Handled with Care?

Protecting Medical Devices from Harm

Gavin Stern
Fresh from the manufacturer and packed with the latest technology, newly purchased medical devices offer great promise to enhance an organization’s delivery of care. But in terms of their care and handling, not all devices live happy lives.

Some devices are handled roughly by clinical staff, who, in the day-to-day tumult of patient care, don’t have the time or luxury to fully appreciate devices’ sophisticated and sometimes delicate inner workings. Other devices may be tossed around by patients, and transportation staff may bump and shove them out of the way. Between patients, devices may be cleaned with solutions that slowly break down their plastic components, seep into crevices, or corrode sensitive electronics.

Then, one day, these devices let out a whimper in the form of an error state and are sent to the healthcare technology management (HTM) department for repairs. There, the biomedical equipment technicians (BMETs) can only shake their heads. “How did anyone find a way to break this part?” they ask. “How could an expensive device be treated this poorly after all the training provided to staff?”

HTM invoices the responsible department for the repair. The amount is staggering. “We barely touched it,” the clinicians fume. “Why did the manufacturer design a device that’s so easy to break?”

The issue is kicked over to the manufacturer, who gets a call for a representative to come and retrain staff. “You didn’t seriously use the device that way, did you?” the rep thinks without saying it aloud. “Why did the training we provided last time fail?”

Medical devices and equipment pass through the hands of people with different skills sets, priorities, cultures, and expertise, and those groups don’t always understand one another very well. When an expensive device is passed between them, why is it such a surprise when the equipment is misused, abused, and shattered—sometimes in spectacular fashion?

The story of how medical devices are misused, abused—and sometimes tortured—is a classic tale of stakeholders who aren’t on the same page and who recognize a frustrating problem where no one group has the full picture. But everyone—from the cleaning crew to the device company CEO—shares in the misery.

Frustrations Are High

HTM professionals like Jennifer DeFrancesco, chief biomedical engineer for the Veterans Integrated Service Network 10, serving Indiana, Michigan, and Ohio, have seen it all: destroyed liquid crystal displays,
batteries malfunctioning or catching on fire, exploding lamps, pole-mounted equipment that tips over, and infusion pump doors broken clean off. It seems that anything that feels gravity’s pull is destined to fall over. “It’s so easy to get frustrated when you see breakages that you feel are avoidable. But in those moments of frustration, remind yourself what your purpose and endgame is in HTM,” DeFrancesco said. “Our goal is to correct the behavior causing the issue, to fix the process, to identify a significant human factors issue we hadn’t identified in the preprocurement or planning process, and ultimately to be trusted technical advisors. You have to focus on the process, not the people involved.”

In one common example, transesophageal echocardiogram (TEE) probes are damaged in the operating room in part because some surgeons prefer not to use them with a mouth guard—a step that manufacturers recommend—because they believe the guard will get in the way. When those TEE probes suffer damage due to the lack of a bite guard or the surgeon tossing the vulnerable instrument onto a table that contains sharp surgical instruments, the repair bill can top $50,000. “No clinician thinks, ‘I’m going to use this for nefarious purposes,’” said Shawna Strickland, associate executive director of the American Association for Respiratory Care. “A lot of the instances of misuse or abuse are from not understanding the piece of equipment, the importance of the equipment, or how it fits in to the plan of care. It’s so easy to damage or lose a part of the equipment, especially when cleaning it.”

### Cover Story

**Proper Handling Tips for HTM Professionals**

### General Considerations
- Allow users to report device problems using an easily accessible (e.g., web-based) method.
- Look into middleware software to collect error messages and alert technicians of problems earlier.
- Review the costs of work orders and pinpoint devices that have excessive costs. Dig down to find the root cause of the device/class expense. Is there a problem with the unit or the device?
- Ensure that device servicing is documented, particularly when it comes from an outside vendor.
- Track “no problem found” issues, which may highlight human factors or design issues.
- Spend ample time evaluating equipment when purchasing it and include stakeholders outside of HTM.
- Ensure that devices that don’t work well are replaced quickly.
- Understand that proper handling of equipment is everyone’s responsibility, not “someone else’s problem.”
- Ensure that equipment storage spaces are well organized.
- Consider investing in a real-time location system to understand where devices are and how they’re being transported.
- Evaluate the device for human factors engineering concerns prior to purchase. What is the training for clinical staff and those servicing the equipment? What is the level of support provided by the manufacturer?

