A ROUNDTABLE DISCUSSION

Combating the Complex Challenge of Healthcare-Associated Infections

Roundtable Participants

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Sean Loughlin Why has concern regarding healthcare-associated infections (HAIs) escalated in recent years?

Donna Swenson One reason is simply because awareness of the problem has increased. The problem has existed for a long time, but people are more aware of it because of media attention, particularly in regard to duodenoscopes. Also, medical devices have become far more complex than they used to be, which has raised questions about how to reprocess reusable devices effectively. Finally, we are seeing problems with antibiotic-resistant bacteria. Bacteria have evolved; we’ve been attacking them, but they have developed defense mechanisms. As a result, our antibiotics aren’t as effective as they used to be.

Michelle Alfa Some HAIs that are related to reservoirs or contaminated medical devices are preventable, and awareness of this has increased. So, we’re seeing more attention given to the concept of exogenous infections, where the organisms are being introduced from the environment or from contaminated medical devices into the patient while they’re in the hospital. This is very different from endogenous infections where the patient’s own normal flora are causing an infection. I would agree that multiantibiotic-resistant organisms are one of the reasons that we’re more aware of the issue, and that’s because we can specifically track these multiresistant microorganisms and know that they are more likely coming from an exogenous source. Because of their unusual antimicrobial resistance profile, it triggers an infection control investigation. If a hospital has five cases of carbapenem-resistant Enterobacteriaceae (CRE), this suggests there may be a point-source issue. Finally, the world is “flat” in terms of the spread of infectious diseases—essentially we’re only “one flight away” from the next multiantibiotic-resistant organism being on our doorstep. We certainly don’t want such multiresistant organisms entering our healthcare facilities and causing HAIs. So we have to be vigilant, ensuring early detection, monitoring, tracking, and preventing the spread of multiresistant organisms as quickly as possible.

Ann Gaffey Patient safety has always been a top priority for hospitals, and we all are quite aware of the 1999 Institute of Medicine (IOM) report, To Err is Human: Building a Safer Health System, which focused on preventing patient harm, as well as subsequent data that have been presented. So, we have more information to look at. At a local level, we see the advantages of incident and event reporting systems. Also, data that are being fed into the patient safety organizations are helping us to identify and address these issues. Recognition has increased that patient safety should really be top of mind for folks who are looking at HAIs and other events that could cause patient harm.
Matt Arduino Awareness of HAIs really didn’t gain traction in the community until the publication of the IOM report in 1999, which stated that about 98,000 deaths a year result from preventable events and errors in healthcare facilities, of which HAIs are a part. In 1999, this translated to about $29 billion a year. Since that report, we now have public reporting through the Department of Health & Human Services (HHS), which also has an action plan for reducing infections. We have the Centers for Medicare & Medicaid Services requirement for conditions of participation for facilities to report data. However, a problem is that not all HAIs are captured through those mechanisms.

Lisa Waldowski Other aspects that have resulted in increased attention include medical device and equipment recalls, along with regulatory and federal agencies making the prevention of HAIs a priority by updating their respective guidelines, as well as communications through advisories, alerts, and other related materials. In addition, the terminology has changed from “hospital-acquired infections” to “healthcare-associated infections,” which underscores the fact that this problem is not isolated to hospitals.

Sean Loughlin Thank you; these comments raise an interesting point about how this problem is portrayed in the media at large. Typically, we see HAIs in the context of dirty instruments, but what you’re articulating here is far bigger and more complex.

Matt Arduino That’s correct. Devices are just one of the causes of HAIs. For example, I was involved in an investigation that focused on contaminated intravenous (IV) solutions. We also are seeing instances of poor water quality at institutions, poor hand hygiene, and poor environmental cleaning. We have seen data where a hospital patient acquired an infection from a previous patient in that same room who was infected with a multidrug-resistant organism (MDRO). Other related areas include contaminated antiseptics and disinfectants, drug diversion, use of multidose vials, and—still in 2016—syringe reuse.

