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INSIDE

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Cardiac Surgery Devices Linked to Fatal Infections

Six patients die in one U.S. outbreak

By Gary Evans, AHC Media Senior Staff Writer

An "insidious" under-the-radar outbreak of waterborne bacteria aerosolized by heater-cooler devices commonly used in cardiothoracic surgery is emerging as a clear and present danger to patient safety, a veteran epidemiologist recently warned at a meeting of infectious disease physicians in Atlanta.

"I use the term 'insidious' to describe this illness in terms of its very delayed onset of symptoms from the time of surgery and the very delayed time [from symptoms] to diagnosis," **Daniel Diekema**, MD, chief of infectious diseases at the University of Iowa, said a May 20, 2016, meeting of the Society for Healthcare Epidemiology of America (SHEA). "I think this is probably the most challenging problem I have been presented as a hospital epidemiologist."

> "I THINK THIS IS PROBABLY THE MOST CHALLENGING PROBLEM I HAVE BEEN PRESENTED AS A HOSPITAL EPIDEMIOLOGIST."

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.

A heretofore obscure Nontuberculous Mycobacterium (NTM) named *Mycobacterium chimaera* — ubiquitous in soil and water but rarely pathogenic — appears to be perfectly adapted to take advantage of these conditions, collecting in

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water and biofilms before being aerosolized over the operating field and the open chest of the patient. Completing this dire equation is that the devices may be difficult to disinfect and continue using with confidence that a patient will not be exposed.

As this issue of *Hospital Infection Control & Prevention* went to press, the FDA had called a meeting of experts on the issue and issued a June 1, 2016, alert that some of the U.S. infections have been traced to the Stöckert 3T Heater-Cooler System by the Sorin Group in Germany.[1] The company also submitted a letter to the FDA outlining measures it is taking to safeguard the equipment. *(See related story in this issue.)*

Moreover, discussions at the SHEA meeting indicate the 3T heater-coolers hold some 85% of the U.S. market and are used in hundreds of thousands of cardiothoracic surgeries annually. A massive recall, even if the FDA deemed that was necessary, appears to be out of the question. In pledging to redouble efforts to make the devices safer to use, the manufacturer made a cogent point to the FDA: "These products play an essential role in maintaining precise patient temperature during these cardiac surgeries and are a necessary part of the modern cardiac operating room infrastructure. No reasonable alternative is available."[2]

Except one: an old school intervention that harkens back to the classic epidemiological decision John Snow took to end a cholera epidemic in 19th century London. He removed the pump handle to the contaminated water supply. Similarly, finding the units difficult or impossible to safely decontaminate, hospitals in the Netherlands and some in the U.S. have taken the radical step of physically removing the heating-cooling units from the OR, running the tubing and hookups needed for 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.

"In my view it is very unlikely that [these units] can be decontaminated," Diekema said. "The experience by people to date has not been very encouraging. After most of the decontamination attempts, ultimately you can regrow the same organism from the unit. This is just my view — not the CDC's, FDA's or anyone else's, necessarily — these units cannot be operated safely unless the air coming out of the exhaust is physically separated from the operating room."

In addition to outbreaks in Europe,[3,4] the CDC reported the largest outbreak to date in the U.S. at the recent Epidemic Intelligence Service meeting in Atlanta.[5] A hospital in York, PA, has notified some 1,300 patients that had cardiac surgery over the last few years after discovering 10 patient infections with *M. chimera*, including six of whom died. These are slow-growing infections that may not appear for years, making case identification and a link to a heater-cooler device challenging.

In the York outbreak, investigators found that case patients had an NTM-positive culture during 2010-2015 obtained from a sterile body site 30 days to 3.5 years following cardiothoracic surgery. Cases had higher odds of undergoing major cardiac surgery involving cardiopulmonary bypass when body temperature was regulated by a heater-cooler unit. In particular, those undergoing bypass operations of more than two hours were at increased risk of infections, the CDC found. All three available case-patient isolates were positive for *M. chimaera* with indistinguishable

pulsed-field gel electrophoresis patterns. The facility removed the heating- cooling units from service prior to CDC investigation, but environmental cultures, including water and air samples taken while the units functioned in a simulated environment, were also positive for *M. chimaera*.

High Degree of Difficulty

The problem — and there are many — is that the *M. chimaera* is exceedingly difficult to detect, treat, and eradicate from devices, shrugging off both antibiotics in humans and powerful disinfectants in machines. It subsequently emerges in post-surgical patients as a slow-growing but potentially fatal infection that may not become symptomatic for a year or more. Though there have been only an estimated 65 to 70 documented cases in the U.S. and Europe, it is a given that more cases are being missed because of the difficulty in detecting infections that appear far removed from the surgical exposure.