### Importance of Training and Collaboration
- Give people the time needed to adapt to changes in technology.
- Own the responsibility for understanding how a device is supposed to work and how it integrates with the rest of the healthcare delivery organization.
- Train frontline technicians on the issues that should be monitored by identifying known failure points and any risks identified in the instructions for use.
- Understand the technical expertise of the device users.
- Provide—and sustain—formal training for clinicians.
- Engage with the departments who are handling the equipment. Take part in committees that are talking about the process (e.g., infection control, environment of care). Step out of the biomed comfort zone.
- Train clinicians to identify failures or breaks.
- Work through solutions collaboratively. Ensure all departments understand the big picture around equipment handling.

### Proper Cleaning and Reprocessing
- Understand how equipment is being reprocessed.
- Spend the time reading and understanding the care and cleaning requirements outlined in the service and user manuals. These can contain useful guidance on proper cleaning chemicals and storage methods.
The consequences of all these actions are increased costs for the healthcare delivery organization (HDO), a lack of availability for clinical use, or, in the worst case, threats to patient safety. When equipment, such as infusion pumps, grows scarce, departments begin to hoard it, making the problem even worse.

**Feeling the Education Heartburn**

Telling everyone to “be careful” and “don’t break stuff” should be easy enough—but of course, it isn’t. HTM departments often are small, and BMETs can’t be expected to be everywhere that medical devices are used.

The responsibility to take care of devices and watch out for damage has to be established as a hospitalwide policy, said Ramana Sastry, director of clinical technologies at the University of California San Francisco (UCSF) Medical Center. The organization loses about $700,000 each year on equipment damage that’s caused by misuse, she reported.

“The biggest heartburn we have is use education,” Sastry said. “In the past, the mistake we made is that we would hold training and then walk away and expect it to be followed. You’ll see compliance go up in the short term, but then gradually it goes back down again. You have to make this a monthly or quarterly program where you engage with educational material so it stays on everyone’s radar.”

But the weight isn’t entirely on HTM’s shoulders—or, at least it shouldn’t be. Manufacturers are responsible for maintaining a lasting presence to encourage staff education, broaden knowledge, and answer any lingering questions. Sometimes, informal conversations can be the most instructive.

“Clinicians often don’t have a good perspective for what goes into the manufacture and maintenance of the equipment, and may not know how much clinical specialists or product representatives really do want to help,” Strickland said. “What makes for good training? For one thing, it helps when the product representatives delivering the education come with clinical experience. That allows for conversations that go deeper than the device itself and helps get closer to the root problems of why the devices are being misused.”

By legal precedent, the HDO is responsible for training its staff to safely use a medical device, said Tom Shoup, a consulting engineer and principal at Foxburg LLC. However, it’s on the manufacturer’s shoulders to ensure that the training provided to the HDO is effective and available. Those resources should be leveraged when new staff members are brought on board who are unfamiliar with a device or if current staff need a refresher.

However, many HTM leaders bemoan education initiatives that fail to produce lasting results. That leaves two other factors that can change: 1) the culture of an organiza-
A ‘No Win’ Situation: Device Failures Due to Cleaning

Device failures caused by cleaning products and practices ranked number 10 on the ECRI Institute’s Top 10 Health Technology Hazards for 2017. Meanwhile, the possibility of healthcare-associated infections (HAIs) resulting from inadequate cleaning of complex reusable devices ranked as the second greatest hazard. Although device cleaning is essential to reducing HAIs and ensuring patient safety, the methods and solutions used can crack plastics, cloud up clear displays, and cause corrosion.

Tobey Clark, engineering supervisor at the University of Vermont’s Technical Services Partnership (TSP), described a “difficult balancing act” in which medical devices are expected to be effectively disinfected and cleaned while limiting medical device damage at the same time. Of an estimated 10% of equipment classified as damaged, Clark blamed a large segment on damage caused during disinfection and cleaning.

“Manufacturer instructions for use (IFUs) often don’t take into account the realities of keeping devices disinfected and clean in a clinical setting,” Clark said. “Some devices are designed such that metal connectors for module expansion are exposed and solutions may enter these points, causing corrosion, damage, and improper operation.”

Central processing staff at TSP were trained to make sure that cleaning solutions did not seep into metal connector areas, thereby reducing corrosion issues. Using a three-dimensional printer, TSP also produced covers to protect metal connectors while cleaning. Although these efforts greatly improved the corrosion problem, they didn’t solve the issue of the cleaning solutions breaking down plastics—a dilemma echoed by several other HTM departments.

