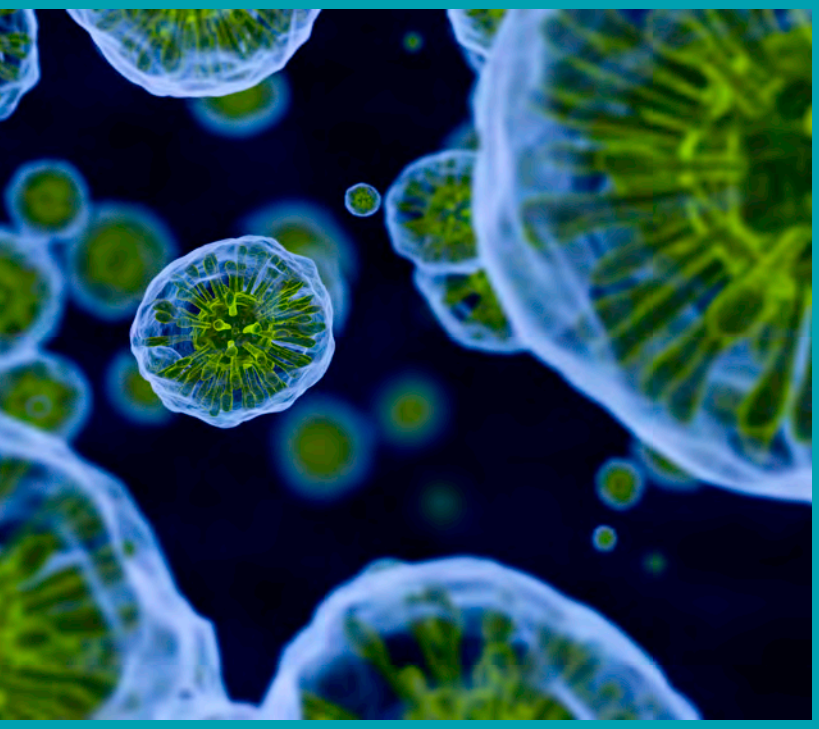
AAMI
Advancing Safety in Healthcare Technology

Preventing Device-Related Healthcare-Associated Infections



Issues and Outcomes from the September 2016 forum, *Medical Technology and HAIs*

In collaboration with AAMI, AHA, CDC, FDA/CDRH, and The Joint Commission

FORUM CONVENERS

AAMI

AAMI, a nonprofit organization founded in 1967, is a diverse alliance of nearly 7,000 members from around the world united by one critical mission—supporting the healthcare community in the development, management, and use of safe and effective medical technology. AAMI serves as a convener of diverse groups of committed professionals with one common goal—improving patient outcomes. AAMI also produces high-quality and objective information on healthcare technology and related processes and issues. AAMI is not an advocacy organization and prides itself on the objectivity of its work.

AHA

The American Hospital Association (AHA) is a not-for-profit association of health care provider organizations and individuals that are committed to the health improvement of their communities. The AHA is the national advocate for its members, which include nearly 5,000 hospitals, healthcare systems, networks, other providers of care and 43,000 individual members. Founded in 1898, the AHA provides education for healthcare leaders and is a source of information on healthcare issues and trends. For more information, visit the AHA website at www.aha.org.

CDC

The Centers for Disease Control and Prevention (CDC) works 24/7 to protect America from health, safety, and security threats, both foreign and in the U.S. Whether diseases start at home or abroad, are chronic or acute, curable or preventable, human error or deliberate attack, CDC fights disease and supports communities and citizens to do the same. CDC increases the health security of our nation. As the nation's health protection agency, CDC saves lives and protects people from health threats. To accomplish our mission, CDC conducts critical science and provides health information that protects our nation against expensive and dangerous health threats, and responds when these arise.

FDA

The Food and Drug Administration (FDA) is an agency within the Department of Health and Human Services. The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation, and by regulating the manufacture, marketing, and distribution of tobacco products.

TJC

An independent, not-for-profit organization, The Joint Commission (TJC) accredits and certifies nearly 21,000 healthcare organizations and programs in the United States. Joint Commission accreditation and certification is recognized nationwide as a symbol of quality that reflects an organization's commitment to meeting certain performance standards.

About This Report

This publication summarizes presentations and provides additional perspectives from experts at the Sept 29–30, 2016 forum, *Medical Technology and HAIs*. This publication is intended to be a helpful information resource, and reflects the expert advice and views of the experts. It is not to be construed as an interpretation of AAMI standards, nor does it constitute legal or regulatory advice.