"The case-finding is very problematic with many patients receiving cardiopulmonary bypass away from home and all their follow-up care is local," Diekema said. "The symptoms are very non-specific; they present months to years after the exposure. And exposure [during] cardiothoracic bypass has not normally — to this point — been considered a risk for this clinical syndrome. The risk mitigation issue is difficult as well, and I think we don't know yet if these units can be decontaminated."

The University of Iowa alerted some 1,500 surgical patients to seek evaluation after becoming aware in January that a patient who had an aortic valve replacement in 2012 had developed *M. chimera* infection that was not responding to treatment. Two other infected cardiac surgical patients were identified as Diekema and colleagues continue the look-back effort.

"Most disturbing is the crude mortality [in all cases] is well over 50%," he said. "The story is not over yet — there are a lot of patients who are struggling with this and not doing well."

Treatment is particularly difficult if the bacteria establish biofilms on prosthetic valves or other implanted materials to assist cardiothoracic function. Diekema underscored this point with a slide of a micro-valve ring removed from a patient in Europe still heavily contaminated with a biofilm despite a year of multidrug therapy.

"We have had similar experiences," he said. "Our index case, who died just last weekend, had continuous mycobacteremia for well over a year despite multiple drug therapy. [There is] just an inability to eradicate this organism in the presence of prosthetic material."

In a joint alert issued last year, the CDC and the FDA called for a number of measures, including using only sterile water in heater-cooler units. However, there are now questions whether that is enough to prevent infections because it is very difficult to disinfect the units after use no matter what quality of water is used. According to a European investigation,[4] some of the units shipped before August 2014 may have been contaminated by the water used to test the devices at the manufacturing plant in Germany.

"These Sorin 3-T units very likely arrived pre-inoculated with *M. chimera*," Diekema says. "The manufacturer changed their manufacturing process in August of 2014, so there may be reasons to believe that units manufactured before August of 2014 may have environmental mycobacterium in the unit at the time of delivery."

Regardless, the larger question is whether units can be safety disinfected after continued use regardless of when they were made. An infectious disease physician from the Netherlands who was involved in some of the investigations in Europe told SHEA attendees during a question and answer session that hospitals in his country have similarly banned the units from the OR, so they are vented into a separate room.

Call to Action

As the potential scale of the problem becomes apparent, there was a sense of urgency and frustration at the SHEA meeting that the issue does not seem to be generating much traction and concern.

"The uptake on this has been a little frustratingly slow, I must say," said **Joseph Perz**, PhD, an epidemiologist in the CDC's Division of Healthcare Quality Promotion. "It is worrisome to me that ID docs and others are still not thinking NTM for these kinds of patients that have had these kinds of procedures."

Perz said the CDC will continue to work with infectious disease groups and present findings at medical meetings to try and heighten awareness.

"It does seem to have emerged under the radar," Diekema said. "I think that the relatively small number of cases, the newness of this disseminated presentation, and the fact that there are no simple solutions are some of the reasons for that. It would be one thing to say, 'Recall these units,' but then there would be no cardiac surgery. It's frustrating when you are sitting in an exam room with a patient, as I have now on several occasions because we are managing these patients out of our ID clinic. They are asking us questions that we ought to be able to answer by now, but we can't."

There may also be a sense among some clinicians that the risk of infection is so low it is easily outweighed by the benefit of having the needed cardiac surgery.

"I normally have a good relationship with our cardiothoracic surgeons but the meeting to bring them in to even talk about this was most angry," a clinician said at the SHEA meeting. "They didn't want to hear about it, [saying] 'Why are we are worrying about this? The risk is so low.' So trying to engage them has been very difficult."

Diekema had a suggestion that took the discussion back to its ethical crux: the patient on the operating table.

"You may want to give your surgeons the number of one of the thoracic surgeons in York, Pennsylvania," he said. "They might take it a little more seriously." ■

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New CDC Guidelines to Identify NTM Infections

Look for NTM in an open-heart surgery patient

The CDC has posted new guidelines to help infection preventionists and epidemiologists identify cases of non-tuberculosis mycobacterium (NTM) in cardiac surgical patients exposed to heather-cooler units during their procedure.[1]

"Given the increasing number of reports we are receiving across the U.S. of facilities that are dealing with this issue, these guidelines can assist healthcare facilities in trying to identify patients with NTM infections that might be associated with exposure to these heater-cooler units," says **Kiran Perkins**, MD, MPH, a medical officer in the CDC Division of Healthcare Quality Promotion. "We are emphasizing a high index of suspicion for NTM infection in patients who had exposure to cardiopulmonary bypass."

