

Performance Improvement

A Multidisciplinary Team Approach to Retained Foreign Objects

Robert R. Cima, M.D., M.A.; Anantha Kollengode, Ph.D., M.B.A.; Amy S. Storsveen, R.N., B.S.N.; Cheryl A. Weisbrod, R.N., M.S.; Claude Deschamps, M.D.; Mark B. Koch, M.B.A.; Debra Moore; Sarah R. Pool, R.N., M.S.

Retained foreign objects (RFOs) after a surgical procedure are one of the more dramatic medical errors that occur in hospitalized patients.¹ These events can be associated with significant patient morbidity or mortality. Furthermore, they can have a significant negative impact on provider as well as institutional reputation and can result in litigation.² The frequency of surgical RFOs is estimated to occur in 1 of 1,000 abdominal operations or up to 1 of every 18,000 operations performed.^{3,4} These reports have evaluated the characteristics of procedures, patients, or operative circumstances that predispose to RFOs. Gawande and colleagues performed the first case-control analysis and identified emergency procedures, unplanned changes in a procedure, and higher body-mass index (BMI) as significant risk factors for surgical RFOs.⁴ However, not all reports of surgical RFOs have demonstrated an association with these risk factors.⁵

Although many authors have described the frequency, types, and outcomes associated with surgical RFOs, few have described concerted institution-based efforts to reduce the frequency of these adverse events. Gibbs stated that rather than relying on a single system, prevention of RFOs warrants development of a multifaceted defense.⁶ This article describes a multidisciplinary effort implemented in all the operating rooms (ORs) and surgical procedural areas at the Mayo Clinic, Rochester (MCR) to address the issue of surgical RFOs.

The RFO reduction effort was led by a leadership team composed of surgeons, nurses, quality management personnel, sentinel event team members, and administrative services personnel. The team's goal was to reduce the incidence of RFOs toward zero. This single team addressed all elements of this initiative in a systematic fashion during the four-year period included in this report. This effort is ongoing and has been divided into three phases: defect analysis and policy review, awareness and communication, and control and monitoring. The RFO reduction effort has resulted in a significant and sustained reduction in the frequency and types of surgical RFOs and has provided a model for all OR quality improvement (QI) efforts at MCR.

Article-at-a-Glance

Background: Retained foreign objects (RFOs) after surgical procedures are an infrequent but potentially devastating medical error. The Mayo Clinic, Rochester (MCR), undertook a quality improvement program to reduce the incidence of surgical RFOs.

Method: A multidisciplinary, multiphase approach was initiated in 2005. The effort, led by surgical, nursing, and administrative institutional leaders, was divided into three phases. The first phase included a defect analysis and policy review. A detailed analysis of all RFOs (both true and near misses) was undertaken to identify patterns of failures unique to our institution and operating room culture. Simultaneously, a review of all relevant institutional policies was performed, with comprehensive revisions focusing on increased clarity and inter- and intrapolicy consistency. The second phase involved increasing awareness and communication among all operating room personnel, including surgeons, residents, nursing, and allied health staff. The education program included all-staff conferences, team training, simulation videos, and daily education reminders and in-room audits. Finally, a monitoring and control phase involved rapid leadership response teams to any events, enhanced staff communication, and policy reviews.

Results: When the program started, MCR was averaging a surgical RFO every 16 days. After the intervention, the average interval between RFO events increased to 69 days, a level of performance that has been sustained for more than two years.

Discussion: MCR experienced a significant and sustained reduction in the incidents of RFOs, attributed to the multidisciplinary nature of the initiative, the active engagement of institutional leadership, and use of the principles of enhanced communication between operating room staff members to improve operating room situational awareness.

Quality Improvement Process

SETTING

Approximately 50,000 operations are performed annually in the 98 main ORs, 3 obstetrical ORs, and 8 labor and delivery birthing rooms on the MCR campus distributed between two acute care hospitals. The staff in the OR include more than 300 surgeons and 450 anesthesia providers, nearly 500 residents, and 1,500 nursing and allied health staff.

The RFO reduction initiative was divided into three distinct phases. The time lines for these phases are shown in Figure 1 (right).

