Creating a Culture of Safety Through Standardization

Clinical Trial Research Findings

John Paul Cerda Sr. RN BSN CNOR CRNFA WCC · Laura R. Schmidt RN BSN CNOR RNFA · Mark Lowenstein

CREATING A CULTURE OF SAFETY THROUGH STANDARDIZATION

John Paul Cerda Sr. RN BSN CNOR CRNFA WCC
Laura R. Schmidt RN BSN CNOR RNFA — Clinical Educator, Adventist Hospital Lodi CA
Mark Lowenstein, Legal Services, Sandy Oregon

Abstract

For decades, adverse events (AE), Retained Foreign Objects (RFO), Never Events (NE), and Retained Surgical Items (RSI) have plagued patients, hospitals, and medical staff alike. Professional organizations such as the Joint Accreditation Council of Hospitals (JACH0), The Association of Operating Nurses (AORN), and The Association of Operating Room Technicians (AST) have developed policies and procedures to prevent poor patient outcomes. The aforementioned organizations have published current literature to combat AEs and RFOs with the recommendation of establishing a Positive Safety Culture (PSC). Research suggests policies and procedures alone are not enough. New innovative technologies and methods for standardizing intraoperative procedures show tremendous potential to vastly improve patient and surgical team safety while reducing stress and unnecessary costs — specifically through the use of a standardized mapped surgical back-table drape. This clinical trial provides evidence of its effectiveness during the intraoperative process.

Background

Routine assessments of patient safety in the operating room have been locally, nationally, and globally recommended by multiple Medical, Nursing, and Technical Boards and Organizations. Yet the persistent problems continue to grow in operating rooms across the country: intraoperative time delays, missed sponge and needle counts, unplanned x-ray use in search of missing soft/hard goods, forced overtime, and surgeon frustration — all leading to poor patient outcomes. JohnMark International has studied and researched these reasons firsthand. A large piece of the solution is **standardization** — the process of making something conform to a defined standard. The mapped back-table drape is a sterile surgical drape used to promote conformity in the OR.

Methods

Based on a mixed-methods approach, a cross-sectional survey followed by voluntary interviews were conducted over a three-month period (July–September 2022) at Adventist Hospital, Lodi, California, involving Surgeons, RNFAs, RNs, CNORs, CSTs, and ORTs across six operating rooms offering robotic surgery, orthopedic sports medicine and joint replacement, OB/GYN, and urology.

Results

Five operating rooms with different surgical specialties were included. Survey feedback was provided by 19 hospital staff across 96 completed surveys. Concerns identified prior to the JMI intervention included: missed surgical counts, delays in surgery, surgeon frustration, no standardized setup, and poor patient outcomes with increased costs. Following introduction of the JMI Mapped Back Table Drape (MBTD), the study found: **zero missed counts**, **zero unplanned x-ray use**, 100% improved ease of counting during relief/break periods, and a 97% reduction in counting-related stress — while aligning fully with AORN and JACHO guidelines.

Background

JOHNMARK INTERNATIONAL (JMI) is believed to have developed the standardization process to be the first of its kind in the operating room through a standardized mapped back-table drape. The study was conducted at Adventist Hospital in Lodi, California across six operating rooms offering robotic surgery, orthopedic sports medicine and joint replacement, OB/GYN, and urology. All participants were strictly voluntary: Board Certified Surgeons, Registered Nurses, CNORs, ORTs, and Certified Surgical Technologists (CSTs).

According to a report published by Aouicha et al. (BMC Health Services, 2022), adverse events remain a global challenge despite a major rise in international interest in patient safety. The QJM International Journal of Medicine (Vol. 108, July 2014) echoes this, stating that invasive surgical procedures carry risk of harm to patients and the need for increased patient safety and improved outcomes.

Multiple journal articles have been published regarding the counting process — most recently AORN's March 2023 publication *Preventing Unintentionally Retained Surgical Items* and *Practices to Aid in the Prevention of Unintentionally Retained Surgical Items*, as well as the August 2022 publication *Retained Surgical Items: Overview of a Persistent Problem*.

The BMC reports that adverse events are rarely related to a lack of technical skills but rather to a **lack of safety culture** among caregivers. Creating a Positive Safety Culture (PSC) was recommended by the Institute of Medicine as an important strategy to improve patient safety and to meet local, national, and global challenges posed by AEs, preventing extravagant awards against hospitals, doctors, and nurses while primarily increasing patient outcomes.

