

How the Universal Protocol Impacts the Incidence of
Wrong-site Surgeries

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Fifty-three-year-old Regina Turner was scheduled for a left-sided craniotomy bypass, but instead she received a right-sided craniotomy surgical procedure (Wolff, 2013). Ms. Turner was the victim of a medical error, wrong-site surgery. Wrong-site surgery is described as performing wrong-side or -site surgery, on the wrong patient, or wrong surgical procedure. “Wrong-site surgery is defined as a sentinel event by the Joint Commission, which found it to be the third-highest ranking event” (Mulloy & Hughes, 2008). It is a medical error that can be prevented with implementation of standardized protocols and compliance among team members in the perioperative setting.

Prior to 2004, safety interventions were not sufficient to prevent wrong-site surgery, and that is when the Universal Protocol was implemented. The Universal Protocol is a policy for the entire team, including the patient, to adhere to throughout the surgical procedure.

The question we are examining is: *Does the mandatory implementation of the Universal Protocol in surgical patients decrease the incidence of wrong-site surgeries?*

Background & Significance

The devastating consequences suffered by Regina Turner were due to a lack of compliance with the Universal Protocol. “The Universal Protocol was created to prevent wrong person/procedure/site surgery in hospitals and outpatient settings. The Universal Protocol consists of the following three steps:

1. A pre-operative/pre-procedure verification process
2. Marking the operative/procedure site

3. A Time Out (final verification) that is performed immediately before starting the operation/procedure.” (Stanford Hospital and Clinics, 2006)

When a patient comes in for a surgical or invasive procedure, it is critical that he or she feels confident and secure in the facility’s commitment to patient safety and quality of care. A study by Nwosu (2015) examined the years 1990 to 2010; during that time 9,744 paid malpractice settlements for surgical medical errors in the United States amounted to \$1.3 billion. Of these cases, 6.6% resulted in mortality, 32.9% led to permanent injury and 59.2% resulted in temporary injury. The costs of these events to the healthcare system and the enormous harm that was caused commanded a change in the surgical protocols. Implementing the Universal Protocol standardizes the preoperative procedure, enhances the function of the healthcare team, and should avoid wrong-site surgery.

Synthesis of the Current Evidence

The Universal Protocol provides a standardized method to ensure proper patient care in the surgical setting. An article by Dillon (2008) describes the importance of the nurse’s role as a patient advocate, especially in a situation where the patient is under sedation. As a nurse, leading the time-out and ensuring that each team member plays their role in the time-out is a vital step in preventing wrong-site procedures. Dillon (2008) discusses various problems that can increase the risk of wrong-site surgeries, such as poor perioperative planning, lack of institutional controls, failure of the surgeon to exercise due care, lack of communication between the patient and the physician and incomplete patient assessment, all of which can be prevented with the time-out.

Compliance and procedure can be compared to before and after the implementation of the Universal Protocol. Johnston's (2009) study investigates the compliance of site-signing practices of emergency and non-emergency orthopedic procedures before and after the Universal Protocol. The study focused on site-signing practices before the time-out protocol was put into place; Johnston (2009) found that signing was conducted in 67% of emergency cases and 90% of elective cases. After implementation of the mandatory time-out protocol, signing was conducted on 61% of emergency cases and 83% of elective cases. Johnston's (2009) findings suggest that although the mandatory time out and surgical site-signing procedures were implemented, only 70% of cases were fully compliant. The study was a biphasic longitudinal study, which Johnston (2009) states was one of the study's strengths in that it provided for a closer look at the surgeon's practices and how that surgeon felt about the idea of adhering to a mandatory protocol. Although there is only partial compliance of the time-out procedure, the surgeons signed 23% of the patient's surgical site, which would not have been adhered to if it were not for the mandatory implementation of the protocol.

There has been an increased success rate of surgical safety since the Universal Protocol was put into effect. However, there are still numerous reports of wrong-site surgeries occurring each year. Ragusa, Bitterman, Auerbach and Healy's (2016) study aims to identify the barriers preventing this goal. These barriers included compliance of hospitals to the guidelines, perceptions of staff involved in the surgical procedures, and the effectiveness of the protocols implemented. The study (Ragusa et al., 2016) found that although there was an overall positive perception on following safety checklists, many staff members did not comply due to other

limiting factors, including time constraints, dismissive replies to checklist questions, and completion of the checklist without all staff members present.

In the opening scenario of Regina Turner, who was a victim of a wrong-site procedure, legal actions were taken against the hospital and the neurosurgeon. After reviewing medical records, Turner's attorney stated that the error took place because not all operative team members participated in the time-out and thus they were unable to catch the errors before they occurred. As per Turner's attorney, who has handled many wrong-site surgery cases and won an award for his work, some healthcare providers believe that they are highly experienced and do not need to take part in the Universal Protocol. With such legal actions taking place, the importance of the Universal Protocol is emphasized and provides the healthcare team with incentives for following the protocol.

