Hospital Infection Control & Prevention

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December 2012 Volume 39, No. 12 Pages 133-144

Volunteers for America: Tennessee cracks meningitis outbreak with existing network built on 'trust'

"By the time we learned this was a problem around the country, the information from Tennessee had already narrowed it down to what the problem was. [It was] a textbook case of how to do it right." **Paul Jarris**, *MD, executive director of the Association of State and Territorial Health Officials.*[1]

By **Gary Evans**, Executive Editor


Marion Kainer, MD

Recent U.S. Senate hearings on the national meningitis outbreak predictably found plenty of blame to go around, but also underscored the wisdom of investing in public health and clinical partnerships.

"These pre-existing relationships allowed us to respond quickly because we trusted each other," said **Marion Kainer**, MD, director of the Healthcare Associated Infections & Antimicrobial Resistance Program at the Tennessee Department of Health (TDH) in Nashville.

Kainer was recognized at a Nov 15, 2012 hearing of the U.S. Senate Health, Education, Labor and Pensions Committee for leading an epidemiological investigation that resulted in the nationwide recall of contaminated steroid products distributed by the New England Compounding Center (NECC) in Framingham, MA. The TDH had access to Centers for Disease Control and Prevention resources and expertise due to an existing partnership between the department and the agency. Moreover, Kainer had cultivated relationships with infection preventionists and key clinicians as part of the departments HAI prevention efforts.

Alerted by an astute clinician, Kainer rapidly assembled a team of IPs, epidemiologists and other clinical and public health contacts. They essentially solved the mysterious outbreak over 18

In This Issue

AHC Media

Financial Disclosure:
Executive Editor Gary Evans, Consulting Editor Patrick Joseph, MD, and Kay Ball, Nurse Planner, report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study.

long days in September and October, prompting a national recall of NECC products. *(See timeline, p. 136.)*

"Fungal meningitis is extremely rare. One of our great challenges was knowing just what we were dealing with as more and more patients fell ill," she said. "Even though we were looking for a fungus — because the initial patient reported to us had been diagnosed with a fungal meningitis — none of the diagnostic tests yielded confirmed results until October 3 — fifteen days after we initiated our investigation of the first case."

The NECC announced a voluntary recall of all its products on Oct 6, 2012, the same day the Food and Drug Administration issued a MedWatch Alert asking providers to stop using any NECC products. At that point, the outbreak numbered 29 cases that included three deaths. As of Nov. 19, 2012 there were 490 infections that included 34 deaths in 19 states. Cases have continued to occur due in part to the prolonged incubation period of the implicated fungal pathogens, but the actions of the Tennessee team clearly saved many lives.

"We did an analysis to assess the potential impact if there had been a delay in the recall from NECC by nine days," Kainer said. "In Tennessee alone, we estimate that by now we would have seen an additional 59 cases and at least five additional deaths."

Still, Kainer emphasized that compounding pharmacies play an important role in health care if the service can be provided with an assurance of sterility and patient safety. (*See related story, p. 138.*)

"Compounding of medications must be performed safely," Kainer emphasized. "Compounding pharmacies do provide a needed service. If compounded products are unavailable to meet the unique needs of some patients, providers may perform compounding or repackaging themselves at the bedside and may also put patients at risk."

The index case

The first case was detected by **April Pettit**, MD, an infectious diseases specialist at Vanderbilt University School of Medicine, who began looking for other risk factors after finding that a patient was not responding to empiric antibiotic treatment for meningitis. Lab tests and

Hospital Infection Control & Prevention®, including **Infection Control Consultant**™ and **Healthcare Infection Prevention**™ (ISSN 0098-180X), is published monthly by AHC Media, a division of Thompson Media Group LLC, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodicals Postage Paid at Atlanta, GA 30304 and at additional mailing offices. Web: www.ahcmedia.com

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This activity is effective for 36 months from the date of publication.

Target audience: Infection control practitioners and infectious disease physicians.

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Subscription rates: U.S.A., one year (12 issues), $499. Add $17.95 for shipping & handling. Outside U.S., add $30 per year, total prepaid in U.S. funds. Discounts are available for group subscriptions, multiple copies, site-licenses or electronic distribution. For pricing information, call Tria Kreutzer at 404-262-5482. Missing issues will be fulfilled by customer service free of charge when contacted within one month of the missing issue date. **Back issues**, when available, are $78 each. (GST registration number R128870672.)

word from family members that the patient had previously received a steroid shot for back pain at an outpatient clinic prompted Pettit to contact Kainer on Sept. 18, 2012. Though she ultimately lost the patient she was trying to save, Pettit's persistence was key to uncovering the outbreak.

