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“After 18 months of continuous use of the data-matrix-coded DMS system throughout our surgical practice, in which some 1,862,373 sponges were counted, we had no retained-sponge events.”

—Cima et al. (p. 55)

Eliminating Retained Surgical Sponges

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Performance Improvement

Using a Data-Matrix–Coded Sponge Counting System Across a Surgical Practice: Impact After 18 Months

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The publication of the Institute of Medicine (IOM) report *To Err Is Human* in 1999 highlighted the state of patient safety in the hospital environment.¹ Following the IOM report, the National Quality Forum released a list of “27 Never Events,” which described those medical errors that should never occur in a United States hospital.² Four of the 27 events directly related to patient safety in the operating room (OR): operations involving the wrong patient, wrong-site and wrong-side surgery, and retained surgical items (RSIs) after surgery. Patient-related hospital errors, especially those occurring in the OR, result in intense and often critical public scrutiny. A dramatic example of OR errors are RSIs after surgery.³

The true incidence of RSIs after intraabdominal surgery in the United States is unknown. Estimates range from 1 in every 1,000 to 1,500 abdominal operations to 1 in every 8,000 to 18,000 inpatient operations.^{4,5} Risk factors for RSIs on the basis of insurance claims data include emergency procedures, unplanned change in operation, and body mass index.⁵ We previously reported our experience of RSIs at the Mayo Clinic, Rochester (MCR).⁶ During the four-year analysis period, 191,168 operations were performed, and 34 RSIs were discovered, resulting in an overall incidence of 0.178 RSIs/1,000 operations, or approximately 1 RSI per 5,500 cases. In our experience, none of the RSIs occurred in patients with the risk factors described in other studies.⁵ However, similar to other reports in the literature, our most common RSI was a cotton sponge product—with 23 sponges (68% of RSIs) retained. Also, consistent with others’ findings, the majority of our RSIs occurred despite a “correct” count being reported before completion of the operation. Surprisingly, those items that are routinely counted most frequently during an operation, cotton sponges, are the items most commonly miscounted and retained.

Although a multidisciplinary effort can significantly reduce the incidence of RSIs, such efforts have not been shown to completely eliminate them for a sustained period of time.⁷ A number of technologies have recently been introduced in an

Article-at-a-Glance

Background: Retained surgical items (RSIs), most commonly sponges, are infrequent. Yet despite sponge-counting standards, failure to maintain an accurate count is a common error. To improve counting performance, technology solutions have been developed. A data-matrix–coded sponge (DMS) system was evaluated and implemented in a high-volume academic surgical practice at Mayo Clinic Rochester (MCR). The primary end point was prevention of sponge RSIs after 18 months.

Methods: Two trials were conducted before implementation. A randomized-controlled trial assessed the system’s function, efficiency, and ergonomics. The second, larger trial was conducted to validate the prior findings and test product improvements. After the trials, the system was implemented in all 128 operating/procedure rooms across the MCR campus on February 2, 2009. The institutionwide implementation was intended to avoid the possibility of having standard unmarked sponges and DMSs in the operating room suite concurrently.

Results: Before implementation, a retained sponge occurred on average every 64 days. Between February 2009 and July 2010, 87,404 procedures were performed, and 1,862,373 DMSs were used without an RSI ($p < .001$). After four cases, the average time to count a DMS decreased from 11 to 4 seconds. Total sponge counting time/operation increased without any increase in overall operative time.

Conclusions: After 18 months, a DMS system eliminated sponge RSIs from a high-volume surgical practice. The DMS system caused no work-flow disruption or increases in case duration. Staff satisfaction was acceptable, with a high degree of trust in the system. The DMS system is a reliable and cost-effective technology that improves patient safety.

attempt specifically to prevent retention of cotton sponge products during surgical procedures.⁸⁻¹⁰ There are two major types of technologies: (1) sponges with unique identifying data-matrix codes (previously known as bar codes) annealed onto the sponge and (2) sponges with a radiofrequency (RF) chip embedded into them. The data-matrix-coded system is solely a counting system for sponge products. If used properly, it records the number of sponges scanned into the case and at the end reconciles the number of sponges scanned out of the case. Depending on the product, the RF technology can act solely as a counting technology or additionally as a detecting technology with the use of a handheld device to scan the patient for the presence of a sponge if one is missing from the final count. The few studies regarding these products are quite limited in scope and do not address the real-world effectiveness of these technologies being implemented across an entire OR practice. Specifically, there are no reports of long-term results on sponge RSI reduction after implementation of a technology in a surgical practice.