Hospitals performing surgeries requiring cardiopulmonary bypass should consider taking the following steps to identify patients at risk, the CDC recommends. Patients meeting the following criteria may represent heater-cooler unit-associated infection and may warrant additional investigation.

Laboratory assessment: Identify NTM-positive cultures obtained from an invasive sample (blood, pus, tissue biopsy, or implanted prosthetic material) using facility's microbiologic database or other appropriate sources. The time period for review is institution-dependent. Some institutions have used a four-year time period to conduct laboratory review, whereas other facilities have opted for a longer time frame.

Clinical assessment: Cross reference NTM-positive cultures with medical and surgical records to identify patients who meet the following clinical criteria (any one of the following):

- prosthetic valve endocarditis;
- prosthetic vascular graft infection;
- sternotomy wound infection;
- mediastinitis;
- bloodstream infection;
- disseminated infection, including embolic and immunologic manifestations (e.g. splenomegaly, arthritis, osteomyelitis, bone marrow involvement with cytopenia, chorioretinitis, lung involvement, hepatitis, nephritis, myocarditis).

Exposure assessment: For patients identified using the criteria above, assess for a history of surgery requiring cardiopulmonary bypass prior to diagnosis of NTM infection.

Additional considerations:

- Consider institution-specific strategies for alerting patients and providers of the risk of infection given exposure to potentially con-

taminated heater-cooler units.

- Order acid-fast bacilli (AFB) culture in any patient with exposure history and meeting the clinical criteria, or presenting with signs or symptoms of NTM infection such as recurrent or persistent fever of unknown etiology, night sweats, joint or muscle pains, weight loss, or fatigue. If AFB culture is positive for *Mycobacterium avium* complex, consider sending a sample for further speciation to an NTM reference laboratory.
- Submit FDA MedWatch Report for positive cases.
- Alert the appropriate local or state health department. ■

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FDA Issues Alert on Devices

Units shipped prior to September 2014 may be contaminated

The FDA issued a June 1, 2016, alert that some of the *Mycobacterium chimaera* infections acquired by cardiothoracic patients in the U.S. may be linked to the Stöckert 3T Heater-Cooler System manufactured by the Sorin Group in Germany.

"Currently, efforts are underway in to determine if the infections in U.S. patients and *M. chimaera* isolates from samples taken from the 3T are linked with *M. chimaera* isolates from European patients who were infected and the *M. chimaera* previously identified at the 3T manufacturer's production and servicing facility in Germany," the FDA stated.[1]

The FDA recently held a meeting to review available data and seek expert scientific and clinical opinion related to all heater-cooler device contaminations, associated patient infections, and mitigation strategies.

A recently published European study describes a link between *M. chimaera* clinical samples from several infected cardiothoracic patients with samples from the heater-cooler devices used during these patient's procedures, and with environmental samples from the device manufacturer's production and servicing facility in Germany. The results of this paper suggest a direct link between the *M. chimaera* to which the European patients were exposed and became infected during open-chest cardiac surgery, and one specific heater-cooler model: the 3T, the FDA reported.

> "IF YOUR FACILITY PURCHASED AND USED THE 3T PRIOR TO SEPTEMBER 2014, BE AWARE THE UNITS MAY HAVE BEEN SHIPPED FROM THE FACTORY CONTAMINATED WITH *M. CHIMAERA*."

The FDA did not cite the specific study, but it appears to be one[2] described at a recent meeting in Atlanta of the Society for Healthcare Epidemiology of America — a meeting at which an FDA official was present. In addition to previous recommendations issued in a 2015 Safety Communication for facilities and staff using heater-cooler devices, the FDA recommends the following:

If your facility purchased and used the 3T prior to September 2014, be aware the units may have been shipped from the factory contaminated with *M. chimaera*. Such facilities should:

- Inform healthcare providers who have performed cardiothoracic surgeries that there is a possibility that their patients may have been infected with *M. chimaera*. Reports to date suggest there may be a higher risk of patient infection associated with surgeries that introduced a prosthetic product/material [e.g., heart valve, graft, LVAD], or heart transplants when the 3T was used.
- Determine a method for patient follow-up and establish patient surveillance in cases of potential exposure, per the recommendations in CDC's Interim Guide for the Identification of Possible Cases of Nontuberculous Mycobacterium Infections Associated with Exposure to Heater-Cooler Units.

For facilities that purchased and used the 3T after September 2014, the FDA recommends continuing to follow the recommendations provided in the 2015 Safety Communication and the manufacturer's most current instructions for use (IFU) for cleaning, disinfecting, and maintenance to reduce the risk to patients.