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Preventing Device-Related Healthcare-Associated Infections

ISSUES AND OUTCOMES FROM THE SEPTEMBER 2016 FORUM, MEDICAL TECHNOLOGY AND HAIs

Contents

Background

Preventing healthcare-associated infections (HAIs) is a top priority in healthcare today, as evidenced by a national initiative in place to address this issue.[1] HAIs are the most common complication of hospital care and one of the top ten causes of death in the United States. Reducing preventable HAIs is an imperative mission to improve patient safety.[2,3] The Centers for Disease Control and Prevention (CDC) estimates that 722,000 HAIs occurred in U.S. acute care hospitals in 2011.[4]

The *National Action Plan to Prevent HAIs: Roadmap to Elimination* attributes as much as $33 billion in annual healthcare costs to preventable HAIs. Although most HAIs are derived from endogenous sources (inside the patient), 20% of HAIs are associated with contamination from the environment, which includes infections related to medical device use.[1] The environment around a patient includes the facility where the patient is located or where the equipment is stored, the people working in the facility, and the medical equipment itself.

HAIs caused by the patient's own microorganisms can be difficult to prevent, but infections associated with diagnostic devices and reusable medical equipment are largely preventable.[5] Contaminated patient-care equipment represents one of the most common sources of infectious agents that cause HAIs.[6]

HAIs represent a break or failure in infection control practices, a failure to maintain a safe environment, a defective product, an unforeseen avenue for exposure, or a combination of these factors. These are frequently system failures, not isolated events. As such, only collaboration among all stakeholders can lead to a comprehensive strategy and an effective mitigation plan.

Device-related HAIs occur when the device itself becomes contaminated and serves as a means of transmission of microorganisms directly or indirectly from an infected individual to another patient. If cleaning, decontamination, or reprocessing is inadequate, a contaminated reusable device may transmit an infection each time it is used. Device-related HAIs often present as multi-event incidents, with contamination issues or problematic practices going undetected until the investigation of a cluster of infections identifies the device as in-common with the infected patients.

As technology advances, medical devices are growing more sophisticated. The increase in complexity requires a corresponding increase in the level of knowledge and skills to safely use, manage, and reprocess the device. However, specialized cleaning and processing resources may be unavailable within a facility. In 2015, the CDC consulted with the Los Angeles County Department of Public Health to investigate a cluster of carbapenem-resistant *enterobacteriaceae* (CRE) infections related to exposure to contaminated duodenoscopes. These technologically complex instruments are difficult to clean, and the investigators reported finding no lapse in duodenoscope reprocessing or evidence of defects in the duodenoscope.[7] Solutions require a systems approach, which addresses purchasing protocols, education and training, resource allocation, and oversight (e.g., monitoring and audits to ensure compliance).

Even when a solution appears obvious, it is still necessary to work within the system to ensure that the solution is implemented and sustainable. For example, many years ago the CDC identified hand hygiene as the single most effective behavior to prevent infection. Yet, as recently as 2013, the National Center for Biotechnology Information reported that "Compliance with hand hygiene practices among healthcare workers has historically been very low, averaging 39%."[1] Washing hands seems like an obvious step—but implementation and sustainability prove to be a significant challenge to healthcare systems.

Forum attendees convene in a combined session, to develop their recommendations to combat HAIs.

Working Together to Fight HAIs

AAMI—a respected institution in the community for setting standards—has responded to the issue of HAIs in collaboration with the Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH), the CDC, The Joint Commission (TJC), and the American Hospital Association (AHA). AAMI and its partners selected more than 100 stakeholders concerned with the use of medical devices—healthcare administrators, clinicians, researchers, instrument processing personnel, and device manufacturers—to attend a Sept. 29–30, 2016 forum, *Medical Technology and HAIs*. The forum's design and direction were informed by a survey of 415 stakeholders representing the wide variety of individuals involved in some way with medical devices (Table 1).

The pre-forum survey identified the items, practices, and situations most likely to lead to contamination and infection (Tables 2–5). Respondents shared their concerns about device-related infections, prioritized the risk of infections related to a variety of devices, and described their observations and recommendations for improvements. The forum was structured to address device-related HAIs in the same context, ensuring that all perspectives were included in deliberations, and that the strategies proposed were comprehensive and realistic.

This event represents important but measured steps on what will be a long journey to address the issues surrounding HAIs. The forum was organized to facilitate the exploration of how and why these device- and equipment-associated transmissions occur, and the identification of solutions to the problem.

The recommendations for preventing device-related HAIs created by forum attendees will be published in early 2017. These recommendations will represent the opinions of highly qualified experts constituting all disciplines involved in the design, development, purchase, use, and reprocessing of medical devices and associated equipment, and the systems in which they are used.

Mitigation strategies and prevention protocols identified by forum stakeholders will be applicable throughout the healthcare industry.

"We can accomplish so much when we team up and tackle these complex issues together."

—Suzanne Schwartz, CDRH

Professional Background	Responses No. (%)
Medical Device Reprocessing	186 (44.81)
Clinical Healthcare Provider	73 (17.59)
Healthcare Management/Administration	52 (12.53)
Medical Device or Equipment Provider	51 (12.29)
Research or Academia	18 (4.34)
Patient/Patient Advocate	10 (2.41)
Healthcare Policy Development/Implementation	9 (2.17)
Medical Device/Equipment Management, Maintenance, Repair	7 (1.69)
Regulatory or Accrediting Agencies	7 (1.69)
Facility Engineering/Management	2 (0.48)

Table 1. Background of pre-forum survey respondents

	Perceived Risk					
	Very Low or No Risk No. (%)	Low Risk No. (%)	Moderate Risk No. (%)	High Risk No. (%)	Very High Risk No. (%)	Weighted Average
Surface Disinfection	10 (3)	25 (7)	69 (19)	143 (39)	124 (32)	3.93
Quality Systems and Risk Management	20 (5)	49 (13)	105 (29)	119 (32)	76 (21)	3.49
HVAC Systems	17 (5)	37 (10)	132 (36)	128 (34)	56 (15)	3.46
Facility Design	20 (6)	53 (14)	144 (39)	109 (29)	44 (12)	3.26
Facility Management	19 (5)	59 (16)	138 (38)	109 (30)	42 (11)	3.26
Special Issues with Ambulatory Care	16 (4)	55 (15)	158 (43)	100 (27)	40 (11)	3.25
Sink and Toilet Placement	19 (5)	60 (16)	152 (41)	93 (25)	47 (13)	3.24

Table 2. Perceived risk of the role of people and the social environment of care in HAI transmission from pre-forum survey of stakeholders.

	Perceived Risk					
	Very Low or No Risk No. (%)	Low Risk No. (%)	Moderate Risk No. (%)	High Risk No. (%)	Very High Risk No. (%)	Weighted Average
Surface Disinfection	10 (3)	25 (7)	69 (19)	143 (39)	124 (32)	3.93
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Sink and Toilet Placement	19 (5)	60 (16)	152 (41)	93 (25)	47 (13)	3.24

Table 3. Perceived risk of the role of the physical environment of care in HAI transmission from pre-forum survey of stakeholders.

	Perceived Risk					
	Very Low or No Risk No. (%)	Low Risk No. (%)	Moderate Risk No. (%)	High Risk No. (%)	Very High Risk No. (%)	Weighted Average
Endoscopic Equipment	7 (2)	27 (7)	65 (16)	111 (27)	195 (48)	4.14
Reusable Surgical Devices	17 (4)	58 (14)	76 (19)	118 (30)	130 (33)	3.72
Suction Devices (intubated patients)	19 (5)	71 (18)	122 (30)	121 (30)	69 (17)	3.37
Cardiovascular Assist Equipment (ventilators, heater/warmers)	21 (5)	86 (21)	126 (31)	112 (38)	60 (15)	3.26
Measuring Devices for Catheterized Patients	30 (8)	93 (23)	158 (39)	85 (21)	37 (9)	3.01
Staff or Visitor-Owned Devices or Equipment	39 (10)	122 (30)	153 (38)	65 (16)	25 (6)	2.79
Patient-Owned Equipment (laptops, cellphones, etc.)	43 (11)	136 (33)	143 (35)	61 (15)	25 (6)	2.73
Non-Fixed Furnishings (beds, nurse-call devices, lights)	46 (11)	137 (33)	159 (40)	54 (13)	12 (3)	2.63
Portable Medical Devices	49 (12)	143 (35)	142 (35)	53 (13)	18 (5)	2.62
Fixed Furnishings/Equipment (lights, sinks, toilets)	53 (15)	131 (32)	155 (38)	49 (12)	13 (3)	2.57

Table 4. Perceived risk of the role of devices and equipment categories (and associated activities) in HAI transmission from pre-forum survey of stakeholders.

	Perceived Risk					
	Very Low or No Risk No. (%)	Low Risk No. (%)	Moderate Risk No. (%)	High Risk No. (%)	Very High Risk No. (%)	Weighted Average
Reprocessing Reusable Devices (cleaning, disinfection, sterilization)	13 (3)	42 (10)	61 (16)	103 (27)	165 (43)	3.95
Point-of-Care Treatment (decontamination, isolation, etc.)	10 (3)	35 (9)	83 (22)	142 (37)	114 (30)	3.82
Design	13(3)	44 (12)	106 (28)	105 (27)	117 (30)	3.7
Device/Equipment Management	25 (7)	65 (17)	137 (36)	108 (28)	44 (12)	3.21
IFUs	44 (12)	78 (20)	96 (25)	96 (25)	70 (18)	3.18
Maintenance and Repair	25 (6)	99 (26)	127 (33)	91 (24)	41 (11)	3.06
Cleaning/Decontamination of Non-Care Equipment	23 (6)	108 (28)	144 (37)	66 (17)	44 (12)	3
Tracking and Monitoring	65 (17)	119 (31)	109 (28)	69 (18)	21 (6)	2.64
Disposal	67 (17)	139 (37)	97 (25)	51 (13)	29 (8)	2.57

Table 5. Perceived risk of the role of device and equipment design, use, and care in HAI transmission from pre-forum survey of stakeholders.

