GE Healthcare

Stealth Infectors

Why common mobile medical devices are frequently overlooked in the fight against healthcare-associated infections (HAIs) and what steps you can take

The rise in healthcare associated infections (HAIs) is raising concerns about the cleanliness of medical devices used in our nation's hospitals.

It's estimated that 5 to 10 percent of hospitalized patients in the U.S. are infected each year by pathogens within the care environment.[1] More than 99,000 deaths annually are attributable to HAIs,[2] making it the 4th leading cause of death in the U.S., claiming more people each year than breast cancer, heart failure, and colon cancer.[3]

According to a 2009 report from the Centers for Disease Control and Prevention (CDC), the annual direct medical costs of these infections range from $28-45 billion.[4]

Mobile medical assets and the spread of HAIs

There is increasing evidence that contamination of reusable medical equipment is a key factor in the spread of HAIs. Equipment used to care for one patient and improperly reprocessed can transmit healthcare-acquired pathogens that lead to HAIs, creating a chain reaction that puts other patients at risk.

An *Infection Control Today* article[5] that summarized scientific data related to the role of environmental hygiene in the spread of infectious pathogens included the following findings from a 2006 study:[6]

- Gram-positive and gram-negative bacteria can survive for months on dry surfaces. This includes such pathogens as VRE, MRSA, Streptococcus pyogenes, Escherichia coli, Pseudomonas aeruginosa, and Shigella spp.
- Viruses from the gastrointestinal tract, such as astrovirus, HAV, poliovirus or rotavirus, can persist on hard surfaces for approximately two months.
- The study concluded that without regular preventive surface disinfection, the most common nosocomial pathogens may be a continuous source of transmission.

Time to look beyond the usual suspects
When considering the problem of patients at risk from improperly cleaned reusable medical devices, the discussion usually focuses on the "biggest offenders" – such as flexible endoscopes, which made the ECRI Institute's 2012 list of Top Ten Health Technology Hazards,[7] and surgical tools. Because these devices are used in invasive procedures and are highly complex in design with many moving parts and small crannies where blood, tissue, and other debris can linger undetected, they are rightfully the subject of major attention when hospitals undertake efforts to improve their cleaning and disinfecting processes.

What may be overlooked, however, is another group of less-obvious carriers of HAI-related pathogens – devices such as IV pumps, sequential compression devices, and telemetry units. In a typical 300-bed hospital, the clinical asset inventory comprises more than 5,000 devices, of which more than 95 percent are mobile medical devices that may be receiving insufficient attention during reprocessing initiatives. Their relative simplicity and ubiquity makes them fade into the woodwork; from a reprocessing standpoint, they are frequently treated more like furnishings than medical equipment. While IV pumps and other highly-utilized devices may be wiped down, they often are not disinfected to the degree required to protect the next patient from cross-contamination.

Converting guidance to action
Scientific studies demonstrate that there is a high risk of cross-contamination from mobile medical assets on the front lines of care, for patients and caregivers alike. For example:

- In a study that examined the effectiveness of disinfection with wipes against MRSA, 42% of **personnel who had no direct contact with the MRSA-positive patients but had touched infusion pump buttons** in the room showed MRSA-contamination on their gloves.[8]
- A study of environmental contamination in rooms housing patients with MDR-AB at a tertiary care hospital showed that **nearly half the rooms were positive for the pathogen with supply carts, floors, infusion pumps, and ventilator touch pads the most commonly contaminated sites.**[9]

Regulatory agencies are putting their weight behind this issue. The CDC has issued guidelines for reducing the transmission of healthcare-acquired pathogens related to the contamination of near-patient surfaces and equipment, stating that "all hospitals are encouraged to develop programs to optimize the thoroughness of high touch surface cleaning as part of terminal room cleaning at the time of discharge or transfer of patients."[10] According to Joint Commission mandates, its accredited hospitals are required to perform "intermediate and low-level disinfection and sterilization of medical equipment, devices and supplies."[11] The Centers for Medicare and Medicaid Services (CMS) has issued templates to assist healthcare facilities in preparing for on-site inspections of environmental infection control practices.