The index case was a man in his 50s who presented four weeks after lumbar epidural injections with an eight-day history of headache and neck pain. Writing with some understatement in the *New England Journal of Medicine*, Pettit concluded, "If an atypical pathogen such as *A. fumigatus* is identified, a careful search for potential sources of exposure should be performed. In this case, the identification of potential exposure through epidural injection and the reporting of the case to the state health department led to an epidemiologic investigation that identified a multistate outbreak of fungal meningitis associated with epidural glucocorticoid injections."[2]

Pettit's public health contact was Kainer, who in turn called **Candace Smith**, RN, an infection preventionist at St Thomas Hospital, which is affiliated with the outpatient neurosurgical center where the index patient received the injection.

"To prevent healthcare associated infections, our team has built very close relationships with infection preventionists," Kainer told the Senate Committee. "These relationships are built on mutual trust and are invaluable in promoting open communication."

The CDC subsequently convened an expert fungal panel to develop diagnostic and management guidance that has been updated through the outbreak.

"This has been very helpful to clinicians, many of whom have never treated fungal meningitis before, and this guidance without a doubt saved a lot of lives," Kainer said. "Of the 33 Tennessee patients who sought medical care before October 3, nine (27.3%) died. Of the 48 patients who sought medical care on or after October 3 — when the first CDC treatment guidance was issued — four (8.3%) died."

Federal, state funds well spent

The department's HAI team includes CDC Epidemic Intelligence Service officers on site to assist in clinical data abstraction, she said. Six members of the team are funded through various federal grants tied to programs in public health epidemiology, laboratory capacity, and emerging infections. Again, the investment in public health infrastructure paid off in spades, as Tennessee was the one state poised to rapidly respond and deconstruct the outbreak.

"Our HAI team had the expertise to conduct on-site visits, to ask the right questions, create a data base, enter and analyze the data swiftly to determine the cause of the outbreak and those at highest risk of getting sick," Kainer testified. "Staff reviewed clinical information and helped track down more than 1,000 exposed patients. Contact by phone or in person was made by local public health staff funded by the state of Tennessee. Outreach included frequent telephone calls and knocking on doors."

Some exposed patients were living in or traveling in other states or were overseas when they developed symptoms, she noted. "Our nurses contacted one patient by contacting a tour operator in Yellowstone Park," Kainer said.

The focus on emergency preparedness and on reducing HAIs enabled rapid communication between public health departments and hospitals. However, some program challenges remain, especially with providers who do not work in hospitals (e.g., ambulatory surgery centers) and with medical specialists who are not traditional emergency response partners, she said.

Another encouraging finding was that the use of electronic health records allowed investigators to monitor the clinical progress of patients, resulting in a tremendous savings of time and resources, she added.

"This has been a devastating outbreak for patients, their families and friends, healthcare providers and clinics," Kainer said. "In Tennessee we still have many patients hospitalized and suffering from complications and others who are exposed and frightened that they may become infected. Sustained commitment to funding from CDC for emergency preparedness and reduction of health care associated infections has supported our productive relationships with partners and healthcare providers across the state."

REFERENCES

1. Wilemon, T. "Disease detectives curbed spread of meningitis" *Nashville Tennessean* Nov. 5, 2012: http://ow.ly/fpL9n
2. Pettit AC, Kropski JA, Castilho JL, et al. The index case for the fungal meningitis outbreak in the United States. *N Engl J Med* October 19, 2012 DOI: 10.1056/NEJMoa1212292 ■

Eighteen long days in the menigitis outbreak

*The following timeline of the response to a meningitis outbreak by the Tennessee Department of Health (DTH) is summarized from submitted written testimony by **Marion Kainer**, MD, director of the Healthcare Associated Infections & Antimicrobial Resistance Program at TDH in Nashville. Kainer testified at a Nov 15, 2012 hearing of the U.S. Senate Health, Education, Labor and Pensions Committee.*

Day 1 Sept 18: Kainer receives an email from **April Pettit**, MD, Infectious Diseases Physician at Vanderbilt University Medical Center (VUMC) about a patient with meningitis caused by *Aspergillus fumigatus*. The patient had a recent epidural injection at a pain clinic. After Kainer and Pettit discuss the case, Kainer speaks with **Candace Smith**, RN, an infection preventionist (IP) at St Thomas Hospital (STH), which is organizationally affiliated with the St Thomas Outpatient Neurosurgical Center (STONC) where the patient received the injection. Kainer requests details of the procedure and states that the infection is a sentinel event of concern, which deserves a careful investigation. She requests that Smith commence an inspection of the pain clinic (e.g. evidence of any construction, water damage) and inquire about any potential additional cases.

