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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 to assess the reliability of the system in preventing WSS and identifying 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 WSS. The fault tree contains 35 faults, most of which fall into five main categories. Despite the Universal Protocol mandating patient verification, surgical site signing, and a brief time-out, a large proportion of the process relies on human transcription and verification. Fault tree analysis provides a standardized 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.

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 clinical 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

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WSS. Referred to as the Universal Protocol, it is composed of three components as follows: (i) preoperative verification process, (ii) marking the operative site, and (iii) "time-out" immediately before the procedure begins [3]. Although 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, neurologic surgery, and otolaryngology. As a result, WSS 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 multicenter studies. A system-level analysis of the process for scheduling a patient for an operation and confirming the correct patient site and procedure doe not currently exist in the literature.

The objective of this study was to perform a fault tree analysis (FTA) of operative scheduling and verification to assess the reliability of the system in preventing WSS and identifying 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. 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 health-care processes, researchers have used FTA along with other probabilistic risk assessment methodology tools to evaluate a range of medical errors and adverse events [10–12].

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 "WSS." 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 WSS 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 two independent reviewers (Z.A.A. and L.M.M.).

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 multidisciplinary team including industrial engineers (Z.A.A. and S.M.) and both junior (R.M.P.) and senior (C.C.) 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 engineers (L.M.M. and R.K.) trained in FTA 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 gives definitions for all relevant terms. Faults were connected with one of the two "gates", which were used to organize the errors as follows:

1. AND gates imply that all connected faults would need to occur to result in the error mentioned previously
2. OR gates imply a single-listed fault that could result in the previously mentioned 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 Figures 2 and 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 five 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, intraoperative imaging, and patient confirmation. Of these, three are connected by an AND gate and two stand alone, implying more redundancy in the day of surgery and 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 and/or omissions [16,17,22]. A common point redundancy was identified where corrections were made to the operating room schedule before the evening of the 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 five studies along with various reasons such as inconsistent nomenclature or counting method along with anxiety and forgetfulness [4,26–28,32].