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Study: Flu Shot Mandates Unsupported by Science

APIC does not back off mandate stance

By Gary Evans, Medical Writer

In a controversial finding that could bolster legal challenges to mandatory flu vaccination of healthcare workers, researchers report¹ that the four randomized controlled trials (RCTs)²⁻⁵ commonly cited to justify compulsory immunization lack scientific rigor and overstate the protective benefit to patients.

The four trials were conducted in long-term care facilities, but have generally been extrapolated to support flu immunization requirements in acute care and other settings. Among other benefits, the studies generally link reductions in resident mortality to higher staff

flu vaccination rates. With healthcare worker vaccination rates lagging in most hospitals, several facilities began mandating immunization several years ago in what has since become a national trend.

...SEVERAL FACILITIES BEGAN MANDATING IMMUNIZATION SEVERAL YEARS AGO IN WHAT HAS SINCE BECOME A NATIONAL TREND.

As the RCTs are often cited in support of such policies, this new Canadian study attacks a core rationale for making flu shots a condition of healthcare employment. After an elaborate deconstruction and analysis using the “dilution” principal of mathematics,

the authors of the study conclude that there is insufficient scientific evidence to mandate flu vaccine as a condition of healthcare employment. “It is unsupported by science —



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that is clearly the answer," says the lead author of the study, **Gaston De Serres, MD**, of the Institut national de santé publique du Québec in Quebec City, Canada. "When you are mandating a public health intervention, you better be sure that the burden of disease that you want to prevent is substantial. At this time, no one knows how many patients are infected annually in the United States by unvaccinated healthcare workers. Nobody knows."

De Serres emphasized that voluntary influenza vaccination should still be encouraged and the findings should not in any way be construed as supportive of the broader anti-vaccine movement.

"I personally receive the [flu] vaccine every year," he says. "I've published hundreds of papers on vaccines and I am a strong advocate of vaccines. But it's one thing to recommend to healthcare workers that the risk of you transmitting influenza to your patients may be very small but we recommend that you take the vaccine. That's one thing, but it is quite another to say if you don't get the vaccine, you're fired. It's completely different."

The findings are compelling enough that professional groups like the Society for Healthcare Epidemiology of America (SHEA) should rethink their endorsement of mandatory flu vaccination, says **Michael Edmond, MD**, clinical professor of internal medicine and infectious diseases at the University of Iowa in Iowa City. (See related story, in this issue.)

"I don't want this to be confused with any kind of anti-vaccine rhetoric, but to me it kind of plays into it," says Edmond, who was not involved in the study. "The anti-vaccine rhetoric focuses on

false claims of adverse effects of vaccines, and that is completely wrong. But on the other side of it, we have to acknowledge the shortcomings of vaccines in an honest way as well. I would argue that we have to look at the science on both sides of it and do what the science tells us to do."

With any intervention to improve quality or patient safety, the expectation for compliance should be directly related to the evidence, he says.

"In this case, we don't have a high level of evidence," he says. "Therefore, to mandate it — and in this case, to say if you are not in compliance you will be fired from your job — to me is just an unacceptable situation."

Dilution Explained

De Serres and colleagues explain the mathematical principle of dilution by giving a real-world example of buying chicken with a 60% off coupon. As additional items are added to the shopping cart, the chicken coupon provides a lower percentage reduction of the total bill. It saves money on the chicken, but the overall savings for the shopper are "diluted" by the inclusion of non-discount items. The same principle of dilution applies in attributing percentage reductions in non-specific outcomes to influenza vaccination like all-cause mortality and influenza-like illness (ILI) caused by other viruses, the authors note.

"We limited our analysis to three outcomes — ILI, laboratory-confirmed flu, and all-cause mortality," De Serres tells *Hospital Infection Control & Prevention*. "And using the principle of dilu-

tion, we looked at what could be reasonable or plausible results that could come from vaccination. We found that the four studies were reporting results for [reductions in] all-cause mortality that were not 50%, not even 100% greater. They were 10 to 12 times greater than could plausibly be achieved if the vaccine was 60% effective.”

