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AHC Media

CDC calls on Congress to fund "protection" programs, save lives

CRE, C. difficile targeted in major project if funding approved
By Gary Evans, Senior Writer

Perhaps the tone was set in the early days of the Ebola outbreak; when projected death tolls and disastrous outcomes were linked to urgent requests for money and resources.

Nevertheless, it is a bit shocking to see the CDC — an agency that often plays a more patient political game of consensus-building — send the realpolitik equivalent of a ransom note to Congress: "Give us the money or people are going to get hurt."

Actually, an estimated 37,000 people are going to die in the next five years of antibiotic-resistant and *Clostridium difficile* infections unless Congress hands over \$264 million dollars to the suddenly unobtrusive CDC.

"If we just stay with business as usual,

there will be hundreds of thousands of infections and tens of thousands of deaths that could be prevented," Tom Frieden, MD, MPH, CDC director, said at a recent press conference. "We

know what needs to be done and it's up to Congress to [provide] the resources needed to protect Americans."

The CDC project appears important enough to warrant that level of funding, as the agency is focusing on two of the most dangerous pathogens currently causing HAIs: *C. difficile* and Carbapenem-resistant

Enterobacteriaceae

(CRE). *C. difficile* causes close to half a million infections annually, and has an estimated death toll of 15,000 patients. While this "deadly diarrhea," as the CDC calls it, is currently causing

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misery and death far and wide, CRE is just beginning to establish itself in the healthcare continuum. Extremely drug-resistant, if CRE gets established in the healthcare system we may start seeing infections that are difficult, if not impossible, to treat.

CRE is leading the vanguard of antibiotic-resistant bacteria, which have rendered useless whole shelves of the nation's formulary and cause more than 2 million infections and some 23,000 patient deaths annually. The CDC is clearly concerned that CRE is going to continue to increase, raising the specter of a practically pan-resistant pathogen moving across the healthcare continuum. The kicker — and perhaps the reason the CDC dubbed CRE the “nightmare” bacteria — is that CRE's drug resistance mechanisms can genetically transfer in nature via plasmids to other types of bacteria, creating the possibility of more and different bugs for which few treatment options are available.

Given the full picture of what the agency is up against, it's little wonder that the CDC raised the stakes by calling out Congress in public.

The agency is requesting the money to set up “protection programs” in all 50 states and ten large cities.¹ The idea is to link healthcare facilities — that see the same group of patients going in and out of their clinics, hospitals, long-term care — with health departments to share information on *C. difficile*, CRE and other problem pathogens.

“These funds will also make it possible to [detect] outbreaks sooner, improve laboratory testing, and track antibiotic resistance much better than we can today,” Frieden said at the Aug. 4 press conference. “We really hope that when all is said and done, we can get the resources we need to help protect Americans so that people aren't unnecessarily at risk of

getting serious and potentially fatal infections in healthcare facilities.”

Based on past experience with CRE and other pathogens, in the absence of such connections and communication the bug will move across the healthcare continuum undetected via transferring patients. As a result, a web of hospitals, clinics, long-term care, and nursing facilities that all treat the same patients at various stages may soon begin experiencing CRE outbreaks, which are difficult to contain because the pathogen is resistant to almost all available antibiotics. Thus, the CDC is proposing the establishment of formal state networks, with the state health department taking the lead and getting the various healthcare settings to communicate and coordinate patient transfers and visits to other settings for care.

“One of the things that facilities can do is to implement warning systems so that when they transfer a patient who's got *C. difficile* or a drug-resistant bacteria, the hospital or nursing home receiving that patient knows that in advance,” Frieden said. “That way, the facility can prepare to isolate the patient in advance before they can spread it to others.”

Specifically, CDC projects that — with full funding — the state protection programs could prevent 619,000 antibiotic-resistant infections and CDIs and the aforementioned 37,000 deaths over five years. The projections are based on an elaborate mathematical model that predicts the consequences of various levels of interventions — from staying at the status quo to establishing fully connected healthcare networks. (*See related story, p. 100.*)

No mathematical model is needed to demonstrate how patients spread infections across the network of healthcare facilities that deliver various aspects of their care. There are sufficient

real world examples. A textbook case of this phenomenon occurred across a spectrum of facilities treating a common group of patients in adjacent counties in Illinois and Indiana. A single strain of the pneumoniae carbapenemase (KPC) variety of CRE infected some 40 patients in an outbreak involving a staggering 36 healthcare facilities. “We observed extensive transfer of KPC-positive patients [throughout] the exposure network of 14 acute care hospitals, long-term acute care hospitals and 10 nursing homes,” the researchers reported.² Eleven of the patients (27.5%) died of the CRE infections, with the authors concluding by calling for the establishment of coordinated CRE networks overseen by public health departments — essentially the very plan CDC is now pitching to Congress for \$264 million. Indeed, the 2011 study was conducted by one of the CDC’s Epicenter Programs, clinical settings that collaborate with the CDC to conduct innovative infection control research.

“There are a number of regions that are making moves in this direction, including a coordinated approach in the state of Illinois,” said **John Jernigan**, MD, director of the CDC Office of HAI Prevention Research and Evaluation in the Division of Healthcare Quality Promotion. “They have a system in place in which they are made aware of every patient identified as being infected with CRE, and these data are placed in a central repository. Other facilities, when they are admitting patients, can query this database and find out if patients coming into their facilities are carriers of these types of germs and for whom they need additional infection control precautions.”

