

# Reducing Preventable Patient Harm Due to Retained Surgical Items: The RSI Bundle

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<https://psnet.ahrq.gov/innovation/reducing-preventable-patient-harm-due-retained-surgical-items-rsi-bundle>

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## Summary

Retained surgical items (RSIs) cause severe yet preventable patient harm. RSIs are the most common category of surgical never events.<sup>1</sup> An RSI occurs when a needle, sponge, or surgical instrument is unintentionally left behind in a patient after incision closure.<sup>2</sup> Ascension Data Science Institute, a part of Ascension health system that provides data analytic support, determined that a patient was harmed from an RSI at their facilities every eight days on average. Because of this finding, Ascension, as a health system, sought to eliminate the harm caused by RSIs and to improve safety culture and staff readiness to change by implementing an RSI-reduction bundle.<sup>2</sup> According to the Institute for Healthcare Improvement (IHI), “A bundle is a set of evidence-based practices—generally three to five—that, when performed collectively and reliably, have been proven to improve patient outcomes.”<sup>3</sup>

The RSI bundle includes five standard elements and one recommended element. The five standard elements include 1) a surgical STOP for wound exploration; 2) a surgical debrief; 3) a visual counter; 4) imaging; and if needed, 5) the reporting of failures to complete the first four elements and incorrect surgical counts that aren't resolved. The use of surgical sponge counter bags to assist with the process of counting sponges and other materials used during surgery is the recommended element in the bundle.<sup>2</sup>

The RSI bundle was implemented in 114 facilities across 12 states in September 2020. After implementation, the average number of days between a patient harm caused by an RSI increased from 8.6 days to 10.3 days, accounting for a 19.8% improvement.<sup>2</sup> Additionally, there was a 13.7% reduction in patient harm, from 0.0488 in pre-bundle implementation to 0.0421 per 10,000 patient-days in the post-bundle implementation period ( $p < 0.0001$ ).<sup>2</sup> Notably, there was a 58.6% increase in near-miss event reporting,<sup>2</sup> which was a positive signal to innovators that the organization's culture was improving.

This innovation was the first widely studied and published multicenter, multiregional RSI-reduction approach in the United States, and it yielded very promising results.<sup>2</sup> It demonstrates that a systemwide bundle-based approach may be beneficial in decreasing patient harms caused by RSIs.

## Contact the Innovator

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2020-01-01

## Problem Addressed

Evidence demonstrates that a bundle of best practices, which includes all elements, is better at reducing avoidable human errors in surgical settings that are complex and fast paced, in lieu of a single element intervention.<sup>6</sup> Prior to this innovation, an intervention in multiple regions and at multiple centers focused on RSI-reduction had not been extensively studied, nor had there been significant publications.<sup>2</sup> The innovators sought to fill that research gap while improving patient safety and outcomes in their organization and making sustained organizational change.

## Description of the Innovative Activity

The all-or-nothing RSI bundle included five standard elements and one recommended element (described below with the third element).

1. Surgical STOP for wound exploration is initiated by the surgeon prior to the first stitch to close the surgical wound.<sup>2</sup> When the surgeon announces, "It is time for our surgical STOP," everyone stops all activity while the surgeon proceeds with wound exploration. The surgeon concludes by announcing "wound explored." If the surgeon does not initiate, another team member should initiate the Surgical STOP by utilizing the "Ask, Request, voice a Concern, and Chain of Command" (ARCC) technique, saying, "I would like to perform our surgical STOP before proceeding with closure."<sup>2</sup>
2. Surgical debrief occurs before the surgeon leaves the room. All team members stop to participate in the debrief. Elements include verification and resolution of incorrect counts; a brief summary of the procedure and key elements, including patient disposition; and a review of successes, challenges, and additional concerns.<sup>2</sup>
3. Visual counter uses a white board that includes the patient identifiers and procedure details. It is used as to track surgical items (including sponges, gauze, needles, and instruments throughout the surgical procedure. The use of surgical sponge counter bags are recommended but not required as a bundle element.<sup>2</sup> These clear plastic bags with pockets are used during the surgical count process. Nurses place sponges in pockets to provide a visual cue of the number of surgical sponges

retrieved.

4. Imaging consists of X-ray or computed tomography used at the discretion of the surgeon. Imaging should be done prior to the first stitch of closure when the soft surgical count or needle count is incorrect and cannot be resolved (i.e., lost on the field) to validate that no items are retained in the patient.<sup>2</sup>
5. Reporting is conducted when there are incorrect surgical counts without a resolution, the surgeon fails to initiate the surgical STOP, and other team members fails to use the ARCC technique to initiate a surgical STOP when necessary.<sup>2</sup>

## Context of the Innovation

More than 300 million surgical procedures are performed each year worldwide. Despite awareness of adverse effects, surgical errors continue to occur at a high rate; 10% of preventable patient harm in health care was reported in surgical settings.<sup>6</sup> RSIs are the most frequent type of surgery-related never events, the most severe of adverse events.<sup>1</sup> Many best practices have been attempted, but evidence is lacking for a reliable way to reduce RSIs.