Day 3 Sept 20: Smith, the IP from STH, contacts Kainer and confirms that the index case had an epidural steroid injection (ESI) at STONC. She provides details of the procedure. Because the Facility Manager of STONC is on vacation, the IP at STH continues to help in the investigation. Kainer contacts **Joseph Perz**, PhD, an epidemiologist in the division of healthcare quality promotion at the Centers for Disease Control and Prevention. She asks Perz whether any cases of Aspergillus meningitis had been reported to CDC from any other ambulatory surgery centers or pain clinics. Fungal meningitis is rare, but is not required to be reported to the CDC. Even without any requirement, clinicians or states often contact CDC about unusual infections. However, no one had recently contacted the mycotics branch at the CDC to report any cases of Aspergillus meningitis. STH reports two additional patients with meningitis with high levels of white blood cells but no known cause. Both had undergone ESIs at STONC. Diagnoses were complicated because the patients appeared to be getting better and the cause of their meningitis was unknown. Kainer works with clinicians to request exhaustive diagnostic tests. The patients also had their ESI performed by the same anesthesiologist at STONC. The preservative-free methylprednisolone acetate used in their ESIs was obtained from New England Compounding Center (NECC). It is arranged for one of Kainer's staff to visit STONC the next morning, along with the IP the ID physician from STH. On this day, STONC closes voluntarily, sequesters supplies and orders new supplies from other distributors.

Day 4 Sept 21: Visit to STONC by TDH staff for a careful review of all procedures and the physical environment. They find no evidence of environmental conditions that would have led to fungal contamination of procedures. TDH contacts the CDC and describes findings of site visit. TDH asks the CDC to help with laboratory testing of patients with meningitis of unknown cause (because fungus is very hard to diagnose) and also for testing of environmental samples from the clinic, if needed. Another patient with meningitis and stroke with a history of ESI at STONC is identified. VUMC also reports yet another patient who had a stroke and had an epidural injection, but at the time it was not clear where the ESI was done (it was confirmed as STONC on Day 7). TDH sends out a Health Alert using its TN Health Alert Network (THAN), asking clinicians to look for and report any cases of meningitis following epidural injection to the TDH. At this time, the leading suspected causes of meningitis are the contrast media and methylprednisolone acetate (MPA) from NECC, as both were used in each patient and are commonly given together for an ESI. Other less likely possibilities include local anesthetic, local skin preparation and needles used for the injection.

Day 8 Sept 25: Two new cases of meningitis are reported to TDH. Both had ESI using MPA from NECC at STONC. However, one of the patients did not receive the suspected contrast,

and the procedure was done by a different anesthesiologist. A Conference call is held with TDH, CDC, NECC and the Massachusetts Department of Health and Board of Registration in Pharmacy (MABRP). NECC states no adverse events reported, no new suppliers of ingredients or changes in procedures. TDH describes severity of cases and that preservative free MPA was the leading hypothesis. TDH requests distribution list and verifies that voluntary recall procedures were in place. TDH staff begin collecting all the medical information needed to conduct their epidemiologic studies. STONC starts contacting potentially exposed patients. A new patient who had an ESI at STONC was admitted to STH with numbness and bowel/bladder control problems, but no headache or fever. Her spinal tap shows signs of meningitis of unknown cause, but with a much lower white blood cell count than the other cases of meningitis.

Day 9 Sept 26: NECC issues a voluntary recall for three lots of preservative-free MPA and provides distribution list of consignees to MABORP and FDA. TDH and CDC draft an Epi-X Alert (national emergency alert system for public health professionals) to report cases of meningitis related to epidural injections. TDH continues to follow up on patients who received ESI at STONC to look for any other unusual illnesses or complications. CDC helps TDH by making available a medical doctor with expertise in treating fungus to assist TN clinicians in caring for patients.

Day 10 Sept 27: TDH staff complete first round of epidemiologic studies. TDH asks STONC to contact all patients who had procedures since July 30. Analysis of the NECC distribution list shows two other clinics in TN received MPA. These clinics are contacted and all MPA is sequestered. Both clinics cease performing ESIs. The first clear evidence that the meningitis cause is not related to the STONC clinic comes from North Carolina (NC), where a patient with meningitis received MPA from NECC.

Day 11 Sept 28: It is still not absolutely clear that the MPA from NECC is the only possible source of contamination. The NC case patient had also received lidocaine and povidone iodine from the same manufacturers used by STONC. The lidocaine was the same lot number. CDC notifies all State Health Departments of situation and urges them to contact clinics who do ESIs and ask them to contact and check on the health of recipients of MPA. The departments use a script prepared by the CDC, which asks that this be done immediately without waiting until after the weekend. CDC issues another national Epi-X alert indicating that this now is a multi-state outbreak and requests reports of meningitis, other neurological infections, and stroke. TDH sends its own alert through THAN to clinicians and hospitals in TN to look for and report meningitis, stroke and focal infections in patients who have had epidural injections. Still, all diagnostic tests on these cases remain negative. The only patient with a confirmed diagnosis remains the first case patient reported. This highlights the difficulty of diagnosing a fungal infection, even when one is looking very hard to find it. TDH continues to work on epidemiologic studies to learn more about these patients, despite not yet having a confirmed diagnosis. TDH requests assistance from CDC to abstract clinical data from patient records (help arrives on Day 14).