Phase I: Defect Analysis and Policy Review

The initial effort of our team was to perform a detailed analysis of all surgical RFO events and any near-miss events reported to the institutional sentinel event team at MCR during the calendar years 2003–2006. The results of this analysis have been previously reported.⁵ During the four-year analysis period, 191,168 operations were performed. There were 34 near-miss events and 34 true RFOs. Near misses were classified as events where there was thought to be a retained object but none could be demonstrated by high-resolution intra- and postoperative imaging; a true RFO was defined as the unintentional retention of a foreign object discovered after completion of the operation. The 34 items retained included 23 sponges, 1 instrument, 3 needles, and 7 miscellaneous items. None of these RFOs occurred in cases that were considered to be high-risk cases as previously defined by Gawande et al.⁴ Another important finding was that in 62% of the true RFO events the “counts” at the end of the operations were considered correct. Root cause analysis (RCA) performed on each RFO event demonstrated that a failure of communication among OR team members was the most frequent contributor to the event. Communication failures is one of the most cited reasons for events leading to inadvertent patient harm,^{7–9} and many of the Joint Commission patient safety standards are aimed at improving communication.⁷

After the detailed defect analysis was performed, a complete review of all procedures and policies relevant to OR efforts to mitigate RFOs was undertaken by surgical and nursing leadership. First, there was an effort to develop a single operational definition of what was considered an RFO. An RFO at MCR was defined as follows:

Time Lines for the Three-Phase Project

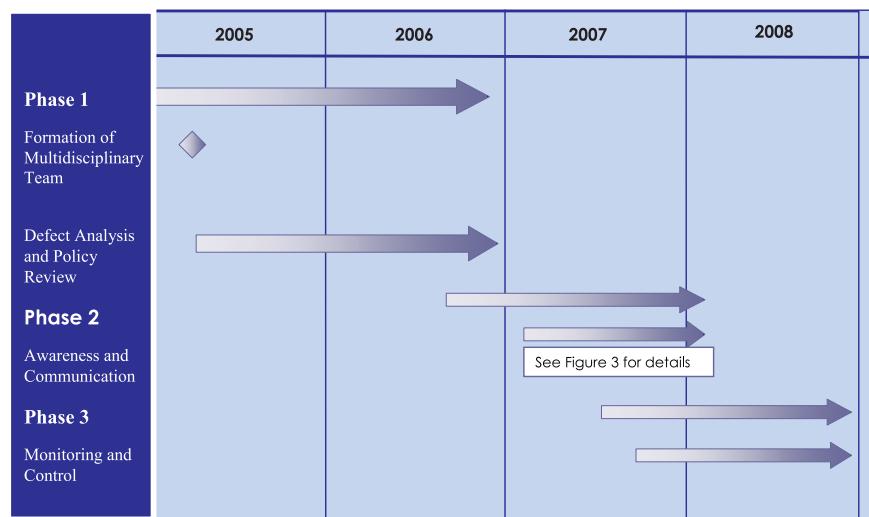


Figure 1. The time line for the three phases of the project are shown.

Any item that is unintentionally left within a patient and discovered by the patient care team after the primary operative skin incision has been completely closed and final sterile dressing applied. In cases of procedures that do not have an incision, an item would be defined as an RFO if found after the operative team has completed the procedure.

Second, our team reviewed all policies and procedures related to the operative counting process. The review of policies included how an instrument and sponge count was to be performed, who performed the count, what was required to be counted, how the count was documented, how to reconcile miscounts when they occurred, how to manage intraoperative imaging for possible RFOs, and who is accountable for responding to adverse events. During this review process, team members discovered that many of the policies had been amended or altered over time in response to specific events without a complete revision of the entire policy or consideration of how it related to other policies. This type of “one-off” amendment in response to specific events resulted in long and confusing policies that often had intra- and interpolicy contradictions. The resulting differences made implementation of uniform practices across the OR environment difficult. In response to these findings, all relevant policies were revised by a leadership team composed of nursing and physician members. These policies were aligned with external standards and internal best practices on the basis of the findings within the defect analysis.¹⁰ Furthermore, great effort was made to ensure intrapolicy and interpolicy consistency. Drafts of revised policies were distrib-

uted to all OR personnel for their review to ensure clarity of the language and identification of any deficiencies. Once staff feedback had been obtained, the revised policies were submitted to the appropriate surgery oversight and institutional committees for approval. Finally, a new policy and an education tool were developed to assist OR staff on how to respond to a miscount or concern about the instance of an RFO. This policy was designed collaboratively by members of the departments of radiology, nursing, and surgery (Figure 2, page 126).