In this study, we describe the technology assessment of a data-matrix-coded sponge (DMS) system through two internal trials and after full implementation in the operating and surgical procedure rooms at MCR. The system includes individually unique data-matrix-coded cotton sponge products (Figure 1, right, also available in online article) and a data-matrix-reading scanner that keeps a running ledger of the sponges scanned onto and off of the sterile field (Figure 2, page 53, also available in online article). Safety performance after implementation, as measured by the incidence of retained sponge products and staff satisfaction, was evaluated.

Methods

COUNTING OF SPONGES

The surgical staff at MCR follow the Association of periOperative Registered Nurses (AORN) recommended practices for counting sponges.¹¹ Our standard sponge-counting policy is to have the certified surgical technician and circulating nurse perform concurrent visual and audible sponge counts throughout the procedure. According to policy, counts had to

The Data-Matrix-Coded Sponge System



Figure 1. The data-matrix-coded sponge (DMS) system includes a wide variety of labeled cotton surgical sponge products. Each sponge or towel has a unique data-matrix tag annealed to the item. This tag contains the unique code identifying the individual sponge. After the sponge is scanned into the scanner, it must be scanned out to remove it from the case sponge ledger. The sponge packs are secured with a band labeled with a “master band.” This data-matrix-coded band has the data for each individual sponge within the package. Scanning this band loads into the scanner all the individual sponges, avoiding the need to scan each individual sponge onto the field. However, each sponge must be scanned out at the end of the procedure. (Figure 1 is available in color in online article.)

be performed at the beginning of the case, with any addition or removal of sponges from the sterile field, at the closure of any body cavity, with change in nursing personnel, and before the last stitch is placed. For the DMS system (pilot cases and after full implementation), the standard counting practices as described were performed, and, in addition, the sponges were scanned using a pole-mounted data-matrix tag reader before adding sponges to or when sponges were removed from the sterile surgical field.

TRAINED OBSERVERS

Quality management services staff trained surgical service nursing staff in proper observational techniques and use of standardized data intake forms. In the first phase (February–March 2008), two trained observers were present in each OR, collecting data independently to determine the inter-observer reliability. In the second phase (August 2008), one trained observer collected the data in each OR during the pilots in the surgical specialties.

Data-Matrix Scanner



Figure 2. The data-matrix scanner shows the type of and the number of sponges still on the sterile field and the number of sponges that have been removed from the sterile field. (Figure 2 is available in color in online article.)

STATISTICAL ANALYSIS

Statistical analysis was performed using Minitab software (version 14.2; State College, Pennsylvania).

TRIAL PHASE 1 METHODS AND METRICS

All testing and evaluation of the DMS system were carried out at MCR, a tertiary-referral academic medical center in the upper Midwest, in 2008. There are 117 inpatient and outpatient ORs, 3 obstetrical ORs, and 8 labor & delivery (L&D) birthing rooms on the MCR campus, distributed between two acute care hospitals. All operating and L&D rooms are staffed by MCR physicians, nurses, and allied health staff. All staff members are employed under one organizational leadership structure with a unified policy and procedure manual for OR

conduct, including sponge counting.

A Plan-Do-Study-Act (PDSA) methodology was adapted to evaluate the DMS system in our ORs. In the first PDSA cycle, a total of 16 cases was randomly assigned to either the DMSs (Pilot A) or standard surgical sponges (Control A) on the basis of the availability of the observer teams. Patients undergoing an elective, weekday procedure in cardiovascular surgery or colon and rectal surgery were eligible for the randomization during the one-week trial period. A trial was performed in two ORs for cardiovascular surgery and two ORs for colon and rectal surgery. Surgical staff in the specialties were trained on the use of the DMS system equipment during the week before the trial. Two trained observers were in the room to independently evaluate system performance and collect appropriate data.

The following technical performance metrics were collected:

- Interobserver reliability
- Average time spent counting a sponge (time spent to count sponges at the beginning of the case, during the case for addition or removal of sponges from the sterile field, during permanent personnel changes, and before the last stitch is placed, divided by the number of sponges used)
- Learning curve for scanning DMSs
- Total time spent to count sponges
- Battery life of the scanner

In addition, the staff's impression of product features and work flow were assessed with a standardized new product survey.