Day 16 Oct 4: A final identification of the fungus-causing illness is still not made, but a specimen from another patient who died shows a fungus that is not Aspergillus. FDA announces that fungus was seen on microscopic examination of an unopened vial of MPA from Lot 08102012. This now is very strong evidence that MPA is the cause of the outbreak. TDH alerts TN healthcare facilities using THAN to cease use of all medications and products from NECC.

Day 17 Oct 5: TDH opens state health operations center to assist in case tracking, active surveillance, and reaching out to all patients who received MPA from NECC at any of the 3 Tennessee clinics - a total of 1009 people. Regional health operations centers are mobilized, using public health nurses to contact hard-to-reach patients and going door-to-door when necessary. Public health nurses maintained regular phone and in-person contact with affected patients for weeks, changing messaging as needed to adjust to the changes in the science and related patient needs. The CDC has another meeting of its expert fungal panel.

Day 18 Saturday Oct 6: The New England Compounding Center (NECC) announces a voluntary recall of all NECC products. The Food and Drug Administration issues MedWatch alert asking providers to stop using any NECC products. ■

Use ASHP tool to evaluate compounding pharmacies

Senate ponders new laws for 'gray area'


Kasey Thompson, PharmD

A compounding-pharmacy assessment tool developed by the American Society of Health-System Pharmacists (ASHP) can provide critical guidance for hospitals in the wake of the national meningitis outbreak.

"The patients who relied on these medications deserved much better," said **Kasey Thompson**, PharmD, ASHP vice president of policy, planning and communications. "We have developed an assessment tool based on our guidelines that helps pharmacists in hospitals and health systems comprehensively evaluate sterile compounding service providers and use comparative data for their vendor selection process. Our guidelines and assessment tool are available free as a public service to the health care community and others."

The online tool includes a number of key questions to help health care facilities evaluate a prospective compounding pharmacy with due diligence. (*See* http://ow.ly/fpNqq)

Thompson testified at a Nov 15, 2012 hearing of the U.S. Senate Health, Education, Labor and Pensions Committee. The panel is considering possible new regulations and other actions in the wake of a national meningitis outbreak linked to contaminated steroid products distributed by the New England Compounding Center (NECC) in Framingham, MA.

"Unfortunately, the NECC appeared to have been operating in a manner that falls far short of standards for compounding sterile preparations," Thompson told the committee. "Further, the scale and scope of NECC's operation more nearly resembles pharmaceutical manufacturing rather than pharmacy compounding."

In general, the majority of compounded medications hospitals use are prepared in-house by pharmacy departments, he explained.

"However, hospitals also enlist the help of qualified compounding pharmacies for some compounded preparations for several reasons," Thompson said. "For example, they may not have the necessary equipment or facilities to prepare some high-risk preparations, or they may face medication shortages for commercial products that can only be replicated by a compounding pharmacy."

ASHP tools and guidelines can help health care facilities make informed choices, but oversight of compound pharmacies is still critical, he noted.

"We cannot rely solely on the due diligence of purchasers to take the place of proper licensing, inspections and oversight of entities producing compounded medications, especially for those entities that are manufacturing in large quantities and shipping across the country," he said. "Pharmacists and other health care providers should not be expected to perform the jobs of regulators by visiting and inspecting pharmacies or manufacturers that they do business with."

The distinction between traditional pharmacy compounding and manufacturing appears to be "a regulatory gray area" between state boards of pharmacy and the Food and Drug Administration, he added.

"We recognize the regulatory challenges of defining the activities in this gray area, but we firmly believe that specific definitions are essential so that mass production of the scope and scale done by NECC falls within the regulatory jurisdiction of FDA, rather than state boards of pharmacy," Thompson testified.

Compounding pharmacies range from small pharmacy operations that compound medications for individual patients directly under their care to large-scale operations that prepare compounded medications in the volumes required to serve the needs of health systems and physician offices, he said.

"A number of variables make distinguishing between compounding and manufacturing difficult," Thompson said. "Therefore, both functions might be better viewed as a continuum of activities stratified by the potential for risk of patient harm — each requiring defined procedures, equipment, training, and quality controls."

Oversight of traditional compounding is clearly within the purview of states, while the FDA at the other end of the continuum oversees pharmaceutical manufacturing, he explained.

