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Prevention of Wrong Site Surgery, Retained Surgical Items, and Surgical Fires: A Systematic Review

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PREFACE

Quality Enhancement Research Initiative's (QUERI) Evidence-based Synthesis Program (ESP) was established to provide timely and accurate syntheses of targeted healthcare topics of particular importance to Veterans Affairs (VA) managers and policymakers, as they work to improve the health and healthcare of Veterans. The ESP disseminates these reports throughout VA.

QUERI provides funding for four ESP Centers and each Center has an active VA affiliation. The ESP Centers generate evidence syntheses on important clinical practice topics, and these reports help:

- develop clinical policies informed by evidence,
- guide the implementation of effective services to improve patient outcomes and to support VA clinical practice guidelines and performance measures, and
- set the direction for future research to address gaps in clinical knowledge.

In 2009, the ESP Coordinating Center was created to expand the capacity of QUERI Central Office and the four ESP sites by developing and maintaining program processes. In addition, the Center established a Steering Committee comprised of QUERI field-based investigators, VA Patient Care Services, Office of Quality and Performance, and Veterans Integrated Service Networks (VISN) Clinical Management Officers. The Steering Committee provides program oversight, guides strategic planning, coordinates dissemination activities, and develops collaborations with VA leadership to identify new ESP topics of importance to Veterans and the VA healthcare system.

Comments on this evidence report are welcome and can be sent to Nicole Floyd, ESP Coordinating Center Program Manager, at nicole.floyd@va.gov.

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EVIDENCE REPORT

INTRODUCTION

STATEMENT OF THE PROBLEM

This systematic review provides an overview over the prevalence, the root causes, existing guidelines, and the effectiveness of interventions to prevent wrong site surgery, retained surgical items, and surgical fires.

Wrong site surgery refers to surgery on the wrong site, the wrong side, the wrong procedure, the wrong implant, or the wrong patient. This encompasses all incidents ranging from wrong-level operations in spine surgery due to complicated diagnostics as well as dramatic cases such as wrong limb amputation. The distinction between wrong site surgery and near-miss is blurred where incisions on the wrong site, e.g., burr holes are concerned. Retained surgical items are items unintentionally left behind in the patient after surgery. The most common type of retained item is a surgical sponge; the mass lesion due to the sponge surrounded by foreign-body reaction is referred to as gossypiboma, textiloma, gauzoma, or muslinoma depending on the material.[1] Some incidents are discovered many years after the surgery, not all incidents are clinically symptomatic, and the event describes unintentionally retaining the entire item as well as device fragments. Surgical fires describe fire incidents in the operating room, including fires on the patients and in the patient, for example airway fires during tracheostomy.

All three events have been targeted by patient safety agencies and professional organizations and many states have mandatory reporting requirements. The events can potentially have devastating consequences for the patients as well as healthcare providers and facilities. Legally, "res ipsa loquitur" (the thing itself speaks) is most likely to apply due to the nature of the events, e.g., wrong site surgery is wrong regardless of the circumstances, and a successful legal defense will be very difficult.[2-5] Most importantly, all three events are considered preventable and must not be deemed to be an acceptable risk of surgery. The events have been termed "Never Events," i.e., events that should never happen.

The National Quality Forum has determined wrong site surgery and retained surgical items to be Serious Reportable Events (defined as events that are errors in medical care that are clearly identifiable, preventable, and serious in their consequences for patients, and that indicate a real problem in the safety and credibility of a healthcare facility) in 2002 and in the current list (defined as unambiguous, largely preventable, and serious as well as adverse, indicative of a problem in a healthcare setting's safety systems, or important for public credibility or accountability); fires in the operating room are included in the Environmental Events.[6] The Joint Commission has issued sentinel event alerts for wrong site surgery as well as surgical fires.[7,8] A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof and serious injury specifically includes loss of limb or function.[9]

Prevalence

It is safe to assume that the events wrong site surgery, retained surgical items, and surgical fires are rare events; however, specific estimates of the prevalence of their occurrence in clinical practice are sparse. Although preventable and despite a number of national and international efforts, by professional organizations and state agencies; information, training and available resources[10]; incidents of wrong site surgery, retained surgical items, and fires in the operating room continue to exist.

Root Causes

The last decade has emphasized surgical safety and several preventative measures have been publicized. The Universal Protocol, the result of a concerted effort to improve surgical safety after a thorough review of root causes, has been implemented in 2004 for Joint Commission accredited hospitals. Risk factors for retained surgical items have received mainstream attention in 2003 after the publication of a landmark study.[11] The Joint Commission issued a sentinel event alert regarding the prevention of surgical fires in 2003.[8] This review concentrates on root causes of occurrences reported since 2004, i.e., in the post-Universal Protocol era that has seen a strong focus on surgical safety. A root cause analysis is a tool for identifying the underlying causes of surgical patient safety problems.[12] Performing a root cause analysis after sentinel events is mandatory for Joint Commission accredited hospitals.

For wrong site surgery incidents in particular it is generally assumed that multiple processes, rather than one specific error, will have contributed to an event.[13] Root cause analyses for retained surgical items are complicated by the delay with which they are discovered making it in many cases impossible to reconstruct the causal chain. Surgical fires are rare, however, the presence of fuels, oxidizers, as well as ignition sources are commonly present in surgical settings. Historically, the use of flammable inhalation anesthetics was associated with surgical fires,[14,15] however, many patients receive oxygen during surgery and operating theatres need to be considered an oxygen-enriched environment where fires will develop more quickly, burn hotter, and are more difficult to extinguish.[16]

Guidelines

A substantial number of recommendations for clinical practice have been published. All three events are rare, but are known surgical safety problems. The Joint commission Universal Protocol has been in effect for accredited hospitals since July 2004 and is endorsed by numerous professional associations and organizations.[17] The VA established a directive on Ensuring Correct Surgery and Invasive Procedures in January 2003 and updated it in 2004 to conform with the Universal Protocol and to extend it to healthcare settings outside the operating room.[18] The first case of retained sponges in the medical literature was reported by Wilson in 1884[19] and more than one separate sponge and instrument count, e.g., preoperative, intraoperative, and before closure of the incision, and the use of radiopaque sponges has been suggested a decade ago.[20] Flammable and explosive anesthetic gases have been avoided for decades and the inherent dangers of electrosurgical units surgical lasers are known.[15,21-24] The National Guideline Clearinghouse is a public repository of evidence-based guidelines.

Effectiveness of Interventions

The Universal Protocol has three components: 1) preoperative verification of the patient, 2) marking of the surgical site when applicable, and 3) performing a "time-out" before the procedure begins. The success of the protocol depends on the adherence to the components. Retained surgical items has been traditionally addressed by surgical counting protocols, however, advances in technology have also made accounting procedures known in commercial fields such as bar coding available to surgery.[25,26] Technical equipment can be the cause of the fires; however, it is also possible to target the team interaction in the operating room in order to prevent fires and to reduce fire damage. Surgeons are most often in control of the ignition sources such as lasers, anesthesia providers typically control the flow of oxygen, and circulating nurses control the fuels such as drapes.[27,28]

This report aims to summarize the available evidence on interventions aiming to prevent wrong site surgery, retained surgical items, and surgical fires. To this end we aimed to identify evaluations of interventions to determine their effectiveness. The research area is impeded by two restrictions. The evaluated interventions are often organizational in nature and the events of interest are rare events. Given the known paucity of study designs traditionally used in evidence-based medicine such as randomized controlled trials (RCTs) in patient safety research, we have included research studies that are typically outside the scope of evidence reviews such as pre-post and post only analyses. Research on rare events is very difficult to conduct. Large samples or long periods of time are necessary to determine whether a patient safety practice has reduced the incidence of an already rare effect. The most prominent surgical safety guideline, the Universal Protocol, is not based on traditional research evidence from intervention evaluations. For this review we aimed to summarize the existing empirical research, meaning evaluations of interventions that report on the outcomes of interest, i.e., wrong site surgery, retained surgical items, and surgical fires. The desired incidence of the event is zero and post-only studies may show us whether the desired goal was achieved with the implemented intervention.

OBJECTIVES OF THE REVIEW

The VA National Center for Patient Safety has requested an evidence review to examine the prevalence of and the root causes of wrong site surgery, retained surgical items, and surgical fires. The evidence review also evaluates current guidelines and the effectiveness of interventions for the prevention of these events. Studies examining VA-specific data are of special interest. The evidence synthesis will be used to develop a standardized, single, strong recommendation to VA cacilities in the effort to eliminate these events.

METHODS

TOPIC DEVELOPMENT

This project was nominated by the VA National Center for Patient Safety. The key questions were developed with input from a technical expert panel consisting of Dr. Douglas Paull, VA National Center for Patient Safety; Robin Hemphill, Director, VA National Center for Patient Safety; Dr. Verna Gibbs, Director, No Thing Left Behind, surgeon/expert in prevention of retained surgical items and surgical fires; Dr. Mark Wilson, Medical Director, VA Surgery Quality Improvement Program, National Surgery Office; and Dr. Edward Dunn, Director of Systems Redesign, surgeon/expert in prevention of wrong site surgery and team training.

The final key questions are:

Key Question 1. What is the prevalence of: wrong site surgery, retained surgical items, and surgical fires?

Key Question 2. What are the identified root causes of: wrong site surgery, retained surgical items, and surgical fires?

Key Question 3. What is the quality of current guidelines in use to prevent wrong site surgery, retained surgical items, and surgical fires?

Key Question 4. What is the effectiveness of the individually identified interventions for the prevention of wrong site surgery, retained surgical items, and surgical fires?

SEARCH STRATEGY

We searched the databases PubMed, CINAHL, CENTRAL and Web of Science to identify individual studies and reviews. The database SCOPUS which includes patent databases and IEEE XPlore focusing on technology were searched to identify technological advances, in particular supporting the prevention of retained surgical items.

In addition to the electronic database search, we scanned the references of included studies and existing reviews and searched the Cochrane Effective Practice and Organisation of Care (EPOC) Group Specialised Register and PubMed Health. Finally, we consulted subject matter experts for pertinent literature.

The medical literature contains many publications giving advice or guidance about preventing wrong site surgery, retained surgical items, or surgical fires. We used the Institute of Medicine definition to determine what publications are “guidelines”. To identify relevant practice guidelines, our primary search was performed by staff at the National Guidelines Clearinghouse (www.guidelines.gov). The Clearinghouse is an initiative of the Agency for Healthcare Research and Quality, whose mission is “to provide physicians and other health professionals, healthcare providers, health plans, integrated delivery systems, purchasers, and others an accessible mechanism for obtaining objective, detailed information on clinical practice guidelines”. An advantage of using the Clearinghouse is that in order to be listed, a document has to meet

a certain set of inclusion criteria, one of which is a standard definition of "clinical practice guideline". Guidelines do not have to be published in the peer reviewed literature in order to be listed in the Clearinghouse, an advantage over computerized database searches in this regard. We supplemented the National Guideline Clearinghouse search with a Google search of guidelines and the topics of interest. The top 20 search results were reviewed by two physician researchers.

Searches were undertaken in February 2013 to identify studies and guidelines published since 2004. The start search date of 2004 was selected to provide currently relevant prevalence estimates, root cause analyses of incidents despite the widely implemented Universal Protocol, and interventions and guidelines building on the Universal Protocol and the discussion for safety in surgery sparked by its implementation. The guideline search was supplemented by a Google search in September 2013 to capture the most current existing guidelines. Searches were restricted to English-language publications as US, and in particular VA-relevant publications, were sought.

STUDY SELECTION

Two independent reviewers screened the titles and abstracts as well as publications obtained as full text for inclusion in the review. Discrepancies in the full text inclusion screening process were discussed in the review team.

Key Question 1 (prevalence) Inclusion Criteria:

- Participants: Data from patients undergoing surgery were eligible for inclusion in the review.
- Intervention: Data from surgical procedures including incisions were eligible for inclusion in the review. Studies exclusively focusing on injections or minimally invasive procedures were not sought.
- Comparator (study design): Studies focusing on prevalence data (i.e., referring to prevalence in the title or abstract of the publication) were eligible for inclusion in the review. Studies reporting a numerator and denominator (e.g., per procedures or lifetime prevalence per surgeon), or a rate were included. In addition, event estimates reported in included root cause analyses (see Key Question 2) and intervention studies (see Key Question 4) with a minimum sample size of 10,000 for wrong site surgery, 100 for retained surgical items, and 1,000 for surgical fire were extracted. Studies reported in scientific journals were eligible for inclusion, raw data from organizational reports were not sought.
- Outcome: Studies reporting the frequency of wrong site surgery, unintentionally retained surgical item, or surgical fire events are eligible for inclusion in the review. Wrong site surgery was defined as wrong site, wrong side, wrong level, wrong procedure, wrong implant, or wrong patient. Events of retained surgical items refer to unintentionally retained surgical items and were not limited to those with documented adverse events for patients. Publications reporting on intentionally placed but then forgotten items, such as stents, or unintentionally lost or broken equipment which was noticed during the procedure and not retained, were excluded. Surgical fires were defined as fires in the operating room or settings for surgical procedures and were not limited to fires on the

patient. Studies reporting only on composite outcomes of never events were excluded.
- Timing: Studies reporting data since the implementation of the Universal Protocol in 2004 were eligible for inclusion in the review; studies exclusively reporting on older prevalence data were excluded.
- Setting: Data from US facilities were eligible for inclusion in the review. Only fires during surgical procedures were included (not all incidents of fires in hospitals or other healthcare facilities).

Key Question 2 (root causes) Inclusion Criteria:

- Participants: Information from staff or patients undergoing surgery was eligible for inclusion in the review. We excluded experimental studies investigating, for example, the flammability of surgical material.
- Intervention: Root cause or risk factor analyses related to surgical procedures were eligible for inclusion in the review. Analyses of surgical procedures including incisions were eligible for inclusion in the review. Studies exclusively focusing on injections or minimally invasive procedures were not sought.
- Comparator (study design): Empirical studies with assessments of incidence were eligible for inclusion in the review. Results of an institutional investigation for one case or literature/database review analyzing more than one case were included. We excluded case reports without reference to a formal, institutional root cause analysis.
- Outcome: Identified causes and risk factors of wrong site surgery, retained surgical items, or surgical fires were eligible for inclusion in the review. Wrong site surgery was defined as wrong site, wrong side, wrong level, wrong procedure, wrong implant, or wrong patient. Incidents of retained surgical items refer to unintentionally retained items and were not limited to those with documented adverse events for patients. Publications reporting on intentionally placed but then forgotten items, such as stents, or unintentionally lost or broken equipment which was noticed during the procedure and not retained, were excluded. Surgical fires were defined as fires in the operating room or settings for surgical procedures and were not limited to fires on the patient. Studies had to differentiate root cause or risk factor analyses by event to be included, studies using composite outcomes of never events were excluded.
- Timing: Root cause analyses since the implementation of the Universal Protocol in 2004 were eligible for inclusion in the review; studies exclusively reporting on incidents occurring earlier were excluded. Only fires during surgical procedures were included.
- Setting: Data from international facilities that are applicable to VA settings were eligible for inclusion in the review.

Key Question 3 (quality of guidelines) Inclusion Criteria:

- Participants: Guidelines aimed at staff or patients were eligible for inclusion in the review.
- Intervention (content): Guidelines addressing the prevention of wrong site surgery or other invasive procedures, the prevention of retained items in surgery or other invasive procedures, and/or the prevention of surgical fires were eligible for inclusion in the review. Wrong site surgery was defined as wrong site, wrong side, wrong level, wrong procedure, wrong implant, or wrong patient. The prevention of retained items refers

to unintended retained items and was not limited to those causing adverse events for patients. Surgical fires refer to fires in the operating room or settings for surgical or other invasive procedures and was not limited to fires on the patient.

- Comparator (study design): Guidelines registered with the National Guideline Clearinghouse (http://guideline.gov/about/inclusion-criteria.aspx) were included. The National Guideline Clearinghouse's criteria for guidelines are: 1. The clinical practice guideline contains systematically developed statements that include recommendations, strategies, or information that assists physicians and/or other healthcare practitioners and patients to make decisions about appropriate healthcare for specific clinical circumstances. 2. The clinical practice guideline was produced under the auspices of medical specialty associations; relevant professional societies, public or private organizations, government agencies at the Federal, State, or local level; or healthcare organizations or plans. A clinical practice guideline developed and issued by an individual not officially sponsored or supported by one of the above types of organizations does not meet the inclusion criteria for NGC. 3. Corroborating documentation can be produced and verified that a systematic literature search and review of existing scientific evidence published in peer reviewed journals was performed during the guideline development. A guideline is not excluded from NGC if corroborating documentation can be produced and verified detailing specific gaps in scientific evidence for some of the guideline's recommendations. 4. The full text guideline is available upon request in print or electronic format (for free or for a fee), in the English language. The guideline is current and the most recent version produced. Documented evidence can be produced or verified that the guideline was developed, reviewed, or revised within the last five years.
- Outcome: Guideline development characteristics and a summary of the underlying evidence base for the guideline were reviewed. Publications without documentation of having been informed by a systematic review were not considered guidelines and were rejected.
- Timing: Guidelines published since 2004 were eligible for inclusion in the review.
- Setting: Guidelines applicable to VA settings were eligible for inclusion in the review.

Key Question 4 (effectiveness of interventions) Inclusion Criteria:

- Participants: Interventions targeting staff or patients involved in surgical or other invasive procedures including preoperative staff were eligible for inclusion in the review.
- Intervention: Interventions addressing the prevention of wrong site surgery or other invasive procedures, retained items in surgical or other invasive procedures, and/or fires in the operating room or settings for surgical or other invasive procedures were eligible for inclusion in the review. Local guideline implementations were included. Interventions aiming to prevent the loss of intentionally placed but then forgotten items, such as stents, were excluded. General fire drills not targeted towards surgical fire prevention were excluded. Evaluations of interventions not specifically addressing the prevention of wrong site surgery, retained surgical items, or surgical fires but reporting on incidents or near misses of the events were also included.
- Comparator (study design): Controlled studies (concurrent control group [e.g., RCT], or studies with historic control group (pre-post study), and uncontrolled studies (post-only) were eligible for inclusion in the review.
- Outcome: Studies reporting wrong site surgery, retained surgical item, and surgical fire

incidents; wrong site surgery, retained surgical item, or surgical fire near misses (close calls, e.g., wrong procedure started but not completed) were eligible for inclusion in the review. Studies presenting data on safety perceptions with regard to wrong site surgery, retained surgical items, and surgical fires were included; studies only reporting on the feasibility or compliance with interventions were not eligible. Wrong site surgery was defined as wrong site, wrong side, wrong level, wrong procedure, wrong implant, or wrong patient. Incidents of retained items refer to unintentionally retained items in surgery or other invasive procedures and were not limited to those with documented adverse events for patients. Surgical fires refer to fires in the operating room and settings for surgical or other invasive procedures and were not limited to fires on the patient. Secondary outcomes were adverse events associated with the intervention, intervention compliance, and other pertinent intervention-specific outcomes.

- Timing: Evaluations published since 2004 were eligible for inclusion in the review. Interventions may apply to the period before, during, and after surgery. Outcomes may be collected before, during or after surgery.
- Setting: Studies in clinical settings were eligible for inclusion in the review.

DATA ABSTRACTION

The data extraction was performed by one reviewer and checked by a second reviewer using a pilot tested and standardized data extraction form. Discrepancies were resolved through discussion in the review team.

For Key Question 1 (prevalence), we abstracted the incidence and the denominator, the timeframe, together with details about the setting, pertinent context information such as existing prevention protocols; separately for wrong site surgery, retained surgical items, and surgical fires. We extracted the type of surgery and categorized studies broadly. We differentiated the denominator, surgical events and near misses, or composite outcomes of events and near misses, or composite outcomes of surgical and other invasive procedure events.

For Key Question 2, the identified root causes for each of the events or composite outcomes were documented in an evidence table summarizing details of the investigated incident, the assessment context and format, and the identified root causes and risk factors.

For Key Question 3, we documented the identified current guidelines in use to prevent wrong site surgery, retained surgical items, and surgical fires. We summarized the scope and intended use of the guideline in an evidence table. The quality of the guideline taking the development of the guideline as well as the underlying evidence into account is also documented.

For Key Question 4, we documented the setting and type of surgery, the study design, the number of patients, participants and/or surgical procedures, and the follow up period. We categorized the focus of the intervention and extracted the intervention components, as well as information on the compliance with the intervention. We extracted the effectiveness results of the intervention in terms of wrong site surgery, retained surgical item, and surgical fire incidents and/or near misses separately for each of the targeted events in evidence tables. In addition, we abstracted adverse events associated with the intervention as well as intervention specific outcomes such as provider

perceptions of safety and composite outcomes (e.g., a composition of events and near misses or composite outcomes of events of interest).

We differentiated post-only, pre-post, cohort studies comparing two cohorts, controlled trials with intervention assigned by the investigator, and randomized controlled trials (RCTs) with patients randomly assigned to the treatment or control group.

QUALITY ASSESSMENT

Quality ratings were performed by two independent reviewers. Discrepancies were resolved through discussion in the review team.

The identified prevalence studies (Key Question 1) are very heterogeneous with diverse samples and assessment methods. We differentiated studies based on the chosen denominator for prevalence estimates such as per procedure or lifetime prevalence per surgeon and highlighted methodological issues limiting the validity of the studies in the narrative synthesis.

The identified root cause analyses (Key Question 2) were very heterogeneous with unique analytic designs. We ranked included analyses based on the number of investigated incidents.

The guidelines (Key Question 3) were assessed using the Appraisal of Guidelines for Research & Evaluation (AGREE II) instrument to assess the 4 guidelines (ref AGREE II, www.agreetrust.org). AGREE was developed to address issues of variability in guideline quality – as the usefulness of a guideline and its recommendations are only as good its own quality. The tool quantitatively assesses the methodological rigor and transparency of how the guideline was developed and presented. The quality of the guideline is defined as the "confidence that the potential biases of development have been addressed and that recommendations are both internally and externally valid and feasible." The AGREE instrument assesses 23 criteria in 6 domains (ranging from 3-10 criteria per specific domain): scope and purpose (3 criteria), stakeholder involvement (3), rigor of development (10 criteria), clarity of presentation (3 criteria), applicability (4 criteria) and editorial independence (2). Each criterion is rated on a scale of 1-10. Details of the criteria are provided in the evidence table.

The identified interventions studies (Key Question 4) were very heterogeneous with regard to settings, reported data, employed study designs, followup periods, and reported details on the intervention. The evidence tables highlight VA-settings and differentiate US and non-US studies. Study design-specific critical appraisal was not performed as the majority of studies used very limited study design such as post-only studies without any comparator or pre-post studies using only a historical comparator. The study design, the outcome characteristics, and the followup period were incorporated into the synthesis.

DATA SYNTHESIS

The information was tabulated in evidence tables to allow a comprehensive overview of the existing evidence. Results were summarized in a narrative synthesis documenting the range of results. Identified intervention studies were very diverse therefore results were not statistically pooled but summarized in a narrative review. We performed subgroup analyses for evidence

from VA settings where possible.

Prevalence, root cause analysis, and intervention studies were grouped by event (wrong site surgery, retained surgical items, surgical fires). Prevalence estimates were transposed to event per 10,000 performed surgical procedures to allow comparisons across studies and differentiated general surgery estimates and surgical specialty data. Root cause analyses were ordered by the number of analyzed events.

Interventions for wrong site surgery were grouped as global Universal Protocol mandate evaluations; preoperative verification, site marking, time out, briefing and checklist implementations; team training and education, and equipment-related interventions. Interventions for retained surgical items were grouped as counting and imaging protocols, team training, and equipment-related interventions. Interventions to prevent surgical fires were grouped as education, equipment-related, or other approaches.

RATING THE BODY OF EVIDENCE

Strength of evidence ratings for intervention studies were drafted by one reviewer and finalized in the review team. We assessed the overall quality of evidence for outcomes using a method developed by the GRADE Working Group. We took the number of studies per intervention, the study designs and inherent limitations, the consistency of results across studies, whether direct or indirect evidence was available, the precision of the results, and publication bias into account.

The GRADE Working Group classifies the grade of evidence across outcomes according to the following criteria:

- High = Further research is very unlikely to change our confidence on the estimate of effect.
- Moderate = Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
- Low = Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
- Very Low = Any estimate of effect is very uncertain.

PEER REVIEW

A draft version of this report was reviewed by technical experts as well as clinical leadership. Their comments and our responses are presented in Appendix B.