Forum Overview

Mary Logan, who was AAMI president and CEO at the time of the event, welcomed attendees and provided an overarching goal: identify a list of specific devices and equipment associated with HAI hazards and reach consensus on potential solutions and mitigation strategies.

Experts from the FDA, the CDC, academia, and industry provided an overview of HAIs and national initiatives working to address the problem. Case studies highlighted the impact of specific device-related HAIs and the challenges created by advanced technology in the modern healthcare environment.

Suzanne Schwartz, MD, MBA, associate director for science and strategic partnerships at CDRH, described a shift from passive surveillance to a proactive approach based on using real-world evidence to support regulatory decisions. She emphasized the need for collaboration. Leveraging the healthcare ecosystem—including patients, clinicians, providers, payers, and device manufacturers—enhances the flow of information that informs FDA surveillance, facilitates the clearance and approval of new devices, and enhances oversight of device-related events.

"Solutions are needed at an ecosystem level," Schwartz said during her keynote speech. "Until we change our model to more of a systems approach, our siloed efforts will only get us so far."

To introduce the impact of advancing technology, Isaac Benowitz, MD, a medical epidemiologist at the CDC, described the reprocessing breakdown associated with a 2013 CRE outbreak in Illinois related to duodenoscopes. The complex design of the duodenoscopes impeded effective reprocessing. However, while facilities recognized the reprocessing challenge and added steps to the cleaning process, they failed to effectively reprocess the instrument. One important lesson learned was the need for collaboration with the manufacturer in solving device-related problems. The case study also demonstrated the need for balancing the use of sophisticated devices with the responsibilities associated with maintaining them.

Mary Logan of AAMI addresses forum attendees. The solution to the challenge of HAIs, she emphasized, does not rest with any one person or institution.

Both Benowitz and Karoll J. Cortez, MD, MHS, medical officer with the FDA, discussed an outbreak of *M. chimaera* ultimately linked to heater-cooler devices used in the operating room during certain open-chest cardiac surgeries. This outbreak demonstrated the importance of considering environmental factors—waterborne contaminants in this case—as a source of a device-related outbreak. A heater-cooler device contaminated with waterborne non-tuberculous mycobacteria, dispersed the aerosolized contaminant into the environment. One lesson learned was that devices that produce aerosolization can unexpectedly

contaminate a sterile environment, as in this case, the sterile operative field.

Cortez also focused attention on the need for early reporting of device-related HAIs to the FDA by using the agency's Medical Device Reporting system. Early, effective communication and collaboration among stakeholders are essential elements to promote an ecosystem that favors prompt identification of medical device-related HAI issues and implementation of mitigation measures. Cortez emphasized the importance of convening FDA advisory panels to help the agency identify problems and provide insight on mitigation measures and solutions to specific public health threats.

Janet Prust, director of standards and business development for 3M Health Care, discussed the process for device development, introduction, and support. She emphasized that risk management is integral throughout the product's life cycle. Users expect a safe and effective product, clear instructions for use, and a process for complaint resolution. Formal complaints are a key mechanism to help manufacturers identify and address issues with their devices. Facilities that have a clear understanding of workflow requirements and effective reporting structures are best positioned to prevent device-related HAIs.

William A. Rutala, PhD, MPH, CIC, director of hospital epidemiology at UNC Health Care in Chapel Hill, NC, emphasized that risks associated with managing increasingly sophisticated technology demand an evaluation of the efficacy of current processing protocols. According to Spaulding's Classification, which specifies how an object will be disinfected depending on its intended use, healthcare facilities use high-level disinfection to process semi-critical devices (i.e., devices that contact mucous membranes or non-intact skin, but do not enter sterile cavities of the body). Rutala suggested that high-level disinfection may not be appropriate for endoscopes, based on years of failures. He instead recommended sterilizing devices that pose a significant or potentially significant infection risk, such as gastrointestinal endoscopes and bronchoscopes.

Lisa Waldowski, DNP, PNP, CIC, infection control specialist for The Joint Commission (TJC), explained the TJC expectations for medical equipment management in healthcare facilities. Managing risks begins with a comprehensive inventory with a clear plan for maintenance, inspection, and testing. Equipment use is to be monitored and any incident suspected or known to be associated with serious illness, serious injury, or death must be reported as required by the Safe Medical Devices Act of 1990. To reduce the risk of infections, a facility must have a plan for performing the appropriate intermediate and high-level disinfection and sterilization of medical equipment and supplies. TJC also requires a plan for collecting information to monitor, internally report, and investigate conditions in the environment including: occupational illness and injury; medical equipment problems, failures, and use errors; and utility systems problems, failures, and use errors.

Non-compliance with the standard for proper reprocessing for both high-level disinfection and sterilization has been rising steadily in critical access hospitals, acute care facilities, ambulatory sites, and office-based surgeries. Contributing factors include non-adherence to the manufacturer's instructions for use (IFUs), not following recommended practices/evidence-based guidelines, no documentation of staff competency, lack of appropriately prepared supervisory personnel, and lack of involvement by infection control. Addressing compliance issues will have a significant impact on the reduction of device-related HAIs.