Historically speaking, that is a spot-on efficacy estimate, as a comprehensive review of the literature estimated an overall flu shot efficacy of 59% in healthy adults ages 18 to 64 years. Evidence was inconsistent or lacking to determine vaccine efficacy in those ages 2-17 and those over 65.⁶ Of course, the vagaries of antigenic “drift” or more dramatic “shift” of circulating, mutable influenza viruses create an ongoing challenge to making an annual vaccine with a good match. For example, last year’s overall flu vaccine efficacy was only 41% against the predominant H1N1 influenza A strain and 55% against circulating B strains.⁷

“It is interesting that most of the organizations and associations that publish support for mandating immunization [in healthcare workers], use data underscoring that influenza is a terrible disease with tens of thousands of deaths annually and hundreds of thousands of hospitalizations,” De Serres says. “Well, that’s irrelevant and will not be affected by the immunization of healthcare workers. The relevant burden of disease [in making an argument for mandated immunization] are only the cases represented by unvaccinated healthcare workers.”

In contrast to the prevented-mortality estimates reported in the papers, De Serres and colleagues project that it actually may take

Researcher Defends Trial Supporting Flu Vaccinations

The author of one of the recently criticized randomized controlled trials on the protective effect of immunizing healthcare workers against influenza defends his research, but emphasizes it applies only to long-term care settings.

A study¹ by Canadian researchers found that the four randomized controlled trials (RCTs) commonly cited to justify compulsory immunization lack scientific rigor and overstate the protective benefit to patients.¹

In an article² published in the same journal, **Andrew C. Hayward**, MD, a member of the National Institute for Health and Clinical Excellence guideline development groups reviewing influenza vaccination in healthcare workers, defended his 2006 RCT.³

The study was designed to assess whether promoting influenza vaccination of staff would reduce influenza-related morbidity and mortality in elderly residents of long-term care facilities, he writes. “We hypothesized that the effect of the vaccine would be confined to periods when influenza was circulating and undertook the study over two years to minimize the risk of being unable to demonstrate an effect in a year with low levels of influenza circulation,” Hayward writes. “...During the period of more intense influenza circulation, we found highly statistically significant reductions in residents’ influenza-like illness (9 fewer reports per 100 residents in intervention vs. control homes).”

Although the findings were highly significant, the statistical confidence intervals were beset with some uncertainty about the full scope of the benefit gained through vaccination.

“We found no significant decreases in any of our outcomes during periods when influenza was not circulating in the community or in the second year when influenza rates were substantially lower than the first,” Hayward notes. “In our discussion, based on our own findings and those from other studies, we concluded that healthcare worker vaccination provides an important level of resident protection in long-term care facility settings. While we claimed that the findings may be generalizable to other settings, we did not intend to imply that the extent of the benefit would be similar in other settings. Indeed, we think the effect is likely to be substantially greater in long-term care facilities for frail elderly residents than in the acute care setting or in long-term care facilities catering for less frail patients.” ■

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from 6,000 to 32,000 healthcare worker immunizations to prevent one patient death from influenza.

“Influenza vaccine is only effective against influenza virus and provides no benefit against other causes of illness or death unrelated to influenza virus,” the authors report. “As more non-influenza causes contribute to the outcome considered, the lower must be the percentage reduction attributed to vaccine effects. Where that is not observed, there is a de facto error in claiming vaccine benefits.”

The paper has the devastating cumulative effect of a legal argument, and indeed concludes with a disclosure endnote that several of the authors have provided expert testimony during legal challenges to mandatory flu vaccination policies in Canada. In a recent case that surprised some, six healthcare workers fired for refusing mandatory flu shots for religious reasons recently won back pay and offers of reinstatement from Saint Vincent Hospital in Erie, PA, after their case was taken up by the U.S. Equal Employment Opportunity Commission. (*For more information, see the February 2017 issue of HIC*).