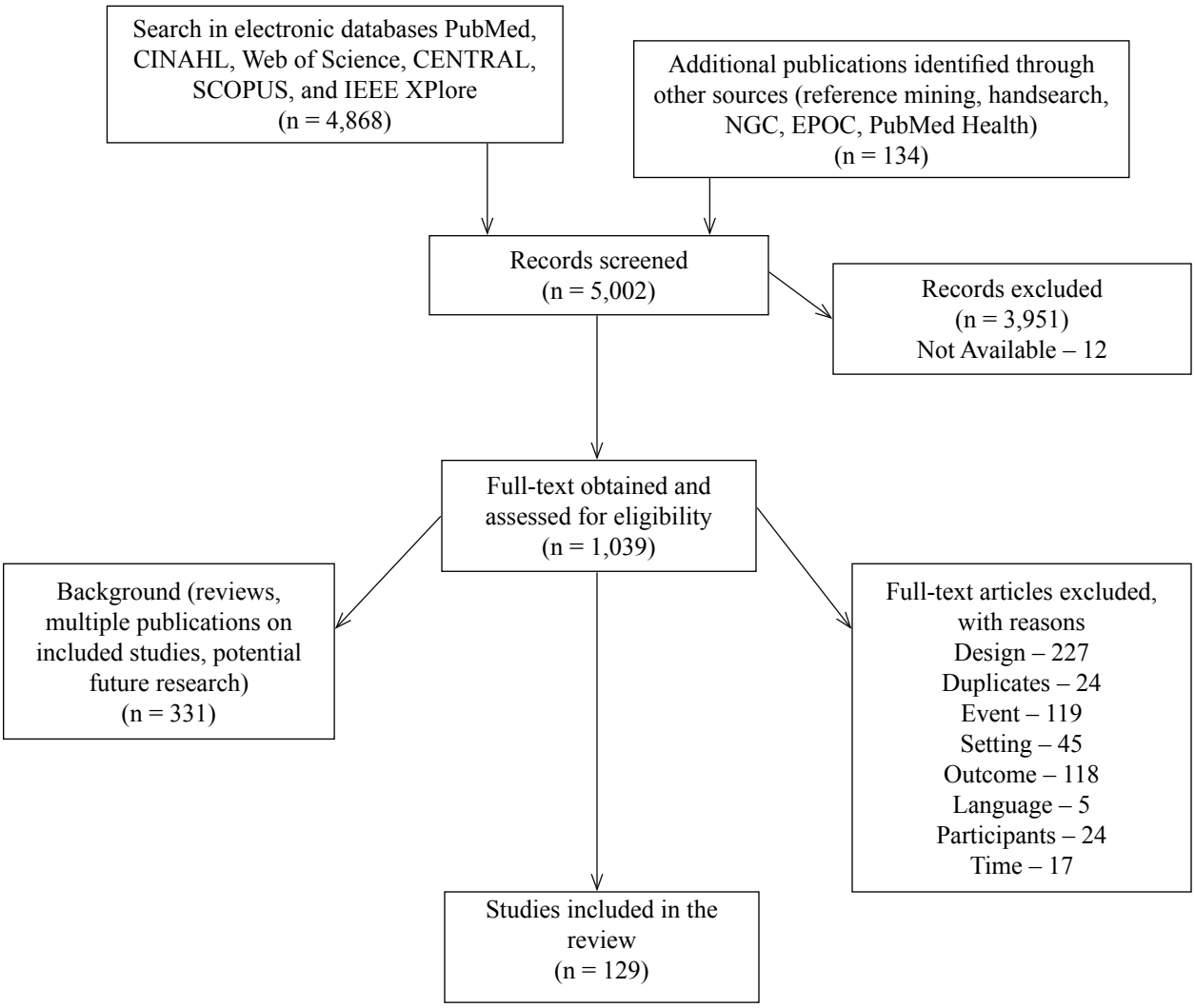
The PROSPERO registration number is CRD42013004524.

RESULTS

The search identified 5,002 publications. Of these, 4,868 were identified in electronic databases. We obtained 1,038 citations as full text publications. The literature flow is shown in Figure 1.

LITERATURE FLOW

Figure 1: Draft Flow Diagram



In total, 129 studies and guidelines were included in the review. Some studies reported on more than one event (i.e., wrong site surgery, retained surgical item, or surgical fire) or more than one review question (i.e., prevalence, root causes, and/or intervention evaluation).

Three thousand nine hundred fifty-one studies were excluded at the title and abstract stage because two independent reviewers classified them as not relevant to the prevention, root causes, interventions or guidelines for the prevention of wrong site surgery, retained surgical items, or

surgical fires. Twelve publications could not be obtained. Three hundred thirty-one publications were classified as background papers and include literature reviews, multiple publications on included studies, and potential future research, and other background material. Two hundred twenty-seven publications were excluded due to the design, e.g. case studies without formal root cause analysis. One hundred nineteen publications were excluded because they did not report on the events of interest (wrong site surgery, retained surgical items, or surgical fires). One hundred eighteen studies were excluded because they did not report on the outcome of interest, e.g. the incident, the prevalence, or the root causes of wrong site surgery, retained surgical items, or surgical fires. Forty-five studies were excluded such as non-US prevalence studies. Twenty-four studies did not report on patients undergoing surgery but were, for example laboratory or technical experiments. Twenty-four studies were identified as duplicates. Seventeen studies were excluded because they reported exclusively on cases of wrong site surgery, retained surgical items, or surgical fires before 2004. Finally, five full text publications were excluded as non-English language publications.

KEY QUESTION #1. What is the prevalence of: wrong site surgery, retained surgical items, and surgical fires?

We identified US studies in the scientific literature reporting on the prevalence of wrong site surgery, retained surgical items, and/or surgical fires in healthcare organizations. The denominator varied across publications and ranged from event rates per procedure, events reported in a specific time frame, the number of malpractice claims, or self-reported lifetime incidence from surveyed surgeons. To obtain a current estimate of the prevalence of events we only included studies that reported on data obtained in 2004 or after.

Prevalence of Wrong Site Surgery

We identified 28 studies reporting on the prevalence of wrong site surgery since the introduction of the Universal Protocol. The evidence table summarizes the identified prevalence estimates. The table differentiates general surgery estimates and estimates from specialties and estimates per performed procedure and other denominators.

Table 1: Evidence Table Prevalence Wrong Site Surgery

ID	Type of procedure	Data source/ setting	Existing prevention protocol	Denominator	Time frame	Other prevalence (e.g., near miss)	Wrong site surgery events	Prevalence estimates
	Surgery – procedure data							
Cima, 2010[29]	Elective surgery	Institutional event line, academic medical center	Electronic surgical listing system, surgery side and site information are required information	N=55,197 procedures	2008	759/55,197 listing errors (1.38%) including laterality: 66%, incorrect side: 14%, other incorrect listing: 11%	0/55,197	n/a
Knight, 2010[30]	Surgery	Institutional data	Anatomic marking form	N=112,500 procedures	2004-2008	n/a	1 event (skin lesion mistakenly removed and intended lesion missed)	1/112,500
Kwaan, 2006[31]	Surgical care	Controlled Risk Insurance Corporation data	n/a	N=2,826,367 operations, 1,153 malpractice claims, 249 surgical care loss observations	1984-2004	n/a	40 cases of wrong site surgery including 25 non-spine events (12 wrong side, 12 wrong site, 1 wrong pt), 15 wrong vertebral level or wrong side spine laminectomy	1 in 112,994 operations (95% CI: 1/76,336 to 1/174,825)
Mulloy, 2008[32]	Surgery	Events reported by survey respondents (N=519 CSSTK survey, 325 UPWSS survey)	UP	Procedure data reported by survey respondents	2001-2006	n/a	7,585 events between 7/2004 and 12/2004, 11,607 events in 2005, 7,320 events in 2006	Rates per 100,000 surgeries: 4.27 in second half of 2004, 3.67 in 2005, 3.14 in 2006
Neily, 2009[33]	Therapeutic and diagnostic procedures, surgical and invasive procedures	Safety database, VA	Directive "Ensuring Correct Surgery and Invasive Procedures" introduced in 2004, first for OR, then OR and non-OR cases	N=2,028,233 OR procedures	2001-2006	105 OR and non-OR reported near misses (incident in which a recognizable step towards a surgical event occurred without being subjected to a surgical or invasive procedure, e.g., wrong procedure on consent form, eye drops in wrong eye); OR: 91, non-OR: 14 incidents; 1.97 reported close calls per month	209 OR and non-OR events (unnecessary surgical procedure including incision and punctures); OR: 107, non-OR: 102 events; data from 210 analyzed events in diverse specialties included ophthalmology: 45, invasive radiology: 45, orthopedics: 26, urology: 23, dentistry: 15, general surgery: 13; the specialty data included 56 wrong pt, 65 wrong side, 41 wrong implant, 31 wrong site, 16 wrong procedure, 1 other; 3.21 events per month	Ophthalmology: 0.52 events per 10,000 OR procedures, orthopedics: 1.2/10,000, all other specialties less than 1 event per 10,000 cases
Neily, 2011[34]	Therapeutic and diagnostic procedures, surgical and invasive procedures	VA	Medical Team Training in addition to "Ensuring Correct Surgery and Invasive Procedures"	n/a	2006-2009	237 OR and non-OR near misses (definition see above; OR: 150, non-OR/ Undetermined: 87; 3.24 reports per month	101 OR and non-OR events (definition see above); OR: 50, non-OR: 51 including ophthalmology: 22, invasive radiology: 22, orthopedics:13; 2.40 reports per month	0.4 adverse events per 10,000 OR procedures (neurosurgery: 1.56/10,000; ophthalmology: 1.06/10,000)
Wu, 2012[35]	Surgery	Medical event reporting system, tertiary care academic hospital	n/a	N=17,606 scheduled surgeries	1-7/2011	151 booking errors in 17,606 surgeries	0/17,606 wrong site events	0/17,606

ID	Type of procedure	Data source/ setting	Existing prevention protocol	Denominator	Time frame	Other prevalence (e.g., near miss)	Wrong site surgery events	Prevalence estimates
	Surgery – other data							
Clarke, 2007[36]	Surgery	Pennsylvania Patient Safety Reporting System	UP	433,528 reports to safety database	6/2004-12/2006	239 or 253 near misses, 174 wrong surgical interventions started	83 pts had incorrect procedures done to completion; estimated 1 wrong site event report per year in 300 bed hospital	n/a
Faltz, 2008[37]	Surgical and invasive procedures	New York Patient Occurrence Reporting and Tracking System (NYPORTS)	n/a	Events reported to NYPORTS during time period	2003-2005	n/a	347 wrong site events reported; surgical procedures including wrong site: 23, wrong side: 27, wrong pt: 2; invasive procedures including wrong site: 21, wrong side: 51, wrong procedure: 68, wrong pt: 33, wrong equipment: 29	n/a
Griffen, 2007[38]	Surgery	Claims data for 5 professional liability insurers	UP in place for half of the reporting period	460 total malpractice claims during time period	2003-2004	n/a	6 wrong patient, organ, or location events	n/a
Mehtsun, 2013[39]	Surgery	National Practitioner Data Bank	n/a	9,744 paid malpractice claims with surgical never events	1990-2010	n/a	4,857 events listed as 1st or 2nd allegation on report including wrong site: 2,413, wrong procedure: 2,447, wrong pt: 27; estimate based on database and existing literature: 1,020 wrong procedure surgery events per year in the US, 1,005 wrong site, 33 wrong pt	n/a
Stahel, 2010[40]	Surgical and nonsurgical procedures	Colorado Physician Insurance company	UP in place for most of the reporting period	Physician self-reported adverse occurrences, 5,937 insured physicians	1/2002-6/2008	n/a	25 wrong pt (14 nonsurgical, 11 surgical), 107 wrong site procedures (29 nonsurgical, 78 surgical) including prostatectomy, vitrectomy, and myringotomy on wrong pts and wrong level spine surgeries, wrong-sided chest tube placement, wrong vascular procedure, enterocolic resection, and organ resection	n/a
	Specialty – procedure data							
Adetayo, 2012[41]	Mastectomy	Chart review, academic medical center	n/a	N=297 pts	2008-2010	n/a	0/297	n/a
James, 2012[42]	Hand, arthroscopic, and spine surgery	American Board of Orthopaedic Surgery (ABOS) database	UP mandate introduced during study period; surgeon signed the site preoperatively in 18/20 cases reported after 2007	N=1,291,396 surgery cases submitted by candidates for board certification	1999-2010	Total incidents (wrong site local or regional anesthesia but error was discovered before incision, wrong site skin incision, wrong site surgical exposure, incomplete operation, wrong procedure, wrong side, wrong digit, wrong level of spine; some incidents discovered and corrected during the operation): 71; reported events per year ranged from 1 case in 2003 to 9 cases in 2005	n/a	Rate of all included incidents was 0.0068%; rate per year ranged from 0.0013 to 0.01; rate post-UPI: 0.0062% (non-spine: 0.0028%)

ID	Type of procedure	Data source/ setting	Existing prevention protocol	Denominator	Time frame	Other prevalence (e.g., near miss)	Wrong site surgery events	Prevalence estimates
Jin, 2007[43]	Cataract surgery	Retrospective review of patients requiring intraocular lens (IOL) exchange at a single eye center	UP introduced at the end of the study period	N=26,667 cataract operations	1998-2005	n/a	3/26,667 wrong intraocular lens implantations	0.011% of 26,667 cataract operations
Lee, 2007[44]	Tooth extractions	Institutional risk management database	n/a	N=10,595 tooth extractions	7/2003-6/2005	n/a	5 wrong tooth or wrong site events	0.047% (5/10,595) per extracted teeth, 0.09% per N of pts
Mody, 2008[45]	Spine surgery	American Association of Neurologic Surgeons member survey	North American Spine Society "Sign, Mark, and Radiograph," UP	Lifetime prevalence per surgeon (N=415 of 3,505 members responded); estimated 1,300,000 spine procedures	2007 survey	15% of respondents reported that they at least once had prepared the incorrect spine level but noticed the mistake before incision	50% reported they had performed 1 or more wrong level surgeries during their career	Estimate assuming 418 wrong level spine operations and about 1,300,000 procedures: 1 in 3,110
Shen, 2013[46]	Strabismus surgery	American Association for Pediatric Ophthalmology and Strabismus member survey	UP, American Academy of Ophthalmology endorsed preoperative checklist available	Lifetime prevalence per surgeon (N=517 of 1,103 members responded); median number of strabismus procedures performed = 1,500	2011 survey	n/a	34% respondents reported having operated on wrong eye or muscle or performed wrong procedure at least once	Mean error rate 1 in 2,506 operations (95% CI: 2,128 to 2,941)
Simon, 2007[47]	Ophthalmol-ogy	Ophthalmic Mutual Insurance company; New York State Health Department database	UP introduced at the end of study period	Claims during time period	1982-2005	14 incidents of wrong eye block	67 wrong lens implant, 15 wrong eye, 8 wrong pt or procedure, 2 wrong corneal transplants	7.4 cases of surgical confusion per 100,000 procedures pre-UP, 5/100,000 post-UP
Vachhani, 201348	Neurosurgery	Institutional Morbidity and Mortality database	UP implemented during study period	N=22,743 surgeries	1999-2011	12 incidents in 7,286 procedures (all wrong level spine surgery) in 5 years pre-UP; 3 incidents in 15,457 procedures (wrong level spine, wrong side cranial surgery) in 7 years post-UP	2 events of wrong level spine surgery were not identified as an error before the end of the procedure pre-UP, 1 occurred post-UP; 1 wrong side cranial surgery occurred post-UP	All included incidents: 0.07% pre-UP, 0.02% post-UP
	Specialty – other data							
Fager, 2006[49]	Neurological surgery	Malpractice claims	Localizing x-rays	275 malpractice claims	Up to 2005	n/a	16 wrong level lumbar spine, 1 cervical, and 1 thoracic events	n/a

ID	Type of procedure	Data source/ setting	Existing prevention protocol	Denominator	Time frame	Other prevalence (e.g., near miss)	Wrong site surgery events	Prevalence estimates
Groff, 2013[50]	Lumbar spine surgery	American Association of Neurological Surgeons and Congress of Neurological Surgeons member survey	74% state preoperative x-ray is performed, 56% radiopaque marker inserted through skin, 73% intraoperative x-ray before bone removal	Lifetime prevalence per surgeon (N=569 respondents of 1,045 surveyed)	2011 survey	66% of respondents have experienced a close call with wrong level exposed but no bone removal, 3% wrong side exposed but no bone removal, 20% wrong level and wrong side but no bone removal	50% have performed a lumbar single-level decompression procedure at the wrong level or on the wrong side (33% wrong level once, 14% wrong level > once, 10% wrong side once, 1% wrong side > once)	n/a
Kelly, 2011[51]	Emergency Medicine procedures	American College of Emergency Physicians Council member survey	UP; 13% unaware of formal time out policy in their ER	Knowledge and lifetime prevalence per surgeon (N=225 respondents of 331 members present)	2009 survey	n/a	7% of respondents knew of an ED case wrong site event, 4% of a wrong pt and 1% of a wrong procedure case	n/a
Perlis, 2006[52]	Mohs Surgery	American College of Mohs Micrographic Surgery member survey	n/a	Lifetime prevalence per surgeon (N=300 of 583 members responded)	2004	n/a	6 respondents had been sued for wrong site surgery	n/a
Schweitzer, 2011[53]	Foot and ankle surgery	American Academy of Foot and Ankle Surgeons member survey	Some cases occurred after the start of the "Sign Your Site" campaign by AAOS and UP implementation	Lifetime prevalence per surgeon (N=319 of 1,094 members responded)	n/a	23% of surgeons reported at least once preparing the wrong surgical site but noticed error prior to incision	13% reported performing at least 1 wrong site surgery, 1% reported 2 wrong site surgeries	n/a
Shah, 2010[54]	Sinus surgery	American Academy of Otolaryngology-Head and Neck Surgery member survey	More than 50% of cases occurred after the UP implementation	Knowledge and lifetime prevalence per surgeon (N=455 [20%[responded)	2009 survey	n/a	9.3% of respondents have had or heard of a case of wrong site sinus surgery	n/a
Shah, 2011[55]	Pediatric oto-laryngologic surgery	American Society of Pediatric Otolaryngology and CHCA directors survey	UP	Lifetime prevalence per respondent (12 of 43 CHCA and 155 of 254 ASPO members responded [56%])	2009 survey	n/a	21% respondents reported involvement in wrong site surgery at some point in their career	n/a
Wong, 2010[56]	Orthopedics	American Academy of Orthopedic Surgeons member survey	AAOS "Sign Your Site" and UP	Lifetime prevalence by surgeon (N=917 of 5,540 invited participants of 20,000 members responded)	2004 survey	8% of respondents reported a wrong site surgery event or near miss, 2% a pt identification problem	Of 22 analyzed events, 59% involved the wrong side, 23% other wrong location, 14 wrong procedure, 5% wrong pt	n/a

Notes: >: more than; CHCA: Child Health Corp of America Hospitals; CI: confidence interval; ED: emergency department; pt: patient; UP: Universal Protocol

We identified a number of studies reporting on surgery in general, with some studies reporting on wrong site surgery events in the operating room as well as outside the operating room, and varying definitions of wrong site surgery, or no further information on how wrong site surgery was defined in the study. Only a few studies provided sufficient data to allow a rate estimate, i.e., the number of events per performed surgical procedures. The prevalence estimates of wrong site surgery ranged from zero[35] to 0.97[34] events per 10,000 procedures. The median of seven studies providing general surgery estimates was 0.09 events per 10,000 procedures.

A prominent study estimating the prevalence of wrong site surgery was published by Kwaan et al.[31] who used an insurance database to arrive at an estimate of 1 event in 112,994 operations (95% confidence interval: 1/76,336 to 1/174,825) from claims data. However, most of the wrong site surgery events must have occurred before the implementation of the Universal Protocol; the estimate is based on data collected between 1985 and 2004. A very similar estimate – one event in 112,500 surgical procedures – was shown by Knight et al.[30] reporting on their experiences over 4.5 years with an anatomic marking form as an alternative to the Universal Protocol. Neily et al.[33] reported on a large VA dataset and concluded that wrong site surgery events occurred in most specialties in less than one event per 10,000 operations between 2001 and 2006 and the estimate for the wrong site events in operating rooms for the period of 2006 to 2009 was given as 0.4 per 10,000 procedures.[34] The studies are reported in more detail in the subgroup section. Two studies reporting on 55,197 elective surgery procedures[29] and 17,606 surgical procedures[35] found no incidents of wrong site surgery.

Five studies published data reported to safety databases, malpractice claims, or physician self-reported adverse events; all used other denominators than the number of procedures. Clarke et al.[36] estimated that given the available data between 2004 and 2006, one wrong site event per year can be expected in a 300-bed hospital. A 2013 study by Mehtsun et al.[39] reviewed paid malpractice claims between 1990 and 2010 and estimated, based on identified events and the existing literature, that 1,020 wrong procedure, 1,005 wrong site, and 33 wrong patient surgery events occur per year in the US. One study[40] reported that 5,937 insured physicians had reported 11 wrong patient and 78 wrong site surgical procedures to the Colorado Physician Insurance company between 2002 and 2008. A further study[37] noted that 347 cases of wrong site events during surgery and invasive procedures were reported to the New York Patient Occurrence Reporting and Tracking System (NYPORTS) between 2003 and 2005. The American College of Surgeon's closed claims study identified 6 wrong patient, organ, or location events in 2003 and 2004[38], however, the majority of cases must have occurred before the implementation of the Universal Protocol.

The literature search also identified a number of studies reporting wrong site surgery estimates for individual surgery specialties. Estimates varied greatly by specialty and ranged between 0.5 for ophthalmology[47] and 4.72 for tooth extractions[44] per 10,000 procedures.

Estimates relevant to spine surgery were reported by James et al.[42] who reviewed 1,291,396 surgery cases submitted by candidates for board certification by the American Board of Orthopaedic Surgery and determined that the total rate of incidents of wrong site local or regional anesthesia, wrong site skin incision, wrong site surgical exposure, incomplete operation, wrong procedure, wrong side, wrong digit, or wrong level of spine was 0.0068%. The rate varied

between 0.0013 and 0.01% between the years 1999 to 2010. Excluding pre-Universal Protocol cases, the rate for hand, arthroscopic, and spine surgery was estimated as 0.0062%; further excluding spine surgery events, the estimate was 0.0028%. A study[48] reviewing institutional data for 22,743 neurosurgery procedures estimated that the wrong site surgery prevalence was 0.2% since the introduction of the Universal Protocol. The number included wrong level spine and wrong side cranial surgery cases, regardless of whether the errors were detected and corrected during the operation or completed. Mody et al.[45] estimated, based on self-reported lifetime prevalence per surgeon and estimated performed spine procedures, a prevalence of wrong level spine operations in 3110 procedures.

Prevalence estimates for eye surgery were reported by Simon et al. (2007)[47,57] who used data from the Ophthalmic Mutual Insurance Company and NYPORTS and estimated there were five cases of surgical confusion (including wrong lens implant, wrong eye, wrong eye block, wrong patient, wrong procedure, or wrong corneal transplants) per 100,000 procedures in 14 months since the implementation of the Universal Protocol. For strabismus surgery, 34% of respondents in a survey for members of the American Association of Pediatric Ophthalmology and Strabismus reported having operated on wrong eye or muscle or performed wrong procedure at least once. The study estimated a mean error rate of 1 in 2,506 operations (95% CI: 2,128 to 2,941) based on the median number of strabismus procedures performed by the surveyed surgeons. An institutional review of cataract operations showed that in 0.01% of procedures a wrong intraocular lens was inserted.[43]

Prevalence estimates by performance on other specialties were reported by Lee[44] who reviewed 10,595 tooth extractions performed between 2003 and 2005 and found a rate of 0.047% of wrong tooth or wrong site events per extracted teeth or 0.09 per number of patients. A small chart review study,[41] investigating the frequency of never events such as surgical site infections and catheter-related urinary tract infections in breast reconstruction, found no wrong site surgery incidents in 297 patients.

Other identified prevalence data came from surveys, usually asking about lifetime prevalence per surgeon. The surveys showed the large variation in estimates across specialties, in particular spine surgery compared to other specialties. In a 2011 survey elicited by the Joint Section on Disorders of the Spine and Peripheral Nerves (Spine Section), half the respondents reported that they have performed a lumbar single-level decompression procedure at the wrong level or on the wrong side.[50] Similarly, the survey by Mody et al.[45] showed that 50% of respondents in a survey for members of the American Association of Neurologic Surgeons reported that they had performed one or more wrong level surgical procedures during their career.

