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INSIDE

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Waning prophylactic drugs raise the stakes on infection prevention

Current trends could lead to more SSIs, patient deaths

By Gary Evans, Senior Staff Writer

The warning flag signaling a post-antibiotic era of untreatable infections has been hoisted time and again to add urgency and much needed action on drug stewardship. But in addition to becoming untreatable, infections are at risk of becoming unpreventable.

Antibiotics used routinely for surgical prophylaxis are losing efficacy against drug-resistant bacteria, which could result in more surgical site infections (SSIs) and thousands of additional patient deaths annually. This insidious nuance to the international problem of antibiotic resistant bacteria is raised in a new modeling study.[1] The research indicates the loss of prophylactic antibiotics routinely provided to surgical and immune-compromised patients to prevent infections could be as disastrous as losing drug efficacy for treatment. An epidemiologist with the Centers for Disease Control and Prevention (CDC), who was not involved in the study, says the findings are concerning.

> "We know that antibiotics are lifesaving when used appropriately for prophylaxis."

"We know that antibiotics are lifesaving when used appropriately for prophylaxis," says **Arjun Srinivasan**, MD, who is leading many of the CDC's antibiotic stewardship efforts to preserve drug efficacy. "The inability to prescribe them prophylactically is just as dangerous as the inability to prescribe antibiotics therapeutically. It is every bit as big of a problem."

The problem is not a theoretical future event. The researchers estimate that between 39-51% of pathogens

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currently causing SSIs are already resistant to standard prophylactic antibiotics. In addition, 27% of pathogens causing infections after chemotherapy are currently resistant to prophylactic drugs administered for those procedures.

"For surgical prophylaxis the beta lactam antibiotics are the workhorse agents, and a lot of resistance has developed to those," he says. "Certainly in the surgical area that is the big category that we are worried about."

If the efficacy of prophylactic antibiotics continues to wane, increasing infections and deaths may lead patients to forego needed procedures and accept their diminished quality of life.

"It's always devastating when an infection happens after surgery, but when you can treat it that's a different story," Srinivasan says. "The prospect of having surgical site infections that you can't treat definitely raises the stakes on infection prevention. Your best option is to prevent the infection from happening because you will be in a tough spot if infection develops."

In a "fairly realistic" scenario, a 30% loss of prophylactic drug effectiveness from current levels would translate to 120,000 additional infections and 6,000 more patient deaths annually, says study co-author **Ramanan Laxminarayan**, PhD, MPH, director of the Center for Disease Dynamics, Economics & Policy in Washington, D.C.

"That is quite a large number when you consider that these infections are a 'side effect' of undergoing surgery," he says. "But what is more subtle and difficult to quantify is the fact that the high risk of infection and mortality could influence decision making on the part of patients as to whether they want to go through with a hip or knee replacement. The real takeaway here is that modern medicine and a lot of surgery depends on effective antibiotics. If we [lose] antibiotics then we have to give up many of the gains of modern medicine."

It's not as if this problem is not already daunting, as SSIs are one of the leading healthcare-associated infections, with more than 150,000 occurring annually at a mortality rate of 3%, according to the CDC. In addition, 75% of patient deaths are directly attributable to the SSI, making prevention critical.

Modeling scenarios

Laxminarayan and colleagues searched the medical literature, identifying meta-analyses and reviews of randomized, controlled trials of antibiotic prophylaxis in preventing infections and deaths after surgical procedures and immunosuppressing cancer chemotherapy. They also investigated the potential consequences of increased antibiotic resistance for the 10 most common surgical procedures and immunosuppressing cancer chemotherapies that rely on drug prophylaxis. The study is thought to provide the first estimates of the potential effect of antibiotic resistance on the efficacy of drug prophylaxis for a range of surgeries and cancer treatments. The primary focus heretofore has been the inability to treat infections caused by agents impervious to the drug formulary.

"It's natural that one would focus on 'reactive' antibiotic use to treat infectious diseases," Laxminarayan says. "That is what clinicians most

frequently encounter as a problem of resistance -- they see a patient with a bacterial infection that does not respond to antibiotics. There hasn't been as much of a focus on prophylactic use and how that varies by physicians. It is hard to perform an experimental design and that is why we had to resort to modeling studies."

Researchers modeled different scenarios of reduction in the efficacy of antibiotic prophylaxis, estimating the additional number of infections and infection-related deaths per year in the United States for each level. For example, if bacterial resistance to prophylactic drugs increases 10%, they project 40,000 additional SSIs annually, a level that would skyrocket to 280,000 infections a year under the 70% scenario.

"The 10% and 30% scenarios are probably the most likely," Laxminarayan says. "It is not hard to imagine that decline in efficacy in the near future -- maybe the next five to 10 years. In fact, it is probably quite likely at the rate at which resistance is increasing."

Local data needed

Thus, antibiotic stewardship programs have been widely recommended and are expected to be the subject of federal regulation in the near future. The Centers for Medicare and Medicaid Services is expected to issue a proposed regulation requiring antibiotic stewardship programs in healthcare settings in 2017. A presidential advisory committee that called for regulation on the issue warned that in addition to treatment issues, "the safety of many modern medical procedures relies on effective antibiotics – cancer chemotherapy, complex surgery, dialysis for renal disease, and organ transplantation become significantly more dangerous as bacterial resistance rises."[2]

Although SSIs caused by bacteria resistant to recommended standard prophylactic agents have increased, insufficient data exist to support or discourage the use of broader spectrum regimens for surgical procedures or cancer chemotherapy, researchers note. However, they point to the potential of new targeted approaches to prophylaxis based on preoperative screening for colonization of resistant bacteria (e.g., rectal swab before prostate biopsy or screening of nasal methicillin-resistant *S. aureus* before pacemaker implantation).

"There will be a certain amount of antibiotic changes for prophylaxis in response to resistance. However, a major barrier is availability of localized susceptibility data, which could tell us whether those antibiotics are likely to work in that particular region or a particular hospital," Laxminarayan says. "For that, what we really need is better surveillance. Certainly, this goes across the board for all antibiotics. A lot could be done right away by picking the appropriate antibiotics based on very localized surveillance antibiograms."

Other countries have shown that national efforts to reduce antibiotic use have stalled the rise of resistant bacteria, which routinely emerge through selective pressure when drug-susceptible strains are killed off.

"There is the potential to reduce antibiotic resistance across the board through better infection control and better use of antibiotics," he says. "Many counties have shown that this is possible. The United Kingdom and France have shown remarkable declines in antibiotic resistance as a result of sustained programs. The United States has seen a bit of a downward trend, but certainly not as much as could have been obtained."

New antibiotics will be part of the long-term solution, but recent developments with other drugs and conditions underscore that new drugs can be expensive. That may be a literal "price we have to pay for inappropriate use of antibiotics in the past," he says.

A 'slow-motion catastrophe'

It has been generally estimated that antibiotics are used unnecessarily or incorrectly about half the time, though recent efforts may be shifting that ratio.

"We often see antibiotics given prophylactically when they are not needed, just like [physicians] prescribe antibiotics for treatment when they are not needed," Srinivasan says. "In some places there are resistance issues that might necessitate a change in the type of agent that is being used prophylactically. If you are going to prescribe an antibiotic prophylactically, you need to know that it is going to be effective against the organisms that most commonly cause the infections. The stewardship program can look at the antibiotic susceptibility data for the hospital, look at the different pathogens suspected, and then help chose the antibiotics that are likely to be most effective prophylactically."

An accompanying editorial by **Joshua Wolf**, MD, of St Jude Children's Research Hospital in Memphis, TN, describes antibiotic resistance aptly enough as a "slow-motion catastrophe."[3]

The "inescapable conclusion" is that the spread of antibiotic resistance will meaningfully increase the risk of infection in patients undergoing surgery and cancer chemotherapy, and that these infections will often be caused by bacteria that are difficult or impossible to treat, he notes.

"Once the reality of routine failure of prophylaxis hits, it will be too late," Wolf warns. "We need to address the problem of antibiotic resistance now. … [W]e already know what to do: develop new classes of antimicrobial drugs, reduce antibiotic exposure in animals and human beings, and prevent diseases through the use of vaccines and infection control. Despite this knowledge, most countries still have no coordinated strategy to reduce antimicrobial resistance, the new drug pipeline is drying up, and only a small amount of progress has been made to reduce the use of antibiotics in livestock."