Healthcare professionals and patients are encouraged to report

adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Company Letter

In a letter submitted to the FDA prior to the June alert, LivaNova Inc. (a U.S. affiliate of the Sorin Group Deutschland) said the company has instituted "changes to the device's labeling, manufacturing and design, and will continue to evaluate potential further changes as our understanding and knowledge continue to develop."[3] The following are excerpts from the LivaNova company letter explaining its view of the situation and actions taken.

The literature currently available highlights that a key consideration with potential NTM transmission is the nature of the organism at issue. NTM is a ubiquitous environmental contaminant that is present in many water supplies, in the air, and in other non-sterile environments. NTM is also frequently identified in hospital environments. Consequently, in a non-sterile environment such as outside of the sterile field of an OR, NTM can certainly be present. NTM presence can result in postsurgical infection only if directly transmitted to the patient.

Generally, there are no reasonable alternatives to using of heater-cooler devices. While the literature is evolving, airborne NTM post-surgical infection appears to be exceedingly uncommon. For example, in an October 2015 publication, Public Health England stated: "This new risk is extremely small. Approximately 1 in 10,000 patients having this type of surgery might be affected. This level of risk is so small that surgery should not be delayed, as the risks of delaying surgery are greater than proceeding," and that "[t]his risk identified above is extremely small compared to the background risk of infection recognized following this type of surgery."

The potential risk of airborne NTM transmission from heater-cooler devices has only recently been recognized, and the understanding of this potential risk is continuing to evolve. At this time, the company believes that a properly maintained device poses minimal risk of disease transmission. LivaNova continues to actively seek appropriate solutions to mitigate any potential risk even further.

LivaNova is continuing to conduct extensive testing and data collection to better understand how airborne NTM infection may be occurring. In this process, the company consulted numerous experts to understand this phenomenon. The current thinking of the company is as follows:

- The failure to clean and disinfect a water circuit of a heater-cooler can allow biofilm formation. NTM is known to proliferate in biofilm and may lead to contamination of the heater-cooler water circuit.
- In operation of the device, air bubbles may be generated in the water tanks and then exit the device as aerosolized particles. The NTM present in the water may be carried by aerosolized particles out of the tank.
- Via air flow, the aerosolized particles may then be dispersed into the surrounding environment.

Labeling Changes

The company implemented a disinfection and drying process at the production facility in August 2014 to supplement the existing cleaning and disinfection process in the field. The company implemented additional manufacturing measures (e.g., disinfection of production equipment, use of sterile filtrated water). In addition, the company is implementing design changes for devices in production (e.g., replacing device tubing, plugging unused overflow outlet).

LivaNova communicated to customers the newly identified potential risk and importance of continuing to adhere to the cleaning and disinfection process. The company also provided information to customers regarding how to handle devices suspected of contamination and environmental monitoring.

Failure to perform adequate cleaning and disinfection per the IFU has the potential to lead to contamination, including NTM contamination. As more information has become available and while our investigation is ongoing, the device's cleaning and disinfection regimen has been revised to require more frequent disinfection of the water circuit (disinfection every two weeks rather than quarterly) with specified disinfectant solutions; weekly water changes; and the addition of hydrogen peroxide solution to the water to act as a preservative and further prevent biofilm formation. ■

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Another Brick in the Wall: Colistin-resistant *E.coli*

Mcr-1 plasmid transfers resistance to last-line drug

In another grim milestone toward a dreaded "Post-Antibiotic Era," researchers have found that horizontal genetic transfer of a novel plasmid *mcr-1*, which confers resistance to the last-line drug colistin in *Escherichia coli*, has now appeared in the U.S.[1]

The possible emergence of untreatable *E. coli* — a common cause of urinary tract and other infections in the community — is enough to rudely awake a medical epidemiologist in the middle of the night. It is a sobering development that the CDC has been concerned about for some time.

First reported in China, the *mcr-1* plasmid that can transfer colistin resistance to *E. coli* has now been found in a U.S. patient. In response to the reports from China, Walter Reed National Military Medical Center in Bethesda, MD, started testing for colistin resistance in all extended-spectrum ß-lactamase (ESBL)-producing *E.coli* clinical isolates submitted to the clinical microbiology laboratory as of May 16. The testing revealed *mcr-1* in an *E. coli* isolate cultured from the urine of a 49-year-old female who presented to a clinic in Pennsylvania on April 26, 2016, with symptoms indicative of a UTI.

The isolate was forwarded to Walter Reed, where susceptibility testing revealed it had an MIC to colistin of 4µg/ml (all others had MICs ≤ 0.25 µ/ml). The colistin MIC — a standard measure of antibiotic resistance — was confirmed by microbroth dilution and *mcr-1* was detected by real-time PCR.