In some cases, additional or more sensitive testing may need to be done on asymptomatic patients suspected as carriers.

“What the coordinated approach allows us to do is to recognize the

emergence of a problem early, say in a single hospital in the region, and to alert the hospitals around them to take additional infection control precautions that they might not otherwise take,” Jernigan said. “[But] sometimes patients can be carriers of these organisms and no one knows because they don’t show up in the routine clinical test. One of the triggers that might be enacted [based on a predefined threshold] is to provide additional testing to patients to find out which patients are carriers and if that patient is moving from one facility to another.”

Still, it’s a fair question to ask why it has taken so long to move on this in other states, even voluntarily with current resources. It would certainly be to the healthcare facilities’ ultimate benefit to work together with their health departments and begin forming these networks in the absence of federal funding. One problem is that unless all facilities in a regional network buy-in and participate in a network, the collaboration is likely to fail, Frieden said.

“Even if an individual hospital makes significant improvements, it’s dependent on other hospitals in the area also making improvements,” he said. “So going it alone isn’t enough. In addition, although there have been some improvements, we know that the systems have to be in place. Just urging doctors to wash their hands or use antibiotics [judiciously] — without having a systematic approach across the hospital to track and ensure that’s happening — just doesn’t result in consistent, sustained improvements.”

The CDC funding would be used to hire health department staff and increase lab capacity so that CRE and *C. difficile* in one location can be identified quickly and the other facilities in the region alerted to the situation.

“To implement a coordinated approach, states need to be able to

identify — number one — all the healthcare facilities in their area and know how they’re connected with regards to how they share patients,” said Jernigan. “They need additional staff to improve these connections and to help the coordination that needs to happen between the healthcare facilities in their area. They need to develop a communication plan so that information can be smoothly and seamlessly shared. Very importantly, they need to work with CDC to use the data available to them for action to better prevent infections and improve antibiotic use for healthcare.”

The funds would also be used to bolster state labs so that pathogens and drug-resistant patterns can be rapidly identified and communicated to a wide variety of facilities, added **Michael Bell**, MD, deputy director of CDC’s Division of Healthcare Quality Promotion.

“There’s the need not only for staffers at health departments but also for building capacity in one form or another at the ever-growing array of healthcare facilities that we’re dealing with,” he said. “Healthcare continues to migrate away from acute care hospitals into ambulatory centers, nursing homes, and a wide range of places that increasingly need assistance to deal with the spread of infections.”

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New CDC efforts to detect and prevent CRE and *C. difficile*

The CDC plan to create state networks of public health and healthcare facilities to prevent Carbapenem-resistant Enterobacteriaceae (CRE) and *Clostridium difficile* infections includes the following key tenets:

Work together

- Infections and antibiotic use in one facility affect other facilities because of patient transfers.
- Public health leadership is critical so that facilities are alerted to data about resistant infections, *C. difficile*, or outbreaks in the area, and can target effective prevention strategies.
- When facilities are alerted to increased threat levels, they can improve antibiotic use and infection control actions so that patients are better protected.
- National efforts to prevent infections and improve antibiotic prescribing could prevent 619,000 antibiotic-resistant and *C. difficile* infections over 5 years.

State and local health departments

- Identify the healthcare facilities in

the area and how they are connected. Know their infection prevention and antibiotic stewardship activities.

- Dedicate staff to improve connections and coordination with healthcare facilities in the area.
- Work with CDC to use data for action to better prevent infections and improve antibiotic use in healthcare settings.
- Know the antibiotic resistance threats in the area and state.

Healthcare facility administrators

- Implement systems to alert receiving facilities when transferring patients who have drug-resistant germs.
- Review and perfect infection control actions within your facility.
- Get leadership commitment to start or join HAI/antibiotic resistance prevention activities in the area.
- Connect with the public health department to share data about antibiotic resistance and other HAIs.
- Make sure clinical staff have access to prompt and accurate laboratory testing for antibiotic-resistant germs.

Prescribers and healthcare staff

- Prescribe antibiotics correctly. Get cultures then start the right drug promptly at the right dose for the right duration. Know when to stop antibiotics.
- Be aware of antibiotic resistance patterns in your facility and area to protect your patients.
- Ask patients if they have recently received care in another facility.
- Follow hand hygiene and other infection control measures with every patient.

Patients and families

- Ask your healthcare provider what they and the facility will do to protect you and your family from an antibiotic-resistant or *C. difficile* infection.
- Tell your doctor if you have been hospitalized in another facility.
- Insist that everyone wash their hands before touching you, and wash your hands often.

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CDC bases infection projections on modeling

The good, the bad, and the ugly of healthcare networks

Computer modeling research shows that healthcare facilities and public health

departments can greatly increase patient safety by working together in coordinated networks and

sharing information about CRE patients, the CDC reports. Some of the case count

projections cited by CDC and others at the early stages of the Ebola outbreak turned out to be greatly overestimated, contributing to the perception by some that ratcheting up the fear level was designed to get the full support needed for the outbreak response. In this case, the CDC has collaborated with other researchers and used modeling methods already developed and time tested.

