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Applying Fault Tree Analysis to the Prevention of Wrong Site Surgery

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Abstract

Wrong Site Surgery (WSS) is a rare event that occurs to hundreds of patients each year. Despite national implementation of the Universal Protocol over the past decade, development of effective interventions remains a challenge. We performed a systematic review of the literature reporting root causes of WSS, and used the results to perform a fault tree analysis in order to assess the reliability of the system in preventing (WSS) and identify high-priority targets for interventions aimed at reducing WSS. Process components where a single error could result in WSS were labeled with OR gates; process aspects reinforced by verification were labeled with AND gates. The overall redundancy of the system was evaluated based on prevalence of AND gates and OR gates. In total, 37 studies described risk factors for Wrong Site Surgery. The fault tree contains 35 faults, the majority of which fall into five main categories. Despite the Universal Protocol mandating patient verification, surgical site signing and a brief timeout, a large proportion of the process relies on human transcription and verification. Fault Tree Analysis provides a standardized

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Author Contributions:
Zachary Abecassis – Primary Author, responsible for compiling the research and composing the original draft of the manuscript.
Lisa McElroy – Responsible for revising major sections of the manuscript. Provided several sources that are included in the discussion. Helped structure the overall study. Critically reviewed manuscript.
Ronak Patel – Responsible for much of the prelimary review of the literature and was imperative in constructing the list of potential errors along with causes. Critically reviewed manuscript.
Rebeca Khorzad – Subject matter expert for the fault tree analysis used in the paper. Assisted with our analysis. Critically reviewed manuscript.
Charles Carroll – Subject matter expert for clinical pre-operative process. Assisted in developing process and critically reviewed errors and process. Critically reviewed manuscript.
Sanjay Mehrotra – Subject matter expert in healthcare systems engineering. Critically reviewed the methods of the paper. Assisted with the selection of the use of fault tree analysis. Critically reviewed manuscript.

perspective of errors or faults within the system of surgical scheduling and site confirmation. It can be adapted by institutions or specialties to lead to more targeted interventions to increase redundancy and reliability within the preoperative process.

Keywords

Medical Errors; Wrong Site Surgery; Fault Tree Analysis; Scheduling; Preoperative Process; Probabilistic Risk Assessment

1. Introduction

Wrong Site Surgery (WSS) is defined as any surgery involving the wrong person, organ, limb, side, or vertebral level; and can be extended to inappropriate anesthetic, dermatological, obstetric and dental procedures as well as emergent procedures occurring outside of the operating room(1). Tragically, several hundred surgical patients undergo WSS each year(2). WSS not only negatively impacts the patient, but the clinicall staff and institution as well. The Joint Commission considers WSS a sentinel event, which is defined as “an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof, including any process variation for which a recurrence would carry a significant chance of a serious adverse event”. In 2003, the Joint Commission invited members from 23 organizations, including the American College of Surgeons and the American Academy of Orthopedic Surgeons, to participate in the development of a protocol to eliminate WSS. Referred to as The Universal Protocol, it is composed of three components: i) preoperative verification process, ii) marking the operative site, and iii) “Time Out” immediately before the procedure begins(3). While the protocol was implemented nationally in 2003, the prevalence of WSS is still high in general surgery, as well as many of the surgical specialties, including orthopedics, neurological surgery, and otolaryngology. As a result, wrong site surgery has remained a Joint Commission National Patient Safety Goal for several years, including 2014(2, 4–7).

Because WSS is a rare event, it is very difficult to evaluate measures to reduce WSS with single-center or even multi-center studies. A system-level analysis of the process for scheduling a patient for an operation and confirming the correct patient site and procedure does not currently exist in the literature.

The objective of this study was to perform a fault tree analysis of operative scheduling and verification to assess the reliability of the system in preventing WSS and identify high-priority targets for interventions aimed at reducing WSS.

2. Material and Methods

A fault is defined as an undesired state usually caused by error. Fault Tree Analysis (FTA) is a tool for understanding how individual faults contribute to an undesirable event (8, 9). The identified faults are arranged in a hierarchy to demonstrate their interaction and identify areas of vulnerability. In an effort to further understand various healthcare processes, researchers have used FTA along with other PRA methodology tools to evaluate a range of medical errors and adverse events (10–12).

