Innovative Technology System to Prevent Wrong Site Surgery, Capture and Reduce Near-Misses: A Longitudinal Review of 1187 cases.

Introduction: Wrong site surgery (WSS) is a preventable error. When these events do occur, they can be devastating to the patient, nursing staff, surgeon, and facility where the surgery was performed. Despite the implementation of protocols and checklists to reduce the occurrence of WSS, the rates are estimated to be unchanged.

Materials and Methods: An innovative technology was designed to prevent WSS through a systems-based approach. The StartBox Patient Safety System was utilized at one site by nine surgeons for a twelve-month period. The incidence of near-misses and WSS was reviewed.

Results: The StartBox System was utilized for 1187 orthopedic procedures including foot, hand, elbow, knee and shoulder. Over the course of these procedures, medical staff recorded 16 near-misses utilizing the StartBox System. The rate of near-misses trended downward after an initial implementation period.

Conclusions: The StartBox System was successful in capturing near-misses and demonstrated the system's ability to improve communication, workflow, logistics and training resulting in a reduction of near-misses. The data generated through the use of the system complements existing safety guidelines and protocols and improves the safety of future procedures.

INTRODUCTION

Medical errors are a leading cause of patient harm. Errors that could lead to patient harm such as wrong site surgery (WSS) are estimated to occur more than 3000 times each day.[1] While safety is the number one priority of healthcare providers, errors naturally still occur and can be devastating to the patient, nursing staff, surgeon, and facility where the surgery was performed.

Processes, checklists and safeguards have been implemented such as the Joint Commission Universal Protocol[2] and the World Health Organization Surgical Safety Checklist.[3] However, failures of safety protocols (e.g. distractions and rushing during time-outs)[4] are some of the factors that lead to the rates of WSS being unchanged.[5]

Gloystein published a recent study demonstrating success of the StartBox System to improve patient safety[6]. In addition to preventing patient harm, the system tracked a number of near-misses, revealing potential issues prior to bad outcomes occurring. In this published study, the StartBox System was utilized for 487 orthopedic procedures at six sites. There were no occurrences of WSS events. Over the course of these procedures, medical staff recorded 17 near-misses utilizing the StartBox System.

Following this report of 487 procedures, an additional cohort of 1187 procedures was studied over a 12-month period at a new site. The overall count of procedures completed with

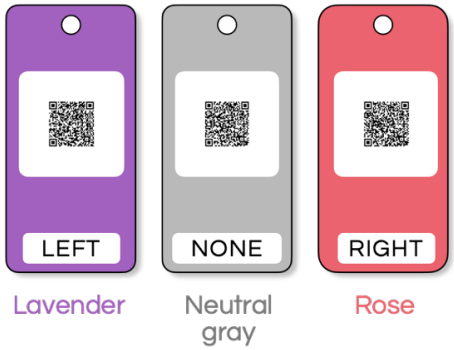
StartBox therefore equals 1684. Whereas the initial 487 procedures was shorter term (less than 6 months), the longitudinal aspect of the 1187 procedures gives insight into trends and the progressive experience with the system. The longitudinal experience is the subject of this report.

MATERIALS & METHODS

The StartBox Patient Safety System (StartBox, Atlanta, GA) is an innovative technology that was evaluated to assess its ability to capture and reduce errors. This longitudinal evaluation was performed using 1187 cases performed by nine (9) surgeons at one site from January 2021 to December 2021. The procedure types include foot, hand, elbow, knee and shoulder.

The StartBox System begins by recording the procedure to be performed (the "decision for surgery") between patient and physician with a mobile application. The System then allows members of the healthcare team to capture data at checkpoints throughout the continuum of care and uses a color-coded visualization that designates procedure laterality. The StartBox kit consists of a card featuring the color code and a QR code that is digitally linked to the patient's procedure in the mobile application (Figure 1). This kit simplifies the workflow relative to an earlier iteration of the system presented in the original study, which consisted of a physical forcing function (surgical blade delivery kit).

Figure 1: StartBox color-coded card with QR code



Any member of the healthcare team can flag errors during the various checkpoints with the mobile application and provide real-time alerts to improve patient safety and procedure outcomes. Upon completion of the procedure, the case data, including near-misses, is stored and aggregated to generate predictive analytics related to future WSS prevention protocol improvements and training opportunities. Near misses related to WSS would include incorrectly booked surgery and improperly performed presurgical time-outs.[1]

The study was carried out with a sequential series using retrospective, deidentified data. The system is designed to protect the confidentiality, availability, and integrity of personal health information as required by HIPAA and satisfy the compliance requirements of institutional ethics committees.

