Wrong-Site Surgery: A Preventable Medical Error

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Abstract

Surgical procedures are common procedures that lead to quality improvements health in outcome despite the fact that surgery is a high-risk business. It is imperative to know that patient safety generates great concern for health care professionals. As a result, Wrong-site surgery (WSS) is a patient safety issue and when it happens it can be devastating for both the patient and surgeon(s). Wrong-site Surgery can be prevented if appropriate and adequate measures are implemented to ensure the correct site of surgery and patient’s safety. In this article, the authors examined increase in rate of WSSs, the causes and factors responsible for WSS, recommendations to prevent the episode of wrong site or wrong patient surgery, and past procedures of interventions.

Keywords: Wrong-site Surgery, medical errors

Introduction

Surgical procedures are common procedures that typically result in sizeable improvements to health outcomes. However, surgery is a high-risk industry. Patient safety is and has always been a great concern of health care professionals. Since the publication of the Institute of Medicine report in 1999, “To Err Is Human”, the issue of patient safety has gained importance in the press and has become a political issue and also gained the attention of patient advocates (Meakins, 2003). Wrong-site surgery (WSS) is a patient safety issue that can be devastating for both the patient and surgeon(s). Wrong-site Surgery is a preventable medical error if intervention systems are implemented to ensure the correct patient, site, and side of surgery. In this article, the authors examined the prevalence of WSSs, the causes and factors contributing to WSS, recommendations to prevent the occurrence of wrong site or wrong patient surgery, and procedures tried as interventions.

Definition

Wrong-site surgery is defined as surgery performed on the wrong site or side of the body, wrong surgical procedure, and wrong patient. The definition includes “any invasive procedure
that exposes patients to more than minimal risk, including procedures performed in settings other
than the operating room, such as special procedures unit, an endoscopy unit, and an
interventional radiology unit” (Mulloy & Hughes, 2008, p. 381). The Joint Commission also
defines WSS as a sentinel event, which may be an unexpected incidence involving death, serious
physical or psychological injuries, or the risk thereof (Mulloy & Hughes, 2008). According to
the National Reporting and Learning Service (NRLS), WSS is classified as any event in which
surgery is performed on the wrong patient, or wrong side area, wrong side marked on theatre list,
and wrong side marked on consent form (Panesar et al., 2011).

Statistics
Wrong-site surgery used to be a rare occurrence, however, data show that it has continued
to increase steadily since 1995 and people are learning more about WSS prevalence. The Joint
Commission and the Pennsylvania Patient Safety Authority (PPSA) provide yearly updates on
the incidence of WSS. However, because the reporting of such events is voluntary, one may
never know the true extent of the problem (Herndon, 2011). Wrong-site surgery is considered to
be the third-highest-ranking event by the Joint Commission. According to Herndon, 2011, data
suggest that the number of WSS, wrong-procedure, or wrong-patient surgeries is not decreasing
despite the intervention of programs like “Sign-Your-Site” and the “Universal Protocol”. However, this observation may be found in orthopaedic surgeries as surgeons are resistant to signing the surgical site and often find excuses for not doing it (Herndon, 2011).

According to researchers, the Joint Commission’s numbers are low. The numbers are 1 out of 27,686 cases, or 1 out of every 112,994 surgeries, 1 in 5 hand surgeons throughout their
career, or 1 out of 4 orthopedic surgeons with 25 years of experience. While reporting an
incident of WSS is voluntary, the number of reported events has increased in recent years. The
number of reported WSSs increased from 15 cases in 1998, to 592 by June 30, 2007. When
broken down into specialty, the most common occurrence happens in orthopedic or podiatric
procedures, general surgery, neurosurgical and urological procedures. According to the PPSA’s
most recent report, in the last quarter of 2010, the most commonly reported events were wrong-
site anesthetic blocks, wrong-vertebral level, wrong-site hand surgery, wrong-eye surgery, and
wrong-side pain blocks, in that order (Herndon, 2011). Moreover, in 2006 the National Health
Service litigation Authority (NHSLA) revealed that trauma and orthopedics had the highest
number of claims (29.8%) when compared to the next specialty, dentistry (16.8%) (Panesar et al
2011).

