

November 2021

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LEARNING OBJECTIVES

1. Explain the importance of a quality PM program
2. Recognize adverse events related to non-functioning, broken, or contaminated instruments
3. Discuss the elements of a successful PM program.

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SELF-STUDY SERIES

Comprehensive PM for surgical instruments

by Malene McLain

Surgical services are a central function in most hospitals. They typically account for 40% of a hospital's operating expenses and generate about 70% of its revenue.¹ Because surgery is such a vital revenue stream for the hospital, keeping costs down is important to ensure that the hospital meets its fiscal responsibilities. A significant portion of an operating room (OR) budget is allocated to cleaning, maintaining, and repairing surgical instruments. To keep ORs running efficiently, it's important to have a plan for ensuring that all surgical instrumentation is functioning safely and effectively and is procedure-ready. A comprehensive preventive maintenance (PM) program helps ensure that instruments are well cared for, free of bioburden, and functioning properly.

Just as routine maintenance of a car can lengthen its lifespan, prevent significant performance changes, and help avoid expensive repairs, surgical instruments can benefit from a PM program. PM and repairs help avert costly damage and extend the lifespan of hospital instrument inventories, both of which save a facility money.

There are also indirect costs associated with using non-functioning, broken, or improperly cleaned instruments, such as avoidable surgical site infections and other adverse patient events. To get an accurate accounting, hospitals cannot just look at the direct cost to repair and maintain instruments; they also need to look at the consequential costs of injuries associated with instruments that are not effectively maintained. Patient safety is a priority and

removing these risks and costs must also be a primary goal.

This self-study article discusses the importance of a PM and repair program, the risks associated with poorly maintained instrumentation, and considerations for a successful PM program.

The value of a quality PM program

A large hospital in the Midwest found that it had reoccurring deep-tissue infections that were traced back to one specific surgeon. This surgeon was using Kerrison rongeurs for the majority of his surgeries. When these rongeurs were inspected, technicians discovered they had retained bioburden inside the instruments. It turned out that these older rongeurs could not be taken apart and cleaned properly in the sterile processing department (SPD).

A senior manager from this facility called an instrument repair company, asking if they could come in and teach their staff how to disassemble, reassemble, and clean the rongeurs properly. After much discussion, the hospital realized that the risk they would be assuming by using existing staff to disassemble and reassemble the instruments for cleaning and inspection was too great. Management decided that the instrument repair company would take on that task. Since the doctor operated on Mondays and Wednesdays, the repair company came in on Tuesdays and Thursdays, at a cost of \$3,000 per day, to disassemble, clean, and adjust the devices. After approximately 24 weeks



Figure 1: Kerrison Rongeur

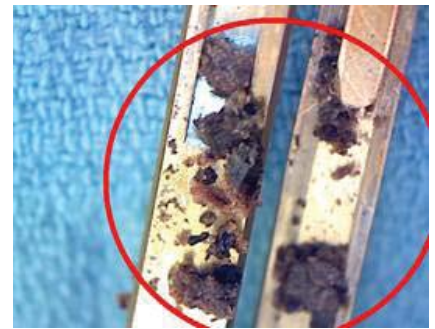


Figure 2: Bioburden inside Kerrison Rongeur

and \$144,000 spent, the cleaning regimen was successful and stopped the deep tissue infections. However, the hospital realized that the most cost-effective long-term solution was to purchase the newer, disassemblable Kerrison rongeurs, which would enable their staff to properly clean the instruments. This eliminated costly weekly visits from the instrument repair company and saved the hospital several thousand dollars in the long run. This example shows the importance of having a PM program that can identify instrument issues before they affect patient care and outcomes.

A quality PM program may not result in immediate cost savings, but the long-term savings can be significant. "Hospitals that had proactive maintenance programs were able to address budgeting issues more quickly and the severity of damage to instruments was reduced when customers embraced education as part of their PM programs."²

Adverse events are costly

The quality and functionality of surgical instruments is a critical factor in ensuring the highest standards and best patient outcomes. When instruments fail or break during a surgical procedure, the consequences to the patient can be catastrophic. An article presented by the National Center for Biotechnology Information stated, "There may be as many as 1,500 incidents a year of poor-quality surgical instruments causing harm."³ In 2008, the U.S. Food and Drug Administration (FDA) published an alert that stated, "Nearly 1,000 incidents of retained pieces of broken instruments (unretrieved device fragments) occur each year, leading to a range of problems including local tissue reactions, infections, disability, and even death."³

The graph shows a percentage breakdown of seven common unretrieved fragment sources.

The high costs associated with this type of preventable harm affect the hospital and its patients and increase overall healthcare costs for the general public. In 2008, it was estimated that preventable harm in the United States costs as much as \$19.5 billion.⁴ Not all this cost is associated with instru-

ment failures or retained bioburden, but it is considered to be a part of the problem.