“Each of the four cluster RCTs used to champion compulsory HCW influenza vaccination policies reports benefits that are mathematically impossible under any reasonable hypothesis of indirect vaccine effect,” the Canadian authors conclude. “...Through this detailed critique and quantification of the evidence, we conclude that policies of enforced influenza vaccination of HCWs to reduce patient risk lack a sound empirical basis. In that context, an intuitive sense that there may be some evidence in support of some patient benefit is insufficient scientific ba-

sis to ethically override individual HCW rights. While HCWs have an ethical and professional duty not to place their patients at increased risk, so also have advocates for compulsory vaccination a duty to ensure that the evidence they cite is valid and reliable, particularly in the absence of good scientific

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estimates of patient impact.”

Though the study could spur legal challenges or raise questions for individual hospitals about their policies, in some sense the train has already left the station on the issue of mandated flu shots for healthcare workers. Mandatory vaccination policies are driving a trend that saw 91% of hospital workers immunized during the last flu season — a far cry from the lagging levels of the voluntary flu shot era. Still, vaccination rates for healthcare workers in long-term care settings fall well below hospitals, with 31% skipping the seasonal shots despite caring for frail and elderly people at risk of serious flu infections, the CDC reports.⁸

‘Do The Right Thing’

One of the groups support-

ing mandated flu shots for healthcare personnel is the Association for Professionals in Infection Control and Epidemiology (APIC). APIC president **Linda R. Greene**, RN, MPS, CIC, FAPIC, makes both ethical and epidemiological arguments in favor of mandatory flu shots.

“It is important in healthcare to take personal action for the public good,” says Greene, manager of infection prevention at UR Highland Hospital in Rochester, New York. “Those are things I don’t think we can dismiss. We need to do the right thing for our patients. APIC has a position paper on this, and certainly from our perspective this is not going to change that. We really feel that mandatory flu immunization should be considered a condition of employment. The data show us clearly that the highest vaccination rates are when there is a mandatory policy in place in an organization.”

This study raises questions, but Greene adds a compelling one of her own: Would you want the healthcare workers caring for your hospitalized family member to be vaccinated against influenza?

“The [researchers] just looked at the RCTs,” she says. “There are a number of other good studies that don’t meet the level of clinical trials, but there are some good case control studies that definitely talk about transmission of influenza from staff to patients. The other thing in the article they talked about is the dilution effect and ILI. However, flu sometimes happens without ILI. We know that many people — particularly the young and healthy — may actually have influenza without even exhibiting signs or symptoms. There are a lot of people

who are not tested, so there are a lot of other variables other than this dilution methodology."

Presenteeism

Although current data are inadequate to support enforced healthcare influenza vaccination, they do not refute voluntary vaccination or other more broadly protective practices such as staying home or masking when acutely ill, the study authors conclude.

"There is a real problem with the healthcare system and it is going to work when you are sick — not only for influenza, but the other respiratory viruses," De Serres says. "You don't want your professionals — your nurses caring for patients — to be at the bedside when they are sick. And that really is not often addressed. It appears to be a sort of magical solution to use the influenza vaccine and coerce vaccination to demonstrate that you really care for patients."

Presenteeism is a widely reported problem that challenges short-staffed facilities, in part fueled by the prevailing mentality that healthcare workers don't want to let their colleagues down by failing to report for duty.

"I found it interesting at the end of the discussion [the authors] say we ought to think about other things in addition to voluntary immunization, like staying home when sick or masking," says **William Schaffner**, MD, a professor of preventive medicine at Vanderbilt University in Nashville. "I find it stunning that they, in effect, recommend those interventions, over which the data are much less [established] than for influenza immunization."

Having long acknowledged the flu vaccine is imperfect and subject to seasonal fluctuations in efficacy, Schaffner nevertheless favors mandatory immunization of healthcare workers despite the Canadian study.