Michelle Alfa Another related component could be described as “management issues.” For example, there may be a protocol on how to reprocess a patient shared piece of equipment, but in actuality, nobody has really been assigned responsibility or is accountable for it. For instance, it’s unclear who’s responsible for the reprocessing or cleaning of, for example, IV poles, blood pressure cuffs, and commodes. The nursing staff might think that housekeeping staff are going to do it, and vice versa. But in actuality, nobody is doing it.

Allison Kumar We also need to consider patient risk factors and what they contribute to the use of devices in this manner, as well as the complexities associated with that. Separate from patient complexities, as devices become more complex, the cleaning and disinfection procedures also become more complex. Adding to Michelle’s point, not only is it a staff management issue in terms of assigning responsibility, but we also have to look at whether staff are properly trained and are able to carry out the very complex procedures that manufacturers are requiring.

Lisa Waldowski In addition to what has been stated regarding the complexities and challenges, I think that with healthcare organizations merging and acquiring a large number of clinics, we are seeing off-site locations often overlooked and practicing in silos, which may pose a risk. Medical devices and equipment may go undetected in these locations, and cleaning, disinfection, and sterilization processes may not be done according to manufacturers’ IFUs or evidence-based guidelines.

Sean Loughlin What are some of the ways that devices can become vectors for the transmission of HAIs or contribute to the dissemination of microorganisms?

Pamela Scott Here at the Food and Drug Administration (FDA), we have been dealing with a number of reports of problems associated with reprocessing of reusable medical devices. These devices have direct contact with both healthcare providers and patients, and the devices themselves can serve as direct conduits for the spread of infection. We’ve already heard several people mention...
the complexity of the devices and the fact that devices are becoming even more complex in their design. With that said, they’re becoming harder to clean, and harder to possibly disinfect and sterilize. We have learned that it can sometimes be difficult for the personnel responsible for cleaning, disinfecting, or sterilizing reusable devices to follow the IFUs. For devices such as ventilators, it’s mostly the internal portions that are in direct contact with patient fluid. And even though they have disposable components that may be replaced for each patient, strict adherence to manufacturers’ IFUs is critical. If the IFU is not followed, these types of devices can also serve as a source of infection.

Michelle Alfa I can provide two tangible examples of HAI transmission via medical devices acting as vectors. One would be a duodenoscope that is contaminated with an antibiotic-resistant organism unbeknownst to the staff, who then use it on a patient and transmit the organism to the next patient. One outcome of this exposure is that an acute infection could result at the time that the device is used on the patient. However, it’s becoming more and more apparent that even colonization with a multiantibiotic-resistant organism is a risk factor for that patient. It may be six months or a year down the road when they get treated with an antibiotic, and because they are colonized with an multi-antibiotic resistant organism, this bacteria survives the antibiotic pressure and is then able to cause an infection, as it is “the last bacteria” surviving. The second example is the heater-cooler device used in cardiac surgery. The heater-cooler is not in direct contact with the patient, but it may create aerosols of unusual water-borne organisms that then end up in the cardiac surgical site. Again, it could take a year or two before the unusual organism results in an infection in that patient, so it is difficult the link the HAI back to the cardiac procedure. These examples of direct and indirect HAI transmission are both affected by the difficulty of tracking the HAI back to the original source.

Donna Swenson In addition to devices becoming more complex, sometimes during product development, the cleaning, disinfecting, and sterilizing of devices are not considered until late in the process. This has resulted in some of these very complex procedures that we see today, because cleaning and disinfecting were afterthoughts in the design of the device. One complication that we’ve seen as a result is an extended exposure time during the sterilization cycle. The good news is that this appears to be changing. I have spent the last year working with a company to address cleaning IFUs early in product development.

Lisa Waldowski The scope of the problem is broader and more complex than many people realize, as a lot of the media coverage has focused on the most egregious problems, highlighting only high-profile outbreak events. On a national level, we do not currently know the actual number of device/equipment-associated HAIs due to our current surveillance and reporting mechanisms.

Sean Loughlin In terms of best practices, what can healthcare facilities do to help alleviate the problem?