RESULTS

Over the course of 1187 procedures, medical staff recorded sixteen (16) *No Gos* in the StartBox System. Information for each of these cases was either corrected or overridden by the surgeon or circulator and the procedure was successfully completed. The StartBox System was effective in preventing wrong site surgery for each of these events.

Nine (9) *No Gos* were due to inconsistent patient information including incorrect date of birth information or naming errors. Five (5) *No Gos* were due to laterality mismatch, including errors made by either the clinic or the surgery center during scheduling. In one particular case, the StartBox record, patient consent forms and surgery order from the clinic all called for a Left Knee procedure; however, the procedure was posted at the surgery center as a Right Knee procedure. Two (2) *No Gos* were due to procedure description errors: both procedures were amended after the original consultation with the patient, and one had incorrect informed consent signed by the patient. (Table #)

There was a relatively even split of the patient care area where these *No Gos* were recorded:

Nine (9) by the preop nurse at check-in on the day of surgery; and Seven (7) by the circulating nurse during the transfer from preop to the OR, before the time out was conducted.

Table 1: Count of *No Go* by type

Type of No Go	*No Go*	Percentage of Total
Patient	9	56%
Laterality	5	31%
Description	2	13%
Site	0	0%
Total	16	

Over time, there was a downtrend in the occurrence of *No Go*s. Eleven (11) of these occurred in months 1-3, which could be considered a training and implementation period. Five (5) occurred in months 4-7 and zero (0) occurred in months 8-12. (Table 2, Figure 2)

The use of StartBox did not result in any reported impacts or use impedance to patient workflow at the clinic or hospital and there were no delays in surgery due to technical difficulties during the time out or failure of the system.

DISCUSSION

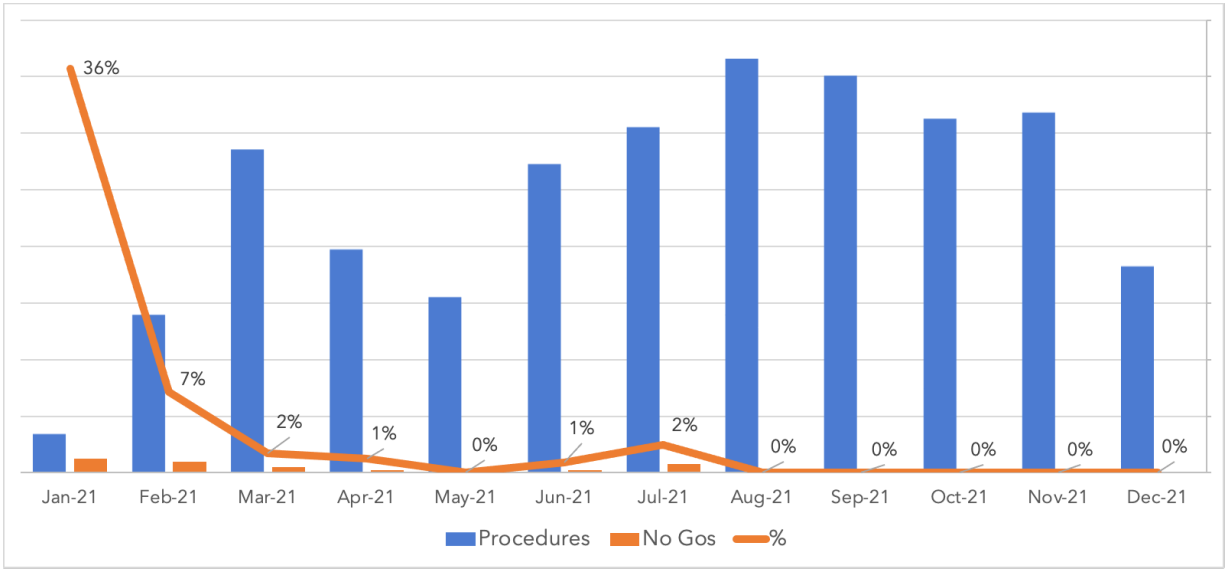
As discussed in the Gloystein study, near-miss analysis can contribute towards preventing rare but serious events, such as WSS.[7] Quantifying near-misses is an important step in understanding the risk of WSS and facilitating a longitudinal review of modified systems and protocols to prevent errors.

In that original seminal study, the *No Go* function of the StartBox System was triggered in 17 of 487 (3.5%) registered procedures in a short-term series (less than 6 months). A limitation of this study was the fact that it was conducted over a relatively short period of time, limiting the ability of the institution to perform in-depth analysis of the near-misses and implement considerable systematic change or evaluate effectiveness of changes. It was hypothesized that the data generated by the StartBox System may improve the safety of future procedures by identifying opportunities for improvement in communication, workflow, logistics and training.