Following the presentations, stakeholders broke up into groups, and the working portion of the forum began.

Progress Toward a Solution: Identifying the People, Places, and Things

"Each stakeholder group has different perspectives, but it was clear that those present had one thing in common—recognition that even though there are no easy answers there is a commitment to work together to find them."

—Janet Prust, 3M

Stakeholders were assigned to one of three groups representing the components of the healthcare environment: people, places, or things.

To keep the format consistent, the groups worked from a common template to identify factors that contribute to contamination and transmission of infection (Appendix A, B, and C). For each factor, the group devised actions, solutions, and strategies to mitigate the transmission of infectious agents, and determined what it would take to implement the strategy. A recorder documented factors and strategies where the group reached agreement. Finally, the participants prioritized the actions, solutions, and strategies supporting each factor.

People, places, and things might seem like discrete focus areas, but they are highly interactive and interconnected. In many cases, the groups identified common contributing factors. For example, is the influence of governance/leadership considered a *people* issue, or does it represent the culture of the *place*? Education and training can relate to *people* if it focuses on the employees' preparation and level of competence. Or, education could fall into a *place* category if it considers the availability of employee training programs in a facility.

The next level of consideration involved all attendees reviewing the same component

George Mills of The Joint Commission (TJC) leads a breakout group at the forum. TJC is the nation's largest accreditation organization for healthcare facilities.

Participants were assigned to one of three groups:

People. Those involved with medical devices and equipment. How do human behavior and the social environment of care (e.g., patients, staff, management, and the public) contribute to HAI transmissions?

Places. Where devices and equipment are used and reprocessed. How does the physical environment of care (e.g., facilities, patient care environment, and governance) contribute to the problem of device-involved HAIs?

Things. The devices and equipment themselves. How do aspects of devices and equipment and associated activities (e.g.,maintenance and reprocessing) contribute to the problem?

(people, places, or things). At this stage, stakeholders shared their completed templates, discussed and prioritized their shared information, and submitted it for consideration by all stakeholders.

The second day of the forum was devoted to the final step in the process—reviewing of all of the elements and strategies by the participants in a plenary session. The work of three separate groups became available for all member's input. Observations and recommendations representing general agreement will be incorporated into a final document for publication in 2017.

While contamination of a device might represent an isolated event, it is also a failure within a system, and often the result of a chain of missteps. Preventing device-related HAIs requires not only identifying the specific causal error, but also the factors within the system that allowed that error to happen. No one participant in the system can solve the problem of HAIs. Changes in practice in one discipline can have a significant impact on others who collaborate in the use and management of healthcare equipment and devices. Policies, procedures, and strategies for a department should be developed in concert with the relevant stakeholders. HAIs are a system problem—prevention requires a system solution.

PEOPLE

Healthcare is primarily a team effort with many people participating—directly or indirectly—in the care of each patient. In addition to the direct caregivers, the pre-forum survey identified others who influence the potential for contamination of devices: the patients themselves, visitors, the public, and personnel in environmental services, infection control/screening/reporting, purchasing, instrument processing, and biomedical engineering. Two additional groups with significant influence are governance/administration and vendors.

Stakeholders participating in the *people* focus group explored the ways in which the actions of people contribute to the risk of contamination, and then devised strategies to address the risk. They identified healthcare providers and environmental services personnel as most likely to contribute to device contamination, followed by patients, visitors, and the public.

Actions of governance/administration were also included because the culture of an organization is sustained by those at the top. The stakeholders documented that "unless this factor is addressed, the probability of success of others is minimal." The successful implementation of any change in practice requires administrative support. The other focus groups shared this observation.

Forum attendees worked together to identify contamination risk factors and to develop proposed solutions.

Inadequate resources and training was the primary concern of the *people* focus group. Training and education are critical for personnel who are responsible for the use of medical devices for patient care; infection control, surveillance, and reporting; purchasing; instrument processing; and biomedical engineering. It is also important for environmental service personnel, governance, and administration. Yet, devices are often introduced into the healthcare environment without sufficient orientation and training. It is difficult to find the time for training when staffing is tight and the workload is daunting—a prime example of how the system can affect strategy. A well-conceived training program cannot succeed when an institution does not provide the resources to implement it. Staff competency is not a core value in a system that doesn't provide training.

Second on the *people* group's list of concerns was a failure to consider the responsibilities and resource requirements related to device management and reprocessing during the purchasing process. Every discipline that interfaces with a device must be included in decision making during the purchasing process. A device that a facility cannot properly maintain poses an obvious risk for contamination, which could lead to infection transmission. The group also noted purchasing inconsistencies within facilities where departments are managed independently of one another. Decision making is fragmented rather than "facility-wide," often resulting in purchasing a variety of different devices for the same purpose. Consistency in purchase decisions enhances education and training, maintenance, and infection prevention.

