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IN THIS ISSUE

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Quest for excellence hits ethical impasse; landmark prevention program shut down

'Lives will undoubtedly be endangered'

A recent controversial move by a federal health agency to shut down a highly successful infection prevention program because it appeared to be involved in human research rather than quality improvement has ominous implications for traditional infection control activities, a leading epidemiologist tells *Hospital Infection Control*.

"This is an example of the road to 'you know where' is paved with good intentions," says **William Schaffner**, MD, chairman of the department of preventive medicine at Vanderbilt University Medical Center in Nashville. "It will have very little benefit to the individual patient, and could actually work to the detriment of patients."

The action was taken by the Office for Human Research Protections (OHRP), a branch of the Department of Health and Human Services (HHS) charged with overseeing and approving research involving human subjects.

Developed at Johns Hopkins Hospital in Baltimore and implemented by 108 intensive care units in the Michigan Keystone project, the program in question has dramatically reduced catheter-related bloodstream infections (CR-BSIs). Indeed, it was heralded as a prime example of the new emphasis on zero tolerance for infections, as the median participating ICU went from an infection rate of 4% to zero over an 18-month period. Overall, the intervention led to a 66% reduction in CR-BSIs, saving a substantial toll in lives and dollars.[1] **(See *HIC*, June 2006, p. 66; January 2007, p. 7.)**

"The results speak for themselves," says **Gary Stephenson**, MS, senior associate director of media relations and public affairs at Johns Hopkins. "They are nothing short of astounding."

Moreover, the program is addressing a huge problem at a time when health care-acquired infections are increasingly viewed as preventable errors by the news media, public, and legislators. It is estimated that some 80,000 CR-BSIs occur annually, causing up to 28,000 deaths. Given that the average cost of care for a patient with the infection is $45,000; such infections could cost up to $2.3 billion annually.[2] Thus, federal interference with

a cutting-edge CR-BSI prevention program — even if prompted by ethical concerns — drew some strong reactions.

"OHRP is interpreting a regulation in a vacuum — without regard for the larger societal and ethical needs to preserve life," **Karen Linscott**, acting CEO of the Leapfrog Group told *HIC*. "While we wait for the way to be cleared for the widespread implementation of this program, lives will undoubtedly be endangered." The influential Washington, DC-based group — which works with both employers and the health care system to promote high-quality care — fired off a strongly worded letter to the HHS secretary demanding that the OHRP action be immediately rescinded. **(See related story, p. 16.)**

Checklist or checkmate?

The CR-BSI prevention program emphasizes hand hygiene, full-barrier precautions during catheter insertion, skin cleansing with chlorhexidine, avoiding the femoral insertion site, and removal of unnecessary catheters. A checklist for proper catheter insertion — which includes the patient's name or room number — also is a key part of the program. **(See checklist, p. 15.)** The program also calls for rigorous data collection and analysis to determine if patient safety and clinical outcomes are improved. To the OHRP, the program appeared to be more of a human research project, which means hospital institutional review boards (IRBs) must approve the activity and patients must be given informed consent.

"They are interpreting the rules that govern this as research and under their interpretation you have to go through a formal IRB review process and you have to have consent," Stephenson says. "We look at the same language in the regulations and we do not see this as research; therefore, you would not have to go though the same process as you would with human subject research. We have complied with what we think their request is — we resubmitted everything for IRB review with a consent waiver. We are still waiting to hear back from them, so this is still hanging in the air."

Spencer Johnson, president of the Michigan Health & Hospital Association (MHA), released a statement noting that to "comply with the OHRP ruling, each participating . . . hospital, for a temporary period of time, has suspended certain activities related to the collaborative. The OHRP ruling did not require hospitals to discontinue patient safety and quality practices previously associated with the . . . project that are now implemented as normal patient care. However, the ruling did result in the halting of certain activities, including collection and reporting of data to the MHA Keystone Center, until such time as the participating hospitals are able to have the project reviewed and approved by their respective [IRBs]."

After a request for more specific information on what has been discontinued and what remains in use in the project (e.g., the checklist), *HIC* was provided the following statement by **Sam Watson**, executive director of the Keystone Project. "Over

(Continued on page 16)

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Appendix J

Central Line Insertion

Care Team Checklist

➢ If any item on the checklist is **not** adhered to or there are any concerns, contact the ICU attending

Purpose:	To work as a team to decrease patient harm from catheter-related blood stream infections
When:	During **all** central venous or **central** arterial line insertions or re-wires
By whom:	Bedside nurse

If there is an observed violation of infection control practices, line placement should stop immediately and the violation should be corrected. If a correction is required, mark yes to question #6 *and explain violation at the bottom of the page and what corrections were made*

Patient's name or Room Number_____

1. Today's date _____/_____/_____
2. Is the procedure: ☐ Elective ☐ Emergent
3. Procedure: ☐ New line ☐ Rewire
4. Site Rite Used: ☐ Yes ☐ No ☐ Internal Jugular ☐Subclavian ☐ Femoral
   If equipment is available, ultrasound guidance should be used for all non-emergent internal jugular line placements. (Optional for subclavian and femoral line placement.)

	Yes	Yes After correction	Don't Know
5. