual surgical morbidity rates was also observed in specific morbidity outcomes, such as surgical infection.
Conclusion	The Veterans Health Administration MTT program is associated with decreased surgical morbidity.
Notes	<i>Although use of checklists was a component of the intervention, it is not possible to isolate the effect of the checklist on reduction of wrong site surgery.</i>

Conrardy, J.A., Brenek, B., & Myers, S. (2010). Determining the state of knowledge for implementing the universal protocol recommendations: An integrative review of the literature. *AORN Journal*, 92 (2), 194-207.

Background	Despite the implementation of Joint Commission’s (JC) Universal Protocol in 2004, wrong site, wrong procedure, wrong person surgery persists.
Objective	The purpose of this study was to determine the current state of knowledge concerning the implementation of the JC’s Universal Protocol. We conducted an integrative review of the literature through a systematic search of the National Library of Medicine’s PubMed database to identify empirical and theoretical documents that discussed the implementation process for the Universal Protocol.
Study Design	Integrative review and synthesis guided by Reason’s Vulnerable Systems Syndrome theory as theoretical underpinnings and Bibb and Wanzer’s Identifying, Organizing, and Synthesizing (IOS) strategy as the conceptual framework.
Population	Not specified in paper
Intervention	Not specified in paper
Outcome	Implied outcomes: wrong site, wrong procedure, and wrong person surgery
Methods	Question guiding review was “ <i>What is the existing state of knowledge about the contributing factors associated with wrong site, wrong procedure, and wrong person surgery and the implementation of the Universal Protocol?</i> ” Literature searched from Jan 1999 to Oct 2008 for English language articles in PubMed, using relevant key words; documents that did not address JC Universal Protocol recommendations were excluded. IOS framework guiding search described in the paper.
Findings	Thirty-four included papers. Significant trends in current practice identified and categorized into 6 domains: universal protocol elements, communication, systems processes, team performance, organizational/cultural behaviour and patient assessment. Missing or confusing gaps (e.g., site verification, marking of surgical site or surgical time out) grouped into 3 categories: universal protocol elements, measurement tools, and data on efficacy of Universal Protocol. There is a lack of any scientific evidence on the usefulness of the Universal Protocol to prevent wrong site, wrong procedure, and wrong person surgery.
Conclusion	The current state of knowledge varies from facility to facility, and the authors noted significant trends, gaps, and areas of concern in the implementation process. Successful implementation of the Universal Protocol has the following elements: a multidisciplinary team approach, active staff/patient participation, supportive hospital administration/leadership, and active communication that promotes a healthy work environment.
Notes	<i>No additional comments</i>

Neily, J., Mills, P.D., Young-Xu, Y., Carney, B.T., West, P., Berger, D.H., ... Bagian, J.P. (2010). Association between implementation of a medical team training program and surgical mortality. *JAMA*, 304 (15), 1693-1700.

Background	There is insufficient information about the effectiveness of medical team training on surgical outcomes. The Veterans Health Administration (VHA) implemented a formalized medical team training program for operating room personnel on a national level.
Objective	To determine whether an association existed between the VHA Medical Team Training program and surgical outcomes.
Study Design	A retrospective health services cohort study with a contemporaneous control group was conducted (n= 182,409 sampled procedures from 108 VHA facilities).
Population	Data collected from VHA Surgical Quality Improvement Program (VASQIP) annual surgical morbidity rates from 108 facilities (74 Medical Team Training (MTT) group; 34 control group) for 3 fiscal years (2006, 2007, and 2008) for major non-cardiac operations
Intervention	Medical Team Training (MTT) program based on crew resource management theory from aviation. MTT included checklist-guided preoperative briefings and postoperative briefings. MTT program began with 2 months of preparation and planning at the facility followed by a 1-day learning session held on site. This was followed up with 4 quarterly follow-up telephone interviews conducted with the team. Detailed program description is provided in the paper.
Outcome	Surgical complexity, patient comorbidity, and sociodemographic characteristics, and observed 30-day mortality rates for major non-cardiac surgery; aggregated mortality rates at the facility level; perceptions of program effect on OR efficiency.
Methods	Outcome data were obtained from the VHA Surgical Quality Improvement Program (VASQIP) in fiscal years 2006 to 2008 and from structured follow up quarterly interviews. The analysis included 182,409 sampled procedures from 108 VHA facilities that provided care to veterans. The VHA's nationwide training program required briefings and debriefings in the operating room and included checklists as an integral part of this process. The training included 2 months of preparation, a 1-day conference, and 1 year of quarterly coaching interviews. The rate of change in the mortality rate 1 year after facilities enrolled in the training program compared with the year before and with non-training sites. For interviews, narrative responses that required interpretation were coded and themes identified.
Findings	The 74 facilities in the training program experienced an 18% reduction in annual mortality (rate ratio [RR], 0.82; 95% confidence interval [CI], 0.76-0.91; P = .01) compared with a 7% decrease among the 34 facilities that had not yet undergone training (RR, 0.93; 95% CI, 0.80-1.06; P = .59). The risk-adjusted mortality rates at baseline were 17 per 1000 procedures per year for the trained facilities and 15 per 1000 procedures per year for the non-trained facilities. At the end of the study, the rates were 14 per 1000 procedures per year for both groups. Propensity matching of the trained and non-trained groups demonstrated that the decline in the risk-adjusted surgical mortality rate was about 50% greater in the training group (RR, 1.49; 95% CI, 1.10-2.07; P = .01) than in the non-training group. A dose-response relationship for additional quarters of the training program was also demonstrated: for every quarter of the training program, a reduction of 0.5 deaths per 1000 procedures occurred (95% CI, 0.2-1.0; P = .001). Thirty five training facilities (42.7%) reported improved communication among OR staff; 34 (46%) reported improved OR awareness; 48 (64.9%) reported improved OR teamwork.
Conclusion	Participation in the VHA Medical Team Training program was associated with lower surgical mortality and perceived improved OR team communication, awareness of safety issues and teamwork.
Notes	<i>This study demonstrates a multifaceted intervention was associated with improved teamwork and reduced surgical mortality. Although use of checklists was a component of the intervention, it is not possible to isolate the effect of the checklist on reduction of wrong site surgery.</i>

Weaver, S.J., Rosen, M.A., Diaz, G.D., Lazzara, E.H., Lyons, R., Salas, E., ...King, H.B. (2010). Does teamwork improve performance in the operating room? A multilevel evaluation. *Joint Commission Journal on Quality & Patient Safety*, 36 (3), 133-142.

Background	Medical care is a team effort, especially as patient cases are more complex. Communication, cooperation, and coordination are vital to effective care, especially in complex service lines such as the operating room (OR). Team training, specifically the TeamSTEPPS™ training program, has been touted as one methodology for optimizing teamwork among providers and increasing patient safety. Although such team-training programs have transformed the culture and outcomes of other dynamic, high-risk industries such as aviation and nuclear power, evidence of team training effectiveness in health care is still evolving. Although providers tend to react positively to many training programs, evidence that training contributes to important behavioral and patient safety outcomes is lacking.
Objective	Evaluation of a quality improvement (QI) project aimed at optimizing teamwork behaviour among OR teams.
Study Design	Multilevel evaluation of OR service line with a control location.
Population	OR teams within a large community hospital system; included 3 surgeons and their teams, including contracted anesthesiology providers; groups located at separated campuses
Intervention	Training curriculum based on TeamSTEPPS™ training program; included targeted competencies, 4-hour didactic session with interactive role playing activities.
Outcome	Trainee reactions; trainee learning (measured with 23-item TeamSTEPPS™ learning benchmark tests); behaviour in the OR (measured with baseline and post training case observations using several observation tools), patient safety culture (measured with Hospital Survey on Patient Safety Culture -HSPOS).
Methods	OR teams recruited between Feb and Mar 2008; groups located at separate campuses (trained campus, n=29; and non-trained campus, n=26) to minimize treatment diffusion. A multilevel evaluation of the TeamSTEPPS™ training program was conducted within the OR service line with a control location. Multilevel evaluation framework based on Kirkpatrick's for levels of training evaluation. Evaluation was a mixed-model design with one between-groups factor (TeamSTEPPS™ training versus no training) and two within-groups factors (time period, team). The groups were located at separate campuses to minimize treatment diffusion. Trainee reactions, learning, behaviors in the OR, and proxy outcome measures such as the Hospital Survey on Patient Safety Culture (HSOPS) and Operating Room Management Attitudes Questionnaire (ORMAQ) were collected.
Findings	All levels of evaluation demonstrated positive results. The trained group demonstrated significant increases in the quantity and quality of presurgical procedure briefings and the use of quality teamwork behaviors during cases. Increases were also found in perceptions of patient safety culture and teamwork attitudes.
Conclusion	The hospital system has integrated elements of TeamSTEPPS™ into orientation training provided to all incoming hospital employees, including nonclinical staff.
Notes	<i>Although use of checklists was a component of the intervention, it is not possible to isolate the effect of the checklist on reduction of wrong site surgery.</i>

Sax, H.C., Browne, P., Mayewski, R.J., Panzer, R.J., Hittner, K.C., Burke, R.L., & Coletta, S. (2009). Can aviation-based team training elicit sustainable behavioral change? *Archives of Surgery*, 144 (12), 1133-1137.

Background	Patient safety is a central theme in medicine and issues leading to unsafe healthcare environments were brought to light by IOM report, <i>To Err is Human</i> . Drawing on analogies between aviation and medicine, programs have been developed based on crew resource management (CRM) that focus on both human and systems issues to improve communication, error management and work culture. It is difficult to objectively quantify the effects of CRM.
Objective	To quantify effects of multidisciplinary aviation-based crew resource management training program on patient safety-related behaviors and perceived personal empowerment.
Study Design	Prospective observational study
Population	There were 857 participants, the majority of whom were nurses (50%), followed by ancillary personnel (28%) and physicians (22%). Setting: 722-bed university hospital; 247-bed affiliated community hospital.
Intervention	Crew resource management training intervention
Outcome	Checklist adoption and use, self-reporting of errors and unsafe conditions, and perceptions of personal and institutional empowerment to create a culture of safety.
Methods	Prospective observational study of checklist use, error self-reporting, and a 10-point safety empowerment survey. CRM intervention was implemented at both a tertiary care academic medical center and a medical school-affiliated community hospital. Preoperative checklist use over time; number and type of entries on a Web-based incident reporting system; and measurement of degree of empowerment (1-5 scale) on a 10-point survey of safety attitudes and actions given prior to, immediately after, and a minimum of 2 months after training. Training program was a 6-hour course on "lessons from the cockpit" that was multidisciplinary and interactive using videos, teambuilding exercises, and open forums. A perioperative checklist, modelled on pre-flight aviation checklists, was developed and posted in each operating room. Checklist use was voluntary at the start of the study, but over time became a compulsory activity whereby scrub nurse instructed not to hand up knife until checklist completed. Checklist compliance was monitored by circulating nurse.
Findings	Since 2003, 10 courses trained 857 participants in multiple disciplines. Preoperative checklist use rose (75% in 2003, 86% in 2004, 94% in 2005, 98% in 2006, and 100% in 2007). Self-initiated reports increased from 709 per quarter in 2002 to 1481 per quarter in 2008. The percentage of reports related to environment as opposed to actual events increased from 15.9% prior to training to 20.3% subsequently ($P < .01$). Perceived self-empowerment, creating a culture of safety, rose by an average of 0.5 point in all 10 realms immediately post-training (mean [SD] rating, 3.0 [0.07] vs 3.5 [0.05]; $P < .05$). This was maintained after a minimum of 2 months. There was a trend toward a hierarchical effect with participants less comfortable confronting incompetence in a physician (mean [SD] rating, 3.1 [0.8]) than in nurses or technicians (mean [SD] rating, 3.4 [0.7] for both) ($P > .05$).
Conclusion	Crew resource management programs can influence personal behaviors and empowerment. Effects may take years to be ingrained into the culture.
Notes	<i>Although use of checklists was a component of the intervention and checklist compliance increased over time, it is not possible to isolate the effect of the checklist on reduction of wrong site surgery (wrong site surgery not an outcome in this study).</i>

de Vries, E.N., Hollmann, M.W., Smorenburg, S.M., Gouma, D.J., & Boermeester, M.A. (2009). Development and validation of the SURgical PATient Safety System (SURPASS) checklist. *Quality & Safety in Health Care*, 18 (2), 121-6.

Background	A large number of preventable adverse events are encountered during hospital admission and in particular around surgical procedures. Checklists may well be effective in surgery to prevent errors and adverse events. Human factors literature and resources on causes, nature and locations of surgical errors, complications and adverse events were consulted in the development of a surgical safety checklist.
Objective	To develop, validate and evaluate a SURgical PATient Safety System (SURPASS) checklist.
Study Design	Real time observation study conducted in two validation periods, including 171 observed procedures (593 process deviations were noted during this time)
Population	171 surgical procedures arbitrarily selected from elective operating room schedule in a tertiary referral centre in Amsterdam
Intervention	Not applicable
Outcome	Process deviations from surgical pathway
Methods	A prototype checklist was constructed based on literature on surgical errors and adverse events, and on human-factors literature. The items on the theory-based checklist were validated by comparison with process deviations (safety risk events) during real-time observation of the surgical pathway. Subsequently, the usability of the checklist was evaluated in daily clinical practice. Further details on observation and validation schedule are described in the paper. After validation, checklist was introduced in daily practice, after instructive presentations for all users, and accompanied all elective procedures from pre-identified sentinel categories. After 5 months of checklist use, a structured interview with staff and residents who had been involved in checklist in practice.
Findings	The multidisciplinary SURPASS checklist accompanies the patient during each step of the surgical pathway and is completed by different members of the team. During 171 high-risk surgical procedures, 593 process deviations were observed. Of the deviations suitable for coverage by a checklist, 96% corresponded to an item on the checklist. Users were generally positive about the checklist, but a number of logistic improvements were suggested.
Conclusion	The SURPASS checklist covers the vast majority of process deviations suitable for checklist assessment and can be applied in clinical practice relatively simply. SURPASS is the first validated patient safety checklist for the entire surgical pathway.
Notes	<i>This paper describes utility and validation of a surgical checklist. It did not evaluate the effect of the checklist on any outcomes, including wrong site surgery.</i>

Haynes, A.B., Weiser, T.G., Berry, W.R., Lipsitz, S.R., Breizat, A.H., Dellinger, E.P., ... Gawande, A.A. (2009). A surgical safety checklist to reduce morbidity and mortality in a global population. *Safe Surgery Saves Lives Study Group. New England Journal of Medicine*, 360 (5), 491-499.

Background	Surgery has become an integral part of global health care, with an estimated 234 million operations performed yearly. Surgical complications are common and often preventable. We hypothesized that a program to implement a 19-item surgical safety checklist designed to improve team communication and consistency of care would reduce complications and deaths associated with surgery.
Objective	To investigate whether implementation of the surgical checklist and the associated culture changes it signified would reduce rates of death and major complications after surgery in diverse settings
Study Design	Prospective cohort study using pre/post design
Population	Eight hospitals in eight cities (Toronto, Canada; New Delhi, India; Amman, Jordan; Auckland, New Zealand; Manila, Philippines; Ifakara, Tanzania; London, England; and Seattle, WA) representing a variety of economic circumstances and diverse populations of patients.
Intervention	Two-step checklist-implementation program using World Health Organization (WHO) 19-item safe-surgery checklist (see paper for details).
Outcome	Primary outcome was occurrence of any major complication, including death, during period of postoperative hospitalization, up to 30 days. Complications defined as per American College of Surgeons' National Surgical Quality Improvement Program; adherence to a subgroup of 6 safety measures as an indication of process adherence
Methods	Between October 2007 and September 2008, eight hospitals in eight cities (Toronto, Canada; New Delhi, India; Amman, Jordan; Auckland, New Zealand; Manila, Philippines; Ifakara, Tanzania; London, England; and Seattle, WA) representing a variety of economic circumstances and diverse populations of patients participated in the World Health Organization's Safe Surgery Saves Lives program. A local data collector was chosen at each site. We prospectively collected data on clinical processes and outcomes from 3733 consecutively enrolled patients 16 years of age or older who were undergoing non-cardiac surgery. We subsequently collected data on 3,955 consecutively enrolled patients after the introduction of the Surgical Safety Checklist. Statistical analysis included frequencies of performance of specified safety measures, major complications, and death at each site before and after implementation of the checklist. Additional analyses included logistic regression analysis to test the robustness of the findings and cross validation to determine effect of checklist at any one site dominated results.
Findings	The rate of death was 1.5% before the checklist was introduced and declined to 0.8% afterward (P = 0.003). Inpatient complications occurred in 11.0% of patients at baseline and in 7.0% after introduction of the checklist (P<0.001).
Conclusion	Implementation of the checklist was associated with concomitant reductions in the rates of death and complications among patients at least 16 years of age who were undergoing non-cardiac surgery in a diverse group of hospitals.
Notes	<i>Although several outcome measures were assessed, rate of wrong site surgery was not measured in this study; therefore, it is not possible to determine the effect of the checklist on reduction of wrong site surgery.</i>

Khoshbin, A., Lingard, L., & Wright, J.G. (2009). Evaluation of preoperative and perioperative operating room briefings at the Hospital for Sick Children. *Canadian Journal of Surgery*, 52(4), 309-315.

Background	Wrong-site, wrong-procedure and wrong-patient surgeries are catastrophic events for patients, medical caregivers and institutions. Operating room (OR) briefings are intended to reduce the risk of wrong-site surgeries and promote collaboration among OR personnel.
Objective	The purpose of our study was to evaluate 2 OR briefing safety initiatives, "07:35 huddles" (preoperative OR briefing) and "surgical time-outs" (perioperative OR briefing), at the Hospital for Sick Children in Toronto, Ont.
Study Design	
Population	
Intervention	
Outcome	
Methods	First, we evaluated the completion and components of the 07:35 huddles and surgical time-outs briefings using direct observations. We then evaluated the attitudes of the OR staff regarding safety in the OR using the "Safety Attitudes Questionnaire, Operating Room version." Finally, we conducted personal interviews with OR personnel.
Findings	Based on direct observations, 102 of 159 (64.1%) 07:35 huddles and 230 of 232 (99.1%) surgical time-outs briefings were completed. The perception of safety in the OR improved, but only among nurses. Regarding difficulty discussing errors in the OR, the nurses' mean scores improved from 3.5 (95% confidence interval [CI] 3.2-3.8) pre-briefing to 2.8 (95% CI 2.5-3.2) post-briefing on a 5-point Likert scale ($p < 0.05$). Personal interviews confirmed that, mainly among the nursing staff, pre and perioperative briefing tools increase the perception of communication within the OR, such that discussions regarding errors within the OR are more encouraged.
Conclusion	Structured communication tools, such as 07:35 huddles and surgical time-outs briefings, especially for the nursing personnel, change the notion of individual advocacy to one of teamwork and being proactive about patient safety
Notes	Although use of checklists was a component of the intervention, it is not possible to isolate the effect of the checklist on reduction of wrong site surgery.

Makary, M.A., Mukherjee, A., Sexton, J.B., Syin, D., Goodrich, E., Hartmann, E., ... Pronovost, P.J. (2007). Operating room briefings and wrong-site surgery. *Journal of the American College of Surgeons*, 204 (2), 236-243.

Background	Wrong-site surgery can be a catastrophic event for a patient, caregiver, and institution. Although communication breakdowns have been identified as the leading cause of wrong-site surgery, the efficacy of preventive strategies remains unknown.
Objective	To evaluate the impact of operating room briefings on coordination of care and risk for wrong-site surgery.
Study Design	Observational prospective pre/post design
Population	Study site include general operating rooms in an academic medical center; sample included surgeons and OR staff (including physicians and nurses)
Intervention	2 minute OR briefing included three critical components: each member states name and role, surgeon leads "time out" as per JC guidelines, and teams discuss and mitigate potential safety hazards. Staff trained to perform OR briefing after anesthesia and before incision.
Outcome	perception of briefings; awareness of surgical site and side
Methods	Authors administered a case-based version of the Safety Attitudes Questionnaire (SAQ), a 17-item OR Briefing Assessment Tool (ORBAT) to operating room (OR) staff at an academic medical center, before and after initiation of an OR briefing program. OR briefings were implemented for 3 months. Items questioned overall coordination and awareness of the surgical site. Response options ranged from 1 (disagree strongly) to 5 (agree strongly). MANOVA was used to compare caregiver assessments before and after the implementation of briefings, and the percentage of OR staff agreeing or disagreeing with each question was reported. To assess OR briefings, care givers were surveyed as they exited their first case of the day.
Findings	The pre-briefing response rate was 85% (306 of 360 respondents), and the post-briefing response rate was 75% (116 of 154). Respondents included surgeons (34.9%), anesthesiologists (14.0%), and nurses (44.4%). Briefings were associated with caregiver perceptions of reduced risk for wrong-site surgery and improved collaboration [F (6,390)=10.15, p < 0.001]. Operating room caregiver assessments of briefing and wrong-site surgery issues improved for 5 of 6 items, e.g., "Surgery and anesthesia worked together as a well-coordinated team" (67.9% agreed pre-briefing, 91.5% agreed post-briefing, p < 0.0001), and "A preoperative discussion increased my awareness of the surgical site and side being operated on" (52.4% agreed pre-briefing, 64.4% agreed post-briefing, p < 0.001).
Conclusion	OR briefings significantly reduce perceived risk for wrong-site surgery and improve perceived collaboration among OR personnel.
<i>Notes</i>	<i>Although there is not explicit description of the use of an OR checklist, a checklist (Figure 1) is presented in the paper; however, it is not clear whether or how the OR briefing included the use of this checklist, e.g. whether the checklist was completed (written) or used as a verbal guide or who completed the checklist. This study collected data on caregivers perceptions of safety. It did not collect data on wrong site surgery; therefore, it is not possible to determine the effect of the checklist on reduction of wrong site surgery.</i>

Hurlbert, S.N., & Garrett, J. (2009). Improving operating room safety. *Patient Safety in Surgery*, 3, 25. Retrieved from www.pssjournal.com/content/3/1/25.