Two independently developed and complementary mathematical simulation models were used to measure the impact of a coordinated approach to prevent the spread of antibiotic-resistant organisms within a group of healthcare facilities interconnected through patient sharing (i.e., a network), using CRE as a test case.¹

“CDC analysis done in collaboration with the Johns Hopkins Bloomberg School of Public Health, the University of Utah and the University of California Irvine School of Medicine clearly shows that we could see many fewer antibiotic-resistant infections and much less *C. difficile* if healthcare facilities and health staff, public health professionals, work together as a team,” **Tom Frieden**, MD, director of the CDC said at an Aug. 4 press conference.

The models are computer simulations that represent hospitalized patients as “agents” and track their dynamic interactions with other patients and CRE status throughout the healthcare system.

The model first projects out five years after CRE enters an area where 10 facilities share patients with no network or interlinked communications. The approach, which is basically the status quo for most healthcare facilities today,

results in 2,000 patients getting CRE, impacting 12% of patients.

No hospital is an island

When a facility acts alone to enhance their infection control practices, the situation improves, but the lack of communication and networking with other facilities undermines the effort to some degree. The independent effort results in 1,500 patients getting CRE, impacting 8% of the total patients.

With a coordinated approach where facilities work together to prevent infections and notify each other of CRE issues before transferring patients, the modeling shows far fewer patients at risk. Four hundred patients are predicted to get CRE, impacting only 2% of the total patients.

The coordinated approach allowed for healthcare facilities to share CRE test results with a central public health authority, which used that information to strategically target prevention activity across multiple facilities. Notification of patient status as CRE-colonized or CRE-infected to facilities receiving a patient upon inter-facility transfer varied by model, and increased in frequency from independent efforts to coordinated approaches.

The models simulated the movement of patients within and between different healthcare facilities and transmission of CRE in a healthcare network based upon key parameter estimates that included inter-facility patient movement, the proportion of colonized patients recognized by routine clinical tests, and effectiveness of barrier precautions in preventing transmission. Further,

models representing both large and small networks of interconnected healthcare facilities illustrate that a coordinated approach to interrupting transmission is more effective than traditional approaches that have relied on individual hospital efforts to independently identify and implement interventions.

“Facilities which go it alone can’t effectively protect their own patients,” Frieden said. “Findings from [this report] offer specific actions to turn the antibiotic resistance epidemic around.”

Given the limited options to gather this kind of data, models are a useful tool to base projections on, said one of the principal investigators, **John Jernigan**, MD, director of the CDC office of HAI Prevention Research and Evaluation in the Division of Healthcare Quality Promotion.

“The use of modeling is an important tool. Sometimes we can’t get the answers we need through traditional epidemiologic study techniques,” he said. “To do so would be impossible or potentially not feasible. Even if we did attempt it, there are so many complexities and weaknesses that it might be hard to interpret those results. In those cases such as this, we have choices. We can take no action. We can take action based upon opinions or guesses or use modeling as a tool to provide additional information that we think is valuable in guiding our actions.”

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CMS calls for infection control improvements, antibiotic stewardship in nursing homes

Use risk assessment to determine hours assigned to IP

A proposed rule by the CMS calls for a sweeping upgrade of infection control in nursing homes, solidifying the role with a new title and making it a higher priority through annual risk assessments and much-needed antibiotic stewardship requirements.

Specifically, the draft CMS regulation would require long-term care settings to have an Infection Prevention and Control Program (IPCP) charged with “preventing, identifying, reporting, investigating, and controlling infections ... for all residents, staff, volunteers, visitors, and other individuals” based upon a facility and resident assessment that is reviewed and updated annually. To spearhead this effort, the nursing home would designate an Infection Prevention and Control Officer (IPCO) with specialized training to have the “major responsibility” for the program.

“It is a very substantial revision — a needed change because it really formalizes the infection control program,” says **Kirk Huslage**, RN, BSN, MSPH, CIC, vice chair of the public policy committee of APIC, and an IP with the North Carolina Statewide Program for Infection Control and Epidemiology, UNC School of Medicine, Chapel Hill. “I was surprised that they put in a requirement for an infection preventionist essentially — the infection control officers. That’s a great step forward and something that is needed.”

Regarding the job title, CMS has been asked by at least one commenter to officially change it to Infection Preventionist, bringing it in sync with the official designation now widely used by APIC and others in the field.

“Infection Preventionist is the

professional title for the expert who manages and coordinates the infection prevention and control program,” **Deb Burdsall**, MSN, RN-BC, CIC, of the University of Iowa College of Nursing, said in a submitted comment on the CMS proposed rule. “This title is frequently used in acute care [and is] recognized by professional infection prevention, control, and epidemiological societies. ... A consistent job title across the entire healthcare continuum will help highlight the expanding role [of the IP.]” (*Editor’s note: The comment period closes Sept. 14, 2015, at 11:59 PM ET. For more information or to post a comment go to <http://1.usa.gov/1hIe6Du>*)

Though this may seem like a minor detail, IPs have been trying to clarify their role in healthcare and raise the profile of their programs. They have largely succeeded in acute care, though APIC had to call a press conference during the Ebola outbreak to emphasize that their prime mission is to prevent HAIs, which strike some 720,000 patients annually and kill some 75,000. Essentially, they warned if IPs were going to have to train healthcare workers about Ebola 24/7, patients were going to start acquiring other infections. The IP role in long-term care has been much more nebulous, but the infection control challenges are formidable in these settings. The new CMS emphasis on antibiotic stewardship and HAIs comes as part of the agency’s first major rewrite of long-term care conditions of participation since 1991. Annually, HAIs in nursing homes cause an estimated 150,000 hospitalizations, 388,000 deaths, and between \$673 million and \$2 billion dollars in additional healthcare costs, CMS stated.