In order to assemble the fault tree, we performed a review of the literature to identify articles reporting the occurrence of WSS. A PubMed search was conducted using the term “Wrong Site Surgery.” Figure 1 displays the results from our search. The initial search returned 278 articles. After limiting the search results to studies published in English, 256 articles remained. We then scanned the titles and abstracts for relevance, resulting in a selection of 55 articles for full text review. Studies reporting circumstances surrounding actual instances or near misses of wrong site surgery were selected for inclusion. After full text review, 37 studies were included in the final analysis and used to create a fault tree. Bibliographies of any relevant publications were reviewed to verify the completeness of the search. The search and initial exclusion were performed by a two independent reviewers (ZAA, LMM).

Faults were identified based on description of circumstances leading up to the occurrence of a WSS within studies included in the review. The preliminary faults were refined and organized based by a multi-disciplinary team including an industrial engineers (ZA, SM) and both junior (RP) and senior (CC) surgeons. A preliminary fault tree was then created and connection (AND/OR) gates were assigned. The fault tree was then vetted by an additional surgeon and industrial engineer (LM, RK) trained in Fault Tree Analysis methodology.

WSS was identified as the final undesirable event in the hierarchy. Intermediate faults were defined as mid-process faults, each a result of additional causes. Basic events were defined as faults that had no additional known reasons for occurrence. Table 1 gives definitions for all relevant terms. Faults were connected with one of two “gates” which were used to organize the errors:

1. AND gates imply that all connected faults would need to occur to result in the error above
2. OR gates imply a single listed fault could result in the above error

We defined redundancy as any process that has the same function as another part that exists so that the entire system will not fail if that part of the process fails. Redundancy within a system is measured by the relative dominance of AND gates. The more AND gates in a given system, the more errors or omissions that could theoretically occur without the system failing.(13, 14)

3. Results

The fault tree and process flow map are shown in Figure 2 and Figure 3. The fault tree includes 35 faults, 25 of which are basic events. Intermediate faults are connected by 11 OR gates and 4 AND gates. The analysis revealed 5 key intermediate faults that together included the vast majority of basic events noted in the literature: OR scheduling, patient confirmation on the day of surgery, site marking, time-out process, and intraoperative imaging and patient confirmation. Of these, 3 are connected by an AND gate, and 2 stand alone, implying more redundancy in the day of surgery, less redundancy in days leading up to surgery.

3.1 Operating Room Scheduling

Nine studies investigated how operating room scheduling and medical records documentation lead to WSS (7, 15–22). Data entry errors and omissions resulted in an incorrect or incomplete entry for the operating room scheduling staff(7, 15, 18, 21, 22). Data entry errors and errors in the consent form or medical record were identified as root causes for these errors/omissions(16, 17, 22). A common point redundancy was identified where corrections were made to the operating room schedule prior to the evening of surgery by the clinic's staff(15, 22).

3.2 Patient Confirmation on the Day of Surgery

Errors or omissions in verifying the procedure with the patient on the day of surgery were identified as causes for WSS by 12 studies (4, 17, 23–32). Seven studies highlighted a failure to confirm either the patient identity or procedure with the patient (17, 23–25, 28, 29, 31). Failure of patients to correctly confirm the correct anatomic site for their procedure was identified in 5 studies along with various reasons such as inconsistent nomenclature or counting method along with anxiety and forgetfulness(4, 26–28, 32).

3.3 Site Marking

Thirteen studies identified the surgical site signing process as the point of failure. Errors included failure to sign the surgical site, ambiguous markings, markings being washed off or rubbed onto another part of the body, covering the mark while prepping the patient, and the patient confirming the wrong site(4, 17, 24–26, 30, 31, 33–38).

3.4 Time-Out Process

An additional 10 studies identified instances where the time out was either inadequately performed or omitted. Cited issues included clinical staff members failing to speak up during the time out, not identifying a patient beyond their name, surgeon absence during the time out, failing to relay vital information in cases of intraoperative surgeon turnover, not performing a second time out after disruptions in the operating room, failing t–o use patient records, and using inaccurate patient records during the time out(15, 17–19, 24–26, 39–42).

3.5 Intraoperative Imaging and Clinical Verification

Intraoperative faults occurring subsequent to the time out were noted in 11 studies. These errors, which involve the intraoperative verification of the surgical patients by the surgeon after the timeout before the first incision, included faulty counting methods due to abnormal spinal anatomy, failure to use intraoperative images during the procedure, inverting the intraoperative images, and misinterpreting cloudy images without consulting radiology(18, 25, 34, 39, 43–49).