"As legislative proposals are considered, it will be important to reaffirm the role of state boards of pharmacy to license and regulate traditional compounding while recognizing that large-scale compounding of sterile products may require oversight

by the FDA in cooperation with state boards of pharmacy," Thompson said. There may be a need for a special category of FDS oversight that falls between compounding and manufacturing but does not require formal drug approval, he said.

"For example, if a compounding pharmacy sells to other organizations and not directly to patients, then they may need to be regulated by the FDA," he said. "[This] would allow hospitals, clinics, and physician offices to purchase sufficient quantities of compounded product as is necessary to meet patient needs, while doing so under the assurance that they are making those purchases from appropriately regulated sources."

Existing laws were not enforced

Testifying on the same panel at the hearing, **David Miller**, vice president and CEO of the International Academy of Compounding Pharmacists (IACP), argued that enforcing existing laws could have prevented the outbreak.


David Miller

"Not only does Massachusetts have state sterility requirements and United States Pharmacopeia Standard compliance requirements, but it retains the right to pull a pharmacy's license if [it] is practicing outside the scope of its licensing requirements," Miller testified. "By all current indications, the operations of NECC were clearly outside of the scope of the state's licensure requirements and their license should have been pulled long ago."

The state and the FDA should have worked together to force the pharmacy to register as a manufacturer and comply with Current Good Manufacturing Practice Guidelines, he told the committee.

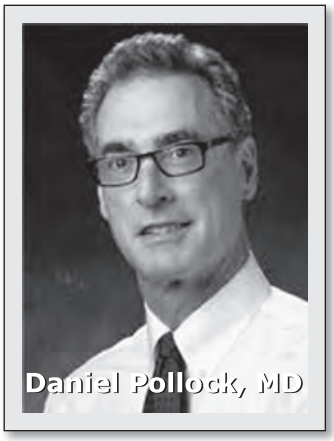
"Unfortunately, NECC showed a blatant disregard for existing rules and regulations," Miller said.

Millions of Americans have unique health needs that off-the-shelf prescription medicines cannot meet. For them, customized medicines — prescribed or ordered by licensed prescribers and mixed safely by trained, licensed compounding pharmacists — are the only way to better health, Miller emphasized.

"As a result, federal requirements designed for large-scale manufacture of uniformly dosed drugs do not apply to compounding pharmacies," he said. "Massachusetts's Board obviously failed to execute its responsibilities both to its citizens as well as patients in other states in which NECC was licensed by not conducting regular inspections." ■

NSHN: The gold standard for HAI surveillance

CDC expanding HAI tracking beyond hospital


Daniel Pollock, MD

The Centers for Disease Control and Prevention's rapidly expanding National Healthcare Safety Network (NHSN) has long been the gold standard surveillance system for health care associated infections (HAIs). From its relative humble origins with a few hundred hospitals in the National Nosocomial Infections Surveillance (NNIS) System, the NHSN continues a dramatic expansion driven in large part by the growing requirements for HAI reporting by state and federal agencies. We recently spoke with **Daniel Pollock**, MD, surveillance branch chief of the CDC's Division of Health Care Quality Promotion, about the expanding role of the NHSN.

Hospital Infection Control & Prevention: How many facilities are now reporting HAI data to the NSHN? Do you have sufficient capacity and budget to meet this demand?

Pollock: "Well, there are 10,000 facilities all together, half of which are hospitals. We are a federally funded program and receive funds through various mechanisms. We are part of the equation but there has to be an investment on the side of the reporting hospital as well. States have been investing — in that they need staff to participate. CMS Medicare has invested in that we are now sending data to Medicare and there is a processing and eventually a posting and use of the data on the CMS side. So it's an investment from many quarters. Clearly, the lion's share is here [at CDC]. We are supporting a large and complex system that requires considerable investment, develop-

ment and maintenance."

You said in a recent speech at a CDC meeting on the NHSN that "Our assumption is that the advent of public reporting and the adoption of data driven performance incentives are transforming the question of whether HAIs will be included in publically reported metrics and pay for performance to when and how." Can you expand on that?

"Right now we are engaged with the CMS value-based purchasing program around how the central-line associated bloodstream infection (CLABSI) data will be used as part of the program — which is also known as a pay for performance program. This could be described as a payment-driven incentivization to improve quality in response to a quality performance metric — namely a CLABSI metric. That is very much in play. It has begun. We have already delivered data to the [CMS] hospital value-based purchasing [system]. We will deliver more data, and right now those are data to establish a baseline. Data reported the next calendar year will be measured [against the baseline]."

You also mentioned in that talk that we are at something of a crossroads between using discharge data versus other measures that would be more valid for comparison and reporting. Is that going to be a critical part of this?