Moreover, attempts to improve prescribing have been met with skepticism or "outright hostility," he notes in the editorial. Indeed, in one study researchers looking at antibiotic stewardship efforts in pediatrics were faced with as much resistance from humans as bacteria. "Respondents ignored reports or expressed distrust about them," researchers found.[4]

That does not bode well for the more subtle problem of controlling prophylactic antibiotics, particularly since post-discharge surveillance for SSIs has been an enduring challenge for infection control programs that may lack the resources to follow-up on all patients after surgery. ■

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Think global, act local

Antibiotic-resistant bugs respect no boundaries

Antibiotic resistance is an exploding global problem that individual nations must face to preserve the dwindling arsenal of infection-fighting drugs, according to a new report by the Center for Disease Dynamics, Economics & Policy in Washington, D.C.

Though antibiotic resistance is a global problem, the solutions lie at national and regional levels.

"Stopping the misuse and overuse of antibiotics, while maintaining access for those who truly need them, is of utmost importance," **Ramanan Laxminarayan**, PhD, MPH, center director, notes in a blog post.[1] "The root of the problem is often attributed to the 'empty pipeline' argument — that if we just had more new antibiotics, resistance wouldn't be a problem. But no matter how many new drugs come out, if we continue to misuse them, they might as well have never been discovered."

The report looks comprehensively at global antibiotic use and resistance in humans, livestock, and the environment, the global antibiotic supply, and actions that can be taken at national levels to minimize antibiotic resistance. The findings outlined in the report include:

• Antibiotic resistance affects many millions of people globally. In developing countries, the problem is compounded by a lack of basic healthcare and public health infrastructure; low rates of vaccination; inadequate access to clean water; a shortage of trained healthcare providers; indiscriminate access to over-the-counter antibiotics in pharmacies; sub-standard quality of available antibiotics; counterfeit and mislabeled antibiotics; and limited availability of drugs in certain cases (particularly of newer drugs, if a resistant infection is suspected).

• Antibiotic-resistant bacteria do not respect borders. Resistant strains that arise in one part of the world can – and do – spread rapidly to other parts of the world, due to increased international travel and globalized trade.

• The global use of antibiotics by humans increased more than 30% between 2000 and 2010 - from 50 billion to 70 billion standard units - and this trend is expected to continue.

• About 80% of antibiotic use takes place in the community, though hospitals contribute greatly to consumption because patients with

the most difficult-to-treat infections are admitted for care. Unchecked use in outpatient and non-prescription settings is a major issue.

• Non-therapeutic antibiotic use in animals - dosing chickens, pigs, or cows with antibiotics to promote growth and prevent infections rather than to cure illness - is growing worldwide. Global animal antibiotic consumption is projected to increase 67% by the year 2030 from a baseline of 2010.

• Strong antibiotic stewardship in its broadest sense is the key to conserving antibiotic effectiveness. ■

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CMS targets infection control in care transitions

A longstanding problem between nursing homes, hospitals

The Centers for Medicare and Medicaid Services (CMS) continues to expand its regulatory reach in infection control, recently announcing a pilot project to assess the infection risks during transitions of care between hospitals and nursing homes.

As infection preventionists are well aware, this is a longstanding problem that often involves communication breakdowns between transferring and receiving facilities regarding patient status or recent history of multidrug resistant bacteria.

The CMS sent out a Dec. 23, 2015, memorandum to its state survey agency directors announcing a three-year pilot project to assess the "continuum of infection prevention efforts between hospitals and nursing homes in order to prevent transmission of infections in both settings."

All surveys during the pilot program will be "educational" - no citations will be issued - and will be conducted by a national contractor. The surveys will focus on existing regulations as well as recommended practices, such as those for antibiotic stewardship and transitions of care, the CMS said.

Ten pilot surveys will be conducted in fiscal year 2016 in nursing homes, followed by surveys in both nursing homes and hospitals in FY 2017 and 2018. The project outcomes include "new surveyor infection control tools and survey processes that can be used to optimize assessment of new infection control regulations," the agency states.

The CMS finalized an infection control survey for hospitals in November 2014, essentially codifying a sweeping array of CDC infection prevention guidelines.[1] In addition, in July 2015, CMS issued a proposed rule that calls for a significant upgrade of infection control in nursing homes, solidifying the role with a new title (Infection Prevention and Control Officer) and making it a higher priority through annual risk assessments and antibiotic stewardship requirements.[2]

The latest pilot survey project "in collaboration with CDC, will better assess compliance with long-term care facility infection control requirements that CMS published in 2015 in a Notice of Proposed Rule-Making," the memo states. "To the extent that such requirements are published in final form, we believe that these educational surveys will help nursing homes become more prepared and help CMS and the CDC develop training materials for both nursing homes and surveyors. In FY 2017, we expect the educational surveys will be conducted in both hospitals and nursing homes."