Poor patient outcomes often lead to extensive monetary damages against hospitals. One such case was reported on January 3, 2020 by ABC7.com, where a patient received more than $10,000,000 for a sponge left in her abdomen. Another case published in *Urology Times* (May 2018) reported that an individual physician indemnity had a total payout for retained surgical items of $26,000,000 over 4 years.

Correspondence: john@johnmarkintl.com

John Cerda RN BSN CNOR CRNFA / US NAVY Veteran · 4730 S. Fort Apache Rd., Suite 300, Las Vegas, NV 89147

Financial Impact of Retained Surgical Items

An analysis of government records, clinical studies, and two major databases of malpractice claims (2002–2012) revealed that a single case of a retained sponge can cost a hospital and the surgeon well over half a million dollars in indemnity payout and legal fees — far more than earlier estimates. With the effect of payment reforms added in, the cost to a hospital is even higher.

The Risk Management Foundation of the Harvard Medical Institutions reviewed thousands of malpractice closed claims. The average indemnity payout for a claim involving a retained surgical item for hospitals and physicians was approximately **$473,000** from 2007–2011. For cases involving permanent major damage to a patient, the average claim was **$2 million**. Notably, a retained surgical item adds an estimated **$9,450** in direct OR time costs — *at approximately $2,000 per minute of surgical time, roughly 4–5 minutes of added OR time to resolve a miscount — roughly nine times the cost of sponge-counting technology itself*.

Physician Indemnity Costs for Retained Foreign Objects

Years	Closed Claims	Paid Claims	Avg. Payout	Largest Payout	Total Payout
2002–2006	727	244	$73,889	$1.35 million	$18 million
2007–2011	892	253	$104,842	$865,000	$26.6 million

Source: Physician Insurance Association of America Data Sharing Project (Graphic Data: Todd Sloane, Becker Hospital Review, Aug. 12, 2013)

Physician Legal Defense Costs for Retained Foreign Objects

Years	Closed Claims	Average Legal Costs	Total Legal Costs
2002–2006	727	$17,805	$12.9 million
2007–2011	892	$29,152	$26 million

Source: Physician Insurance Association of America Data Sharing Project

$473K
Avg. indemnity payout per RSI claim (2007–2011)

$2M
Avg. claim for permanent major damage

$26M
Single physician payout over 4 years (RSI)

$9,450
Est. direct OR time cost per retained item (at $2K/min)

The Joint Commission's April 2023 Sentinel Event data review covering January–December 2022 cited **Unintended Retention of Foreign Objects** among the ten leading sentinel event types. The Joint Commission states: *"one of the most important things you can do to prevent unintended foreign objects is simply to incorporate a count process"* and standardize count policies on all procedures.

The standards and recommendations proposed by The Joint Commission, AORN, The Association of Surgical Technologists, and the World Health Organization are well intended — yet the persistence of adverse events demonstrates that policies and procedures alone are insufficient. Only now is the concept of true **STANDARDIZATION** beginning to emerge as the pivotal solution.

The JMI Method of Standardization

JMI METHOD OF STANDARDIZATION is a simple but highly effective tool used intraoperatively to assist the intraoperative staff with the counting process. It requires minimal training, saves hospitals time and money, and decreases surgeon and staff frustration. The JMI patented method of standardization for intraoperative surgical counting processes and policies supports and enhances hospital policies, AORN standards, AST standards, and WHO guidelines to enhance positive patient outcomes.

JMI conducted a research study of the intraoperative counting process. The primary goal was to enhance positive patient outcomes and create a culture of safety. JMI developed a **STANDARDIZED** counting system which incorporated the use of a Standardized Back Table Drape and a sterile single basin ring stand.

Figure 1. JohnMark International Mapped Back Table Drape — left-side and right-side standardization shown.

Methods

Study Design & Settings

Based on a mixed-methods approach, a cross-sectional survey was followed by voluntary intraoperative surgical staff incorporating the JMI standardization method regarding surgical counting. The trial was concluded with a comparison survey. Semi-structured interviews were taken, providing a phenomenological context encircling the data.

Phase 1: Questionnaire Survey

Participants

The questionnaire was voluntary and directed at operating room staff. Total number of OR staff for this study was 19, consisting of Surgeons, Nurses, and Technicians.

Measures

The questionnaire was developed by JMI and Laura Schmidt RNFA and Clinical Educator. Overall, the questionnaire totaled 19 items. All items examined patient safety regarding: intraoperative surgical counting; adverse events operating room staff encountered; and the benefits of using and incorporating a standardized Mapped Back Table Drape (MBTD) setup to enhance and improve the counting process and advance Positive Safety Culture (PSC).