Routine surveillance, a process for testing items that are determined to be ready for patient use to see if they are contaminated, helps to identify contamination before transmission occurs, and facilitates identification of sources of contamination in a facility. Surveillance programs should be developed based on the statistical risk of contamination. The *people* group felt that current protocols for surveillance and reporting are lacking or inconsistent and therefore not sufficiently effective. Too often, practices are reactive instead of proactive. When potential sources of infection are not identified, the likelihood of device contamination increases. The group concurred that surveillance should be addressed by the *places* group, and that this is an excellent example of the systems nature of infection prevention.

Healthcare providers and environmental service personnel were both cited by the *people* group as contributors for device contamination. The group identified a lack of training or understanding of their role in infection control as two contributing factors. Both of these can be related to short staffing and complex patient assignments identified by the *places* group—a clear demonstration of the interaction of people, places, and things that can result in device contamination.

PEOPLE GROUP

The top-ranked factors in the ***people*** category that contribute to the risk for HAIs:

1. Inadequate resources and training
2. Failure of healthcare providers to implement best practices (practices based on scientific evidence that they will produce the desired outcome)
3. Environmental services practice failure
4. Actions of patients
5. Actions (or inaction) of governance/leadership

Another observation relates to an increasingly mobile society that incorporates a wide variety of ethnic groups for whom English is not a primary language. Language barriers can have significant impact on the efficacy of training and the resulting competency level of some personnel.

Communication in general can be a barrier to effective device management. The quality and timeliness of each participant's work is somewhat dependent upon information provided by others. When there is an inconsistent feedback loop among those involved with medical device use and management, important information can be miscommunicated or lost entirely.

Visitors and the public are frequently unaware of infection-control practices. It's important to educate non-patients—who can still influence device-related transmission of infections—about the role of personal protective equipment, hand hygiene, and the importance of staying away from the health-care facility when they're sick. Facilities are responsible for identifying risk factors and educating their non-patients. This includes providing signage encouraging hand hygiene and not visiting when sick—representing another indication of the systems nature of infection prevention.

All three focus groups identified the significance of education and training. When a facility expects its employee to perform a task or assume responsibility, it must provide orientation, structured education and training, and an oversight policy to validate competence and adherence to standards. All three groups emphasized the importance of effective communication, following standard precautions, and zero tolerance for work-arounds and shortcuts.

PLACES

While it might appear that transmission of HAIs is primarily the result of the failure of an individual to do his or her job responsibly, aspects of the physical facilities where devices are used can contribute significantly to infections. Stakeholders discussed the impact of 12 environmental factors on HAI transmission.

Specific to environmental surfaces, the group recommended establishing protocols based on standards and regulatory criteria, selecting products consistent with protocols and device specifications, and ongoing monitoring. Disinfectants are only effective if used properly and in accordance with instructions. This requires that users have education, training, competency assessment, and the required amount of time to perform the job adequately. The first "fix" that the *places* group identified is a *people* responsibility. This intersection demonstrates the systems nature of infection prevention.

Environmental services personnel who work in hotels and hospitals receive the highest wage for their industry, with a mean annual income of $25,750.[8] However, this is modest compensation when compared to other hospital personnel, despite being key players in infection prevention. The first consensus recommendation from the *places* focus group was acknowledging the value of each contributor to infection prevention. Governance and leadership must establish facility practices that reinforce and reward those who are essential to preventing the spread of infection.

Building a business case when proposing purchases or changes in practice is vital when communicating to other disciplines—an observation shared by the other groups. A business case demonstrates the value of a proposal in terms of its impact on the problem at hand and the resources available for implementation. The attitude of "because the doctor wants it" should have less influence on purchase decisions than issues such as "it won't fit in our low temperature

PLACES GROUP

Stakeholders ranked the first seven factors:

1. Inadequate disinfection of surfaces, fixtures, crevices, and hinges
2. Inadequate quality systems and risk management practices
3. Issues with the HVAC (heating, ventilation, and air conditioning) system and filters
4. Inadequate facility design
5. Issues with facility management
6. Improper sink and toilet placement
7. Special issues in ambulatory settings

Additional factors identified by stakeholders were not ranked:

- Issues with waste disposal
- Inadequate environmental monitoring
- Issues with steam and water quality
- Aged or outdated facilities
- Inadequate signage, labeling, written instructions, and standard operating procedures

sterilizer." A business case should demonstrate that a purchase or proposal "will do what we need it to do" and "we have what it takes to make that happen."

The second priority item, quality management and risk management, highlights the need to balance resources with responsibilities when maintaining a culture of safety. Quality management is the process of actively assessing practices to determine the extent that they achieve desired outcomes (e.g., a reduction in infections associated with the use of medical devices). Risk management represents the implementation of practices that reduce patient risk, and subsequently limit a facility's exposure to liability. There is a distinct relationship between quality and risk—as quality outcomes increase, the potential for adverse outcomes decreases.