Phase II: Awareness and Communication

After the detailed defect analysis and the policy and procedure review were completed, a multiphase broad-based communication and education campaign was initiated (Figure 3, page 127). In the initial phase, a mandatory all-staff meeting was convened for all OR personnel. This meeting included all staff surgeons, anesthesiologists, resident physicians, nursing staff, and allied health personnel. In total, more than 2,500 staff either attended the meeting or viewed delayed video recordings. During this meeting, institutional, surgical, and nursing leadership discussed the data and findings from the systematic defect analysis as well as a review of all the new policies to be implemented to address the surgical RFOs. Misconceptions about risk factors for RFO events and staff concerns about processes of investigations of RFOs were addressed in this open forum. The primary goal of the all-staff meeting was to ensure that all team members understood the reality and scope of the problem and to improve the lines of communication between the OR staff and leadership as well as among the OR team members. An unintended consequence of this effort was to highlight the low level and poor quality of communication within the OR environment.

The next step, which also focused on team communication and education, was led by the department of hospital surgical services. The Conscientious Count Campaign was designed as a multifaceted program to educate nurses, certified surgical technicians, and surgical assistants on the proper counting techniques and revised count policies. It included production of a video documenting the correct counting process, which was reviewed at surgical services staff meetings. The correct counting process is based on the recommendations of the Association of Operating Room Nurses guidelines for counting sponges, instruments, and miscellaneous surgical items.¹⁰ These recommendations discuss when counts are needed and how they are performed, which requires current, visual, and audible counts by two surgical services team members. Additional education included team training in the Mayo Simulation Center

and in-room audits with immediate feedback provided by frontline nurse managers. Daily “reminders” of appropriate counting technique, policies, and procedures were included in staff morning reports. The standardized counting process was implemented across all surgical specialties and surgical units, including labor and delivery, after a month-long intense training and education effort led by our OR nursing educators.

Another initiative directed at improving situational awareness by all members of the OR team was use of a counting white board with standardized documentation criteria (Figure 4, page 128). Designed by nursing leadership and refined with input from all of the OR staff, the white boards were placed in every OR. In the recognition that each specialty may have unique counting needs, magnetic labels for specialty specific items were manufactured and placed on the white boards to specifically track these unique items.

The last phase of the education effort was the introduction of two “Red Rules.” These rules, presented to and refined by the OR staff and then adopted by the OR leadership group as *inviolable* rules of conduct in the OR, were as follows:

1. The Universal Protocol for patient identification and procedural pauses¹¹ must be followed.
2. All counts of instruments and sponges must be performed by two team members in the standardized manner. During the closing pause, the surgeon and residents are to stop all activity other than performing the required appropriate local wound exploration, thus avoiding any interruptions of the count process.

Unlike other organizations that have a formalized exploration of the entire abdominal or chest cavity, our data did not demonstrate retention of items in areas distant from the localized operative field, and thus we concentrated our practice on a focused exploration in the region of operation. These rules were printed and prominently displayed in all ORs after they were shared with all surgeons, residents, anesthesiologists, nursing, and allied health personnel (Figure 5, page 129). Any team member can invoke a Red Rule to stop the procedure in the interest of patient safety. OR leadership staff respond in real time to the OR if there is any reported violation of the Red Rules to support the staff in the room and ensure patient safety.

Phase III: Monitoring and Control

After the initial staff education program, the team made the transition in its efforts from monitoring and process control. First, a rapid response event leadership team was formed. This team included surgeon, nursing, and administrative leadership members. Additional ad hoc members included quality man-

An Incorrect Decision Tree

Incorrect Counts: Discrepancy (**more** or **less**) in needles, sponges, instruments, or miscellaneous items between the sterile field and the white board/Tally Sheet.**