In announcing this latest CMS program, the agency cited the national Ebola experience, saying it highlighted the critical importance of infection prevention programs in protecting both healthcare personnel and patients.

"Translating lessons learned from the Ebola outbreak, including the importance of core infection prevention practices, to every setting where individuals receive healthcare is a significant opportunity to increase the safety of U.S. healthcare facilities," the CMS notes.

The role of nursing homes in healthcare delivery has expanded significantly, with more than 3 million people now under long-term care. The CMS cites the following factors in targeting nursing homes for improved infection control:

• 1 to 3 million serious infections occur every year in these facilities;

• Common infections include urinary tract infections, diarrheal diseases, antibiotic-resistant staphylococcal infections, and other multi-drug resistant organisms;

• Infections are a major cause of hospitalization and death - as many as 380,000 people die from infections in nursing homes every year.

A clear need

"There is a clear need to assess the continuum of infection prevention efforts between hospitals and nursing homes to prevent transmission of infections in both settings," the CMS states. "Assessments in these educational, pilot surveys will allow for further review of infection prevention practices by the healthcare facilities, as well as examination of infection prevention during transitions of care."

While no citations will be issued, if an "immediate jeopardy" deficiency is noted inspectors are to call the CMS Regional Office for their area. In addition, where the risk of non-compliance is documented, technical expertise can be provided. Sustainable improvements can then be measured using the CDC National Healthcare Safety Network (NHSN) data, the CMS reports.

"Through this effort, issues related to the spread of HAIs between facilities in a local community will also be addressed," the CMS states. "After the survey findings are determined, a team of infection control professionals will use those survey findings to develop an action plan for improvement and to organize on-site technical assistance."

CMS staff will communicate details and updates regularly with regional offices and state survey agencies throughout the three-year pilot. The selection of the facilities to participate in this pilot will be communicated at a later time to the regional offices, the agency said. ■

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Ebola survivors suffer lingering symptoms

Aftershocks in U.S. healthcare workers

U.S. healthcare workers who survived Ebola after acquiring it from patients have suffered a wide variety of symptoms and maladies, with only one survivor considered symptom-free at five months after discharge, according to the Centers for Disease Control and Prevention (CDC).[1]

Though it is not completely clear in all cases if post-Ebola symptoms are the result of damage inflicted during infection or reflect some lingering presence of the virus, none of the healthcare workers are considered an infectious threat to patients or the public and most have returned to work or other activities.

However, Ebola clearly does not end at discharge, as survivors report a panoply of recurrent pains, aches, nerve tingling, hearing and vision problems, extreme fatigue, anxiety, and depression. For example, one of the U.S. nurses occupationally infected with Ebola described nightmares and fears about a future recurrence of the virus or some unintended consequences of novel treatment.[2]

"There are many unanswered questions about post-Ebola virus disease symptoms," says **Tim Uyeki**, MD, MPH, a CDC epidemiologist who has co-authored several papers on the Ebola response. "Prospective, longitudinal research studies of Ebola virus disease survivors — along with a comparison group of persons who did not have Ebola — are needed to better understand the frequency, severity, duration, and pathogenesis of the complications, sequelae, and symptoms experienced by Ebola survivors."

In one of the more shocking cases, a Scottish nurse who had been successfully treated for Ebola in January 2015 was readmitted last October for meningitis thought to be caused by surviving virus in her brain.[3] She recovered again, but joins the cases of Ebola viral persistence in the eyes, semen, and other so-called "immune privileged" body sites, which may have evolved to mitigate collateral damage during an inflammatory immune response.

In one of the U.S. cases included in the CDC report, a physician who had completed treatment and was discharged from Emory University Hospital in Atlanta later developed vision problems and almost went blind in his left eye. He eventually recovered, but not before the affected iris actually changed color from blue to green and the virus was recovered in mutated form from the infected eye.

