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CDC Calls for Massive Patient Notification on Heater-Coolers

Risk is low, but number of potentially exposed patients staggering

By Gary Evans, AHC Media, Senior Staff Writer

The CDC is alerting hospitals that hundreds of thousands of open-heart surgery patients may be at risk of slow-growing infections caused by heater-cooler devices that were intrinsically contaminated during production.

"New information indicates that these [Stöckert 3T] devices, manufactured by LivaNova PLC (formerly Sorin Group Deutschland GmbH), were likely contaminated … during manufacturing," the CDC stated in an Oct. 13, 2016 health advisory.[1] "Hospitals should advise potentially exposed patients to seek medical care if they are experiencing symptoms such as night sweats, muscle aches, unexplained weight loss, fatigue, or unexplained fever."

The patients may have been exposed to Nontuberculous *Mycobacterium chimaera* (NTM), a rarely pathogenic bacteria that is capable of causing life-threatening infections in this particular situation. Hospitals should "consider" notifying patients in writing about the risk going as far back as 2012, the CDC recommended. *(See Q&A on notifying patients, in this issue.)*

> HOSPITALS SHOULD "CONSIDER" NOTIFYING PATIENTS IN WRITING ABOUT THE RISK GOING AS FAR BACK AS 2012

"Almost a quarter of a million patients a year are undergoing surgeries that require use of this [heater-cooler] device," says **Joseph Perz**, PhD, an epidemiologist in the CDC's Division of Healthcare Quality Promotion. "The information we have seen is that Soren units account for about 60% of [U.S.] market share. This device has been on the market for a number of years so it is a large number of patients."

An advisory by the FDA issued

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the same day says, "The 3T devices manufactured at this facility were distributed worldwide. In response to the *M. chimaera* findings in August 2014, the manufacturer added cleaning and disinfection procedures to the production line in September 2014. Samples taken at the same manufacturing facility, by the German regulatory authorities in July 2015, did not show *M. chimaera*, potentially indicating the contamination at the manufacturing facility had been resolved."

Risk Hard to Rule Out

However, the FDA is aware of some 3T devices manufactured after September 2014 which have tested positive for *M. chimaera*. "It has not been confirmed whether these devices were contaminated at the manufacturing facility or became contaminated at the user facility," the FDA states. "To date, the FDA is not aware of *M. chimaera* patient infections associated with 3T devices that were manufactured after September 2014."

Thus, infection preventionists should not consider the risk eliminated even if the devices were purchased after 2014.

"A question that we are getting is does it make a difference if you acquired a new machine after the end of 2014," Perz says. "The FDA has used that [date of demarcation] to help facilities to prioritize which machines to keep in service, but again there is not enough evidence to say that the risk is eliminated after that date."

As previously reported in *Hospital Infection Control & Prevention*, heater-cooler devices are used during cardiac surgical procedures to warm and cool a patient's blood during cardiopulmonary bypass. The units have a closed-circuit system to circulate water, but can create an aerosol that is vented into the immediate environs by an exhaust fan. The NTM collects in water and biofilms, from where it can be aerosolized over the operating field and the open chest of the patient.

The clinical and infection prevention issues are daunting. The infections may take months to years to emerge, meaning cases are likely to be missed unless an astute clinician traces infection back to heart surgery. Moreover, the NTM infections may be antibiotic resistant and the devices can be difficult to disinfect and continue using with confidence that a patient will not be exposed. The threat has been underscored by outbreaks in Europe and last year in Pennsylvania and Iowa. The CDC reports 29 confirmed cases in the U.S., but given the litany of problems identifying cases there are probably more cases that have gone undetected.

The CDC estimates that in hospitals where at least one infection has been identified, the risk of infection was between about 1 in 100 and 1 in 1,000 patients. Patients who have had a prosthetic device or material implanted appear to be a higher risk of NTM infections. Patients with NTM infections following cardiac surgery may present with a variety of clinical conditions including endocarditis, surgical site infection, hepatitis, and kidney problems, the CDC reports. The CDC recommends that hospitals performing open-chest cardiac surgery should immediately assess their use of heater-cooler devices and determine whether they are currently using -- or have previously used -- 3T devices. Facilities should ensure that they are implementing current

FDA recommendations to minimize patient risk to infections associated with heater-cooler devices.

Informed Consent

Informed consent is on the table, as the CDC stresses that it is "imperative" that patients and providers are apprised of the risk of infection.