"To the best of our knowledge, this is the first report of *mcr-1* in the U.S.," the researchers reported.

Interestingly, the patient reported no travel history in the prior five months. Continued surveillance to determine the true U.S. prevalence of this gene in the U.S. is critical, the authors stressed. The *mcr-1* gene has been found primarily in *E. coli* but has also been identified in other species of Enterobacteriaceae from human, animal, food, and environmental samples on every continent, the researchers report.

> "CLINICIANS HAVE AVOIDED USING IT[COLISTIN] BECAUSE IT MAY CLEAR AN INFECTION BUT DAMAGE THE PATIENT'S KIDNEYS."

Colistin is a last-line drug for good reason. Clinicians have avoided using it because it may clear an infection but damage the patient's kidneys. In one case reported in *Hospital Infection Control & Prevention*, a patient chose to have his leg amputated below the knee — removing the site of infection — rather than continue to take colistin and face going on dialysis. Thus, it's only now being used in cases where nothing else works, but if this *mcr-1* plasmid spreads, the formulary could finally be completely empty for certain infections. The patient outcome was not clear from the original report, but according to some press reports the woman survived.

CMS to Collect Drug Use

In a related development — one widely seen as a first step toward an anticipated regulation requiring antibiotic stewardship programs in healthcare settings — CMS has issued a proposed rule to begin collecting hospital prescribing data as a quality measure.

Hospitals would send their information to CMS through the CDC's National Healthcare Safety Network (NHSN) Antimicrobial Use module. CMS would then include the data on its Hospital Inpatient Quality Reporting program. Healthcare facilities can then compare "their antibiotic prescribing to national benchmarks and evaluate and improve antimicrobial prescribing as needed," the CMS stated.

The CMS is expected to issue a proposed rule requiring antibiotic stewardship programs in hospitals in 2017. Judicious and appropriate use of antibiotics have become critical as multidrug resistant bacteria — some essentially untreatable — have arisen after decades of flagrant and often unnecessary administration of antibiotics. ■

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WHO Convenes Zika Panel: Fate of the Olympics

Request from U.S. Senator apparent tipping point

Relenting to a growing chorus of international concern, the WHO will seek the opinion of a committee of infectious disease experts before it makes a final decision on allowing the Summer Olympics to be held in Rio de Janeiro.

After stonewalling formal pleas from an independent group of concerned scientists, the WHO conceded that action was needed in a June 1 letter to U.S. Sen. **Jeanne Shaheen** (D-NH) from **Margaret Chan**, MD, director-general of the WHO. Having requested that action, Shaheen released Chan's letter, which states in part:

"Given the current level of international concern, I have decided to ask members of the Zika Emergency Committee to examine the risks of holding the Olympic Summer Games as currently scheduled," Chan wrote. "The experts, well versed in travel medicine, the epidemiology of vector-borne disease, seasonal patterns of mosquito-borne infections, and risk communications, will meet shortly. Their advice to me will be immediately made public on our website together with the names and affiliations of the experts."

Proceed with Caution

The history of outbreaks and epidemics, particularly the pattern of cluster and dispersal, support proceeding with caution. The 2002-2003 SARS outbreak started with an index case in a Hong Kong hotel, and then at least one case was reported in some 20 countries. Mourners at Ebola funerals gathered to intimately grieve the dead and then scattered to their villages with the virus in tow. The infamous Spanish flu pandemic of 1918 was aided and abetted by WWI soldiers based in close quarters and then dispatched across the globe.

In this sense, an array of scientists and assorted academics and medical types had the weight of history on their side in recently urging the WHO to cancel the Olympics in Rio due to an epidemic of Zika virus.

"[Our] concern is for global health," they stated in a prior appeal to the WHO. "The Brazilian strain of Zika virus harms health in ways that science has not observed before. An unnecessary risk is posed when 500,000 foreign tourists from all countries attend the Games, potentially acquire that strain, and return home to places where it can become endemic. Should that happen to poor, as-yet unaffected places (e.g., most of South Asia and Africa) the suffering can be great. It is unethical to run the risk, just for Games that could proceed anyway, if postponed and/or moved."

Of course, the Zika virus is not spread by close contact like the aforementioned diseases. It is primarily spread by mosquitoes and is sexually transmitted. However, it is now widely thought the virus has mutated and it is certainly conceivable that travelers returning from the Olympics could cause outbreaks in countries with both *Aedes* mosquitoes and impoverished living conditions.

The WHO was not convinced, however, and initially rejected calls to cancel, delay, or move the games. "Based on current assessment, cancelling or changing the location of the 2016 Olympics will not significantly alter the international spread of Zika virus," the WHO recently stated before reversing its position. "Brazil is one of almost 60 countries and territories which to date report continuing transmission of Zika by mosquitoes. People continue to travel between these countries and territories for a variety of reasons. The best way to reduce risk of disease is to follow public health travel advice."

Instead of moving or cancelling the games, the WHO advised pregnant women not to travel to areas with ongoing Zika virus transmission, including Rio de Janeiro. "Pregnant women's sex partners returning from areas with circulating virus should be counselled to practice safer sex or abstain throughout the pregnancy. ... Whenever possible, during the day, [those attending the Olympics should] protect themselves from mosquito bites by using insect repellents and by wearing clothing — preferably light-colored — that covers as much of the body as possible." The WHO also said it was working with Brazil to further mitigate the risk before the games by eradicating populations of mosquitoes that transmit Zika.

Conflict of Interest?

The concerned scientists group was skeptical that an 11th hour attack on mosquito populations will sufficiently reduce the risk, questioning whether the WHO has a conflict of interest in blocking efforts to delay or move the games.

"We are concerned that WHO is rejecting these alternatives because of a conflict of interest. Specifically, WHO entered into an official partnership with the International Olympic Committee, in a Memorandum of Understanding that remains secret," the group states. "There is no good reason for WHO not to disclose this Memorandum of

Understanding, as is standard practice for conflicts of interest. Not doing so casts doubt on WHO's neutrality."

Also, in a May 30 letter after the WHO rejected their plea, the health experts group noted that "It is not true that 60 countries have the new, more dangerous strain of virus that is causing microcephaly and brain damage in children in Brazil. While routine travel out of Brazil already has exported that viral strain somewhat, the Olympics are different because they summon travelers from literally every country in the world and can spread infection with unsurpassable efficiency. Not even other mass gatherings like the World Cup have the global reach of the Olympics. ... Rio's official data show that the rate of mosquito-transmitted disease is three times higher in early 2016 than early 2015, including a surprising increase in the precise neighborhood of the Olympic Park."

For more information on Zika virus check out AHC Media's on-demand webinar: The Zika Virus: Separating Fact from Fiction — A Discussion with Experts. For all the latest AHC Zika coverage, please visit AHCMedia.com/Zika. ■

Group A Strep Outbreak Kills Four In Long-Term Care

HCWs sickened, others may have spread asymptomatically

An unusually large and persistent outbreak of Group A *Streptococcus* (GAS) in a nursing home was spread in part by infected and colonized healthcare workers, underscoring the importance of reporting symptoms, seeking treatment, practicing rigorous infection control, and not working sick, an officer in the CDC Epidemic Intelligence Service recently reported at the annual EIS meeting in Atlanta.

GAS outbreaks can be difficult to control because those merely colonized and asymptomatic can still infect their contacts, says **Srinivas A. Nanduri**, MD, an EIS Officer at the CDC. A strep outbreak could hit a hospital if lapses of infection control occur, but the long-term care environment has characteristics that may enhance spread, he says.

"Clusters of Group A strep infections can also occur in hospitals," he tells *Hospital Infection Control and Prevention*. "However, it is extremely unlikely that an outbreak of this magnitude would occur at an acute care hospital. In nursing homes, the population at risk, length of stay, staffing patterns, policies, and many other underlying factors are different from those found in acute care hospitals. Also, this particular outbreak is unique even among nursing home outbreaks in having affected a very large number of residents and staff."

In February 2015, the Illinois Department of Public Health (IDPH) identified a cluster of GAS infections at a nursing home. After multiple interventions, mass antibiotic prophylaxis was implemented from April 28–May 2, 2015. Infections re-emerged in late June. In November, the IDPH requested assistance to assess risk factors for infection and recommend control measures.[1]

Nanduri and EIS colleagues defined cases as GAS infection among residents or employees, confirmed by culture or antigen detection. They surveyed employees and observed infection control practices. To identify disease risk factors, they conducted a case-control study comparing resident cases occurring from May 3 to November 10 to controls for the same time period. To identify asymptomatic colonization, they collected throat and wound cultures from residents receiving wound care and throat cultures from employees linked to cases.

A total of 57 cases and four deaths occurred in 2015. The total included 17 cases (10 residents and seven employees) that occurred after the mass antibiotic prophylaxis.

"All symptomatic employees in the outbreak had pharyngitis," he says. "Ill residents had a wide spectrum of presentations, with some having severe bloodstream infections and others having pharyngitis or wound infections."

All the deaths were in residents and the mortality in those four cases was attributable to GAS infection, he says. "It is important to note that many of these residents had underlying illnesses which increase their risk of invasive GAS infection and worsen prognosis if they become ill," Nanduri says.

An employee survey identified seven self-reported, previously unrecorded workers with GAS illnesses since May 2015. "Employees should self-report if they have symptoms suggestive of infection with GAS," he says. Besides relying on self-reporting by employees, GAS prevention strategies include the following:

- education of staff about the symptoms suggestive of GAS infection,
- active surveillance for GAS symptoms suggestive of infection through reminders when employees present to work each day,
- employee health services

should establish procedures for tracking absences, and
- develop sick leave policies that are non-punitive, flexible, and encourage sick employees to stay home.

Infection Control Lapses

Investigators observed multiple lapses in hand hygiene and wound care practices, which contributed to the spread of strep. All (8 of 8) case-patients included in the case-control study received wound care versus 8 of 24 (33%) in the controls. One employee and four residents were colonized with GAS. The outbreak strain matched 96% of typed isolates (27 of 28).

"The healthcare workers were wearing gloves for wound care, illustrating the importance of always performing hand hygiene before and after using gloves," he says.

As per CDC guidelines for care of wounds infected with GAS, Nanduri cited the following precautions:

- Wounds with no dressings or with dressings that do not adequately contain drainage — contact and droplet precautions are advised.
- Wounds with dressing covers that adequately contain drainage — standard precautions are advised. ■

REFERENCE

1. Nanduri SA, Arwady MA, Edens C, et al. Prolonged Outbreak of Invasive Group A *Streptococcus* Among Nursing Home Residents — Illinois, 2015. Epidemic Intelligence Service Conference. Atlanta: May 2-5 2016.

Zika Testing: Virus Detection in Serum and Urine

CDC: 195 pregnant women with Zika in U.S.

More widespread testing for Zika virus is now available, as the FDA recently issued an Emergency Use Authorization (EUA) for a Qualitative Real-Time RT-PCR test.

In addition, the CDC recently announced a urine test that can detect the virus for up to two weeks. Real-time reverse transcription–polymerase chain reaction (rRT-PCR) is the preferred test for Zika virus infection because it can be performed rapidly and is highly specific. However, in most patients, Zika virus RNA is unlikely to be detected in serum after the first week of illness.

Recent reports using adaptations of previously published methods suggest that Zika virus RNA can be detected in urine for at least two weeks after onset of symptoms, the CDC noted. Currently, the CDC Trioplex rRT-PCR assay is the only diagnostic tool authorized by the FDA for Zika virus testing of urine. Other laboratory-developed tests will need in-house validations to adequately characterize the performance of the assay and meet Clinical Laboratory Improvement Amendments requirements. Further investigation is needed to determine the sensitivity and utility of Zika virus rRT-PCR on urine specimens collected ≥14 days after onset of symptoms.

On the basis of the newly available data, the CDC recommends that Zika virus rRT-PCR be performed on urine collected <14 days after onset of symptoms in patients with suspected Zika virus disease. Zika virus rRT-PCR testing of urine should be performed in conjunction with serum testing if using specimens collected <7 days after symptom onset. A positive result in either specimen type provides evidence of Zika virus infection. Procedures for the collection and submission of body fluids, including urine specimens, have been described previously. CDC recommendations for Zika virus testing of serum and other clinical specimens remain unchanged at this time. CDC will continue to review and update guidance for Zika virus testing as new data become available.

Developed by Focus Diagnostics Inc. (a subsidiary of Quest Diagnostics in Madison, NJ), the test will detect Zika virus RNA in blood samples. The test should only be used for individuals meeting CDC virus clinical criteria (e.g., clinical signs and symptoms associated with infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission) by qualified laboratories designated by Focus Diagnostics, Inc., the FDA emphasized.

The EUA does not indicate formal FDA approval indefinitely, and can expire or be terminated or revoked by the Department of Health and Human Services. According to a fact sheet posted by the FDA, Zika transmission is occurring in 35 countries and territories in the Americas, seven countries and territories in Oceania/Pacific Islands, and one country in Africa.

If Zika virus infection is suspected based on current clinical and epidemiological criteria, the RT-PCR test may be ordered. As chikungunya and dengue infection can have early symptoms resembling those of Zika infection — and co-infection with these viruses is possible — testing for those viruses should be considered as well.

Zika virus RNA is typically detectable in serum for approximately seven days following onset of symptoms. Contact your state or local health department to facilitate testing, the FDA advises.

As of June 1, 2016, there were 618 travel-associated cases of Zika reported in the U.S. There were no vector-borne cases reported, but 11 cases were due to sexual transmission and there was one case of Guillain-Barré syndrome. In addition, as of May 26, 2016, there were 195 pregnant women with Zika in the U.S.