Other survey data showed that of the members of the American Academy of Orthopedic Surgeons only 8% of survey respondents reported a wrong site surgery event or near miss.[56] Thirteen percent of foot and ankle surgeons reported to have performed at least one wrong site surgery and one percent reported two.[53] Twenty-one percent of respondents reported involvement in wrong site surgery at some point in their career performing pediatric otolaryngologic surgery in a 2011 survey.[55]

Three identified studies reported on other outcomes: six respondents of 300 members of the American College of Mohs Micrographic Surgery had been sued for wrong site surgery.[52] Seven

percent of the American College of Emergency Physicians Council member survey respondents knew of an emergency department wrong site case, 4% of a wrong patient, and 1% of a wrong procedure case.[51] Finally, in a survey for members of the American Academy of Otolaryngology Head and Neck Surgery, 9% of respondents have had or heard of a case of wrong site sinus surgery.

Several prevalence studies highlighted which interventions and policies aiming to prevent wrong site surgery were in place at the time the prevalence estimate was obtained. For the majority of studies, the Universal Protocol had been in effect for some or all of the observation period, in addition, specialty endorsed campaigns such as "Sign Your Site" or preoperative checklists endorsed by the American Academy of Ophthalmology[46,54] were available.

VA Subgroup Analysis: Prevalence of Wrong Site Surgery

We identified two studies reporting on large VA setting datasets. Neily et al. (2009)[33] reported the prevalence of incorrect surgical procedures within and outside of the operating room between 2001 and 2006. In this study, adverse events were defined as incidents in which the patient had undergone a surgical procedure unnecessarily and the definition included all injections and administration of regional or general anesthetic not needed for the planned procedure. The specialty orthopedics (1.2 events per 10,000 cases) was second to ophthalmology (1.8 events per 10,000 cases) for the number of reported adverse events occurring in the operating room. None of the other specialties had more than one event per 10,000 cases. In a subsequent article in 2011, Neily et al.[34] reported on data obtained in 2006 to 2009 and estimated that 0.4 adverse events occurred per 10,000 operating room procedures. Estimates for neurosurgery alone were 1.56 per 10,000 cases and 1.06 per 10,000 cases for ophthalmology.

Prevalence of Retained Surgical Items

We identified 20 journal publications reporting on the prevalence of retained surgical items. Studies varied how they defined events and near misses, e.g., whether items identified before wound closure would be classified as an event or near miss incident. The evidence table summarizes the identified studies, differentiating general surgery estimates and data from surgical specialties. We extracted the type of retained item where reported. In the evidence table we have reserved the retained surgical item event column for incidents of unintentionally retained items that were only discovered postoperatively. The prevalence estimate only includes unintentionally and not discovered items at the time of the procedure and is limited to the number of operations as the denominator.

Table 2: Evidence Table Prevalence Retained Surgical Items

ID	Type of procedure	Data source/ setting	Existing prevention protocol	Denominator	Time frame	Other prevalence outcomes	Retained surgical item events	Prevalence estimate
	Surgery – procedure data							
Camp, 2010[58]	Pediatric surgical procedures	National Inpatient Sample and Kid's Inpatient Database	UP in place during last portion of study period	N =1,946,831 hospitalizations	1988-2005	n/a	413 patients with retained foreign body left during a procedure	0.18 per 1,000 pediatric surgical pt discharges; 0.97 for transplant, 0.96 for gynecologic, and 0.75 for vascular
Chen, 2011[59]	Surgical and medical procedures	Use of AHRQ PSI 5 (Foreign body left during procedure) to flag events in VA inpatient administrative data and electronic medical record data	19/23 surgical procedures had documentation of correct surgical counts, 4 with disagreements	N=2,342,690 discharges, 28 of 158 acute-care hospitals	10/2002-10/2007	42 foreign body events and near misses; 23 related to surgical procedures including sponge/gauze: 12; instrument/device fragments: 7; discovered during original procedure: 9/23; site reopened before leaving OR: 2, in 7 cases surgeon decided to remove later; 19 medical procedure events and near misses including 13 guidewires or fragments (53% related to device malfunction), 11/19 detected at time of procedure	14 surgical foreign bodies discovered postoperatively; 8 medical procedure foreign bodies not discovered at time of procedure	n/a (rate of true and false positives = 0.14 per 1,000 cases in sample and 0.12/1,000 cases across all VA hospitals)
Cima, 2007[60]	Events in main ORs and labor and delivery unit	Incidents reported to sentinel phone line or website in academic medical center	21/34 events with correct counts recorded; in 18 cases, intraoperative x-rays were obtained which identified 12 items	N=191,168 operations	2003-2006	n/a	34 retained foreign object events (item unintentionally retained and discovered after wound closure or when the pt had left the OR) including 23 sponges, 3 needles, 1 instrument, and 7 others items	0.178 per 1,000 operations (1:5,500)
Cima, 2011[61]	Surgery	Single academic medical center	UP, sponge counting protocol	87,404 procedures	2/2009-7/2010	3 manual miscounts caught by electronic system	0 retained sponges in 87,404 procedures with new system	0/87,404
Egorova, 2008[62]	Surgery	Medical Event Reporting System, Total HealthSystem, administrative hospital, and NY State Cardiac Surgery report databases	Counts of instruments and supplies (study only reviewed count discrepancies)	N=153,263 surgeries	2000-2004	17 near misses and events with incorrect counts; 11 items were removed prior to closure	5 events without count discrepancy but item subsequently discovered (1 yr followup); 6 events with count discrepancy (1 yr followup)	1:7,000 surgeries (0.014%)
Greenberg, 2008;[63] Greenberg, 2008[64]	Elective general surgery	Medical center data	2004 AORN protocol for counting instruments and sponges or bar coding surgical sponges	N=298 operations	n/a	n/a	0/148 retained items and 0/150 in other intervention	n/a

ID	Type of procedure	Data source/ setting	Existing prevention protocol	Denominator	Time frame	Other prevalence outcomes	Retained surgical item events	Prevalence estimate
Hunter, 2010[65]	Surgery	Academic medical center data	X-ray protocol	N=appr. 11,374 surgeries (1,034 per month)	8/2008-7/2009	n/a	2 sentinel cases of retained foreign items in 11 months	2/11,374
McIntyre, 2010[66]	Surgery	Medical center data	Routine surgical postoperative x-rays for abdominal, thoracic, spinal, and gynecological procedures, sponge counting before and after incision and closure; new count and x-ray policy introduced during study period	About 12,000 surgical procedures per year	n/a	n/a	3 events in 2 years before protocol introduction, 0 events in 18 months after	3/24,000 pre, 0/18,000 post protocol implementation
Rupp, 2012[67]	Surgery	Academic health system data	Sponge ACCOUNTing System, later radiofrequency detection system implemented	n/a	Before and after 2006	n/a	0 retained items in 2,285 pts after radiofrequency intervention, 1 retained surgical item per 36,000 operations before ACCOUNTing System, 1/54,000 operations after	1/36,000 after second intervention, 1/54,000 before
Stawicki, 2012[68]	Any surgery	Data from 7 teaching institutions	In 55/59 cases surgical counts performed; 13 of 27 cases had imaging performed but the item was missed on initial x-ray interpretation; radiofrequency tagging systems were in place in 2 cases where items were missed	N=411,526 cases	1/2003-12/2009	Additional 3 items recorded but not analyzed (incomplete data)	59 unintentionally retained surgical items identified within a pt after final skin or fascial closure of the wound, including 30 surgical sponges, 5 non-sponge textiles (towel, cottonoid, packing), 12 metallic items (needle, wire, drill/screw), 11 non-metallic items (drain/tubing, polyurethane/cement)	Retained surgical item rate: 1/6,975
Vannucci, 2012[69]	Intraoperative CVC placement	Academic medical center	Root cause analysis after first 2 cases, mandatory training for new interns, CVC checklist, training module for residents	Procedures performed in 6 years	n/a	n/a	4 retained guidewires	1:3,291 (95% CI: 1/10,000 to 8/10,000)
	Surgery – other data							
Griffen, 2007[38]	Surgery	Claims data for 5 professional liability insurers	n/a	460 total malpractice claims closed in 2003 and 2004	2003-2004	n/a	20 retained foreign bodies	n/a

ID	Type of procedure	Data source/ setting	Existing prevention protocol	Denominator	Time frame	Other prevalence outcomes	Retained surgical item events	Prevalence estimate
Lincourt, 2007[70]	Surgical procedures	Medical records and reports from institutional Risk Management; academic medical center	In 4 events, incorrect counts were followed by inadequate x-rays (item outside the x-ray field)	n/a	1996-2005	n/a	30 unintentional retained foreign body events, including 3 ray-tec sponges, 13 lap pads, 13 instruments, 1 basket from broken device	n/a
Mehtsun, 2013[39]	Surgery	National Physician Data Bank, paid malpractice settlements	n/a	9,744 paid malpractice claims with surgical never events	1990-2010	n/a	4,857 events of a surgical retained foreign body listed as 1st or 2nd allegation on report; estimate based on database and existing literature: 2,024 retained foreign body incidents per year in the US	n/a
Samples, 2004[71]	Surgical procedures	VA National Center for Patient Safety SPOT database	n/a	Events during time period	2000-2004	29 close calls of retained sponges	41 adverse events involving retained sponges (peanut sponge, gauze pads, laparotomy pads, surgical towels, folded surgical drapes)	n/a
	Specialty – procedure data							
Adetayo, 2012[41]	Mastectomy	Chart review, academic medical center	n/a	N=297 pts	2008-2010	n/a	0/297	n/a
Lutgendorf, 2011[72]	Vaginal deliveries	Labor and delivery unit data	Vaginal sweep; count and x-ray protocol implemented during study period	N=10,500 deliveries (post)	appr. 2005-2011	n/a	4 retained sponges with vaginal sweep, 0 events after protocol implementation	Rate 1/5,000 deliveries before intervention, 0/10,500 after
Morse, 2010[73]	Bowel surgery	Retrospective analysis of elderly pt in single academic medical center	n/a	151 pts	1/2008-3/2009	n/a	0/151 foreign body retained after surgery	0/151
Teixeira, 2007[74]	Cavitary trauma surgery	Academic trauma center data	Weekly morbidity and mortality conference; sponge and instrument counts	N=10,053 trauma operations	1998-2005	n/a	3 iatrogenic retained foreign body events, all after laparotomy, all surgical sponges	Rate 0.1% (3/10,053 operations); expected incidence of 0.12% for cavitary surgery and 0.14% for laparotomies
	Specialty – other data							
Simonsen, 2010[75]	Tonsillectomy and adenoidectomy	Malpractice claims from 16 medical liability insurance companies	n/a	154 claims filed or closed between 1985 and 2006	1985-2006	n/a	3 retained foreign bodies including 1 retained nasopharyngeal packing, 1 broken suture needle	n/a

Note: AORN: Association of PeriOperative Registered Nurses; CVC: central venous catheter; pt: patient; OR: operating room; yr: year

Eleven studies reported prevalence data of unintentionally retained items in unspecific surgical and medical procedures. Prevalence estimates varied widely and ranged between zero retained sponges[61] and 3.04 retained guidewire[69] events per 10,000 surgical procedures. The median estimate across nine studies was 1.43 in 10,000 procedures. The most commonly reported item was a surgical sponge.

Four authors reported per-procedure data for individual surgical specialties, i.e., bowel surgery, breast reconstruction, vaginal deliveries, and cavitary trauma surgery.[41,73,74] The bowel and the breast reconstruction surgery studies presented zero events but reported on less than 300 patients. A study reporting on experiences with a new prevention protocol for vaginal deliveries showed zero events in 10,500 deliveries but noted that previously, sponges were forgotten at a rate of 1 in 5,000 deliveries despite the practice of vaginal sweeps. A study by Teixeira et al.[36] analyzing a large time frame ranging from 1998 to 2005 reported a rate of 0.1% of retained items in cavitary trauma surgery; in all instances this was a surgical sponge.

It is noteworthy that several studies highlighted that the events occurred despite the existing precautions. Ten studies explicitly reported that the hospitals had a counting protocol and two studies highlighted that imaging did not identify all items: Cima et al.[44] reported that 21/34 events occurred in operations where the counts were recorded as correct and of 18 included cases, intraoperative x-rays were obtained but the x-ray only identified 12 of the items. Similarly, Lincourt[70] reported that in four events incorrect counts were followed by inadequate x-rays because the item was outside the x-ray field.

VA Subgroup Analysis: Prevalence of Retained Surgical Items

We identified one VA setting study reporting a per-procedure estimate. Chen et al. (2011)[59] investigated the validity of the patient safety indicator "Foreign body left during procedure" and followed up incidents reported between 2003 and 2007. The study identified 42 instances of events and near misses associated with surgical or medical procedures observed over 28 hospitals with 2,342,690 recorded discharges. In total 14 surgical foreign bodies were discovered postoperatively and eight events occurred in medical procedures and were not discovered at the time of the procedure. A 2004 analysis of the VA National Center for Patient Safety SPOT database identified 29 close calls and 41 cases of adverse events involving retained sponges.[71] The sponges were discovered before and after wound closure or were found when searches were initiated due to incorrect sponge counts; however in some cases, retained sponges were detected days, weeks or years later when x-rays were taken for symptomatic patients during routine x-rays, or during autopsies.

Prevalence of Surgical Fires

The literature review identified no study reporting a per-procedure estimate of surgical fires. None of the included US intervention studies reported on the prevalence. The included prevalence studies are summarized in the evidence table.

Table 3: Evidence Table Prevalence Surgical Fires

ID	Type of procedure	Data source/setting	Existing prevention protocol	Denominator	Time frame	Fire events	Prevalence estimate
Metzner, 2011[76,77]	Surgical procedures requiring anesthesia	American Society of Anesthesiologists Closed Claims Project database	n/a	5,230 claims	1985-2007	91 cautery burns or fires since 1990; 27 cautery fires and at least 1 death due to airway fire during laser surgery by 2004	n/a
Simonsen, 2010[75]	Tonsillectomy and adenoidectomy	Malpractice claims from 16 medical liability insurance companies	n/a	154 claims filed or closed between 1985 and 2006	1985-2006	2 airway fires (1.3%)	n/a
Smith, 2011[78]	Otolaryngology and head and neck surgery	American Academy of Otolaryngology-Head and Neck Surgery member survey (N=349 out of 2300 members responded)	n/a	Lifetime prevalence by respondents	n/a	23% of responding surgeons had experienced at least 1 OR fire in their career; 10 had experienced 2 fires; 2 reported 5 fires	n/a

Note: OR: operating room

The survey among members of the American Academy of Otolaryngology-Head and Neck Surgery showed that a quarter of responding surgeons had experienced at least one operating room fire in their career. A review of 154 malpractice claims from 16 medical liability insurance companies between 1985 and 2006 identified two airway fires.[75] Metzner et al.[76] reported 91 closed claims due to cautery burns or fires in the American Society of Anesthesiologists Closed Claims Project database since 1990. The publication highlighted that operating room fires account for nearly a fifth of monitored anesthesia care claims. A previous analysis in 2004[77] reported 27 cautery fires at that time and at least one death caused by an airway fire during laser vaporization of tracheal stenosis.

Prevalence estimates, i.e., the rate per surgical procedure was not reported in the literature.

VA Subgroup Analysis: Prevalence of Surgical Fires

We did not identify any VA setting study reporting on the prevalence of surgical fires.

KEY QUESTION #2. What are the identified root causes of: wrong site surgery, retained surgical items, and surgical fires?

The results of the root cause, risk factor, and contributing factor analyses are documented by event.

Root Causes of Wrong Site Surgery

We identified 23 analyses investigating wrong site surgery events. The evidence table summarizes the identified studies, ordered by the number of investigated incidents. We only included studies reporting exclusively or at least in part on time periods with the Universal Protocol had been in effect. We have broadly structured the causes and risk factors by operating room provider behavior, patient or case related factors, equipment factors, and other factors.

Table 4: Evidence Table Root Causes Wrong Site Surgery

ID	Country, setting/ surgery	Event	N events	Assessment context, format	Existing prevention protocol	Provider behavior risk factors/causes (N)	Pt/case risk factors/ causes (N)	Equipment risk factors/ causes (N)	Other factors
Clarke, 2007;[36] Clarke, 2008[79]	US, general surgery	Wrong site surgery (wrong pt, procedure, side, or part) near misses	427	Reviewed hospital and ambulatory surgical center reports	UP	Actions of surgeon (92), action of anesthesia provider (29), errors in positioning pt and preparing site (20), not verifying site markings (16), problems with marking the site (6), failure of formal time out process (59)	Incorrect info from pts (17), most event involved symmetrical anatomic structures	n/a	Scheduling errors (111), office records not available (4); causes summarized as resulting from misinformation or misperception
Mody, 2008[45]	US, spine surgery	Wrong site surgery	418	Survey data, provider characteristics and reported events correlated	"Sign, Mark, and Radio-graph", UP	Higher rate of wrong level surgery seen with increased age of surgeon (p=0.024)	n/a		No association with annual surgical load, no difference between surgeons in academic or private practice
Neily, 2009[33]	US, VA, therapeutic and diagnostic, surgical and invasive procedures	OR and non-OR reported near misses and events	342	Root cause analysis	VA Directives for OR, then OR and non-OR introduced during study period	Ranked by frequency: communication problems (e.g., informed consent issues, problematic communication of critical info/handoffs with missing info), time out problems (e.g., pt not properly identified), non-standardization/other, human factor problems, OR schedule problems, training/education, other root causes, problems with policy, documentation, staffing problems, time pressure	n/a	n/a	n/a
Faltz, 2008[37]	US, general surgery	Wrong pt, wrong side, wrong site procedures	254	Root cause analyses submitted to NYPORTS	New York State's 2001 Pre-Operative Protocol, UP	Communication failure, team issues, noncompliance with procedures, inadequate training, consent issues, incomplete history and pt information, failure to correlate available information, inadequate pre-procedural verification, site marking issues, inadequate time-out	Inadequate pt identification	Room set-up issues	Inadequately designed procedures, lack of compliance monitoring, production/time pressures, complete info not available (e.g., lab report), inaccurate/incomplete scheduling info

ID	Country, setting/ surgery	Event	N events	Assessment context, format	Existing prevention protocol	Provider behavior risk factors/causes (N)	Pt/case risk factors/ causes (N)	Equipment risk factors/ causes (N)	Other factors
Neily, 2011[34]	US, VA, therapeutic and diagnostic, surgical and invasive procedures	OR and non-OR reported near misses and events	237	Root cause analysis	VA Directive for OR, and non-OR	Human factors or structural problems (17), critical information not communicated (14), training/education - general (9), pt info not obtained/ accessed (9), no time out (9), policies not followed (7), documentation problematic (6), communication problems – general (6), pt not properly identified in time out (5), implant not verified in time out (5), staff distracted (5), problems with informed consent (4), time out problems - general (3), site not verified in time out (3), site not marked in time out (3), consent not properly checked in time out (3), radiologic images not properly reviewed in time out (3), time pressure (3), training and education for physicians (2), staffing problems – inappropriate use of staff (2), short staffed (2), Directive not followed (1), time out not done in meaningful way (1), site not marked correctly in time out (1), fatigue (1)	Pts had same last name (12), pt characteris-tics a problem – e.g., dementia (3)	n/a	Critical clinical processes not standardized (36), root cause indiscernible/ un-codeable (13), other root causes – general (10), policy needs improvement (4), lack of policy (2)
Shen, 2013[46]	US, Strabismus surgery	Wrong procedures, wrong muscles, wrong eyes, wrong pts, miscel-laneous	173	Survey data, self-reported events and causes	UP, Ameri-can Acad-emy of Oph-thalmology endorsed preoperative checklist available	Contributing factors: esotropia/exotropia/ recession/resection confusion (34), hypertropia/ hypotropia confusion (12), inattention or distraction (19), following preset pattern (9), Kerstenbaum-Anderson confusion (3), wrong preoperative plan (5), no time out (7), lack of site marking/incorrect draping (4), wrong medical record consulted (2), change in schedule/new order (1), new assistant (3)	Ocular torsion (20), scarring/ reoperation/ bleeding (8), similar pt names (2), sequential pts with similar deviation (1)	n/a	n/a
Kelly, 2011[80]	UK, multiple settings and surgeries	Wrong intraocular lens (IOL) implants	164	NRLS database search, submitted principle reason extracted	n/a	Inaccurate biometry (29), wrong IOL selection (21), transcription error (10), handwriting misinterpretation (7), change in list order (8), right/left eye confusion (4), wrong IOL written on theatre white board, wrong pt notes (2), communication errors (2)	Pt ID issue (4), wrong IOL power implantation after complicated surgery (3)	n/a	Optimal IOL power unavailable in stock (3), no causal reason documented (62), misfiled biometry (4)
Stahel, 2010[40]	US, general surgery	Wrong pt, wrong site procedures	132	Root cause analyses	UP	Misinterpreted test results (18), failure to diagnose or misdiagnosis (14), delayed diagnosis (6), failure to perform test (3), other diagnosis error (4), unnecessary treatment (110), medication error (6), delayed treatment (12), wrong treatment concept (3), failure to treat (8), other treatment issues (4), written communication error (33), verbal communication error (26), handover info error (10), other communication issue (51) inadequate procedure planning (92), guideline violation (2), no time out (77)	Wrong indication for procedure (1)	Technical treatment error (21), environmental safety or security issue (1)	Other system issues (24)

ID	Country, setting/ surgery	Event	N events	Assessment context, format	Existing prevention protocol	Provider behavior risk factors/causes (N)	Pt/case risk factors/ causes (N)	Equipment risk factors/ causes (N)	Other factors
Simon, 2007;[57] Simon 2007[47]	US, ophthal-mology	Surgical confusions (wrong implant, transplant, eye, eye block, pt, or procedure	106	Ophthalmic Mutual Insurance company; NY State Health Department database	UP introduced at the end of study period	Surgeon alone responsible (35), surgeon and others responsible (58), staff but not surgeon responsible (6)	n/a	n/a	Unknown responsibility (7)
Blanco, 2009[81]	US, general surgery	Wrong site occurrences and near misses	97	Analyzed reports using the Pennsylvania Safety Authority Wrong site Surgery Error Analysis Form	UP, Pennsylvania Safety Authority Checklist Error analysis form available online	n/a	Existence of bilateral pathology significantly more common among actual events than near misses	Non-standard setup of OR or surgical equipment sign. more common among events than near misses	n/a
Cohen, 2010[82]	Canada, craniotomy	Wrong site craniotomy	35	Literature database search, Google News, disciplinary actions and survey from state medical licensing boards, court records from civil lawsuits	n/a	Contributing factors to ≥2004 cases: assuming prepped side is correct side (1), surgeon ignored team member questioning laterality (1), failure to notify resident that operating on wrong side (1), failure to mark incision site (2), failure to complete/follow time out (4), side not indicated on consent form (2), failure to check medical records (1), failure to fill out necessary document before procedure (1), reliance on memory (1), surgeon accepted full responsibility (1), laterality mix-up in medical record (1)	Contributing factors to ≥2004 cases: pts with same first name (1)	Contributing factors to ≥2004 cases: physician moved OR table (1), non-conventional MRI scanning (1)	Summarized as communication breakdown, inadequate preoperative checks, technical factors and imaging, human error
Shah, 2010[54]	US, sinus surgery	Wrong sinus or wrong sided endoscopic sinus event	21	Survey data, self-reported example events	n/a	n/a	n/a	Radiographic error with inverted image (10)	
Kwaan, 2006[31]	US, non-spine surgery	Wrong site surgery	13	Case review	n/a	Clinic note or consent form with incorrect note (1), site or side not specified in consent form (6/9)		Incorrectly printed magnetic resonance image (1)	Errors in OR scheduling (4), multiple lesions not identified/documented in clinic visit (3), radiologic findings not available (2/4)

ID	Country, setting/ surgery	Event	N events	Assessment context, format	Existing prevention protocol	Provider behavior risk factors/causes (N)	Pt/case risk factors/ causes (N)	Equipment risk factors/ causes (N)	Other factors
Mallett, 2012[83]	US, surgery and medical procedures	Wrong site, procedure, and pt; surgical and non-surgical events	8	Root cause analysis using VA Triggering and Triage Cards	UP	Rules, policies and procedures (22), human factors – scheduling, fatigue (7), human factors – communication (8), human factors – training (3), barriers (6)	n/a	Environment and equipment (3)	Frequent failure modes: 1. Procedure consent form w/out needed detail/ not obtained, 2. Lack of workflow standardization/ responsibilities and flow of information, unaware that documents have to be reconciled and who is responsible for pre-procedure verification
Mitchell, 2006[84]	UK, neurosurgery	Wrong side surgery	8	Surgeon interviews	Varied	Site not marked (6), incorrect marking (1), pt positioned incorrectly by assistant (1)	Multiple simultaneous operations on same pt (1)	Difficulty accessing imaging results (1)	Outside distraction during positioning (7), replacement surgeon as scheduled surgeon could not be found (1)
Schein, 2012[85]	US, eye surgery	Wrong intraocular lens (IOL) implants	7	Identified cases resulting from a formal review or root cause analysis	UP, AO recommen-dations	No verification of intended IOL (1), handwriting misinterpretation (1), misread +/- IOL (1)	Wrong patient IOL calculation printout (2)	Measurement form changed (1), similar lens model name (1)	n/a
Duthie, 2010[86]	US, operative and non-operative settings	Wrong pt Venous Doppler Ultrasound, wrong sided needle localization, wrong site radiation procedure, wrong site CT scan, wrong sided surgical procedure	5	Examined cases from a large urban academic medical center	n/a	Ineffective check (2), reliance on verbal processes (2), site not specified (1), lack of safety checks (1), lack of checklist with critical repeat backs (1), interruptions (1), passive time-out procedures (1)	Pt identifica-tion issue (1)	Manual overrides (1)	Summarized as cognitive underspecification, cognitive flips, automode processing, skill-based errors
Neily, 2012[87]	US, VA, eye surgery	Wrong eye implant, in-correct nerve block, wrong site excision of lesion, wrong site excisional biopsy	4+	Root cause analyses	UP	Multiple pt lens or paperwork in the OR (1), site marking confusion (2+)	Biopsy site confusion with pts with scars or lesions (1)	Change in clockface orientation tool during surgical handoff (1)	n/a

ID	Country, setting/ surgery	Event	N events	Assessment context, format	Existing prevention protocol	Provider behavior risk factors/causes (N)	Pt/case risk factors/ causes (N)	Equipment risk factors/ causes (N)	Other factors
Jin, 2007[43]	US, cataract surgery	Wrong IOL implants	3	Review of pts requiring IOL exchange	n/a	Inattention of technicians or nurses passing along the wrong lens during surgery (3)	n/a	n/a	n/a
No author, 2008[88]	US	Wrong site surgery	1	Health Care Quality staff interviews	UP	Failure to notice site marking, failure to conduct a time-out	Uncommon surgical procedure	n/a	n/a
Knight, 2010[30]	US, skin lesion removal	Wrong site surgery	1	JC required institutional event analysis	Anatomic marking form	Pt not marked	Elderly and confused pt	n/a	n/a
Knight, 2006[89]	US, inter-ventional radiology	Wrong site surgery	1	Root cause analysis	UP	Failure to mark procedural site, lack of time-out for verification check	n/a	Crowded, noisy control room, images orientation not matching pt orientation	n/a
Lee, 2010[90]	US, inguinal hernia surgery	Wrong side surgery	1	Root cause analysis	Extended Time Out	Inadequate marking (not visible after draping)	Pt also had left inguinal hernia (right side was scheduled)	n/a	n/a

Note: The number in parentheses shows the number of causes unless specified differently (number of times the variable was considered a contributing factor); AO: Academy of Ophthalmology; ID: identification; JC: Joint Commission; N: number; NRLS: UK National Reporting and Learning System maintained by the National Patient Safety Agency for National Health Service providers; n/a: not reported/not available; NYPORTS: New York Patient Occurrence Reporting and Tracking System; OR: operating room; pt: patient; pts: patients; UP: Universal Protocol; w/out: without

We have identified a number of studies investigating the causes of wrong site surgery events through reviewing large institutional or insurance or state databases. We searched the international literature; however, the evidence table only shows studies in settings that are largely comparable to the VA. Most studies are US-based, data from the UK and Canada are also included.