Ann Gaffey As a start, it’s important for facilities to have a multidisciplinary product and equipment safety committee in place that has responsibility and accountability for evaluating equipment that’s being considered for purchase or use by their caregiver teams. This committee should include key team members, including physicians, nurses, infection prevention experts, biomedical equipment experts, and pharmacists. Sometimes we fail to include the end users, but it’s vitally important to give them an opportunity to use or test equipment in a simulation environment or in situ.

Michelle Alfa The importance of adequate and ongoing training of staff cannot be underestimated. Word-of-mouth training from somebody who’s been doing it before isn’t good enough; an actual formal, well-documented process is needed, followed by ongoing competency assessments.

Allison Kumar Adding to that point, we really have to emphasize that everyone should be trained to follow manufacturers’ validated
cleaning, disinfection, or sterilization instructions. The FDA guidance notes that manufacturers should make sure that the instructions have been validated. If we don’t know which instructions are being followed, or if the instructions that are being followed at one hospital are different from those at another hospital, then it’s very difficult to determine the root cause of infections that emerge. Another aspect is working with manufacturers to really encourage hospitals to report incidents or suspected infections that they feel could be attributable to reusable medical devices. In addition to reporting these infections to the manufacturer, they also need to be reported to the FDA and Centers for Disease Control and Prevention (CDC). Surveillance needs to be an active best practice for hospitals, in order to gain a working knowledge of the characteristics of emerging infections. Only then can we get an early jump on understanding what could be causing these infections to spread. In the grand scheme of things, we’re never going to be able to totally eliminate HAIs, but efforts on reducing their incidence need to improve.

Dawn Tomac I want to stress the importance of including infection prevention staff in product selection, because they need to complete an evaluation of new devices for appropriateness and safety issues, followed by a rigorous surveillance process after they are selected.

Donna Swenson Last September, a health alert was put out by CDC and FDA basically telling healthcare facilities that they need to review their procedures for cleaning, disinfecting, and sterilizing reusable medical devices. From what I can see, the majority of hospitals have not done that yet, and I think it’s critical that they do. I’ve been in a few hospitals where they didn’t think they had a problem, but after we reviewed their procedures, it was discovered that they did. It seems that most facilities don’t think they have a problem until something happens. Then, they are part of an outbreak investigation. So, it’s critical that healthcare facilities audit their practices to ensure that their education, training, and competency practices are sufficiently rigorous.

Ann Gaffey I’ve had a slightly different experience from the work I’ve been doing with hospitals and certainly from the risk management perspective. I am seeing a more heightened awareness. Health systems in certain geographic areas are now requiring physician offices and large practices that might be doing endoscopies, for example, to have stricter policies in place. I am seeing a greater reach by infection prevention professionals from the healthcare systems out into

Joint Stakeholder Event to Focus on HAIs, Reusable Medical Equipment

AAMI, the Food and Drug Administration Center for Devices and Radiological Health, The Joint Commission, and the American Hospital Association are sponsoring an invitation-only stakeholder event in the Washington, DC, area on Sept. 29–30 that will examine how reusable medical devices and equipment contribute to direct and indirect transmission of HAIs.

The forum will focus on the role that devices and equipment play in enabling nonendogenous infections, transferring pathogenic organisms from an infected individual to another directly or by dispersing the pathogenic organisms into the patient care environment.

“We’re going to look at this as a systems issue—not only how this happened, but how each element, including device, design, IFUs, cleaning, reprocessing, equipment maintenance, personnel practices, training, facility design, and even manager practices, contributes to the problem,” said Joe Lewelling, vice president of emerging technologies and health IT at AAMI.

Combating HAIs, said Lewelling, will require a risk management approach—one that involves identifying areas of transmission risk, determining what can be done to mitigate those risks, and identifying resources that hospitals and others in healthcare can use to help learn about and address the problems.

Rather than simply conversing about the problem, Lewelling said that the forum will seek to “develop recommendations and produce real solutions that the healthcare community can endorse and implement in order to reduce the occurrence of these infections.”
these ambulatory areas to do education and actually using tracer methodology to assess staff competency. I’ve been encouraged by what I’ve seen. Also, for risk management professionals, it’s clear that awareness is significantly heightened as a result of not only patient harm but also the potential for regulatory and other financial implications for the organization.