A ‘No Win’ Situation: Device Failures Due to Cleaning

infusion pump malfunctioned and overdosed a patient. The incident occurred soon after a new cleaning solution, which weakened the plastic in some medical devices, was introduced in the hospital. In this infusion pump, the syringe saddle weakened and eventually cracked, causing the infusion pump to sense the wrong syringe type. UCSF filed a MedWatch report, and the Food and Drug Administration issued a public health notification in 2007.

Upon examination, Fechter found that more than 75% of 650 syringe pumps showed cracks in their plastic housing. He also presented findings showing that different cleaning solutions, even some recommended by manufacturers in their IFUs, could weaken and damage the plastic housing of medical devices. Overall, Fechter estimates that UCSF lost $2 million to disinfectant-related damage over the past five years.

“Manufacturers will give a list of approved cleaning products for their devices, but they won’t all meet infection control needs. In a lot of cases, they only told us what we can’t use instead of what we can use. We’re stuck between a rock and a hard place,” Fechter said. “Most biomeds see a crack in the corner of the equipment and assume it was just dropped. And maybe that’s true in most cases. But after being exposed to these cleaning solutions, the impact strength of the plastic has been degraded. They may fail without any impact. Things may look okay on the surface, but the plastic has much less strength.”

Fechter and other HTM professionals have called for better communication from manufacturers on the types of plastics used in their devices and the appropriate cleaning solutions to use on them, as well as designs that can better handle liquid wipe-downs. On the other hand, manufacturers rely on plastics suppliers and may themselves not know the exact chemical makeup of the plastics used or how the vast number of cleaning solution combinations and techniques will affect the various types of plastics.
tion (i.e., how equipment and maintenance is valued) and 2) the design of the equipment itself.

Andrew Currie, director of engineering at Johns Hopkins University Hospital in Baltimore, MD, uses financial incentives to combat what he describes as a “chronic baseline” of equipment breakages that “goes to the heart of training.”

“If people don’t have the time to understand how to use a device or piece of equipment properly, they break it. They often don’t have the time, and it costs the hospital real money,” Currie said.

Like many hospitals, it’s common to find $1,000 ultrasound probes hanging on an IV pole in the operating room. Physical damage to medical devices eats up 20% of the Johns Hopkins HTM departmental budget, about $770,000 in the most recent fiscal year. To combat that behavior, Currie bills customers—usually the clinical departments—when BMETs find obvious physical damage to medical equipment.

“That’s really our only incentive to get people to change their ways and take care of the equipment. You don’t start getting action until you start hitting them in the wallet. But when they see the bill, you have their attention. We’ve had lots of initiatives to try to correct things, but it doesn’t seem to take hold long term,” Currie said. “For one thing, hospital staff changes over frequently.”

One thing that doesn’t disappear with staff turnover is rugged equipment. That’s why Currie seeks out devices that can handle the punishment that users will impart. “Finding good equipment is about the only way that we can solve this long term,” he said.

Although it may cost more upfront to get an incubator that’s built like an Abrams Tank, the lifetime cost may actually be lower due to a longer lifespan and fewer repairs. However, not all complicated equipment can be “toughened up,” and many customers don’t necessarily want to buy the most heavy-duty option available.

Building Solutions into the Device
In many instances, misuse and abuse occur because the device isn’t meeting the customer’s needs. That could be because the manufacturer misunderstood what works for the customer or the customer’s needs changed. Other times, it could be because the device was just poorly designed. The manufacturer holds the keys to designing a device that is either less likely to break from physical abuse and/or uses human factors principles to reduce the likelihood of misuse.

Of course, that can be difficult to achieve, according to manufacturers and human factors experts.

Pete Doyle, a human factors engineer at the Johns Hopkins Hospital in Baltimore,

A cracked syringe saddle in this patient-controlled analgesia pump caused the pump to sense a wrong syringe size, resulting in an overdose being delivered to the patient.

Insights from the Frontlines
At Huntington Hospital in Pasadena, CA, Director of Clinical Technology Izabella Giers uses several forward-thinking methods to encourage the proper care and handling of medical devices.

- Tracking misuse and abuse using a physical damage code in the computerized medical maintenance system. The number and cost of device repairs are reported to the hospital’s environment of care (EOC) committee on a quarterly basis.

- Presenting device damage to the hospital’s clinical leadership group, including lots of photos. “That helps bring it to reality, so they realize how much device abuse and misuse costs the hospital,” Giers said.