When compared to the Ebola in the patient's blood during hospitalization, the virus sequenced from ocular fluid by researchers[4] "identified a single nonsynonymous

mutation, as well as two silent mutations and two mutations in noncoding regions. The significance of these mutations is unknown. However, these findings are in contrast to results that showed no changes in viral consensus sequences acquired over several days from a single patient.[5] All personal protective equipment and materials that were used during paracentesis and laboratory testing were sterilized by means of autoclaving before disposal."

Overall, 11 patients with Ebola were treated in U.S. hospitals and nine survived. The dead include Thomas Duncan, a Liberian man who developed symptoms after arriving in the United States from Africa. He died Oct. 8, 2014, in a Dallas hospital after infecting two nurses who survived. The other fatality was Martin Salia, MD, a surgeon who was a native of Sierra Leone and a U.S. citizen. He died Nov. 17, 2014, at the University of Nebraska biocontainment unit. The two deaths among the 11 U.S. cases translate to a 15% mortality rate, nearly four-fold less than the 58% rate in healthcare workers who acquired Ebola in West Africa and remained there for care. As of Nov. 1, 2015, the World Health Organization (WHO) reported that a total of 881 healthcare workers have been infected with Ebola during patient care and 513 of them have died. With a few threads of possible transmission still being followed, the WHO reports 28,598 Ebola cases with 11,299 deaths in the outbreak.

Eight survivors surveyed

In a breakdown of U.S. cases, two healthcare workers acquired Ebola in the United States; two — Duncan and a U.S. physician — became symptomatic after travel from West Africa; and the remainder were infected in Africa and became symptomatic before arriving in the United States for treatment.

The U.S. survivors are primarily healthcare workers, but also include a photojournalist and a missionary aid worker who helped disinfect personal protective equipment in West Africa.

"Among the eight U.S. survivors who we surveyed, most reported that their symptoms resolved or improved over time," says CDC lead author **Lauren Epstein**, MD, an officer in the Epidemic Intelligence Service. "However, only one survivor reported complete resolution of all symptoms at the time we conducted the survey in March 2015. We did not specifically assess whether survivors returned to medical work; however, 75% of the survivors returned to normal daily activities within eight weeks after discharge."

The CDC administered a questionnaire by telephone or in person to the U.S. survivors about symptoms, diagnostic testing, and treatment occurring any time during the recovery period. Medical records were not reviewed and the CDC determined that the survey did not meet the definition of human research that would require oversight by an institutional review board.

The median interval from hospital discharge and survey administration was five months. All survivors reported having had at least one symptom during the recovery period. These symptoms ranged from mild to more severe complications requiring rehospitalization or treatment. The most frequently reported symptoms were lethargy or fatigue, joint pain, and alopecia, an autoimmune disease that causes hair loss. Five patients reported eye problems, including pain, discomfort, or blurriness. Of these patients, four underwent ophthalmologic evaluation, and two were treated for unilateral uveitis, an inflammation of the iris or other parts of the eye that can cause blindness. They were diagnosed with uveitis from two weeks to eight weeks after hospital discharge for Ebola treatment.

Six patients (75%) reported experiencing psychological or cognitive symptoms, including short-term memory loss, insomnia, and depression or anxiety, the CDC reported. Three patients reported experiencing paresthesia or a tingling sensation in the peripheral nerves, and one received treatment for peripheral neuropathy nerve damage. Two patients were rehospitalized briefly for febrile illness that was not related to Ebola.

Survivors need specialty care

Given the findings, some Ebola survivors "may benefit from psychological and subspecialty assessment - rheumatologic, musculoskeletal, neurologic, and ophthalmologic — in addition to primary care," Epstein says.

Hospital Infection Control & Prevention asked Uyeki if there are any particular precautions or special measures that Ebola survivors who are healthcare workers need to take to return to patient care?

"Our survey did not address these issues," he says. "However, persons who have recovered from Ebola virus disease who are asymptomatic do not pose any risk of Ebola virus transmission to the general public or to close contacts."

In light of a study[6] finding that Ebola can persist in semen for at least

nine months, the CDC recommends male survivors abstain from unprotected sex until semen tests negative twice.