Pamela Scott Since 2009, FDA has stressed the importance of institutions establishing a quality program that’s focused around the reduction of HAIs. This would include procedures for monitoring adherence to the program and a chain of accountability. It’s also critical that senior-level management be actively engaged in the development and continued implementation of such a program. Although we’ve already discussed training, I wanted to add that hospitals should consider some of the certification programs that are available, as they promote consistency and quality. I also wanted to emphasize the importance of making sure that the staff performing these activities understand the importance of the role they play in reducing the incidence of HAIs in the healthcare setting. Organizations should be encouraged to keep abreast of FDA and CDC safety communications and other information that we make available for healthcare providers. Another source of information is the CDRHNew webpage (www.fda.gov/MedicalDevices/NewsEvents/News), which provides news and updates and allows users to sign up for email notifications.

Matt Arduino We’ve been looking at CRE transmission in regard to the flushing of commodes. Air sampling has revealed positive hits in hospital bathrooms and even ICUs, even for folding or modular commodes, which might not even have lids. I know one facility that we have been working with actually had their engineering departments make some lids to put over their hoppers. And we do know that C. difficile can actually generate a spore aerosol.

"Having sterilization experts and other key stakeholders involved early in product development is crucial." —Donna Swenson, president at Sterile Processing Quality Services, Inc

supply department. Training, clear procedures, and assigned responsibilities are needed to resolve these situations.

Ann Gaffey We have missed opportunities to become more highly reliable. For busy staff working in these environments, having tools such as checklists can help add consistency and reliability to the work.

Sean Loughlin Are there other “environment of care” considerations that are not getting the attention they deserve in the fight against HAIs?

Michelle Alfa More attention needs to be paid to the aerosol spread of organisms. There’s a big difference between an “airborne” pathogen and an organism present in patient secretions that get aerosolized and distributed throughout the healthcare facility. One example would be HAIs due to Clostridium difficile. Even though you may have a patient on isolation precautions because they have a C.difficle infection, there is evidence that C. difficile spores can be transmitted to patients in other rooms—not necessarily through staff carrying them on their hands, but through the aerosolization of the spore form of this organism. The aerosolization results in transmission of C. difficile spores to patients who are distant from the patient who generated the C. difficile spores. In other words, it is possible that HVAC systems can indirectly spread organisms when aerosols are generated.

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We’ve discussed how device design can be a challenge in the battle against HAIs. What’s being done to address that challenge, both in terms of improving designs and improving reprocessing instructions?

As we discussed earlier, having sterilization experts and other key stakeholders involved early in product development is crucial. We need to foster an open, collaborative environment in the design of devices, so that they not only achieve their intended purpose but also are cleanable and sterilizable.

As a part of that process, we also need to look at the compatibility of the materials involved in devices, so that we know which chemicals and appropriate high-level disinfectants, or even ethylene oxide, are available to use on them.

To give credit where credit is due, the 2015 FDA guidance to manufacturers is a key domino that really has focused attention on the validation of cleaning for reusable medical devices. But one thing I’m very concerned about is the fact that the new guidelines do not affect historically cleared devices that are still in use, and in many instances, their design makes them very difficult to clean. We need to find a way to deal with these reusable medical devices that were historically cleared without consideration to validation of cleaning. The impact of the 2015 FDA guidance document on device design can be seen as there are new autoclavable bronchoscopes that are available and I’ve also seen disposable ureteroscopes as well. The change to designing disposable medical devices does bypass the reprocessing issues, and this is good as long as the cost isn’t prohibitive and as long as they take into consideration the biodegradable aspect of such devices. So I do think we are seeing changes as a result of the 2015 FDA guideline.

