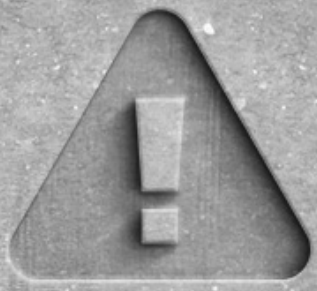
STAY ALERT

ECRI'S LIST OF TECH HAZARDS

BY K. RICHARD DOUGLAS



A JANUARY 2015 ARTICLE IN USA TODAY DETAILED SEVERAL INCIDENTS OF FATAL ILLNESSES IN SEATTLE, PITTSBURGH AND CHICAGO RELATED TO A SUPERBUG BACTERIA KNOWN AS CARBAPENEM-RESISTANT ENTEROBACTERIACEAE (CRE). THE BACTERIA IS OF REAL CONCERN TO MEDICAL PROFESSIONALS BECAUSE IT RESISTS EVEN "LAST DEFENSE" ANTIBIOTICS, ACCORDING TO THE STORY. IN EACH CASE, THE INVESTIGATION OF THE SOURCE OF THE DEADLY BACTERIA TURNED OUT TO BE A SPECIFIC TYPE OF ENDOSCOPE USED ON A HALF MILLION PATIENTS ANNUALLY.

MARK WAKEFIELD
CBET, director/account manager, Physical Asset Services-Clinical Engineering at Littleton, Parker, and Castle Rock Adventist Hospitals

1 FLEXIBLE SCOPES

Conventional cleaning of these endoscopes proved to be insufficient to remove all bacteria. This problem leads ECRI Institute's list of the "Top 10 Health Technology Hazards for 2016." ECRI points out that flexible endoscopes, and duodenoscopes in particular, are constructed in such a way that makes thorough cleaning difficult. The proper reprocessing of these scopes is critical to the well-being of patients. Biologic debris must be removed prior to sterilization or disinfection. The need for this pre-cleaning step is just one area of concern identified by ECRI Institute in this year's list.

ECRI Institute's Health Devices Groups says that the list "identifies the potential sources of danger that we believe warrant the greatest attention for the coming year." ECRI points out that the list does not necessarily reflect the most frequently reported problems, or those with the most severe consequences, but instead those issues demanding the most immediate attention.

Besides the concerns about flexible endoscopes, the list also includes:

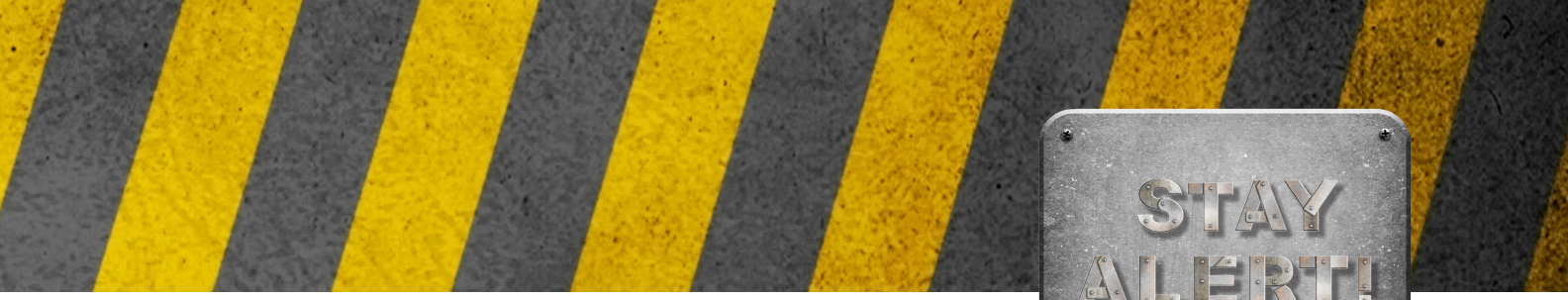
- Missed Alarms Can Have Fatal Consequences
- Failure to Effectively Monitor Post-operative Patients for Opioid-Induced Respiratory Depression Can Lead to Brain Injury or Death
- Inadequate Surveillance of Monitored Patients in a Telemetry Setting, May Put Patients at Risk
- Insufficient Training of Clinicians on Operating Room Technologies Puts Patients at Increased Risk of Harm
- Errors Arise When HIT Configurations and Facility Workflow Do Not Support Each Other
- Unsafe Injection Practices Expose Patients to Infectious Agents
- Gamma Camera Mechanical Failures Can Lead to Serious Injury or Death
- Failure to Appropriately Operate Intensive Care Ventilators Can Result in Preventable Ventilator-Induced Lung Injuries
- Misuse of USB Ports Can Cause Medical Devices to Malfunction

The ECRI Institute considers several criteria when forming its list. Those criteria include severity, frequency, breadth, insidiousness, profile (is it publicly known) and preventability. Nominations for the list come from ECRI Institute's own engineers, scientists, clinicians and other patient safety analysts.