Cutting corners to speed up a process indicates a disconnect between responsibilities and resources, which negatively impacts both quality and risk. Either there is too much to be done in the amount of time allotted, or there aren't enough people available for the department's workload. This puts the patient at risk, increases the facility's risk for liability, and constitutes a reactive rather than proactive setting. The group recommended using checklists and creating efficiencies, standardizing practices when possible, not tolerating deviation from standards, and ensuring monitoring, oversight, and a feedback loop.

The *places* group recommended the strategy of recognizing and celebrating successes. A "Good Catch" award acknowledges an employee who averted an incident or potential problem by speaking up in time to fix the issue. The success of such recommendations requires a system that supports them is adopted. Stakeholders acknowledged that the recommendations would require a culture shift if the practices were not already in place.

The heating, ventilation, and air conditioning (HVAC) system is integral to maintaining specific environmental characteristics for specialty areas such as the operating room, isolation, and sterile processing areas. Old or outdated systems that cannot maintain the required number of air exchanges, pressure differentials, or temperature and humidity levels are contributors to infection. An underperforming HVAC system can harbor microorganisms that cause HAIs. Older systems can be difficult to maintain, especially if they contain parts from different manufacturers. All HVAC systems require scheduled cleaning and maintenance. Communication with end users is important when problems with a system might impact service. Water systems (in particular, those that provide high-purity water) also have implications for infection control and require similar surveillance and maintenance protocols.

The forum was marked by passionate and intelligent debate about the challenge of HAIs, which threaten patient safety and drive up healthcare costs.

Poor facility design and repurposing workspace in older facilities lead to similar problems that occur when the workspace does not support the implementation of best practices. For example, plumbing connections may direct the placement of sinks and toilets into an unsatisfactory location, creating an infection control challenge. Using decontaminating instruments in an area that lacks negative pressure creates the potential for contaminants to disperse into the general atmosphere. Contaminated items should remain segregated and not be transported through clean or public areas. In part, because healthcare facilities are held accountable for the regulations in place at the time they were built, many old facilities fall far short of current standards.

THINGS

The *things* focus group discussed factors related to the design, use, and maintenance of medical devices and healthcare equipment. Members of that group identified 16 factors that have an impact on device-related HAIs.

The group agreed that consistent and effective cleaning, disinfecting, and sterilization of instruments, devices, and equipment have the greatest impact to reduce the transmission of infection. The second factor identified as having a high potential impact to reduce HAIs was point-of-use treatment of contaminated devices. Clinicians using medical devices (e.g. surgical instruments or diagnostic equipment) have an obligation to maintain cleanliness when the device is in use and then prepare it properly for return to the processing department. Stakeholders observed a poor understanding of the importance of early decontamination of equipment. Soil that dries on an instrument or device before it can be reprocessed can interfere significantly with cleaning and reduce the efficacy of the sterilization process.[9] Stakeholders recommended incorporating point-of-use treatment into education and training, the manufacturer's IFU, and in policies and procedures. Point-of-use care also includes awareness of the need to clean often-neglected touchpoints on devices. Periodic monitoring using a test method that detects "invisible" soil can be an effective approach to increasing awareness and modifying behavior.

Issues with device design was third in the rankings. The design process focuses on performance but often fails to consider human factors and "usability." For example, many touch screens and bar scanners cannot tolerate harsh disinfectants.

Stakeholders identified manufacturer IFUs as an opportunity for improvement. The IFU is the primary resource for information regarding the use and management of devices validated for use in the healthcare environment. However, many forum participants expressed concern that IFUs are rarely user friendly and are often ignored by healthcare providers. IFUs, they said, appear focused on mitigating manufacturer liability, with disclaimers prioritized over the instructions. Stakeholders recommended designing IFUs in a standardized format to make it easier to find specific information. To facilitate compliance, they suggested including an explanation (the "why") for the "Do Not" list. An effective IFU might include a logically organized format with electronic access that includes images or videos for visual guidance.

The group unanimously recommended involving all stakeholders in the purchase process. Clinicians focus on the purpose of the device and ease of use; infection preventionists consider the impact of the device on the environment; sterile processing and environmental services personnel assess the resources available for preparing the device for use.

