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INSIDE

FDA: 5% of Duodenoscopes Still Contaminated After Reprocessing

A clear and present danger to patients

By Gary Evans, Medical Writer

In reporting continuing problems disinfecting complex duodenoscopes, FDA officials recently sought input from an infection control advisory panel at the Centers for Disease Control and Prevention (CDC). They received it in no uncertain terms.

"I am deeply uncomfortable with the period that has gone on with us being aware of this level of risk and the inability to disinfect these devices," said **Lisa Maragakis**, MD, MPH, co-chair of the CDC's Hospital Infection Control Practices Advisory Committee (HICPAC). "It really does call for a disposable product or a complete paradigm shift and redesign," she said at the meeting, held May 16-17 at the CDC in Atlanta.

> "FDA IS CONCERNED THAT HIGH-LEVEL DISINFECTION IS NOT SUFFICIENT TO ENSURE THE SAFE USE OF THESE DEVICES IN ALL CASES."

Duodenoscopes became a national concern in 2014, when the CDC reported[1] a 2013 outbreak of carbapenem-resistant Enterobacteriaceae (CRE) linked to the devices. The intricate scopes are used to assess the pancreas and other organs in endoscopic retrograde cholangiopancreatography (ERCP).

Over the ensuing years, there has been a series of FDA actions and alerts, device recalls, modifications, and new reprocessing instructions. According to the FDA, the levels of exposures,

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infections, and deaths linked to the devices have declined since 2015.

However, post-market surveillance of the devices reveals that roughly 3% to 5% of reprocessed duodenoscopes remain contaminated with potentially infectious organisms, **Shani Haugen**, PhD, microbiologist at the FDA Center for Devices and Radiological Health, said at the HICPAC meeting.

Committee members raised the issue of informed consent, asking Haugen what patients should be told before undergoing procedures with duodenoscopes.

"FDA believes that with appropriately selected patients — patients that need to have ERCPs conducted — the benefits of the procedure outweigh the risk of infection," she said.

The response was somewhat equivocal, considering the FDA recommended in 2015 that clinicians "inform patients of the benefits and risks associated with ERCP procedures, including the risk of possible infection."[2] In any case, informed consent for these procedures is a gray area because clinicians would essentially be telling patients that the device being used on them cannot be reliably disinfected.

"You don't do a surgical procedure and say, 'There is a chance that the scalpel I use may be contaminated,'" said HICPAC member **Deverick Anderson**, MD, of Duke University Medical Center. "You don't do a central line and say, 'Five percent of the time, the central line is not going to be sterile.' That is just not part of the conversations we have."

Maragakis concurred, saying, "It is fundamentally different from a side effect of a medication or the risk of a procedure. This is really a safety flaw in the device itself if it cannot be adequately cleaned and disinfected."

Haugen underscored the sheer scale of the issue, reminding that some 500,000 ERCPs using duodenoscopes are performed annually in the U.S. The comment drew a response from a patient safety advocate, HICPAC liaison member **Paul Conway**, of the American Association of Kidney Patients in Tampa, FL.

"The volume of the number of procedures done is less relevant when we are talking to a federal agency," he said. "What's more important is understanding that the patient interest starts with the first patient — patient number one. The onus is on all stakeholders in this process to raise the question and educate patients on both the risk and the exact device that is being used. Informed patients can make important decisions."

The issue is difficult because the relative risk of using duodenoscopes must be weighed against the alternative of doing open abdominal surgery to assess the organs.

"As an individual patient, I would be willing to consider a modest risk if my life was at stake and this was the alternative to open surgery to assess my gallbladder. But I would like to know what that [risk] is," said **Michael Bell**, MD, a CDC medical epidemiologist and designated federal officer on HICPAC.

Disturbing Data

The FDA issued warning letters in March 2018 to duodenoscope manufacturers for failing to comply with a prior order for post-market

surveillance studies of the devices in use. The FDA is now receiving more of these reports, and the results presented at HICPAC seem troubling.

"Up to 5.4% of properly collected samples tested positive for high-concern organisms, which are more often associated with disease, such as *E. coli* and *Pseudomonas*," Haugen said.

Another 3.6% of the scopes tested positive with low- to moderate-concern organisms, likely related to environmental contamination, she said.

"These interim data tell us that improvements are necessary, and the FDA is committed to taking additional steps to reduce infections and contamination further," Haugen said.

The FDA post-market surveillance studies mirror contamination levels that have been reported in the literature.[3,4]

"In general, in larger studies, a contamination rate of about 2% to 5% is frequently observed and is consistent with the [FDA] post-marketing surveillance results," Haugen said.

The clear conclusion was that the standard protocol at many hospitals of reprocessing these scopes with high-level disinfection (HLD) — even if it is performed twice consecutively[5] — leaves patients at risk.

"Current practices for reprocessing duodenoscopes are not sufficient to avoid all infections," Haugen said.

"FDA is concerned that high-level disinfection is not sufficient to ensure the safe use of these devices in all cases. With that said, however, in appropriately selected patients, the benefits of using a duodenoscope still outweigh the risks of infections."

In the name of transparency and quality improvement, some HICPAC members urged the FDA to make the contamination data presented at the meeting available to patients and consumers.

"These reports are publicly available, and so someone should be able to come up with the same numbers if they do a deep dive into our database," Haugen said.

The FDA should go beyond saying the data are available on the internet and clearly disclose the information to patients, emphasized HICPAC member **Jan Patterson**, MD, director of the Center for Patient Safety and Health Policy at University of Texas Health San Antonio.

"It would be important to have the contamination rate in the post-market surveillance publicly available by device, by manufacturer," she said. "Public reporting of these types of things is very powerful in terms of finding solutions. It needs to be publicly available in something other than reports that are buried on the internet."

Haugen asked committee members to express their level of concern with the current situation and give the FDA input on future action.

"The data that you have shown us are highly concerning, and would be concerning to anyone that saw them," Maragakis said.

Other HICPAC members concurred without a formal vote, and Haugen said she will communicate this concern to her colleagues at the FDA.

"We will take back the input that you provided, and we are going to continue to have discussions," she said. "The FDA is committed to further reducing infections associated with these devices."

Manufacturers 'Disingenuous'

HICPAC members also favored the idea of requiring that manufacturers demonstrate the scopes can be decontaminated in real-world conditions before shipping them out — not in post-market surveillance.

"I think it is disingenuous for manufacturers of a device not to test if it can, in fact, be cleaned and disinfected by following the instructions for use [before] sending it out to facilities," said HICPAC member **Hilary Babcock**, MD, MPH, medical director of occupational health at Barnes-Jewish and St. Louis (MO) Children's Hospitals. "They should be responsible for demonstrating that the scopes can be decontaminated before they send it to my facility and make it my responsibility to fix something that I cannot fix."

With so many different designs and multiple manufacturers, it is difficult to correctly follow the reprocessing procedures, said **Darlene Carey**, MSN, RN, a HICPAC liaison member for the Association for Professionals in Infection Control and Epidemiology.

"The steps are so convoluted that it is difficult, at best, for a technician that has spent 20 years doing this to come out successful," said Carey, an infection preventionist at Gwinnett Medical Center in Lawrenceville, GA.

This perception has been confirmed in FDA "human factor" studies that looked at efforts to reprocess the scopes, Haugen said.

"Some reprocessing staff missed one or more steps in the process and needed additional training to complete the process properly," she

said. "The descriptions of some of the processing steps in the user manuals were unclear. FDA is considering these data as we develop our next steps in this area."

HICPAC member **Elaine Dekker**, RN, an IP at Zuckerberg San Francisco General Hospital and Trauma Center, said the variety of devices and different reprocessing instructions point to the need for more standardization of duodenoscopes.

"I know companies are competing for business, but I think there needs to come a time where they are not competing to have the best product but working together to make a safe product," she said.

Reprocessing instructions, some of which have as many as 40 steps, further endanger patients by raising the likelihood of a breach in aseptic technique at any point in the process.

"If you look at your scope reprocessing room, you would be amazed at the number of charts hanging on the walls that they have to flip through to get the right scope for what they are doing," Dekker said.

"It is a hard process, and the scope manufacturers need to take that into account as well."

Death of a Patient

The failure to adequately disinfect the devices has been linked to outbreaks of CRE and other pathogens, several of which have been stopped after facilities went to more stringent reprocessing measures such as ethylene oxide (EtO) sterilization.

Appearing before HICPAC to tell of her husband's death in 2013 after an ERCP procedure led to CRE infection, **Carla Warner** of Statesville, NC, humanized the issue and called for all scopes to be sterilized.

"I watched as a man who was once strong and innovative became unable to lift himself off the couch or do even the simplest of tasks for himself," she said.

"I saw his knuckles turn white as he clenched the sheets in excruciating pain. I listened as he gasped for air as his oxygen levels plummeted. I heard him crying out to me not to leave his side due to the hallucinations he experienced during his delirium."

In calling for more stringent sterilization measures, Warner said she will continue to speak out in the name of her late husband, Bill.

"I am doing my part by spreading the word, and now, I'm asking you do to yours," she told HICPAC during the public comment period. "Help push for the only right answer in this scenario, which is sterilization of all scopes."

In August 2015, FDA issued voluntary supplementary measures, including EtO sterilization, use of liquid chemical sterilant processing system, and repeat HLD.

However, only 12% of 249 facilities responding to a 2018 survey[6] reported using EtO sterilization.

In addition, 63% used repeat HLD, 53% conducted surveillance via microbiological culturing, and 35% were using liquid-chemical sterilization.

"In general, ethylene oxide sterilization provides a higher margin of safety than either high-level disinfection or liquid chemical sterilization," Haugen said.

"[EtO] sterilization of duodenoscopes led to cessation of outbreaks in at least three different healthcare facilities."[7,8]

Additional sterilization technologies are in development for duodenoscopes, but "currently, there are no FDA-cleared terminal low-temperature sterilizers," she said.

Asked about the processes used by the facilities that reported the scope contamination data, she said the vast majority were using the manufacturer's recommended cleaning process and then high-level disinfection.

"To my knowledge, none of these samples were from ethylene oxide sterilized devices [or those] that were subjected to chemical sterilization," Haugen said.

"Some of these facilities do conduct double high-level disinfection. However, this initial interim analysis indicates that it did not have an impact on contamination rates."

EtO Challenges

While EtO appears to be the obvious alternative, challenges include costs, particularly for small hospitals. The process also reportedly shortens the "use life" of the scopes and can contribute to long wait times in the sterilization process.

"When we talk about EtO sterilization and chemical liquid sterilization, we are talking about long times, like 12 hours, 24 hours," said **Karen DeKay**, MSN, RN, CNOR, CIC, a HICPAC liaison member for the Association of periOperative Registered Nurses.

HICPAC member **David Henderson**, MD, a hospital epidemiologist at the National Institutes of Health Clinical

Center, also pointed out that using EtO "eats them up pretty fast."

The FDA's Haugen said, "Yes, we have received anecdotal reports of device damage after EtO sterilization."

HICPAC member **Loretta Fauerbach**, MS, CIC, an infection preventionist, traced the root of the duodenoscope contamination issue back to the historical perception that some infections are the inevitable result of patient care.

"We allowed certain device-related infections to become the norm," said Fauerbach, an IP consultant in Gainesville, FL.

"We thought we could not get to zero. In applying that to duodenoscopes, we know that very vulnerable patients may be exposed to this 5% contamination rate."

The situation makes it imperative that the FDA "help to force the technology to sort of reboot the human factor, because you always have someone who may make a mistake or not do the process thoroughly," she said.

The FDA should require devices that can be readily accessed for cleaning be sterilized before use on the next patient, she added.

"That is going to be a lot of work for the FDA and the manufacturers to address, but knowing that you can reach zero [contamination], I think we should reach zero for complications as well," Fauerbach said. ■

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IPs Key to Preventing Waterborne Infections

New CDC website is aimed at helping facilities investigate water-related outbreaks

As the Centers for Disease Control and Prevention (CDC) expands its focus on waterborne pathogens, infection preventionists are viewed as having a critical role in their facilities' water management plans.

"We envision these water management programs to be very multidisciplinary — they require expertise from different areas of the hospital," says **Kiran M. Perkins**, MD, MPH, a team lead for outbreak and response at the CDC. "IPs are an obvious part of that program. They play a critical role in this area. They need to really think through all the areas of the hospital where patients could be exposed to water and increased risk of infections."

Perkins and colleagues "reviewed internal CDC records from Jan. 1, 2014, through Dec. 31, 2017 … to identify consultations that involved potential or confirmed transmission of water-related organisms in healthcare." The study[1] excluded *Legionella*, which is under the purview of another branch at the CDC.

"Of 620 consultations during the study period, we identified 134 consultations (21.6%), with 1,380 patients, [that were related to water in a healthcare facility]," Perkins and colleagues wrote.

"We identified a variety of plausible water-exposure pathways,

including medication preparation near water splash zones and water contamination at the manufacturing sites of medications and medical devices," they reported. *(See the sidebar on the right for more information.)*

Although water-related investigations comprise almost one-fourth of the CDC consultations reviewed, they probably only represent a fraction of these outbreaks nationally.

Waterborne infections really came to the fore in 2017, when the Centers for Medicare & Medicaid Services (CMS) mandated water management programs after a series of *Legionella* outbreaks. While the primary focus of the CMS memo has been *Legionella*, the agency document also calls for water management programs to control "other opportunistic pathogens in water."[2]

"The way the CMS memo is worded, we are hopeful that employers understand it is not just specific to *Legionella*," Perkins said.

Other waterborne pathogens of concern include nontuberculous mycobacteria (NTM), *Pseudomonas* species, and a host of other bugs.

"These organisms can be transmitted to patients, directly or indirectly, through typical water uses involving showers, sinks, and toilets," the CDC investigators report.

As a resource for investigating water-related outbreaks, Perkins recommends guidelines[3] on the CDC's new "From Plumbing to Patients" website, available at: https://bit.ly/2MG64iI.

The guidelines include checklists and key issues to consider when investigating an outbreak that may be related to water.

"That is targeted at what a facility might be encountering — maybe an outbreak or spike of cases of water-related infections," Perkins says.

"They can see if there is something that could be remediated. That checklist asks about the pH of the water, the hot and cold temperatures — things of that nature. It helps guide facilities to look at certain areas of water quality."

Unlike *Legionella* investigations, which can be triggered by a single case, investigating other waterborne

Waterborne Bugs: Common Routes of Transmission

Suspected in CDC outbreak investigations

The CDC reports[1] that in its consultations related to "potential or confirmed transmission of water-related organisms in healthcare," the following were suspected as "plausible ... routes of transmission" in at least two investigations:

- "Injection/medication preparation near sink;
- Nutrition (including breast milk and infant formula) preparation near sink;
- Patient care supplies stored by sinks and toilets in intensive care unit;
- Contaminated water from [NICU] sinks;
- Contaminated water from operating room scrub sinks;
- Contaminated sink drains;
- Contaminated dialysis wall boxes;
- Use of nonsterile ice for patient care among immunocompromised patients;
- Use of contaminated water in dental water lines;
- Water introduction during respiratory therapy;
- Use of tap water during bronchoscopy procedures;
- Use of nonsterile water for humidification reservoirs of infant incubators in NICU;
- Use of nonsterile water and inadequate disinfection of heater-cooler devices used during cardiac surgery;
- Intrinsic contamination of medical products due to water contamination at production site;
- Poor medical device reprocessing procedures;
- Poor cleaning and disinfection of hydrotherapy rooms and equipment;
- Water from contaminated shower heads;
- Hot tub use by surgical personnel;
- Water contamination of specimens/reagents in the laboratory." ■

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pathogens requires a little more detective work.

"With the other water-related organisms, we don't have as much, at this point, of a systematic approach," Perkins says. "We are learning more as we go. I think what triggers an investigation is really dependent on the organism, the setting, and the patient population."

The critical concept in a water management program is to be proactive, not waiting for infections to appear before you begin looking at factors that could degrade water quality.

"Make sure you are doing everything you can at the facility level to [ensure] that these organisms are not being perpetuated throughout the water system or causing biofilm formation," she says.

Water Hazards

One of the recurrent causes of waterborne outbreaks in healthcare is storing patient care items or preparing medication near sinks, toilets, or other water sources.

"We hear about that all the time," Perkins says. "Providers, nursing staff, medical techs — all of the people that are entering the patient area — need to understand that basic concept: Keep medication and patient care items away from water sources."

Some of this can be mitigated by design — for example, by using stand-alone sinks that do not have attached countertops.

"Another engineering issue with sinks is when the faucet is right over the drain," she says.

"There is a risk of a direct splash up from the drain. There could be multidrug-resistant organisms [MDROs] in the drain, and those can splash up and colonize the faucet."

If that occurs, the faucet may become contaminated with colonies of bacteria, in some cases contaminating the water as it flows through, she notes.

To avoid this recurrent cause of water-related outbreaks, some healthcare facilities are offsetting faucets so they are not placed directly over the drain.

With *Legionella* excluded in this study, the CDC found that NTM was the most common cause of water-related healthcare outbreaks, often in connection with surgery or contaminated medical devices.

"This is where we really have to pay attention to the continuum of clinical care — all areas where water can be introduced," she says.

"For example, should this be a sterile water source instead of just tap water?"

Of course, tap water is safe for public consumption, but it poses a threat to patients if it enters the body during medical procedures.

"We have consulted on outbreaks of NTM in outpatient settings, where they are doing things like cosmetic or liposuction procedures," Perkins says. "They are doing somewhat invasive procedures but not using sterile water. This is an extreme example, but rinsing a wound with tap water is obviously a set up for an NTM or other water-related organisms."

NTM outbreaks also are being identified in clinics that perform injections, such as those for joint pain.

"Those are common procedures where there could be the introduction of water," she says. "Practitioners need to really pay close attention to that."

More than one-third of the CDC water-related consultations involved pathogens that were resistant to multiple antibiotics.

"These MDROs are definitely in the environment of patient care settings," Perkins says.

"Often, these organisms are living in sink drains, toilets, on bed rails and things of that nature. If they are not paying close attention to infection control practices, healthcare workers could potentially transmit these MDROs to patients."

As more invasive procedures move beyond the hospital, there is the expectation that more water-related infections will occur in ambulatory care.

"Unfortunately, we don't have a national surveillance system for all water-related organisms to know if they are increasing nationwide or in ambulatory care settings," Perkins says. "I think, anecdotally, there are reasons that they could be. Outpatient settings often do not have the regulatory oversight and IP capacity that acute care settings have." ■

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Researchers Show Understaffing Translates to Infections

Columbia study shows link between staffing, HAIs

Understaffing of registered nurses for two consecutive work shifts showed a statistically significant increase in healthcare-associated infections (HAIs), researchers report in a new study.[1]

"Clinically, it makes sense because if the understaffing is for only one shift, nurses can manage the workload," says lead author **Jingjing Shang**, PhD, RN, associate professor at Columbia University School of Nursing in New York City. "However, if [the unit is understaffed] the whole day, the consequences will show up."

Shang and colleagues examined "whether [HAIs] and nurse staffing are associated using unit-level staffing data." Previous studies have suggested there is a link, but "the association between HAIs and nurse staffing are inconsistent and limited by methodological weaknesses," the authors noted.

They analyzed data from a large urban health system in the period between 2007 and 2012. HAIs were diagnosed using CDC definitions. To allow for the incubation period of pathogens, researchers assessed staffing levels two days before infection onset.

Overall, using a measure of patient-days, 15% of patients "had one shift understaffed, defined as staffing below 80% of the unit media for a shift, and 6.2% had both day and night shifts understaffed. Patients on units with both shifts understaffed were significantly more likely to develop HAIs two days later," the authors reported. HAIs included in the analysis were urinary tract infections, bloodstream infections, and cases of pneumonia.

"If only one shift was understaffed, the risk was also high but not significant," Shang says. "In the units that had both day and night shifts understaffed, we definitely saw this significant increase of the infection rate."

The study also showed an increase in infection risk when units lacked support staff such as licensed practical nurses and nurse assistants. The bottom line for hospital leaders is that dollars saved by cutting staffing will result in the expense and suffering of HAIs.

"In addition to their medical and financial impacts, HAIs also have psychological and social consequences for patients such as depression, anxiety, disability, and job loss," Shang and colleagues emphasized.

Hospital administrators are the primary audience they wanted to reach with the paper, Shang says, thus its submission to the *Journal of Nursing Administration*.

The threshold of 80% median unit staffing to define understaffing was drawn from previous research by the authors, serving as the line of demarcation between sufficient nursing levels and increasing risk of HAIs.

As nurse staff levels decrease, the likelihood rises that corners may be cut, resulting in lapses and breaches of infection control measures such as hand hygiene and glove use.

Previous studies are limited in the way they assessed the effect of staffing on nursing, often averaging staffing over the whole hospital, Shang tells *Hospital Infection Control & Prevention*. "They are not very specific on a unit level," she says.

The Columbia study sought more precision on the unit and shift level, using payroll data to determine when the nurses clocked in and out, she says.

"The infections in our study are based on CDC definitions," Shang says. "They are very precise, and are based on lab results, cultures, and symptoms. We measured the staffing very precisely, and the infections are based on clinical outcomes — not administrative data." ■

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Infection Prevention and Cardiac Implants: Sometimes, More Is Less

Ineffective interventions common

Cardiac implantable electronic devices (CIEDs) restore safe heart rhythms but carry a risk of infections that can be fatal in one in eight patients.

"As the patient population receiving these invasive devices is increasingly older and more medically complex, CIED infection incidence has doubled over the past decade," researchers report.[1]

"At the same time, the number of patients receiving CIEDs continues to increase, with more than 300,000 new devices placed annually in the United States."

The authors "[measured] the association between … specific infection prevention interventions and procedure-related [CIED] infections," finding in some cases practices that are unnecessary and even harmful.

The method was a retrospective cohort review of the infection status of CIED patients at Veterans Health Administration (VA) hospitals. The researchers used a sampling of procedures entered from fiscal years 2008 through 2015.

Out of 2,098 procedures, the researchers "identified 101 procedure-related CIED infections."

The "factors associated with increased risk for infections" included "wound complications," "revisions including generator changes," "an elevated international normalized ratio," and "methicillin-resistant *Staphylococcus* colonization [MRSA]."

According to the authors, "Clinically effective prevention interventions included preprocedural skin cleaning with chlorhexidine … and receipt of beta-lactam antimicrobial prophylaxis."

However, the authors found that many common "interventions are ineffective, and that the simplest strategies (those designed to limit bleeding risk and avoid implantations in patients with active infections) have the strongest potential to improve CIED infection outcomes."

Hospital Infection Control & Prevention spoke with the study's corresponding author, **Westyn Branch-Elliman**, MD, MMSc, an assistant professor of medicine at Harvard Medical School, and an Investigator with the VA Boston Center for Healthcare Organization and Implementation Research. This interview has been edited for length and clarity.

HIC: Did you find any temporal results that would suggest these CIED infections are increasing over time?

Branch-Elliman: We did not specifically evaluate for temporal changes. However, other studies have demonstrated that rates of infection have been increasing with time, in parallel with an increase in the comorbidity index of the patients receiving cardiac device implantation procedures.

HIC: Can you elaborate on the risk factors, such as wound complications and MRSA colonization?

Branch-Elliman: MRSA is a well-characterized risk factor for many types of procedure-related infections, so we were not surprised that it was associated with an increased risk of cardiac device infection in our sample.

The association is probably partially due to factors inherent to the patients who are MRSA-colonized — they tend to be sicker and have more healthcare exposures than patients without MRSA colonization — and partially due to the nature of the organism.

Another factor may be that this organism is resistant to the most commonly used prophylaxis agent, cefazolin; thus, standard prophylaxis regimens may not be as effective in MRSA-colonized patients as in patients without MRSA.

We also found that peripheral arterial disease was related to increased risk of infection. This might be because good blood flow is needed for wound healing and for good immune system functioning.

The host immune system plays a key role in preventing postoperative infections by cleaning up any low-level contamination that may occur around the time of the procedure.

Revision procedures have been demonstrated in other studies to be associated with a higher risk of infection.

This is probably because there is more scar tissue present in these cases, and thus, less blood supply to the area. A good blood supply is critical for both wound healing and clearance of low-level bacterial

contamination that may occur after skin incision.

HIC: Was ineffective treatment related to these risk factors — or were these patients at significant risks regardless of treatment?

Branch-Elliman: Any time a device is placed, there is a risk of infection. Infection prevention interventions can reduce the risk of infection, but not entirely eliminate it.

Some patients, based on their personal risk factors and specifics of their cardiac device procedure, are at higher risk of infection than others. These higher-risk patients may derive more absolute benefit from some infection prevention interventions than lower-risk patients.

HIC: Do you have any data on patient mortality related to the infections?

Branch-Elliman: I do not have that information available for this cohort, but prior studies suggest that the mortality rate from deep cardiac device infections approaches one in eight patients.

In work we previously published, we found that almost half of the patients (42%) who developed *C. difficile* after receiving prolonged prophylaxis died.

HIC: How common were the ineffective practices, such as continuation of antibiotics?

Branch-Elliman: Continuation of antimicrobial prophylaxis after skin closure was extremely common in the cohort — about half of the patients in our sample received this ineffective and likely harmful intervention.

Our group has demonstrated that continuation of antibiotics for greater than 24 hours in this population is associated with increases in postoperative adverse events, including increased rates of *C. difficile* infections.

In other surgical populations, we have also found that increasing duration of prophylaxis is associated with increases in rates of acute kidney injury, which can lead to long-term chronic kidney disease. These data strongly suggest that we need to find effective ways to de-implement this low-value, and potentially harmful, practice.

HIC: You conclude that frequently used interventions are less effective than simpler strategies. What will it take to change the culture and move away from the interventions that don't work well?

Branch-Elliman: De-implementation of ineffective practices can be particularly challenging. Our group is actively investigating what factors drive current antimicrobial prescribing practices and what factors are perceived to be associated with positive practice change. We hope that this work will shed light on the best ways to reduce unnecessary antimicrobial use and ultimately to improve clinical care. ■

REFERENCE

1. Asundi A, Stanislawski M, Mehta P, et al. Real-world effectiveness of infection prevention interventions for reducing procedure-related cardiac device infections: Insights from the veterans affairs clinical assessment reporting and tracking program. *Infect Control Hosp Epidemiol* 2019; 4:1-8. doi: 10.1017/ice.2019.127. [Epub ahead of print].

Workers Working Sick: Are Your Patients Safe?

Misguided policies incentivize a dangerous practice

Unfortunately, "working while sick" has historically been an all-too-common practice in healthcare, endangering patients and other healthcare staff. The fact that this trend continues unabated recently led to a call for action on presenteeism by infection control advisors to the Centers for Disease Control and Prevention (CDC).

Marion Kainer, MD, MPH, a liaison member of the CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC), cited a recent outbreak in which a patient with hepatitis A transmitted the virus to another patient and six healthcare workers.

"As we investigated, we became aware of an extraordinary punitive policy that required healthcare personnel to take personal leave before sick leave would kick in," she said at the HICPAC meeting, held May 16-17 at the CDC in Atlanta.

"[That] means that every single one of those infected healthcare workers worked while they were symptomatic. I honestly have never been aware of such punitive sick leave policies," Kainer said.

HICPAC is updating CDC infection control guidelines[1] for healthcare workers originally published in 1998.[2] In doing so,

the draft addresses the issue of presenteeism, with the version discussed by the committee recommending "sick leave options that encourage reporting of potentially infectious exposures and illnesses and that discourage presenteeism."

The CDC recommends that workers have ready access to clinicians with expertise in exposure and illness management to ensure prompt testing and treatment. Policies for exposed or ill healthcare workers should specify both how work restrictions are imposed and under what conditions staff can return to duty.

The draft further recommends ensuring there are no communication breaks between occupational health services, healthcare personnel, and others about return-to-work policies and restrictions.

"Implement processes and sick leave policies to encourage healthcare personnel to stay home when they develop signs or symptoms of acute infectious illness (e.g., fever, cough, diarrhea, vomiting, or draining skin lesions) to prevent spreading their infections to patients and other healthcare personnel," the HICPAC draft guidelines state.

The committee also agreed to a revision that includes contract workers as well as regular employees in all sick leave policies.

The new guidelines certainly discourage presenteeism, but HICPAC members were concerned that the matter needs more emphasis, possibly as an appendix or in a separate document.

Discouraging presenteeism certainly has been emphasized by HICPAC member **Hilary Babcock**, MD, MPH, medical director of occupational health at Barnes-Jewish and St. Louis (MO) Hospitals.

For example, she explained last year at IDWeek in San Francisco that healthcare sick leave policies often are poorly communicated and haphazardly enforced. She pointed out that 44% of 232 respondents in a national survey reported they had a single pool of paid days off that they used for both vacation and illness. *(See* Hospital Infection Control & Prevention*, December 2018.)*

"We also have that at our place," Babcock told HICPAC members at their recent meeting.

"People have a single bank of time off, and both vacation and sick leave come out of that. So, the same things end up happening in practice."

That said, HICPAC does not want to be overly prescriptive with healthcare sick leave policies, preferring to let various types of facilities adopt and enforce their own strategies.

"We are not specifically saying how this should work because this [guideline] applies to a huge range of [facilities]," Babcock said. "I don't think we could really be very specific, but we tried to push forward these kinds of policies."

Concurring was HICPAC liaison member **Mark Russi**, MD, MPH, professor of medicine and epidemiology at Yale University in New Haven, CT.

"I think rather than making arguments to local administration, it is more powerful to say that there is an overarching statement from CDC which says that the policy should discourage presenteeism and be nonpunitive," he said.

Others noted in the discussion that presenteeism is essentially a human resources (HR) issue, saying that HR should be involved rather than putting the onus on occupational health to enforce such policies.

HICPAC liaison member **Paul Conway**, of the American Association of Kidney Patients in Tampa, FL, said patient advocacy groups could bring the issue of presenteeism to the forefront.

"Patient safety organizations can engage on this as patients," he said. "It is a public health issue and a workforce issue. Patients are also in the workforce and are concerned about public health. We can say this is the standard the CDC is recommending, and can work with our patients to start asking questions."

Even if done as a separate document, it would be useful to determine what sick leave policies are being used in healthcare settings, said HICPAC liaison member **Linda Spaulding**, RN, DNV GL NAIHO/CIP Surveyor in Milford, OH. "I have been in places where if you call out three times in a year, you get terminated," she said.

Options discussed included HICPAC partnering with professional organizations on presenteeism, creating a toolkit, and addressing issues of temp workers and physicians who are not necessarily hospital employees.

"I think that would really be invaluable," Kainer said. ■

REFERENCES

1. CDC HICPAC. Infection Control in Healthcare Personnel: Infrastructure and Routine Practices for Occupational Infection Prevention Services. Oct. 15, 2018. Available at: https://bit.ly/2JsbUPF.
2. CDC HICPAC. Guideline for infection control in health care personnel, 1998.

HOSPITAL INFECTION CONTROL & PREVENTION

CME/CE INSTRUCTIONS

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CME/CE QUESTIONS

1. **In post-market surveillance of duodenoscopes, the FDA reported a 5.4% contamination rate with:**
   a. *Acinetobacter baumannii*.
   b. low- to moderate-concern organisms.
   c. intrinsic pathogens from manufacturing plants.
   d. high-concern organisms.

2. **In general, the FDA said which of the following provides a higher margin of safety in reprocessing duodenoscopes?**
   a. Ethylene oxide sterilization
   b. High-level disinfection
   c. Liquid chemical sterilization
   d. Steam sterilization

3. **The Centers for Medicare & Medicaid Services memo mandating water management programs calls for control of:**
   a. *Legionella*.
   b. MRSA.
   c. other opportunistic pathogens in water.
   d. A and C

4. **Westyn Branch-Elliman, MD, MMSc, said continuation of antimicrobial prophylaxis after skin closure for cardiac implants has been linked to increased rates of:**
   a. heart failure.
   b. *C. difficile*.
   c. patient recovery.
   d. readmissions.

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.