These experts base part of their nominations from investigating incidents, testing medical devices, speaking with other health care professionals, observing operations, assessing hospital practices and reviewing the literature, according to ECRI.

There should be a preventable element to any item that makes it on the list. ECRI also says that the absence of a topic from a previous year should not be perceived as any indication that it is a hazard that no longer deserves attention.

Of the 10 issues identified by ECRI, there are several which directly require some intervention from the HTM department. Addressing some problems may require outside help.



It may require a joint effort between HTM professionals and their IT colleagues, according to Mark Wakefield, CBET, director/account manager, Physical Asset Services-Clinical Engineering at Littleton, Parker, and Castle Rock Adventist Hospitals in the Denver, Colorado area for Catholic Health Initiatives/Centura Health.

"Some of the most obvious resources for addressing these concerns are the hospital IT and biomed/clinical engineering departments. If the concerns and steps listed previously are going to be addressed and utilized, these two departments are going to need a good working relationship," he says.

"Unfortunately, it is not uncommon to find an inherent divide between these two groups of highly trained and intelligent individuals. If this is the case, a possible solution is to create a team of dedicated individuals that work as a liaison between these groups, i.e. an independent CE/IT department that does not retain 100 percent responsibility for either career field," Wakefield explains.

"This group endeavors to translate IT's and CE's actions and responsibilities in terms that can be better understood for both parties, while maintaining a workflow of mutual benefit. In my current hospital system, this has been done successfully and has helped bridge the gap in communication," he adds.

Other sources that should be considered are OEMs and third-party vendors as well as staff from other hospitals. Vendors are a good resource for reviewing not only their hardware and software, but in providing application and workflow reviews and equipment utilization. Third-party vendors can often provide a non-biased review of the same information. In larger hospital systems, utilizing the work and successes of each other's hospitals, can help reduce the "silo" effect of working alone and/or re-creating the wheel. Working together also helps create standardization which so often appears to be lacking in health care.

ECRI Institute's Health Devices Group says that the purpose of the annual list encompasses several concerns and recommendations. They say that the list is intended to help HTM professionals in several ways

"The list is intended to help HTM professionals' patient safety priorities. The list highlights the healthcare technology safety topics that we believe warrant attention for the coming year (since we publish the list at the end of the preceding year)," according to the ECRI Institute's Health Devices Group. "While not all hazards on the list will apply at all health care facilities, the list can provide a starting point for patient safety discussions."

In order to address these risks, ECRI suggests that HTM professionals develop action plans to help reduce the risks.

"The complete report describes the problem, provides practical recommendations for action, and lists sources of additional information or guidance," according to the ECRI Institute.

ECRI Institute's Health Devices Group says the list draws widespread attention to these important safety issues, which can help HTM professionals obtain the resources needed to address the hazards for the betterment of patient care.

FLEXIBLE SCOPES

From dirty endoscopes to the misuse of USB ports and HIT configuration concerns, there are several hazards for patients and staff that can be remedied through the efforts of the HTM professional.

The worst problem areas on flexible scopes tends to be the scope's channels and the elevator mechanism.

"Most types of endoscopes can be reprocessed effectively provided that staff carefully adhere to the vendor recommended reprocessing protocol," the ECRI Institute says.

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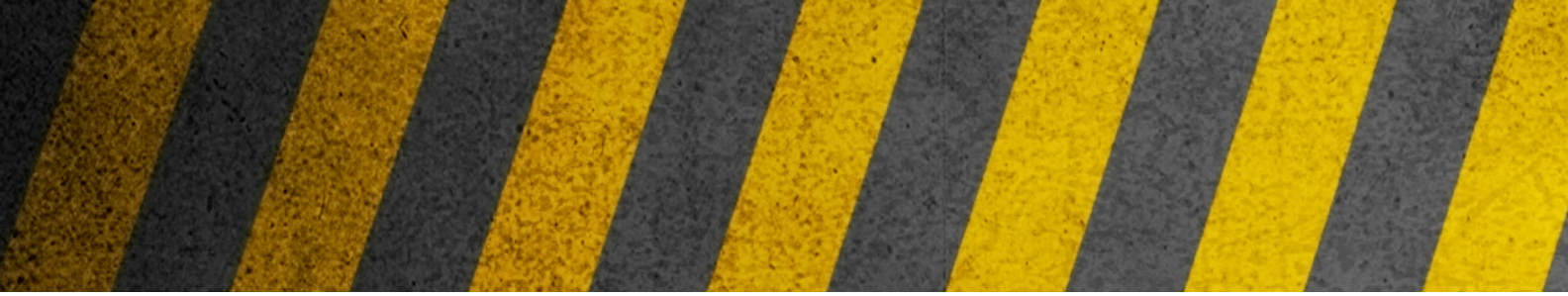
"Often, reprocessing failures can be traced to some breach of that process – for example, if staff skip or do not adequately perform a manual step in the reprocessing protocol or fail to account for the impact of changes made in the supplies used," the ECRI Institute adds.