"Informed consent is something we are asking hospitals to consider going forward," Perz says. "There is also some information that having a prosthetic device implanted as part of the surgery may increase the risk. That is something that can be discussed with patients. When you think about managing the retrospective risk, we are not in favor of only limiting patient communication to those who had the 3T exposure and an implant. We don't think there is enough information there. Our advice is unless you have completely removed that exhaust consider notifying a broader [number of] patients."

Hospitals should notify cardiothoracic surgeons, cardiologists, infectious disease physicians and other clinicians about the risk of infection associated with 3T heater-cooler devices. In addition, hospitals should review their facility's microbiology laboratory database and records of surgical procedures for any positive NTM cultures in surgery patients that might indicate a possible case, the CDC recommends.

It should be noted that risk of infection is relatively low and cardiac procedures can be lifesaving so there is no recommendation at this time to pull the plug on all heater-cooler devices. However, continued use of the devices should be done according to the latest manufacturer's recommendations, including maintenance and proper positioning of devices to minimize the risk of patient exposure, the CDC advises.

For its part, the FDA recommends that facilities that use the 3T devices "should immediately remove from service any heater-cooler devices, accessories, tubing, and connectors that have tested positive for *M. chimaera* or have been associated with known *M. chimaera* patient infections at your facility."

Hospitals using 3T devices manufactured prior to September 2014, should "strongly consider transitioning away from the use of these devices for open-chest cardiac surgery until the manufacturer has implemented strategies for these devices to mitigate the risks of patient infection. Use of these devices should be limited to emergency and/or life-threatening situations if no other heater cooler devices are available," the FDA recommends.

"We are looking at both short- and long-term solutions," Perz says. "Longer-term solutions include making sure that other models on the market are in fact safe and can they be made safer? Are there ways to mitigate the effect specifically around the Soren 3T? I think we are all waiting eagerly for more clear guidance on that."

"CDC is asking hospitals to formulate plans to reach patients directly," Perz says. "Patient communication is really important but I would say equally important is communicating with medical providers, to make sure this risk is on their differential. They understand when evaluating a patient to be thinking about open heart surgery as an exposure and to take the right steps. Because the diagnosis is not straightforward -- even if it is on your mind you have to make sure that you are ordering the right tests and so on."

Similarly, finding the units difficult or impossible to safely decontaminate, hospitals in the Netherlands and some in the U.S. have physically removed the heating-cooling units from the OR, running the tubing to the patient through a wall that prevents aerosolization from the device fan to enter the sterile field. That's what the University of Iowa did after identifying three patients with *M. chimaera* infections.

"We wanted to be able to tell our patients that we eliminated this risk, and we felt the only way to do that was to remove heater-cooler devices from our operating rooms," **Daniel Diekema**, MD, chief of infectious diseases at the University of Iowa, noted at an FDA meeting earlier this year. "Our OR air, like in many institutions, I assume, is continuously monitored for positive pressure and air exchanges, and we confirmed that even with a heater-cooler unit running with this portal open to accommodate the tubing, it did not impact the airflow and the positive pressure in our operating rooms. We have had no complaints from our perfusionists about this. They have been pleased with the solution. I readily admit and understand that the OR layout in many institutions does not allow for this to be done as easily as we were able to do it."

Better engineering solutions are needed long-term, he says.

"We know now that we have a bioaerosol generator that's in a critical area of the hospital. It's unacceptable, and we have to figure out an engineering solution for that, whether it involves filtration, whether it involves UV, whether it involves a careful evaluation of the differences in design … I think all of these things need to be considered as a more permanent

engineering solution is designed."

Unintended Consequences?

While the solution seems to be working for Iowa, the CDC does not have the data to recommend widespread adoption of this method of mitigating the problem, Perz says.

"Device management really falls primarily to the FDA," he says. "So while we have a role as far as facilitating discussion and helping identify options CDC can't make a blanket recommendation for hospitals to move [the devices] out of the room. There can be unintended consequences. For facilities like the University of Iowa to talk about this publicly -- that they have been able to manage it -- that is a good thing. You basically have removed the potential exposure for your patient population. There may be other ways of capturing that exhaust and we hope to get more concrete advice on that."

Clinicians should also be aware that periodic testing of heater-cooler devices to identify units contaminated with *M. chimaera* is not recommended at this time because the results can be confounded by sample collection challenges, a long culture time, and a high rate of false-negative tests, the FDA advises.

Similarly, if *M. chimaera* infections develop they can be difficult to detect and to treat. **Chuck Daley**, MD, Chief of the Division of Mycobacterial and Respiratory Infections at National Jewish Health in Denver, CO, outlined the troubling aspects of the cases at the FDA meeting on June 3, 2016.

