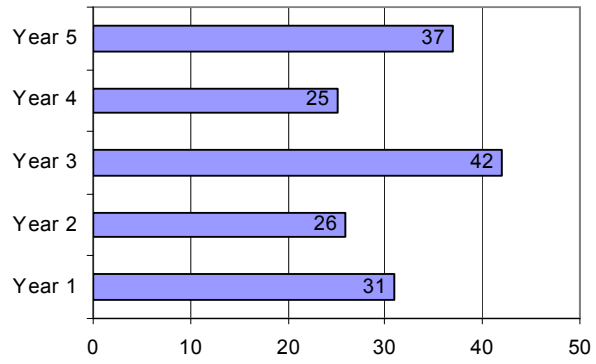
SPOTLIGHT ON PATIENT SAFETY

Data, trends, and learning from the Minnesota Adverse Health Events Reporting System

April 2009 *www.health.state.mn.us/patientsafety*

Retained Foreign Objects

In the more than five years that the Minnesota Department of Health has been collecting information about adverse health events, retained foreign objects (RFO) have been among the most frequently reported events. Since 2003, a total of 161 RFO's have been reported, with annual totals ranging from 25 to 42 per year.



While the vast majority of these events did not result in any lasting harm to the patient, RFO's often require follow-up surgery to remove the object, and can increase a patient's risk of infection or post-surgical complications. Like many adverse events, their causes include both individual and systems factors; patient characteristics can also sometimes play a role. Their persistence as one of the most commonly reported adverse health events indicates that, while we have come a long way in implementing best practices for prevention, we still do not fully understand all of the reasons why RFO's can occur, and how they can be prevented.

This newsletter describes the types of objects that are most commonly retained, the types of procedures which accounted for most RFO's, the outcome to the patient, the presence of accurate sponge and object counts in RFO cases, and the root causes of these events.

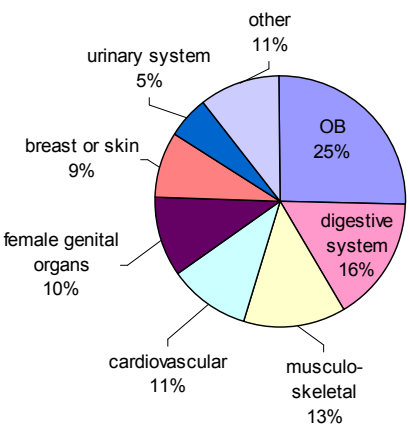
SPOTLIGHT ON PATIENT SAFETY is a periodic publication of the Minnesota Department of Health that highlights trends in adverse health event data submitted to MDH, along with recent journal articles of note and upcoming events. If you have suggestions for future topics, send them to diane.rydrych@state.mn.us.

Types of Procedures with RFO's

The type of procedure most commonly linked to RFO's was obstetrical, generally vaginal deliveries or cesarean sections. These procedures accounted for a quarter of RFO's, followed by digestive system procedures such as laparoscopic abdominal procedures, inguinal hernia repairs, colectomies, and gastrectomies, which accounted for 16 percent of RFO's.

Hysterectomies accounted for ten RFO's in a five-year period, including both abdominal and vaginal approaches and procedures that had to be converted from vaginal to abdominal mid-procedure.

The placement or extraction of pacemakers, ICD's, or LVAD's was associated with six RFO cases. In most of these cases, the RFO was a sponge that was packed into the wound pocket and not removed.



Retained Foreign Objects, con't.