“Everyone agrees that infections are a significant problem in nursing homes, but that is not necessarily because nursing homes are intrinsically bad places to be,” said **Christopher Crnich**, MD, PhD, hospital epidemiologist at William S. Middleton VA Hospital in Madison, WI. “You’ve got a fairly frail and susceptible population, so it is important to focus on how we can prevent infections. To their credit, I think a lot of nursing homes have been doing a lot of these things [proposed by CMS].”

Another new aspect of the CMS proposed rule is that the IPCO would have professional training in infection prevention.

“While nurses and other healthcare professionals may be likely candidates for the IPCO role, many of these professionals may have only received training in basic infection control practices in their core professional preparation for licensure,” CMS states. “The responsibility and necessary knowledge for an IPCP likely goes well beyond basic infection control training. Therefore, we propose to require that the IPCO be a healthcare professional with specialized training in infection prevention and control beyond their initial professional degree. Considering the diverse nature of the resident population and of the healthcare delivery model, the qualifications, training, and time needed by an IPCO at each facility would vary widely, thus we are not at this time proposing more specific requirements.”

The traditional perception has been that infection control is a part-time task, possibly a shared duty between workers in long-term care.

“We hold a course for long-term care and infection prevention every year in North Carolina and repeatedly, when we ask about jobs at the facility, [class members] will raise their hand for two or three different jobs,” says Huslage. “That really dilutes their ability to do any kind of substantial infection control interventions or surveillance. Dedicating the role is great because it is really going to give a little more gravitas to infection prevention in that setting and allow a more systems approach to infection prevention instead of this kind of piecemeal thing that has been going on.”

On first read it appears CMS is proposing a much more substantial job definition that will be someone’s “major responsibility.”

“We understand that infection control is often assigned to a nurse who may have other administrative or patient care responsibilities,” CMS states in the proposed rule. “We want to allow sufficient flexibility for facilities . . . but also ensure that an IPCO has the time and resources necessary to properly develop, implement, monitor and maintain the IPCP for the facility. Thus, we require that the IPCP be a major responsibility for the individual assigned as the facility’s IPCO.”

That certainly sounds like a win for resident safety, but the CMS appears to leave a loophole when it addresses this requirement in the estimated costs of the regulation. The CMS estimated a \$284 million annual cost for enacting such infection provisions in long-term care settings nationally.

“The percentage of the RN FTE (full time equivalent position) that would be required at each facility will vary greatly,” CMS states. “We believe that each facility would have to determine the appropriate percentage based upon its facility assessment, especially its assessment of the acuity of its resident population. A facility with a generally healthy population of elderly individuals

would likely require many fewer hours than a facility with a large percentage of subacute residents or residents that are on ventilators. For the purposes of determining an estimate, we believe that the average facility would designate an RN to be the IPCO and that individual would need to commit about 15% percent of a FTE to his or her responsibilities under the IPCP”

That is essentially six hours a week, says Huslage, who was drafting APIC’s formal comments to CMS when he spoke to *Hospital Infection Control & Prevention*. “I would certainly hope that there would be more than that — something like a 25% to 50% effort,” he says. “But I think they are allowing for some flexibility because there are nursing homes that are primarily convalescent care. The infection control job requirements are not as demanding [with] relatively healthy residents.”

That means risk assessments of infection control at the facility and the acuity of residents must be used to determine an appropriate level of hours for the IPCO. Likewise, the decision to put a resident under isolation measures involves a kind of risk-benefit analysis. Social interaction is an important component of long-term care, but residents with multiple indwelling devices or UTIs caused by MRSA, for example, might be candidates for isolation.

“It is challenging because it is a home-like environment - you cannot treat somebody like you would in a hospital,” Huslage says. “With contact precautions it is a kind of risk-based assessment, where you are looking at the resident, the complexity of care, the presence of line devices and a lot of other things in making an assessment of the transmissibility of that patient. We can make that patient-centered choice about not only what does their case require, but what is their risk to

other people.”

The CMS proposed rule would require stewardship programs that include antibiotic-use protocols and a system for monitoring drug administration in long term care.

“Nursing homes are the next frontier where new antibiotic-resistant organisms may emerge and flourish,” the CMS stated. “Organisms such as *Clostridium difficile* and MRSA are known concerns. Nursing homes need to have the tools to participate in surveillance, learn and use infection control and containment practices, and adopt a proactive approach to preventing spread while being good stewards of antibiotics to preserve effectiveness of the agents we have today.”

There is compelling evidence now that antibiotic resistance is a problem that must be addressed across the healthcare continuum, says Crnich. Writing comments for the Society for Healthcare Epidemiology of America (SHEA), Crnich said the antibiotic stewardship requirements may take some out-of-the-box thinking for nursing homes, who typically don’t have an infectious disease physician or other antibiotic experts on staff.

“For example, making better decisions about when to take a urine culture,” Crnich says. “If the nursing home is doing a better job of testing people who have a high probability of infection and avoiding testing people with a low probability of having infections actually that can lead to a significant reduction in antibiotic use.”

In the absence of such stewardship strategies, some long-term care facilities are pouring on the antibiotics. “Some studies suggest that individuals who stay at a skilled nursing facility for six months have about a 60% to 75% chance of being exposed to at least one antibiotic,” he

says. “[There are reports of residents] having a dozen antibiotic courses in a single year, which is an extraordinary amount of antibiotic pressure.”