"This delay [in infection onset] that we keep hearing about is remarkable, with a time to presentation being a median of 21 months," he says. "This is not something that clinicians know about. We have to educate them and make them understand that this syndrome actually exists. The other thing that they're not expecting to see are infections of the prosthetic valves due to a mycobacteria or vascular graft infections. … If we have delays in diagnosis, that means delays in therapy. Delays in therapy mean worse treatment outcomes."

Adding another level of difficulty, the NTM can be resistant to the macrolide antibiotics that may be used for such infections, Daley says. Moreover, trying to head off the problem by giving prophylactic regimens of macrolides before a procedure may select out drug-resistant bacteria. "When I hear discussion about prophylactic regimens and giving macrolides -- well, if you do that and it fails and the patient now has macrolide resistance. You have doomed the patient," Daley says. "So I'm very concerned about this idea of preventive therapy. … The bottom line is that I think that if we cannot find earlier diagnosis, basically earlier case finding, we do not have much hope in curing many of these patients. If we found them earlier, perhaps we could intervene and do surgery again, remove the infected graft. But at the time that they're being found, they're often so sick it is very difficult to do that." ■

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CDC Q&A for Hospitals Notifying Patients About Heater-Cooler Devices

Don't base risk assessment solely on prosthetic implant

The CDC recently issued the following answers to common questions about notifying cardiac surgical patients potentially exposed to contaminated heater-cooler devices.

How far back in time should hospitals go to notify patients?

CDC: Hospitals should consider notifying patients in writing if they were exposed to the Stöckert 3T devices during open-chest cardiac surgery at their institution since Jan. 1, 2012. Hospitals that did not use the Stöckert 3T device during this entire time period should adjust the patient notification timeframe accordingly.

What is the rationale for active patient outreach? Why use this time frame?

CDC: Based on our current understanding, the majority of patients who become infected from exposure to these devices will develop symptoms within months of their exposure. Pursuing active patient outreach using a longer time frame of approximately four years is expected to benefit most of the patients who have developed symptoms but have

not yet been diagnosed. However, any patient who has had cardiac surgery with the Stöckert 3T device – including patients who had their surgery prior to 2012 – should be aware of this risk in the event that they develop concerning symptoms. Other forms of patient outreach (e.g., through advocacy channels or the media) will be helpful in this regard. Likewise, ongoing efforts to raise awareness among clinicians is expected to benefit all patients, regardless of when their exposure occurred.

Our hospital acquired a Stöckert 3T device after September 2014. Should we still notify patients?

CDC: Patients who were exposed to Stöckert 3T devices manufactured after September 2014 should also be notified. While the risks associated with these newer devices may be lower, some have tested positive for *M. chimaera*, possibly as a result of cross contamination from accessory devices.

Our hospital conducted retrospective case-finding and we did not identify any probable cases – do we still need to send patients letters?

Yes, while case finding is important, negative results cannot be relied upon to determine an absence of risk.

Our hospital conducted retrospective case-finding and we identified a probable case that had surgery before Jan. 1, 2012. Do we need to extend the time period of our notification?

CDC: Decisions to extend notification farther back in time using individualized patient letters may best be considered on an institution-specific basis. The likelihood of identifying undetected infections diminishes with time. However, directly notifying individual patients who have been identified as having actually acquired an infection from a contaminated heater-cooler device is advisable regardless of when the exposure occurred.

Are only patients who have had prosthetic material implanted during their cardiac surgery at risk for M. chimaera infections? Should our hospital only notify patients who have had prosthetic material implanted?

CDC: Although there is some evidence that patients who have prosthetic material implanted during their open-chest cardiac procedure may be at higher risk of developing infection, heater-cooler devices associated NTM infections have also occurred among patients who did not have placement of prosthetic material. Therefore, hospitals should not determine which patients to notify based on whether they have had the placement of prosthetic material during their procedures.

In 2015, our hospital took measures to mitigate risk to patients by following updated manufacturer's recommendations for disinfection and cleaning and updated guidance from the FDA. Do we still need to notify patients?

CDC: Yes, hospitals should still notify patients. A possible exception pertains to hospitals that have taken additional steps (e.g., moved the Stöckert 3T device out of the operating room) to eliminate patient exposure to the exhaust from these devices. These hospitals may consider not notifying patients who had surgery after these interventions if they are confident that the risk was abated.

The Stöckert 3T device(s) at our hospital tested negative for M. chimaera. Should we still notify patients?