"The short answer is yes. Because the fork in the road has two different paths from it — one of them is to use coded claims or other administrative data that take the infection preventionists out of the supply chain. The hospital themselves or someone the hospital would hire could analysze the administrative data without an IP ever even looking at it. We know that there are fundamental shortcomings in the use of hospital discharge data alone to ascertain whether or not a case meets criteria for an HAI. There has been study after study that substantiates the concern that claims data alone should not be used as an outcome measure in the HAI domain. That is a road from the fork that we do not support. We do see value in the use of claims data as a tool, rather than as an outcome measure."

Just to clarify, the NHSN does not use claims data for surveillance?

"We do not. What we are saying is that it is fine for IPs to use the discharge data as a safeguard to see whether there may have been a surgical site infection that ultimately was picked up and that has a discharge code that suggests an infection. It should be corroborated with a review of that record. IPs can miss cases so the discharge data can serve potentially as a backstop under those circumstances. And we're fine with that, it's just when you use the discharge data alone as the outcome measure there are many, many cases that are missed."

Is part of the challenge to convince hospitals that it's worth the bang for the buck to invest in collecting good HAI surveillance data?

"Yes, part of the challenge is communicating that to do the type of active surveillance that is necessary for HAI prevention there is an investment. It is the price of doing business in a way that preventing those infections is a top priority. No question, that is part of our communications. We want this to be seen as a standard business practice across the industry. And to that end we work very closely with the American Hospital Association and some of the other national associations on NHSN matters. We communicate with them regularly, we have a monthly call and we communicate between calls. We keep them posted as to what changes are on the horizon for NHSN, what the potential impact is for their member hospitals, and we work with them to educate them to respond to issues that arise. I would say the hospital industry on the national level has an understanding of the level of commitment that is needed. That doesn't necessarily translate down to each and every hospital, but I think we are making good progress."

The old CDC NSIS system began to draw criticism for establishing a kind of benchmark range for hosptials rather than encouraging an aggressive pursuit of HAI eradication. There has been a dramatic culture change on that issue with the idea of pushing HAIs to zero.

"We're strong proponents of wanting to get to zero with HAIs. It's a good thing to be making progress. It's a good thing to have a summary metric that compares favorably to the national aggregate, but the best thing of course is to drive to zero across the board for all of these infections. I think increasingly that is seen as an achievable objective for some infections — not necessarily all. But it is a mindset and it does require a commitment that translates to resources. We see a continuing problem with *C. diff* and one that seems to be becoming more difficult. We have made significant progress certainly with CLABSIs in intensive care units."

Isn't the NHSN system ultimately limited to the data you receive? There are anecdotal reports of in-house debates on whether an infection should be a reportable HAI.

"We are dependent on hospitals that are reporting to have staff that have committed themselves to understanding the protocols and to engaging in active surveillance and to abiding by our structures for reporting. In some cases, that doesn't happen. We are working closely with states and with CMS on strategies for validation. Validation is tied closely to training, because some of what we learn in the process of validating data is a reflection of a lack of understanding and not so much an intentional omission. That may be something we can address better in training."

But do you think you are seeing the real picture — actual decreases in clinical events?

"I think we are seeing measureable decreases and also persistence of some problems. So yes, we use the data and recognize that there are shortcoming and we want to address those, but even still the data can be very important as an indicator of the direction we are headed across the various infection types.

The NHSN system is expanding into long-term care, health care worker vaccination data and dialysis settings. Does this reflect the necessary move of HAI surveillance beyond the hospital?

"That is what we are after. We recognize that more and more health care is delivered outside the hospital walls and we want to make sure that some of the tried and true methods for detecting and responding to infections can be applied regardless of where care is being rendered, including extending our capacity for surveillance to ambulatory surgery centers, dialysis facilities and long-term care."

What about antibiotic stewardship measures and antimicrobial resistance?

"We are introducing that. Antimicrobial use and resistance reporting is a part of the NHSN that we are developing right now. It will be possible for hospitals to report this data electronically. One of the reasons that it has been so difficult in the past to capture antimicrobial use and resistance data across the board has been the labor intensiveness of manual methods of entering those data. We are moving to a fully electronic means of reporting both antimicrobial use and resistance data so that hospitals will have antibiogram information that is reported electronically from microbiology results and pharmacy [data]."

Yes, infection preventionists have been clearly concerned about the burdens of data collection and the impact it will have on their programs.

"Absolutely. The whole process can be burdensome and labor intensive, particularly if we are dependent on manual [methods] rather than electronic. What we have been talking about these last few minutes is the tail end of the supply chain of actually delivering [the data] to us. But what we also need to work on and focus on are the earlier steps in the supply chain. [Things that] would enable infections to be detected electronically from data entered into electronic health records systems [in order to] enable the denominator data — such as central line days, catheter days, ventilator days — to be ascertained electronically. So we want to move up the supply chain as well in those steps that remain labor intensive for the IPs." ■

Hospital flu shot rates entering the public realm

CMS reporting in 2013, public access in 2014

Your influenza vaccination campaign is coming into the public spotlight, and that means more pressure than ever on the logistics of administering and tracking those vaccinations.