According to a January 2021 report by The Joint Commission, the highest number of sentinel events (events that result in death, permanent harm, or severe temporary harm) for surgical or invasive procedures was unintended retention of a foreign object. Between 2018 and 2020, there were 362 reported events of retained foreign objects. Even though the FDA mandates that any serious injury or death caused by surgical equipment must be reported, there is no mandate to report it to the Joint Commission.^{5,6}

By establishing a comprehensive, thorough PM program, a hospital can mitigate much of the risk of adverse events related to broken devices or retained bioburden. SPD follow the original equipment manufacturer's instructions for reprocessing and repair, but it can be expensive to return instruments to the manufacturer for repair. In 2014, the U.S. Centers for Medicare and Medicaid Services (CMS) updated their 42 CFR 482.41(c)(2) standard concerning the equipment maintenance requirements for hospitals. The standard now allows hospitals to seek alternative methods for inspection and repair of surgical instrumentation that may be less expensive, but these methods must still ensure that instruments are safe for use and fully functional.⁷

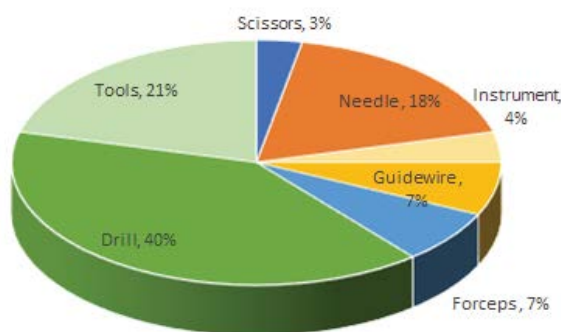


Figure 3: Distribution of broken instruments in reported patient safety incidents between August 2004 and December 2010 (Dominguez E, Rocos B., June 10, 2019). Patient Safety Incidents Caused by Poor Quality Surgical Instruments. Cureus 11(6): e4877. doi:10.7759/cureus.4877)

Alternative Equipment Maintenance (AEM) programs

The Code of Federal Regulations CFR 482.41 (c)(2) states that "Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and equipment." It also states that all equipment must be tested before initial use and after repairs or upgrades to ensure that it is functioning properly and is safe to use

on patients. As noted by CMS, an AEM program allows a healthcare facility to "adjust its maintenance, inspection, and testing frequency and activities for facility and medical equipment from what is recommended by the manufacturer, based on a risk-based assessment by qualified personnel."

AEM programs are strictly regulated to minimize risk to patients and other people in the hospital. The maintenance must adhere to specific guidelines for documenting how the instruments are inspected and repaired. Once an SPD decides to adhere to AEM activities, it needs to determine what type of maintenance strategy it will employ. The types of maintenance strategies include *PM* (time-based), *predictive maintenance* (condition-based), *reactive maintenance* (corrective, breakdown or run-to-failure), or *reliability-centered maintenance*.

A PM program may not seem to be cost-effective at the beginning. However, in the long run it can save a hospital thousands of dollars every year because it's designed to identify small problems before they become major issues. According to the Centers for Medicare and Medicaid Services, a PM program is "a strategy where maintenance activities are performed at scheduled time intervals to minimize equipment degradation and reduce instances where there is a loss of performance."⁸ Regardless of whether a hospital follows the original equipment manufacturer's maintenance instructions or an AEM program, all maintenance must be accurately documented to provide a record of maintenance activity.

Considerations for a successful PM program

Avoid disruption

Surgical instruments need to be ready whenever they are needed for a case. Therefore, SPD managers need to develop PM programs that will ensure as little disruption to their hospitals' surgery schedules as possible. For example, they need to determine which trays are the most frequently used, and then make sure scissors are sharpened, needle holder jaws are inspected for wear, and osteotomes, rongeurs, and other cutting devices are tested for sharpness on a regular schedule that works around the surgical schedule. A PM plan will include a schedule for all instrument sets to be routinely inspected for serviceability when they can easily be pulled out of use.

Maintain communication

In addition, thorough and timely communication is a must between the SPD and the surgical services department to mitigate any problems with unavailable trays or instruments. Because surgical volumes can change, there needs to be precise communication as to when the instruments or sets will be down for inspection, maintenance, or repair and when they are expected to be back in inventory.

Plan for the unplanned

The SPD also needs to make sure there are enough sets/instruments available for high-volume case days. A maintenance and repair program should never interrupt surgery schedules to the point of needing to cancel cases. Responsive communication with the repair company is another important factor in managing instrument inventories to ensure that the hospital is prepared to handle surges and emergent cases.