CDC: Yes, hospitals should still notify patients. In general, methods for sampling and microbiological testing of heater-cooler devices for *M. chimaera* are neither reliable nor timely. Therefore, negative test results do not necessarily indicate that devices are not presently contaminated or that they have not been contaminated in the past. ■

A Bold New Day for Infection Prevention in LTC

CMS finalizes rule for infection control, drug stewardship

The CMS has finalized its new infection control regulations for long-term care, revising a few areas in response to comments while implementing landmark changes to protect increasingly vulnerable resident populations.

For veteran long-term care infection preventionists like **Deborah Burdsall**, PhD, MSN, RN-BC, CIC, the CMS action was validation of decades of efforts to improve infection control in long-term care (LTC).

"It is so exciting that people are finally really paying attention to infection prevention in long-term care," she tells *Hospital Infection Control & Prevention*. "I started looking at long-term care 43 years ago and have been in infection prevention in [the field] for about 30 years. People got tired of hearing me fuss about infection prevention and how the infrastructure had to be improved in long-term care."

The CMS rule moves firmly in that direction. Though there are several caveats and phased-in requirements, the CMS is essentially requiring long-term care facilities

to conduct risk assessments and implement a system "for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, volunteers, [and] visitors."[1] Moreover, the CMS reports in the final rule that many commenters agreed on the importance of having infection control programs in nursing homes.

"We agree that infection control is very important for residents, as well as the staff and other individuals who work or visit the facility," the CMS states in the rule. "We believe the requirements that are finalized in this rule will contribute to the reduction in HAIs, which should result in a reduction in physical harm to residents and others, as well as a decrease in the associated healthcare costs."

High Acuity

Major changes in the delivery of care and aging demographics of the population have led to nursing home residents with high acuity and a commensurate need for more elaborate healthcare.

"We have seen a huge shift in the LTC population over the last 10 years," Burdsall says. "It has gone from essentially being a residential community to a post-acute environment where you have people transitioning from acute care areas. Infection prevention is so important. It used to be you had people who were older, but essentially stable and living in a home-like environment. Now you have people who are coming out of acute care episodes, whether it be illnesses, post-surgical, hip replacements, knee replacements, wound care [etc]. So, you have people who are healing, and infection prevention is important because they have become more vulnerable."

Long-term care facilities have long argued they don't have the resources to fund infection control programs akin to hospitals. The CMS makes some concessions in that respect, but it's fair to say those arguments are no longer persuasive. Consider this finding by the CDC: *Clostridium difficile* caused some 115,400 infections with onset in nursing homes in the United States in 2012, comprising nearly one-quarter of all U.S. *C. diff* cases. Of those, some 8,700 (8%) residents died within 30 days of diagnosis.[2]

Given that antimicrobial misuse drives *C. diff* infections and selects out drug-resistant bacteria, the CMS is requiring antibiotic stewardship programs in LTC.

"[W]e are finalizing the requirement for LTC facilities to establish and maintain an [infection prevention program], which must include, among other things, an antibiotic stewardship program that includes antibiotic use protocols and a system to monitor antibiotic use," the CMS states.

Overall the CMS estimates that there are between 1.6 and 3.8 million healthcare-associated infections in LTC facilities annually, resulting in 150,000 hospitalizations and 388,000 deaths. These LTC infections and attendant consequences cost between $673 million to $2 billion annually. Of course, these events go well beyond the numbers, Burdsall reminds.

"There is the economic cost of infections and that spreads across all of this, the people affected, the healthcare organizations," she says. "But there is also the personal cost of the infection, which can mean loss of life, loss of function and abilities. Having seen people go through infections, it's terrifying, painful and expensive. Infection prevention and control really has to be looked at from a biological, psychological, sociological, and spiritual aspect of human care. You have to look at it that way -- it's a human issue. Any type of guidance or regulation that steers people in that direction is important."

Risk Assessment

Some suggested in comments that the CMS require certain staffing levels to meet the requirements, but the agency disagreed and said facilities should determine staffing needs based on their infection control risk assessment.

"In this final rule, each facility must conduct and document a facility-wide assessment to determine what resources are necessary to care for it residents competently during both day-to-day operations and emergencies," the CMS states. "That assessment must include, among other things, the resident population and the care required by that population considering the types of diseases, conditions, physical and cognitive disabilities, overall acuity, and other pertinent facts that are present in that population, as well as the staff competencies that are necessary to provide the level and types of care needed by that population."

In terms of training, the CDC and CMS are exploring opportunities to jointly develop LTC infection prevention training programs. The Association for Professionals in Infection Control and Epidemiology also has training and a certificate for LTC, Burdsall notes.