The evidence table documents a large number of individual causes, risk factors, or contributing factors. The studies vary how much detail is known or reported about each event, some analyses reported only on broader categories after reviewing individual events, and some studies organizing structures to analyze the surgical mistakes such as VA Triggering and Triage Cards.[83]

While some causes appear unique to the specific surgical field, e.g., implanting a lens model with a similar name during eye surgery,[85] others appear not specific to surgery, e.g., problems created by not communicating critical information between team members,[45] consulting the wrong medical record,[46] transcription errors[80] or distractions.[84]

Some reasons were frequently identified as contributing to a number of analyzed wrong site surgery events within a dataset and are also reported very frequently across different studies. In terms of provider behavior, a frequently reported cause or contributing factor was communication problems between staff members within or across units.[33,34,80,82,83] This included missing information that should have been available to the operating room staff, omitting critical information, staff members not speaking up although they noticed that the procedure targeted the wrong side, as well as lawsuits showing that a surgeon ignored team members questioning laterality. Clarke et al.[79] summarized a review of 174 wrong site errors affecting a patient and 253 errors not directly affecting a patient reported to the Pennsylvania Patient Safety Reporting System that wrong site errors result from misinformation or from misperception. Misinformation may result from information obtained in other departments; misperception may result for example from right-left confusions.

In terms of patient or case characteristics a number of studies highlighted that patient identification problems were common, including the unfortunate circumstance that similar or identical first or last names or even similar clinical conditions were the cause of the wrong site surgery.[34,37,46,80,82,86] Incorrect information from patients or families and confused patients were also named as a contributing factor why the error was not detected.[30,34,36] In addition, some surgical procedures always involve symmetrical structures where laterality is a major concern.[36,80]

A few studies reported equipment-related issues such as the room set up, including moving the operating room table, recently changed forms with information in different places, or forms lacking crucial information such as the laterality of the planned procedure.[37,40,81-83,85,87,89] Some studies highlighted that error was introduced when imaging results were misinterpreted because the patient orientation was confused, such as non-conventional MRI scans with feet first rather than head first.[54,82,89]

A large number of studies identified policies as the source of wrong site surgery. This concerned either the failure of staff to follow existing policies, technically correct but practically useless policies, or the lack of policies. A number of studies reported that not following standard

procedures, such as the lack of site marking or not performing time out, was the cause or a contributing factor to the investigated cases of wrong site surgery.[30,33,34,36,37,40,46,82,85,86,88,89] For these cases it was typically pointed out that the organizational procedure was in place, but it was not followed by staff. Other studies showed that a procedure was technically followed but it was practically inadequate because the surgical site had been marked but the mark was not visible after draping or time out was not performed in a meaningful way.[34,86,90] Finally, several studies, including large datasets investigating several hundred cases of wrong site surgery reported that the lack of procedures or standardization of procedures caused wrong site surgery events.[34,37,83] An institutional review of wrong site surgery cases by Mallett et al.,[83] for example, concluded that frequent failure modes were 1) The procedure consent form did not contain needed detail, such as the laterality of the procedure, or the consent form was not obtained by the practitioner; and 2) A lack of workflow standardization, with staff not realizing that various documents had to be reconciled against one another, and no clearly identified responsibility to determine pre-procedure preparation.

Finally, several root cause analyses showed that mistakes or changes early on in the process, such as errors or changes in scheduling, mistakes on clinic paperwork or consent forms, and incorrect draping, are likely to be carried forward and result in wrong site surgery without further safety checks in place.[31,36,46,84,91] Clarke et al.[79] outline how misperception can result from right-left confusion, for example with unconventional patient positions, and combined with conformation bias, i.e., a tendency to confirm the earlier mental impression regardless of the physical facts, cause wrong site errors.

VA Subgroup Analysis: Root Causes of Wrong Site Surgery

We identified three studies reporting on VA-specific data. Neily et al. (2009)[33] analyzed root cause analysis reports between 2001 and 2006 and concluded that communication problems were the most frequently reported cause of wrong site therapeutic and diagnostic procedures (21%), closely followed by time out problems (18%). A followup report analyzing 2006 to 2009 reports[34] concluded that the category Critical Clinical Processes Not Standardized was the most frequent root cause (18%). The category described situations in which a clinical process was left to the judgment of the clinician to accomplish. The second most common cause category was termed Human Factors or Structural Problems (8%). This category described problems with the human-machine interface, look-alike packaging of different implant components, and other problems with the environment or time pressures, distraction, or fatigue.

Finally, Neily et al. (2012)[87] reported on an evaluation for "shared lessons learned" to prevent incorrect surgery by using examples reported to the reporting system for adverse events through the National Center for Patient Safety. The selected examples describe specific and concrete situations that occurred regardless of the Directive "Ensuring Correct Surgery and Invasive Procedures" and involved the availability of multiple lenses in the operating room leading to confusion, ophthalmologist and anesthesia misinterpreting the meaning of the site mark, a biopsy site confusion attributed to multiple scars and lesions, or a case involving a surgical team taking over from the initial team, with both surgical teams using a clock face orientation tool but with a 180 degree discrepancy in how it was placed.

Root Causes of Retained Surgical Items

We identified only a small number of risk factor analyses in the international literature reporting on retained surgical items. Other studies reported the results of formal institutional root cause analysis for individual cases evaluated in their organization (between one and three investigated cases).

The evidence table summarizes the identified root causes, contributing factors, and risk factors. All 18 included studies reported exclusively or at least in parts, on recent cases which happened in the last decade despite existing policies and available technology. The table is ordered by the number of investigated events.

Table 5: Evidence Table Root Causes Retained Surgical Items

ID	Country, setting/surgery	Event	N events	Assessment context, format	Existing prevention protocol	Provider behavior risk factors/ causes (N)	Pt/case risk factors/ causes (N)	Equipment risk factors/ causes (N)	Other factors
Camp, 2010 [58]	US, National Inpatient Database and Kid's Inpatient Database	Retained foreign body by Pediatric Quality Indicator code	413	Case-control study with multivariable regression analysis	n/a	n/a	Statistically significant higher odds of retained foreign bodies in gynecology procedures (OR 4.13)	n/a	n/a
Wan, 2009[92]	International, multiple settings and surgery	Gossypi-boma/ retained sponges	254	Literature review to 6/2008; primary author reported risk factors	n/a	Shift changes (9), incomplete count (absent or interrupted; 8), poor communication (e.g., hierarchy and lack of cooperation; 5), no clear standardized count policy (3)	Emergency procedure (6), lengthy procedure (6), unexpected change in procedure (3), multi-cavity cases (>1 surgical field/ procedure; 3), high BMI (4)	Use of non-radiopaque sponges (7)	n/a
Stawicki, 2012[68]	US, surgery	Retained surgical items	59	Retrospective, multi-center case-control study 2003-2009; multi-variate analysis	55/59: surgical counts; at least 13: imaging, 2 with radiofrequency tagging system	Safety omission/variance: OR 10.7 (95% CI 2.98, 38.9, p<0.001)	BMI: OR 1.11 (95% CI 1.02, 1.2, p=0.019); procedure duration: OR 1.41 (95% CI 1.03, 1.92, p=0.006)	n/a	Unexpected intraoperative events: OR 6.97 (95% CI: 2.04, 23.7, p<0.001)
Chen, 2011[59]	US, VA, Surgical and medical procedures	Foreign body left during procedure	42	Administrative data and electronic medical record	Counts	n/a	BMI ≥30 (surgery: 35%)	Related to device failure or malfunction (surgery: 30%, medical procedures: 53%)	n/a
Samples, 2004[71]	US, VA, Surgical procedures	Retained sponges	41 events, 29 close calls	VA National Center for Patient Safety SPOT database	AORN recommendations	Counts not recorded; suboptimal communication in surgical team; lack of clarity in x-ray requests leads to incomplete interpretation by radiologist; attending physicians not familiar with AORN standards	Changes or complications in surgical procedures	Radiopaque sponge not used consistently; music and conversation contribute to lapse in concentration; stressful OR environment with people coming and going and multiple hand-offs of responsibility; inability to obtain stat X-ray reading from radiology department hinders validation of incorrect count	Incorrect counts are common; local policy differs from AORN; productivity pressure; inconsistent policies for incorrect counts or missing sponge is not visible on x-ray leaves staff without direction; count audits focus on documentation not process; surgeons role in count not clearly defined

ID	Country, setting/surgery	Event	N events	Assessment context, format	Existing prevention protocol	Provider behavior risk factors/ causes (N)	Pt/case risk factors/ causes (N)	Equipment risk factors/ causes (N)	Other factors
Cima, 2007[60]	US, main OR and labor and delivery unit	Item unintentionally retained and discovered after wound closure or when the pt had left the OR	34	Root cause analyses	21/34 events with correct counts recorded; some intraoperative x-rays	Failure of communication among OR team members most frequent contributor to event	No event occurred during emergency operation; only 41% had excessive blood loss (majority did not)	n/a	No unplanned changes in operations; 41% events in operations performed after hours
Lincourt, 2006[70]	US, Surgical procedures	Unintentional foreign object remaining in the body (sponges, instruments)	30 pts	Case-control study 1996-2005; multivariate analysis	Counts performed in most cases	Incorrect counts (RR 16.2, 95% CI: 1.3-197.8, p=0.02) predicts event	n/a	n/a	Total number of major procedures performed (RR 1.6, 95% CI: 1.1, 2.3, p=0.008) predicts event
Healy, 2012[93]	Ireland, obstetrics	Retained vaginal swabs	16	Closed claim analysis	n/a	Practitioner error (16); no documentation regarding swab count (8); lack of staff knowledge, skills, and competency in procedure for perineal suturing (16)	n/a	n/a	Workload issues, interruption or task delegated due to emergency (4)
Moffatt-Bruce, 2012[94]	US, endovascular procedures; multicenter	Retained intravascular items; intravascular: guide wire, catheter/ catheter fragment, coil	13 cases with intravascular items; 83 other cases	Multicenter retrospective case-control study over 6 year period	7/13 items were missed on initial confirmatory post-procedural imaging	n/a	Technically difficult procedures (6), difficult/emergent setting (2)	Equipment failures (5), lack of equipment familiarity (2)	n/a
Modrzejewski, 2011[95]	International, multiple settings and surgery	Migrated foreign body from peritoneal cavity into colon	10	Literature review	n/a	Circumstances may have been caused by hurried activity of surgical staff	Hemorrhaging during surgery reported in 3 cases and 2 cases with caesarean section	n/a	n/a
Whang, 2009[96]	US, single academic medical center	Retained foreign body	7	Root cause analysis	Surgeon-dependent intraoperative surveillance radiography	Suspicion not communicated to radiologist (5), x-ray never read by radiologist (1), x-ray results not communicated to care team (1)	Inadequate image quality due to pt obesity (1),	Poor image quality (1), item outside of radiograph's field of view (1)	n/a
Gibbs, 2011[97]	US, minimally invasive surgery	Retained surgical items in minimally invasive surgery	4+	Incident reports, focused reviews, root cause analyses	n/a	Sponges counted but intraoperative location not accounted for by OR personnel, no transparent system for accounting of instruments and other surgical items; communication between radiologists, radiology techs, and surgeons when performing surveys for retained items	n/a	n/a	Summary: events occur because of problems with multi-stakeholder OR practices and problems in communication

ID	Country, setting/surgery	Event	N events	Assessment context, format	Existing prevention protocol	Provider behavior risk factors/ causes (N)	Pt/case risk factors/ causes (N)	Equipment risk factors/ causes (N)	Other factors
Vannucci, 2012[69]	US, academic medical center	Retained guidewires	4	Root cause analysis	Mandatory training for new interns after first 2 cases	Inadequate supervision by attending provider (4), inexperienced resident performing the procedure (2), medical student involvement (1)	Concurrent transesophageal echocardiogram (3), unstable hemodynamics (2)	Multiple open venous access kits (4), double access procedure requiring multiple guidewires on surgical field (2)	n/a
McIntyre, 2010[66]	US, surgical procedures	Retained laparotomy sponges	3	Root cause analyses	Routine x-rays for selected procedures, sponge count	n/a	Obese pt and image off center, should have received 2 films to cover abdomen, firm read by resident not surgeon (1); no sponge count due to emergent operation and tail of sponge only visible at edge of x-ray (1)	n/a	Inconsistency in documenting and accounting for packs intentionally left, no policy for obtaining post-operative x-ray (1)
Teixeira, 2007[74]	US, Cavitary trauma surgery	Surgical sponges left behind	3	Institutional records	Weekly morbidity and mortality conference; sponge and instrument counts	n/a	Emergent case with risk factor requiring damage control (2)	n/a	n/a
Hunter, 2010[65]	US, surgery	Sentinel events of retained foreign objects	2	Institutional records	Counts	Miscommunication – radiologist told nurse there was an item visible, nurse reported to surgeon that no foreign item was seen (1)	n/a	n/a	Counts were correct so no radiographs taken (1)
Agrawal, 2012[98]	US, obstetrics	Retained vaginal sponge after repair of vaginal tear during delivery	1	Root cause analysis	Standard counting protocol of sponges before and after procedure	Failure to perform standard counting protocol; information management and communication: breakdown of teamwork among physician and nurse, hierarchical boundaries, culture of poor communication; human resources/ people: addition of newborn, failed human memory, busy clinical environment	n/a	n/a	Policy or procedure: lack of reminders to perform count, recent implementation of policy
Connelly, 2011[99]	US, orthopedics	Retained plastic pulsatile lavage irrigator tip	1	Root cause analysis	n/a	n/a	n/a	Nozzle tip not included in count; off label modification of pulse irrigator tip	n/a

Note: AORN: Association of periOperative Registered Nurses; BMI: body mass index; N: number; n/a: not reported/not available

Included studies analyzed the published cases or their own institutional data. Some studies only reviewed specific cases such as retained intravascular items and migrated items from peritoneal cavity into the colon, or cases specific to selected surgery, such as minimally invasive surgery or obstetrics.

Camp et al. (2010)[58] determined in a multivariate regression analysis that among pediatric surgical admissions, a foreign body left during a procedure occurred with the highest likelihood during gynecologic operations.[58] A study published by Wan et al.[92] reviewing 254 cases of gossypiboma reported that risk factors were case specific, for example emergency procedures, or related to the surgical environment with shift changes, incomplete counts, or poor communication. A recent multivariate analysis by Stawicki et al.[68] also reported that the occurrence of any safety variance such as incorrect counts at any time during the surgical procedure was associated with an elevated retained surgical item risk. The analysis showed further that body mass index, unexpected intraoperative events, and procedure duration were also independently associated with an increased risk. A second multivariate analysis published by Lincourt et al.[70] reported that incorrect counts and the total number of performed major procedures were statistically significantly predictive of the risk of retained foreign bodies after surgery.

In terms of provider behavior, several studies reported safety omissions such as incomplete or not documented counts as a contributing factor.[68,70,92,93,97,98] Communication shortcomings were also frequently reported.[60,65,92,97,98] A series of root cause analyses determined that in five out of seven cases the lack of communicating suspicions, such as inaccurate sponge count not communicated to the radiologist, was a core problem.[96] Cima et al.[60] concluded after reviewing institutional root cause analyses that failure of communication among operating room team members was the most frequent contributor to events.

Case related factors, such as emergency or technically difficult procedures, were determined to be causal or contributing factors in a number of studies.[68,74,92,94] However, Cima et al.[60] reviewing 34 events pointed out that none occurred during an emergency operation. Furthermore, while 41% of cases showed evidence of excessive blood loss, the authors pointed out that most patients did not. The patients' Body Mass Index was a significant predictor in the multivariate analysis of 59 cases reported by Stawicki[68,] contributed to four cases reported by Wan et al.,[92] and one institutional root cause analysis speculated that using an additional x-ray in order to cover the entire abdomen of an obese patient may have been warranted.[66]

The analysis of the international published case studies by Wan et al.[92] suggested that the use of non-radiopaque sponges was responsible or contributed to 7 cases. A study reporting on foreign bodies left during surgical and medical procedures in VA settings concluded that approximately 40% of events were related to a device failure or malfunction, in particular in medical procedures.[59] Similarly, a study by Moffatt-Bruce investigating retained intravascular items showed that equipment failures and lack of equipment familiarity was a factor in almost half of the analyzed cases.[94]

Unexpected intraoperative events was a significant predictor of events in the Stawicki et al.[68] analysis. However, the analysis by Cima et al.[60] pointed out that there were no unplanned changes in operations in any of the 34 cases of unintentionally retained items. An Irish study

analyzing 16 retained vaginal swabs reported that a quarter was associated with workload issues and interruptions.

Several studies pointed to problems with policies, in particular the institutional root cause analyses. One study stated that although the technology is available to staff, the lack of a policy when to obtain post-operative x-rays contributed to one case of a retained laparotomy sponge.[66] It should be noted that several studies reported that a count policy was in place but it was either not standardized, or otherwise ineffective, or items were retained (e.g., broken off nozzle tip) that were not counted.[92,97,99]

The more detailed institutional root cause analyses showed also that typically more than one factor contributed to an event. An analysis of the root causes of a retained vaginal sponge after repair of a vaginal tear following normal vaginal delivery showed that the fundamental error in the case was the failure to perform the standard protocol of counting sponges before and after the procedure.[98] Factors that contributed to the error and the resulting adverse event were the lack of visual reminders to perform the recently implemented policy, a breakdown of teamwork among physician and nurse, hierarchical boundaries, a culture of poor communication, the addition of a newborn baby, failed human memory, and a busy clinical environment.

VA Subgroup Analysis: Root Causes of Retained Surgical Items

Two VA setting studies reported root causes of retained surgical items. Chen et al. (2011)[59] investigating incidents reported between 2003 and 2007 showed that 30% of surgical and 53% of medical foreign bodies were related to a device failure or malfunction. This included instruments breaking off during the procedures and device fragments accidentally being left in the patient. An analysis of retained sponge incidents recorded in the NCPS SPOT database by Samples and Dunn[71] identified a large number of contributing factors, including inconsistent policies and practices when sponge counts are incorrect, or when a missing sponge is not visualized on x-rays, which leaves staff without clear direction (in particular as incorrect sponge counts are commonplace and usually not associated with an actual retained sponge). However, the analysis took place in 2004 suggesting that most analyzed cases occurred before the implementation of current standards.

Root Causes of Surgical Fires

We identified 15 root cause analyses reviewing published fire incidents, survey data, and individual fire incidence formally investigated in an organization. The evidence table, ordered by the number of analyzed fire incidents, summarizes the studies.