In U.S. territories, there were 146 pregnant women with Zika virus infection. There were 1,110 locally acquired cases and five travel-associated cases in the territories. ■

REFERENCE

1. FDA. Fact Sheet for Health CareProviders: Interpreting Zika Virus RNA Qualitative Real-Time RT-PCR Test Results. April 28, 2016: http://1.usa.gov/24iK3bQ.

Presenteeism: Working Sick Endangers Patients

Long-term care workers say work sick or no pay

In findings that further underscore the "presenteeism" phenomenon, investigators found that more than 40% of healthcare workers with influenza-like illness reported to work, putting patients and co-workers at risk of infection, an officer in the CDC Epidemic Intelligence Service recently reported at the annual EIS meeting in Atlanta.

"Our results are consistent with studies that I have read in the literature based on certain occupation groups, physicians, and nurse practitioners," says **Sophia K. Chiu**, MD, an EIS officer at the CDC.

Healthcare settings, where an estimated 14.6 million influenza cases received medical attention in 2013–14, are known sites for influenza transmission.[1] Healthcare workers with influenza-like illness (ILI) who continue working despite CDC's recommendation not to work until being afebrile for ≥24 hours, contribute to influenza transmission. Of course, not everyone who reports ILI has the actual flu, but the CDC recommendation is that ILI is defined as fever and cough or sore throat. "So the recommendations are not based on whether the person tests positive for influenza," she says.

Chiu and colleagues used a national internet survey of 1,914 healthcare workers during the 2014–15 influenza season to calculate the frequency of working with self-reported ILI. Of 414 (21.6% overall) healthcare workers reporting ILI during the 2014–15 season, 183 (41.4%) reported working with ILI (median: 3 days). Pharmacists (67.2%) and physicians (63.2%) had the highest frequency of working with ILI. By setting, hospital-based workers had the highest frequency of working with ILI (49.3%). The most common reasons for working while ill included the following:

- still being able to perform job duties,
- not feeling bad enough to miss work,
- having a professional obligation to co-workers, and
- difficult to find coverage.

"We think these [reasons] are amenable to education and training of healthcare personnel with the goal of changing social or cultural norms; for example, about how sick one has to be to take sick leave and also reminding HCWs about how and when influenza can be transmitted," Chiu tells *HIC*. "Hospitals and other institutions can make arrangements so there is a pool of healthcare personnel that is scheduled to be on standby to fill in for ill colleagues. This can alleviate that feeling of burdening colleagues. There are some systems like this in place for some physicians and nurses, but it could be extended for all personnel."

Among respondents working in long-term care facilities, the main reason for working ill was more disturbing, as the most said they were not able to afford lost pay.

"However, that doesn't necessarily mean they don't have paid sick leave," she says. "It could be they used all of it up. We don't exactly know what the paid sick leave structure is to all the people that responded to the survey. We didn't directly ask about that, but it is an incentive to stay home while you're sick [if you have sick leave]. We asked institutions to consider implementing paid sick leave policies." ■

REFERENCE

1. Chiu SK, Black C, Yue X, et al. Health Care Personnel Working While Having Influenza-Like Illness — United States, 2014–15 Influenza Season. Epidemic Intelligence Service Conference.

COMING IN FUTURE MONTHS

- APIC in Charlotte – look for breaking news, blogs, and tweets
- Dialysis infection control — the wild, wild West?
- Which antibiotic stewardship model works best for your facility?
- Infection prevention and the transgender patient

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CME/CE INSTRUCTIONS

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CME/CE QUESTIONS

1. Heater-cooler devices used during cardiac surgical procedures have a closed circuit system to circulate water, but can create an aerosol that is vented into the immediate environment by an exhaust fan.

a. True
b. False

2. Though there may be underlying factors contributing to the death of patients infected with *Mycobacterium chimaera*, Dan Diekema, MD, said the crude mortality rate for the patients infected via heating-cooling devices was "well over:"

a. 20%.
b. 35%.
c. 50%.
d. 60%.

3. In another milestone toward a dreaded "post-antibiotic era," researchers reported:

a. MRSA resistant to vancomycin.
b. Anthrax resistant to ciprofloxin.
c. Group A *Streptococcus* resistant to penicillin.
s. *Escherichia coli* resistant to colistin.

4. An unusually large and persistent outbreak of Group A *Streptococcus* in a nursing home was fueled in part by:

a. Asymptomatic carriers.
b. Vaccine failure.
c. Social gatherings in a small room.
d. Strep strain resistant to all first-line drugs.

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.