Implementing a Standardized Safe Surgery Program Reduces Serious Reportable Events

Terrence Loftus, MD, MBA, FACS, Deb Dahl, BSE, MBA, FACHE, Bridget OHare, BS, MS, ASQ, SSBB, Karlene Power, RN, BSN, MSN, Yvette Toledo-Katsenes, BA, MBA, Ryan Hutchison, BSIE, MBA, David Jacofsky, MD, Kathleen Harder, PhD

BACKGROUND: Patient safety in the perioperative period is essential for delivery of quality patient care. Mainstream quality organizations have implemented safe surgery recommended practices for ensuring patient safety. Effectively implementing safe surgery practices should result in a reduction in serious reportable event (SRE) rates.

STUDY DESIGN: This retrospective cohort study compared results before and after implementation of a standardized safe surgery program across a large health care system. Observational audits were performed to assure adoption of the new process. Serious reportable event rates (retained surgical item, wrong site, wrong patient, and wrong procedure) were tracked. Statistical analyses were performed on the SRE rate and days between SREs.

RESULTS: A total of 683,193 cases in the operating room and labor and delivery were evaluated over a 4-year period. The SRE rate before implementation was 0.075/1,000 cases and after implementation was 0.037/1,000 cases. There was a 52% reduction in the SRE rate ($p < 0.05$). The mean time between SREs increased from 27.4 days to 60.6 days ($p < 0.05$). Robotic and nonrobotic cases were affected equally; however, a significant difference in SRE rate persisted between robotic and non-robotic cases ($p < 0.05$). Robotic cases are 7 times more likely to incur an SRE. Audits demonstrated that the compliance rates for the program improved to 96% after complete system implementation.

CONCLUSIONS: An effectively implemented standardized safe surgery program results in a significant reduction in SREs. Robotic cases are at high risk for an SRE. (J Am Coll Surg 2015;220:12−17. © 2015 by the American College of Surgeons)

Patient safety in the perioperative period remains a challenge, and the demand for a process that reduces risk grows with greater awareness of this problem. The World Health Organization's (WHO) Safe Surgery Saves Lives Program demonstrated a reduction in rates of death and complications in adult patients undergoing noncardiac surgery across a diverse group of hospitals[1] based on their published guidelines of recommended practices supporting safe surgery.[2] The National Quality Forum (NQF) has also continued to advance the drive to improve patient safety and reduce the incidence of serious reportable events (SREs) during the course of surgical procedures.[3] The National Quality Forum has taken the position that every health care organization is accountable for patient safety and the quality of care it delivers.

The SREs related to safe surgery are largely preventable, and health care organizations should take measures to assure that processes are in place to reduce and even eliminate these events where possible. On October 1, 2008, the Centers for Medicare and Medicaid Services[4] stopped reimbursing hospitals for 4 specific types of SREs applicable to surgery. They are: Wrong surgery or invasive procedure performed on a patient; surgery or invasive procedure performed on the wrong body part; surgery or invasive procedure performed on the wrong patient; and foreign object unintentionally retained after surgery. With this added incentive, developing

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From the Division of Care Management (Loftus, Dahl, OHare, Toledo-Katsenes, Hutchison) and Perioperative Services (Power), Banner Health, and The CORE Institute (Jacofsky), Phoenix, AZ, and the Center for Design in Health, University of Minnesota, Minneapolis, MN (Harder).

Correspondence address: Terrence Loftus, MD, MBA, FACS, Banner Health, Division of Care Management, 1441 N 12th St, Phoenix, AZ. 85006. email: tloftus@cox.net

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Abbreviations and Acronyms
L&D = labor and delivery
OR = operating room
RSI = retained surgical item
SRE = serious reportable event

a standardized approach to eliminating SREs became a priority for every health care delivery system in the country. If nonpayment for an SRE wasn't enough motivation, a recent analysis of paid malpractice claims for SREs, from the National Practitioner Database, calculated the average payment per claim was $133,055.[5]

Working with a cognitive psychologist who designs processes and technology to improve human performance in health care delivery, and a multidisciplinary implementation team, we hypothesized that systematically implementing a standardized safe surgery process rooted in cognitive psychology and human factors engineering principles would result in a significant reduction in the 4 surgically related types of SREs. The processes used in this study to prevent wrong-site, wrong-surgery, and wrong-patient events and prevent unintentionally retained foreign objects were developed at the University of Minnesota.[6-8]

METHODS

This was a retrospective cohort study spanning a 4-year period, comparing results before and after implementation of a standardized safe surgery program designed to reduce the incidence of SREs. For purposes of this study, SREs were defined as any reported retained surgical item (RSI), wrong site, wrong patient, or wrong procedure. The program was implemented in all of the operating rooms (OR) and labor and delivery (L&D) areas within our system. Twenty-two hospitals, ranging in size from an 18-bed critical access facility to a 668-bed level 1 trauma center, along with 8 ambulatory surgery centers, participated in the implementation. The patient population included all patients undergoing a surgical procedure in these areas. The baseline period included 12 months before the beginning of the system implementation and extended until the system compliance score on monthly audits of the safe surgery process exceeded 95% for all OR and L&D areas. This was to allow for all personnel to be trained in the new process and for any additional remediation required after implementation. Complete system implementation occurred over a 20-month period. The total baseline period was 32 months. The comparison study period began after the baseline period and ran for 16 months. The system compliance score on monthly audits exceeded 95% during the comparison period.

Observational audits were performed in each area by quality control nurses. Each month, 10 cases were selected at random per facility, and quality control nurses were present in the operating room to observe the case from beginning to end to note if all program elements were followed. Checklists were used to assist the observational auditors to document performed elements of the safe surgery program. Surgery team members did not use checklists as they performed the process; however, the surgical team could access descriptions of program elements and rationale if requested.

A multidisciplinary team of surgeons, nurses, quality personnel, a cognitive psychologist, process engineers, and administrative support were involved in defining the implementation process to prevent unintentional RSIs after surgery and the process to prevent wrong-site, wrong-patient, and wrong-procedure events. This team was instrumental in implementing this practice across the system based on our previously described process.[9] Because this was a system-wide initiative, it required approval of the Board of Directors and support by the Senior Management Team. This study was determined to be exempt by the system's Institutional Review Board (Project # 100-14-0008, Reference # 014229).

The processes contained within the safe surgery program focused on 2 areas. The first involved patient-focused steps to prevent wrong-site, wrong-patient, or wrong-procedure events. The second involved robust sponge, sharp, and instrument counts to prevent RSIs. These processes were designed to channel behavior toward improved performance by addressing the strengths and weaknesses of human information processing. The gaps in which errors could occur were closed and the process was mistake-proofed.[10] For example, because human memory is fallible, a Time Out Towel (Ansell Sandel Medical Solutions, LLC) was used as a memory trigger to help the surgical team remember to perform the timeout. This is a sterile bright orange towel printed with the words "TIME OUT." As part of the safe surgery program, it is placed over the operative site or Mayo stand and is not removed until the surgical team completes the timeout. The steps for the patient focused process to prevent wrong-site, wrong-patient, and wrong-procedure events are:

1. Patient identification by care providers (surgeon, preoperative nurse, anesthesia, and circulating nurse);
2. Site marking with reference to source documents;
3. Handoff between preoperative nurse and OR nurse including verifying site marking;
4. Introduction of patient to OR team and matching patient's identification band to documents on entry to OR;