Table 6: Evidence Table Root Causes Surgical Fires

ID	Country, setting/ surgery	Event	N events	Assessment context, format	Existing prevention protocol	Provider behavior risk factors/ causes (N)	Pt/case risk factors/ causes (N)	Equipment risk factors/ causes (N)	Other factors
Smith, 2011[78]	US, otolaryngology	OR fires	100	Survey data American Academy of Otolaryngology-Head and Neck Surgery members	n/a	n/a	Endoscopic airway surgery (27), oropharyngeal surgery (24), cutaneous/ transcutaneous surgery (23), tracheostomy (18)	Monopolar electrosurgical ignition source (59), laser source (32), light cord melted drapes source (7), bipolar electrosurgical unit (1), anesthesia machine source (1); 81% of fires occurred while supplemental oxygen was in use, common fuels included endotracheal tube (31%), OR drapes/towels (18%) and flash fires (11%)	n/a
Richter, 2008[100]	International, pharyngeal surgery, tonsillectomy, tracheostomy	Electro-surgery related fires including endotracheal tube fires and flash fires	31+	Literature review, staff interview in single tertiary pediatric institution	n/a	n/a	n/a	Endotracheal tube leak with high oxygen concentration (7), high oxygen concentration during trachea incision (23), dry gauze pack Sevoflurane concentration (1); high concentrations of anesthetic gas and oxygen that accumulated due to lack of cuffed endotracheal tube or pharyngeal packing; eschar debris on electrode blade associated with flash	n/a
Metzner, 2011[76,77]	US, Surgical procedures requiring anesthesia	Cautery burns or fires, laser airway fires	27+	American Society of Anesthesiologists Closed Claims Project database	n/a	n/a	Most cautery fire burns occurred on the face or in the airway	Use of supplemental oxygen most often listed as inciting event; alcohol-based preparation solution cited in some cases	n/a
Pierce, 2011[101]	US, surgery	Laser-induced fires	16	Industry-compiled Laser Accident Database	n/a	n/a	High oxygen environment due to facial surgery (2), endotracheal tube ignition during laser surgery (7)	Ignition of surgical drapes during laser surgery (2), ignition of laser device itself (4)	n/a
Rocos, 2012[102]	UK, NHS providers	Fires in the OR	13	Fires reported to NRLS between 2004 and 2011, causes extracted	n/a	Misuse of equipment causing ignition (2)	n/a	Presence of flammable skin prep fluid (chlorhexidene, povidone-iodine)/prep soaked swabs and drapes (11)	n/a

ID	Country, setting/ surgery	Event	N events	Assessment context, format	Existing prevention protocol	Provider behavior risk factors/ causes (N)	Pt/case risk factors/ causes (N)	Equipment risk factors/ causes (N)	Other factors
Haith, 2012[103]	US, burn center	OR fire injuries	5	Institutional review and case report	n/a	n/a	Risk increases with procedures involving the face and neck (e.g. tracheostomy and tracheobronchial surgery)	Ignition sources include electrocautery, lasers, faulty OR equipment; common use of oxygen/nitrous oxide mixtures or enriched oxygen for minimally complex procedures and disposable drapes add to the risk (fuel source and drapes trap gas); use of electrocautery near an oxygen/nitrous oxide mixture source resulted in injuries	n/a
No author, 2008[104]	US (2), Netherlands (1)	Surgical boom fires	3	ECRI investigation and literature review	n/a	n/a	n/a	Loose oxygen hose fitting within equipment manager box (2), electrical short (2), worn oxygen hose (1), dust collected in electrical outlet (1)	n/a
Meltzer, 2005[105]	US, pediatric hospital, neurosurgery	Surgical fire	3	Multidisciplinary systems-based analysis to identify causal factor for 1 case, literature review	n/a	n/a	Pt's excessive amount of hairspray combined with staff failing to allow the prep solution to dry completely prior to draping (1)	Electrocautery use in oxygen-rich environment in the presence of alcohol based prep solution (1), combination of alcohol-based surgical prep solution and use of monopolar electrocoagulator (1)	n/a
No author, 2006[106]	US, surgery	Surgical fires and near-misses	2 fires, 1 near miss	Case reports	Institutional fire prevention policy (1)	Surgeon refused to allow water to be cleaned up (1), staff unfamiliar with equipment (1); Mayo stand placed on electrocautery foot pedal (1)	n/a	Multiple providers entering and leaving room (1); water pooling on floor near exposed electrical plug (1); packing material containing alcohol, staff unaware (1)	n/a
Kaddoum, 2006[107]	US, adenotonsillectomy	Flash fire in oropharynx during in children	2	Case reports	n/a	n/a		Leak around endotracheal tubes raised oxygen concentration in oropharynx combined with electrocautery (2)	n/a
Laudanski, 2010[108]	US, anesthesia	Anesthesia machine fires	2	Case analysis with series of experiments	n/a	n/a	n/a	Moisture wick in breathing circuit caught on fire due to crossed wires (2)	n/a
Beesley, 2006[109]	UK, emergency laparotomy	Surgical fire	1	Reflective account using Gibbs' reflective cycle	n/a	Started surgery before prep was dry using pencil diathermy rather than scalpel; saline not readily available	Emergent bowel perforation repair	n/a	Smoke detector did not go off

ID	Country, setting/ surgery	Event	N events	Assessment context, format	Existing prevention protocol	Provider behavior risk factors/ causes (N)	Pt/case risk factors/ causes (N)	Equipment risk factors/ causes (N)	Other factors
Cady, 2007[110]	US, cyst removal	OR fire	1	Legal deposition	n/a	Wrong oxygen concentration	Anesthesia difficult (obese pt, high blood pressure, claustrophobia)	Supplemental oxygen	n/a
Herman, 2009[111]	US, organ procurement	Surgical fire	1	Root cause analysis	Annual fire education within organization (some team members from outside hospital)	Lack of awareness of role in preventing fires (technician had no control over flammable liquids, surgeon left alcohol-soaked gauze sponge on pt and placed electrocautery device in close proximity), lack of communication between OR team members (anesthesiologist observed surgeon place gauze around tracheostomy and presumed it was soaked in saline), no water readily available to extinguish flames	n/a	Alcohol moistened sponges combined with electrocautery	n/a
Lypson, 2005[112]	US, facial surgery	Surgical fire	1	Organizational review involving chief of staff, chief of surgery, chief of anesthesiology, and safety case management committee	n/a	n/a	n/a	High likelihood of a draping problem resulting in oxygen being trapped and subsequently igniting when the cautery unit was used	n/a

Note: NRLS: UK National Reporting and Learning System maintained by the National Patient Safety Agency for National Health Service providers; n/a: not reported/not available; OR: operating room

The majority of included root cause analyses did not identify a single cause but described combinations of factors that contributed to an operating room fire. Most details were reported by Smith et al.[78] who structured the contributing factors by type of otolaryngology surgery and listed the ignition source, the fuel, and the presence of oxygen, describing several different fire scenarios. The data were obtained by sending a questionnaire to otolaryngologists and the 349 respondents described 100 fires they had experienced in clinical practice. The authors summarized that the most common ignition sources were electrosurgical units, lasers, and light cords. The described fires occurred most often during endoscopic airway surgery, followed by oropharyngeal surgery, cutaneous or transcutaneous surgery of the head and neck, and during tracheostomy. Over eighty percent of fires occurred while supplemental oxygen was in use. In terms of fuels, commonly involved substances were endotracheal tubes and operating room drapes or towels, but flash fires, where no substrate burned, were also common.

Only a few studies highlighted explicitly problematic provider behavior such as misuse of equipment causing an ignition[102] or starting the surgery before the preparation solution was dry and not having saline readily available for cases of fire[109] but several, primarily, equipment-related causes could also be attributed to staff behavior, such as using electrocautery near an oxygen nitrous oxide mixture source.[103,106] Results of a formal root cause analysis of a single fire occurring in an organization showed that lack of awareness of the roles in preventing fires was apparent, starting from a scrub technician without control over flammable liquids to a surgeon leaving an alcohol-soaked gauze sponge on the patient and later placing an electrocautery device in close proximity to this known fuel source.[111] Furthermore, communication problems were also attributed the event, with the anesthesiologist observing the surgeon placing the gauze around the tracheostomy and mistakenly presuming that it was soaked in saline rather than alcohol.

With regard to case-related factors, Haith et al.[103] investigating victims of operating room fires in a burn center concluded that risk increases with procedures involving the face and neck such as tracheostomy and tracheobronchial surgery. An analysis of the American Society of Anesthesiologists Closed Claims Project database[76] highlighted that claims associated with fire almost always occurred in the setting of surgery on the head, face, and neck.

As outlined, Smith et al.[78] described several ignition sources such as monopolar electrosurgical ignition sources and lasers specific to surgery, while other risks such as faulty equipment, light cords, or crossed wires were also reported.[78,103,104,108] Other authors highlighted endotracheal tube leaks or draping problems which raised the oxygen concentration and trapped oxygen;[100,112] several authors pointed out the risks of supplemental oxygen.[76,78,103,110]

A review of fires reported in the NHS between 2004 and 2011 showed that 11 out of 13 fires were attributed to the presence of flammable skin preparations[113] and in particular alcohol-based preparation solutions were also cited in other studies as a major cause of surgical fires.[105,109,111] However, the analysis of 100 otolaryngology fires explicitly mentioned that alcohol-based preparation solution was among the group of less common fuels.[78]

VA Subgroup Analysis: Root Causes of Surgical Fires

We did not identify any studies reporting on root causes of surgical fires specifically in a VA setting.

KEY QUESTION #3. What is the quality of current guidelines in use to prevent wrong site surgery, retained surgical items, and surgical fires?

The National Guideline Clearinghouse staff identified four guidelines relevant to our three topics areas of wrong site surgery, retained surgical items, and surgical fires. Supplemental Google searches in September 2013 did not identify additional documents meeting the Institute of Medicine definition of a guideline. The four guidelines were: 1) Quality Improvement guidelines for preventing wrong site procedure and wrong person errors: application of the Joint commission "Universal Protocol for presenting wrong site, wrong procedure, wrong person surgery" to the practice of interventional radiology by Society of Interventional Radiology (SIR) 2009,[114] 2) Prevention of unintentionally retained foreign objects during vaginal deliveries by Institute for Clinical Systems Improvement (ICSI) 2012,[115] 3) Perioperative protocol. Healthcare protocol by ICSI 2012,[116] and 4) Practice Advisory for the Prevention and Management of Operating Room Fires by the American Society of Anesthesiologists Task Force on operating room fires 2013.[117] Three of the four guidelines were on focused primarily on the target topics. However, the guideline on applying the Universal Protocol to the specialty of interventional radiology also included minimizing wound infection rates for surgical patients. For this guideline, references and recommendations on wound infection were not reviewed or discussed. Details of the objectives, target population, outcomes, and major recommendations are listed in Table 7.

Table 7: Evidence Table Guidelines for the Prevention of Wrong Site Surgery or Other Invasive Procedures, Retained Items in Surgery and Other Invasive Procedures, and the Prevention of Surgical Fires

Guideline title	Guideline objective	Target population	Major outcome	Description of methods	Methods to formulate recommendations	Major Recommendations: Limited to wrong site surgery, retained foreign bodies and OR fires
Prevention of unintentionally retained foreign objects during vaginal deliveries. Health care protocol[115]	To describe the necessary steps, which if implemented, should prevent unintentional retention of foreign objects during vaginal delivery.	Patients who present with an anticipated vaginal delivery.	Eliminate rate or number of unintentional foreign bodies left following vaginal delivery.	Literature search of clinical trials, meta-analyses, systematic reviews, or regulatory statements and other professional order sets and protocols. Search terms for the current revision include retained foreign objects and labor and deliver from May 2009 through June 2011.	Expert Consensus	**Clinical Highlights** Sponges/soft goods, sharps, and miscellaneous items will be counted for vaginal deliveries. Sponges/soft goods with radiopaque markers are only soft goods present in the delivery field. Establish accurate count processes for baseline and final counts. If the baseline count is not accurately performed before using any countable items, all subsequent controls should be considered compromised. For compromised and reconciled counts, a radiograph shall be obtained to ensure that a foreign object has not been unintentionally retained.
Perioperative protocol. Health care protocol*[116]	To eliminate the wrong surgical procedure or surgery performed on the wrong body part or on the wrong patient. To eliminate unintentionally retained foreign objects during a surgical procedure. To improve the adherence to the key components of the Perioperative Protocol.	Adult and pediatric patients undergoing a surgical procedure in a hospital inpatient, outpatient, or freestanding surgical center.	Effectiveness of surgical site marking, Time-Out, and Hard Stop for prevention of wrong surgical procedure, wrong site, or wrong patient. Effectiveness of baseline count, radiologic imaging, and operating/ procedure room survey for prevention of retaining of foreign objects.	Literature search was divided into two stages to identify systematic reviews (stage I) and randomized controlled trials, meta-analyses, and other literature (stage II). Search was from November 2009 through 2012 included terms: Medicare never events, quality, new fires in operating room, patients awake/ anesthesia awareness, safe site, foreign bodies, fever, pressure ulcers, infection, wound protection, preoperative skin preparation, gown and glove procedures, surgical drapes, removal of Foley catheters, glycemic	Weighting According to a Rating Scheme	**Clinical Highlights** Preoperative verification process includes patient identification, procedure(s), site(s), laterality and level. Process is confirmed by source documents, consent form, medical record and discussion with the patient. Additional verification must occur at designated perioperative points. All procedure sites, including level, position, laterality, multiple sites/digits in same anatomic location, and bilateral procedures will be marked with surgeon's initials. Surgeon should follow preoperative verification process prior to marking sites. Initials must be visible at time of incision. Anatomical diagram shall be used to identify surgical site not visible through surgical drape. Procedures involving level will have preoperative imaging available in area where procedure is performed. Intraprocedure imaging with opaque instruments marking specific bony landmarks will be compared to preoperative imaging Time-Out is performed just prior to start of procedure (after surgeon gowned) with active verbal confirmation by all professionals involved. Repeat Time-Out will be performed for multiple procedures or position changes. Intraoperative pause performed for procedures involving level, implants and/or laterality after orifice or midline entry. A pre-procedure briefing will be conducted to present the plan for the procedure and confirm with team members what will be needed during the procedure and when it will be needed. When a hand-off is required, a structured process should be followed.

Guideline title	Guideline objective	Target population	Major outcome	Description of methods	Methods to formulate recommendations	Major Recommendations: Limited to wrong site surgery, retained foreign bodies and OR fires
				management, antibiotic administration and environmental controls. Databases searched include PubMed, Cochrane, National Guideline Clearinghouse, and National Institutes of Health.		A Hard Stop will occur when either the verification process is incomplete and/or a discrepancy is identified. The procedure will not proceed until the discrepancy is resolved. Baseline counts should be effectively and reliably performed for soft goods and sharps. Imaging is required if the final count is unable to be reconciled.
Application of the Joint Commission "Universal Protocol for preventing wrong site, wrong procedure, wrong person surgery" to the practice of interventional radiology[114]	To provide guidelines for a safe, accurate, and consistent process for verifying the interventional procedural treatment site.	All patients having an interventional radiology procedure.	Incidence of wrong site, wrong person, or wrong procedure surgery.	Literature search performed using Medline database from 1980 to 2009. A critical review of peer-reviewed articles is performed with regard to the study methodology, results, and conclusions. Qualitative weight of these articles is assembled into an evidence table.	Expert Consensus (Delphi) Standards documents of relevance and timeliness are conceptualized by the Standards of Practice Committee members. When evidence of literature is weak, consensus is reached by a minimum of 12. Used a Modified Delphi Consensus Method (80% agreement).	**Planning/Evaluation.** Patient should participate in the planning of procedure. If possible, indicate the side and site at the time of procedure scheduling or preprocedural evaluation (by referring staff) in IR clinic. All potentially necessary images/reports are available at time of procedure. Mark or annotate region of interest on films/images. **Preprocedural Marking.** The interventional radiologist or designee are responsible for insuring that correct structure and side are identified on previous studies, may require marking a film with intended site of treatment. Patient marking necessary only when direct puncture into area of interest is based on external landmarks and possibility for left/right or level errors. **Time Out.** Time out should be performed and preprocedural information with staff and physicians performing procedure, including a review of patient's orientation. Confirm correspondence between image guidance system image and orientation, and correct patient's information displayed on image monitor before procedure. **Postprocedure.** Confirm that all permanent images are correctly labeled regarding patient and side before archiving. **Success Rates.** There is no literature evidence to determine an acceptable success rate in executing these steps. Success rates should approach 100%, but will have to be locally determined and monitored.

Guideline title	Guideline objective	Target population	Major outcome	Description of methods	Methods to formulate recommendations	Major Recommendations: Limited to wrong site surgery, retained foreign bodies and OR fires
Practice Advisory for the Prevention and Management of Operating Room Fires: An Updated Report by the American Society of Anesthesiologists Task Force on Operating Room Fires[117]	1) Identify situations conducive to fire, 2) Prevent the occurrence of OR fires, 3) Reduce adverse outcomes associated with OR fires, and 4) Identify elements of a fire response protocol.	Anesthesiologists or other individuals working under the supervision of an anesthesiologist.	1) Any OR or procedure area where anesthesia care is provided. 2) Specific subset of fires that occur on the patient, in the airway, or in the breathing circuit.	Advisory is based on findings from literature published since the original Advisory was approved in 2007. Literature obtained from PubMed and other healthcare databases, direct Internet searches, Task Force members, liaisons with other organizations, and from hand searches of references located in reviewed articles.	Findings from the aggregated literature are reported by evidence category, level, and direction. Evidence categories refer specifically to the strength and quality of the research design of the studies. A directional designation of benefit, harm, or equivocality for each outcome was indicated.	**Advisory for Education.** All anesthesiologists should have fire safety education for OR fires, with emphasis on risk created by an oxidizer-enriched atmosphere. **Advisory for OR Fire Drills**. Anesthesiologists should periodically participate in OR fire drills with entire OR team during dedicated educational time. **Advisory for Preparation**. Anesthesiologist should participate with entire OR team (time out) to determine whether a high-risk situation exists. If a high-risk situation exists, team should take a joint and active role on how a fire will be prevented and managed and each member be assigned a specific fire management task to perform in event of fire. In every OR and procedure area where a fire triad can coexist (i.e., an oxidizer-enriched atmosphere, an ignition source, and fuel), a visible protocol for prevention and management of fires should be displayed and equipment for managing a fire readily available. **Advisory for Prevention of OR Fires.** Anesthesiologist should collaborate with all members of team throughout procedure to minimize presence of an oxidizer-enriched atmosphere in proximity to an ignition source. Surgical drapes should be configured to minimize accumulation of oxidizers under drapes and from flowing into surgical site. Flammable skin-prepping solutions should be dry before draping. Gauze and sponges should be moistened when used in proximity to ignition source. For high-risk procedures, anesthesiologist should notify surgeon when there is potential for an ignition source to be in proximity to an oxidizer-enriched atmosphere, or for increased oxidizer concentration at surgical site. Any reduction in supplied oxygen to patient is assessed by monitoring (1) pulse oximetry and, if feasible, (2) inspired, exhaled, and/or delivered oxygen concentration. For laser procedures, a laser-resistant tracheal tube is used. Tracheal cuff of laser tube should be filled with saline and colored with an indicator dye. Before activation, surgeon should give anesthesiologist adequate notice, so they can (I) reduce delivered oxygen concentration to minimum required, (II) stop nitrous oxide, and (III) wait a few minutes after reducing oxidizer-enriched atmosphere before approving activation. For cases involving an ignition source and surgery inside airway, cuffed tracheal tubes should be used, if appropriate. Anesthesiologist should advise surgeon against entering trachea with ignition source. Before activating ignition source inside airway, surgeon should give anesthesiologist adequate notice, and then follow steps I-III above.

Guideline title	Guideline objective	Target population	Major outcome	Description of methods	Methods to formulate recommendations	Major Recommendations: Limited to wrong site surgery, retained foreign bodies and OR fires
						For moderate or deep sedation, an ignition source, and surgical site around face, head, or neck, anesthesiologist and surgeon should develop a plan for level of sedation and supplemental oxygen, and consider a sealed gas delivery device (also if exhibits oxygen dependence). * If moderate or deep sedation is not required, and patient does not exhibit oxygen dependence, consider an open gas delivery device. Before activating ignition source around face, head, or neck, surgeon should give anesthesiologist adequate notice, then they should (1) stop delivery of supplemental oxygen or reduce oxygen concentration to minimum required and (2) wait a few minutes after reducing oxidizer-enriched atmosphere before approving activation. **Advisory for Management of OR Fires**. When an early warning sign is noted, halt procedure and call for an evaluation of fire. When a fire is present, immediately announce fire, halt procedure, and initiate fire management tasks. For fire in airway or breathing circuit, as fast as possible: * Remove tracheal tube; Stop flow of all airway gases; Remove all flammable and burning materials from airway; Pour saline or water into airway. For a fire elsewhere on or in patient, as fast as possible: * Stop flow of all airway gases; Remove all drapes, flammable, and burning materials from patient; Extinguish all burning materials. If the airway or breathing circuit fire is extinguished: * Reestablish ventilation by mask, avoid supplemental oxygen and nitrous oxide; Examine tracheal tube for retained fragments; Consider bronchoscopy to assess injury and remove debris; Assess patient's status and devise a plan for ongoing care. If the fire is elsewhere on or in the patient is extinguished: * Assess patient's status and devise a plan for ongoing care; Assess for smoke inhalation injury if patient was not intubated. If the fire is not extinguished after first attempt: Use carbon dioxide fire extinguisher in, on, or around the patient. If fire persists: Activate fire alarm; Evacuate patient, if feasible; Close door to room to contain fire and do not reopen or attempt to reenter; Turn off medical gas supply to room.

We assessed the quality of the guidelines with the AGREE II tool. The assessed domains and scoring guide are shown in Table 8. While all guidelines scored about equally well in the stakeholder involvement, there were large differences in the other domains, for examples: rigor of development (low of 23 to high of 50) and editorial independence (low of 5 to high or 14), as shown in the table.

Table 8: AGREE Items and Domains Including Quality Ratings of the Four Guidelines

Agree II Domain & Criteria	Guideline Assessment			
DOMAIN 1. SCOPE AND PURPOSE	**SIR: Preventing wrong site, wrong procedure, wrong person surgery**	**ICSI: Retained foreign objects during vaginal deliveries**	**ICSI: Perioperative protocol**	**ASA: Operating room fires**
1. The overall objective(s) of the guideline is (are) specifically described.	5	7	7	7
2. The health question(s) covered by the guideline is (are) specifically described.	2	7	7	6
3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.	2	6	7	6
Total of Domain 1:	**9**	**20**	**21**	**19**
DOMAIN 2. STAKEHOLDER INVOLVEMENT				
4. The guideline development group includes individuals from all relevant professional groups.	5	6	6	7
5. The views and preferences of the target population (patients, public, etc.) have been sought.	7	7	7	7
6. The target users of the guideline are clearly defined.	7	7	7	7
Total of Domain 2:	**19**	**20**	**20**	**21**
DOMAIN 3. RIGOR OF DEVELOPMENT				
7. Systematic methods were used to search for evidence.	2	4	7	5
8. The criteria for selecting the evidence are clearly described.	1	1	1	5
9. The strengths and limitations of the body of evidence are clearly described.	1	4	7	7
10. The methods for formulating the recommendations are clearly described.	6	2	2	7
11. The health benefits, side effects, and risks have been considered in formulating the recommendations.	7	7	7	7
12. There is an explicit link between the recommendations and the supporting evidence.	1	3	7	2
13. The guideline has been externally reviewed by experts prior to its publication.	7	5	5	7
14. A procedure for updating the guideline is provided.	1	7	7	2
Total of Domain 3:	**26**	**33**	**43**	**42**

DOMAIN 4. CLARITY OF PRESENTATION				
15. The recommendations are specific and unambiguous.	2	6	7	7
16. The different options for management of the condition or health issue are clearly presented.	3	7	7	7
17. Key recommendations are easily identifiable.	1	7	7	7
Total of Domain 4:	**6**	**20**	**21**	**21**

DOMAIN 5. APPLICABILITY				
18. The guideline describes facilitators and barriers to its application.	1	7	7	1
19. The guideline provides advice and/or tools on how the recommendations can be put into practice.	1	6	6	5
20. The potential resource implications of applying the recommendations have been considered.	1	1	1	1
21. The guideline presents monitoring and/or auditing criteria.	1	7	7	1
Total of Domain 5:	**4**	**21**	**21**	**8**

DOMAIN 6. EDITORIAL INDEPENDENCE				
22. The views of the funding body have not influenced the content of the guideline.	1	1	7	4
23. Competing interests of guideline development group members have been recorded and addressed.	6	7	7	1
Total of Domain 6:	**7**	**8**	**14**	**5**

Note: We requested additional information on the methodology used in developing the 2009 Quality Improvement Guidelines for Preventing Wrong Site, Wrong Procedure, and Wrong Person Errors: Application of the Joint Commission "Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery" to the Practice of Interventional Radiology. The organization was unable to provide us with additional details regarding their methods, which is therefore reflected in the ratings for the AGREE II criteria for rigor of development. However, they did make two comments in response. 1) Since their 2009 publication, wrong site prevention standards set by the JCAHO have changed so most hospitals have revised their practices since their publication. 2) The society has a consensus processes, but the manuscript was largely a summary of the cited literature, a review of JCAHO policies at the time it was written, and the opinion of the authors in collaboration with the SIR Standards of Practice Committee.

Based on the AGREE II criteria the overall quality was high for stakeholder involvement and scope and purpose. There was considerable variability for the other domains of guidelines development and most had methods problems with regards to transparency and rigor of development. Also, two of the guidelines were developed for one specialty (interventional radiology or obstetrics). The obstetrical guideline was limited to the narrow adverse event of retained objects during vaginal delivery.

Common themes found across guidelines were the regular use of checklists, importance of standardized communication between the surgical team members, and multiple rechecking throughout the operative process. Specific steps and protocols for preventing wrong site surgery, retained foreign bodies, and surgical fires were outlined in detail for all guidelines. In terms of the quality of these guidelines, the AGREE II scores for "rigor of development" varied between 26 and 43 points for the 4 guidelines. By comparison, an assessment of recent guidelines by the US Preventive Services Task Force scored 51 points on the AGREE II scale.

KEY QUESTION #4. What is the effectiveness of the individually identified interventions for the prevention of wrong site surgery, retained surgical items, and surgical fires?

The 70 identified intervention evaluations are documented separately for each type of event (wrong site surgery, retained surgical items, or surgical fires). Data from VA facilities are highlighted in a subgroup analysis. Strength of evidence assessments are shown for each event.

Interventions to Prevent Wrong Site Surgery

We identified a large number of intervention evaluations addressing the prevention of wrong site surgery (49 studies).

To date, five studies have been published that evaluate the effect of the Universal Protocol mandate. The evidence table summarizes the compliance, the effect on near misses or composite outcomes, and the effect on event incidents.