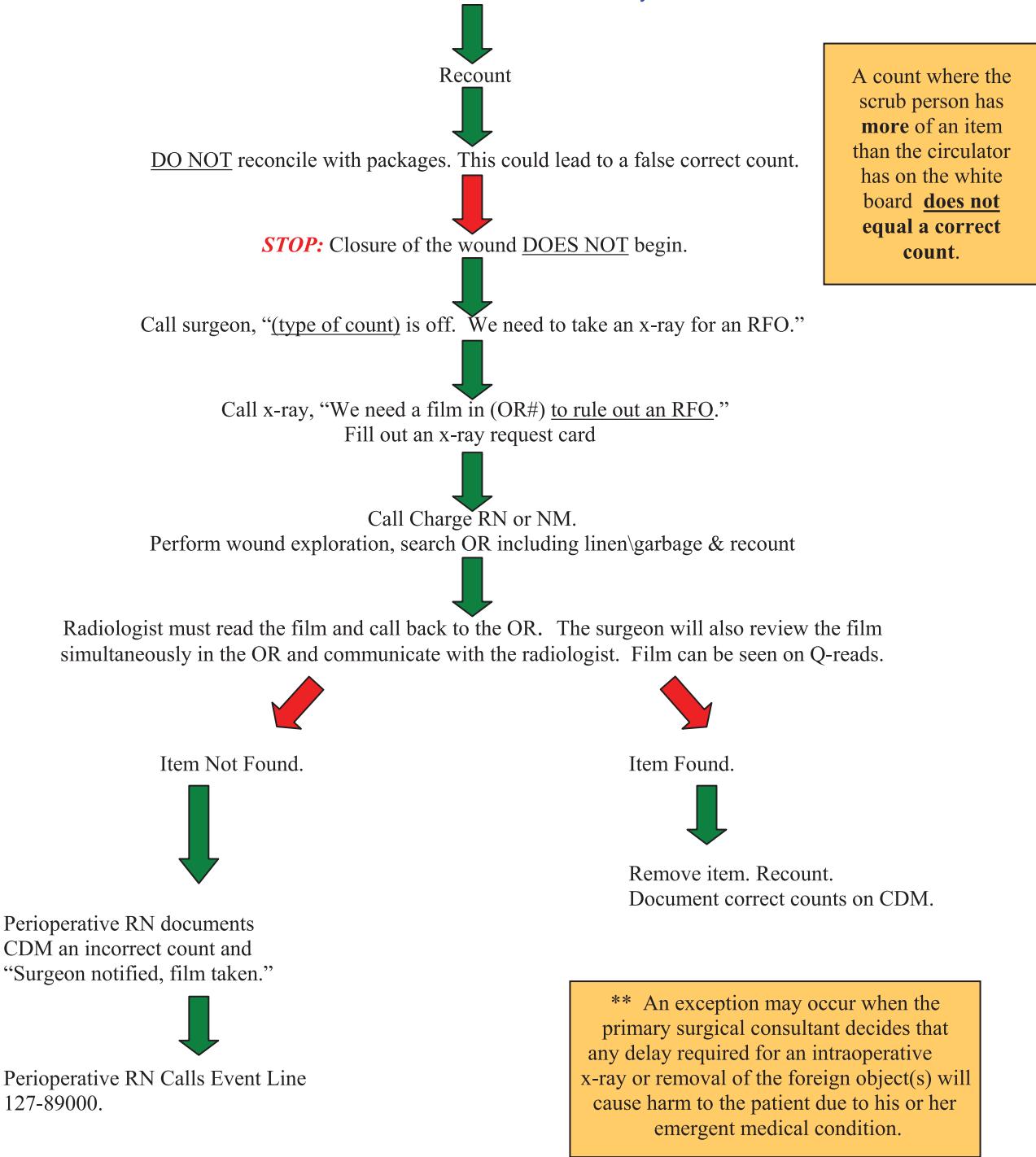


Figure 2. An incorrect-count decision tree was developed to assist operating room (OR) personnel in a standard approach to a miscount or possible retained foreign object (RFO) event. RN, registered nurse; NM, nurse manager; Q-read, Quick read (a digital imaging system); CDM, clinical documentation manager (application in the electronic medical record used for all OR-related documentation).

Phase II: Awareness and Communication Plan, 2007



Figure 3. A multiphase broad-based awareness education campaign was initiated. RFO, retained foreign object; OR, operating room.

agement services, nursing education, and institutional sentinel event personnel. This team was informed of any near-miss or real RFO event in the OR. Within 12–24 hours of the event, a meeting was convened that included the event response team and all OR personnel involved in the incident, including the surgeons, residents, nurses, and allied health staff. The purpose of the meeting was to debrief all team members as to their recollection of the events and circumstances contributing to the event. This process was not designed as a replacement for the formal sentinel event RCA or to assign responsibility for the event. Rather, it was intended to quickly inform OR leadership of the circumstances to determine areas of potential system weakness. Once the leadership team performed the analysis of the event, a memo describing the circumstances of the event and findings was prepared and shared with all OR personnel within 24–48 hours of the event (Table 1, page 130). Furthermore, once the formal RCA was completed, the findings were shared with the leadership team and then OR personnel during the morning report.