TRIAL PHASE 2 METHODS AND METRICS

In the second PDSA cycle, a trial was performed in four ORs in each of the following specialties: colon and rectal, cardiovascular, and general surgery. DMSs were used in all elective cases in each of the four ORs for a period of one week. Trained observers were present in the surgical suite to help with any technical difficulties experienced by the staff. The observers were not assigned to specific cases but moved from case to case.

Data were gathered from a total of 57 surgeries in the single week. In this phase, upgrades to the DMS system software were made on the basis of feedback from staff from the first phase in regard to the patient data entry screens. In addition to the metrics used for first phase, data were collected to verify accuracy of the "master bands," which was a new packaging style introduced by the manufacturer. Master bands contained unique sponge-identifying information of the 5 or 10 sponges included in the pack, thereby eliminating the need to scan in each sponge from the package. However, each individual sponge must be scanned out when it is removed from the sterile field.

IMPLEMENTATION PHASE 3 METHODS AND METRICS

In November 2008, after review of the trial data, it was decided to implement the DMS system in all operating and L&D rooms at MCR. After education and training of all surgical services staff, use of the DMS system was begun across the MCR campus on February 2, 2009. Evaluation of use, performance, and staff satisfaction were assessed one year after implementation. Institutional Review Board approval was obtained for data collection, staff survey, data analysis, and publication.

Results

TRIAL PHASE ONE

Interobserver Reliability. The interobserver reliability for sponge counting in the trial rooms was determined to be excellent, with the mean count times recorded by the two observers not being statistically different ($p < .650$).

Time to Count. The average time to count a sponge for control sponges was 4.0 seconds ($n = 335$) versus 11.4 seconds for the DMSs ($n = 365$; $p < .05$). The average time to count was significantly different ($p = .002$) between the colon and rectal (8 seconds) and cardiovascular services teams (13 seconds). The times to count at three different stages (at start of the case, during the case, and at the end of the case) were also significantly different ($p = .006$). The average time to count a sponge for the DMSs at the start of the case was 6 seconds, whereas the time to count in a sponge during the case was 12 seconds, and the average time to count out a sponge was 16 seconds. The average time to count a sponge in the same OR for four days (learning curve effect) is shown in Figure 3 (right). The average time to count a sponge decreased from 11 seconds on day 1 of the trial to 5 seconds on day 4—or about the same as for counting unmarked sponges—for the colon and rectal surgery ORs.

Battery Performance. To assess the duration of scanner battery performance during longer procedures, the percent charge left in the battery over the duration of the case without placing it in the charger was measured. The units retained a charge of 40% or higher after five hours of use.

TRIAL PHASE TWO

The goals of the second phase trial were to (a) conduct the study in a larger setting, assess the impact on work flow across

Average Time to Count a Sponge with Use of the Data-Matrix Coded Sponge (DMS) System in a Single Operating Room (OR)

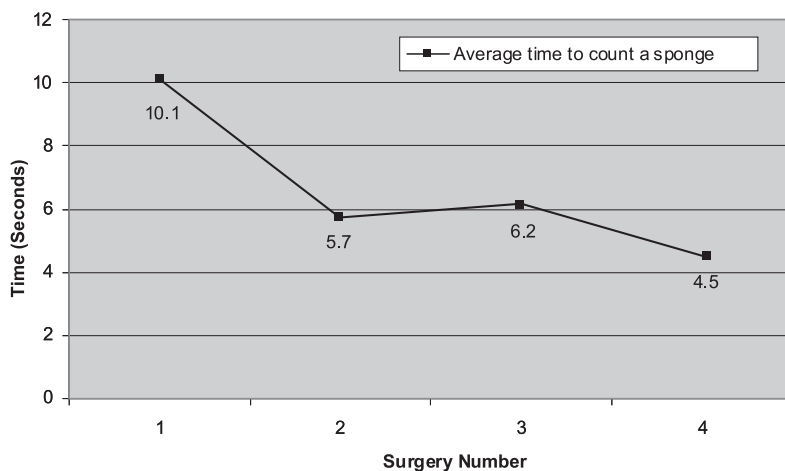


Figure 3. The learning curve for use of the sponge system in a single operating room demonstrated that after four cases the time to count individual sponges decreased from 10.1 seconds on Day 1 to 4.5 seconds on Day 4.

more diverse case types, and validate the Phase 1 results; (b) assess the changes made to the scanner-user interface on the basis of the staff feedback; and (c) study the effectiveness of the new master-band packaging released by the company to speed up the count-in process (especially in emergent situations).