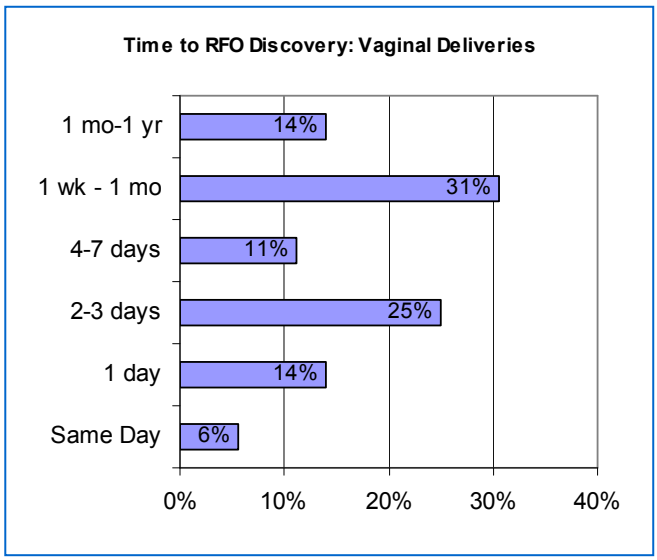
As noted above, a quarter of all retained foreign objects between 2003 and 2008 happened during obstetrical procedures, with nearly all of those cases involving vaginal deliveries. Since mid-2008, when the Minnesota Hospital Association kicked off its "Safe Count" campaign to eliminate retained sponges in labor and delivery, the number of such cases has dropped to nearly zero. Therefore, the following discussion describes trends in labor and delivery RFO's reported almost exclusively prior to the start of the Safe Count campaign.

RFO's in Vaginal Deliveries

The overwhelming majority of objects retained during vaginal deliveries were sponges. Only one RFO in a vaginal delivery case was something other than a sponge; in that case, the objects retained were laminaria.

Discovery/Treatment

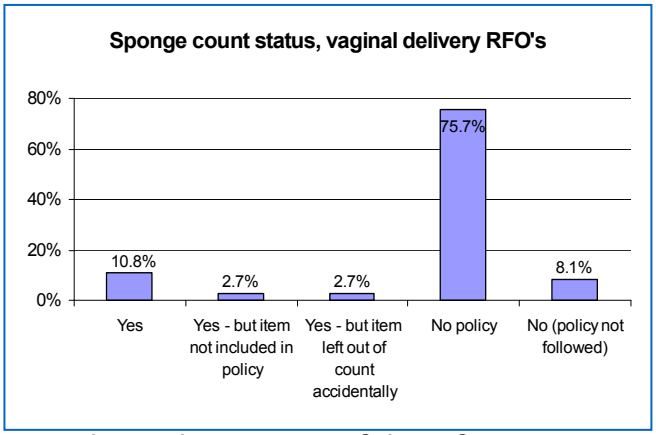
The majority of the sponges retained after vaginal deliveries were discovered within five days of their retention, although several were not discovered until the six-week postpartum checkup.



Most commonly, RFO's after vaginal deliveries were discovered by the patients themselves, when the object fell out or was pulled out in the hospital or at home. In a number of cases of retained vaginal sponges, though, the patient either presented to her doctor for a regular post-partum visit where the sponge was discovered, or presented to a clinic or ED based on symptoms related to the RFO. In those cases, the RFO was removed by a physician or nurse.

Counting

For vaginal deliveries, only 16 percent of cases indicated that a count was done, and even in some of those cases the count did not include the particular type of object that was ultimately retained. More than 75 percent of vaginal delivery RFO cases indicated that no policy was in place for sponge counting after delivery. An additional eight percent of cases indicated that a policy was in place but was not followed; often, this was because the policy was new and had not been fully operationalized or imbedded in labor and delivery at the time of the event.



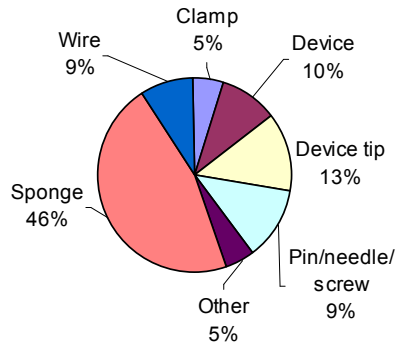
Since the implementation of the Safe Count campaign in mid-2008, the percentage of hospitals that require sponge counts after vaginal births has increased dramatically. Currently, all of the nearly 70 hospitals participating in the campaign indicate having a sponge/sharp counting policy in place for all vaginal deliveries.