In 2021, Yamaguchi et al. observed that using radiofrequency identification technologies and novel computer-aided diagnosis software might be better than the traditional approach of manual count verification alone.<sup>8</sup> However, these technologies are not versatile. They interfere with other technology, such as pacemakers, and require surgical teams to bring in additional radiologists and add accessories in busy operating rooms (ORs). Therefore, adoption in clinical settings remains challenging.<sup>7</sup> Additionally, evidence suggests that an all-encompassing bundle that facilitates better communication and incorporates human factors principles is more effective than single technology-based interventions at reducing harm caused by preventable human errors in fast-paced and highly complex surgical settings.<sup>6</sup> In lieu of a single component intervention, the innovators sought to create an intervention that embraced a bundle of best practices and that could be utilized in ORs.

## Results

Carmack et al specifies, the number of consecutive days without harm caused by an RSI increased from 8.6 days to 9.2 days during the bundle activation and ongoing education periods.<sup>2</sup> Then, the days between harms increased to 10.3 days following the bundle implementation period.<sup>2</sup> Overall, there was an 19.8% increase in the average number of days between RSI events from the baseline period in 2019 to the post-bundle implementation period in 2021.<sup>2</sup> The rate of RSI harm was reduced from 0.0488 per 10,000 patient-days in the pre-bundle implementation period to 0.0421 per 10,000 patient-days in the post-bundle implementation period ( $p < 0.0001$ ), accounting for a 13.7% reduction. Notably, there was also a 58.6% increase in near-miss reporting,<sup>2</sup> which was a positive signal to innovators that the organization's culture was changing. Near misses are either (a) no-harm good catches or (b) error, but no harm.<sup>2</sup> An example of a near miss that the bundle helped identify involved a surgical nurse who identified an unresolved sponge

count and requested a surgical STOP. A surgeon explored the wound to find a sponge; it was removed before the first stitch.<sup>2</sup>

## **Innovation Patient Safety Focus**

RSIs are the most common category of surgical never events.<sup>1</sup> Never events are serious and costly errors that may lead to consequential harm, or in the most serious cases, death to patients. They should never happen in the provision of health care.<sup>4</sup> Per the Centers for Medicare and Medicaid Services, never events are often identifiable and preventable.<sup>4</sup> According to the IHI, bundles have been proven to improve patient outcomes.<sup>3</sup> Because of this, Ascension Data Science Institute has heavily supported measuring the uptake of the RSI bundle throughout their healthcare system to improve patient safety.

## **Planning and Development Process**

After identifying an opportunity to improve surgical safety by reducing the incidence of RSIs, Ascension leaders formed a multidisciplinary workgroup to perform an evidence review on RSIs and identify evidence-based guidelines.<sup>2</sup> The workgroup reviewed every event reported through their event reporting system during a six-month period and manually coded event reports to understand the objects retained as part of RSIs.<sup>2</sup> Two common themes and findings that emerged from the workgroup review were (1) intraorganizational guidelines were not rooted in evidence and (2) policies varied within the organization.<sup>2</sup> For example, surgeons had different definitions of an RSI. Additionally, policies varied around surgical count processes and whether to initiate a surgical stop. Organizational culture and inadequate communication were common underlying causes in many reports.<sup>2</sup> Based on the workgroup's findings, the Innovation team developed the RSI bundle that was deployed to the entire health system in September 2020. It was fully implemented in October 2020.<sup>2</sup>

Ascension recognized the importance of communicating about the bundle in a way that was simple to understand but that didn't oversimplify the process itself. They did this by making the process steps clear and easy to follow. After they determined a simple plan for providers to follow in highly complex procedures, they knew their innovation was ready for dissemination.

Additionally, the Ascension innovation team created tools and materials for dissemination across their organization, including toolkits and videos. Ascension's patient safety team went to their local sites to disseminate the educational materials and provide in-person support.

The Ascension Data Science Institute created a robust measurement system via Tableau to monitor uptake of the innovation processes and outcomes. In Tableau, the team established a system that tracked whether the surgical centers were using every element of the RSI bundle. This way, the innovators would know when problems with RSI prevention bundle compliance occurred and they could address potential problems in the process for individual sites or the entire organization.

## Resources Used and Skills Needed

This innovation requires both physician and nonphysician resources.