JMI handed out a survey to all voluntary participants at the end of each surgical procedure, where a single staff member completed the questionnaires. All questionnaires were placed in a secured box. The survey was completely voluntary. Anonymity and confidentiality were maintained.

Data Analysis

The initial questionnaire consisted of yes/no questions for the three months prior to introduction of the MBTD at a weekly OR staff meeting. The MBTD was used during each surgical procedure for a period of three months. At the conclusion, a second survey was administered to all participants, collected by JMI, and placed in a box for comparison — capping a six-month study. The study was graphed to represent descriptive analysis, percentages, and standard deviations.

Pre-JMI Baseline Results

The following data was collected during the three-month baseline period (July–September 2022) before introduction of the JMI Mapped Back Table Drape. Responses are from 19 voluntary OR staff members across 96 completed surveys.

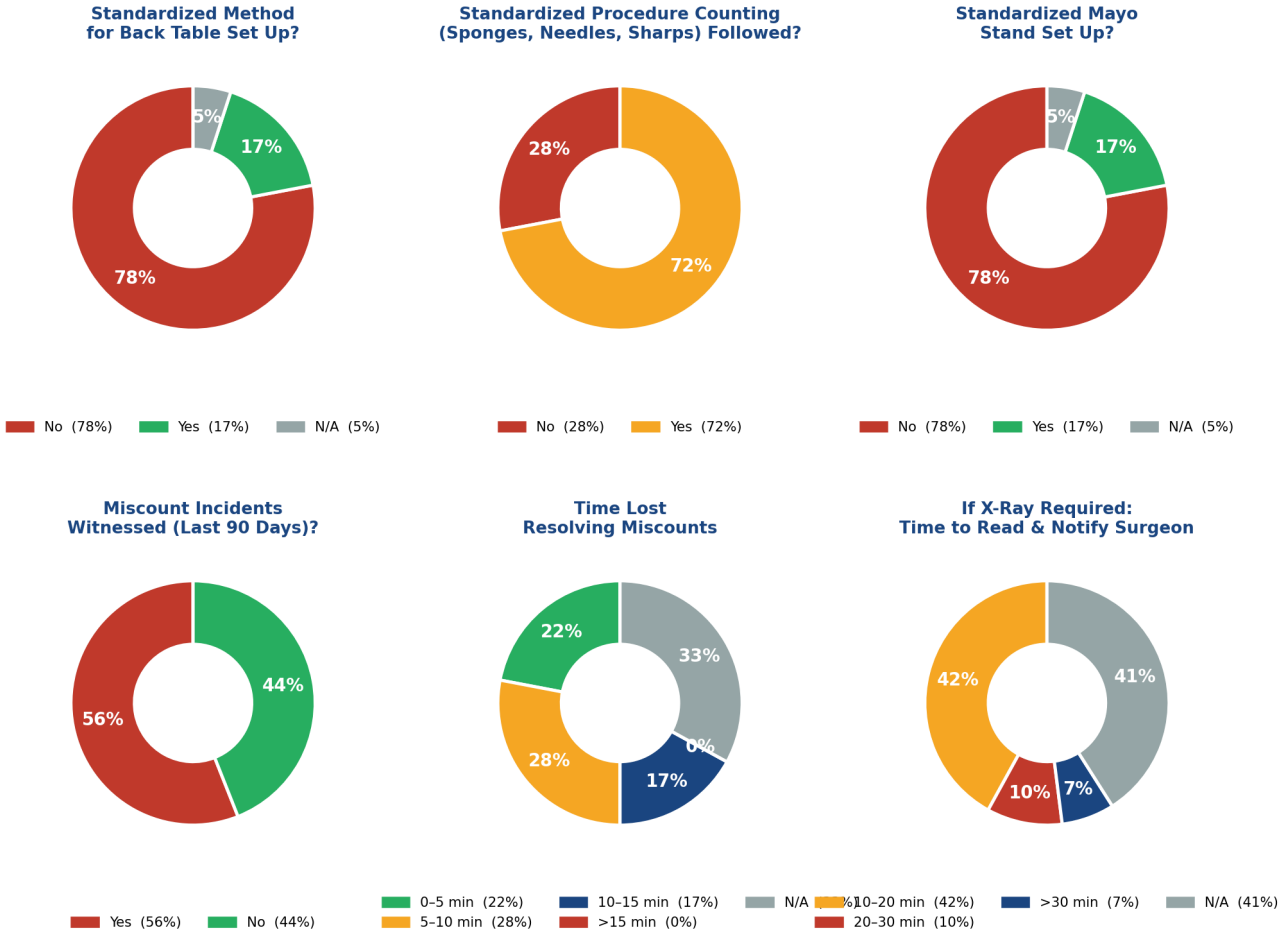
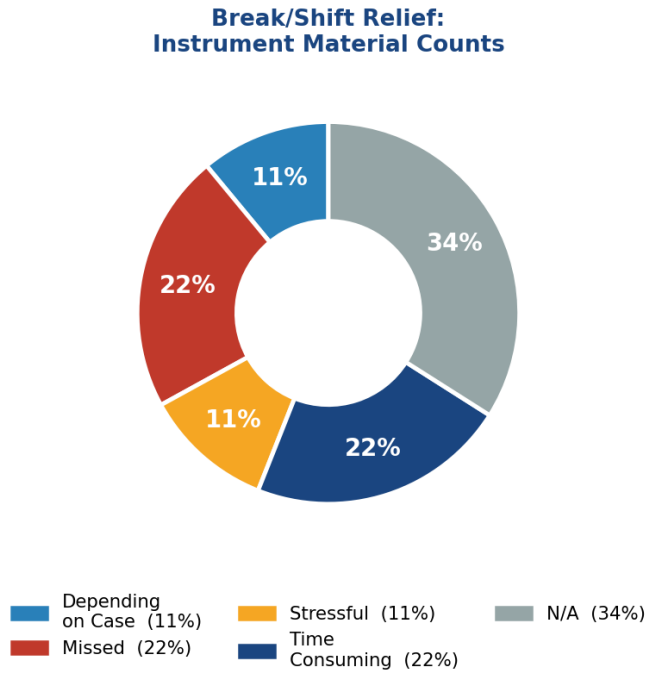