"It is very encouraging that the CDC and CMS are working together to try to provide [resources]

for people who want to work in LTC," she says. "If you look at how the CMS responded to the comments, they talk about 'prevention.' They want to get prevention in there -- it is not just infection control. The other thing that they are really focusing on is that you have to know your [resident] population, what services you are providing, and you have to do a facility risk assessment. That has to be a 'living' document. They are really focusing on this mechanism to drive identifying and addressing risk with the programs that you put in place."

Some commenters on the proposed rule warned the CMS about the negative effects of the hospital approach of isolating a resident – with, for example, MRSA – because people in LTC may greatly benefit from socialization and interaction.

"We agree with the commenter that isolation should only be used when necessary to control the spread of infections and should be the least restrictive as possible to the resident," the CMS states in the final rule.

IP Role can be Divided

The CMS also moved away from requiring a single designated IP, saying "we agree that LTC facilities should have the flexibility to determine if more than one individual should be designated to be responsible for the facility's IPCP. … Depending upon the facility, we understand that there is a substantial variation in the amount of resources required for the [IP program], especially the amount of time the IP needs to devote to those responsibilities. For some facilities, especially small and rural LTC facilities, it may not be feasible or even necessary to have one staff person devote a substantial amount of their time to [the program] or have it be their primary responsibility."

Again, the facility risk assessment should inform this decision, the CMS states, "In addition, we are finalizing the requirement that the IP work at the facility at least part-time."

Overall, the major theme is that LTC is not an island, but a part of an interactive continuum of care, where risk is assessed and addressed at facilities that are in communication with each other.

"I am very excited about the comments and the careful, thoughtful responses by CMS," Burdsall says. "I think this is realistic. The barriers we fought for years but are finally coming around. The thing I like about this document is that there is flexibility to focus on evidence-based practice." ■

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IPs Target HAI Reduction Goals for 2020

HHS national plan sets ambitious goals

Although considerable progress has been made in reducing targeted healthcare-associated infections (HAIs), the Department of Health and Human Services (HHS) has set a new baseline and established ambitious new goals for 2020.

Using 2015 targets as a baseline, the HHS "National Action Plan to Prevent Health Care-Associated Infections"[1] sets the following goals for healthcare by 2020:

- Reduce central line-associated bloodstream infections (CLABSI) in intensive care units and ward-located patients by 50%.
- Reduce catheter-associated urinary tract infections (CAUTI) in intensive care units and ward-located patients by 25%.
- Reduce the incidence of invasive healthcare-associated methicillin-resistant *Staphylococcus aureus* (MRSA) infections by 50%.
- Reduce facility-onset methicillin-resistant *Staphylococcus aureus* (MRSA) in facility-wide healthcare by 50%.
- Reduce facility-onset *Clostridium difficile* infections by 30%.
- Reduce the rate of *Clostridium difficile* hospitalizations by 30%.
- Reduce surgical site infection (SSI) admission and readmission by 30%.

The data are reported to the CDC's National Healthcare Safety Network (NHSN). Reductions are tracked using a standardized infection ratio (SIR), which compares actual number of HAIs to the

predicted number of infections. The results since the program began in 2009 have been decidedly mixed, with CLABSIs falling by an impressive 50% by 2014, but *C. diff* only dropping 8% and CAUTIs showing no decline. We asked **Susan A. Dolan**, RN, MS, CIC, hospital epidemiologist at Children's Hospital Colorado and 2016 president of the Association for Professionals in Infection Control and Epidemiology, to comment on the new HHS goals.

HIC: Can you speak a little bit to how the broad goals in the HHS plan translate down to the individual infection preventionist?

Dolan: The HAI action plan we look at as sort of an overarching report card. It does reflect the work that IPs do each and every day to keep their patients safe. The IPs are actually the ones doing the measurement and interpretation of the definitions through NHSN. We do that and then we are also the ones submitting that data to NHSN. The good thing is these national targets -- these standardized infection ratios -- are the same SIRs we use when we are determining if our own facility is measuring up with what we expected. So not only are we using it as an overarching report card, but we use many of these measurements and metrics at the local level and even the state and regional level to see what progress we are making. If we see problems in one area, we can target that.

HIC: You also have mentioned the CDC's Targeted Assessment for Prevention (TAP) programs to use the data to drive improvements.