Tackling the problem

Protecting the safety of patients is a priority for all healthcare providers. The growing body of knowledge about the link between environmental contamination and HAIs reinforces concerns that are already top-of-mind for hospital executives, who ranked patient safety and quality among their list of top challenges in 2011.[12]

The challenge lies in execution. Most hospitals are lacking clear-cut, detailed guidelines on how to approach this complex and pervasive problem. As the CDC notes, "there is no standard method for measuring actual cleanliness of surfaces or the achievement of certain cleaning parameters or for defining the level of microbial contamination that correlates with good or poor hygienic practices."[13]

Having worked with a number of healthcare organizations on this issue, GE Healthcare has developed a methodology to assist providers in developing and implementing effective policies, programs, and competencies to enable effective cleaning of mobile medical assets that require low-level to high-level disinfection.

Clarify the issues by determining your baseline
Most healthcare organizations acknowledge that mobile device cleanliness is an issue, but few have an accurate sense of the scope of the problem in their facilities. A critical first step in improving the cleanliness of mobile medical assets is to evaluate your facility's current state of environmental hygiene.

The CDC suggests a number of objective methods to measure environmental contamination, including Direct Practice Observation, Swab Culture, Agar Slide Cultures, Fluorescent Markers, and ATP Bioluminescence.[14]

In our experience in working with hospitals on evaluating environment hygiene, Fluorescent Markers and ATP Bioluminescence are preferred for their ease of implementation and low cost.

Fluorescent Markers – These chemical markers, available in gel, powder, and lotion, are placed on high-touch objects and fluoresce under black light to reveal poorly cleaned areas. They provide the basis to evaluate levels of cleaning and a quantitative mechanism to demonstrate improvement.

Adenosine Triphosphate (ATP) Bioluminescence – This method detects the amount and location of ATP, an enzyme present in all living cells, which remains on a medical device after cleaning. The solution is swabbed on a random sampling of devices over 2-3 days across different shifts and the swabs tested in a luminometer. Results can reveal overall cleanliness and highlight problem areas that may need improvement.

Sample testing throughout your facility will enable you to establish a baseline of cleanliness that can be used to guide improvement efforts and serve as a benchmark to monitor progress. For example, the results may reveal varying levels of cleanliness in sample areas. This may suggest that there are different cleaning methodologies and workflows across your facility – some more successful than others. Or it may indicate that designated cleaning personnel in one area are performing at a higher level – or are held to higher standards – than those in other areas.

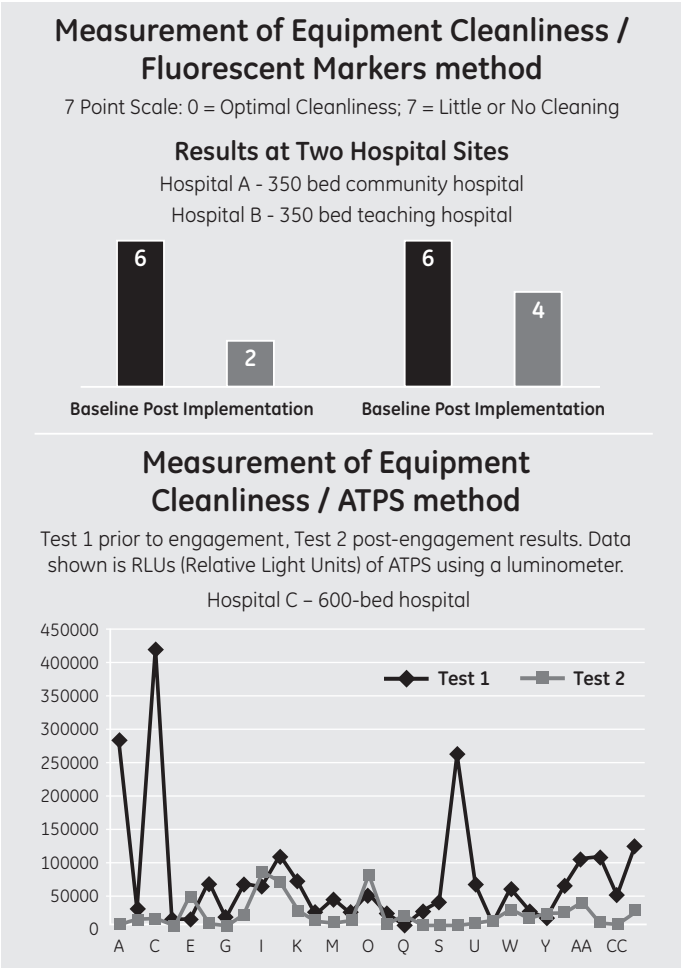
Using the baseline data and the insights that derive from it in combination with a review of existing policies, procedures, and competencies (see "Create the right policies" below) can help you devise an action plan that is realistic, focused, and measurable.