ECRI points out that under current recommendations, some scopes are still not being effectively disinfected.

"However, for some types of endoscopes – duodenoscopes in particular – concerns exist that the devices cannot be reliably cleaned even when the recommended protocol has been followed," according to the ECRI Institute. "Industry, regulatory bodies, and the research community have been grappling with this



2 HTM'S RESPONSE

3 MISSED ALARMS

issue since it was discovered that disinfection was sometimes failing even when manufacturer instructions were being diligently followed."

The ECRI Institute recommends periodic culturing of duodenoscopes as a way to monitor for colonization with infectious agents. Its recommendations and associated resources are available on the "CRE and Duodenoscope Resource Center" webpage at www.ecri.org/cre."

HTM'S RESPONSE

Wakefield says that of the items on the 2016 list, USB ports and HIT configuration are the two areas where his CE group is leading the way.

"We are working with IT/IS, but have been independently developing data security scripts for updating and managing the data security settings for medical devices," he says. "The automatic script makes it easier and more time efficient to upload data security patches from the Operating System (OS) providers as well as from the equipment manufacturers. This has created a more systematic and standardized approach across my current hospital system."

There's no doubt that more than a few HTM professionals have lamented their concerns about user errors and the ability of clinicians to understand the operation of a device. ECRI Institute includes insufficient training of clinicians on operating room technologies on its list of hazards. They say that approximately 70 percent of "accidents involving medical devices can be attributed to user error or the technique of use."

"HTM professionals are being challenged by leaders in their field to become more involved and play a larger role in educating and training users on new technologies used in the operating room and elsewhere in the hospital," according to the ECRI Institute.

George Mills, Director of the Department of Engineering at the Joint Commission, reinforced this point while referring to topic No. 5 on ECRI Institute's 2016 list in a February 11 webinar broadcast to the clinical engineering community.

"HTM professionals should not accept 'Sure, I know how to use that' from a clinician when they are first using new equipment. Rather, they should be proactive about demonstrating to clinicians the tricks they picked up during training, demonstrating newer features or aspects of use as a way to communicate the value of training and to assess whether additional training is needed," according to the ECRI Institute.

This extends to acquisition. If the HTM professional is involved in the process from the start, they can "inform purchasers and clinicians of the potential roadblocks that they see and provide input about the training requirements that would be needed to avoid those roadblocks," according to the ECRI Institute.

HTM professionals are often the ones directly receiving the complaints from OR clinicians. The HTM staff know which features are being used, which ones are causing difficulty and the ones that may require additional training.

"It wouldn't be an unusual circumstance for a facility to purchase a technology because it offers an advanced feature, only to find that the device or feature is not being used because clinicians have not been properly trained on its use and are uncomfortable with it. One consequence in that scenario is that HTM professionals would need to service both old and new technologies," according to the ECRI Institute.

HTM professionals also can provide input about factors that would make their own support efforts easier for instance, purchasing an anesthesia machine that requires two to three hours of annual maintenance as opposed to a device with similar performance that requires eight hours of downtime twice a year, according to the ECRI Institute.

Wakefield agrees, the HTM department can influence these issues at the point of purchase.

"One way that HTM departments can be proactive in regards to these issues is to be plugged into the capital equipment purchasing process," Wakefield explains. "For example, in the aforementioned CE/IT group, all medical equipment must be reviewed and vetted out before final approval for purchase can be obtained. The process includes reviewing manufacturer literature, MDS2 sheets, and DICOM conformance statements to see if the equipment is compatible with the IT network."

"If the equipment fails to meet any of the established criteria, it will not be approved for purchase or use. This review process, along with CE's review, has helped our hospital system standardize on equipment, which in turn has helped obtain bulk purchase pricing on equipment, due to standardization, as well as minimize capital expenditures on equipment that cannot be used," Wakefield says.

HIT configurations were identified in this year's list. Conflicts with facility workflows are the issue. Wakefield says there are steps that can be taken to help mitigate this problem.

"There are several steps that may be taken to help move down the path of minimizing, if not resolving, possible configuration versus user workflow errors," he says. "These steps may include, but not be limited to: Review any past incidents where errors have been made due to the incompatibility between HIT configurations and facility workflow. This may be completed by reviewing your local incident reporting system. Were there lessons learned that need to be followed up on and or implemented?"

Wakefield also says to identify equipment and interfaces where the greatest risk of error may occur. Patient monitoring, radiology modalities, PACS systems, and drug or prescription processing systems are all examples of a good place to start.