Time to Count. The two specialties, colon rectal and cardiovascular surgery, that participated in the first pilot showed a decline in the mean count times for the DMSs from 8.0 seconds to 4.5 seconds and from 13.2 seconds to 11.2 seconds, respectively. In the general surgery ORs—a new specialty for the study—mean counting times were similar to those observed in Trial 1 for the other specialties.

IMPLEMENTATION PHASE THREE

The DMS system was implemented across the MCR campus on February 2, 2009. An institutionwide implementation was performed rather than a multiphased approach to avoid the possibility of having standard unmarked sponges and DMSs in the OR suite concurrently. Implementation followed a two-month period of staff education and training.

After 18 months of continuous use in 87,404 operations/procedures, 1,862,373 DMSs were used without a single sponge retained. During this period, our institution continued the practice of postoperative high-resolution x-rays in a dedicated radiology unit at the completion of surgery. In the preceding six years, MCR was averaging a cotton sponge RSI every 64

Interval Between Retained Sponge Items (RSIs), January 2003–July 2010

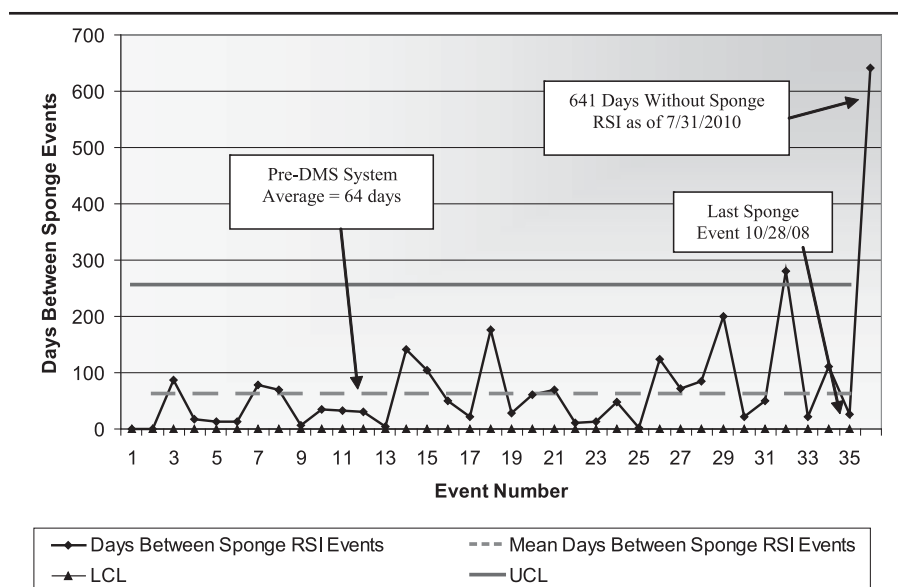


Figure 4. This G-chart presents the interval between sponge RSIs from January 2003 through July 2010 at Mayo Clinic Rochester. The data-matrix coded sponge system was introduced in February 2009. DMS, data-matrix-coded sponge; LCL, lower control limit; UCL, upper control limit. (Figure 4 is available in color in online article.)

days (Figure 4, page 55, also available in online article). This change in event frequency represents a significant reduction ($p < .001$) related to the implementation of the DMS system. System performance on RSI prevention is monitored daily by our surgical safety team [R.R.C., J.C., S.P., C.W.] in collaboration with the Institutional Sentinel Event group. To date, there have been three reported events where the manual count had reconciled all the sponge counts as correct but the DMS system was not reconciled. Intraoperative x-rays or wound exploration revealed the sponge before completion of the procedure, thus avoiding an RSI.

STAFF SURVEY

After each of the two trials and after one year of system use, OR staff were electronically mailed a multiquestion survey. Return of the survey was voluntary. No effort was made to ensure that staff had completed both surveys or had been in the OR during the entire year after implementation. Each question used a 5-point Likert scale, with 1 indicating “strong dislike” and 5 indicating a “strong liking.” The summary of the results from the survey are provided in Table 1 (page 56). Additional comments from the staff were documented in the comments section of the survey. The percentage of 4 and 5 scores (4,

“somewhat like the DMS system”; 5, “strongly like the DMS system”) increased during the first year of use. Confidence in reliability of the system was relatively unchanged. Given the limits of the survey methodology, a statistical analysis of the survey results was not conducted.