"If you take the RCTs all by themselves — off to the side — our Canadian colleagues have a point, but I don't believe their point carries the day," he says. "They only looked at the RCTs. These provide the most rigorous data, but we recognize that RCTs on this question are hugely difficult to do. If we are going to address the

"...THERE ARE ANY NUMBER OF OBSERVATIONAL STUDIES OF ONE KIND OR ANOTHER THAT COULD BE ADDED. ..."

entire question of the scientific, professional, and ethical basis of mandates, you ought to look at the entire body of evidence. There are any number of observational studies of one kind or another that could be added. Obviously they have profound scientific limitations also, but at least in my mind they add to the body of evidence that makes mandatory influenza immunization more than reasonable."

A past president of the Foundation for Infectious Diseases and a frequent host of its annual flu vaccine press conference, Schaffner has long advocated immunization for healthcare workers and others as recommended by the CDC. As mentioned, the Canadian study focused on the questionable pre-

vented-mortality estimates linked to vaccinating healthcare workers, but there are secondary benefits that should also be noted, he says.

"That is not the only issue to consider," Schaffner says. "We also don't want to make patients ill with influenza, and that issue is not addressed. They put much of their emphasis on the most severe endpoint. Similarly, they didn't look at any other potential benefits of immunization such as worker absenteeism during an influenza outbreak, or the extended [protective] benefit to the worker's family. These may not be the primary issues underlying a mandate, but they sure have come up in virtually every discussion of influenza vaccination mandates that I have read or written about."

Schaffner says the issue boils down to a central question: How much evidence is necessary in order to make a recommendation for a mandate?

"From my point of view, the accumulated evidence, including and beyond the RCTs, is sufficient on a scientific, professional, and ethical basis," he says. "There must be 20 professional societies now that have agreed with this [mandated] position." ■

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Will SHEA Drop Flu Shot Mandate of HCWs?

Author of guidelines defends policy in wake of critical paper

In a political climate where even widely accepted science may be challenged, the Society for Healthcare Epidemiology of America (SHEA) and other proponents of mandatory flu shots for healthcare workers should be wary of refuting a paper¹ that recently cited a lack of data to justify such policies.

“Given the assault on science that we are likely to see over the next four years in the U.S., SHEA must lead by ensuring that all of its recommendations are solidly based in evidence and that expectations for compliance with interventions correlate with the strength of the evidence,” notes **Michael Edmond**, MD, clinical professor of internal medicine and infectious diseases at the University of Iowa in Iowa City. “Just as we must defend vaccines from false claims of adverse effects, we must also truthfully acknowledge their limitations and shape our policy on science not opinion.”

Edmond wrote those comments in a blog post² challenging SHEA to drop its recommendation for mandatory flu vaccinations, and further elaborated his position in comments to *Hospital*

Infection Control & Prevention.

“We should reserve things like that for interventions that have the best evidence, the highest quality of evidence to support them,” he says. “Flu vaccination is a good idea. Unfortunately, the flu vaccine is not a good vaccine

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in terms of effectiveness. Right now that is what we have to work with, and I still feel that there is a benefit to healthcare workers, but we don’t have a high enough level of evidence to mandate it and threaten someone’s livelihood.”

As an alternative, flu vaccination should be voluntary, but highly encouraged to get as many healthcare workers immunized as possible.

“But to say that we are going to fire you?” he says. “Over the last 10 years or so there have been years where the vaccine is barely 20% effective — one year it was 10% effective. Are you are going to fire people because they didn’t get a vaccine that is 10% effective? And we can’t even prove if they got it, it would reduce influenza in patients. We would have to have a very tight set of data to take it to that level. I can’t think of another example that is taken to this extreme, without a very high level of evidence to support it.”

While clarifying that she spoke for herself and not for SHEA, one of the authors of the association’s flu vaccination position paper reminded *HIC* that the Canadian paper is a re-analysis of four randomized controlled trials (RCTs) evaluating the effect of staff vaccination on patient outcomes in long-term care settings.

“The Canadian paper does not present new data,” says **Hilary M. Babcock**, MD, MPH, medical di-

rector of the BJC Infection Prevention and Epidemiology Consortium at Barnes-Jewish and St. Louis Children's Hospitals. "Recommendations supporting mandatory influenza vaccination for healthcare workers are built on more than just those four supportive RCTs."