While adding to the general negative trends of selecting out resistant bugs and losing drug efficacy, unnecessary antibiotic use is bad medicine period. Antibiotic use is one

of the major causes of adverse drug events in residents, and can contribute to colonization with resistant bacteria that may eventually become a clinical infection. By wiping out commensal gut flora, a course of antibiotics can clear the way for *C. difficile* to set up in the patient’s gut.

“It’s not only a population health

issue, it’s an individual patient safety issue,” Crnich says.

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FDA concerned with alcohol exposures to pregnant, breast feeding healthcare workers

Asks manufacturers to update safety data

Alcohol-based hand hygiene rubs, ubiquitous in hospitals and widely praised for their efficacy and ease of use, may pose some level of risk to expectant mothers and their unborn babies, the FDA warns. As hand hygiene is performed constantly throughout a hospital workday a small level of alcohol may begin to accumulate and flow through the bloodstream. No problem for most workers, but what about those expecting?

“No known safe threshold exists for fetal alcohol exposure,” **Colleen Rogers**, PhD, lead microbiologist in the FDA’s Division of Nonprescription Drug Products (DNDP) said at a preliminary hearing on a recently proposed FDA rule.

The FDA is calling for a major review of the active ingredients in hospital antiseptics. As it currently stands, alcohol rubs and other healthcare antiseptics are being used in the absence of updated scientific data on the effects of prolonged exposure to healthcare workers, particularly those who are pregnant or breast-feeding. Infection preventionists have until Oct. 28, 2015 to submit comments on the controversial proposed rule by the FDA.¹

“Alcohol-based healthcare antiseptics are not only used frequently

in the healthcare setting, but they are also recommended for use by authoritative bodies such as the CDC,” Rodgers said. “There are no data on the effects of systemic alcohol exposure due to healthcare antiseptic use during pregnancy, but maternal alcohol ingestion is the leading known cause of developmental and cognitive disabilities in children and a preventable cause of birth defects. Based on alcohol exposure data from non-pregnant adults, ‘moderate’ hand rub use led to a maximum systemic exposure equivalent to approximately 10% of the alcohol in a glass of wine or a bottle of beer. The implications of even this low exposure are unclear.”

The FDA would have to find compelling evidence to limit the use of alcohol rubs in hospitals, as a former CDC outbreak investigator made it perfectly clear what was at stake.

“This would lead to increased healthcare-associated infection rates and take U.S. infection control backwards at least 15 to 20 years,” warned **William Jarvis**, MD, an independent infection control consultant who spoke on behalf of industry at the hearing.

Healthcare settings nationwide transitioned from soap and sinks to the alcohol hand rubs after the CDC recommended the move in

2002 guidelines that cited improved compliance by healthcare workers and high efficacy against nosocomial pathogens. The notable exception is *C. difficile*, a spore former that may require the use of soap and water. Citing the worst-case scenario, Jarvis said removing alcohol rubs and returning to the old soap and water approach would have a devastating effect on patient safety. It would require more healthcare worker time, likely undermining compliance and providing less killing power than alcohol even when workers do comply.

“[The] rest of the world has moved forward [with alcohol rubs],” he said, “The WHO has their worldwide Hand Hygiene Campaign. All of this would occur during a time when antibiotic-resistant pathogens are on the rise and infection prevention is needed more than ever. Given that hand hygiene is thought to be the most important method to decrease healthcare-associated infections, patient safety would be significantly adversely impacted.”

The FDA proposed rule requests additional scientific data to support the safety and effectiveness of certain active ingredients used in healthcare antiseptics marketed under the over-the-counter drug monograph.

“The FDA recommends that

healthcare personnel continue to use these products consistent with infection control guidelines while additional data are gathered,” the agency said in a statement. “Healthcare antiseptics are primarily used by healthcare professionals in hospitals, clinics, doctors’ offices, outpatient settings and nursing homes. They include hand washes and rubs, surgical hand scrubs and rubs (with or without water), and patient preoperative skin preparations, including pre-injection preparations. The most common active ingredients in healthcare antiseptics marketed under the over-the-counter drug monograph include alcohol and iodines. These products are different from consumer antiseptics, such as antibacterial soaps and hand sanitizer rubs, which are not part of this proposed rule.”

The FDA would require manufacturers who want to continue marketing healthcare antiseptic products to provide additional data on the active ingredients’ safety and effectiveness. This would include data to evaluate absorption, potential hormonal effects, and development of bacterial resistance. Once the proposed rule is finalized, ingredients for which adequate safety and effectiveness data have been provided would continue to be available, the FDA concluded in the proposed rule.

Given the unprecedented national emphasis the last few years on reducing HAIs and staving off a post-antibiotic era, members of the antiseptic industry have been understandably taken aback by the data demands.

“First, let’s remember we’re speaking about a healthcare setting where a significant number of infections do occur. The pathogens are becoming more and more virulent, and we have fewer effective therapies. So infection prevention is critical,” **Dave Mackay** of GOJO Industries

told the FDA. “These products have been used safely for many decades. They are the current standard of care. Despite the decades and frequency of use, there have been no identified chronic health related issues. Yet the benefit to the patient is undisputed.”