Figure 2. Pre-JMI Standardization Questionnaire Results — JMI Standardization Study, July–December 2022.

Break & Shift Relief: Instrument Counts



During break and shift changes — historically one of the highest-risk moments for count errors — staff reported that the current methodology was often missed, stressful, or time-consuming. 34% of responses were N/A (case-dependent), while 22% reported counts were routinely missed and another 22% found them time-consuming. The JMI Mapped Back Table Drape was specifically designed to eliminate ambiguity during these transitions by providing a clearly mapped, standardized sterile field that any incoming scrub technician can orient to immediately.

Semi-Structured Interviews — Participants

Following the mixed-methodology approach, the second part of the study incorporated semi-structured interviews. Participants were selected deliberately to include at least one staff member from each intraoperative role: two Board Certified Surgeons, one RNFA, one OR Nurse, three CNORs, one OR Technician, and two Certified OR Technicians. The majority of interviews were conducted immediately at the conclusion of the six-month data collection.

Results — Overall Assessment

Five operating theatres with different surgical specialties were included in the study. The degree of safety in the OR as it related to the counting process was deemed 'Acceptable.' However, most agreed the counting process could be much improved, as there were many issues which threatened patient safety frequently.

Post-JMI Intervention Results

The following results were recorded during the three-month intervention period (October–December 2022) using the JMI Mapped Back Table Drape at Adventist Hospital, Lodi Memorial. Results represent data from 96 completed surveys.