Influenza vaccination of staff is an important part of any facility's comprehensive influenza prevention and management plan, which should also include early identification and isolation of patients as well as comprehensive and common sense sick time policies that direct ill healthcare workers to stay home, she says.

"We all agree that a better influenza vaccine is sorely needed, one with more effective and more durable protection," Babcock says. "But while we are waiting for a better vaccine, we should use the one we have. Most people agree that high levels of staff influenza vaccination coverage are desirable. The literature clearly shows that a mandate is the most reliable and durable way to reach those levels."

Babcock also co-authored a blog post³ responding to Edmond, emphasizing key points summarized as follows in support of mandatory flu vaccinations:

- **Not all people with flu show classic influenza-like illness (ILI) symptoms.** This is often missed in criticisms of vaccine effectiveness. Studies that look just at vaccine effect on ILI will likely miss true influenza outcomes, while also capturing infections due to other viruses not covered by influenza vaccination.

"WE ALL AGREE THAT A BETTER INFLUENZA VACCINE IS SORELY NEEDED, ONE WITH MORE EFFECTIVE AND MORE DURABLE PROTECTION."

- **Since clinical testing is usually prompted by typical ILI symptoms, lab-confirmed influenza in missed cases may not be determined.**

- **Asymptomatic people with flu can still shed the virus.** The role of asymptomatic infection has been noted in numerous studies of households and experimental challenges.

- **Healthcare workers come to work sick.** Studies consistently note that some 75% of healthcare workers with febrile ILI admit to working while ill, a startling yet unsurprising fact that does not capture those with atypical, mild, or even asymptomatic infection. This is a major infection prevention issue.

- **Patients are at higher risk for complications from influenza than the general public.** Many patients won't be adequately protected by receiving the vaccine themselves. Most HCWs are healthy and therefore more likely to have a robust immune response to vaccine than already-ill patients, many of whom are elderly and/or immunosuppressed. ■

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Wanted: The Next Generation of Infection Preventionists

New APIC president sees shifting demographics

A national survey of 4,078 infection preventionists shows that the field is approaching a demographic cliff, as 41.6% of respondents were age 56 years or older.

Partial results¹ of the "Mega-Survey" by the Association for Professionals in Infection Control and Epidemiology (APIC) showed that 1,164 (28.7%) IPs were age 46-55; 1,541 (37.4%)

were aged 56-65; and 172 (4.2%) were age 66 or older.

"That tells us that we need to begin to engage younger people, as the IPs of today are retiring," says **Linda R. Greene**, RN, MPS,

CIC, FAPIC, president of APIC and manager of infection prevention at UR Highland Hospital in Rochester, New York. “We need to make sure we have a knowledgeable, competent work force.”

Though more details will be upcoming as additional analysis of the survey is completed, the partial results underscore that IPs are primarily concerned with staffing and resources.

“The issue of staffing levels for IPs is perhaps among the most urgent and common concerns expressed by IPs,” the APIC survey notes. “Thus staffing levels, organizational structure, and support of IP programs will be the subject of an upcoming analysis as more of the survey results are published”

A related factor may be that approximately one-third of IPs are working beyond hospital settings across the continuum in long-term care facilities, outpatient settings, and ambulatory care.

“In infection prevention that seems to be the most urgent issue — particularly when we think about when I first started infection prevention over 25 years ago, it was really confined to acute care,” says Greene. “But if we look at infection prevention across the continuum of care, there is a need for knowledgeable and competent IPs to facilitate all of the other settings like long-term care.”

The majority (82%) of respondents had a primary discipline of nursing. Among all participants, the mean salary was \$76,933 (median, \$75,000; range, \$25,000-\$225,000). Individuals with current CIC certification had higher base compensation than those without current CIC certification (\$85,911 vs \$68,817). The factors most frequently reported by partici-

pants as the criteria for compensation included experience (54.6%), performance measures (41.0%), highest degree earned (38.8%), and CIC certification (31.5%), APIC reports. Surveillance and investigation were reported as the most frequent activities by IPs, accounting for approximately 25.4% of infection prevention efforts.