THINGS GROUP

Risk factors in order of priority:

1. Inadequate cleaning/disinfection of reusable devices
2. Poor device management at point of use
3. Device design issues
4. Device management issues
5. Non-adherence to manufacturer's instructions for use (IFUs)
6. Improper maintenance/repair of devices
7. Lack of cleaning/disinfection of non-patient care devices (e.g. phones, electronics, etc)
8. Poor device tracking and monitoring
9. Improper device disposal

Other factors identified but not ranked by the stakeholders:

- Delays in treatment and reprocessing
- Insufficient inventory for case load
- Incompatibilities in disinfection or sterilization processes
- Transportation of contaminated devices
- Inadequate or improper storage
- Single-use devices
- Spaulding's Classification scheme

Lessons Learned

"If you want to change a situation, try substituting 'we' any time you say 'they.'"
—Rod Parker, Stryker

HAIs represent a break or failure in infection control practices, a failure to maintain a safe environment, a defective product, an unforeseen avenue for exposure, or a combination of those factors. These are frequently system failures, not isolated events. Resolution involves a shift in focus from fixing the problem (reactive) to preventing the problem (proactive). That requires developing an organizational culture that promotes collaboration among all stakeholders in pursuit of a comprehensive strategy and an effective mitigation plan—a "just culture" (personal accountability) or a "culture of safety" (overall organizational prioritization of safety). Such a culture values openness and honesty in addressing situations where there is potential for improvement and situations that represent potential liability for the facility.

Focusing on *people*, *places*, and *things* provided structure to the workshop and helped organize discussions and recommendations. But it also served to identify the important concepts that are essential to the success of any program. The most important observation was the systems nature of infection prevention. Contamination and transmission are rarely isolated events; they are the product of a complex, interactive environment (system) that was not adequately designed to prevent them. Collaboration and communication are integral to infection prevention. Finally, education and training, oversight, and validation of knowledge and performance were elements captured in the recommendations from all three focus groups.

Infection prevention relies on the integral relationship between people, places, and things. Successful prevention strategies must address the contribution of all three.

The first step in implementing a successful and enduring HAI prevention program is to ensure that the facility as a whole is on board with the program. Every group noted that the physical environment, governance/leadership priorities, resources available, and facility culture have a direct impact on the ability to prevent HAIs. Facility structure and culture can either promote or inhibit collaboration—it is difficult to impossible to implement prevention strategies that are not actively supported. There must be accountability for HAIs at all staffing levels within a facility, including senior management and all other facility staff.

The traditional department-oriented structure of healthcare delivery organizations is not conducive to collaboration. Rather, it promotes silos and results in narrowly focused thinking and decision making: Success is determined by the impact of a decision on the department, not the facility as a whole. Purchase and policy decisions do not include input from stakeholders outside the department. A manager cannot justify the purchase of an item if savings related to the purchase are realized in another department. An integrated approach that crosses departments would be more effective.

Preventing adverse events of all types requires everyone to be vigilant and to speak up when they observe something troubling, in addition to a robust system of clinical surveillance for device-related HAIs. Pointing out a problem is risky unless there is a culture of safety where the facility rewards such behavior and there is no fear of punish-

Factors considered essential for success:

- A system committed to infection prevention—a culture of safety
- Education and training; oversight and on-site, ongoing verification of staff competency
- Effective use of resources
- Collaboration
- Purchase decisions involve all stakeholders and consider reprocessing requirements

ment. The traditional culture of "blame and shame"—rushing to establish who is at fault when something goes wrong—is not conducive to sustained improvement. Behavior that is rewarded flourishes, while behavior that is stifled or punished disappears. A safety culture rewards best practices, personal growth, and continuing education. It maintains zero tolerance for suboptimal performance (i.e., accountability at all staffing levels). Without support and enforcement, policies and strategies have little effect.

A safety culture also limits liability after a safety failure by addressing the situation with honesty and transparency. According to a policy addressing medical risk and liability recently published by the American Academy of Pediatrics, "there is broad consensus that open and honest communications are ethically indicated when medical care doesn't turn out as expected. Additionally, increasing evidence indicates that such communications can promote a culture of safety and reduce the consequential harms to patients after medical errors."[10]

Staffing decisions impact the ability to prevent HAIs. When facilities are inadequately staffed, the employees assume a greater workload—sometimes more work than can be performed safely. Increased stress levels, high staff turnover, rushing, and taking shortcuts lead to mistakes.

Successful education and training require effective communication. This can be especially challenging when employees, patients, and visitors speak English as a second language. In the workplace, it can be difficult for individuals learning a second language to speak up when they don't understand something. Verifying adequate comprehension is a core component of good communication. When you're not sure if someone "gets it," ask them to describe or demonstrate what was learned.

There may not be funds available to remodel an older facility or build a new one, but administration must make realistic decisions based on available resources. Repurposing workspace may not be possible if the facility structure does not support components essential for the new space. Plumbing may not be available for a sink in a new isolation room. The HVAC system might not be sophisticated enough to provide required temperature and humidity levels and positive pressure for a sterile procedure room. Reprocessing a technologically sophisticated device might require equipment that the facility does not have.

Infection prevention requires "big picture" thinking. A patient's device-related infection results from contamination that could have come from numerous sources. Because so many factors impact the potential for contamination and transmission related to a device, effective strategies must address the device as a process, including purchase, maintenance/reprocessing, use, and storage. That approach to prevention requires collaboration and commitment from everyone involved, support from the facility for the resources required for implementation, acknowledgement and reward for achievements, and a commitment to improvement when performance falls short.

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