Table 9: Evidence Table Intervention Evaluation Wrong Site Surgery – Universal Protocol

ID	Country, setting/surgery type	Study design N F/u	Intervention focus	Intervention components	Compliance	Other/ intervention-specific outcomes	AE	Effect on Near misses or composite outcomes	Effect on event incidents
James, 2012[42]	US, ABOS database, orthopedic surgery (hand, arthroscopic and spine surgery)	Time series, N= 1,291,396 cases F/u: 6 years	Universal Protocol mandate	Preoperative verification of pt and site, surgical site marking, time-out before procedure for repeat verification	n/a	n/a	n/a	Incidence rate (wrong site local or regional anesthesia, wrong site skin incision, wrong site surgical exposure, incomplete operation on the wrong site, wrong procedure, wrong side, wrong digit, wrong level of spine) 1999-2005: 0.0072%, rate after mandate (2006-2010): 0.0062% (p=0.55); non-spine incidents 1999-2005: 0.0042%, 2006-2010: 0.0028% (p=0.303)	n/a
Mulloy, 2008[32]	US, members of AORN and American Hospital Association	Pre-post N=519 respondents CSSTK surgery, 325 UP survey, N=91 for near miss data	Universal Protocol, AORN Correct Site Surgery Toolkit	Universal Protocol for Wrong Site, Wrong Procedure and Wrong Person Surgery, AORN Correct Site Surgery Tool Kit including CD rom educational program, pocket card, template for policy development, copy of protocol and guidelines for implementing, FAQ, letters to RN, physician, CEO and risk managers, pt info	CSSTK: 97% for 2 pt identifiers, 81% for site marking, 74% for time out; UP: 91% 2 pt identifiers, 69% site marking, 45% time out	68% changed practices, 45% revised hospital policy after CSSTK, 92% found CSSTK helpful, 90% felt empowered to stop procedure	Survey showed criteria too flexible, diverse interpretations, more education required for improved uptake, lack of consequences for non-performers	7,585 events between 7/2004-12/2004, 11,607 events in 2005, 7,320 events in 2006	Rates per 100,000 surgeries: 1.93 in 2001, 3.30 in 2002, 2.91 in 2003, 3.77 in first half of 2004, 4.27 in second half of 2004, 3.67 in 2005, 3.14 in 2006 (n.s.)
Simon, 2007;[47] Simon 2007[57]	US, State health department, ophthalmology	Pre-post N=n/a F/u: 14 mos	Universal Protocol	Universal Protocol in effect	n/a	n/a	n/a	Pre: 52 surgical confusions (wrong pt, wrong eye, wrong eye block, wrong implant, wrong transplant) in 49 months (7.4 incidents per 100,000 procedures), post: 10 incidents in 14 mos (5/100,000 procedures), p=0.26	n/a

ID	Country, setting/surgery type	Study design N F/u	Intervention focus	Intervention components	Compliance	Other/ intervention-specific outcomes	AE	Effect on Near misses or composite outcomes	Effect on event incidents
Starling, 2011[118]	US, academic dermatologic surgical practice, skin cancer pts	Post only N=7,983 procedures F/u: n/a	Universal Protocol	Joint commission protocol implemented; pre-procedure pt ID verification (wristband), site identification with surgeon and pt input, photo of site, pre-operative Time Out	n/a (100% implied)	n/a	n/a	n/a	0 wrong site surgery events in charts of 7,983 cases
Vachhani, 2013[48]	US, academic neurosurgical practice	Pre-post N=22,743 surgeries F/u: 7 years	Universal Protocol	Pre-procedure verification of pt ID, surgical site, pre-operative time-out	n/a (non-compliance contributed to 1 of 3 wrong site cases)	n/a	n/a	12 incidents (0.07%, all wrong level spine surgery) in 5 years prior to Universal Protocol; 3 incidents (0.02%, wrong level spine, wrong side cranial surgery) in 7 years after implementation ($p<0.001$)	2 events of wrong level spine surgery that were not identified as an error before the end of the procedure occurred pre-Universal Protocol, 1 occurred post-Universal Protocol

Notes: ABOS: American Board of Orthopaedic Surgery; AE: adverse event associated with intervention; CSSTK: Correct Site Surgery Toolkit; F/u: Follow up; mos: months; ID: identification; N: number of patients or procedures

Five large US studies investigating the effect of the Universal Protocol mandate were identified. A 12-year time series reported by James et al.[42] used the American Board of Orthopaedic Surgery database to which candidates for board certification submit a list of their cases. The study found a reduction in incidence rates of wrong site local or regional anesthesia, wrong site skin incision, wrong site surgical exposure, incomplete operation, wrong procedure, wrong side, wrong digit, or wrong level of spine after the mandate (0.0072% to 0.0062%) but the results were not statistically significant (p=0.55), even when cases related to the spine were excluded (p=0.303). Similarly, Simon et al. using Ophthalmic Mutual Insurance Company data and cases reported to NYPORTS[47,57] found a reduction from 7.4 to 5 surgical confusions (wrong implant, transplant, eye, eye block, patient, or procedure) per 100,000 procedures in the 14 months after the mandate (p=0.26). However, a study with a 7 year followup period[48] reported a statistically significant (p<0.001) reduction from 0.07% wrong site surgery (all wrong level spine surgery events) versus 0.02% (wrong level spine and wrong side cranial surgery events) analyzing the morbidity and mortality database of the department of neurosurgery. A study analyzing two national mailed surveys to 800 randomly selected registered nurse members from the Association of periOperative Registered Nurses and 800 acute care hospitals from the American Hospital Association database showed no statistical significant reduction of reported wrong site surgery events in 2006 but respondents found the Correct Site Surgery Tool Kit helpful and indicated that the elements in the Universal Protocol were detecting system flaws.[32] A post-only study noted that at their institutions, no wrong site surgery event occurred according a chart review for 7,983 patients undergoing skin cancer treatment, the pre-Universal Protocol rate was not reported.

We identified 21 studies in the international literature evaluating the effects of implementing a time out procedure, a surgical checklist, pre- or peri-surgical briefings, or verification protocols. Some interventions were local operationalization of the Universal Protocol elements 1) preoperative verification of the patient, 2) marking of the surgical site, and 3) performing a Time Out before the procedure begins. Other studies focused on the introduction of checklists that guided some or all stages. The studies are summarized in the Evidence table.

Table 10: Evidence Table Intervention Evaluation Wrong Site Surgery – Preoperative Verification, Site Marking, Time Out, Briefing and Checklist Implementations

ID	Country, setting/ surgery	Design N F/u	Intervention focus	Intervention components	Compliance	Other/intervention-specific outcomes	AE	Effect on near misses	Effect on event incidents
Ablinger, 2010 [119]	Switzerland, urban medical center	Pre-post N=15,461 cases F/u: 18 mos	Surgical checklist based on WHO Safe Surgery Checklist	Implementation of 13-item surgical safety checklist "4-step-protocol" for every patient undergoing surgical procedure in OR	n/a	n/a	n/a	n/a	Pre: 1 event in 4,901 cases over 52 months. Post: 0/10,560 cases over 18 months (n/s)
Bergal, 2010[120]	US, orthopedic surgery	Post-only, N=200 pts F/u: n/a	Pt participation in site marking	Involving pts in preoperative site marking; detailed verbal and written instructions; mark surgical site with "YES" prior to arrival in pre-op	68.2%; correct site: 67%, correct marking: 62%	n/a	n/a	n/a	0/200 wrong site surgery events
Butcher, 2011[121]	US, Minnesota facilities	Pre-post N=n/a F/u: n/a	Minnesota Time Out Process	Initiated by Minnesota Safe Surgery Coalition; surgeon-initiated time out with specific roles for all team members, with goal to have the Time Out become culturally accepted and a community standard	n/a	n/a	n/a	n/a	1 wrong site procedure every 30 days compared to 1 every 12 days before rollout
DeFontes, 2004[122]	US, Kaiser Permanente medical center	Pre-post N=6,795 procedures/ year, 59 OR staff, 60 surgeons F/u: 1 year	Briefing	Preoperative safety briefing; similar to preflight checklist; surgeon, anesthetist, circulator, scrub discuss background of case, assess risks, and offer relevant information and expectations	n/a	Good safety climate: 51.1% to 62.9%; minimal cost	n/a	Pre: 2 near misses, post: 5	3 wrong site surgeries in year pre-intervention, 0 in year since implementation
DiGiovanni, 2003[123]	US, foot-and-ankle practice	Post-only, N=100 pts F/u: n/a	Pt participation in site marking	Involving pts in pre-operative site marking; detailed verbal and written instructions: mark non-operative site with "NO" prior to arrival in pre-op	Marked: 63%; fully compliant: 59%; marked, but not fully compliant: 4%; non-compliant: 37%	n/a	n/a	n/a	0/100 wrong site surgery events
Duggineni, 2011[124]	UK, university hospital	Post only N=n/a F/u: n/a	WHO surgical safety checklist	Checklist instituted for all minor oral surgical procedures under local anesthetic	100%	n/a	n/a	n/a	0 wrong side surgery

ID	Country, setting/ surgery	Design N F/u	Intervention focus	Intervention components	Compliance	Other/intervention-specific outcomes	AE	Effect on near misses	Effect on event incidents
Garnerin, 2008[125]	Switzerland, academic medical center, anesthesia practice	Pre-post N=252,855 procedures F/u: 1 year	Verification protocol	Verification protocol for checking pt ID and site of surgery developed by interdisciplinary team; anesthetist to perform checks, pt asked to participate if able using open-ended questions (no prompting), corroborated with medical record, wristband, and scheduling information, site compared with medical record, surgeon check and schedule; protocol distributed to all anesthesia staff as pocket-sized document; audit and some feedback	Compliance improved for all but 1 criterion; ranged from 59% (full compliance with protocol pt ID check) to 99% (ID wristband)	n/a	Some staff objected ("I already know that pt"; "It's the obvious surgical site"); lack of collaboration with surgical services	n/a	Pre: 4 wrong site anesthesia and 0 wrong site surgery in 181,710 procedures; 0 cases of wrong pt or wrong site anesthesia during and post intervention (71,145 procedures)
Harrington, 2009[126]	Iraq, US Army OR	Post only N=900 procedures F/u: 15 mos	Time Out	Time Out procedure, responsibility of routinely reinforcing rests with preoperative nurses; site verification procedure; surgical Time Out consisting of pt ID, procedure, location by circulating nurse, with assent from all members of peri-operative team	n/a	Practice supports team building	n/a	n/a	0 events in 900 procedures
Johnston, 2009[127]	Canada, academic orthopedic practice	Pre-Post N=48 procedures pre, 231 cases post F/u: 1 year	Time Out	Pre: Site signing - initials of operating surgeon or surgical resident in surgical field documentation; Post Time Out in addition to existing practice	Pre: in 67% emergent and 90% elective cases initials visible; post: 61% and 83%; Time Out prior to skin incision: 70%, after incision: 19%, not performed: 11%	n/a	n/a	n/a	0 wrong site surgery pre and post
Khoshbin, 2009[128]	Canada, pediatric hospital	Pre-post N=n/a F/u: 2 years	Pre-operative OR briefing and Time Out	Pre-op briefing (huddle): diagnosis, equipment needs, positioning, special considerations before start of the day; peri-operative surgical Time Out: presence of correct pt, marking of correct site and side, correct pt position, procedure to be performed, availability of implants/equipment, statement any time team members should voice concerns, etc.	Pre op briefing completion rate 64.1%; Time Out 99.1%	Survey (scale 1-5): team discussion important for pt safety: surgeons 4.4, anesth. 4.7, nurses 4.9; pre-op briefing has improved safety: surgeons 3.3, anesth. 3.1, nurses 4.0; Time Out has improved safety: surgeons 3.3, anesth. 3.1, nurses 4.2	Some surgeons and anesthesiologists felt pre-op briefing had little to do with safety (more an annoyance, staff overburdened with too many changes)	n/a	Since implementation of both interventions 0 wrong side surgeries (1 year), compared to 1-2 events per year previously (8 events in 3 years)
Knight, 2010[30]	US, community-academic health system	Post only N=112,500 procedures F/u: 4.5 years	Anatomic marking form	Alternative to Universal Protocol; procedure and intended surgical site marked in clinic, signed by pt; form delivered to pre-op, where site is marked by perioperative nursing staff	Self-reported adherence 65% for most or all procedures	n/a	7% were very dissatisfied with anatomic marking form and alternative process	n/a	1/112,500 event post-intervention in 4.5 years (skin lesion mistakenly removed and intended lesion missed)

ID	Country, setting/ surgery	Design N F/u	Intervention focus	Intervention components	Compliance	Other/intervention-specific outcomes	AE	Effect on near misses	Effect on event incidents
Lee, 2007[44]	US, oral and facial surgery center, UCSF	Pre-post N=10,595 tooth extractions (pre) F/u: 10 mos	Time Out protocol, guidelines for wrong tooth/ wrong site surgery	Clinical guidelines developed and circulated to educate; Time Out protocol implemented	n/a	n/a	n/a	n/a	Post: 0 wrong tooth or wrong site surgery in 10 mos, pre: 5 events in 2 years (10,595 extractions; event rate was 0.047% per extracted teeth, 0.09% per N of pts)
Lee, 2010[90]	US, community non-profit institution, pediatric pts	Pre-post N=309 (pre), 274 (post) F/u: n/a	Extended Time Out	Pt safety briefing checklist includes confirmation of ID, procedure, technical details, special equipment, etc.; before anesthesia induction; aims to improve communication and teamwork	100% (all members of surgical team)	Improved confidence and prepared for procedure due to improved communication	Time to incision for elective surgery 24 $\pm$ 3 vs 25 $\pm$ 8 min (p=0.33); urgent: 36 $\pm$ 7 vs 32 $\pm$ 16 min (p=0.25)	Post: 1 (without briefing surgery would have started on wrong side)	1/274 wrong site surgery post intervention (left inguinal hernia repaired, then right side (=scheduled) repaired, pre: similar events pre and post implementation
Lee, 2012[129,130]	New Zealand, 3 major elective surgery hospitals	Post only N=35,416 operations analyzed F/u: first 7 mos and 12 mos 4 years later	Checklist	Preoperative surgical safety checklist functioning as Time Out; carried out after anesthesia induction, prior to preparation and draping; checklist similar to Pronovost et al.; pt ID, correct consent form, site marked and confirmed, all peri-operative team members in agreement (check each), correct pt position, corresponding set up, concerns	First year 87% complete, 4-5 years later 98%	n/a	Some surgeons refused to be involved in first year (1.2% objections)	3 near misses, captured by checklist in first year (0.4%), 0 incidents in year 4 and 5	0/35,416 wrong site operations
Leonard, 2004[131]	US, Orange County Kaiser	Post only N=n/a F/u: n/a	Briefing	Peri-operative briefing consisting of four sections for surgeon, circulator, scrub, and anesthesia emphasizing communication and shared expectations; developed by multidisciplinary team; some facilities brief after anesthesia induction, others with pt awake	n/a	Employee satisfaction increased by 19%, perceptions of safety climate improved from good to outstanding	n/a	n/a	Wrong site surgeries went from being a problem to 0 events after implementation

ID	Country, setting/ surgery	Design N F/u	Intervention focus	Intervention components	Compliance	Other/intervention-specific outcomes	AE	Effect on near misses	Effect on event incidents
Lyons, 2010[132]	US, academic neurosurgical practice	Post only N=6,345 pts F/u: 8 years	Checklist	Operative Site Checklist; confirmation of pt ID, confirmation of correct medical record, correct x-ray, correct operation, correct consent form, etc.; completed by attending surgeon	99.5% compliance; emergency cases more likely to be non-compliant initially	Successful spread to other campuses	n/a	n/a	0/6,345 wrong site surgeries in 8 years
Makary, 2007[133]	US, academic medical center, surgery	Pre-post N=n/a F/u: n/a	Briefing	Tool to enhance communication; name introduction, surgeon leads Time Out, care teams discuss and mitigate potential safety hazards	100% compliance with OR briefing protocol	Self report: "Pre-operative discussion increased my awareness of the surgical site and side": pre-briefing mean 3.18 (scale 1-5), post 3.74 ($p<0.001$); "Surgical site was clear to me before incision": pre 4.45, post 4.75 ($p<0.002$)	n/a	n/a	n/a
Norton, 2010[134]	US, academic children's hospital	Pre-post N=n/a F/u: n/a	WHO Safe Surgery Checklist for pediatric population	Checklist tailored to pediatric population; 3-part framework: sign in, time out, sign out; mandatory verbal contributions from each member of OR team	80-90% in pilot; sign in: 85-100%, time out: 95-100%, sign out: 80-100% in implementation period	n/a	Not all surgeons comfortable with responsibility for time out/sign out; more labor intensive than UP	1 unmarked site; consent, site-marking, and equipment problems	n/a
Reid, 2011[135]	UK, English NHS Trusts	Post only N=n/a F/u: 2 years	WHO Safe Surgery Checklist	National Patient Safety Agency requiring implementation of WHO checklist for every surgical pt; local adaptations and additions, briefings and debriefings	Checklist 89%; 32% use checklist and briefings; 33% use checklist, briefing, and debriefing	n/a	Negative clinician attitudes: 77%; obligation rather than commitment/tool to improve communication and teamwork: 78%; not having enough time: 37%	41% reported checklist captures near misses	n/a
Wauben, 2011[136]	The Netherlands, 5 academic and community hospitals	Post only N=522 time outs F/u: n/a	Time out	Use of participatory design to create time out procedure combined with team-based debriefing	81%, partially in 2%, not at all in 5%; documentation missing in 12%	Average time out 96 seconds (SD=63s); average debriefing 58 seconds (SD=58s)	1 hospital stopped participating after 1 day (intervention too time consuming)	18 risk sensitive events including incorrect pt history (8), wrong side identified (2), pt identification (5)	n/a
Wood, 2009[137]	US, community hospital	Pre-post N=n/a F/u: n/a	Site marking	Surgeons mark site in pre-op area; standardized order sets; 2-year culture of safety initiative	n/a	n/a	Initial pushback from surgeons	n/a	No event before or after implementation

Notes: AE: adverse event associated with the intervention; CI: confidence interval; F/u: Follow up; mths: mos; ID: identification; N: number of patients, participants, or procedures; NHS: National health service; OR: operating room; pts: patients; UCSF: University of California San Francisco

Ten studies were post-only interventions reporting their experiences with interventions after implementation without reporting on a comparator. The other studies were pre-post studies comparing the effects of the intervention to a historic comparison period.

One study assessed the effects of a verification protocol developed by an interdisciplinary team combined with audit and feedback[125] and reported no cases of wrong patient or wrong site anesthesia during and post intervention in a one year followup period with 71,145 procedures after previously experiencing four wrong site anesthesia cases (none resulted in wrong site surgery).

Four studies focused primarily on site markings. One study used an anatomic marking form to indicate the intended surgical site, signed by the patient at the same time as the surgical consent form, and the surgical site was then marked by preoperative nursing staff.[30] The post-only study reported one incident of wrong site surgery (a skin lesion was mistakenly removed and the intended lesion was missed) in 112,500 patients over 4.5 years. One intervention required surgeons to see patients in the pre-op area and mark the site before entering the operating room as part of a culture of safety initiative, no events were reported for pre- or post-intervention periods; however, the observation period was not specified.[137] Patient participation in the site marking process was tested in two studies.[120,123] Both studies reported no incidents of wrong site surgery post intervention but noted that the patient markings were not reliable and compliance was only between 59 and 68%.

Eight studies focused explicitly on the time out process. One publication[121] reported that the time out campaign initiated by the Minnesota Safe Surgery Coalition has improved the incidence rate in Minnesota facilities so that events now occur every 30 days compared to every 12 days before rollout. A post-only study of a US Army operating room in Iraq[126] reported that their protocol has been successful in 900 procedures; all personnel have to assent when the information is reviewed; the responsibility of reinforcing the time out rests with the perioperative nurses. A Canadian orthopedic practice added a time out procedure to their surgical site signing process; there were no wrong site surgical procedures before and after the intervention.[127] Lee et al.[90] tested an extended time out procedure that was designed to promote communication and teamwork. One near miss occurred and the authors thought that without the intervention the procedure would have started on the incorrect side, however, one incident of wrong site surgery also occurred (left inguinal hernia repaired but right inguinal hernia was scheduled). Three hospitals in New Zealand[129] reported that a checklist, introduced to facilitate the time out process, prevented three potential wrong site surgery events in a 17--month long observation period (months immediately following the intervention and four years later). A study addressing the prevention of wrong site tooth extractions[44] reported no events in 10 months after the introduction of a clinical guideline and implementing a time out protocol (the event rate was 0.047% per extracted teeth and 0.09% per number of participants).

Nine publications reported experiences with introduced surgical briefings, often supported by a checklist. A study at a Kaiser Permanente medical center[122] showed that a preoperative safety briefing was associated with no incident of wrong site surgery compared to three events in the year pre-intervention. The introduction of pre-operative and peri-operative operating room briefings resulted in no wrong site surgery in over a year compared to one to two events per year

previously in a Canadian children's hospital.[128] Lyons[132] reported no wrong site surgery events in eight years after initiating an intraoperative checklist program at the Department of Neurological Surgery at Mayo Clinic in Arizona (pre-intervention rate not known). One publication[131] reported that wrong site surgeries, which had been a problem in the past, have not occurred since introducing a perioperative briefing, however the followup period and pre-intervention data were not specified. Makary[133] showed that operating room briefings reduced staff's perceived risk for wrong site surgery but data on event incidents were not reported.

Four studies evaluated the use of the WHO surgical safety checklist; a Swiss study reported no wrong site surgery in 10,560 cases since implementation[119], a second study also reported no wrong side surgery after instituting the checklist but did not specify the followup period or the number of procedures.[124] One publication described that the reported benefits of implementing the checklist across English NHS Trusts included that more near misses were captured but the study did not report numerical data on wrong site surgery incidents[135] and a study adapting the checklist for pediatric patients also reported successfully identifying near misses.[134]

Only selected studies[30,90,125,128,129,135] reported adverse events of the interventions, such as staff experiencing the intervention as an additional burden. Lee et al.,[90] the only study reporting comparative data, found that the introduced extended time out protocol did not statistically significantly increase the time to incision.

We also identified 13 studies not directly focusing on elements of the Universal Protocol. The studies evaluated team training interventions or interventions primarily targeting the safety climate in the organization. The identified studies are summarized in the evidence table.