Dolan: Yes, the other nice thing the NHSN has done with this work is that they have been able to look at high performers to see if they can help inform the science. On the other hand, they can also target the low performers – it's not a punitive thing, but they use it as an opportunity to go out and evaluate and educate individuals at those locations so they can help to bring those numbers up. You want to look at where is your bang [for the buck] to try to move these needles. By using that methodology of targeting the low and high performers they can really focus on where those low performers are and make some real-time improvement efforts. They make sure first of all that they are doing all the things that they should be doing correctly. Are they doing surveillance correctly, implementation measures – standard of care type measures that we should be doing? Are those all being implemented reliably? Also, they say look at these high performers – is there something we can learn from them?

HIC: It's really striking how formalized and structured this has become. I can remember when NNIS had 300 hospitals and everybody just basically benchmarked their data.

Dolan: That's correct, and now this is a very large organization with a lot of organizations including APIC. And one of the other roles that APIC has – and it's something I've seen make a difference over time – is to help to make sure that we are informing and working with CDC to make these NHSN definitions for HAIs accurate and relevant as much as possible. For example, when we are looking at BSIs related to central lines – the CLABSIs. Whn we looked at that really closely at the unit level, as our providers and our nursing staff were describing these patients, it became clear to us that some type of CLABSIs by the current definition included patients that were not getting infected because of bad care of their catheter or their line. It was really because of their underlying conditions and treatments -- something [else] resulted in getting infections in their blood.

For example, an oncology patient who is on a specific chemotherapy and/or has recently had a bone marrow transplant that has altered the integrity of their intestines. There is opportunity for [pathogens] to leak out into the blood stream. Those you can't prevent even with 100% perfect care of the catheter. So, we helped work on the definition and we called those the mucosal barrier injuries or MBI. And we tracked those for several years with NHSN and now when they set the metric based on the 2015 baseline, that baseline will no longer have the CLABSIs we were classifying as NBIs. So hopefully what that new measures will be are the ones that we think probably are preventable. That's a good example of getting these measurements more accurate and relevant to the patients we are measuring.

HIC: These goals are ambitious, do you think they are attainable – particularly a 30% reduction in *C. diff*?

Dolan: I think if they really wanted to be overly ambitious they might have gone with 50% or higher. I think 30% is probably a reasonable target. Will we get there? I don't think anyone really knows, but I do think it's reasonable. Ambitious but reasonable. And the reason I say that is as you look at the report card progress in 2014 -- they didn't make a lot of progress -- there's an 8% reduction [in *C. diff*]. So, when they started to see that the needle wasn't moving on the *C. diff* target people began to really question this. [That became] a major impetus for the development

and the strong and heavy movement toward antibiotic stewardship. It's quite a robust effort that is taking place across the whole continuum of care. A lot of the emphasis on this is not just in hospitals, but also on the community impact.

HIC: The HHS has set an overall agency goal to speed the uptake of antibiotic stewardship programs which are currently only established in 40% of hospitals. Of course, reining in antibiotics should reduce *C. diff*, which is often triggered by antimicrobial therapy.

Dolan: I think that what they are trying to do is to align many of these federal programs. I wouldn't call them silos, because they are trying to bridge the difference of federal organizations and the efforts that are happening. There is a concerted effort to try to make sure that they are interconnected. [Antibiotic stewardship] concerted effort across these various federal programs. ■

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'Clean It Like You Mean It' Improves Quality, Reduces Costs

This article originally ran in the September 2016 issue of Hospital Peer Review

The author and editorial team have nothing to disclose.

A nursing-led program designed to get clinicians to follow best practices at a New York City hospital has significantly reduced the incidence of central line-associated bloodstream infections (CLABSIs) in neonatal, pediatric, and pediatric cardiac intensive care settings.

The "Clean It Like You Mean It!" program at Morgan Stanley Children's Hospital, part of the New York-Presbyterian system, sought to limit CLABSIs because they are largely preventable if nurses and other clinicians follow the proper protocols, says **Regan Morimoto**, RN, CCRN, clinical nurse II at the hospital and one of the program leaders.

The program team consisted of Morimoto and another nurse from the pediatric intensive care unit (PICU), one nurse from the pediatric cardiac intensive care unit (PCICU), and one from the neonatal intensive care unit (NICU). They had the full support of management but carried out all the tasks in the initiative. They also were available around the clock for consultation.

"If a PICU nurse in the middle of the night saw a line that had some redness or was starting to get clotted, we would get a text or a picture. I could advise the nurse and the next day I could check it and talk to an attending about why it hadn't been pulled yet," Morimoto says. "The totally open communication among the staff was very important."