"Work one-on-one with clinical users of equipment to ensure that proper workflows are identified and are compatible with the equipment and their interfaces with HIT. What departments have the highest risk of error? Intensive care units and the chaotic workflow of emergency rooms, operating rooms or imaging departments with the potential of overdosing patients are also good examples," he explains. "All are important areas but which area takes the priority?"

"Work with HIT departments to evaluate clinical workflows and data requirements to identify how systems may or may not be tailored to work cohesively with each other," he adds. "Are the technologies or software being utilized by IT and the hospital compatible with, and configurable to, the clinical workflow?"

He suggests involving key stakeholders from all areas so that complete buy-in to the processes and resolutions may be obtained. This does not imply there will always be 100 percent agreement, but instead, can a consensus be reached so that everyone can move forward together with a plan of action.

ECRI Institute agrees that the need for cooperation between HTM and IT is important.

"For instance, HIT systems are highly configurable and must be tailored to meet a facility's individual care practices at a care area or unit level," according to the ECRI Institute.

"More than just familiarity with the care practices and workflow, this requires knowledge of the capabilities of the HIT system itself, the available infrastructure to support the system, the other devices and systems in use, and a host of other considerations," according to the ECRI Institute. "Thus, optimal configuration of an HIT system will require collaboration among clinicians, the facility's IT department, HTM professionals, and the HIT vendor."

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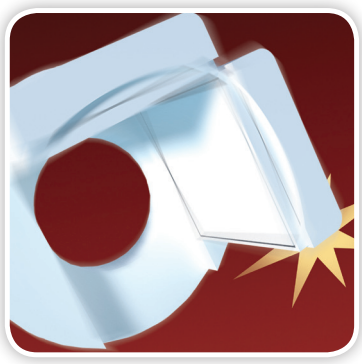
MISSED ALARMS Alarm fatigue from false alarms plays into another hazard on the list. Missed alarms can end in a fatality.

The over-activation of alarms has been a central focus within health care in recent years. But, as ECRI points out, alarm fatigue is only part of the current concern.

"Alarm fatigue is a key aspect of the problem – and one that gets a lot of attention – but it is not the only factor that needs to be considered. Efforts to address alarm fatigue typically help prevent missed alarms by stripping away the noise – literally and figuratively," ECRI points out.

"They reduce the number of alarms that sound for clinically insignificant conditions so that care providers are

4 GAMMA CAMERAS



5 USB PORTS

more likely to notice, and be available to respond to, the conditions that truly require attention. Such efforts are a necessary step toward improving how clinical alarms are managed, but on their own are not sufficient to prevent all missed alarms," according to ECRI Institute's Health Devices Group.

ECRI says that health care facilities also need to consider "will an alarm activate when warranted (e.g., can the medical device reliably detect a particular patient condition, and has the device been set up properly)? Will the alarm signal be reliably communicated to a person who can respond? Does that person know how to respond appropriately?"

What is the role of the HTM professional as it relates to this issue? ECRI points out that at many hospitals, HTM professionals have played very active roles in alarm improvement programs. Activities where the HTM department has been instrumental in finding a solution to this issue include obtaining and analyzing alarm data, assessing alarm notification technologies and processes and training staff on the proper use of medical devices and communications technologies.

GAMMA CAMERAS

Mechanical failures in gamma cameras can lead to injury or death, as the list of hazards points out. ECRI Institute adds that a technician should never leave a patient unattended in a scan room. Staff should always be present to respond to a potential emergency.

The ECRI Institute also highlights the importance of having an effective program in place to manage and promptly respond to safety-related recalls. For complex technologies like gamma camera systems, even seemingly minor notices could have significant safety implications.

Recall notifications do not always fully describe all the problems that are addressed by the prescribed corrective actions. Also, because gamma cameras include very complex electromechanical systems, users may not recognize that actions specified in the recall are intended to prevent a mechanical failure.

USB PORTS

Rounding out some of the areas where HTM professionals can have a direct impact on the ECRI list of hazards is with the inappropriate use of USB ports. ECRI Institute has this advice:

"Make sure hospital staff understand the intended purpose of USB ports on medical devices. And as a corollary, make sure they know what uses are inappropriate. For particularly sensitive equipment, consider the use of USB locks," according to the ECRI Institute.

ECRI also suggests the widespread use of mobile technology can be a factor.

"Since we know that hospital staff, visitors, and sometimes patients have personal devices they want to keep charged – and that phones have been known to cause problems with medical devices – provide safe charging options, where possible," according to the ECRI Institute.

Practical steps to address these concerns, based on solid information and insights, can place the HTM department in a position to safeguard patients and staff. The thought that goes into ECRI Institute's list, along with actionable steps to address these concerns, will create a safer health care environment and make the best use of the expertise available from every biomed.