Greene comes in as the 2017 APIC president as the field undergoes continuing transition. *Hospital Infection Control & Prevention* asked her to discuss a few goals or themes she will pursue.

Greene: This is a single year in the long history of an organiza-

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tion. So for me, and I think for most presidents, we want to build on what has happened before. If you go back to our mission [statement], it is ‘to create a safer world through infection prevention.’ Our ultimate vision is healthcare without infections. How do you get there is the question. I think from a patient safety perspective that we are continuing to move in that direction. From an organizational perspective, we are broadening our influence. For example, we want to make sure that APIC is at the table when we have discussions about infection prevention and the need for IPs. We were fortunate just last month to be invited to the president’s advisory council on combating antimicrobial resistance. They wanted to know what the workforce

looked like and what the educational needs are. So those are the types of things that we want to build on.

HIC: You state that another area of personal interest is promoting leadership. Can you elaborate on that concept?

Greene: By promoting leadership, I don’t mean that every IP is a manager — but they are a leader. Their job is to help bridge that gap between the evidence and the implementation — to bring that evidence to the bedside and help facilitate [safer care]. If you think of the typical surgeon, for example, trying to get them to engage in best [infection control] practices requires some unique leadership skills. There is the science and then there is that ability to really influence people and help them understand the downstream effect from a single patient.

HIC: The downstream effect of transmission to other patients?

Greene: When I was a staff nurse, when I took care of a patient I only thought about that patient’s good. But part of our job as IPs, and the larger job that we need to help healthcare providers understand, is that there is a downstream effect from a single patient’s infection. They may have drug-resistant organisms that can be spread and cause other infections. These are things that APIC has worked on, but I hope to again use some examples to really heighten that awareness so front-line care providers understand.

HIC: What are some of your other goals?

Greene: The other thing is to create those collaborative relationships — not only with care providers, but with organizations we are working really closely with like SHEA. We have complementary skills and putting them together

will ultimately help patients. That is something we have started over the last two years, but we continue to accelerate it. We hope to launch a leadership program this

year [aimed at] the IP and the epidemiologist. At the end of the day, I think all of these things will help fulfill the mission of a safer world of infection prevention. ■

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MRSA Screening Has Collateral Benefits

VA program credited with reducing infections by 80% since 2007

The Department of Veterans Affairs Veterans Health Administration's active screening campaign to reduce methicillin-resistant *Staphylococcus aureus* (MRSA) continues to make significant progress, with healthcare-associated infections dropping 87% in ICUs from October 2007 to September 2015, researchers report.¹

Lead author **Martin E. Evans**, MD, an infectious disease physician at the University of Kentucky in Lexington, reports that infection rates fell 80% percent in non-ICUs, and 81% percent in spinal cord injury units.

The VA implemented the MRSA Prevention Initiative nationwide in October 2007. It includes having a dedicated MRSA prevention coordinator at each hospital. Interventions include universal active surveillance on admission, which triggers contact isolation precautions for those colonized or infected with MRSA. The program also includes monthly updates on MRSA nares screening, clinical culture results, and data on patient movement. *Hospital Infection Control & Prevention* asked Evans to comment on some of the key aspects of the program.

HIC: This latest paper certainly documents continued success with your MRSA infection reductions. You also describe a “collateral effect” of this program in a

previous paper.² Can you explain what you mean by that term?

Evans: When we do MRSA swabs on admissions and find that patients are positive and put them in isolation, [we wanted to find out] how many times we accidentally get them in isolation for a gram-negative multidrug-resistant organism like an ESBL [extended spectrum beta-lactamase], CRE [carbapenem-resistant Enterobacteriaceae], multidrug-resistant *Pseudomonas*, or *Acinetobacter*. Those kinds of things.