The program used continuous education sessions, central line maintenance protocol, weekly surveillance, and a good dose of cheerleading by nurse champions to reduce CLABSIs. After a year, the results were impressive:

- The NICU CLABSI rate decreased by 55%. (The NICU did not fully participate in the program. The result lends more support to the effectiveness of the program.)
- The PICU CLABSI rate decreased by 21%.
- The pediatric cardiac intensive care unit CLABSI rate decreased by 100% to zero.
- The average length of stay (LOS) decreased by 4% (1.11 days) in the NICU and by 35% (4.87 days) in the PICU since 2013. It increased by 2% (0.32 days) in the PCICU.
- The total number of CLABSIs for all units decreased by 25%.
- These outcomes resulted in a fiscal effect of $37,134 over nine months, with a projected annual savings of $99,024.

Not Always an Easy Path

The first challenge was getting buy-in from the nurses, Morimoto says. They were all for reducing infections, but were wary about slowing the pace in the unit to scrub hubs on medication pumps and syringe lines.

The effort kicked off with a traveling CLABSI Carnival that visited each nursing unit in January and February 2014, providing cupcakes and freebies to get the nurses involved. The CLABSI Carnival appeared again during the hospital's Nurses' Week celebration. The project team met with more than 100 nurses and gave hands-on demonstrations of "Scrub the Hub" — the central message

in the project encouraging nurses to pay extra attention to this detail with central lines. Nurses answered trivia questions on central line care, reviewed central line dressings and changes, learned about the use of alcohol-impregnated caps on needleless ports, and reviewed central line change policy and central line care.

Nurses took well to the effort as long as they felt their voices were heard when they wanted a central line pulled or had other input, Morimoto says.

"One of the first things we instituted was a two-person line dressing change, which was difficult because we don't have resources nurses. That meant you had to pull a nurse who had their own workload to come watch you change the dressing," Morimoto says. "But we thought it was very important to have another set of eyes, someone to speak up and say 'you might not be sterile anymore.'"

The next hurdle involved residents and rotating staff. Residents start every two weeks, requiring that fresh education each time. In addition, some residents were coming off rotations where they had been instructed to order central line cultures but now had to be taught not to in the ICUs. Plus, they had to tell parents that the child would have a needlestick instead of using the central line.

The nursing team went to the fellows overseeing the residents and presented the CLABSI project, which resulted in better understanding when residents arrived for ICU rotations and better compliance during their stays. Afterward, a nurse disagreeing with a resident could call the fellow to make the final decision.

With the program originating with the ICU nurses, compliance was not immediate in other departments.

"We would leave our kid in radiology and they would come back with everything that was in the peripheral line now running through the central line with the same tubing. That was just horrifying to us," Morimoto says. "We thought about going to the doctors, but instead we went to the nurses and begged them to be accountable for what's going on with those lines. We would even send primed, brand-new, fresh lines done by us to them if they needed that, but we ended up getting good cooperation from the other nurses."

Some services, like oncology, were resistant to the CLABSI project and did not want to change practices when a patient moved from the floor to the ICU. But attending physicians in the ICU stood up for the project and explained that there is no data to support daily central line cultures if the parent consents to peripheral cultures.

Reminder Hangtags on IV Poles

The "Clean It Like You Mean It!" program used a variety of methods to keep the message in front of nurses and reinforce the CLABSI prevention best practices. The team developed "Scrub the Hub" IV pole hangtags for all patients with central lines.

CLABSI prevention posters were placed in all three units, and the team provided CLABSI prevention education in groups and one-on-one.

The team also conducted weekly central line surveillance for 32 weeks, assessing more than 300 central lines for appearance, needleless caps, central line sites, and dressings.

At one point the team decided to take a break from taking blood cultures off the central line to see if contamination from nurse error had any influence on the CLABSI rate.

The policy at the hospital was not to take cultures from central lines, but doctors were ordering them because that option popped up when entering orders in the electronic record. The nursing team did not have the authority to stop the central line cultures, but they went to a critical care quality and safety meeting with all the attending physicians.

"We just asked if they would do what we want for a little while and just stop that practice so we can see if it makes any difference," Morimoto says. "Because the CDC's gold standard is to use peripheral lines for blood culturing, they were willing to stand behind us. We actually had some great results from not accessing our central lines and that was information we use to validate this change."

The program was funded mostly with a $10,000 grant from the American Association of Critical-Care Nurses, with a good portion of those funds covering the off-duty time of nurses spent on the project. The hospital spent $2,752, with 25% of those funds spent on posters, 25% on staff gift giveaways, 22% on educational material, 12% on food, 9% on printed water bottles, and 7% on team shirts.