In 2009, correct patient and correct site/side surgery was listed as the top priority in the
World Health Organization’s (WHO) 10 objectives for safe surgery. Wrong-site and wrong-
patient surgery was projected to occur in about one in 50,000 to 100,000 procedures in the
United States of America, an equivalent of 1500 to 2500 incidents each year (Chan et al., 2010).
According to a study of 126 cases of wrong-site or wrong-patient surgery in 2001, 76% of the
surgeries were carried out on the wrong-site, 13% on the wrong patient, and 11% involved the
wrong procedure. Moreover, a survey of 1050 hand surgeons revealed that 21% of surgeons had
performed wrong-site surgery at least once in their career (Chan et al., 2010).
Regardless of the prevalence of wrong-site surgery, WSS is a medical error that should not occur and is preventable if the causes are known and measures are taken to address the causes of WSSs.

Discussion

In order to prevent the occurrence of WSS, it is important to first identify and understand what the factors contribute to this medical error. Medical errors should be rare or non-occurring because they are preventable. They are not complications of medical care that may not be preventable in some situations. Take for instance, an infection that occurs after a surgery regardless of the necessary antibiotics before and after the procedure, and the use of proper surgical techniques (Herndon, 2011).

One of the factors associated with wrong-site surgery is non-technical skills (human factors). Humans working in complex systems like the high-risk industry of surgery will inevitably make mistakes. Health care professionals must learn from these mistakes and provide ways to improve performance and prevent these mistakes from re-occurring. Majority of the errors taking place during surgeries can be accredited to failures in non-technical skills like decision-making, situation awareness, communication, teamwork, and leadership (Panesar et al., 2011). Miscommunication from the time the procedure is scheduled can lead to a catastrophic mistake during the operation. While many errors are caught before they have the chance to cause harm to the patient, unless the organization systematically studies its processes and systems for weaknesses in its capacity to prevent errors from getting to patients, you are leaving a lot to chance. Therefore, one must pay attention to the system in order to identify where improvement is needed. However, the practices that are obvious in reducing the possibility of wrong-site surgery may not get the attention it deserves (Butcher, 2011).

There is evidence supporting a link between sleep deprivation/fatigue and medical/surgical errors (Herndon, 2011). While the evidence is overwhelming, surgeons still continue to argue and disagree with the data. According to experts, performing surgery after a sleepless night is equivalent to driving with a blood alcohol level of 0.1 percent, which is a level considered legally drunk in the US. Surgeons preforming elective surgery after sleeping less than 6 hours the night before had an 83% higher risk of serious complications (Herndon, 2011). Moreover, a previous study has also shown that error rates are doubled with sleep deprivation (Herndon, 2011). This information supports the argument that WSS is a preventable error because if the causes of the problem are known, taking measures to make sure that the errors do no occur can prevent WSS. If the causes are human errors, then it should be easier to interfere with the problem. Physicians who are aware that sleep deprivation is linked to medical errors have the power to make sure that they prevent the errors by acknowledging that they are at risk of making errors and taking steps to improve their performance and stopping WSS. Patient’s safety is after all the first priority. Authors believe physicians have the duty to provide the highest quality care to the patient that they are serving; they should do everything in their powers to make sure that they do not cause any harm. One of the recommendations is that institutions implement policies in order to avoid elective surgeries by fatigue surgeons and they should facilitate the rescheduling of these surgeries (Herndon, 2011). Another option is to train physicians to recognize the signs so they can address them. However, studies have shown that chronically sleep deprived individuals are not aware of their cognitive deficits (Herndon, 2011).
If surgeons do realize that there are too tired to perform a surgery, it is expected that they that
will speak up because not doing so would mean that they knowingly place the patient at risk.
This would be a violation of their oath to do no harm.