RFO's outside of Labor and Delivery

Literature related to RFO's shows that nationally, the most common type of retained object is a sponge or cottonoid. These findings are mirrored in Minnesota, where nearly 50 percent of all RFO's outside of vaginal deliveries were sponges (including VAC sponges).

The second most commonly retained object was a broken or inadvertently separated device tip or component, such as a catheter or pain pump insertion sheath, cannula tip, catheter locking device, or intubation blade tip.

Type of Object Retained, non-labor and delivery RFO's 2003-2008

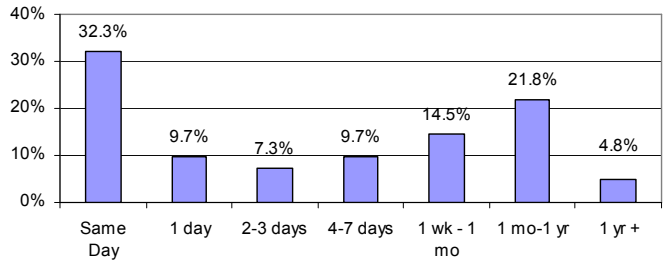


Broken guidewires accounted for nine percent of non-labor and delivery RFO's. Roughly a third of the retained wires were guidewires for breast biopsies or localization procedures in the breast or lung. The remaining retained wires were guidewires used as part of a PICC line or central line placement, or wires used in orthopedic procedures.

Discovery

The median number of days between the retention of a foreign object and its discovery was four days. Nearly a third were discovered within a day, usually either immediately after closure or within a few hours. However, a quarter were discovered a month or more after the initial surgery; in most of these cases, the object was discovered during a later surgery in response to symptoms that may or may not have been related to the presence of the RFO.

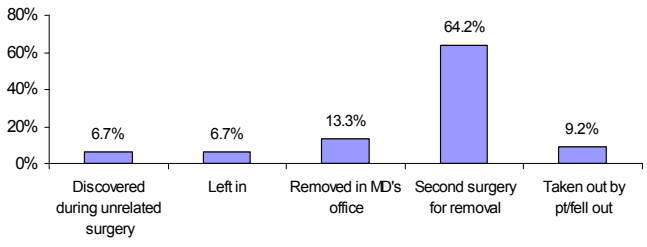
Time to RFO Discovery, non-labor and delivery cases 2003-2008



Overall, the most common required treatment for RFO's outside of labor and delivery was to have the patient undergo a second procedure to remove the object. This happened in 64 percent of RFO cases, with the timing of the second surgery ranging from a few minutes or hours to several years after the retention of the object. In a handful of cases, the object was discovered and removed during a second planned surgery, where no RFO had previously been suspected.

In nearly a quarter of cases, the object fell out or was removed by the patient, or was removed by a physician or other clinician through non-surgical means. A decision not to remove the RFO was made in roughly seven percent of cases, as the removal may have posed risk to the patient.