So we went to our corporate data warehouse, which is the VA's big collection of data for all patients for many decades. We asked that question — how many people who turn out to be MRSA-positive on admission subsequently are found to have a multidrug-resistant gram-negative organism? And the answer was 44%. So that means that 44% of our patients who are swabbed [for MRSA] and put in isolation subsequently had a gram-negative [organism]. The odds of having a gram-negative culture were 2.5 times greater for those who screened [positive for MRSA]. So that, to us, was a benefit of doing MRSA swabbing. We really hadn't intended going after other organisms. But this was a clear situation. When patients were isolated for MRSA, they were also being isolated for other organisms that could be a problem

and which we weren't looking for.

That was followed up by [another study] that took a look at what was going on with gram-negative bacteremias in the VA systems before and after the implementation of the MRSA prevention initiative in 2007. So essentially what [the researchers] found is that the rates of gram-negative bacteremias were going up steadily over time until 2007 when the MRSA initiative was enacted, and since then they have steadily gone down. It could be we were isolating patients accidentally, and for that reason there was less transmission of gram-negatives going on within facilities.

HIC: As you are well aware, some hospitals have gone to a more horizontal approach, emphasizing standard precautions and use of such measures as chlorhexidine bathing and mupirocin. Despite your obvious success, is this alternative approach something you may consider for certain pathogens and medical situations?

Evans: I think if you look at the VA program, the MRSA bundle is a four-part thing. The first one is active surveillance, which you might interpret being silo-like and vertical because it only focuses on MRSA. The second component is contact precautions, and as we've already talked about with the collateral-benefit paper you are probably

putting a bunch of people into isolation who have gram negatives as well. You don't know that because you are not looking for them, but you are getting the benefit of doing that. So that is more of a horizontal thing, since it is not strictly MRSA and affects other organisms as well.

The third component of our MRSA program is hand hygiene, and you can't say that is not a horizontal approach. Then the fourth one is a culture transformation where infection control becomes everyone's business. I would also interpret that as being horizontal. It's kind of like throwing a stone in a pond — the ripples that we get just because of the MRSA program. We just have to be careful about thinking of the MRSA prevention initiative as being only silo and vertical, because it is anything but that.

HIC: What about the movement by some hospitals to drop contact precautions for MRSA?

Evans: Some [hospitals] have stopped contact precautions and tracked their hospital infections

over time and found no change [in infection rate]. So the conclusion is that you don't really need to do contact precautions for MRSA if you're doing really good hand hygiene and these other horizontal-type things.

I just want to throw out a word of caution. My concern is about these studies — the ones that look at what happens while the patient in the hospital. The patient is admitted, and theoretically they are not colonized with MRSA. So they do not go into contact precautions. Then if [the patient gets] colonized with the organism, it takes a little bit of time to develop a hospital-acquired infection. The length of stay for most patients is like 5 to 7 days.

There is the possibility that patients acquire the organism while in-house and they develop an infection, but it does not appear until after discharge. In our own data within the VA, we are finding that a portion of MRSA infections occur within 30, 60, or 90 days [post-discharge].

There is a large portion of those that occur in that time frame, and ostensibly they were from picking up the organism while in-house. In individuals who get colonized, their infections tend to appear after discharge. So when people study, write, and report that they stopped contact precautions and nothing happened, it well could be because their observation interval is too short. They don't pick up the infections that occur because they occur after discharge. ■

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Fatal Infection Resistant to All Antibiotics

New Delhi enzyme present in patient treated in India

Another warning sign of a looming post-antibiotic era comes in the form of a fatal infection resistant to all available antibiotics in the United States, the CDC reports.¹

The case occurred last August in a female patient in an acute care hospital in Reno, NV, who died of carbapenem-resistant Enterobacteriaceae (CRE) that was resistant to 26 antibiotics. The pathogen was *Klebsiella pneumoniae* that was isolated from a wound specimen.

Of note, the patient had recently been hospitalized in India, and the specific enzyme conferring pan resistance was first discovered in that country: New Delhi metallo-beta-lactamase (NDM).

The patient in her 70s was admitted to the unnamed hospital on Aug. 18, 2016, with systemic inflammatory response syndrome likely triggered by a hip infection.