Wrong-site surgery is mostly caused by a lack of a formal system to confirm the surgery
site. A breakdown of a system that verifies the correct site is also one of the main causes (Mulloy
& Hughes, 2008). According to the Joint Commission, the chief root causes of WSS are
communication failure (70%), procedural noncompliance (64%), and leadership (46%) (Mulloy
& Hughes 2008). Among the system factors are lack of a checklist to make sure every check was
performed, exclusion of certain surgical team members, and relying completely on the surgeon to
determine the correct site. Some of the process factors include inadequate patient assessment,
inadequate care planning and medical record review, miscommunication among members of the
surgical team and the patient, and more than one surgeon involved in the procedure. Patients are
important tools for the prevention of WSS; they should be involved in the process and also have
the obligation to make sure that they verify the plan with the team. There is need to be
communication between the patient and team, as well as communication between the team
members. Having more than one surgeon may cause leadership problems because a more
experienced doctor may not want to take advice from a doctor with less experience. In addition,
the doctor or nurse may feel intimidated if they have to correct the doctor. This should not be the
case because the patient should come first, if an error is observed, the person has the obligation
to correct the staff and bring it to the attention of the surgeon. Errors caused by these types of
factors are preventable. Therefore, the prevalence of WSSs should not be high. It should be
something of a rare occurrence because we know what the issues are.

The risk factors associated with WSS are emergency cases, multiple procedures, multiple
surgeons, deformities, obesity, room changes, unusual equipment or set up, and time pressure
(Mulloy & Hughes, 2008). Surgeons should take their time during a surgery so they get the
procedure done correctly. Not doing so may place the patient at risk for complications, which
violates the physician’s oath to do no harm.

**Intervention**

While it seems to be clear how to prevent wrong site surgery, WSS is still a major
problem mainly because physicians have not listened to the data that shows the causes of WSS.
In order to prevent WSS from occurring, surgeons and other professionals need to accept the
scientific data and make the essential and appropriate changes to improve patient safety.
According to literature, there is limited research on WSS and limited empirical evidence on
preventing WSS. None of the studies available offered quantitative evaluations of strategies to
prevent WSS (Michaels et al., 2007, Mulloy & Hughes, 2008). The reason for that may be the
non-mandatory reporting of WSS. As a response to the increasing number WSS and years of
malpractice claims, In 1997, the American Academy of Orthopedic Surgeons (AAOS) developed
an awareness campaign designed to prevent WSSs; the campaign was called “Sign Your Site”
(Mulloy & Hughes, 2008).

According to surveys done at the time of the campaign, although 90% of AAOS members
were aware of the program, only 40 % essentially signed the site (AAOS Now, 2011). This
shows that providing people with the information is one step of the journey, getting them to
change their habits will be another step. In an attempt to address the continued acceleration of reported WSS cases and its impact on patients, families, and health care costs, the Joint Commission along with the AAOS, and leaders from other organizations organized a summit, which was designed to unite health care professionals to address and develop strategies to decrease or eradicate WSS. Ultimately, The Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery was established (Mulloy & Hughes, 2008). The aim of the protocol is to prevent WSS and it is to be used in all areas where invasive procedures are conducted in a health care facility, including non-operating-room settings. The three requirements by the protocol are: 1- preoperative verification process, 2- marking the operative site, and 3- taking a time out (Michaels et al., 2007, Mulloy & Hughes, 2008). Today, the Universal Protocol is obligatory for all surgeries (AAOS Now, 2011).

The AAOS derived its protocol from the Canadian orthopaedic Association (COA) and it had 3 key points: the first was to “review the operative procedure with the patient and operating room personnel before surgery”, second, “review the patient’s chart in the operating room before surgery”, third, “write your initials at the operative site-sign your site” (Meakins, 2003, p.86).