Discussion

RSIs after surgical or invasive procedures continue to challenge OR staff as significant medical errors. Cotton sponges are the most common retained items despite national standards for sponge counting.^{5,6,12} In a multiphase technology assessment of a DMS system at MCR, which entailed two internal randomized controlled trials, the system performed within the specified technical parameters and did not disrupt the flow of the surgical case. After 18 months of continuous use of the DMS system throughout our surgical practice, in which some 1,862,373 sponges were counted, we had no retained-sponge events. There was no increase in overall operative time related to this sponge-counting technology. The learning curve for use was extremely short (< four cases). Staff satisfaction with the system was acceptable, with a high degree of confidence in the reliability of the system.

Although many retained sponges are detected in the early postoperative period, reports of retained sponges causing chronic symptoms or incidentally being found years to decades after the index operation are unfortunately quite frequent.¹³⁻¹⁶ RSIs including sponges are associated with significant morbidity (small-bowel fistula, obstruction, visceral perforation, re-operations to remove the object) and, rarely, death.¹² Despite national practice standards related to sponge and instrument counting, these protocols are apparently not sufficient to avoid RSIs.¹¹ As noted by Christian et al., the counting procedures are well designed and nearly universally performed and account for as much as 14% of total operative time.¹⁷ Unfortunately, this seemingly “easy” counting task is error prone because it is performed in a discontinuous fashion throughout a complex procedure with multiple interruptions, competing demands and tasks, and possibly numerous participants, which leads to errors.

As our previous experience has demonstrated, reliance on

Table 1. Percent of 4 (“Somewhat Like”) or 5 (“Strongly Like”) Scores on a Voluntary Staff Survey Regarding the Data-Matrix–Coded Sponge (DMS) System (N =)*

Question	Before DMS System Implementation (2 Trial Periods)	One Year After DMS Implementation
How do you rate the DMS–counting process?	41%	60%
How comfortable do you feel with the DMS process?	65%	82%
Compared with the manual sponge counting process, how would you rate the DMS–counting process?	18%	52%
Compared with the manual sponge counting process, did the DMS–counting process decrease stress associated with counting?	0%	31%
The DMS–counting process is very efficient.	53%	59%
Do you have a high level of confidence in the accuracy of the DMS–counting process?	88%	81%

* The responses are from a convenience sample of staff who voluntarily completed the survey. The number of respondents varied from 65 in trial phase one to 60 in trial phase two and 204 one-year postimplementation.

policy and repeated education efforts does not lead to zero-sponge RSIs.^{6,7} Even with those efforts, during this study period three near-miss events occurred that would not have been detected until the patient had left the OR and had his or her postoperative x-ray if it had not been for use of the DMS system. In the absence of a highly reliable and accurate accounting system for sponges, interventions based solely on educating staff or expecting them to strictly adhere to all counting policies will likely not be completely successful.⁷

In other industries where repetitive tasks are performed or products need reliable tracking in a high-throughput system, there is a strong reliance on technology. In regard to accounting for surgical sponge products, there is limited literature on the use of RF sponge-tracking systems. Macario et al., reporting on the initial clinical experience in the use of RF sponge-tracking systems in a proof-of-concept trial in eight patients, found 100% detection of a single sponge placed in the abdomen.⁹ At present, there is no published trial or real-world clinical experience with an RF system through which to evaluate its effectiveness. Bar-code technology, which has been used for decades in numerous industries, has an established track record of success in improving safety in the health care environment.^{18,19} Greenberg et al. evaluated the performance of the DMS system in a randomized controlled trial in 300 general surgery operations.¹⁰ Use of the DMS system as compared with the standard process led to the identification of significantly more count discrepancies. Greenberg et al. also found that total time devoted to sponge counting increased significantly from 2.4 to 5.3 minutes. Furthermore, some type of difficulty with

the technology was reported for 17 of the 150 cases. In our studies, we did not assess the number of counting discrepancies, if any, that required resolution. We also found that the DMS system increased sponge-counting time. However, the learning curve was quite short, and after four cases using the technology the time that staff spent in counting sponges (mean, five seconds) was very similar to the time associated with the standard counting process of non–DMS sponges (mean, four seconds). Although we did find that time devoted to sponge counting with the DMS system did increase, it did not increase the overall case length; sponge counting is a parallel process that occurs during the course of the operation rather than just at the end of the procedure. Furthermore, the time to count—that is, scanning time—was reduced by 50% by the introduction of master tags for each pack of sponges.