- Convening a quality coaching group on a quarterly basis. The group involves quality safety representatives selected from each department. They’re responsible for relaying education initiatives, such as proper handling, back to their department.

- Make EOC and departmental rounds on an ongoing basis to keep an eye on how equipment is used and stored.

- Post cheat sheets and fliers in visible areas to reinforce handling principles.
MD, noted that “any product that triggers frustration may likely be abused, so attention to design for usability is important. Organizational factors may come into play when time stress contributes to rough handling. Size, footprint, mobility, and reliable power sources—factors that affect product acceptance and consequently handling—should be considered when integrating the product into the environment.”

Although work environment and workflow should be taken into account for a given device, competing priorities and design constraints mean that fragility often is unavoidable. Sturdiness is constrained by several goals and objectives, including a desire to pack in the latest technology and the need to be light for portability by transport teams, including air crews.

“This is one of the most tortuous aspects of equipment design. A lot of designers want to put lots of fancy features in. On the other hand, a lot of users want the basic features to work really well, for the device to be bulletproof and last forever. One of the tricks in design is figuring out the magic set of features and functions that will satisfy enough users for there to be a big market,” Shoup said.

Beyond the product itself, design decisions also are affected by the user and use environment. All of these factors must work in concert. For example, when installing wall-mounted displays, one must consider means to prevent IV poles from colliding with them.

“The best way to ensure a device can’t be misused is to design it in a way that prevents misuse. But, of course, that’s not always possible, said Mark DeSilets, vice president of research and development at Mizuho OSI. “I’d love to tell you we always get it right the first time, but that’d be a lie,” he said. “Users find ways to handle equipment in ways that were unforeseen by the development team and undiscovered during the clinical evaluation process. Therefore, we are left to remedy discovered misuse through product updates subsequent to release.”

Specific human factors considerations that manufacturers may take into account include the control activation force required to initiate a device action. Providing reasonable control forces and feedback to users when the device is actively processing commands can help prevent pounding on buttons when a quick response is not observed. Other considerations include how securely multiple devices and their accessories are mounted, keeping the center of gravity in mind to prevent, for example, an anesthesia machine tipping when wheeled over an elevator gap. Of course, the ever-present challenge of managing cables is important to prevent trip hazards that can pull equipment to the floor. In addition, a device’s susceptibility to insults such as fluid ingress, vibration, drops, and heat speaks volumes about the quality of its workmanship.

“From a human factors standpoint, it seems pretty clear. From a manufacturing standpoint, it can be hard for us to implement these human factors principles. But we’re getting better at that,” said Pachu Cuesta, clinical manager for medication management solutions at Becton Dickinson and Company in Vista, CA.

Trying to get the human factors design just right for a new medical device requires a substantial investment of time and money. At Mizuho OSI, the process begins with simulated use testing and in-house valida-

---

**Medical Device Handling Tips for Clinicians**

- Report any breakages that you see.
- Ensure that equipment is clean before sending it for repair.
- Take care in labeling broken devices.
- Slow down.
- Be aware of the value and vulnerability of equipment.
- Treat equipment with respect.
- Disconnect wires by pulling the plug rather than the wire.
- Ensure items aren’t placed in an area where they can be dropped.
- Watch out for collisions with other objects when moving equipment.
- Don’t spill liquids.
- Be careful when stacking devices.

---

Disinfectant damaged the LED camera arm of this robotic surgical system, and the camera housing subsequently cracked. The replacement parts cost $8,000. At least three camera arms were destroyed.
tion, where clinicians come in to try out the new product. That's followed by a limited release of the device to a select few customers, who can let the designers and engineers know what issues, discomforts, or annoyances slipped through the cracks before the full market release. Three-dimensional printing and modeling assist in the application of good human factors principles.

“But there's no substitute for people who have experience in applying human factors in devices,” DeSilets said.

Even with all that effort, many manufacturers will admit that they sometimes get design elements wrong. User interfaces may have worked well in the lab but were not “broadly loved” in the market, DeSilets said. The fix can be as easy as installing differently designed grips on a device or changing a user interface.

Other cases are real head scratchers. In one example, healthcare workers pulled out critical pins that supported the carbon fiber spinal frame, from a surgical table. These “T-pins,” explained DeSilets, secure a frame to which supports for the head, arms, chest, hip, and leg are attached. Removing the pins opened the possibility of an anesthetized patient falling to the floor.