Appendix E of the 2015 FDA document that Michelle mentioned provides a list of medical devices for which we now request that manufacturers provide the protocols and complete test reports for the validation of the reprocessing instructions, in what we traditionally call a 510(k) submission, which is a premarket notification submission. It is one type of submissions that manufacturers submit for new devices that they intend to bring to the market in the U.S. So again, Appendix E lists devices that tend to be more complex in design, that are more difficult to clean and disinfect or sterilize. They are also devices where we have seen problems in the past, that tend to pose a greater likelihood of microbial transmission and, therefore, represent a higher risk of infection if they’re not adequately reprocessed. The other thing I want to mention that we have highlighted on the FDA website, as well as in some of the past joint efforts that we’ve done in terms of our workshops and past AAMI/FDA summits, are the factors that companies need to take into consideration to improve the design of devices. One component is incorporating the ability to clean, disinfect, and sterilize the device as part of manufacturers’ design controls. That’s going to help improve the design of the device as it relates to being able to reprocess the device. We also encourage manufacturers and designers to look at the ability of the system or devices to be disassembled if they do have internal component or multiple components. In addition, it is important for designers to consider the use of noninterchangeable connectors for critical connections. For example, tubes that are used with endoscopes for direct patient connection shouldn’t be interchangeable with tubing used for waste drainage. It is important that device manufacturers clearly identify connecting accessories as well as single-use components that must be discarded after each patient use and cannot be reprocessed.

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—Matt Arduino, branch chief in the Division of Healthcare Quality Promotion and Infection Prevention at the CDC in Atlanta, GA
"We need to make sure we involve our infection prevention staff in the front end when acquiring equipment, as well as during ongoing review of current equipment that we have in place."

—Dawn Tomac, director of quality and safety at Avera Health in Sioux Falls, SD, and a member of the Association for Professionals in Infection Control and Epidemiology’s Practice Guidance Committee

Sean Loughlin This problem is clearly very broad in scope, but if you could give one tip or bit of an advice to healthcare delivery organizations on how to deal with HAIs, what would it be?

Donna Swenson I would just reiterate what I said is terms of auditing their processes. We need to make sure healthcare staff are consistently following the procedures that they’re supposed to be following.

Michelle Alfa My one tip would be for healthcare sites to implement monitoring of cleaning compliance of their environmental services staff and provide them with ongoing feedback to make sure that all patient care high-touch sites are being properly cleaned and disinfected. There is no doubt that the environmental reservoir of antibiotic-resistant bacteria plays a role in HAI transmission. I believe that improving the cleaning compliance of the healthcare environment will help the most in reducing HAIs.

Ann Gaffey Hospital leaders and others in healthcare really need to understand and sustain the urgency around this problem. It requires diligence in holding each other accountable as team members to do the right thing, and to that end, I think there are opportunities to help support staff to speak up in a culture that supports safety. That means encouraging teamwork and communication, as well as committing to training and formal education. It also means having ongoing education in order to help sustain the work—which is a key point of focus for healthcare leadership.

Lisa Waldowski A good starting point includes a multidisciplinary approach, starting with a risk assessment. This involves a comprehensive inventory, monitoring, maintenance, and tracking of all medical equipment and devices. This process involves facilities, materials management, engineering, infection prevention and control, and clinical department representation.

Matt Arduino I agree with that wholeheartedly: You need an interdisciplinary team along with the involvement of the C-suite and resources made available to do this. I also agree that you need to start with the risk assessment. Whenever you look at a new piece of equipment, the team should look at that and evaluate any potential risk that that instrument would pose and whether it would be actually usable in all situations.

Dawn Tomac We need to make sure we involve our infection prevention staff in the front end when acquiring equipment, as well as during ongoing review of current equipment that we have in place. We need to ensure device manufacturers have a well-defined process for cleaning that is easy to read and may also have to include video demonstration of how to clean devices, as many personnel who reprocess devices are not as well trained and English may not be their first language. We need to take into account the end user and the end cleaner of those devices, as well as other factors going forward.

Pamela Scott I wanted to emphasize the importance of making sure that staff have access to the manufacturer’s reprocessing instructions.

Allison Kumar Healthcare facilities should keep monitoring FDA and CDC safety communications and reporting adverse events to both manufacturers and the FDA.