4. Discussion

Wrong Site Surgery (WSS) is a catastrophic event that still occurs at an unacceptably high rate in the United States, despite national implementation of the Universal Protocol in 2003. WSS, like many sentinel events, occurs as a result of a cascade of seemingly harmless errors, or faults(50). A popular metaphor is *the Swiss Cheese Model* developed by James Reason, which states that in a complex system, a catastrophe is typically prevented by a series of barriers, each with its own respective weakness (51). This phenomena has been observed in several areas within healthcare(52). We performed a literature-based fault tree analysis of the individual errors within the process of operative scheduling and clinical verification that can ultimately lead to WSS. While WSS is a rare event overall, many of the faults leading up to WSS occur frequently. Therefore, targeting individual faults that are the most probable can theoretically lead to a system less susceptible to WSS. Efforts to standardize processes of care and eliminate opportunities for human error to go unmitigated have been most effective in preventing sentinel events similar to WSS(53). These efforts reduce the likelihood of error by creating *reliability* within the system. By creating additional processes that serve a similar function as other pieces of the process, more errors or omissions can occur without the system failing and a WSS occurring.

Our analysis identified three main areas of vulnerability: 1) transcription errors in documents prior to the day of surgery, 2) failure of intraoperative verifications, and 3) omitting steps in the day of surgery verification. Though the majority of errors were identified on the day of surgery (17/35 faults) these processes were supported by robust verification processes, corresponding with the various requirements of the Universal Protocol. In contrast, those errors that occurred prior to the day of surgery had far less verification requirements, creating the potential for an initial error to propagate through the system leading up to the day of surgery. This is confirmed by the current literature that describes how outpatient medical record errors have contributed to confusion on the day of surgery, ultimately resulting in WSS(24, 54). Unfortunately, many hospitals rely heavily upon manual transcription of patient information for operating room scheduling, typically due to a lack of standardization in the necessary forms(6, 17, 55).

The Joint Commission, along with 23 other national organizations, has been working for over a decade to standardize and implement guidelines for pre-operative measures to prevent WSS (3, 56). These guidelines, known as "The Universal Protocol", address many issues that contribute to the occurrence of WSS, but important work remains. Human error – whether from forgetfulness, distraction, or interruption – can have disastrous effects on any system lacking sufficient redundancy (53, 57, 58). At a minimum, adherence to a pre-surgical checklist along with the time-out has shown to reduce morbidity and mortality by up to 50 percent(59). Though effective when performed correctly, the compliance rate for the Universal Protocol has been recorded as low as 70 percent(60). Reasons for non-adherence are multifactorial. Surgeons frequently cite their intimate knowledge of their cases when omitting certain steps on the checklist, particularly site-marking(61, 62). One study that investigated site marking found that even when surgeons attempt to follow the Universal Protocol, they incorrectly perform steps such as signing the site of incision in a location that was out of view to the surgical team(63). By using a fault tree to view the system as a whole, we can now plainly identify both areas to target for improvement, as well as those where progress has been made.

While there is a common misconception that WSS occurs because of high case volume, the fact is that an adverse event is more likely to occur when there is a lack of reliability in a system (64). Surgical scheduling is a tightly coupled system, where there is a high degree of dependence among components (e.g. schedulers, procedure staff, and equipment). Conversely, hospitals are loosely coupled systems, where tasks are separated by extensive physical distance and time(65). Interventions aimed at eliminating WSS should take these conflicting designs into consideration and, at least in part, incorporate standardized scheduling and verification forms along with a well-defined protocol for managing and documenting any discrepancies(66, 67). In addition, automated population of preoperative documentation will help to ensure that manual transcription errors do not occur. Much research in this area has already been done, but dissemination of results is limited by inconsistent terminology within and between hospitals(68).

The use of CPT® Codes in scheduling may offer a way of allowing for consistent terminology in the process of surgical scheduling. This can be combined with correct side and site information to add further redundancy to the process, allowing for a more precise scheduling and further decrease in errors and the likelihood of WSS. This process is currently being implemented in our institution.

This study has several limitations that warrant discussion. WSS is a rare event and consequently, the quantitative studies on the specific causes fluctuate in quality. Therefore, some of the root causes may be excluded from the study. Finally, there are no connections to patient outcomes as the fault tree has not been populated with any probabilities.