This next stage of control could be a formidable challenge, as there are tens of thousands of African men among the estimated 18,000 Ebola survivors. The WHO recently reported that a cluster of cases in Liberia were the "result of the re-emergence of Ebola virus that had persisted in a previously infected individual. Although the probability of such re-emergence events is low, the risk of further transmission following a re-emergence underscores the importance of implementing a comprehensive package of services for survivors that includes the testing of appropriate bodily fluids for the presence of Ebola virus RNA."[7]

The governments of Liberia and Sierra Leone, with support from partners including WHO and CDC, have implemented voluntary semen screening and counselling programs for male survivors in order to help affected individuals understand their risk and take necessary precautions to protect close contacts. In addition, the Ministry of Health of Liberia and the U.S. National Institute of Allergy and Infectious Diseases are conducting a five-year study of thousands of survivors in Liberia and their close contacts. The findings and other research might change the treatment and follow-up of healthcare workers or other Ebola survivors, possibly developing ways to stave off or mitigate the aftershocks through interventions earlier in the course of treatment. ■

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HCV infections in Utah hospitals linked to drug diverter

More than 7,000 patients advised to seek testing

Two Utah hospitals have notified thousands of patients that they may have been exposed to hepatitis C virus linked to an infected nurse with a history of drug diversion.

Health officials have urged some 7,200 patients at McKay-Dee Hospital in Ogden and Davis Hospital and Medical Center in Layton to get tested for HCV. The followup of former patients began after a patient and a former nurse tested positive for the same HCV strain.

The nurse lost her medical license in December 2014 after admitting to stealing medication from her employer, according to published reports. She was fired from McKay-Dee in 2014 after the hospital found evidence she had stolen morphine and dilaudid. Authorities expanded the investigation to include patients at Davis Hospital and Medical Center after they learned the nurse was caught diverting IV Benadryl while employed there in 2012 and 2013.

McKay-Dee recently sent letters to nearly 4,800 patients informing them that they may have been exposed to HCV between June 17, 2013 and Nov. 25, 2014. Davis Hospital and Medical Center sent letters to nearly 2,400 patients informing them that they may also have been exposed to HCV between June 17, 2011 and April 11, 2013.

There are reports of more HCV infections being identified beyond the nurse and the index case, but the state health department did not start updating the tally until the offer of free HCV testing to all contacted patients ended on Jan. 31.

There have been recurrent outbreaks of HCV traced back to addicted healthcare workers stealing opioids and other medications. They may contaminate solutions in doing so, sometimes trying to cover their tracks by replacing pain

medication with saline. As a result, cross transmission among patients may occur or the worker may be the HCV source, if infected. The latter appears to be the case at Utah hospitals, where the infected nurse worked in the emergency departments of both facilities.

The investigation began when a blood donor with no reported risk factors for HCV tested positive for the virus. Public health investigators found he had previously been a patient at McKay-Dee medical center and was treated by the nurse in question. ■

APIC: Proposed changes to human research rule could have unintended consequences

Exemptions should be granted for infection control research

The Association for Professionals in Infection Control and Epidemiology (APIC) warns that proposed revisions to the Federal Policy for the Protection of Human Subjects – the "Common Rule" – may have unintended consequences if infection prevention research is not excluded from approval by institutional review boards (IRBs).

Commenting on the recently issued notice of proposed rulemaking (NPRM),[1] APIC said infection control research conducted in quality improvement efforts should not require IRB approval.

"Our members have concerns related to activities that would meet the quality improvement (QI) exclusions," APIC states. "We believe that it is equally and in some cases more important to study the effectiveness (outcome measure) of a practice as it is to increase use of the practice (process measure). It is possible that increasing the use of a process may not provide benefit to a patient population or improve the outcome."

For example, as currently written, evaluation of staff training to improve the use of gloves to prevent transmission of microorganisms would be excluded from the IRB process, but "evaluating the impact of the use of gloves on decreasing transmission of microorganisms would require IRB approval - despite the fact that the use of gloves is a well-established best practice," APIC says in the letter. "In order for the intervention to be successful, investigators must know not only how to best educate providers on the process, but also be able to evaluate the outcome of the intervention, in this case the reduction in transmission."

Many infection preventionists participate in state or regional QI collaboratives that measure the outcome of individual or bundled interventions. These QI collaboratives often have a rapid start up and implementation phase, frequently with timelines mandated by the Centers for Medicare and Medicaid Services, APIC continued.

"Requiring such projects to be subject to IRB approval could act as a disincentive for participation in many organizations due to the added paperwork and burden," APIC warns. "To support the work we perform on a daily basis, our members recommend that both QI processes and outcomes are included in the Common Rule excluded activities."