“The patient developed septic shock and died in early September,” the CDC reported. “During

the two years preceding this U.S. hospitalization, the patient had multiple hospitalizations in India related to a right femur fracture and subsequent osteomyelitis of the right femur and hip. The most recent hospitalization in India had been in June 2016.”

What was remarkable about the infection was that it was resistant to whole classes of antibiotics and impervious to the last-line option colistin. The isolate appeared to have some susceptibility to fosfo-

mycin, which is not available as an IV drug in the United States.

“It’s not approved by the FDA,” says **Alex Kallen**, MD, one of the CDC investigators in the case. “It’s approved for oral use to treat urinary tract infections, so that wouldn’t be an appropriate antibiotic to use in this case.”

Though there are other mechanisms of resistance in gram negative bacteria, the CDC is still hoping to surround and contain NDM as cases are identified.

“As of Jan 6, 2017, there have been 175 [NDM] cases in U.S. so far,” Kallen says. “The place where we see it most commonly is in Illinois, and interestingly that is related to a duodenoscopy outbreak that they had a few years ago where there was transmission to some 30 patients. So, a big chunk of that comes from that outbreak.”

In terms of CRE overall, it is still very unusual to find isolates that are resistant to all antibiotics.

“We have a big surveillance system that looks for CRE around the country,” Kallen says. “We didn’t identify any pan-resistant isolates out of hundreds of isolates that we tested from that. We also do a lot of reference testing, particularly for gram negatives like *Pseudomonas* and *Acinetobacter*. You do see more resistance in those from time to time. If you look at all of those, we have seen less than 10 [that are pan-resistant].”

That said, it is almost certain that more are out there because the CDC surveillance system is passive and relies primarily on clinicians voluntarily reporting unusual isolates.

“There is no requirement for people to report to us,” he says. “They send them to us when they want specialized testing.”

One of the take-home messages of the Nevada case — as was found critical during the Ebola outbreak — is that the travel history of the patient may trigger isolation and containment measures before a culture is confirmed.

“That is a risk factor that is under-appreciated,” Kallen says. “I think, unfortunately, the history of exposures outside the United States is not [captured] as regularly as it should be. If you identified someone you could get them in appropriate precautions quicker, which decreases the risk of transmission. Time and again when we see these, it is usually the same story — a person who has had a hospitalization for a long period of time gets transferred, ends up in a U.S. hospital, and a week or so into their stay they end up with one of these

organisms. That results in us having to screen lots of contacts and things like that [that could be avoided] if we took the history up front.”

No secondary transmission was found, suggesting that spread may be less likely to occur in short-stay acute care hospitals as opposed to long-term acute care facilities that can be reservoirs for CRE. In the latter setting, there are more opportunities for contact for longer periods, and isolation measures are much more difficult to maintain.

“We are taking a kind of containment approach, so when we identify these novel organisms we screen contacts and try to find evidence of transmission,” Kallen says. “The good news is, we don’t find a lot of transmission, especially in short-stay acute care hospitals. But where we are finding problems with transmission are in longer-stay facilities like long-term acute care hospitals.” ■

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CME/CE QUESTIONS

1. In an analysis of randomized controlled trials claiming healthcare worker flu vaccinations, Canadian researchers looked at which outcome?

- a. Influenza-like illness
- b. Laboratory-confirmed influenza
- c. All-cause mortality
- d. All of the above

2. A comprehensive review of the literature estimated an overall flu shot efficacy of 59% in:

- a. Healthy adults age 18 to 64 years
- b. Those age 2-17 years
- c. Those over 65 years
- d. All the above

3. According to Andrew C. Hayward, MD, his 2006 randomized controlled trial on the protective effect of healthcare worker vaccinations in long-term care could be expected to yield the same results in acute care settings.

- a. True
- b. False

4. A national survey of 4,078 infection preventionists shows that the field is approaching a demographic cliff, as 41.6% of respondents were age:

- a. 40 years or older.
- b. 46 years or older.
- c. 56 years or older.
- d. 60 years or older.

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.