- Create an RSI workgroup to support the development, implementation, and sustainability of the innovation.
- Gain buy-in from executive leadership.
- Commit to accountability and a patient safety culture in the organization.
  - Ascension supported this by creating a campaign to improve psychological safety. To sustain the gains from this campaign, Ascension is launching a “We Got Your Back” cultural campaign in 2024. The campaign establishes a patient safety culture within their organization and supports providers when they report near misses or RSI incidents or escalate any threats to patient safety.
- Identify and use patient safety champions to disseminate and sustain the innovation.
- Engage staff and frontline providers in the innovation.
  - For example, implement the use of a “wingman”. A wingman supports their fellow coworkers and advocates for patients. Additionally, they are a proponent for a safer care environment. A wingman is often a frontline staff person trusted by their colleagues. Staff and frontline providers will confide in this person who will then serve as a spokesperson and advocate for their peers, therefore supporting the engagement of staff and frontline providers.<sup>2</sup>
- Implement a data-driven platform, such as Tableau (Tableau Software, LLC, Seattle), to track outcomes. The measures are built into Ascension’s harm dashboard on Tableau. The Tableau platform provides many useful visualizations such as monthly charts and “days between harm” charts. It is updated daily.
- Develop infrastructure to support the innovation, including using online courses that are live but also self-paced, using Tableau to create the harm dashboard, hosting monthly “safe table” discussions where safety stories are shared, implementing safety coaching programs, leveraging patient safety expert communities, creating a psychological safety campaign, and providing high-reliability training for frontline caregivers.
- Form teams to support intervention quality.
  - Local teams complete 20 observations of the innovation per month.
  - Auditors review at least 20 operating room procedures per month.

## Funding Sources

Ascension funded this innovation through its internal patient safety program.

## Getting Started with This Innovation

The innovators identified three key components to getting started with this innovation: organizational support, champions, and a tolerable implementation pace.

Ascension identified organizational buy-in as a necessity in getting started with this innovation. If leadership and frontline staff do not support the innovation, then it will struggle to get off the ground. Support can be gained with a robust plan for education and training and by gathering insights and incorporating them into the training process and innovation.

Champions are valuable when starting this innovation. Champions support the implementation and celebrate the progress the organization is making instead of pointing out areas for improvement. Champions give permission for the organization to fail, make improvements, and try again. Champions provide feedback to organization leadership on how the initial rollout of the innovation is progressing. They help create a culture of patient safety by fostering commitment and a cheerful outlook among the frontline staff.

To ensure the successful implementation of this innovation, it is crucial to adopt a step-by-step approach at a tolerable pace for the frontline providers at local sites. The chief clinical officer (CCO) plays a pivotal role in guiding the implementation, with assistance from assigned learning modules, spanning a month for training. Sites are required to conduct a thorough gap analysis over another month, followed by a two-month window to implement the designated bundle. Throughout this journey, close monitoring and tracking of adoption rates are imperative, particularly in collaboration with CCOs overseeing any sites that may need additional support for implementation. This comprehensive approach ensures a methodical and effective integration of the innovation, ultimately contributing to improved patient outcomes and fostering a commitment to high reliability and just culture in healthcare practices.

### **Sustaining This Innovation**

To sustain this innovation, Ascension found it essential to measure how the innovation was progressing via monitoring by local and national executive leaders, as well as by the frontline providers who are doing the work. Both groups must assess how the innovation is progressing in terms of reliability measures, like near misses or days between RSIs. The innovators measured two process measures, rates of RSI bundle compliance and near-miss reports of potential RSI events, and one outcome measure, rates of RSI harm events. The RSI harm event rate is per 10,000 patient days. Because the Innovation team believes that reliability measures are key to sustainability, it suggests that internal and external monitors assess how the innovation is progressing via reliability measures like near misses or days between RSI events.

There must be reachable goals for these reliability measures. For example, a goal of 90% adherence may be reasonable for a specific measure because 100% adherence would not allow for unavoidable circumstances.

To sustain this innovation, organizations should establish programs that reinforce wins, listen and respond to feedback, and share progress on the innovation. For example, Ascension implemented a Good Catch

Award program to reinforce wins in patient safety, storytelling in large meetings to spread learning from root-cause analysis and serious safety events, process reliability audits to maintain vigilance in Ascension's systems and processes, monthly review of data at national-level quality committee meetings, and dashboards with simple and intuitive data visualization for all team members to get a pulse on progress toward the goal of zero RSIs. Innovators must listen in order to understand what is happening in the organization's culture. When people speak up, the organization must respond by either making adjustments or by explaining the rationale for their decisions. Additionally, the innovators said that sharing progress on the innovation garnered greater commitment and buy-in from their organization.

### **Adoption Considerations Use by Others (Use By Other Organizations)**

According to Ascension, published literature shows that RSI bundles are used widely but only in limited scope (e.g., one surgical unit, one hospital, or one teaching setting).<sup>5</sup> Ascension's innovation is unique in its widespread scope of 100+ hospitals across a large geographical area, and it has not yet been replicated by any other organizations.

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### **Footnotes**

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