Another tactic to keep the OR staff aware of the RFO initiative was use of posters tracking the number of days since the last RFO. These posters were placed at the entrances to the ORs. In addition, RFO procedures and policies were randomly reviewed by nursing leadership at staff morning reports. Finally, quarterly all-staff meetings were held that focused on OR safety, team communication, and RFO performance updates.

Results

The impact of this multidisciplinary effort to reduce surgical RFO resulted in a significant decline in the frequency of RFO events (Figure 6, page 131). Before initiating this effort, we averaged an RFO or near miss once every 16 days. With the interventions, the interval extended to an average of one RFO every 69 days. This level of performance has been sustained for more than two years.

Surgery involves multiple items, including sponges, needles, and equipment. These are counted as part of the baseline count and in subsequent counts that occur throughout the case. The number of items routinely counted in a case often exceeds 100 unique items. Greenberg et al. reported that

counting of multiple items is performed, on average, 16 times per case; each of these counts represents an opportunity for error.¹² Assuming the potential for RFO opportunities is 25 per operative case, a defect per million opportunities (DPMO) analysis shows a decline from 0.52 to 0.11 per 1,000 surgeries. In other terms, this represents an increase in the Sigma performance level of 5.6 to 6.0 (Figure 7, page 131); a process is considered to be at Six Sigma level when there are 3.4 DPMO.

Discussion

MCR identified our rate of RFOs, especially surgical sponges, as a major quality and patient safety issue in 2005. A multidisciplinary multiphase approach was instituted with a goal of zero RFOs. This three-phased approach, which consisted of detailed analysis of our institutional experience, including review and revision of relevant policies, broad and focused educational programs, and continuous participation and monitoring by surgical and nursing leadership, led to a significant reduction in RFOs within 2 years. These efforts contributed to a reduction in the frequency of surgical RFOs from an average of one every 16 days to one in 69 days.

Surgical RFOs are often dramatic examples of medical errors. They can lead to significant patient harm and (1) negative impact to the reputations of both providers and health care organizations and (2) negative financial impact due to financial write-offs and legal claims.² Frequently, RFOs have been viewed

Sample Operating Room (OR) White Board

Figure 4. A sample OR white board is shown, with labels designating the required place for the documentation of all counted items and pertinent patient information in the OR (patient information removed). In the lower right corner is a place for any items intentionally tucked into the wound and not under the direct control of a member of the surgical team.

as isolated unfortunate events that often lead to mitigation approaches designed for the circumstances of each event. This is a common problem with a sentinel event RCA approach to individual events.¹³ Some system and patient factors have been associated with a higher risk of RFOs (emergency cases, change in the planned procedure, and higher BMI patients).⁴ However, the analysis of MCR RFOs did not reveal an association with these factors.⁵

Given the inability to identify any patient or procedural characteristics that predisposed for RFOs at our institution, a more broad-based approach to finding a solution was required. Although much of the available literature regarding surgical RFOs focuses on the types of objects retained and the circumstances surrounding the events, these sources lack recommendations about how institutions should analyze and improve their systems to minimize these events.

The multidisciplinary team, under the auspices of the surgical quality assessment and safety committee led the initiative

toward zero RFOs. As described, this program was divided into three phases: (1) failure analysis and policy review, (2) staff awareness and education, (3) monitoring and control.

The first phase required a detailed systematic evaluation of our RFO experience. This was coupled with a detailed review and revisions of existing policies and procedures in order to establish clear definitions, internally consistent policies, and performance expectations. For example, gaps were discovered in our system processes in the event of a miscount and the response time for intraoperative films were inconsistent. The policy was simplified (Figure 2) and updated to reflect "STAT" orders for suspected RFOs and to require review of the film by radiologist and consultant or designee within 30 minutes. All intraoperative films requested to evaluate possible RFOs are ordered as "rule out RFO." The item missing is *not* specifically noted on the x-ray request because this may predispose the radiologist to focus his or her initial read toward that object and to ignore other findings. Once read, the radiologist calls into the