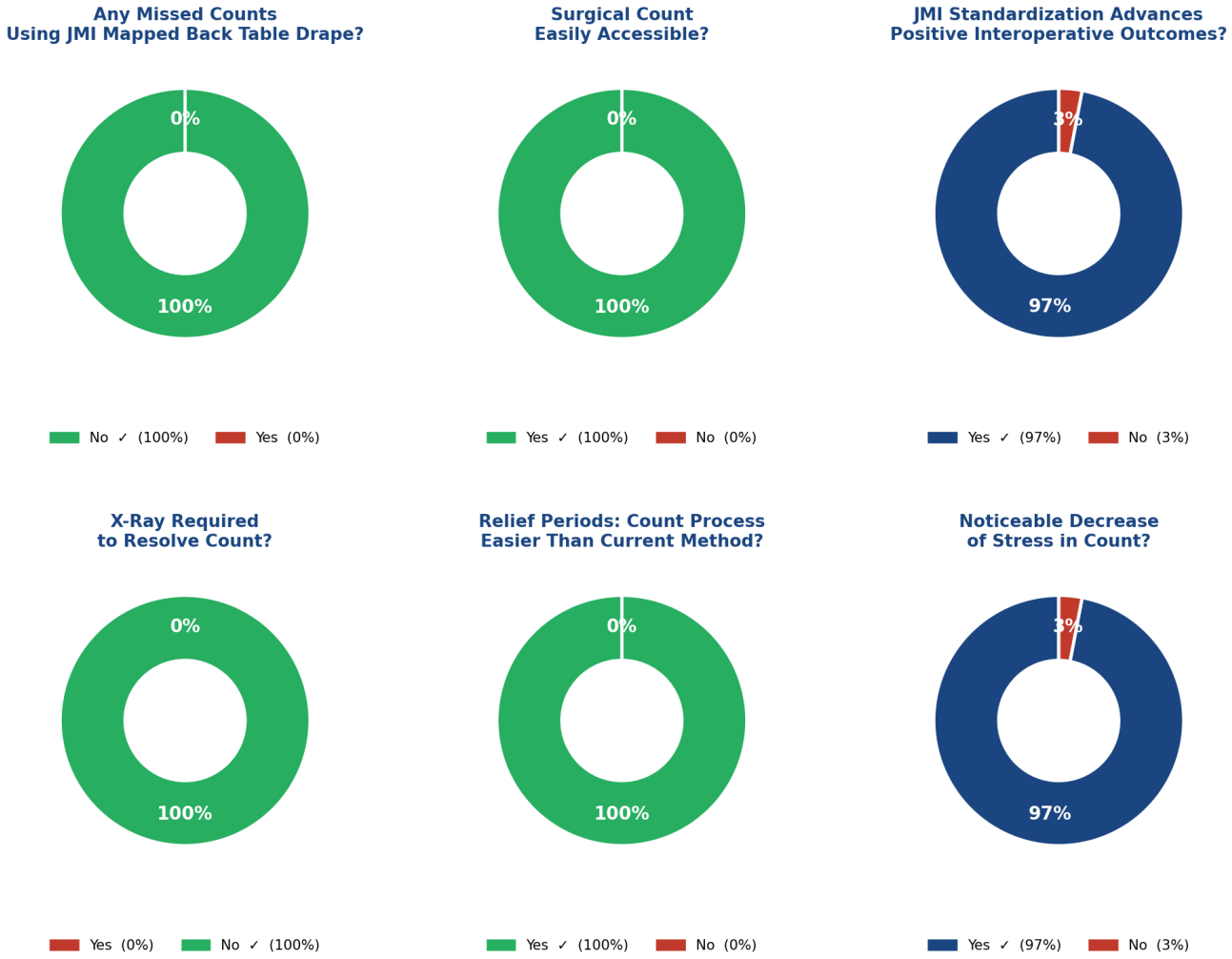
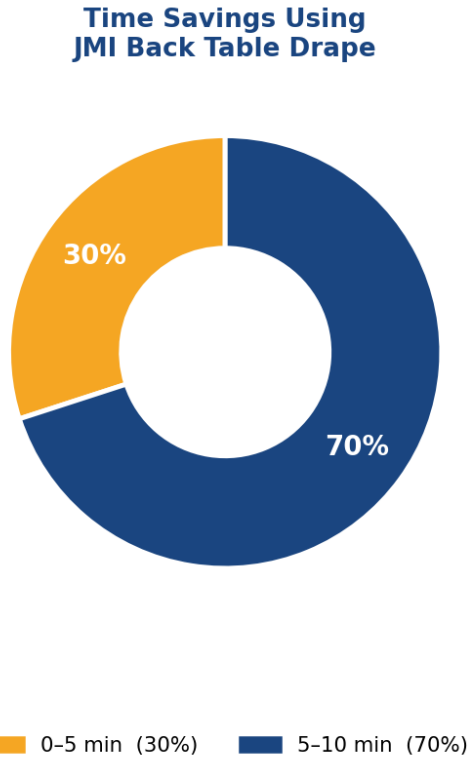


Figure 3. Post-JMI Intervention Results — JMI Standardization Study, October–December 2022, Adventist Hospital Lodi Memorial.

Time Savings & Staff Interviews



Time Savings per Procedure

Staff reported that use of the JMI Mapped Back Table Drape saved between **5–10 minutes** per surgical procedure in the majority of cases. Across high-volume ORs performing dozens of procedures weekly, these savings translate to significant cumulative time recovered — reducing forced overtime, relieving surgical team fatigue, and directly lowering operating costs.