Before & After: Insights from three hospitals
The following graphs demonstrate the experiences of three large healthcare organizations that engaged GE Healthcare for assistance in improving the cleanliness processes for their mobile clinical assets, specifically infusion pumps. The graphs show the baseline status at the outset of each engagement compared with the state of cleanliness measured three months following the implementation of process improvements. Hospitals A and B utilized the fluorescent marker detection method, while Hospital C used the ATP method.

GE Healthcare asset management experts conducted the baseline evaluations, assisted the internal performance improvement teams (typically led by a CNO and/or infection preventionist) in developing and implementing new cleaning processes, and helped guide the re-testing post-implementation.

In all cases, the current-state evaluation was conducted by sampling infusion pumps throughout the facility. Because IV units are used so widely in patient care, the sample touched virtually every department. Policy and process development at both hospitals included:

- Defining roles and responsibilities



- Creating a standardized workflow
- Writing an equipment cleanliness policy
- Developing equipment cleaning competencies among designated staff. A key challenge in mobile device hygiene is training people on the proper cleaning methods and materials to utilize.
- Determining timetables for evaluation cycles

Among the key insights from these engagements:

- **Lack of process standardization leads to poor results.** At one facility, for example, some pumps were sent to Central Sterile for cleaning while others were the responsibility of the nursing staff. Without a clear-cut workflow process and delineation of responsibility, no one was held accountable.
- **When equipment is left in a room, it usually doesn't get cleaned.** A process that assigns responsibility for removing mobile devices from the room – adding it to the discharge checklist, for example – typically results in higher rates of disinfection.
- **Facilities lack effective means of signaling** whether devices have been decontaminated. Suspecting that the equipment is not clean, many front-line personnel take it upon themselves to give devices a cursory wipe-down – which is ineffective at best or totally counter-productive in the case of equipment that had been clean and is now recontaminated.

The high cost of HAIs

In addition to driving high mortality and morbidity rates, HAIs have significant operational implications for a healthcare organization:

- Reduced access to care: HAIs result in higher length of stay (LOS) – 22 days on average versus five days for a non-HAI patient[15] – tying up beds and other resources that could be made available to reimbursed patients.
- Unreimbursed care: The cost of caring for a patient with an HAI typically exceeds the payments that a facility receives. One study showed that such infections reduce net inpatient margins by $5,018 per HAI patient.[16]
- Higher readmissions: Patients with HAIs have a 30% readmission rate compared with 6% for non-HAI patients. Beginning in 2013, more than 2,000 hospitals with high readmission rates soon after discharge will forfeit approximately $280 million in Medicare funds.[17]
- Revenue penalties and rewards: A key provision of the Patient Protection and Affordable Care Act (PPACA) to be implemented in 2015 mandates that hospitals performing in the bottom quartile with regard to healthcare-associated conditions will lose one percent of their overall Medicare reimbursement.[18] In addition, the Medicare Value-Based Purchasing (VBP) program will reward hospitals for quality and efficient in several key areas, including HAIs; those incentives will be funded from penalties exacted on under-performing hospitals.[19]
- High legal costs: Healthcare acquired conditions, which include HAIs, accounted for over 12 percent of total legal liability costs insured by healthcare facilities in 2007.[20]

- **The primary driver of post-implementation improvement was not the process itself,** but the degree of involvement from leadership in engaging staff members and holding them accountable. In Hospital A, the nursing supervisor and manager took a strong stand on compliance and the results reflected their insistence on following process. The take-away is that while many different workflows can be a pathway to improving equipment cleanliness, none will be successful without consistent leadership from key managers.

Create the right policies by asking the right questions
Here are 10 questions that can help your team initiate meaningful discussions around current equipment disinfection policies and procedures, and how they can be improved.

1. **Who is responsible for cleaning?**

   We find that responsibility for cleaning mobile medical equipment typically falls into one of three groups. The most common is Central Sterile or a group within Central Sterile. In some cases, housekeeping takes the lead, and in rare cases facilities management is responsible. Too often, the designated group underperforms and nurses take over the role out of a sense of responsibility to their patients. Although done with the best of intentions, the result is usually that devices are superficially cleaned or not cleaned at all.