The nation’s two leading infection control healthcare epidemiology associations cautiously endorsed the FDA action while emphasizing that hand hygiene, surgical skin preps, and other antiseptics are essential to prevent HAIs, which cause 75,000 patient deaths annually. The statement by APIC and the Society for Healthcare Epidemiology of America (SHEA) reads in part:

“APIC and SHEA strongly agree with FDA’s advice that these products continue to be used consistent with infection control guidelines while additional data is being gathered. Healthcare antiseptics are an important component of infection control strategies in hospitals, clinics, and other healthcare settings, and remain a standard of care to prevent illness and spread of infection. . . . Since all infection prevention and control guidelines are evidence-based, it is important to stay up-to-date on safety and effectiveness data to protect healthcare personnel and their patients.”

The FDA cited new scientific information and concerns expressed by outside scientific and medical experts on FDA advisory committees. The work practices and science have changed since the FDA began reviewing healthcare antiseptics in the 1970s. Among the changes cited by the agency are its own safety standards, the frequency of use of some of the products, hospital infection control practices, new technology that can detect low levels of antiseptics in the body, and increased knowledge about the impact of widespread antiseptic use. The research paradigm is different as well, with the FDA looking for data on

the effects on healthcare workers — not the traditional focus on the safety and efficacy in patients.

“This seems obvious, but it’s an important point that is very pertinent to our discussion because it results in a different benefit/risk profile than we’re used to thinking about since the benefit of the drug occurs in a different person than the risk,” **Theresa Michele**, MD, director of the DNDP at the FDA, said at a Sept. 4, 2014 hearing on the proposed rule.

For example, new lines of research suggest that for at least some healthcare antiseptic active ingredients, systemic exposure (full body exposure as shown by detection of antiseptic ingredients in the blood or urine) is higher than previously thought, the FDA states. The agency is particularly concerned about the effects of repeated daily exposure to antiseptic active ingredients.

The frequency of dosing is a critical area of concern for the FDA.

“I mean, if you really think about it with the healthcare antiseptics, [healthcare workers are] probably the poster child for maximal use when it comes to frequency of dosing,” said **Dennis Bashaw**, PhD, director of the FDA’s office of clinical pharmacology. “You use it when you come in the room. You use it when you leave the room. You use it before you start a procedure. You do it over and over again. There’s no other topical dermatological that you’re going to use as many times per shift, per 8-hour, 10-hour, 12-hour period, as you’re going to use a topical healthcare antiseptic.”

The chemicals diffuse through the skin and accumulate as they are constantly replenished, an effect that may be compounded by healthcare workers who develop irritated and chapped or broken skin. While there is little data on the effects of alcohol on healthcare workers, there is even less on the other major antiseptic ingredient,

iodine.

“One small study showed an increase in urinary iodine concentration after a single day of surgical scrub use,” Bashaw said. “Although we don’t have a lot of information about absorption as a result of healthcare antiseptic use, data on

iodine absorption are available. Iodine is known to cross the placenta. It is also actively concentrated in the mammary gland and secreted in breast milk.”

REFERENCE

1. Food and Drug Administration. Safety

and Effectiveness of Health Care Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record. Fed Reg May 1, 2015: <http://1.usa.gov/1SDshKy>. ■

Consumer group: Why leave chlorhexidine out?

Skin prep being used more and more – but is it safe?

The FDA is being taken to task for a failure to include chlorhexidine in its recently announced plan to review the safety of active ingredients in antiseptics used in healthcare.

A group that includes Consumers Union, publishers of Consumer Reports, submitted a comment to the docket for the proposed rule, stating:

“We would like to strongly recommend the inclusion of chlorhexidine in this initiative. Chlorhexidine is undergoing a rapidly expanding role in the prevention of hospital acquired infections. Many researchers are advocating the use of chlorhexidine every day on every patient in the ICU. However, we feel both the safety and efficacy of chlorhexidine has not been substantiated. There are significant concerns regarding the developing of antibiotic resistance and the long term effects of expanded chlorhexidine usage on the patient’s and facility’s microbiome.”¹⁻³

The exclusion problem may have arisen because the FDA proposed rule is primarily focused on the effect of antiseptics on healthcare workers, while chlorhexidine is often used to

decolonize and eradicate the bacterial flora on patients’ skin. Such practices have been shown to reduce infections with methicillin-resistant *Staphylococcus aureus* (MRSA) and other pathogens.

However, the advocacy group warned that researchers have found evidence of bacteria developing resistance to chlorhexidine. They cited a study that found patients who were bathed daily with chlorhexidine were more likely to develop central-line bloodstream infections with reduced susceptibility to the skin prep solution.⁴

In addition, the group cited “significant concerns regarding industry influence and research integrity of chlorhexidine. There have been at least four articles which have compared chlorhexidine plus alcohol to another antiseptic but attributed the increase in efficacy to chlorhexidine alone.³ ... Therefore, we recommend that chlorhexidine be included in the FDA’s proposed regulation calling for more complete safety and effectiveness data on antiseptics.”

Among those signing off on the comment were Kevin T. Kavanagh, MD, MS, Health Watch USA,

Lexington, KY 40509; Lisa McGiffert, Consumers Union Safe Patient Project, Austin, TX; and Jean Rexford, Connecticut Center for Patient Safety, Fairfield, CT.