Table 11: Evidence Table Intervention Evaluation Wrong Site Surgery – Team Training, Education, Other Approaches

ID	Country, setting/ surgery	Design N F/u	Inter-vention focus	Intervention components	Compliance	Other/intervention-specific outcomes	AE	Effect on Near misses	Effect on event incidents
No author, 2009[138]	US, academic medical center	Pre-post N=n/a F/u: 5 years	Training	Multi-year training program incorporating interdisciplinary, team-based format, building work flow into policies	n/a	n/a	n/a	n/a	Several episodes of wrong site events to 0 events for >5 years
Chang, 2004[139]	Taiwan, academic medical center, oral surgery practice	Pre-post N=7800-8500 extractions per year F/U: 3 years	Education/ Clinical guideline	Clinical guideline to prevent erroneous tooth extractions; description in written order, inform pt about tooth position and reason for removal, operator should verify order with pt, communicate with referring dentist if unclear, check tooth position before and after forceps application; staff training	n/a	n/a	n/a	n/a	8 wrong site extractions in 3 years pre-intervention (annual rate 0.026%, 0.025%, 0.046%), 0 events 3 years after ($p<0.01$)
DeJohn, 2012[140,141]	US, eight hospitals and ambulatory surgical centers	Pre-post N= n/a F/u: n/a	Joint Commission's Center for Transforming Healthcare project	Targeted Solutions Tool (TST); Robust Process Improvement methods—including Lean Six Sigma and change management—to pinpoint causes, and develop targeted solutions; 29 main causes of wrong site surgery identified within 3 sites of care: scheduling, pre-op/holding, OR; individual solutions developed to avoid the identified risks; audits	n/a	n/a	n/a	Decreased cases with identified risks from 39% to 21% in scheduling, 52% to 19% in pre-op, and 59% to 29% in the OR ($p<0.001$); reduced incidence of cases with >1 defect (scheduling 57%, pre-op 72%, OR 76%)	n/a
Johnson, 2012[142]	US, community health system	Pre-post N=n/a F/u: 1 year	Pt safety course to create a culture of safety	Crew Resource Management, TeamSTEPPS, communication techniques; video vignettes featuring coworkers, audience response system to engage learners and promote participation, mandatory attendance; SBAR, callout and check back technique	Nearly all intended participants	n/a	n/a	n/a	During the year before course implementation 12 root cause analysis requiring events occurred, 4 in the year after
Logan, 2012[143]	US, academic medical center	Pre-post N=98 cases pre, 100 post F/u: 1 year	Audit	Clandestine audit of Universal Protocol, feedback/discussions; permanent white board template with prompts for required information implemented in addition to existing Time Out, presurgical checklist	Compliance increased in all dimensions, Time Out 98%, checklist 90%	n/a	n/a	0 near misses pre and post	n/a
Mallett, 2012[83]	US, academic medical center	Pre-post N=n/a F/u: 1 year	Process Redesign	Universal Protocol and WHO surgical checklist plus common cause analysis results (VA Triggering and Triage Cards) addressed by multidisciplinary team through process redesign; focused education initiatives for all faculty, residents, and clinical staff; creation of a zone of silence to minimize distractions during peri-procedural time period	Pre-procedure verification: 100%; site marking: high compliance; limited for Time Out	n/a	n/a	n/a	Pre: 8 wrong site surgery events in 21 mos, post: 0 event in 1 year

ID	Country, setting/ surgery	Design N F/u	Inter-vention focus	Intervention components	Compliance	Other/intervention-specific outcomes	AE	Effect on Near misses	Effect on event incidents
Neily, 2012[87]	US, VA	Post only N=132 F/u: 2 years	Education	Sharing of lessons learned through quarterly surgery adverse events reports and surgery root cause analysis lessons	76% of respondents had seen surgical lessons that were shared	75% gained new knowledge to prevent incorrect surgery	n/a	n/a	n/a
Neily, 2009[33]	US, VA	Pre-Post N=n/a F/u: 2 years	VA directive Ensuring Correct Surgery and Invasive Procedures	Directive consistent with Universal Protocol (6/2004 update)	n/a	n/a	n/a	OR close calls increased from appr. 0.5 events per month to 2; reported non OR close calls decreased slightly to appr. 0.2 reports/month	OR events increased from appr. 1.5 reports per month to 2; reported non-OR events increased from appr. 1 to 2 reports (estimated from graph)
Neily, 2011[34]	US, VA	Timeseries N=n/a F/u: 3 years	Medical Team Training	Training requires 2 mos planning with core change team; 1-day face to face learning session, mandatory attendance, 12 mos follow-up and coaching; emphasis on pre-op briefing and post op debriefing; in addition to VA directive for ensuring correct surgery	n/a, training presumably 100%	n/a	n/a	Rate of close calls increased from 1.97 per month to 3.24 ($p \leq 0.001$)	Event rate decreased from 3.21 to 2.4 per month ($p=0.02$); highest harm category (safety assessment code 3) dropped 14% (rate ratio 0.86; 95% CI 0.75, 0.97; $p=0.02$) each year (drop of 0.17 events per 100,000 surgeries per year)
Paull, 2013[144]	US, VA	Post only N=76 trainees F/u: n/a	Education	Simulated thoracentesis with variable scenarios designed to test teamwork and communication in preventing or catching errors before they cause harm to pts	n/a	Self reported confidence in ensuring correct surgery and invasive procedures improved	n/a	n/a	n/a
Ricci, 2012[145]	US, academic health system	Pre-post N=517 team members, 19,000 cases annually F/u: 2 years	Crew Resource Management program	System of effective teamwork, open communication, and optimized decision making in high-risk environments applying aviation techniques; initial 6-h training program (education, case-study discussions, team building exercises etc.), mandatory for all OR personnel; tools (checklists, feedback mechanisms) emphasis on communication (e.g., using the names of team members) and shared expectations during and at end of procedure; refresher courses planned	Compliance with local "time-out" policy increased from 6.7% to 99% 4 mos after training	Malpractice payout 4 years before: $793,000, after: $0	n/a	n/a	Annual wrong site surgery and RFI incidences ranged from 3 (0.016) to 7 (0.037) in 3 years before implementation; first 14 mons after: 0 events, second year: 5 events (0.026)

ID	Country, setting/ surgery	Design N F/u	Inter-vention focus	Intervention components	Compliance	Other/intervention-specific outcomes	AE	Effect on Near misses	Effect on event incidents
Russell, 2013[146]	US, academic medical center	Post only N=728 preoperative regional blocks F/u=1 year	Training/ Team development	Development of dedicated perioperative block nurse team; 3-week competency-based orientation program, orientation manual; simulations with regional anesthesiologists; pre-procedural time-out	n/a	Perioperative efficiency increased by 26%, service productivity increased by 12%, on-time OR starts increased by 7%	n/a	No wrong-site blocks during study period	n/a
Zohar, 2007[147]	US, community hospital	Pre-post N=15,856 pts F/u: n/a	Zero tolerance policy, peri-operative checklist	Education phase for involved caregivers; pre-operative readiness checklist completed by nurse at each care setting; readiness failures documents for analysis; zero tolerance policy for errors in pt readiness for anesthesia and surgery – pt returned to parent department, surgical procedure delayed until error corrected	n/a	Days between failures increased over time: 6.6 in 2003, 11.2 in 2004, 14.7 in 2005; failure decrease over time: 2004 OR 0.59, 2005 OR 0.49	n/a	112 failures (0.71%) including incorrect patient (4), absent/ incorrect side identification (34) or pt identification (20)	n/a

Notes: ABOS: American Board of Orthopaedic Surgery; AE: adverse event associated with the intervention; F/u: Follow up; mos: months; ID: identification; NHS: National Health Service; OR: operating room; pts: patients; RFI: retained foreign item; UCSF: University of California San Francisco

The identified studies used diverse interventions to address the prevention of wrong site surgery. Three studies were post-only studies reporting only on the period after the implementation of the intervention without comparative data, the others reported on a historical comparator.

Five interventions focused on team training. Two[142,145] used Crew Resource Management, a system of effective teamwork, open communication, and optimized decision making in high-risk environments; one study combined it with TeamSTEPPS, a teamwork system for healthcare professionals to improve patient safety. Both pre-post interventions reported a reduction in a composite outcome (events requiring root cause analysis, wrong site surgery *and* retained surgical items); the exact effect of the intervention on wrong site surgery alone is not known. One VA setting team training study was identified; described in more detail in the VA subgroup analysis section.[34] One study[138] reported no wrong site events after implementing a multi-year training program that incorporated an interdisciplinary team-based format for more than five years after having experienced several episodes pre-intervention. No further description of the intervention was reported and despite the success, the organization plans to add additional preventative measures such as a time out script and a checklist based on the WHO checklist. One study implemented a dedicated perioperative block nurse team, successfully avoiding wrong site anesthesia blocks during the one year study period.[146]

Some studies used, primarily, educational approaches to prevent wrong site surgery. One study[143] reported the effects of a clandestine audit by medical students who observed adherence to Universal Protocol requirements. After feedback and discussions, and implementing a whiteboard template with prompts for the required information, compliance increased for all elements and no near misses were identified pre- or post-intervention. A VA setting study reported by Neily et al.[87] also used a unique approach, i.e., sharing lessons learned through adverse event reports while an additional VA setting study reported by Paull et al.[144] used surgery simulations to train participants. One study developed a clinical guideline to prevent erroneous tooth extractions in combination with staff training and reported a significant improvement in the three years implementing the intervention in a Taiwanese academic medical center.[139]

Several publications in the existing literature address the initial success associated with the Joint Commission's Center for Transforming Healthcare tool "Targeted Solutions Tool" (TST). Participating hospitals reviewed their procedures to identify weaknesses that could potentially lead to errors, and sought ways to counteract them. Reported risk reductions were 46% in scheduling, 63% in pereop and 51% in the operating room; however the frequency of wrong site surgery incidents has not been reported yet.[140,141] One study[83] showed the effects of a process redesign that was based on a common cause analysis which used the root cause analysis methodology proposed by the VA National Center for Patient Safety Triggering and Triage Cards. The study reported that after experiencing eight events in 21 months prior to the intervention that no further wrong site procedures, or person events have occurred in the following year. A publication by Neily et al.[33] analyzed the effect of the VA Directive Ensuring correct Surgery and Invasive Procedures (see VA subgroup analysis). A multifaceted, cross-organizational study established a zero tolerance policy for documentation failures in the operating room holding area and patients would be returned to the parent department, delaying the surgical procedure, until the error was corrected.[147] Incorrect patient and incorrect identification of the side of surgery errors decreased over time; however, the study did not report on the frequency of actual wrong site surgery incidents.

The review also identified nine studies that primarily targeted technical equipment. The studies are summarized in the evidence table.

Table 12: Evidence Table Intervention Evaluation Wrong Site Surgery - Equipment

ID	Country, setting/ surgery	Design N F/u	Intervention focus	Intervention components	Compliance	Other/intervention-specific outcomes	AE	Effect on near misses	Effect on event incidents
No author, 2011[148]	US, community medical center	Pre-post N=n/a F/u: n/a	Reporting simplified	Encouragement of reporting incidents and near misses, procedure for reporting streamlined; Intervention in addition to Universal Protocol	100% compliance with Universal Protocol	Improved safety culture	n/a	n/a	Pre: 1 event, post: 0
Ammerman, 2006[149]	US, academic neuro-surgery practice	Post only N=100 pts F/u: n/a	Intraoperative x-ray	Routine intraoperative x-ray to reduce incidence of incorrect level surgery	n/a	n/a	n/a	15% potential wrong-level laminectomies prevented with x-ray; 15% wrong level exposures	0/100 wrong site and wrong level laminectomies
Asopa, 2012[150]	UK, lumbar spine surgery	Post only N=64 F/u: n/a	Imaging technique	Technique to avoid incorrect level lumbar spine surgery; intraoperative fluoroscopy with radiopaque marker ID of level, repositioning and re-imaging of level after skin incision, and re-imaging after surgery to confirm site	n/a	n/a	n/a	n/a	0/64 cases of incorrect level discectomy
Cima, 2010[29]	US, academic medical center	Pre-post N=5,299 procedures (pre), 4354 (post) F/u: 1 year	Computerized listing system	Changes to computerized surgical listing system based on error analysis; mandatory entries for laterality	n/a	Reduction in listing errors from 1.5% to 0.54% (gynecologic surgery); from 2.06 to 0.49% (colorectal surgery)	n/a	n/a	Pre: 0 wrong pt surgeries, post: no adverse outcomes from errors
Henley, 2008 [91]	UK, single NHS trust hospital	Post only N=40,000 F/u: 1 year	Pt identity band	Identity band placed by pt, info filled in by team members during path to OR, and removed just before incision, band placed in medical record	n/a	n/a	n/a	Minor error rates were similar but identified earlier	n/a
Irace, 2010[151]	Italy, neurosurgical practice	Post only N=818 procedures F/u: 96 mos	Intraoperative radiograph	To confirm spine level and side; wire placement at desired level pre-operatively, confirmation radiographically prior to laminotomy; verbal confirmation by surgeon	n/a	n/a	No complications	1 wrong level initially explored in 818 procedures (0.12%)	0 wrong site surgery events in 818 procedures
Ku, 2011[152]	Taiwan, medical center	Pre-post N=22,000 pts F/u: 1 year	Radiofrequency ID	Patient Advancement Monitoring System-Surgical, radiofrequency (RFID) to control pt flow process through peri-operative processes, quality and efficiency of care	100%	Pt ID check correction rates increased from 75% to 100%; 78% felt system was easy to use; 91% felt it was conducive to improving pt ID and promoting surgical safety	n/a	n/a	0 wrong pt or surgical procedure events pre and post

ID	Country, setting/ surgery	Design N F/u	Intervention focus	Intervention components	Compliance	Other/intervention-specific outcomes	AE	Effect on near misses	Effect on event incidents
Nowitzke, 2008[153]	Australia, academic neurosurgical practice	Post only N=17 F/u: n/a	Computer-assisted image guidance	Technique for thoraco-lumbar level localization; standard image intensifier radiology, adjacent, contiguous images of desired plane displayed; lowest-possible radiation exposure, reproducible technique, versatile, recordable, interpretable by non-specialists	n/a	n/a	No complications	n/a	0 cases of incorrect level surgery
Upadhyaya, 2012[154]	US, single academic institution spine surgery	Pre-post N=52 F/u: n/a	Percutaneous fiducial screw placement	Pre-operative placement of percutaneous screw at level of intended surgery using CT guidance, followed by intra-operative fluoroscopy for intraoperative localization	n/a	0 complications; intraoperative localization fluoroscopy time reduced from 15 to 3 mins	n/a	n/a	Pre and post 0 wrong level surgeries

Notes: AE: adverse event associated with the intervention; F/u: Follow up; mos: months; ID: identification; OR: operating room; pts: patients

Half the identified studies used a post only design, reporting zero events since implementation of the intervention; however, only selected studies specified the followup period. The other studies reported pre-post data; all studies reporting on events reported zero wrong site surgery incidents post intervention.

Five national and international studies reported on imaging techniques designed to prevent wrong site spine surgical procedures and in particular, wrong level spine operations intraoperatively, alone or in combination with other protocols.[149-151,153,154]

Cima et al[29] redesigned the computerized surgical listing process, in particular to avoid errors in laterality, arguing that errors in this early stage of documentation may establish an incorrect mental model for operating room personnel which sends them on a trajectory toward an error unless there is credible conflicting information brought forward. The study reports no adverse outcomes from errors in a one year followup period; there were also no wrong patient surgery before the redesign. A Taiwanese study[152] reported their experiences with a radiofrequency patient identification program (Patient Advancement Monitoring System-Surgical). The feedback was generally positive and there were no wrong patient or wrong surgical procedures before and one year after the implementation. A UK study used a patient identify band worn until the moment of surgery when the band was filed with the patient records; the study found minor error rates to be similar but identified earlier and prior to the patient being at risk.[91]

One study107 simplified the incidence reporting system in order to encourage reporting of incidents and near misses and reported that post intervention 100% compliance with the Universal Protocol and an improved safety culture was achieved. The study reported no further wrong site surgery events; however, the followup period was not specified.

VA Subgroup Analysis: Effectiveness of Interventions for the Prevention of Wrong Site Surgery

We identified four studies evaluating interventions and policies within the VA.

Neily et al.[33] showed wrong site surgery data (wrong patient, wrong side, wrong site, wrong procedure, wrong implant) stratified by occurrence before any directive (before January 2003), after the directive for operating room cases only (January to June 2004) and the updated directive Ensuring Correct Surgery and Invasive Procedures (applicable after June 2004). The graphs did not show a reduction in event associated with the directives, but showed instead that in particular reporting of close calls increased after implementing the directives (numerical numbers not reported). A followup publication in 2011[34] showed that the rate of reported adverse events decreased from 3.21 to 2.4 per months ($p<0.02$) between 2001 and 2009; in addition, a medical team training program had been implemented nationally between 2006 and 2009. The reporting of close calls increased statistically significantly from 1.97 to 3.24 per month ($p<0.001$).

A third VA study[155] reported on an approach to share lessons learned through quarterly surgery adverse event reports and surgery root cause analysis lessons. A survey showed that 75% of respondents stated that they gained new knowledge to prevent incorrect surgery. Finally, a recently published study by Paull et al.[144] showed that simulated thoracentesis with variable scenarios designed to test teamwork and communication in preventing or catching errors before they cause harm to patients increases self-reported confidence in ensuring correct surgery and invasive procedures.

Strength of Evidence: Effectiveness of Interventions for the Prevention of Wrong Site Surgery

We identified 49 published evaluations of wrong site surgery prevention approaches. Evaluated interventions were very diverse ranging from evaluations of the Universal Protocol, individual components of the Universal Protocol, briefings and the use of checklists, team training and educational approaches, as well as equipment-related changes, or other unique approaches.

Only the Universal Protocol was evaluated in more than one study, studies provided data for followup periods of more than two years, and reported on wrong site surgery incidents together with a denominator. One of the studies[48] reported a statistically significant reduction. No other intervention was evaluated in more than one study, with studies reporting on a concurrent or historic comparator, a followup period of at least two years or 50,000 observations, and reporting on the outcome of interest.

Based on the available evidence, in particular the lack of replication, study designs, followup periods, lack of reported denominators, and reported outcomes, the existing evidence base regarding interventions to prevent wrong site surgery is low with the exception of the Universal Protocol. For the latter, the strength of evidence is classified as moderate. However, the intervention was only evaluated through secular changes and other factors may have contributed to the effect and statistically significant effects were only seen in one study. Future research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Interventions to Prevent Retained Surgical Items

We identified 14 publications reporting on 15 intervention studies aiming to prevent retained surgical items. One study reported on data after implementing a sponge counting protocol and after implementing a radiofrequency detection system to track surgical sponges.[67] The evaluations are summarized in the evidence table.

Table 13: Evidence Table Intervention Evaluation Retained Surgical Items

ID	Country, setting/ surgery	Design N F/u	Intervention focus	Intervention components	Compliance	Other/ intervention-specific outcomes	AE	Effect on near misses	Effect on event incidents
			Counting/ imagine protocol						
No author, 2007[156]	US, academic medical center	Pre-post N=n/a F/u: 2 years	Count practices	Standardization of best practices for count and count verification (what to count, when to count, procedure for incorrect count, documentation); noncompliant clinicians followed up; distraction management; required time-out when any staff member feels situation in room is unsafe (e.g., when delegating tasks); position statement on prioritizing tasks and handling interruptions; introduction of appropriately assertive communication methods; minimizing frequent policy changes	Quarterly audits, data n/a	n/a	n/a	n/a	8 events in 18 mos before, 0 events two years after intervention
No author, 2009 [157]	US, academic medical center	Pre-post N=n/a F/u: > 1 year	Count protocol	Printed checklist verified and signed by attending surgeon; unreconciled list triggers freeze for all OR personnel while surgeon and radiologist read films; each team member responsible for a set of items in OR.	n/a	Checklist documentation can be used for near miss analysis	n/a	n/a	0 unintentionally retained objects for > 1 year"
Hunter, 2010[65]	US, academic medical center	Post only N=1,034 surgeries per month F/up: 11 mos	X-ray protocol	Criteria for obtaining intraoperative x-rays specified (BMI >35, emergency procedure, actual procedure different from scheduled, accurate count not possible, count discrepancy); responsibility for RFI shared between radiologist and operating team; detailed form for radiology when RFI is suspected; reference guide for radiologists; radiology report communicated to physician before pt leaves OR; documentation	21% in the beginning, later 71%	Quick identification of RFI on radiographs	n/a	n/a	2/11,374 sentinel cases of RFIs in 11 months after implementation
Lutgendorf, 2011[72]	US, armed forces health system, academic obstetrics practice	Pre post N=10,500 deliveries (post) F/u: 2 years	Count and x-ray protocol to reduce occurrence of retained sponges after vaginal delivery; versus vaginal sweep	Developed by multidisciplinary team; sponge count before and after all vaginal deliveries; provider to initiate sponge counts, nurses verify and document counts; if count incorrect, and vaginal sweep ineffective, thorough exam and x-ray; use of larger, radiopaque sponges; sponges laid out side by side on delivery carts to facilitate counting; avoidance of sponges in vagina if possible; tail left in view at all times if placed in vagina; global training of providers and nurses	Regular audits, data n/a	Cost of protocol implementation appr. $2.50 per delivery; counts took appr. 1 min	Initial concerns of difficulty in using larger sponges and time consuming counts were unfounded as implementation occurred	n/a	Rate of 1/5,000 deliveries with event (sponges) in 5 years with vaginal sweep, 0/10,500 deliveries in 2 years after new protocol implemented
McIntyre, 2010[66]	US, academic medical center	Pre-post N=about 12,000 surgical procedures per year F/u: 18 mos	Count and x-ray policy	X-ray after any procedure in which body cavity is opened or wound is considered large enough to retain instrument or sponge; film obtained regardless of whether final closure has occurred, packing left, or additional surgery planned; x-ray must cover entire surgical field, interpreted by senior level resident or attending, relief counts must occur before change of personnel; baseline sponge counts mandatory, communication of packing or removal of packing; if abdominal cavity is explored landmarks from diaphragm to symphysis must be visualized; staff tutorial	n/a	Cost of routine surveillance films: $63,825 for 990 films	n/a	n/a	3 cases in two years before all policy changes were implemented, 0 cases in 18 mos since implementation

ID	Country, setting/ surgery	Design N F/u	Intervention focus	Intervention components	Compliance	Other/ intervention-specific outcomes	AE	Effect on near misses	Effect on event incidents
Rupp, 2012[67]	US, academic health system	Pre-post N=n/a F/u: n/a	Count protocol	Sponge ACCOUNTing System; several structural elements, medical personnel training, equipment (e.g., sponge holder racks) to facilitate accurate accounting of soft goods/sponges	n/a	inexpensive	n/a	n/a	1 retained item per 36,000 operation before implementation, 1/54,000 after
			Team training						
Cima, 2009[158]	US, academic medical center	Pre-post N=50,000 operations annually F/u: 2 years	Conscientious Count Campaign	Phase I: defect analysis; tools collaboratively designed; Phase II: awareness and communication, mandatory meeting for all OR personnel; team communication and education, videos and printed materials, team training simulation, in-room audits with feedback, standardized counting process; "Red Rules" (inviolable OR rules, Universal Protocol, Correct Count Process followed); Phase III: monitoring and control, rapid response event team formed to deal with events within 24-36 hours to provide real time feedback, non-punitive approach to errors	99.4% compliance in 3rd quarter in daily random audits of baseline count, tucked item documentation, and final counts	Defect per million opportunities analysis shows decline from 0.52 to 0.11 per 1,000 surgeries; increase in Sigma performance level of 5.6 to 6.0.	n/a	RFI or near miss from 1 every 16 days to 1 every 69 days	RFI or near miss from 1 every 16 days prior to intervention to 1 every 69 days sustained for 2 years
Johnson, 2012[142]	US, community health system	Pre-post N=n/a F/u: 1 year	Pt safety course to create a culture of safety	Crew Resource Management, TeamSTEPPS, communication techniques; video vignettes featuring coworkers, audience response system to engage learners and promote participation, mandatory attendance; SBAR, callout and check back technique	Nearly all intended participants	n/a	n/a	n/a	During the year before course implementation, 12 root cause analysis requiring events (e.g., retained item, fire); 4 in the year after
Ricci, 2012[145]	US, academic health system	Pre-post N=517 team members, 19,000 cases performed annually F/u: 2 years	Crew Resource Management program	System of effective teamwork, open communication, and optimized decision making in high-risk environments applying aviation techniques; initial 6-h training program (education, case-study discussions, team building exercises etc.), mandatory for all OR personnel; tools (checklists, feedback mechanisms) emphasis on communication (e.g., using the names of team members) and shared expectations during and at end of procedure; refresher courses planned	Compliance with local "time-out" policy increased from 6.7% to 99% 4 mos after training	Malpractice payout 4 years before: $793,000, after: $0	n/a	n/a	Annual wrong site surgery and RFI events ranged from 3 (0.016) to 7 (0.037) in 3 years before implementation; first 14 mos after: 0 events, second year: 5 events (0.026)
			Equipment						
Cima, 2011[61]	US, academic medical center	Pre-post N=87,404 operations (post) F/u: 18 mos	Data-matrix coded sponge (DMS) system	System includes a wide variety of labeled cotton surgical sponge products; each item has a unique data-matrix tag; bulk scanning in, each sponge must be scanned out at end of procedure	n/a	Count time decreased with repetition; 82% feel comfortable with DMS process	Additional $11.63 average cost per case by using DMS system, longer count time vs. manual (11.4 vs. 4.0 seconds); only 59% rate the DMS process as very efficient	3 incorrect manual counts caught	0/87,404 retained sponges over 18 mos study period, compared to retained sponge every 64 days prior; significant change in event frequency ($p<0.001$)

ID	Country, setting/ surgery	Design N F/u	Intervention focus	Intervention components	Compliance	Other/ intervention-specific outcomes	AE	Effect on near misses	Effect on event incidents
Greenberg, 2008[64]	US, academic medical center, general surgery	RCT N=56 OR staff, 36 surgeons; control: n=148 operations interven-tion: n=150 operations F/u: 60 days	Bar coding surgical sponges versus traditional counting protocol	Control group: standard Peri-Operative Registered Nurses protocol for counting instruments and sponges, simultaneous manual count by ST and circulator, and written record; when removed from sterile field, sponges were counted and placed in sterile bags with 10 sponges per bag, count manually performed by both ST and RN Intervention: same as control with addition of SurgiCount Medical; sponges scanned when placed on sterile field and counted; when removed from sterile field scanned again and counted before being placed into bags by RN; concurrent counts with ST in bar code arm were not required	44% of personnel answered end of study surveys	Detection of sponge discrepancy: 13 (control) vs 32 (intervention), p=0.008; retained or misplaced sponges: 12 vs 21 p=0.17; miscount s: 1 vs 11 p=0.007; cases with sponge discrepancy: 12 vs 24 p=0.049; cases with retained or misplaced sponge: 11 vs 17 p=0.32; confidence in ability to track sponges: 7.5, SD 7.3 on scale from 1 to 10	17 technological difficulties (background scanning, scanning out while scanner set to scanning in, bar code abandoned in 5/150 operations due to time constraints); mean time to resolve discrepancy: 12.7 (control) vs 13 min (intervention) p=0.61; total time counting: 8.6 vs 12 min, p<0.0001; sponge counting: 2.4 vs 5.3 min, p<0.0001	3 retained sponges found before pt left OR in bar code group	0 retained sponges in both groups at 60 days of f/u
Pelter, 2007[159]	US, community medical center, elective surgical procedures	Controlled trial N=50 pts, 16 OR personnel surveyed F/u: n/a	Numbered surgical sponges	Sequentially numbered surgical sponge product to improve ease of counting compared to routine sponge counting	n/a	Count time: 44 sec (control) vs 28 sec (intervention) p=0.098; length of procedure: 72 vs 65 mins (p=0.633); ease of use: 81% respondents agreed; 94% thought sponges are safe to use, 38% thought product would increase pt safety; 44% felt more confident with count	n/a	n/a	n/a

ID	Country, setting/ surgery	Design N F/u	Intervention focus	Intervention components	Compliance	Other/ intervention-specific outcomes	AE	Effect on near misses	Effect on event incidents
Rupp, 2012[67]	US, academic health system	Pre-post N=2,285 pts (post) F/u: 10 mos study period, mean f/u 20 mos	Radiofrequency detection system	RF Surgical Systems Inc. incorporated adjunct to standard sponge-counting algorithm including Sponge ACCOUNTing System; RFDS tagged sponges; RF wand; staff training, flow diagrams of protocols, educational materials, assessment and feedback	n/a	35 miscounts (1.53%); increased cost by $13.54 per case	n/a	1 near miss detected with RFDS (in drapes; routine protocol did not detect it)	0 retained items in 2,285 pts, prior to implementation the rate was 1 event per 54,000 operations
			Other						
Neily, 2012[87]	US, VA	Post only N=132 F/u: 2 years	Education	Sharing of lessons learned through quarterly surgery adverse events reports and surgery root cause analysis lessons	76% of respondents had seen surgical lessons that were shared	60% felt their facility is less likely to incur an RSI due to participation in Surgical Lessons Learned	n/a	n/a	n/a
Vannucci, 2012 [69,160]	US, academic medical center, CV catheter placement	Pre-post N=n/a F/u: n/a	Education, checklist	Multidisciplinary root cause analyses, mandatory training for new hospital interns, CVC checklist to guide and document every placement; further system changes	n/a	n/a	n/a	n/a	Retained guidewires have decreased since introducing the catheter and guidewire skills module

Notes: AE: adverse events associated with intervention; appr.: approximately; CVC: central venous catheter; ID: identification; min: minutes; N: number of patients, participants, or procedures; OR: operating room; pt: patient; RF: radiofrequency; RFI: retained foreign item; RN: registered nurse; sec: seconds; ST: surgical technologist; vs: versus

Six studies reported their experiences with implementing sponge or instrument count and/or imaging protocols. The protocols outlined the count procedure (e.g., what should be counted and when), specified responsibilities for various team members, and provided guidelines when x-rays should be taken to ensure that no item was left behind. All reported improvements but only four indicated there were no incidents between one and two years after the intervention implementation.[36,66,72,157] Most protocols were developed at the organization but one study[67] reported a reduction from 1/36,000 to 1/54,000 after implementing the standardized Sponge ACCOUNTing System.