5. Conclusion

In conclusion, Fault Tree Analysis (FTA) is a valuable tool for understanding the interaction of errors or faults within a system(9). Our analysis revealed that although progress has been made in reducing WSS, continued efforts are needed to increase the reliability of the system. WSS occurs as a result of a cascade of errors, many of which occur outside of the OR(69). Standardizing processes such as OR schedule data entry and verification, and implementing quality assurance measures aimed at increasing adherence to the Universal Protocol, can help minimize the risk of WSS. However, creation of the fault tree is only the first step in a fault tree analysis. Now that a comprehensive fault tree has been developed, individual institutions or surgical sub-specialties can adapt the tree to specific settings and circumstances. This may involve modifications to the tree structure in centers where special protocols have been developed. Beyond qualitative analysis, each fault within the tree can be with center or specialty-specific data to calculate which combination of faults are most likely to lead to WSS.

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Highlights

- Performed a systematic review of literature reporting on root causes of Wrong Site Surgery
- Used Fault Tree Analysis to organize the collected errors and assess the reliability of the system
- Evaluated overall redundancy of preoperative process and located key areas for improvement in the days prior to surgery

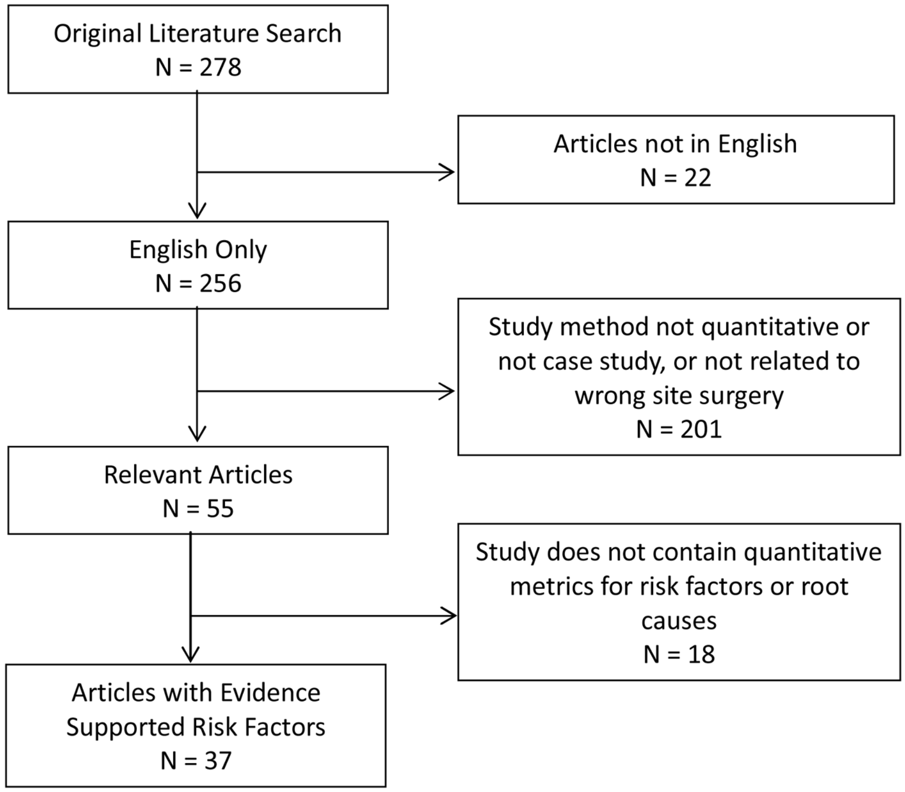

Figure 1.
Search Strategy
Literature review search strategy.