Theory–Practice Gap: Staff Interview Excerpts

Surgeon 1

> *"Most nurses and technicians in the OR know the importance of surgical counting and how it is supposed to be done, however it is usually performed incorrectly with disregard to hospital policy or any counting standard."*

Nurse 1

> *"We have so many new OR techs and I am fairly new myself that I can't keep up with how each new tech is counting. Each surgical case is so different even if it's the same procedure but a different tech."*

OR Technician 1

> *"The part I hate about my job as a relief scrub is I always have to adjust to someone else's setup in the middle of a case where I can't immediately find items on the back table, then I get yelled at by the surgeon. This part of my job is very stressful and very unsatisfying."*

Surgeon 2

> *"Many near-misses occur, and they are not reported so long as the problem was resolved without any harm to the patient."*

Failing Counting Processes & Underreporting

During the interviews, volunteer staff noted that not everything is reported in the OR. Near-misses routinely occur but are not formally documented so long as the problem was resolved without harm to the patient. This systemic underreporting masks the true scope of the problem and prevents meaningful system-level improvement.

Standardizing the Counting Process

The prevention of RSIs cannot be overstated. A standardized counting process must be rigorously prioritized and incorporated into each surgical procedure to encompass effective communication, standardized count boards, and counting drills. In the operating room, regular drills are in place for fire, code blue, and Malignant Hyperthermia scenarios. Yet after decades of patient injuries — the most common being a retained sponge — not a single hospital has established a standardized protocol for conducting counting drills, as it is generally regarded as methodical routine practice.

The reader of this article should recognize that despite intraoperative standards, policies, recommendations, RFID technologies, protocols, and laws — as long as humans are involved in the intraoperative process, there will be human error. The goal of standardization is not to eliminate human involvement but to minimize the cognitive load and ambiguity that leads to error.

JohnMark's Methodology: Standardizing the Counting Process

The standardization process for surgical counting flows from the patient sterile field, to the Mayo stand, to the back table at either side of the patient, and into the unsterile final count receptacle (Figure 4). The JMI surgical count and setup method maintains laterality for easy access and heightened visibility for viewing at all times during the surgical procedure.

JMI Standardized OR Setup — Figure 4

Figure 4a. JMI Mapped Back Table Drape — full table overview showing tray organization and orange laterality stripe.