Red Rules Poster

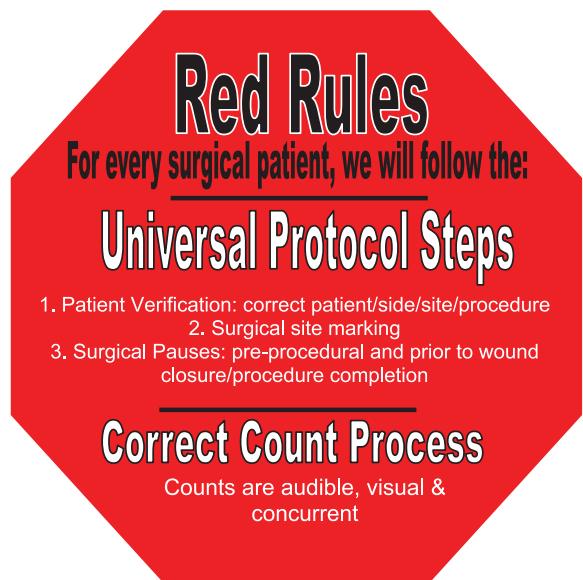


Figure 5. The Red Rules poster, displayed in every operating room (OR), provides the two inviolable rules of conduct in the OR. The poster informs all staff members that adhering to appropriate counting policy is at a level of importance equal to following the Universal Protocol to ensure patient safety.

OR and reviews all item seen on the film with the surgeon, at which time the radiologist is specifically informed of what item the team believes is missing. Response time for intraoperative RFO films and adherence to policy were reviewed monthly by the surgical quality assessment and safety committee to ensure compliance.

The second phase of the program was an intense educational effort directed at all OR personnel regarding the scope and details of the RFO problem at MCR. Again, this was approached in phases. The first was the all-staff meeting, which served many purposes important to the success of this initiative:

1. It ensured that all staff (physicians, nurses, and allied health staff) in the OR heard a single consistent message regarding RFOs.

2. It demonstrated a unified and engaged leadership team.

3. It articulated a clear and organized set of policies and procedures related to RFO reduction and prevention.

4. It set expected performance standards for all personnel in the OR.

All these elements are known to be essential for the successful implementation change within an organization.¹³

Initiated at the same time as the all-staff meeting was an extensive education effort (Conscientious Count Campaign).

This education effort included daily morning report, reviews of the appropriate and standardized counting protocols, reviews of related policies, and in-room audits. This program served to reinforce the training and performance of all OR personnel on the standardized approach to counting and responding to potential RFO events. Again, this protracted education effort, which stressed improving direct communication between all team members to improve OR "situational awareness," has been shown to be one of the most important components for successful institutional change.¹⁴

The white board served as a tool to standardize documentation of items used and any items that are tucked, thus improving the situational awareness of items placed in the surgical field. Furthermore, its use improved communication between OR staff members and was a more reliable mechanism than having to rely on the surgical staff's short-term memory. It also helped in auditing the compliance to the new guidelines of documenting counted and tucked items by nursing leadership performing daily observational audits. The new counting and documentation policies and guidelines were implemented in all ORs at the same time. However, development of specialty-specific white boards were rolled out one specialty at a time after a detailed analysis of their unique instrumentation needs. Random audits are performed daily for 5% of the cases for each specialty by the specialty nurse manager. The baseline count, tucked item documentation, and final counts are audited, and compliance has been 99.4% or higher for the latest quarter (third quarter, 2008). In the event of a miscount, compliance with the established policies and procedures is determined and documented by specialty or overall surgical nursing leadership. Importantly, all the information and findings are fed back to the OR team members.

The last phase of our effort demonstrated a new resolve by leadership to respond to RFO events. Previously, these events were addressed by the institutional sentinel event (SE) team, often in isolation and without participation of key surgical leaders (though these leaders were often invited to participate). The SE effort was often too focused on developing an RCA for the individual event and did not address the broader cultural and communication issues that exist in the OR environment. Nor did this process allow for active monitoring of the OR environment to identify the more latent safety issues. Finally, the process was slow, and the proposed solution to the event was often implemented some time after the event. All these issues reflect criticisms of the RCA process.^{15,16}

To address these concerns, a rapid leadership response team was formed to address the event within 24–36 hours with all

Table 1. Examples of Key Information from Memos to Staff After a Retained Foreign Object (RFO) Event or Near Miss*