According to Thakkar and Mears (2012), there is still room for improvement within the protocol. Their article discusses the potential for errors occurring even with the appropriate use of the Universal Protocol. The study focuses on the preoperative issue of surgical prep solution causing the removal of the surgical site marking. This article supports our research question as it shows that adherence to the Universal Protocol will decrease wrong-site surgery, but there are still processes that need to be perfected in order to remain compliant with the Universal Protocol, such as using a marker that will not fade during surgical prep.

All the articles we reviewed support our argument that the mandatory implementation of the Universal Protocol helps decrease the incidence of wrong-site surgery. Although there is mandatory implementation of the Universal Protocol, our research suggests that there is

decreased incidence of wrong-site surgery due to the policy, but poor adherence. The Universal Protocol is beneficial, and with adherence, wrong-site surgeries would be minimized or eliminated in the future.

Proposed Intervention

The Universal Protocol is composed of a three stage process: pre-procedure verification, marking the procedure site, and a time-out confirmation.

Pre-Procedure Verification

According to Ragusa and Colleagues (2016), patient safety can be facilitated by improving team communication. This is important because many clinical errors occur when there is a lack of communication between team members. Communication can be improved by listening to feedback of the surgical team members, making changes accordingly, and including the patient in their care. This involves patient identification, procedure verification, and proper patient documentation.

Marking Procedure Site

To improve this step of the protocol, the healthcare team can use a “wipe-proof” pen to mark the site. Making sure that the correct site is marked is an important component of the time-out procedure. Thakkar (2012) explained that when the surgical staff marks the site, some markings are erased due to the preparations used in disinfecting the site, including a chlorhexidine-and-iodine-based solution.

Time-Out Confirmation

As the patient’s advocate, the nurse should take the lead in the time-out procedure in the

operating room. The nurse can lead the surgical team and make sure that a time-out procedure is called. Additionally, the tools used to start the procedure could be out of reach of the surgical team until fulfillment of the Universal Protocol.

Additional Interventions

Monthly in-service meetings can be conducted to improve compliance with the Universal Protocol. Johnston (2009) showed that in emergent and nonemergent cases, the preoperative skin signing, and “time-out” protocol are not being practiced by team members in all surgical procedures. Educating the staff on the importance of minimizing the risks associated with not following the protocol increases the likelihood of adherence.

It would also be in the best interest of the hospital to create a new position of quality-assurance officer to monitor compliance with the Universal Protocol. Wolff’s article, “Surgeon operates on wrong side of brain -- time-out compliance is questioned,” (2013) is an example of legal actions that could occur due to noncompliance. Preventing legal issues becomes an incentive for the healthcare team to follow the Universal Protocol.

Plan for Implementation

The implementation for the proposed interventions for the Universal Protocol is as follows:

Pre-Procedure Verification

To successfully prevent clinical errors and improve communication among team members, it is vital to encourage everyone to speak up, including all team members and the patient. A “speak-up box” could be put outside the nurses station for individuals to anonymously

communicate their concerns.

Marking Procedure Site

Although the surgical team may be following the universal protocol by signing the site, the downstream process could still lead to wrong-site surgeries. To prevent the erasure of the marking site by surgical prep solutions, a special ink pen will be implemented that would not be removed by disinfectants.

Time-Out Confirmation

Dillon (2008) describes a metal plaque that is inscribed with the words “time-out” and is placed on top of the surgical instruments as a reminder to implement the protocol.

Additional Implementation

In-service meetings for the Universal Protocol should be mandatory for all surgical team members. Attendance should be taken for all individuals who participated in the meeting.

The position of the quality-assurance officer would be to file a report that would be reviewed by upper management. If wrong-site surgery occurs, legal actions would be documented on file at the hospital. In a trial, this could be used against the surgeon; the surgeon would then bear responsibility for the error that occurred, rather than the hospital.

Criteria for Evaluation

The proposed interventions for the Universal Protocol can be evaluated as follows:

Pre-Procedure Verification

The application of the “speak-up box” could be evaluated monthly by reviewing how frequently concerns are being addressed and what the concerns are with regard to communication

barriers.

Marking Procedure Site

To evaluate the effectiveness of the indelible marker, a study could be conducted to test the marker with various disinfectants.

Time-Out Confirmation

The implementation of the nurse's role in the time-out and the surgical plaque could be evaluated by reviewing the trend of wrong-site surgery incidences.

Additional Evaluations

The in-service meetings would be evaluated through the attendance sheet monthly to monitor compliance. An incentive for participation in the meetings would be a yearly bonus presented to those who attended. Lastly, the reports gathered from the quality-assurance officer could be evaluated monthly by reviewing the incidences.

Conclusion

Prior to the Universal Protocol, there were no specific interventions in place for the surgical teams to follow. Therefore, there was little for us to compare the Universal Protocol to. A common trend throughout all of the articles reviewed explained that different hospitals had their own procedures to prevent wrong-site surgery (e.g., surgical checklists), but there were no mandatory processes for implementation. Based on the literature obtained, it is evident that the use of the Universal Protocol has been effective in decreasing wrong-site surgeries. However, compliance and other factors continue to cause surgical errors. It is our conclusion that the interventions proposed above could change the future of wrong-site surgeries.

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