Much as found by Greenberg et al.,¹⁰ a survey of our staff at the time of testing and implementation demonstrated no strong preference for use of the bar-coding technology but recognition of the improved accuracy. However, after a year of use, staff impressions substantially improved. Staff clearly are more comfortable with the system and associated process. Importantly, a sizable number of staff believe that the DMS system has reduced the stress of counting in our ORs.

COST-BENEFIT

Although the addition of any new technology requires an analysis of the economic impact, only limited data are available on the economic cost of RSIs. In the analysis of RSI cases reported by Gawande et al., the cost per event averaged

\$52,581 for compensation and legal-defense expenses.⁵ However, others have suggested that total legal costs are much higher, exceeding \$200,000 per event.^{20,21} Furthermore, recent Medicare changes in 2008 made RSIs nonreimbursed events, which needs to be factored into the institutional cost of RSIs.²² Because RSIs are fortunately a rare event, assessing the economic impact of prevention strategies is difficult. Modeling has been used to estimate the cost-effectiveness for different modalities to detect/prevent RSIs. Dossett et al., who modeled the use of routine intraoperative x-rays for all emergent open-cavity cases, found that it was an economically appropriate approach.²³ Although emergent cases are one risk factor for RSIs, others include obesity, high blood-loss procedures, changes in operative plan, and multiple-team cases.^{5,24} Targeted screening for RSIs on the basis of risk factors is one approach. However, in an evaluation of nearly a quarter million operations at a single institution, none of the 34 RSIs occurred with one of the reported risk factors.⁶ Given the uncertainty of targeted screening, technology applied universally needs to be considered. Regenbogen et al. used standard counting, a DMS system, mandatory x-rays, and RFID to model selective and universal screening for prevention of sponge RSIs.²⁰ They concluded that data-matrix coding was the most cost-effective modality when balancing prevention of a retained sponge and the cost of implementation, whereas selective and universal x-rays were considered prohibitively expensive, with RFID falling somewhere in between. The implementation costs and one-year utilization at our institution has resulted in an average case cost increase of \$11.63 directly related to the DMS system.

Cost factors associated with the prevention of sponge RSIs or dealing with sequela of such events must be quantified by each institution to determine the cost-benefit of implementing this OR patient safety technology. For example, the additional OR time required in resolving miscounts during the case has been shown to average 13 minutes per event.¹⁰ The time spent in meetings for the involved staff and completion of a root cause analysis for such events, the reporting process, and implementing solutions all need to be considered. Finally, in an era of mandatory public reporting of major adverse patient events, the institution's reputation might be negatively influenced by such publicity.

LIMITATIONS

This study represents a single institution's experience with the DMS system. OR processes vary widely, and introducing any new technology requires a detailed analysis of the affected work flows and institution's needs. In addition, the highly cen-

tralized organizational structure of our institution may limit the generalizability of our experience to other organizations. All stakeholders in the OR are employees of the Mayo Clinic. An essential element of our organizational culture is to build consensus for process change. However, if organizational leadership decides that a specific process change is aligned with institutional goals, then that process will be implemented. In other organizations, the influence of individuals or groups might hamper the successful implementation of the DMS system. Finally, implementation of the DMS system was part of a multiyear staff education and quality improvement process, which most likely significantly contributed to the successful implementation.

Summary and Conclusion

A high-volume academic surgical practice eliminated cotton sponge RSIs through the implementation of a DMS system and has maintained this performance level for more than 18 months. Through a multiphase trial, we determined that the technology was simple to use and could be implemented across a large multispecialty surgical practice with minimal work-flow disruption. The technology was acceptable to the users, and the economic impact of implementation on a per-case cost was considered acceptable, given the significant improvement in patient safety. This technology, which appears to be reliable and effective, should be considered as an adjunct to standard OR sponge-counting practices. **J**

Online-Only Content

See the online version of this article for

Figure 1. The Data-Matrix-Coded Sponge System (color version)

Figure 2. Data-Matrix Scanner (color version)

Figure 4. Interval Between Retained Sponge Items (RSIs), January 2003–July 2010 (color version)

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The Data-Matrix Coded Sponge System



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Data-Matrix Scanner



Figure 2. The data-matrix scanner shows the type of and the number of sponges still on the sterile field and the number of sponges that have been removed from the sterile field.

