



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

September 2013

Prepared for:

Department of Veterans Affairs
Veterans Health Administration
Quality Enhancement Research Initiative
Health Services Research & Development Service
Washington, DC 20420

Prepared by:

Evidence-based Synthesis Program (ESP) Center
West Los Angeles VA Medical Center
Los Angeles, CA
Paul G. Shekelle, M.D., Ph.D., Director

Investigators:

Principal Investigators:

Susanne Hempel, Ph.D.
Paul G. Shekelle, M.D., Ph.D.

Co-Investigators:

Melinda Maggard Gibbons, M.D., M.S.H.S.
David Nguyen, M.D.
Aaron J. Dawes, M.D.

Research Associates:

Isomi M. Miake-Lye, B.A.
Jessica M. Beroes, B.S.
Roberta Shanman, M.S.



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.

Recommended citation: Hempel S, Maggard MA, Nguyen D, Dawes AJ, Miake-Lye IM, Beroes JM, Shanman R, Shekelle PG. Prevention of Wrong Site Surgery, Retained Surgical Items, and Surgical Fires: A Systematic Review. VA-ESP Project #05-226; 2013

This report is based on research conducted by the Evidence-based Synthesis Program (ESP) Center located at the West Los Angeles VA Medical Center, Los Angeles, CA funded by the Department of Veterans Affairs, Veterans Health Administration, Office of Research and Development, Quality Enhancement Research Initiative. The findings and conclusions in this document are those of the author(s) who are responsible for its contents; the findings and conclusions do not necessarily represent the views of the Department of Veterans Affairs or the United States government. Therefore, no statement in this article should be construed as an official position of the Department of Veterans Affairs. No investigators have any affiliations or financial involvement (e.g., employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties) that conflict with material presented in the report.

EXECUTIVE SUMMARY

BACKGROUND

The VA National Center for Patient Safety has requested an evidence review to examine the prevalence 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 were of special interest. The evidence synthesis will be used to develop a standardized, single, strong recommendation to VA facilities in the effort to eliminate these events.

The 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?

METHODS

We have performed a systematic review of the literature to estimate the prevalence in US settings (Key Question 1) and the root causes (Key Question 2) of wrong site surgery, retained surgical items, and surgical fires. We have identified guidelines (Key Question 3) in use to prevent wrong site surgery, retained surgical items, and surgical fires and studies evaluating interventions aiming to prevent these events (Key Question 4).

Inclusion criteria were as follows: Publications addressing patients undergoing surgery and staff involved in surgical procedures were eligible for inclusion in the review. Interventions and guidelines aiming to prevent wrong site surgery, retained surgical items, and surgical fires were included. Prevalence data studies (Key Question 1), empirical root cause analyses (Key Question 2), guidelines registered with the National Guideline Clearinghouse (Key Question 3), and controlled and uncontrolled intervention evaluations (Key Question 4) were included. Primary outcomes were the incidence and the prevalence of wrong site surgery, retained surgical items, and surgical fires as well as the incidence of “near misses” (close calls), together with a denominator for the individual or composite outcomes of interest; identified root causes and risk factors; and the evidence base of guidelines. Studies in clinical settings published since 2004 were eligible, prevalence data were restricted to US settings, and root cause analyses were limited to settings applicable to VA facilities.

We searched the databases PubMed, CINAHL, CENTRAL, Web of Science, SCOPUS, and IEEE Xplore in February 2013 to identify individual studies and reviews. In addition, we scanned the references of included studies, searched the Cochrane Effective Practice and Organisation of Care (EPOC) Group Specialised Register, PubMed Health, the National Guideline Clearinghouse registry, and consulted experts for pertinent literature.

Inclusion screening was performed by two independent reviewers to reduce reviewer errors and bias. The data extraction was performed by one reviewer and checked by a second reviewer using a pilot tested and standardized data extraction form. Guidelines were assessed for quality using AGREE II criteria performed by two independent reviewers. Strength of evidence ratings were drafted by one reviewer and finalized with the review team. Discrepancies were resolved through discussion in the review team.

The PROSPERO registration number is CRD42013004524.

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. We performed subgroup analyses for evidence from VA settings where possible.

Prevalence, root cause analyses, and intervention studies were grouped by event (wrong site surgery, retained surgical items, surgical fires). Prevalence estimates were transposed to events per 10,000 performed surgical procedures to allow comparisons across studies. 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. The strength of evidence of the conclusions regarding the interventions was assessed using the GRADE classification system.

PEER REVIEW

A draft version of this report was reviewed by technical experts, as well as clinical leadership. Reviewer comments were addressed and our responses were incorporated in the final report.

RESULTS

The search identified 5,002 publications. Of these, 4,868 were identified in electronic databases. We obtained 1,039 publications as full text. In total, 125 empirical studies and four guidelines were included in the review. Some studies reported on more than one event (i.e., wrong site surgery, retained surgical item, or fire) or more than one review question (i.e., prevalence, root causes, intervention evaluation).

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

We identified 28 studies reporting prevalence estimates for wrong site surgery, 20 studies reported on retained surgical items, and 3 on surgical fires.

Definitions of events and procedure scope varied in the identified prevalence studies. 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 operations 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.

Definitions of events and procedure scope varied in the identified prevalence studies. 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.

We did not identify any per-procedure estimate of the prevalence of surgical fires. 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.

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

We identified 23 root cause analyses for wrong site surgery, 18 studies reported on retained surgical items, and 15 on surgical fires.

The 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. from right-left confusion when interpreting imaging results. A number of studies reported that not following policies; 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 events.

Given the prevalence, we only identified a limited 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 makes it impossible 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.

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

We identified four guidelines included in the National Guideline Clearinghouse registry. 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.

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 review identified 70 evaluations of diverse intervention approaches aiming to prevent wrong site surgery, retained surgical items, and surgical fires.

Apart from global Universal Protocol evaluations, the level of evidence was very low. Interventions lacked validation from replications and most studies had insufficient or no comparators, sample sizes were inadequate, and followup periods were typically short.

Although many publications in the existing literature refer to the need for better communication, we identified very few empirical evaluations of communication-focused interventions. In recent years authors have frequently urged the use of technology such as radiofrequency identification tags to prevent the retention of surgical items. One study found a statistically significant reduction in event frequency with a data-matrix-coded sponge counting system. Cost-effectiveness considerations need to consider the cost of the devices as well as the medico-legal costs of potentially prevented consequences of incident. The review identified only few empirical intervention evaluations aiming to prevent surgical fires and only one study evaluated the approach in more than 200 procedures.

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.

FUTURE RESEARCH

This evidence report concentrated on the published scientific literature and many of the prevalence estimates involved data cleaning procedures and applying consistent definitions. However, several states have now introduced mandatory reporting of wrong site surgery, retained surgical items, and surgical fires and a comprehensive review of the regularly published state records would provide a valuable addition to the existing evidence base.

As more data are collected, analyses of a large number of root cause analyses for Joint Commission accredited hospitals are available which should 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 wrong site surgery, retained surgical items, or surgical fires in practice or the publications reported on intermediate outcomes. In addition, the existing literature is not well suited to draw confident conclusions from reported evaluations.

Future studies should not rely on standard statistical tests and evaluations formats given that changes in the frequency in a rare event are investigated. Other methods of empirical evaluation, such as the use of adherence to process measures identified in institutional root cause analyses, use of near miss data, and the use of run charts or 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.