Morimoto suggests that any nurse-centric quality improvement project will be most successful if it originates or at least is driven by the nurses themselves.

"Ultimately we are the stopgap at the bedside and the last person who can ensure that we're doing everything right," Morimoto says. "I'm lucky to work in an ICU where our nurses feel empowered and don't have any trouble saying 'no' to a doctor. The project succeeded in large part because the nurses cared and took ownership." ■

Emerging *Candida auris* Infects 13 in U.S.

Four deaths, some cases transmitted in healthcare

Four patients have died and nine others were infected as the 13 cases of a drug resistant strain of *Candida auris* that is emerging globally have been reported in the United States by the CDC.[1]

According to the CDC, seven of the cases occurred between May 2013 and August 2016. Six additional cases are still under investigation. Among the seven cases detailed in the report, patients with *C. auris* were reported in New York, Illinois, Maryland and New Jersey.

All of the patients had serious underlying medical conditions and the four deaths could not be attributed solely to *C. auris* infections. Transmission between patients in the same hospital or long-term care facility was strongly suggested by identical fungal strains in two incidents, the CDC reported.

"[W]hole-genome sequencing results demonstrate that isolates from patients admitted to the same hospital in New Jersey were nearly identical, as were isolates from patients admitted to the same Illinois hospital," the CDC reported.

In addition, isolates from one patient were detected on environmental surfaces in the healthcare environment and some patients were persistently colonized. The CDC recommended hospitals put identified patients with *C. auris* in contact isolation precautions and room cleaning with an EPA-registered fungal disinfectant.

> "IN NURSING HOMES, PROVIDERS SHOULD CONSIDER THE LEVEL OF PATIENT CARE BEING PROVIDED AND THE PRESENCE OF TRANSMISSION RISK FACTORS WHEN DECIDING ON THE LEVEL OF PRECAUTIONS."

"In nursing homes, providers should consider the level of patient care being provided and the presence of transmission risk factors when deciding on the level of precautions," the CDC stated. "If such patients are transferred to other healthcare facilities, receiving facilities should be notified of the presence of this multidrug-resistant organism to ensure appropriate precautions are continued."

Most of the *C. auris* strains in the U.S. were drug-resistant, but didn't have the multidrug characteristics of the international strains. This suggests that the strains were acquired locally rather than acquired via travel, the CDC noted.

First reported in 2009 in Japan, *C. auris* has now been identified in other parts of Asia, Africa, South America and the United Kingdom. The pathogen was previously detected in the U.S. in 2013, so there is concern that it will become recurrent given its emergence now and growing global presence. ■

REFERENCE

1. Centers for Disease Control and Prevention. Investigation of the First Seven Reported Cases of Candida auris, a Globally Emerging Invasive, Multidrug-Resistant Fungus — United States, May 2013–August 2016 *MMWR Early Release* / November 4, 2016: http://bit.ly/2fmiHvq

COMING IN FUTURE MONTHS

- Deadly measles complication supports higher vaccination rates
- Highlights from IDWeek 2016
- Assuring surgical instrument reprocessing in central services
- New initiative aimed at cutting BSIs in dialysis

HOSPITAL INFECTION CONTROL & PREVENTION

CME/CE INSTRUCTIONS

To earn credit for this activity, please follow these instructions:

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CME/CE QUESTIONS

1. Which of the following were identified as challenges to infection control related to heater-cooler devices?

a. can create an aerosol that is dispersed by an exhaust fan
b. infections may take months to years to emerge
c. infections can be antibiotic resistant
d. all of the above

2. According to the CDC, patients who were exposed to Stöckert 3T heater-cooler devices manufactured after September 2014 do not need to be notified of the risk of developing infection?

a. True
b. False

3. In a CMS regulation on long-term care, which of the following is correct regarding a required infection preventionist?

a. Must be one person
b. Must be a full-time employee
c. Must work at facility at least part time
d. Cannot be a new employee

4. The HHS national goals for infection reduction for 2020, call for what rate of reduction for facility-onset *Clostridium difficile*

a. 10%
b. 20%
c. 30%
d. 40%

CME/CE OBJECTIVES

Upon completion of this educational activity, participants should be able to:

1. Identify the clinical, legal, or educational issues encountered by infection preventionists and epidemiologists;
2. Describe the effect of infection control and prevention issues on nurses, hospitals, or the healthcare industry in general;
3. Cite solutions to the problems encountered by infection preventionists based on guidelines from the relevant regulatory authorities, and/or independent recommendations from clinicians at individual institutions.

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