Background	Despite the introduction of the Universal Protocol, patient safety in surgery remains a daily challenge in the operating room.
Objective	To describe one community health system's efforts to improve operating room safety through human factors training and ultimately the development of a surgical checklist.
Study Design	Unclear
Population	200 OR staff and 60 surgeons undertook training
Intervention	Human factors training for OR staff and surgeons; OR preoperative briefing by the attending surgeon using a checklist similar to the WHO checklist was at the core of the training. A post-operative briefing was also encouraged to critique the conduct of the case.
Outcome	Operating room culture (as measured by "survey from the AHRQ"); operating room efficiency and miscommunication events
Methods	Human factors training was contracted to an outside agency and conducted in 2005. Training session was multidisciplinary and lasted 4 hours; Training was mandatory for OR staff (n=200) and voluntary for surgeons (n=60). An observer was stationed in the OR throughout the day and kept track of the number of times the circulating nurse left the room to get equipment. They also looked at miscommunication events and how they impacted the conduct of the case, the dynamics of the team, availability of equipment, and patient safety. Surgeons who conducted briefings were compared with surgeons who did not compare briefings.
Findings	Between 2005 and 2009, 6000 cases done had preoperative briefings.
Conclusion	Using a combination of formal training, local studies documenting operating room safety issues and peer to peer mentoring, we were able to substantially change the culture of the operating room. Efforts have prepared the team for successfully implementing a standardized checklist to improve operating room safety throughout the entire health system. Based on findings the authors recommend a multimodal approach to improving operating room safety.
<i>Notes</i>	<i>Data provided on 5 items from survey for 2 time points only - "pre-2005 and 2009". No data to account for other changes or events occurring in the hospital at this time that may have impacted on results. No raw numbers provided. Unable to determine origin of data collected, e.g. 200 OR staff and 60 surgeons, or subset of this. Data does not support authors' broad claims, conclusions and recommendations. This study did not collect data on wrong site surgery; therefore, it is not possible to determine the effect of the checklist on reduction of wrong site surgery.</i>

Thomassen, O., Brattebo, G., Heltne, J-K., Softeland, E., & Espeland, A. (2010). Checklists in the operating room: Help or hurdle? A qualitative study on health workers' experiences. *BMC Health Services Research*, 10, 342. Retrieved from <http://www.biomedcentral.com/1472-6963/10/342>.

Background	Checklists have been used extensively as a cognitive aid in aviation; now, they are being introduced in many areas of medicine. Although few would dispute the positive effects of checklists, little is known about the process of introducing this tool into the health care environment. In 2008, a pre-induction checklist was implemented in anaesthetic department.
Objective	To explore the nurses' and physicians' acceptance and experiences with pre-induction checklist.
Study Design	Qualitative study using focus group interviews
Population	26 Nurse anaesthetists, 4 consulting anaesthetists, 4 residents that served seven operating theatres in neurosurgery, plastic surgery, burn surgery and otolaryngological surgery
Intervention	Pre-induction checklist
Outcome	Not applicable
Methods	Study sample participated in developing, implementing and using the pre-induction checklist. Final version of the checklist was used in care of 502 patients over 13 weeks. Focus group interviews were conducted after one and five months, during which time the checklist remained unchanged. Focus group interviews were conducted with a purposeful sample of checklist users (nurses and physicians) from the Department of Anaesthesia and Intensive Care in a tertiary teaching hospital. Focus group interviews lasted 60 minutes, using interview guide with broad, open ended questions. Data saturation achieved after 2 nd interview. The interviews were analysed qualitatively using systematic text condensation (see paper for more detail).
Findings	Participant views summarised in 5 main statements. Users reported that checklist use could divert attention away from the patient and that it influenced workflow and doctor-nurse cooperation. They described senior consultants as both sceptical and supportive; a head physician with a positive attitude was considered crucial for successful implementation. The checklist improved confidence in unfamiliar contexts and was used in some situations for which it was not intended. It also revealed insufficient equipment standardisation. Five statements explained in more detail in the paper.
Conclusion	Authors report the findings suggest several issues and actions that may be important to consider during checklist use and implementation.
Notes	<i>This is a qualitative study focused on user experience. Effectiveness of checklist to prevent wrong site surgery cannot be determined.</i>