Think of this first season of reporting as a test. The Center for Medicare & Medicaid Services (CMS) will not publicly report the health care worker flu vaccination rates until 2014.

But as of January 1, CMS is requiring hospitals to report the vaccination rates of employees, licensed independent practitioners (non-employee physicians, advance practice nurses and physician assistants) and adult students, trainees and volunteers who are at least 18 years old. (The Joint Commission recommends tracking vaccinations among all contracted workers, but that is not being reported by CMS.)

For many hospitals, calculating the numerator is the easy part. You must count and report the number of individuals who received the vaccine, said they received it elsewhere, declined the vaccine, or who have a medical contraindication of either a severe egg allergy or a history of Guillain-Barre Syndrome within six weeks of a previous influenza vaccination. There is also a category for "unknown." *(See frequently asked questions, p.142)*

However, the denominator is causing some headaches. CMS asks you to include all individuals (employees, licensed independent practitioners, etc.) who were in your hospital for at least 30 days between October 1 and March 31. The measure counts a "day" as any part of a day in your facil-

FAQs on tracking flu vaccination rate

The Centers for Disease Control and Prevention answers to common questions on reporting health care worker influenza vaccination rates include the following:

The HCP Influenza Vaccination Summary Form in NHSN defines the influenza season as July 1 to June 30. Does this mean that my facility is required to report on twelve months of data when we do not vaccinate for all twelve months?

No. Although influenza may occur any time of the year, you should report data for the period specified in the NHSN protocol, which is from October 1 to March 31 for the denominator, including all vaccinations given during the influenza season in the numerator. The July 1 to June 30 time period is used by NHSN to clearly define the end of one influenza season and the beginning of the next influenza season. For the 2012-2013 influenza season, NHSN is allowing facilities to report data for only half of the influenza season to align with the CMS rule that requires acute care hospitals to report data beginning on January 1, 2013. For subsequent influenza seasons, data for the entire reporting period (October 1 to March 31) are required to be reported as specified in the NHSN protocol.

What types of nurses are counted as licensed independent practitioners?

All advanced practice nurses should be included in the licensed independent practitioner category. Advanced practice nurses include nurse practitioners, nurse midwives, clinical nurse specialists, and nurse anesthetists.

Would you count health care personnel (HCP) who are not working with patients for 30 days or more, but because of staff meetings, etc. are physically in the facility for 30 days or more?

Yes. Individuals who perform any work duty in the facility for 30 days or more from October 1 to March 31, are included in the count, regardless of clinical responsibility or patient contact.

My acute care hospital owns several outpatient provider practices that are physically separate from the main hospital campus. Employees of these clinics are on the hospital's payroll, so should we include them in our HCP influenza vaccination reporting?

No. These employees should not be counted in the vaccination reports since they do not physically work in the acute care hospital.

Many of our HCP also work at another facility in town. Must they be reported by every facility at which they work?

Yes. These reports describe vaccination rates among HCP working at a specific facility, so all eligible HCP must be counted by each facility where they work.

My hospital is part of a multi-hospital system that has one corporate payroll. Each hospital has its own NHSN number, so how should each hospital report its total number of HCP?

Each facility should report the total number of HCP who physically work in that facility. If a healthcare worker (HCW) physically works in multiple facilities in the hospital system for 30 days or more from October 1 to March 31, this individual should be counted in the total number of HCP for each facility where he/she works.

Should I count an employee who starts at my facility after October 1, or leaves their position after October 1?

Yes. All employees, non-employee licensed independent practitioners, and non-employee students and volunteers aged 18 and older who physically work at the facility for 30 days or more from October 1 through March 31, regardless of exact stop and start dates, should be counted.

Should HCP who are employees of the healthcare system (e.g., university), but who are not hospital employees, be included?

Non-hospital employees should only be included if they are physically in the facility for 30 days or more from October 1 to March 31 and meet the criteria for either the licensed independent practitioner category or the adult students/trainees and volunteers category. They would not be in the employee category if they are not on the hospital's payroll.

Are other licensed contract workers/non-employees such as nurses, technicians, therapists, etc. reported?

Non-employee licensed or credentialed providers other than physicians, advanced practice nurses, and physician assistants are not required to be reported. ■

ity. (You cannot use data on fulltime equivalent employees.)

Some hospitals plan to count their non-employees in the most liberal way.