In addition, APIC expressed concern about the unintended consequences when the regulations are put into place.

"The NPRM notes that public health activities that would not fall under the exemption act include exploratory studies to better understand risk factors," APIC says.

Hospitals and other health settings are required by regulation to report healthcare-associated infections and certain process measures, such as healthcare personnel influenza immunization, to the CDC. The data is examined in efforts to better stratify risks and identify opportunities for improving the health of the population in the future. Furthermore, with new and/or rapidly emerging infectious diseases, the risks may be unknown, APIC stated.

"To require IRB approval before the public health authority can collect data on risk factors will unnecessarily delay detection of those risks," APIC said in the comments. "Not exempting these activities could have a profound unintentional impact not only on public health's ability to perform its duties, but also its ability to halt ongoing transmission of an infectious agent. As pointed put in the NPRM, the line between public health surveillance and epidemiologic research is difficult to establish. We recommend further defining the difference between the two activities, specifically under what purpose or context the activities would be excluded from the Common Rule." ■

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IPs must be involved in construction at the onset

New construction and renovation in hospitals and other healthcare settings can pose an infectious threat to patients via dust and contaminated water, but infection preventionists may not be called into a project until its final stages.

"A lot of what we hear and see is that infection control only gets involved in the end, specifically to approve dust barriers," says **Richard A. Vogel**, MS, CIC, the author and editor of new APIC guidelines on the issue and an Infection Control Specialist at New York Presbyterian Hospital. "Actually, their input is needed right from [the beginning of] the design and throughout construction. That's where the shortcomings are – getting them involved early."

APIC created the Infection Prevention Manual for Construction & Renovation to help IPs protect patients during the seemingly endless process of renovation and new construction in healthcare settings.

"Hospitals are aging, there is new technology, there is the wish for a higher level of amenities for the patients, and required support services [for those amenities]," Vogel says. "It's a never-ending cycle of making things better, and there is a lot of competition, so people want the best and the newest."

The IP should be included in all phases of construction project planning to ensure that such items as sinks, soiled and clean utility rooms, and airborne isolation rooms are properly laid out to meet the needs of the space, the manual states. This should include meeting regularly with facility and project managers to discuss upcoming renovations.

"The IP should be involved in projects from the initial planning stages through completion," the APIC manual states. "A common challenge is lack of engagement from administration and getting support for infection control programs."

One way to get support is to demonstrate the need for an infection control during construction and the importance of input from IPs. Factors to highlight include the following:

- the need to comply with regulatory agencies, including state regulations, Facility Guidelines Institute, and Joint Commission requirements;
- the need to demonstrate to administration the value of the program;
- the need to demonstrate how input from IPs results in an enhanced outcome and/or where the lack of input resulted in an adverse outcome.

"The main risk from construction renovation is the dust that could contain aspergillus spores - and other fungal infections are also possible," Vogel says. "Water can be a problem also during construction because often the water flow to a certain area is shut down, which gives you a nice environment for Legionella to grow."

The manual provides policies and procedures, resources, models, examples, and educational material. This material can be used by new and experienced IPs and for facilities of different sizes and patient populations, both as examples of how other facilities have developed their infection control during construction programs, and as templates to adapt for their own facilities.

For example, the manual includes in-depth explanations about infection control risk assessment (ICRA) requirements, timing, and who should be included on the team. Based on the results of the ICRA, the design of the space should be accommodated to meet the requirements. These include issues such as patient placement and relocation, standards for barriers, phasing, protection from demolition, training, impact of utility outages, removal and movement of debris, and use of bathrooms and food areas for construction contractors.

A notification process should be implemented so that the project manager alerts the IP of upcoming projects. This will allow an ICRA to be completed before construction begins. If a training program is required for contractors, it is important to add that into the policy, the manual recommends. An example policy included in the manual outlines the following key points for the ICRA:

- An ICRA is developed for all projects that may affect the health of patients.
- The ICRA is multidisciplinary, documented assessment process intended to proactively identify and mitigate risks from infection that could occur during construction activities.
- The process must take into account the patient population at risk, the nature and scope of the project, and the functional program of the healthcare facility.
- The ICRA determines the potential risk of transmission of various air- and waterborne biological contaminants in the facility.
- The ICRA should be a part of integrated facility planning, design, construction, and commissioning activities. ■

Editor's note: More information on the APIC construction manual including details for purchase are available at: bit.ly/1K98Tfs.