“They were confused because there were two sets of pins. It’s difficult to imagine how people could be confused about which pins support which part of the device, and even so, that they could remove the pins accidentally under load,” DeSilets said. “I’m a bodybuilder and I’ve tried to pull those pins out under load. It’s really hard. I can’t imagine how they managed to do that by accident.”

The immediate response from Mizuho OSI was to retrain users so they would not pull out the wrong set of pins. The permanent solution was redesigning the next generation of tables to lock automatically.

“The wrong sterilization process was used during the steam sterilization of this scope, causing the entire tray to melt. The scope was beyond repair. A crack in the housing allowed fluid to drip onto the circuit board of this syringe pump, resulting in pump failure.
matter how hard somebody tries,” DeSilets said. “We work hard to make it impossible for all but the most malicious of users to do any harm.”

Moving the Needle on Culture
The use of design and training as a means to prevent medical device abuse seems like common sense: Be careful, read the instructions, follow your training, and design tough and easy-to-use products. But can it really be that simple? Doyle thinks that approach can go a long way toward reducing incidents of abuse. Once a good, robust design is developed, the rest depends on the users’ or maintainers’ knowledge, skills, and attitudes. The user must know that dropping an end-tidal CO₂ sensor on the ground can cost $5,000. Staff who are responsible for cleaning the equipment must know how cleaning solutions can be a major source of damage. Skillful manipulation may be required to set up and use instrumentation.

Attitude also plays a part. Doyle said that he contemplates whether a shift has occurred in the way staff view expensive equipment. If high tech is common and no longer a novelty, perhaps it doesn’t garner as much respect as it once did. Users, including clinicians who are strapped for time, need to know the value and vulnerability of the equipment and treat it with skill and an attitude of respect.

BMETs and clinicians report a wide variation in device culture depending on the HDO. Don Armstrong, a certified biomedical equipment technician at Stanford Health Care in Palo Alto, CA, has seen not only different cultures but also very divergent handling procedures, at no less than seven separate hospitals.

“In some smaller hospitals, equipment was left in place and cleaned between patients. There wasn’t a need to move it between big units. In big facilities, there’s a transport team and sterilization unit. The device is put on a rack and then taken up to be used as needed,” Armstrong said. “It’s such a huge chain of events that have to happen. A device could travel half a mile on a cart between patients.”

Other facilities are moving toward a central, off-site sterilization model. With additional transport considerations and more changing of hands, the links in the chain can break down. That’s a major reason why it’s important for HTM professionals in particular to lead the way in communicating device misuse and handling issues—and ideally those concerns will be echoed by the highest levels of the HDO.

“Maintaining the technology is a huge capital base and requires its own separate, director-level voice to be heard by executive leadership. We’re no longer a ‘fix it’ shop—you have to ask for it,” Sastry said. “Clinical engineering needs to get to the next level of evolution.”

With high-level leadership, HTM gains the ability to influence hiring and onboarding to ensure that all new employees start out in a culture that respects the value of medical devices and their role in the HDO. Being willing to take that step forward and communicate with other departments is a crucial aspect of getting everyone on
board—not only to reduce misuse but also the costs and potential patient safety risks that come with it.

HTM’s evolution also requires strong communication at ground level. BMETs can strive to develop the soft skills needed to work with clinicians on how equipment should be used.

“When we see a nurse doing something inappropriately or wrong with a medical device, too often we basically tell them ‘you’re an idiot.’ We offend people by just showing them where the ‘off’ button is,” said David Francoeur, senior director of brand and quality at Sodexo Clinical Technology Management in Nashville, TN. “Instead, we can use that as an opportunity to be humble and train people on the proper way to use the device. The lack of that communication skill set hampers us as an industry.”

One important way to foster effective communication is carefully documenting statistics on use error and physical damage, ideally using a computerized maintenance management system. That information allows all stakeholders to understand what the baseline is and track the effects of process improvement.

“Sometimes we see a reluctance to point out misuse of equipment. People don’t want to stir the pot by calling things ‘user error.’ But when you don’t point out these issues, you lack the data needed to address them. Don’t be accusatory—be realistic,” said Donna Marie Dyer, senior director of biomed operations at GE Healthcare. “All stakeholders need to focus on the common goals. We all want to put patient safety first, have highly technical equipment that works properly, reduce costs, and be efficient. If we can stick to what we have in common, that breaks down the other barriers that are at play.”

Reference