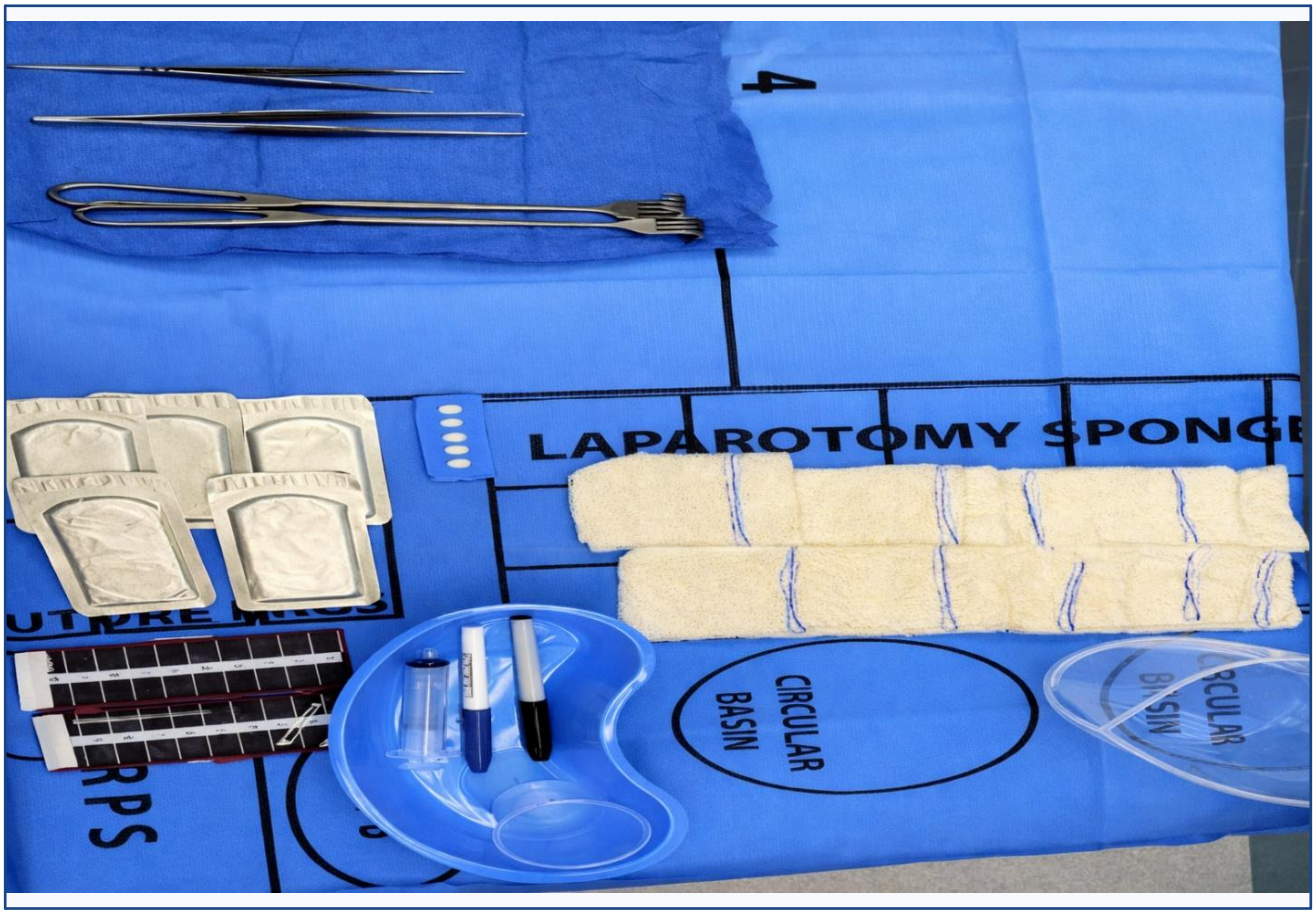


Figure 4b. JMI Mapped Back Table Drape close-up — labeled zones for Laparotomy Sponges, Circular Basins, Sharps, and Sutures.

Current Non-Standardized Methodology

For contrast, the following images illustrate the typical non-standardized sterile drape and OR setup currently in use at many facilities — informally referred to by OR staff as *"Operation Chaos."* The absence of any spatial mapping or zone labeling means that every scrub technician sets up differently, making handoffs during break and relief periods particularly error-prone.

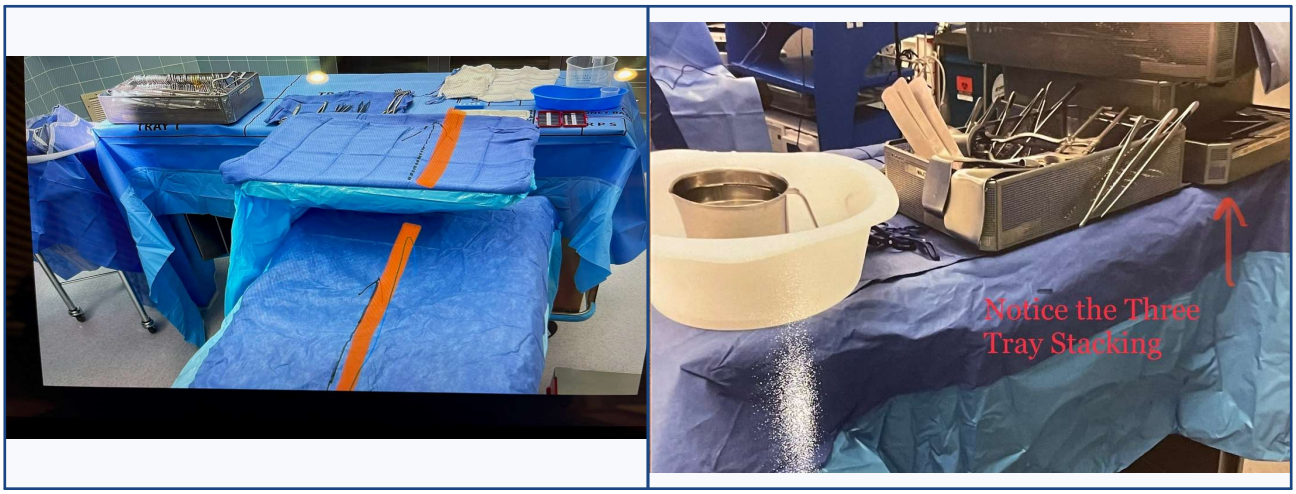


Figure 5. Left: Typical non-descript sterile back table drape (blank field, no mapping). Right: Non-standardized "free-for-all" OR setup — note the three-tray stacking and absence of spatial organization.