2. **Is cleaning performed centrally or on the floors?**

   Choosing between a centralized or distributed model is an important and sometimes difficult decision for hospitals to make. On the one hand, cleaning equipment on the floors (the distributed model) allows for better par management, an increase in availability, minimized transportation, and a reduced risk for personal injury or damage to the equipment itself. On the other hand, a centralized model enables better management of the cleaning process, forces the redistribution of assets, and results in greater control over prioritization and assignment of the cleaning activities.

3. **Have you created a policy for determining the level/degree of cleanliness you need?**

   The industry struggles with the question of how clean is clean. Studies published in many periodicals, including the American Journal of Infection Control, indicate that caregivers can transfer infectious disease from equipment to patients.[21] This evidence supports the development of formalized policies regarding the reprocessing of mobile medical devices between patients.

   There are many guidelines and recommended practices to draw on while developing your policies, including those issued by the CDC, the Association for the Advancement of Medical Instrumentation (AAMI), equipment manufacturers, facility chemical management, and the EPA. Applying the expert guidance of these resources to your facility's unique needs and capabilities around mobile device cleanliness can help you develop customized policies that will help protect your patients and healthcare workers, as well as your equipment.

4. **Is there a standardized process in place for cleaning?**

   While such a process may exist on paper, you need to take a reality check. Ask different staff members working on the same nursing unit to describe how they get dirty IV pumps cleaned. Don't be surprised if the responses range from: "We clean it ourselves" to "It's placed in soiled utility for central" to "EVS cleans them." The amount of variation found in staff answers indicates the level of risk that a contaminated pump will be used on the next patient.

5. **Is the process followed – who actually cleans or does not clean?**

   This question can elicit valuable information from the nursing staff. You may hear such responses as "The pump is supposed to go down to central but we always clean it before it goes to the next patient", or "EVS is great about cleaning equipment when the room is turned over so I just pull what I need from a clean room for the next patient." If so, a deeper dive into equipment cleanliness may be needed.

6. **Do cleaning solutions/methods meet manufacturers' protocols? Do cleaning solutions/methods meet infection control protocols?**

There are literally thousands of mobile medical devices in a hospital from a wide range of manufacturers, each with complex cleaning instructions. As a result, it can be a daunting task to (A) identify the cleaning agents that will comply with all requirements and (B) train personnel on the appropriate cleaning methodologies. The risk of error is high. For example, disinfectant wipes are a common item in hospitals and they contain the chemical compound glutaraldehyde. Equipment with a protective screen covering a display – such as mobile x-ray machines, ventilators, and monitoring equipment – should not come into contact with acetone or glutaraldehyde as those elements will hasten the deterioration of the protective screen. Yet, it's not unusual for us to see devices being swabbed with disinfectant wipes.

7. How do your personnel know that a piece of equipment is clean (signaling)?

In facilities across the nation, nurses struggle to determine if a piece of equipment is clean – unless they clean it themselves. We showed a group of IV pumps to nurses at two hospitals and asked whether they could identify the clean units. At the first hospital, 41% said they could single out the clean units, with most (98%) making that determination on the basis of whether the power cord was coiled or not. At the second hospital, none of the nurses could identify the clean pumps and stated that they had no reliable way to judge a unit's clean status on a regular basis.[22]

In our work with hospitals, we see many signaling methods in use. Among the most common:

- Coiling the cord: Since equipment can be plugged in and used without uncoiling the cord, this methodology is not sound.
- Plastic bags: Plastic bags have many drawbacks. They are not environmentally sound and can become a trip/suffocation hazard if not disposed of properly. If the equipment is still wet prior to bagging, you can create a terrarium effect that promotes the growth of harmful organisms.
- Tagging equipment: Like coiling the cords, tagging can be misleading. We have seen tags left on units that are in use.
- Banding: One of the more effective approaches is the use of self-adhesive paper bands placed around the equipment after cleaning. Positioned to prevent the user from operating the device – over the controls, for example -- bands can be a highly visible flag that the unit is ready for use. Conversely, a device without a band is similar to a medicine or food package without its plastic seal, warning the potential user that it has been opened/used previously and may be contaminated. One drawback with bands is litter – paper bands removed and discarded on the floor can become a problem without personal accountability and adequate policing measures.

  The caveat for banding and all other methods is that they are only as effective as the processes and chain of accountability attached to them. No method will be successful unless there is a clear delineation of who is responsible for signaling and when, where, and how it should happen.