"Most places cannot determine how many days their non-employed physicians and other licensed independent providers actually spend in the facility," says **Melanie Swift**, MD, FACOEM, director of the Vanderbilt Occupational Health Clinic in Nashville. "The safest course of action is probably to assume everyone with access and credentials to be in the facility are spending 30 or more days there."

How to count on NHSN

Although for this first year the reporting begins on January 1, you can begin counting from October. The reporting occurs through the National Healthcare Safety Network (NHSN), a surveillance system maintained by the Centers for Disease Control and Prevention.

You can report monthly cumulative totals through NHSN, but CMS will receive the data only once — on May 13, 2013.

Some hospitals are struggling with the logistics of tracking non-employees. Harbor-UCLA Medical Center in Los Angeles can expect to report a high vaccination rate, no matter how it is counted. With a policy that requires those not receiving the flu vaccine to wear a mask during the flu season, Harbor-UCLA vaccinated 89% of employees last year and expects to reach 90% or above this year.

But gathering the data for the denominator will be a challenge, says **Erika Sweet**, RN, MSN, NP, with Harbor-UCLA Employee Health Services.

"Medical students may come in for two weeks rotation, they're off for two weeks, then they come back for another two weeks. We have residents that do the same," she says. They also have students cycling into the hospital from nursing schools and other programs. "The non-employee category is very difficult because nobody except their instructor knows exactly what time period they're going to be here during any specific rotation."

Some employee health professionals plan to count employees and non-employees who have spent even a day in the hospital, despite the 30-day instruction. **Bruce Cunha**, RN, MS, COHN-S, manager of employee health and safety at the Marshfield (WI) Clinic, notes that hospitals have various types of providers who rotate through or who work in temporary positions. "The best they're going to get out of this is some kind of general ball-park figure," he says.

And some employee health professionals wonder why they shouldn't count people who worked fewer than 30 days during the flu season. "Should it matter how many days they're in your hospital if they're not vaccinated? Aren't they just as much of a risk on any one day they're there?" says Cunha.

Measure may be tweaked

Comments from employee health professionals actually might prompt some minor changes in the measure for future reporting.

"We realize that facilities may have feedback on some issues and difficulties they encounter in meeting the reporting guidelines during this first year of reporting," says **Megan Lindley**, MPH, epidemiologist with the CDC's National Center for Immunization & Respiratory Diseases in an email to HEH. "We will take all of the input that is offered and will reevaluate the specifics of the protocol and measure after this first reporting period to see if there are changes we can make in order to improve the reporting experience for users and the accuracy and reliability of the data."

Some concessions have already been made to make it easier for facilities to comply. For example, employees and non-employees can report in writing (online or on paper) that they have received the flu vaccine outside the facility. They are not required to produce documentation.

Swift called that "the saving grace of the CMS measure ... so an electronic survey sent to all licensed independent practitioners is a viable way to ascertain their vaccination status."

[*Editor's note: More information about the influenza immunization reporting criteria is available at* http://ow.ly/felo9 ■

CNE/CME 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. Log on to www.cmecity.com to take a post-test; tests can be taken after each issue or collectively at the end of the semester. First-time users will have to register on the site using the 8-digit subscriber number printed on their mailing label, invoice or renewal notice.
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 successfully completing the last test of the semester, your browser will be automatically directed to the activity evaluation form, which you will submit online.
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COMING IN FUTURE MONTHS

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CNE/CME Objectives

Upon completion of this educational activity, participants should be able to:

- Identify the clinical, legal, or educational issues encountered by infection preventionists and epidemiologists;
- Describe the effect of infection control and prevention issues on nurses, hospitals, or the health care industry in general;
- 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. ■

CNE/CME Questions

1. Marion Kainer, MD, did an analysis to assess the potential impact if there had been a nine-day delay in the recall of contaminated products causing the meningitis outbreak. How many more patients did she estimate would have died in Tennessee alone?
   A. at least five
   B. there would have been 59 more infections, but no deaths
   C. less than three
   D. none of the above

2. Given the continuing oubreaks, Kainer strongly recommended closing compounding centers and letting experienced clinicians assemble medications at the bedside.
   A. True
   B. False

3 . David Miller, vice president and CEO of the International Academy of Compounding Pharmacists, cited which of the following in arguing that enforcing existing laws could have prevented the meningitis outbreak.
   A. Massachusetts has state sterility requirements and the right to pull a pharmacy's license
   B. U.S. Pharmacopeia Standards could have been enforced
   C. Massachusetts and the FDA could have worked together to force the pharmacy to register as a manufacturer and comply with current practice standards
   D. All of the above

4. Which of the following has been a primary driver of the rapid expansion of the CDC National Healthcare Safety Network?
   A. The addition of international infectious disease data
   B. The inclusion of patient falls and other adverse non-infectious events
   C. State and federal mandates to report infections
   D. All of the above

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