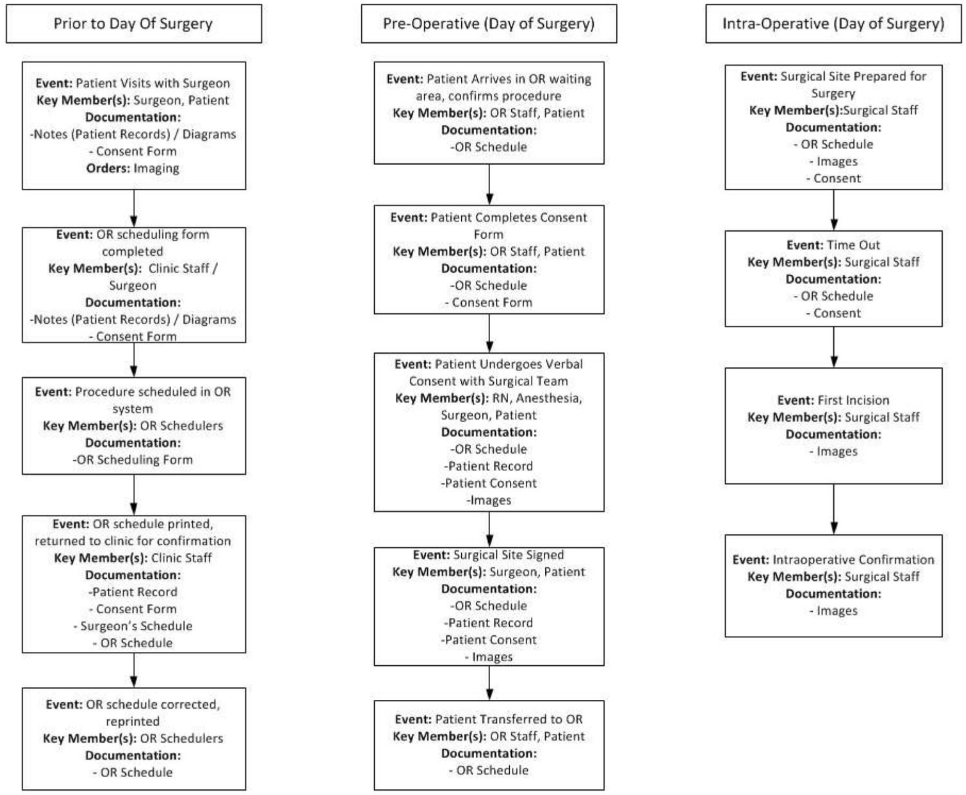

Figure 2.

Process Flow Map

Process map of work flows for preoperative scheduling and verification activities performed prior to the day of surgery, on the day of surgery prior to the operation and on the day of surgery in the operating room.

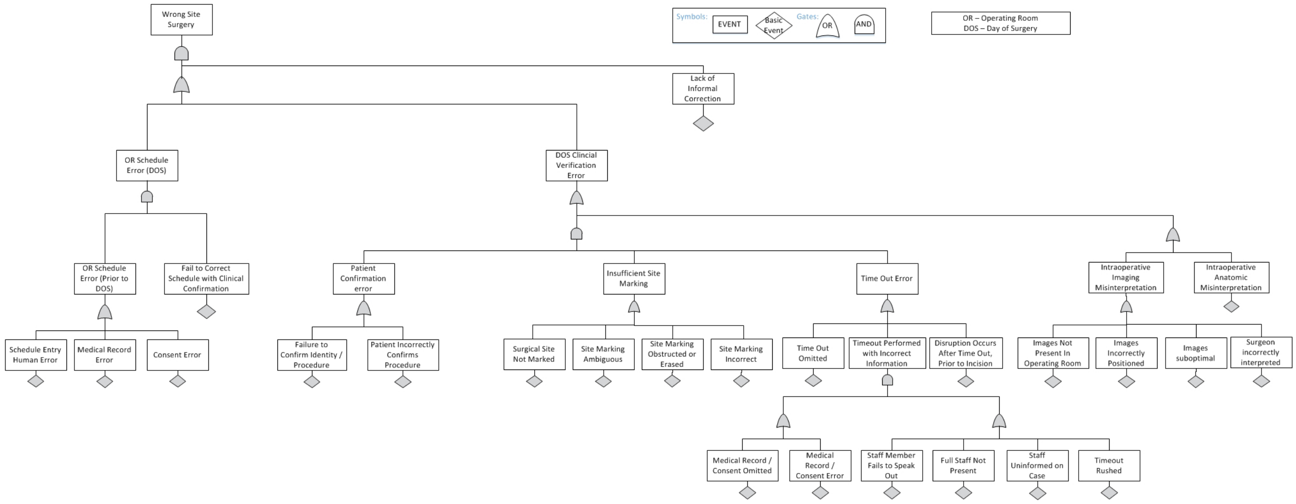

Figure 3.

Fault Tree Diagram

Fault Tree Diagram of Wrong Site Surgery

Table 1

Definitions of Relevant Terms

Term	Symbol	Definition
Fault		An abnormal undesirable system element induced by a failure
Gate		A connector used to link lower events that are related to an above event (e.g. a gate would connect oversleeping with lower events such as forgetting to set an alarm or setting an alarm too quietly)
OR Gate		Either bottom event results in the occurrence of the above event
AND Gate		In order for the above event to occur, both lower events must occur
Basic Event		A lower most event that cannot be further developed
Top Event		The target undesired event (e.g. Wrong Site Surgery Occurs)
Intermediate Event (Sub Fault)		The result of a logical combination of lower level events (e.g. X event and Y event occur and result in Z intermediate event)
Redundancy		Redundancy within a system is measured by the relative dominance of AND gates. The more AND gates in a given system, the more errors or omissions that could theoretically occur without the system failing.