Treatment of RFO's, non-labor & delivery 2003-2008

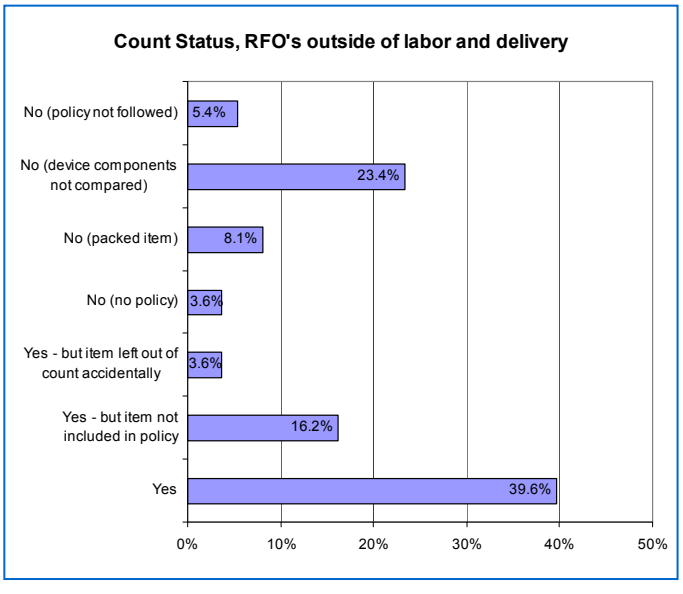


COUNTING

Despite the attention paid to retained objects, they continue to occur with some regularity. RFO data reported over the last five years reveals that issues related to counting may be a major contributing factor, either through incomplete count policies, divergent counting practices, or the lack of a standard for comparing instruments, devices or other items before and after their use. While counting policies have become widespread, the RFO data show that counting policies do not always include all items introduced into the surgical field, and may not always cover all areas of the hospital or all types of procedures.

Across all reported RFO cases, outside of vaginal deliveries, 40 percent indicated that a complete count was done, with the count including the type of object that was retained. Only four percent of RFO cases outside of labor and delivery indicated that they had no policy in place for counting items such as sponges and sharps.

In roughly 20 percent of non-labor and delivery RFO cases, however, while a count was done, the retained item was either inadvertently left out of the count, or the type of item that was retained



Sixteen percent of non-labor and delivery RFO cases indicated that the policy did not include the specific type of item that was retained. For example, several pins were retained during orthopedic procedures, where the count policy did not include directions to count pins. Several dental procedures did not include throat packing materials in their count policies, so there was no reconciliation or accountability for removal of those materials after the procedure.

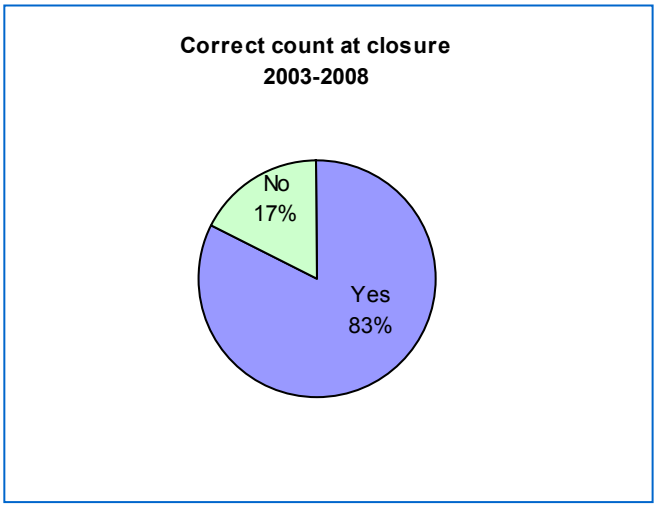
Policies for counting sponges, sharps and other items were also frequently missing in cases where items were packed or tucked into a wound cavity for later removal. In roughly eight percent of non-labor and delivery cases, wound packing was placed that was intended to be retained in the wound for a period of time, and thus was not part of the count. In those cases, no policy was in place to account for the removal of the packed/tucked item at a later time.

In the case of instruments, policies may or may not include the counting of whole instruments, but very few include a visual inspection or comparison of the size, shape or length of the object before and after use. Twenty three percent of non-labor and delivery RFO's did not include a policy to compare instruments before and after usage to check for breakage.

The types of devices most often involved in these types of cases were catheters, where the object retained was an introducer sheath fragment, locking device, or sleeve. Other device tips or components left in a patient's body across the five year period but not subject to a before/after comparison included a cone cannula and the tips of an ultrasound gel bottle, Scanlon tunneler, coagulator device, and uterine manipulator.

Count Accuracy

Most studies that have examined RFO's have concluded that, in the majority of cases, the count that was conducted was accurate. This was also the case in Minnesota, where 83 percent of cases with a count reported that the count was accurate despite the presence of a retained object. In other words, counts that appear accurate can often be incorrect, and an accurate count may not be a guarantee that an object has not been retained, particularly if the counting process was flawed.



Root Causes – All RFO's

Across all types of adverse events, communication breakdowns and issues related to policies and procedures are the most commonly cited cause of adverse events. In general, this is also true of retained foreign objects, with communication problems cited in 46 percent of all RFO cases and rules/policies/procedures in 70 percent. However, the pattern of root causes varies greatly between vaginal delivery cases and other types of RFO.