Conclusion

Retained surgical items remain a persistent phenomenon within the surgical arena. Currently, multiple organizations — including JACH0, AORN, WHO, and AST — align with individual hospital policies and procedures for the sole purpose of producing and enforcing intraoperative standards to protect patients from harm during the operative process.

As this study has proven, and as echoed by the aforementioned professional associations and multiple publications, **standardization is a must** if we are to protect our patients from near-misses, retained foreign objects, unnecessarily prolonged surgeries, and unplanned intraoperative x-ray use to locate surgical items in a surgical cavity.

The research was conducted strictly on a voluntary basis. It was observed that senior operating room technicians — while voicing commitment to their personal setups — were willing to continue on with a non-standardized status quo. By contrast, active CNOR nurses embraced the mapped back table drape specifically for the ease of counting during break periods and shift changes.

Multi-Faceted Benefits of the JMI Mapped Back Table Drape

As proven in this study: **(1)** Increased positive patient outcomes; **(2)** Zero unplanned intraoperative x-ray use; **(3)** Ease of the counting process across all staff roles; **(4)** Decreased stress during intraoperative counting; **(5)** No retained surgical items or near-misses; **(6)** Time savings of 5–10 minutes per procedure; **(7)** 100% staff agreement on improved count accessibility during relief periods; **(8)** Full alignment with AORN, JACHO, AST, and WHO guidelines.

The mapped back table drape is believed to be the first of its kind to direct standardization in the operating room. Some would argue how a 'simple mapped back table drape' could have such a profound impact on the intraoperative process. The answer is straightforward: examine the decades of negative effects hospitals, staff, and — most significantly — patients have suffered from a non-standardized operative process.

Authors, Contributors & Disclosures

John Paul Cerda Sr., RN BSN CNOR CRNFA WCC

Adventist Hospital Lodi, CA — President, JohnMark International, Inc.

John Paul Cerda Sr. is an officer and party in interest in JohnMark International, Inc., the underwriter of this study, and declares that he has material financial interests related to the promotion of the research described in this paper.

Correspondence: *John@johnmarkintl.com*

Mark Lowenstein, Legal Services

Sandy, Oregon — Vice President, JohnMark International, Inc.

Mark Lowenstein is an officer and party in interest in JohnMark International, Inc., the underwriter of this study, and declares that he has material financial interests related to the promotion of the research described in this paper.

Correspondence: *Mark@johnmarkintl.com*

Laura R. Schmidt, RN BSN CNOR RNFA

Clinical Educator, Adventist Hospital Lodi, CA

Laura R. Schmidt has no declared affiliation that could be perceived as posing a potential conflict of interest in the publication of this article.

Bibliography of References

1. Aouicha, W., Tlili, M.A., Sahli, J., et al. (2022). Patient safety culture as perceived by operating room professionals: A mixed-methods study. *BMC Health Services Research, 22*(1), 799. https://doi.org/10.1186/s12913-022-08175-z

2. Sentinel Event Data Summary. The Joint Commission. (2023). Retrieved April 8, 2023 from https://www.jointcommission.org/resources/sentinel-event/sentinel-event-data-summary

3. Sloane, T. (2013, August 12). The high cost of inaction: Retained surgical sponges are draining hospital finances and harming reputations. *Becker's Hospital Review.* https://www.beckershospitalreview.com/quality/the-high-cost-of-inaction-retained-surgical-sponges-are-draining-hospital-finances-and-harming-reputations.html

4. Sentinel Event Alert, Issue 51. The Joint Commission. (October 17, 2013). https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/sea_51_urfos_10_17_13_final.pdf

5. Rafter, N., Hickey, A., Condell, S., et al. (2015). Adverse events in healthcare: Learning from mistakes. *QJM: An International Journal of Medicine, 108*(4), 273–277. https://doi.org/10.1093/qjmed/hcu145

6. Kyle, E. (2023). Preventing unintentionally retained surgical items. *AORN Journal, 117*(3), 192–199. https://doi.org/10.1002/aorn.13885

7. Saver, C. (2022). Retained surgical items: Overview of a persistent problem in health care. *AORN Journal, 116*(2), 111–115. https://doi.org/10.1002/aorn.13747

8. Goodwin, B. (2018, May 1). Retained surgical item lawsuits will cost you. *Urology Times.* https://www.urologytimes.com/view/retained-surgical-item-lawsuits-will-cost-you