Nursing leader: Nurse-to-nurse hostility may go back to ancient competition for men

'Women need to celebrate the accomplishments of other women'

In a gender-loaded assessment that might be labeled sexist if stated by a man, a female nursing leader says the field's "bullying" culture may have its roots in the ancient competition among women for male mates.

"Theories suggest that age-old female 'competition' has shifted from competing over a man to competing over status, respect, and position in the nursing environment," says **Renee Thompson**, DNP, RN, CMSRN. "The same behaviors once witnessed between two women fighting over a man are the ones witnessed today in the behavior of bullies."

After some 20 years in nursing, Thompson is a public speaker and nursing consultant as CEO and president of RTConnections, LLC. Her candid assessments of nursing culture were made in a recent blog post.[1]

In Thompson's view, the lack of gender diversity in the profession creates more conflict, as nurses commonly express they would rather work with men. Some 90% of the more than 3 million nurses in the U.S. are female.

"And let's face it ladies, we are not always that nice to each other," she notes. "Women can be catty and cruel, yet we allow this bad behavior to continue because, 'That's just the way women are.' Women need to celebrate the accomplishments of other women. Every day, find one reason to compliment a co-worker who is female. Be the role model for female-female admiration — not aggression."

Compared to physicians, nurses are a silent majority that suffers in silence, lacking the power to make change and becoming more likely to take their frustrations out on each other. "Becoming a bully helps certain nurses to gain some of the perceived power they are missing in their profession," she says. "Nurses need to learn how to articulate their value. This can be accomplished through advancing their degrees, obtaining certification, and inviting themselves to the decision-making table. Getting involved provides nurses the voice they need to overcome feelings of oppression and powerlessness."

The irony is that nurses are among the most empathetic, caring, and compassionate human beings in this world. The healthcare industry has become so accustomed to "nurses behaving badly" that scale of the problem has been somewhat lost, Thompson notes in citing these alarming statistics:

- Sixty percent of all new nurses quit their first job within the first six months due to the bad behavior of their co-workers.
- Forty-eight percent of new graduating nurses are afraid of becoming the target of workplace bullying.

"Every day of my life, a nurse reaches out to me asking for help," Thompson wrote. "We are hemorrhaging really good nurses because of workplace bullying."

REFERENCE

1. Thompson, R. Why is Bullying So Prevalent in the Nursing Profession? *The Sentinel Watch: Nursing,* Nov. 5, 2015. http://bit.ly/1mZOFzG. ■

COMING IN FUTURE MONTHS

- CRE: How big is the bottom of the iceberg?
- CDC wants to do more preventing, less reacting in outpatient outbreaks
- Avoiding CMS penalties for infections and other 'HACs'
- To prevent, remove the vent

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.

HOSPITAL INFECTION CONTROL & PREVENTION

CME/CE INSTRUCTIONS

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

1. Read and study the activity, using the provided references for further research.

2. Scan the QR code to the right or log on to AHCMedia.com then select "My Account" to take a post-test. *First-time users must register on the site.*

3. Pass the online tests with a score of 100%; you will be allowed to answer the questions as many times as needed to achieve a score of 100%.

4. After completing the test, a credit letter will be emailed to you instantly.

5. Twice yearly after the test, your browser will be directed to an activity evaluation form, which must be completed to receive your credit letter.

CME/CE QUESTIONS

1. In a modeling scenario a 30% loss of prophylactic drug effectiveness from current levels would translate to how many additional infections annually?

A. 80,000
B. 99,000
C. 6,000
D. 120,000

2. What key component was cited by an antibiotic prophylaxis researcher to fight increasing drug resistant pathogens?

A. immediate discontinuation of broad spectrum antibiotics for prophylaxis
B. localized antibiograms
C. using monoclonal antibodies to boost immunity in surgical patients
D. All of the above

3. Investigators are finding that Ebola virus can persist in the eyes, semen, and other body sites called:

A. immune privileged
B. host deficient
C. autoimmune targets
D. inflammatory pockets

4. According to a new APIC manual, an infection control risk assessment before renovation or construction should address such issues as:

A. patient placement and relocation
B. impact of utility outages
C. removal of debris
D. all of the above