Assess repair companies

There are many companies that offer instrument/equipment repairs, but not all offer the same quality of service. Hospitals should research what each company offers in terms of service, frequency, cost, experience of repair technicians, guarantees, and accountability. Furthermore, what works for one hospital may not work for another hospital. Factors such as surgical volume, the number of instrument sets in inventory, the number of personnel, the instrument maintenance budget, and the availability of extra instruments all play a role in determining the type of PM program that will be best for a specific hospital.

Assess your issues

In order to develop a successful PM plan, both the hospital and the repair company need to have a thorough understanding of the extent of the problem. Specifically, they

need to assess how many instruments are failing, the number of times an instrument or set has been serviced in a specific amount of time, how often surgeries have been delayed or canceled due to instruments that are broken or unavailable, and what these issues have cost in the past. This will give the hospital a basis from which to negotiate a contract with a repair company, and it will help the repair company understand the level of involvement that will be required.

Establish and implement the plan

Between the hospital and repair company, a plan is then negotiated that will allow continuity of service to the operating room while also making sets available to be inspected. Often the plan will include a negotiated number of trays to be serviced per visit/year. This then correlates to the number of trays that the repair teams and the hospital staff can handle in a given service visit, which then correlates to the number of visits needed per week/month/year. Once a plan is established, it needs to be implemented and documented to ensure sets are being serviced as contracted.

Repair companies can work onsite within the hospital to repair and inspect surgical instruments and devices. More often, however, they either arrive with a truck in which they perform the work, or for more complex repairs they have the instruments shipped to their facilities. Typically, work is done onsite if repairs are not too extensive.

Protect instruments, patients and budgets

The cost of healthcare has skyrocketed in the past 10 years. That cost is increased by each surgical case that has an adverse outcome because of a broken, non-functioning, or dirty instrument. Hospitals have a duty to ensure patient safety and prevent avoidable adverse events, but they also need to find ways to contain healthcare costs.

When sterile processing leaders invest in robust, comprehensive PM programs, they also help keep instrument purchasing costs down. Instead of being discarded, the majority of poorly functioning instruments can be repaired and effectively maintained. And since it is less expensive to repair an instrument than to buy a new one, performing PM on a hospital's instrument inventory will help reduce the long-term cost of surgical asset management. Improving patient safety while also reducing instrument management costs creates a win-win situation for hospitals. **HPN**

Malene McLain, MS, BS, CST, CRCST is a training manager for STERIS Corporation. She is a certified surgical technologist and a certified surgical technician, with more than 16 years experience in operating room and education settings. She holds a master's degree in healthcare leadership from Siena Heights University and has managed two surgical technology programs at the collegiate level.

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Figure 4: Inside a lab



Figure 5: Instrument sharpening

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Comprehensive PM for surgical instruments

Circle the one correct answer:

1. What is the typical percentage of a hospital's revenue attributed to surgical services?
 - a. 50%
 - b. 20%
 - c. 40%
 - d. 70%
2. Non-functioning, broken, or improperly cleaned instruments can cause surgical site infections.
 - a. True
 - b. False
3. There may be as many as _____ incidents a year of poor-quality surgical instruments causing harm.
 - a. 1,200
 - b. 1,000
 - c. 1,500
 - d. 500
4. A comprehensive and thorough PM program will _____.
 - a. Mitigate the risk of adverse events
 - b. Cost millions of dollars per year
 - c. Only be effective if they repair 500 instruments a year
 - d. Help a hospital pass The Joint Commission audit
5. The _____ allows hospitals to seek alternative methods for equipment maintenance and repairs.
 - a. FDA
 - b. OEM
 - c. CMS
 - d. DHHS
6. _____ is a strategy where maintenance activities are performed at scheduled time intervals to minimize equipment degradation and reduce instances where there is a loss of performance.
 - a. Predictive Maintenance
 - b. Reactive Maintenance
 - c. Reliability-Centered Maintenance
 - d. Preventive Maintenance
7. When assessing a repair company, a hospital needs to look at cost, frequency of service, and _____.
 - a. Accountability
 - b. Experience of repair technicians
 - c. Guarantees
 - d. All the above
8. A PM program helps assure that instruments are _____.
 - a. Repaired every week
 - b. Procedure-ready
 - c. Replaced every 6th use
 - d. Steam sterilized
9. The biggest percentage of unretrieved device fragments was from:
 - a. Needles
 - b. Drills
 - c. Forceps
 - d. Guidewires
10. Investing in a robust, comprehensive PM program ... _____.
 - a. Helps keep instrument costs lower in the long run
 - b. Costs millions of dollars to implement
 - c. Helps with employee satisfaction
 - d. Makes surgeons angry

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