8. Clean-dirty boundaries – how are they established? How is equipment segregated?

Depending on whether you choose a centralized or decentralized model of cleaning (as discussed in question 2), your choices for creating a clean/dirty boundary differ. In a decentralized model, you will either need to clean the equipment in a soiled utility room or out in the hall. In a centralized model, the equipment will be removed from the hospital flow in a well-defined cleaning room. The goal in both cases is to effectively separate the cleaning and storage processes to avoid cross contamination or contamination of other devices in the vicinity. This is where understanding your infection control policy is critical. In a centralized model, the focus is less about the space itself and more around how the devices are transported. Are carts used? Are these carts only used for dirty equipment? Do the carts need to be contained within plastic? There are many solutions to each model, but care must be taken to create strongly followed processes.

9. Upon patient transfer, what happens to equipment?

The PACU and the ED are particularly challenged by frequent transfers. Consider how two different hospitals handle the same scenario:

The patient is wheeled into the PACU from the OR and placed on an IV Pump and a sequential compression device (SCD).

- General Hospital: When the patient is transferred to a room, the IV and SCD are disconnected and wiped down in the PACU bay to await the next patient. Meanwhile, the original patient reaches the room and is placed on a new IV pump and SCD.
- Metro Hospital: When the patient is transferred to a room, the IV pump and SCD are unplugged and accompany the patient to the room, where they are plugged back in.

  General Hospital has three problems. The first is inventory size and device utilization. They need two large inventories of equipment, one in the PACU and one on the med-surg unit where patients are transferred. When surgeries are done for the day, the equipment sits idle in the PACU unavailable to staff in other areas. The second problem is cleaning effectiveness. Is the PACU staff using the proper methods to clean the equipment? The third issue is productivity. Should high-paid and overworked nursing staff spend time cleaning equipment?

  Metro Hospital has the more effective approach. As the originating area, the PACU has a large inventory of equipment. A much smaller inventory is kept on the floor, to supplement for breakage or admits from other areas. Nursing has no cleaning responsibilities and does not have to stage a second set of equipment, making patient care a more immediate concern. PACU should have enough equipment for the day's cases, with a small contingent of units for unplanned cases. This lessens the waste of a full inventory being locked up at night.

10. Upon patient discharge, what happens to equipment?

This time the patient is discharged and leaves the room. In General Hospital, the IV pump and SCD are left in the room

and wiped down by housekeeping to await the next patient. In Metro Hospital, the equipment is moved to the soiled utility room. Once cleaned, the devices are moved to the clean supply room ready for use.

Inventory utilization issues again plague General Hospital. Leaving units in an empty room effectively takes them out of circulation for the rest of the facility. Plus this method puts cleaning in the hands of the housekeeping staff, who may not be trained and qualified to perform this function. At Metro Hospital, the appropriate staff members clean the equipment and then signal that the devices are clean by placing them in the clean supply room where they are immediately available as needed. Nurses do not need to search rooms, since there is always a unit in the clean supply room.

A threat that touches 100% of your patients

With the alarming statistics on the rise of HAIs and the seemingly intractable rate of preventable deaths that occur each year as the result of hospital care, improving patient safety has become a nationwide mandate. Significant headway is being made as healthcare organizations develop effective policies and competencies in key areas, like the reprocessing of surgical devices.

It's important to recognize, however, that non-invasive mobile medical devices also carry the potential for patient harm. The average hospital has thousands of these devices, many of which are not being adequately cleaned. The risk they pose may be even greater, from a population perspective, than that of an endoscope or surgical saw. Surgical patients represent only a portion of the census, typically around 50 - 60%.[23] Thus out of every ten patients, only about half will come into contact with surgical devices, while all ten will, at some point, be cared for in a room or cubicle that contains IV pumps, telemetry units, compression devices, and other indispensable therapeutic equipment. A patient who comes in for open-heart surgery, for example, will spend three hours in the OR and five or more days in a succession of rooms that may harbor deadly pathogens carried by seemingly safe devices.

Preventing HAIs takes vigilance on all levels. Examining how your organization manages the cleaning of its mobile medical devices is critical to meeting your infection control objectives and your mission of safeguarding patients.

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About GE Healthcare
GE Healthcare provides transformational medical technologies and services that are shaping a new age of patient care. Our broad expertise in medical imaging and information technologies, medical diagnostics, patient monitoring systems, drug discovery, biopharmaceutical manufacturing technologies, performance improvement and performance solutions services help our customers to deliver better care to more people around the world at a lower cost. In addition, we partner with healthcare leaders, striving to leverage the global policy change necessary to implement a successful shift to sustainable healthcare systems.

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