Interval Between Retained Sponge Items (RSIs), January 2003–July 2010

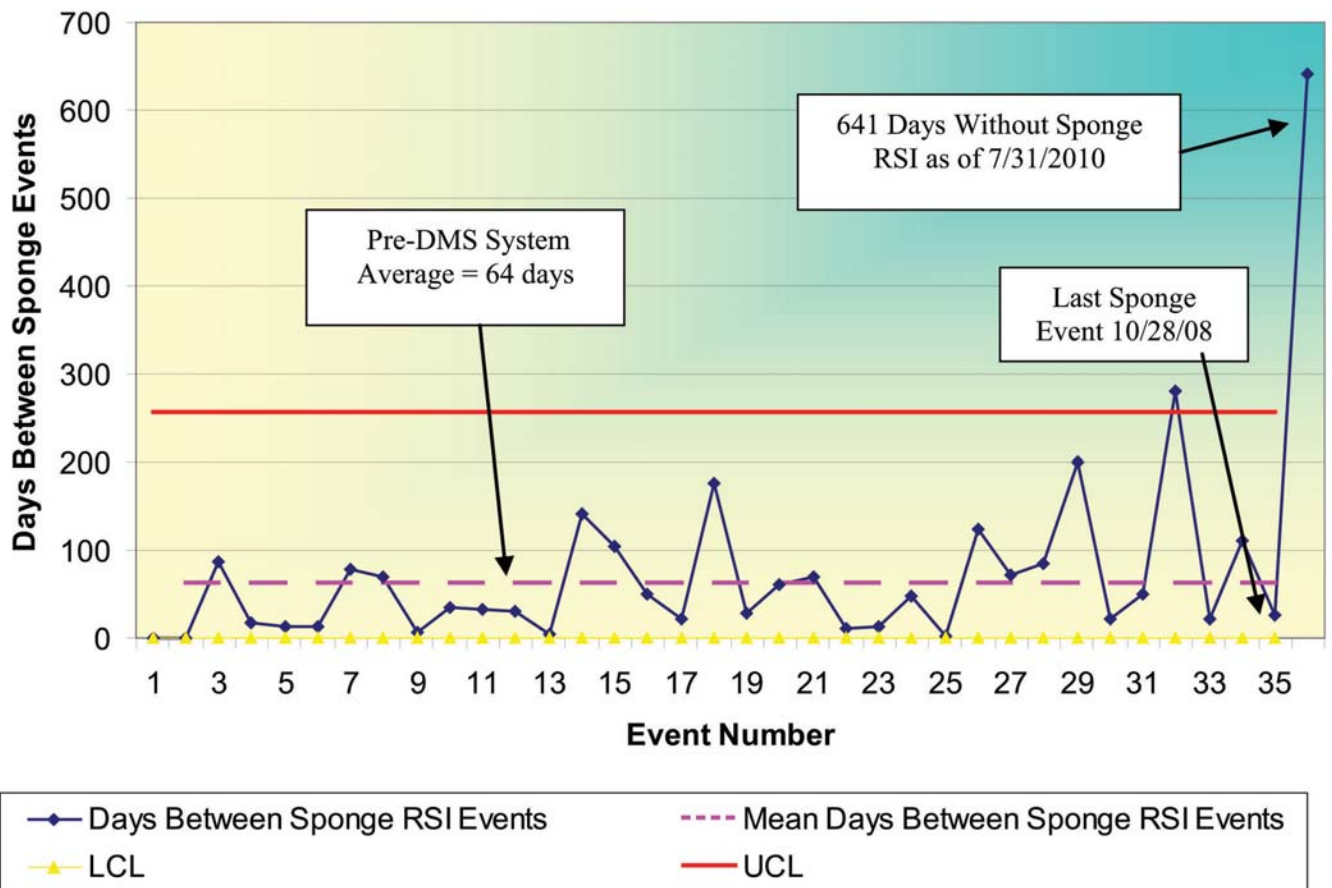


Figure 4. This G-chart presents the interval between sponge RSIs from January 2003 through July 2010 at Mayo Clinic Rochester. The data-matrix coded sponge system was introduced in February 2009. DMS, data-matrix-coded sponge; LCL, lower control limit; UCL, upper control limit.