Preoperative Verification Process

The purpose of preoperative verification process is to make sure that all relevant information and studies are available before starting the procedure. They must be reviewed to ensure that there is consistency in both documents and if there are any discrepancies, they must be addressed before proceeding with the procedure (Mulloy & Hughes, 2008). This process is an ongoing process until the start of the procedure. This step is important because this is where errors in the record are most likely to be captured if there are any missing information or discrepancies between the chart and studies like radiology reports or other labs works. Staffs need to be vigilant and not rush through the process, or bypass it altogether. It is where patient’s identity will be verified and make sure that the record matches with the patient, including the correct procedure to be done.

Marking the Operative Site

The purpose of marking the site is to identify and mark the site where surgery will be done; it is the site of incision or insertion (Mulloy & Hughes, 2008). It is important that the marking resist the scrubbing during skin preparation and that the mark is visible after patient has been prepped and draped (Mulloy & Hughes, 2008). In addition, it is also recommended that the surgeon in charge do the site marking and it must be unmistakable by using the surgeon’s initials or the word “YES”; the letter “X” is considered ambiguous. Site marking is essential in preventing WSS. Therefore, it is important to use a skin marker that is able to resist the scrubbing during preparation. In order to test the hypothesis that some skin markers can survive skin preparation with a chlorhexidine-based skin preparation solution in a manner that is similar to that of an iodine-based solution, a test was conducted using 9 types of skin markers (Mears et al., 2009). The markings were subjected to a chlorhexidine-based and iodine-based solution to see if the markings remained intact or if they got erased. The result showed that no marker was significantly better than another. In all cases, the markings decreased significantly after they were subjected to the chlorhexidine-based skin preparation. In order to increase the effectiveness
of site marking in preventing WSS, there need to be a better skin marker or a chlorhexidine-based skin solution that does not erase site markings (Mears et al., 2009).

Some of the guidelines for marking the site include marking the site with a marker that is sufficiently permanent so that it can remain visible. The method of marking should be consistent throughout the organization (Mulloy & Hughes, 2008). Authors believe this is very important because it will decrease confusion, and it will ensure that WSS does not take place. If the method is used and recognized throughout hospitals then surgeons will not mistake a marking on a patient that is not the intended site. This requirement is likely to play a big role in decreasing the occurrence of WSS. Moreover, marking should be done while patient is still awake; the patient must also be involved if possible. This requirement also places the responsibility of getting it right on the patient.

**Time Out**

The purpose of time out is to do a final verification of the correct patient, procedure, and site. The process requires active communication among all members of the surgical team. The surgery must not start until all concerns, questions, or uncertainties are resolved. As noted earlier, lack of communication is one of the factors leading to WSS. Active communication by all members of the surgery team should prevent the occurrence of WSS, providing no other factors are at play.

**Interventions Tried**

Organizations have tried a number of ways to reduce the risk of wrong site surgery. In orthopaedics, surgical checklist is one of the initiatives that have been tried. Since surgery is considered a high-risk industry, tools invented in the aviation industry are being used in surgery in order to lower the risk of medical errors. The checklist is one of those tools that the World Health Organization began in 2007. The program was aimed at improving the safety of surgical care globally (Panesar et al., 2011). The checklist comprises of a core set of safety sets. The steps in the checklist have been shown to be associated with a reduced risk of death and major complications in a range of clinical settings. There are three phases in the checklist. The first is the “Sign-in”, which is done before administering the anesthesia. It mainly involves patient identification, consent, and site marking. The second is the “Time-out”, which occurs prior to the incision. Its purpose is to confirm the patient, site, and procedure. The last step is the “Sign-out” to confirm the procedure that was done, the instrument and swab counts, and the plans for post-operative management (Panesar et al., 2011). These steps are redundant; however, it’s believed that the process will improve reliability of the clinical processes and may reduce complications by 50%.