REFERENCES

1. Kavanagh KT, Saman DM, Yu Y. Reply to “Planned Analyses of the REDUCE MRSA Trial”. *Antimicrob Agents Chemother* 2014 Apr;58(4):2486-2487.
2. Kavanagh KT, Calderon LE, Saman DM. Viewpoint: A response to “Screening and isolation to control methicillin-resistant *Staphylococcus aureus*: sense, nonsense, and evidence.” *Antimicrob Res Infect Cont* 2015;4:4.
3. Maiwald M, Chan ES. Pitfalls in evidence assessment: the case of chlorhexidine and alcohol in skin antiseptics. *J Antimicrob Chemother* 2014;69(8):2017-2021.
4. Suwantarant N, Carroll KC, Tekle T, et al. High prevalence of reduced chlorhexidine susceptibility in organisms causing central line-associated bloodstream infections. *Infect Control Hosp Epidemiol* 2014;35(9):1183-1186. ■

Do you know proper PPE removal procedures?

PPE ‘doffing’ problems may be common for patient isolation

Fewer than one in six healthcare workers followed the correct

recommendations for removal of personal protective equipment (PPE)

after patient care, likely contaminating themselves and increasing the risk of

transmission to others, researchers report.¹

Observations of workers for the study took place October 13-31, 2014. With Ebola still very much in the news at that time, the findings are somewhat surprising, but likely would be similar at many other hospitals.

“Very few facilities report this kind of data, but I think it is highly likely that we are just one of many [hospitals],” says **Nasia Safdar**, MD, PhD, co-author of the paper and infectious disease epidemiologist at William S. Middleton Veterans Hospital in Madison, WI. “There’s no national benchmark for [PPE] compliance and there’s no requirement to routinely collect this sort of information. We assume that things were happening because there is a policy, but really people were not able to comply because they had competing priorities [or other reasons]. It just never reached anyone’s radar until Ebola happened. I think this is a good time if we want to change practice using Ebola and MERS as the reason. We tell them about MERS and Ebola, but also about *C. difficile* and MRSA and the things that we [frequently] see in this country. And who knows what could be coming tomorrow?”

What came yesterday was severe acute respiratory syndrome (SARS), which hit Toronto healthcare workers hard in 2003 with respiratory infections that were sometimes fatal. Donning and doffing of protective gear was an issue during the outbreak, which involved a coronavirus similar to today’s MERS.

Though Safdar’s was a relatively small study, involving 30 healthcare workers, the findings echo similar PPE issues in Ebola care and training. Of particular concern, Safdar and colleagues found that workers had a very difficult time following the correct doffing process when using contact

precautions that require much less PPE – and have no respiratory component – than pathogens like Ebola and MERS.

In the study by Safdar and colleagues at the University of Wisconsin, a trained observer watched healthcare workers entering and exiting rooms where patients were under designated isolation precautions on various units of the hospital. For removing PPE, the CDC recommends that gloves should be removed first, followed by the “gentle” removal of the gown from the back while still in the patient’s isolation room. Of the 30 workers observed removing the gear, 17 removed the gown out of order; 16 wore their PPE out into the hallway; and 15 removed their gown in a manner that was not gentle, which could cause pathogens from the gown to transfer to their clothes.

Overall, 43% of HCWs (13 of 30) removed their PPE in the correct order. However, only 17% removed their PPE in the correct order and properly disposed it in the patient room. Only 13% of the workers (4 of 30) removed their PPE in the correct order and did so gently as recommended. Twenty-three percent (7 of 30) failed to remove their gloves gently. Another 40% incorrectly removed their PPE in the hallway, outside of the designated isolation area in the patient room. Fifty-seven percent (17 of 30) incorrectly removed their gown before removing their gloves. Half (15 of 30) incorrectly removed their gown with a lot of movement, including wriggling their arms out and pulling the whole gown over their head with

or without untying it as instructed. On the positive side, 60% (18 of 30) of workers properly disposed of their PPE in the patient room. In the end, only four healthcare workers followed all CDC recommendations for the removal of PPE in the correct order and manner after patient care.

“We found that many HCWs did not tie the back of their gown, leading to the gown falling over the patient and increasing the risk of contamination,” the authors report. “Additionally, many HCWs removed their PPE – both gowns and gloves – by rolling the equipment against their previously uncontaminated work clothes or bare hands before disposal. These breaches of PPE removal protocol may be due to a lack of awareness of the proper protocol, time constraints, or lack of realization of the importance of proper PPE removal.”

The next step is feeding the results back to workers, which has been shown to be an effective way to improve compliance with the hand hygiene, Safdar says.

“We are now consistently over 95% [compliance] with hand hygiene,” she says. “I think that ought to be possible to do with PPE too, but we are just at the beginning with this,” she says. “We do frequent audits to see if any change is happening [and to assess] barrier compliance.”