Brief Description of Event	Root Causes Identified	Strengths Identified	Opportunities for Improvement	Next Steps Delineated
Near Miss: Needle count off, intraoperative film ordered, patient closed because patient condition before film was reviewed	Patient condition Communication gap among OR staff and radiology	Adherence to the current process	Radiology process for RFO rule-out Communication between OR staff and radiology	State in request "rule out an RFO" to expedite review in less than 30 minutes. Do not move the patient from OR if patient condition warrants to facilitate additional films to rule out an RFO.
Near Miss: Needle count off, after exhaustive search in OR three different intra-op films taken and needle not found; second exhaustive search in OR yielded no needle. Patient closed and survey film revealed needle.	Technology limitation of intraoperative film vs. survey film Surgeon's preference for a particular trochar may or may not have played a role.	Adherence to the current process Appropriate interventions taken	Review of policy for missing microneedles (definition, process steps for missing microneedle) Standardization of equipment	Develop policy for microneedles. Review laparoscopic equipment available to the surgical team and their application to the procedure being performed.
A counted-out (after final pause) sponge was tucked to protect the abdominal viscera during closure, resulting in a retained sponge.	Use of sponge in a nonrecommended fashion as a viscera retainer Not following existing current policy for final count and verbalizing tucked items	Survey film of all patients even when counts are correct.	Training of new fellows and residents on current best practices Communication among OR staff	Use rubber viscera retainers or "fish" for viscera retainer. Bag off all counted out sponges in all specialties. Provide training for all new residents and fellows.
Argon beam coagulator's grey tape (non-radio opaque) was replaced with black tip (radio opaque) without any notification from manufacturer. The tip was not removed and was retained.	Communication lapse between manufacturer and users	Survey film of all patients even when counts are correct.	While the functionality of the tape replacement was improved to make it radio opaque, the change was not communicated to the users by the manufacturer.	Notify all users throughout the institution. Remove all mislabeled equipment from supply. Contact manufacturer and get issue resolved. Notify FDA.

* OR, operating room; FDA, Food and Drug Administration.

personnel involved. The clearly stated purpose of the meeting was to understand the circumstances of the event and to not be punitive or assign blame. Important to the success of these meetings was the involvement of surgical and nursing leadership and the development of an open and secure environment to share the events, understand the failures, and create plans to share the lessons learned with all the OR personnel. A summary of the event and lessons learned were quickly disseminated in a written memo from the leadership group to all personnel and shared in all areas often within a few days of the event. A non-punitive approach to addressing this type of medical error has

been shown to improve staff satisfaction, performance, and communication and to be integral to processes that support institutional crisis management.^{17,18}

A number of barriers to the success of this initiative were identified, including poor interaction between the leadership of the different stakeholders, no standardized institutional or department response to RFO events, and poor accountability for addressing the problem of RFOs. However, the major barrier to success was a long-standing culture of poor communication between our OR staff members. The tradition of surgeon primacy in the OR led to a culture lacking in basic communica-

cation skills, poor situational awareness, and concern about questioning the course of events in the OR. This initiative helped our organization clarify issues with our existing processes to avoid RFOs as well as design and implement solutions. However, the most important benefit was that it highlighted the underlying behavior and communication failures between our staff members. This finding drove the latter half of the initiative to focus on teaching and improving team communication.

Summary and Conclusions

In summary, MCR identified the incidence of RFOs as a serious quality performance issue in the OR. To address this problem, a multidisciplinary leadership group was formed that took a systematic evidence-based approach to analyzing the factors contributing to RFO events. Guided by institutional data, OR leadership engaged the entire OR staff in a broad-based communication/education program and incorporated system redesign to minimize future RFOs.

The OR environment is complex, and manual counting of surgical items is an inherently error-prone process. MCR continues to perform postoperative survey films for all surgeries in which a body cavity is opened, which we believe is the best defense currently available to detect unrecognized RFOs, despite all of our best efforts to improve the intraoperative processes of counting and documentation. We believe that we have reached a performance boundary with our current process and await either implementation of a new technology or a fundamental change in how our entire surgical process is performed. **J**

Days Between Potential Retained Foreign Object (RFO) Events, January 2003–October 2008

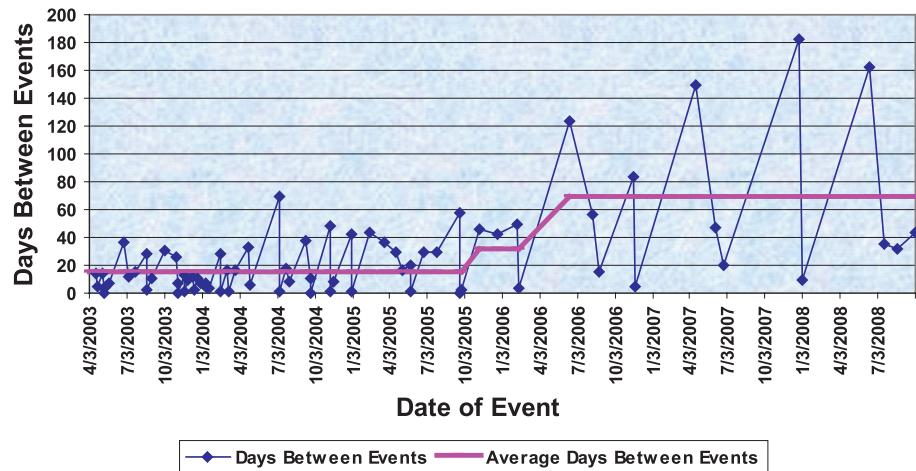


Figure 6. The frequency of potential RFO events declined significantly after the initiation of the reduction effort. We used a G-Chart, which has significantly greater detection power over conventional binomial-based approaches, particularly for infrequent events and low “defect” rates such as RFOs. MCR was averaging a surgical RFO every 16 days, which was extended to every 69 days as of October 2008.

Defects per Million Opportunities (DPMO) and Sigma Level, Mayo Clinic, Rochester, Minnesota, 2003–2007

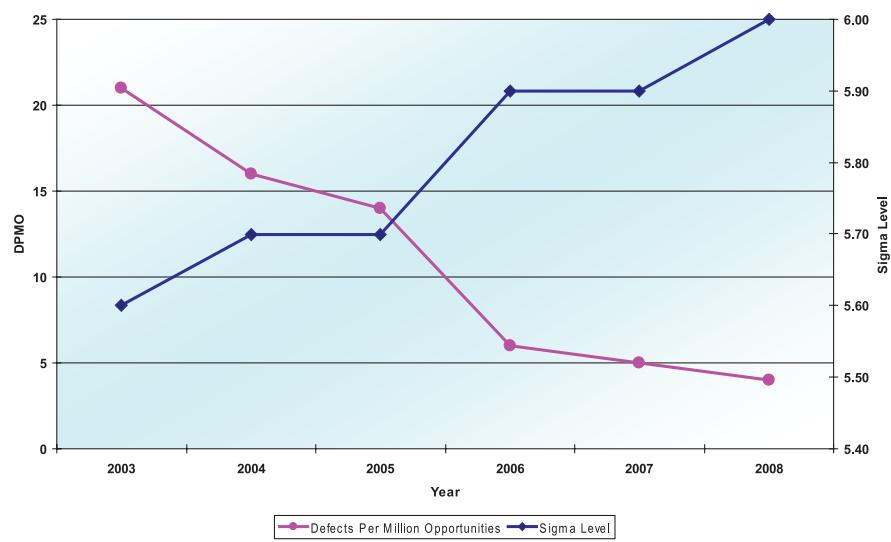


Figure 7. The defects-per-million-opportunity analysis is shown, assuming 25 chances (defect opportunities) per surgical case for an error resulting in a retained foreign object.

Robert R. Cima, M.D., M.A., is Associate Professor, Department of Surgery, Mayo Clinic, Rochester, Minnesota. **Anantha Kollengode, Ph.D., M.B.A.**, is Quality Analyst, Quality Management Services. **Amy S. Storsveen, R.N., B.S.N.**, is Charge Nurse, and **Cheryl A. Weisbrod, R.N., M.S.**, is Director, Surgical Services. **Claude Deschamps, M.D.**, is Professor and Chairman, Department of Surgery. **Mark B. Koch, M.B.A.**, is Associate Administrator, Administrative Services. **Debra Moore** is Nursing Analyst and **Sarah R. Pool, R.N., M.S.**, is Nursing Educator, Surgical Services. Please address correspondence to Robert R. Cima, cima.robert@mayo.edu.

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