We identified three team training approaches aiming to prevent retained surgical items. One was a multifaceted and multi-disciplinary campaign exclusively designed to reduce retained foreign objects which resulted in a significant and sustained reduction in incidents in a pre-post analysis.[158] Johnson's[142] patient safety course showed that the number of root cause analysis requiring events was reduced but it did not specifically report on the included retained surgical items. A third educational intervention applied aviation safety techniques to surgery (Crew Resource Management Program) and did also only report on a composite outcome of wrong site surgery and/or retained item incidents.

Four studies evaluated equipment-associated innovations. An RCT by Greenberg et al.[64] comparing bar coding technology with the standard Peri-Operative Registered Nurses protocol reported no retained sponges in either group (N=300) but noted that the system was useful to detect miscounted and misplaced sponges. Cima et al. (2011)[61] reported that a data-matrix-coded sponge counting system has eliminated sponge retained surgical items based on experiences in an 18-month period with 87,404 procedures (compared to before implementation where a retained sponge occurred on average every 64 days). The results represent a statistically significant reduction in event frequency. Rupp et al.[67] reported that no items were retained in 2,285 patients when changing to a radiofrequency detection system; the rate was 1/54,000 prior to the intervention implementation when only the Sponge ACCOUNTing System was used. The numbered sponge evaluation did not report on incidents but noted that staff felt more confident with the product.[159]

VA Subgroup Analysis: Effectiveness of Interventions for the Prevention of Retained Surgical Items

One VA study was identified. Neily et al.[155] reported on an educational intervention through quarterly surgery adverse events reports and surgery root cause analyses and reported that 60% felt their facility is less likely to incur a retained surgical item due to participation in "Surgical Lessons Learned" but no incidence data were presented.

Strength of Evidence: Effectiveness of Interventions for the Prevention of Retained Surgical Items

We identified 15 evaluations, including one RCT evaluating interventions for the prevention of retained items. However, only one of the studies (using a data-matrix-coded sponge counting system) demonstrated a statistical significant effect of the intervention compared to a concurrent or historic comparator.[61] Our knowledge about the comparative effectiveness of different approaches to prevent retained surgical items is very limited. Given the rare event that is studied, analyses with longer follow-up periods may change our current knowledge.

Interventions to Prevent Surgical Fires

We identified eight studies evaluating interventions to prevent surgical fires. The studies are summarized in the evidence table, broadly categorized by approach (education, equipment, other).

Table 14: Evidence Table Intervention Evaluation Surgical Fires

ID	Country, setting/ surgery	Design N F/u	Intervention focus	Intervention components	Compliance	Other/intervention-specific outcomes	AE	Effect on near misses	Effect on event incidents
Education									
Flowers, 2004[161]	US, community medical center	Post only N=n/a F/u: n/a	OR fire drill, new fire safety plan	OR-based fire scenarios, roll-play activities	n/a	Self-reported improved confidence in handling OR fires, improved knowledge of location and use of fire suppression devices	Communication difficulties associated with knowledge that drill was not real	n/a	n/a
Galvagno, 2009[162]	US, academic anesth. program	Pre-post N=29 anesth. residents F/u: 9 mos course	Critical action procedure education	Administration of critical action procedure tests (including airway fire) to improve knowledge about how to respond to rare and potentially catastrophic events	18/29 completed test	Percent of correct response in airway fire test scores increased from 20 to 80%; 90% agreed it was a worthwhile learning experience	n/a	n/a	n/a
Lypson, 2005[112]	US, academic medical center	Pre-post N=152 interns F/u: n/a	Fire safety education	Training station with video education, surgical fire brochure, and multiple choice test	n/a	61% unaware of risk of surgical fires prior to education and 87% felt they would know how to prevent surgical fires after education	n/a	n/a	n/a
Equipment									
Lunn, 2005 [163]	US, academic medical center	Post only N=23 pts F/u: 1-24 months	Microdebrider bronchoscopy	Metal tube attached to suction with oscillating tracheal blade; avoids need for laser or electrocautery devices	n/a	n/a	1 pt required admission for dyspnea, found to have undiagnosed bilateral vocal cord paresis	n/a	0/23 complications such as airway fires
Militana, 2007[164]	US, academic medical center	Post only N=25 pts F/u: n/a	Use of laryngeal mask airway	Use of laryngeal mask airway to prevent airway fires	100%	n/a	1 pt needed different size to achieve adequate airway seal	n/a	0/25 airway fires despite use of electrocautery
Rezaie-Majd, 2006[165]	Austria, academic medical center	Post only N=1,515 pts F/u: 1990-2004	Superimposed high-frequency jet ventilation	Designed for laryngotracheal surgery, two jet streams with different frequencies applied simultaneously; avoids tracheal tubes or catheters	n/a	Adequate oxygenation and ventilation achieved in 1,512 pts	No major hemorrhage, or aspiration of debris	n/a	0/1,515 airway fires
Other									
Johnson, 2012[142]	US, community health system	Pre-post N=n/a F/u: 1 year	Pt safety course to create a culture of safety	Crew Resource Management, TeamSTEPPS, communication techniques; video vignettes featuring coworkers, audience response system to engage learners and promote participation, mandatory attendance; SBAR, callout and check back technique	Nearly all intended participants	n/a	n/a	n/a	Pre: 12 root cause analysis requiring events in 1 year (e.g., retained item, fire), post: 4 in 1 year

ID	Country, setting/ surgery	Design N F/u	Intervention focus	Intervention components	Compliance	Other/intervention-specific outcomes	AE	Effect on near misses	Effect on event incidents
Mathias, 2006,[166], Williams, 2008[167]	US, community health care system	Pre-post N=n/a F/u=n/a	Scoring system to identify intraoperative fire risk; OR fire drills	Assessment of elements of fire triangle: incision over the xiphoid process, open oxygen source, available ignition source. Protocols for all OR providers based on fire risk score; yearly OR fire drills	n/a	Communication among surgical team members and identification of the fire risk triangle improved	n/a	n/a	No significant fire or injury to a pt due to fire since imple-mentation, 2 fires before but study periods not specified

Note: AE: adverse event associated with intervention; anesth.: anesthesia; F/u: Follow up; N: number of patients, participants, or procedures; OR: operating room; SBAR: situation, background, assessment and recommendation

Three educational interventions such as fire drills were evaluated. All reported improvements in provider knowledge; however, no data on the effect of fire incidents was presented.

Of three equipment-related studies, two interventions reported on experiences with two anesthesia techniques: use of laryngeal mask airway and superimposed high-frequency jet ventilation for laryngotracheal surgery. Both reported that no airway fires occurred but only the jet ventilation study reported on a substantial sample (N=1,515) and a 14 year followup period. One study tested a bronchoscopy tool and found no complications such as airway fires; however, the sample was limited to 23 patients.[163]

One identified intervention[142] evaluated the effect of a patient safety course to create a culture of safety on serious events that would require a root cause analysis according to the Joint Commission but did not specify which events occurred. One institution developed a fire risk assessment system used for every patient and announced by the circulating nurse during the time out before surgery begins in combination with yearly fire drills. No significant fire or injury to a patient due to fire occurred since its implementation; however, the followup period was not specified.[166,167]

VA Subgroup Analysis: Effectiveness of Interventions for the Prevention of Surgical Fires

We did not identify a study evaluating fire prevention interventions in a VA facility.

Strength of Evidence: Effectiveness of Interventions for the Prevention of Surgical Fires

Given the limitations of study design (primarily post-only) and insufficient followup periods for all but one study, and the limited outcomes utilized in most studies, the quality of the evidence is very low.

SUMMARY AND DISCUSSION

PREVALENCE

Definitions of events and procedure scope varied in the identified prevalence studies for wrong site surgery. The median prevalence estimate for wrong site surgery was 0.09 events per 10,000 surgical procedures. Two recent surveys showed that 50% of spine surgeons had performed one or more wrong level spine surgical procedures during their career in recent surveys. Lifetime prevalence estimates cover a wide time span and the estimates include the period pre-Universal Protocol so newer estimates may change. A systematic review by DeVine et al.[168] identified estimates ranging from 0.09 to 4.5 per 10,000 performed surgical procedures. A 2012 systematic review on errors of level in spinal surgery concluded that the current literature does not provide a definitive estimate of the occurrence of wrong-site spinal surgery.[169]

Definitions of events and procedure scope varied in the identified prevalence studies for retained surgical items. The median prevalence estimate for retained surgical items was 1.43 events per 10,000 surgical procedures. The most commonly reported item was a surgical sponge. Several studies highlighted that a number of events were discovered even when surgical counts were recorded as correct. The Joint Commission has added the unintended retention of foreign objects to the sentinel event policy in 2005 and reviews between 17 and 188 voluntarily reported events yearly.[170]

We did not identify any estimates of the prevalence of surgical fires per procedure. One survey showed that 23% of responding otolaryngology and head and neck surgeons had experienced at least one operating room fire in their career, and an analysis of the of the American Society of Anesthesiologists Closed Claims database highlighted that operating room fires accounted for nearly a fifth of monitored anesthesia care claims. Current online fire prevention resource material prepared by the ECRI Institute extrapolated from the 2007 Pennsylvania Patient Safety Reporting system data that the number of fires occurring nationally ranges from 550 to 650.[171]

Comparing prevalence estimates is difficult, in particular, as definitions of the never event of interest varied or, in some cases, were not reported. Studies varied in their differentiation between near misses and event incidents, whether surgical and anesthesia-related care processes were combined in prevalence estimates, and the scope of eligible procedures. We considered different prevalence estimates, such as estimates per procedure or lifetime prevalence per surgeon. Each estimate comes with specific limitations. Most estimates are likely to be an underestimate of the actual occurrence of events, documented is only the frequency of *reported* events.

ROOT CAUSES

The identified root cause analyses report a large number of individual causes, risk factors, or contributing factors. A frequently reported cause for wrong site surgery events was communication problems between staff members within or across units. Studies showed how errors resulted from misinformation (e.g., incorrect information obtained from other departments) and misperception (e.g., right-left confusion when interpreting imaging results). A number of studies reported that not following policies, such as time out, not performing safety

procedures in a meaningful way (e.g., passive time out), inadequate policies (e.g., site markings not visible after draping), omissions (e.g., laterality was not specified on the consent form), and lack of standardization of procedures contributed to the events.

Given the suspected prevalence, we only identified a small number of root cause analyses for retained surgical items. This may in part be due to the fact that events may not be discovered immediately but instead are identified days or even years later, which may make it more difficult to reconstruct the contributing factors. Case specific, e.g., emergency procedures, or factors related to the surgical environment, with shift changes, incomplete counts, or poor communication, were identified as contributing factors.

Surgical fires were caused by combinations of ignition sources, fuels, and the presence of oxygen. Based on a survey for otolaryngologists, one study identified different fire scenarios and determined that the most common ignition sources were electrosurgical units, lasers, and light cords; common fuels were endotracheal tubes and drapes or towels, and in the large majority of cases, supplemental oxygen was in use. Fire risk increases with procedures involving the face and neck. A recent review concluded surgery will always carry a risk of fire and reducing this risk requires a concerted effort from all team members.[172]

GUIDELINES

We identified four guidelines included in the National Guideline Clearinghouse registry, which uses systematic reviews of the evidence to assess the benefits and harms of care options and thus informs optimal patient care. One guideline targeted surgical fires, one on preventing wrong site surgery, one on preventing retained foreign objects, and the fourth covered both wrong site surgery and retained foreign bodies. Two guidelines were specialty specific (interventional radiology and obstetrical) and therefore covered narrow patient populations.

Based on the AGREE II criteria, the overall quality was high for stakeholder involvement and scope and purpose. There was considerable variability for the other domains of guideline development and most had methods problems with regards to transparency and rigor of development. Common themes found across guidelines were the regular use of checklists, importance of standardized communication between the surgical team members, and multiple rechecking throughout the operative process. Specific steps and protocols for preventing wrong site surgery, retained foreign bodies, and surgical fires were outlined in detail for all guidelines.

INTERVENTIONS

The review identified numerous evaluations of interventions aiming to prevent wrong site surgery, retained surgical items, and surgical fires. However, evaluations lacked replication and most studies had insufficient or no comparators, sample sizes were inadequate, and followup periods were typically short. The evaluations provide some empirical evidence for approaches to prevent wrong site surgery, retained surgical items, and surgical fires; however, apart from global Universal Protocol evaluations, the level of evidence was very low.

Although many publications in the existing literature refer to the need for better communication,[173,174] we identified very few empirical evaluations of communication-focused interventions. The wrong site literature repeatedly referred to the importance of all surgical team members needing to feel comfortable to speak up in order to prevent errors and misunderstandings. The retained surgical item literature includes many publications suggesting that counts are documented in full view of the team so that all team members can point out problems. The surgical fire literature refers frequently to the need for surgical teams to discuss the fire hazard of procedures preventatively, this includes communication across disciplines to communicate issues that are not immediately obvious, e.g., it is the responsibility of the anesthesia care team to inform the surgical and nursing personnel about the presence of a high concentration of oxygen in the surgical field; and in the case of a fire, instant, cooperative action is essential.[175,176]

The included interventions studies show that the implementation success of safety practices varies and those studies reporting compliance show incomplete adherence to the intervention components. In addition, surveys show that although staff may be familiar with the general safety procedure such as Rescue, Activate, Confine, Evacuate (RACE) as suggested by ECRI, a substantial number may not be able to execute the required steps, for example, locating the medical gas supply cut off in order to confine the fire.[177,178]

The prevention of wrong site surgery was addressed in a substantial number of identified studies. Studies reported on a variety of approaches such as local adaptations and implementations of the Universal Protocol; experiences with preoperative verification, surgical site marking, time out procedures; team training and education; as well as equipment-centered approaches. Several protocol changes used checklists to guide preoperative site verification, surgical site marking, and time out stages. The use of checklists is attributed to the airline industry which acknowledges that humans working in a complex system inevitably make errors when attempting to carry out procedures by memory alone, checklists free up mental capacity, and external prompts may be necessary to improve communication by prompting all team members to speak up.[179-182]

In recent years, authors have frequently urged to make use of technology such as radiofrequency identification tags to prevent the retention of surgical items.[183] One identified study found a statistically significant reduction in event frequency with a data-matrix-coded sponge counting system.[61] Cost-effectiveness considerations need to consider the cost of the device as well as medico-legal costs of potentially prevented consequences of incidents. Regenbogen et al.[184] concluded from a decision-analytic model comparing no tracking, routine counting, universal x-ray, bar-coded sponges, and two radiofrequency-tagged models that given medical and liability costs exceeding $200,000 per incident, novel technologies can substantially reduce the incidence of retained surgical sponges, at acceptable cost.

The review has identified only a few intervention studies aiming to prevent surgical fires and only one study evaluated a specific approach in more than 200 procedures. Some authors have suggested solutions based on the general principle of eliminating or reducing one of the elements of the fire triangle, most frequently oxygen, either by reducing the concentration[185] or by challenging the practice of supplementing with oxygen.[186,187] Others have questioned this recommendation and suggested to assess the comparative risks of insufficient oxygen to

patients and the risk of surgical fires[188,189] hence clinical guidelines need to balance competing factors.[190,191] Unique to this surgical never event is that fires can happen very fast, and when they occur, harm to the patient will also occur very fast, resulting in the need for staff to react very quickly in an extreme situation.[192] A recent literature review on surgical fires concluded that the risk of fire can be reduced with an awareness of the risk and good communication.[172]

Conclusive evaluations of interventions to reduce the incidence of wrong site surgery, retained surgical items, or surgical fires are still relatively few in number. Evaluations of interventions aiming to prevent a rare event present a number of challenges in design and interpretation. The most challenging is the limit of inferential statistics. Some studies report reductions in events of 20 to 35% but these are not statistically significant. If an event occurs once in 20,000 occurrences, to have sufficient power to detect a reduction to once in 30,000 occurrences would require a sample of 5,000,000 observations. This is simply beyond the capacity of most interventional studies; therefore, drawing conclusions from evaluations that use traditional methods of inference is problematic when the event is very rare.

Methodological challenges should not mean that empirical evidence for the success of the interventions is not urgently needed. Process measures are only useful if the process is linked to meaningful outcomes.[193] The existing literature is saturated with publications suggesting, but not evaluating, approaches that are intended to prevent wrong site surgery, retained surgical items, and surgical fires. Whether the ideas work in practice and are sufficient in preventing sentinel events remains to be shown. Researcher and practitioners may need to consider other methods of evaluation. Examples are the use of adherence to those process measures that have been identified in a root cause analysis as causal or significantly contributing to events in the target organization. In addition, the more frequent "near miss" outcome could be utilized to identify organizational shortcomings and to evaluate interventions.[194] Furthermore, the use of run charts or statistical process control may be needed to evaluate the effectiveness of interventions to reduce these rare events. Only one of the included studies reported time to event data.[158]

LIMITATIONS

The prevalence data show that all three events are rare. However, the true incidence frequency is not known; this review is limited to the number of reported incidents. The reporting is likely to be influenced by medico-legal considerations which would aim to minimize incidents, while a documented increase in incidents after the implementation of the Universal Protocol has been attributed to an increased awareness.[180,195] A further complication is that reporting standards vary widely by institution and are changing over time. We have addressed this issue by including different measures of prevalence including anonymous self reports from surgeons. All methods have inherent advantages and disadvantages. While the self reports should be a better estimate of the true effect given that they are independent from medico-legal considerations, they nonetheless measure recall of incidents, not incidents directly.

We have limited the review to guidelines meeting the criteria of the National Guideline Clearinghouse. This has excluded many tools that are not guidelines as defined for the evidence review but nonetheless are intended to provide guidance to clinicians. Additionally, the quality of the development of the guidelines was variable. Also, the topics and specialties covered were

different for each guideline, which made comparisons across guidelines less relevant. In order to advance evidence-based guidelines, new as well as currently published guidelines should follow criteria outlined by the Institute of Medicine.

This report is a summary of the evidence and we have to conclude that the evidence base for the prevention of wrong site surgery, retained surgical items, and surgical fires is still very limited. Nonetheless, the existing literature includes many suggestions that may be tested empirically in future studies or that are suggested by common sense, such as interventions targeting the compliance to the Universal Protocol, the use of fire retardant surgical drapes, or protocols ensuring to let skin preps dry before the patient is draped or before allowing a heat source in proximity.[196-205] On the other hand, we have stretched the definition of evidence to include post-only studies given the paucity of the research. A recent Cochrane review on interventions to prevent wrong site surgery and other invasive procedures included only one study (Mahar et al., 2011[206]).

RECOMMENDATIONS FOR FUTURE RESEARCH

Our evidence report concentrated on the published scientific literature and many of the prevalence estimates involved data cleaning procedures, checking for misclassifications, applying consistent defintions, and establishing how to deal with missing data.[181] However, several states have now introduced mandatory reporting of wrong site surgery, retained surgical items, and surgical fires.[207-209] A comprehensive review of the regularly published state records would provide a valuable addition to the existing evidence base.

More data are accumulating on a large number of root cause analyses of sentinel events by the Joint Commission accredited hospitals, submitted voluntarily or by the complaint process. This critical information can be used to advance the prevention of wrong site surgery, retained surgical items, and surgical fires. Studies should employ multivariate analyses analyzing multiple, competing potential causes.

Existing prevalence estimates and root cause analyses results vary considerably, factors influencing the variability should be investigated in future analyses. The VA, with its centralized organizational structure, sophisticated electronic health record and databases, and culture of reporting is in an ideal position to address open questions.

Each reviewed content area identified numerous promising practices that have either not been empirically tested in their effectiveness to reduce the outcomes of wrong site surgery, retained surgical items, or surgical fires in practice or studies reported on intermediate outcomes or process measures, such as compliance or acceptance, and were therefore not considered for this evidence review.[173,185,210-257] In addition, the existing identified literature is not well suited to draw confident conclusions from reported evaluations, and more empirical evaluations reporting incidents and a denominator such as the number of performed procedures are needed.

However, future studies should not rely on standard statistical tests and evaluations formats given that changes in the frequency in a rare event are investigated. Studies evaluating the adherence to process measures identified in institutional root cause analyses, tracking the more frequent “near misses”, or using run charts and statistical process control would advance the evidence base

to determine which interventions can successfully reduce the frequency of wrong site surgery, retained surgical items, and surgical fires.

CONCLUSIONS

- Wrong site surgery, retained surgical items, and surgical fires are rare events, although estimates of just how rare are imprecise. A rough estimate of incidence is 0.09 for wrong site surgery events and 1.43 for retained surgical items. The goal of these "never events" is zero.
- Root cause analyses have demonstrated a variety of individual causes, however, the most commonly identified factor for all three "never events" was communication between staff members.
- National Guideline Clearinghouse-registered guidelines for preventing wrong site surgery, retained surgical items, or fires are surprisingly few, focused on highly specific applications, and of uneven methodology quality. This paucity of guidelines may be because the Universal Protocol is considered to be "the" guideline.
- Conclusive evaluations of interventions to reduce the incidence of wrong site surgery, retained surgical items, or surgical fires are relatively few in number and present a number of challenges in design and interpretation. The most challenging is the limit of inferential statistics. Some studies report reductions in events of 20 to 35% but these are not statistically significant. If an event occurs once in 20,000 occurrences, to have sufficient power to detect a reduction to once in 30,000 occurrences would require a sample of 5,000,000 observations. This is simply beyond the capacity of most interventional studies, therefore drawing conclusions from evaluations that use traditional methods of inference is problematic when the event is very rare. Other methods of empirical evaluation, such as the use of adherence to process measures identified by institutional root cause analysis, and the use of run charts or statistical process control, may be needed to evaluate the effectiveness of interventions to reduce these rare events.

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