In order to estimate how many incidents of WSS in orthopaedics that were reported to the National Patient Safety Agency that could have been prevented by the checklist, the preventability of the cases were assessed (Panesar et al., 2011). Of the 316 incidents classified as WSS, detailed review revealed that WSS events occurred in 133/316 cases, the remaining 183 were excluded because they were misclassified. The result showed that the checklist could have prevented 28/133 patient safety incidents; that’s 21.1%. The checklist is found to be an extremely effective tool in preventing ‘near misses’ and ‘actual harm’ in surgeries. However, it is
of limited use in ensuring correct filling of the consent form and generation of operation room lists. Therefore, other tools like briefing and debriefing may help (Panesar et al., 2011).

Another study in Hong Kong looked into the process of designing a new surgical safety checklist to prevent wrong patient and wrong site/side surgery using ‘failure mode and effects analysis’ (FMEA), and to conduct a compliance audit on the use of the checklist (Chan et al., 2010). The process involved the identification of key steps in risks associated with a patient’s journey through elective surgery. The checklist process was re-designed and incorporated into a new safety checklist called ‘123-Surgical Safety-123’. Once the checklist was implemented, the compliance audit was done to evaluate the effectiveness of the checklist (Chan et al., 2010). The newly designed process was patient-centered and it involved a series of longitudinal steps of checkpoints from upstream (consenting process) to downstream (operating theatre) with repeated/redundant cross-checking at key steps.

There are three steps before arriving at the operating room and three other steps in the operating room. At each step, there was one person designated to check the correctness of the items on the checklist. The steps are: 1- Consenting process, which verify the patient’s name, diagnosis, procedure to be done, and site of operation. The surgeon in charge verifies these information and mark the site before signing the form. 2- Sending of patient to the theatre. A staff nurse will verify the correctness of all information, including the marking before taking the patient to operating room. 3- Theater reception. The theater nurse will verify the corresponding information. 4- Sign-in. the anaesthetist is responsible for checking and confirming the patient’s information. If under local anaesthesia, the surgeon in charge will do the checking. 5- Time-out (surgical pause), it is a mandatory final step to verify the patient’s identity, site, and procedure to be done. A read-aloud and cross-checking is done with all members of the surgical team present.

The surgeon in charge is responsible to lead the time-out. Lastly, marking is checked as a system redundancy. 6- Sign-out. At the end of surgery, a nurse initiates a final checking, debriefing regarding the procedure, specimen labeling, and other related issues (Chan et al., 2010). During the study period, a total of 322 patients were operated. The compliance audit was done on all checklists collected for these patients. The overall compliance was above 95%. The checklist became mandatory for all elective surgeries in Hong Kong hospitals. While the checklist had a great compliance rate, whether or not the checklist will improve the outcome of surgical patients remains unknown. Ongoing monitoring, audit of the usage of the checklist, and the effectiveness of the policy are suggested (Chan et al., 2010).

Conclusion
Wrong site surgery is a preventable medical error that may place the patient’s health at risk. The occurrence of WSS seems to be increasing. However, this may be due to the fact that reports of such incidents are increasing. There are limited research and evidence on prevention of WSS. While there are a number of measures organizations have taken to reduce the prevalence of WSS, one may not know exactly how effective they are if we don’t know for certain how big the problem is. Because reporting is voluntarily, it is hard to say if the Universal Protocol for Preventing Wrong-Site Surgery is making a major difference. The prevention of such events will not happen overnight, in order to eradicate WSS, all surgical staffs must acknowledge that the problem exists and that they play a role in its occurrence. Therefore, they also play a great role in
preventing it from happening. It will not get to zero WSS, but with recognition, knowledge, and the right tools, WSS is preventable. Making it mandatory to report WSS may also help in decreasing the prevalence because if surgeons and institutions know that they must report and may be face with high penalties, then they probably would put more efforts in making sure that they lower WSSs.

References