Root Causes	Labor & Delivery	Other RFO's	All Adverse Events (2008)
Communication	43%	47%	58%
Training	26%	21%	38%
Fatigue/Scheduling	11%	5%	6%
Environment/Equip.	51%	41%	45%
Rules/Policies	97%	62%	63%
Barriers	17%	8%	20%

While communication problems were common among RFO's in vaginal deliveries, a lack of rules/policies/procedures related to sponge counts was cited far more often in these cases. The root cause analysis for nearly every RFO after a vaginal delivery indicated policies/procedures as a contributing factor, primarily due to the lack of a counting policy for this type of procedure prior to the Safe Count campaign.

Environment/equipment issues were also cited in roughly half of all vaginal delivery RFO's. Often, this was related to a lack of tailed sponges in the delivery room or a physician or clinician preference for standard non-tailed or non-radiopaque 4x4's that can become compact and more difficult to count when saturated with blood.

For RFO's occurring in procedures other than vaginal deliveries, root and contributing causes were closer to the pattern for other, non-RFO adverse events. Communication problems were particularly apparent with tucked or packed items, where clinicians generally did not communicate the placement or number of items to other team members.

Specific examples of root or contributing causes, across all RFO's, include:

- No policy in place for sponge counting in labor and delivery;
- Lack of clarity in policies in terms of how items should be counted (i.e. packs of sponges counted together, or sponges counted individually);
- Policy to not move patient to PACU until count is reconciled not followed;
- Count policy did not include certain items (tucked items, wires, clamps, devices);
- Roles of team members in calling for and implementing count not clear;
- Supply packs for labor and delivery included non-radiopaque and/or non-tailed sponges that are more easily retained;

- Surgeon doing procedure preferred to use non-radiopaque gauze for this procedure, and staff felt obligated to honor surgeon's request for non-standard materials;
- No training on new instrument, so team was unaware of risk of breakage/ retention;
- Presence of vendors and others in the room during procedure led to confusion about the post-procedure count and to an item not being included in the count;
- No policy for counting/documenting number of sponges packed into wound pocket – and no clear assignment of responsibility for their removal;
- No communication by physician about placement of sponge/gauze;
- Lack of communication about number of gauze packs pre-cut for a procedure, and different practices for cutting them;
- Not all staff trained on counting policies, or training did not include travelling nurses;
- Reliance on memory to perform the count, with no place to document whether or not it was performed or to serve as a trigger;
- No policy/practice for comparing instruments after use to ensure that breakage/retention has not occurred.

The contributing causes cited for RFO's indicate that while having a counting policy in place is important, equally important is to ensure that all team members understand its details, including the types of items that should be included, who is responsible to call for it and carry it out, and how to respond in the event that counts do not reconcile after a procedure.

However, even the best-designed policy cannot overcome the human tendency to err at a consistent rate; as the data clearly show, sponge, sharp and instrument counts are commonly correct even when an RFO is present, indicating that the count itself was flawed. This points out the need to counteract human fallibility with redundancies (involving multiple staff in counts), technical support (only allowing use of tailed or radiopaque sponges), documentation and visual aids, and changes to organizational culture in certain departments to reinforce the importance of counting and the risk associated with RFO's.

Preventing RFO's

As with other types of adverse health events, RFO's have varied causes that cross multiple systems. In some cases, clear policies are not in place to require counting or comparison of all objects. But even when those policies are present and followed, human fallibility, distractions, or cognitive bias can lead to falsely correct counts and the illusion of safety. Effectively reducing the risk of RFO's requires taking several important steps:

- Ensure that policies requiring counting of sponges, sharps, and other objects are in place for *all* procedural areas, not just in the OR.
- Examine policies to make sure that the responsibility for initiating, documenting and reconciling all counts is clear.
- Develop documentation to support the consistent application of the count policy; and audit documentation regularly.
- Use white boards or other visuals during the procedure to visually document items to be counted, and the counts themselves.
- Make sure that count policies require two people to directly view and verbally count each item included in the count.
- For invasive procedures that involve the use of devices or instruments containing multiple

parts, or with a risk of breakage, ensure that your count policy includes a visual comparison of the instrument or device before and after use, and clearly outlines who should be responsible for the inspection and for reconciliation of potentially broken devices. This may be particularly important with devices that have been involved in multiple RFO's in Minnesota, such as catheters and pain pumps, and with guidewires.s

- Consider the risk of breakage or separation of instrument/device parts when ordering new instruments, and when training staff on their use.