REFERENCE

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COMING IN FUTURE MONTHS

- All together now: “Yes I Prevent Infections” (YIPI).
- A preview of the proposed CMS antibiotic stewardship regulation
- Prepare for The Joint Commission survey of inpatient dialysis
- OSHA stubbornly moves ahead on infectious disease rule



HOSPITAL INFECTION CONTROL & PREVENTION

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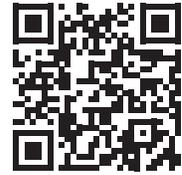
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CNE/CME INSTRUCTIONS

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CNE/CME QUESTIONS

- 1. An outbreak investigation of pneumoniae carbapenemase (KPC) found that how many different healthcare facilities were involved?**
 - A. 18
 - B. 28
 - C. 31
 - D. 36
- 2. Computer modeling research projected what percentage of CRE would be reached after 5 years in a group of facilities that share patients but have not established a network and began openly communicating?**
 - A. 12%
 - B. 16%
 - C. 18%
 - D. 22%
- 3. The FDA was criticized for leaving which of the following out of its review of hospital antiseptics?**
 - A. Iodine
 - B. Antibacterial soap
 - C. Chlorhexidine
 - D. None of the above
- 4. Researchers looking at health care workers removal of PPE observed them leaving which type of isolation room?**
 - A. Contact
 - B. Droplet
 - C. Airborne
 - D. All of the above

CNE/CME 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 health care 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.

Hospital Infection Control and Prevention

This confidential salary survey is being conducted to gather information for a special report. Watch in coming months for your issue detailing the results of this survey and the overall state of employment in your field.

Instructions: Select your answers by filling in the appropriate bubbles **completely**. Please answer each question as accurately as possible. If you are unsure of how to answer any question, use your best judgment. Your responses will be strictly confidential. Do not put your name or any other identifying information on this survey form.

1. What is your current title?

- A. infection control coordinator
- B. infection control director
- C. infection control manager
- D. infection control professional
- E. infection control/employee health
- F. other _____

2. What is your highest degree?

- A. LPN
- B. ADN (2-year)
- C. Diploma (3-year)
- D. BSN
- E. MSN
- F. MS
- G. master's other
- H. PhD
- I. MD
- J. other _____

3. What is your sex?

- A. male
- B. female

4. What is your age?

- A. 20-25
- B. 26-30
- C. 31-35
- D. 36-40
- E. 41-45
- F. 46-50
- G. 51-55
- H. 56-60
- I. 61-65
- J. 66+

5. What is your annual gross income from your primary healthcare position?

- A. Less than \$30,000
- B. \$30,000 to \$39,999
- C. \$40,000 to \$49,999
- D. \$50,000 to \$59,999
- E. \$60,000 to \$69,999
- F. \$70,000 to \$79,999
- G. \$80,000 to \$89,999
- H. \$90,000 to \$99,999
- I. \$100,000 to \$129,999
- J. \$130,000 or more

6. Where is your facility located?

- A. urban area
- B. suburban area
- C. medium-sized city
- D. rural area

7. In the last year, how has your salary changed?

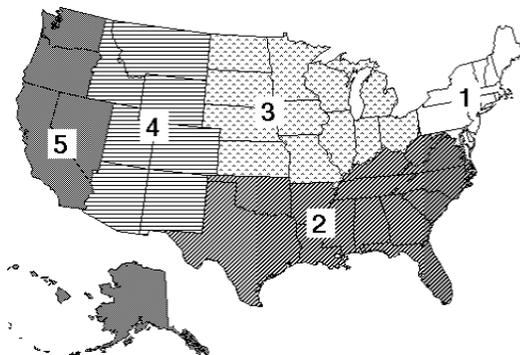
- A. salary decreased
- B. no change
- C. 1% to 3% increase
- D. 4% to 6% increase
- E. 7% to 10% increase
- F. 11% to 15% increase
- G. 16% to 20% increase
- H. 21% increase or more

8. What is the work environment of your employer?

- A. academic
- B. agency
- C. health department
- D. clinic
- E. college health service
- F. consulting
- G. hospital
- H. private practice

9. Please indicate where your employer is located.

- A. region 1
- B. region 2
- C. region 3
- D. region 4
- E. region 5
- F. Canada
- G. other



10. Which best describes the ownership or control of your employer?

- A. college or university
- B. federal government
- C. state, county, or city government
- D. nonprofit
- E. for profit

11. How long have you worked in infection control?

- A. less than 1 year
- B. 1-3 years
- C. 4-6 years
- D. 7-9 years
- E. 10-12 years
- F. 13-15 years
- G. 16-18 years
- H. 19-21 years
- I. 22-24 years
- J. 25+ years

13. Which certification best represents your position?

- A. RN
- B. CIC
- C. MT(ASCP)
- D. FAAN
- E. CPHQ
- F. other _____

12. How long have you worked in healthcare?

- A. less than 1 year
- B. 1-3 years
- C. 4-6 years
- D. 7-9 years
- E. 10-12 years
- F. 13-15 years
- G. 16-18 years
- H. 19-21 years
- I. 22-24 years
- J. 25+ years

14. How many hours a week do you work?

- A. less than 20
- B. 20-30
- C. 31-40
- D. 41-45
- E. 46-50
- F. 51-55
- G. 56-60
- H. 61-65
- I. 65+

15. If you work in a hospital, what is its size?

- A. <100 beds
- B. 100 to 200 beds
- C. 201 to 300 beds
- D. 301 to 400 beds
- E. 401 to 500 beds
- F. 501 to 600 beds
- G. 601 to 800 beds
- H. 801 to 1,000 beds
- I. >1,000 beds
- J. I don't work in a hospital

Deadline for Responses: Nov. 2, 2015

Thank you very much for your time. The results of the survey will be reported in an upcoming issue of the newsletter, along with an analysis of the economic state of your field. Please return this form in the enclosed, postage-paid envelope as soon as possible. If the envelope is not available, mail the form to: Salary Survey, AHC Media LLC, P.O. Box 550669, Atlanta, GA 30355.