Table 2: *No Go* by month

Month	1	2	3	4	5	6	7	8	9	10	11	12
Procedures (by Month)	14	56	114	79	62	109	122	146	140	125	127	73
No Gos (by Month)	5	4	2	1	0	1	3	0	0	0	0	0
% (by Month)	35.7%	7.1%	1.8%	1.3%	0.0%	0.9%	2.5%	0.0%	0.0%	0.0%	0.0%	0.0%
Procedures (Cumulative)	14	70	184	263	325	434	556	702	842	967	1094	1167
No Gos (Cumulative)	5	9	11	12	12	13	16	16	16	16	16	16
% (Cumulative)	35.7%	12.9%	6.0%	4.6%	3.7%	3.0%	2.9%	2.3%	1.9%	1.7%	1.5%	1.4%

Figure 2: Procedures and *No Gos* by Month



In this subsequent longitudinal study, the *No Go* function of the StartBox System was triggered in 16 of 1187 (1.4%) registered procedures. During the initial period of this study, a higher rate similar to the original study was observed: 12 of 325 (3.7%) over 5 months. Following this initial period, as the procedure volume increased, the near-miss count decreased and ultimately approached zero. (Table 2, Figure 2)

This data demonstrates the ability of the StartBox System to objectively inform the clinical team of recurring errors. Specifically, protocol changes and improvements to communication were implemented to improve the rate of error. In particular, these corrective actions served to reduce the occurrence of patient demographic errors such as name differences (including the use of legal names vs. names on insurance card vs. nicknames) and date of birth errors. While these errors may not have led directly to patient harm, they are part of the general category of discrepancies that can create an unsafe environment where wrong patient procedures can occur.

Beyond this type of improvement, the system did consistently capture and assist in the correction of five (5) laterality errors. These are the most common types of WSS, ranging from 70% to 81% of overall events[8,9] and their correction illustrates the importance of the system providing an important safety block to those serious errors translating into patient harm.

CONCLUSION

The StartBox System is designed to complement safety checklists, standardize and streamline workflows, integrate computerization, and provide a final constraint to prevent WSS. Improved communication helps prevent patient harm. And by capturing near-misses through a real-time, data-driven approach and reducing the occurrence of these errors, the system can improve patient safety.

1187 procedures were completed with StartBox during a longitudinal study. 16 near-miss events were captured, demonstrating the ability of the StartBox System to objectively inform the clinical team of recurring errors, including laterality errors, which are the most common type of WSS. A downward trend was observed over the twelve-month period of the study, with zero near-misses reported during the last five months of the period. This suggests that the StartBox System can help healthcare facilities and providers improve their patient safety and risk profiles over time.

[1] Yoon RS, Alaia MJ. Using "Near Misses" Analysis to Prevent Wrong-Site Surgery. J for Healthcare Quality; 2015;37(2):126-132.

[2] Agency for Healthcare Research and Quality, Patient Safety Network. Universal protocol for preventing wrong site, wrong procedure, wrong person surgery. 2003. https://www.jointcommission.org/standards_information/up.aspx (Accessed April 11, 2019).

[3] World Health Organization. WHO Surgical Safety Checklist. 2009. https://www.who.int/teams/integrated-health-services/patient-safety/research/safe-surgery/tool-and-resources (Accessed July 22, 2022).

[4] Health Research & Educational Trust and Joint Commission Center for Transforming Healthcare. (2014, August). Reducing the risks of wrong-site surgery: Safety practices from The Joint Commission Center for Transforming Healthcare project. Chicago, IL: Health Research & Educational Trust. Accessed at www.hpoe.org.

[5] James MA, Seiler JG, 3rd, Harrast JJ, Emery SE, Hurwitz S. The occurrence of wrong-site surgery self-reported by candidates for certification by the American Board of Orthopaedic Surgery. J Bone Joint Surg Am. 2012;94(1):e2(1-12).

[6] Gloystein DM, Heiges BA, Schwartz DG, DeVine JG, Spratt D. Innovative Technology System to Prevent Wrong Site Surgery and Capture Near Misses: A Multi-Center Review of 487 Cases. Front Surg. 2020 Oct 23;7:563337. doi: 10.3389/fsurg.2020.563337. PMID: 33195386; PMCID: PMC7644953.

[7] Aspden, P., Corrigan, J.M., Wolcott, J., & Erickson, S.M. Patient safety: Achieving a new standard for care. Washington, DC: National Academies Press;2004.11.

[8] Seiden SC, Barach P. Wrong-side/wrong-site, wrong-procedure, and wrong-patient adverse events: Are they preventable? Arch Surg. 2006;141(9):931-939.

[9] Clarke JR, Johnston J, Finley ED. Getting surgery right. Ann Surg. 2007 Sep;246(3):395-403, discussion 403-5.

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