- Have a clear process outlining the steps to be followed in the case of non-reconciled counts, and clear accountability for initiating those steps.

- Only use radiopaque soft goods. Ensure that packets of supplies for any given procedure only include radiopaque sponges/pads, and that all staff and physicians understand that a personal preference for non-radiopaque soft goods will not be accommodated.

- Consider routine post-op xrays or other screening methods for high-risk patients at the end of surgery. This could include certain orthopedic procedures, procedures that involved a change in approach, long surgeries with significant staff turnover or high blood loss, or highly complex or emergency procedures.

- Explore the use of barcoded sponges or other items, but remember that such technical approaches are not intended to replace manual counts and may run the risk of fostering complacency in counting practices.

- Develop and implement a policy for specifying removal and reconciliation of tucked sponges or gauze, if one is not in place. The policy should provide clear guidance on communication and documentation of tucked items, as well as orders and accountability for their removal.

A number of these best practices related to development and effective implementation of sponge/sharp counting policies formed the basis of the Safe Count campaign, which has nearly eliminated retained sponges in vaginal deliveries statewide. In a relatively short period of time, labor and delivery units across the state have successfully changed their cultures so that sponge counting and visual inspections are now the community standard rather than the exception.

Eliminating retained foreign objects in all clinical areas involves addressing a number of complicated issues, including the use of a wide range of instruments or devices, the adoption and use of new devices that may pose an unknown risk of breakage, complicated procedures involving many instruments and soft goods, and a culture in which deviation from the standard materials or standard count policy is the norm. However, the success to date in Minnesota's labor and delivery units, along with the wealth of data collected on RFO's across five years, provides a strong starting point for developing a safer, more reliable process for prevention of RFO's statewide.

Retained Foreign Objects: recent literature

Retained foreign bodies after surgery.
Lincourt A, Harrell A, Cristiano J et al
Journal of Surgical Research 2007; 138 (2): 170-174

This article describes a retrospective review of cases with retained foreign bodies identified by ICD-9 code. The authors found that having a greater number of surgical procedures or an incorrect count were more likely to experience an RFO, and that surgeries with multiple surgical teams, unexpected changes in surgical procedure, long OR times, emergency procedures, and after-hours cases did not lead to a higher risk of RFO.

Incidence and Characteristics of Potential and Actual Retained Foreign Object Events in Surgical Patients
Cima R, Kollengode A, Garnatz J et al
Journal of the American College of Surgeons 2008; 207: 80-87

This study examined near miss and actual RFO events reported between 2003 and 2006 at the Mayo Clinic. The authors found 34 actual RFO's out of 191,168 surgeries performed, with the majority being sponges. Most RFO's occurred in cases with correct sponge counts; post-operative films identified 20 RFO's, all in patients with correct counts. No RFO's occurred during emergency or high blood-loss procedures. The authors conclude that reliance on counting as the only means to avoid RFO's is unreliable, and recommend investigating new technologies designed to achieve reliable counts.

Risk Factors for Retained Instruments and Sponges after Surgery
Gawande A, Studdert D, Orav E et al
New England Journal of Medicine 2003; 348: 229-235

A study of medical records for 54 patients with 61 retained objects. The study indicated that patients with RFO's were more likely than controls to have had emergency surgery or an unexpected change in surgical procedure, had a higher mean body mass index, and were less likely to have had counts of sponges and instruments performed.

MN Department of Health
85 E. 7th Place
PO Box 64882
St. Paul, MN 55164-0882
www.health.state.mn.us/patientsafety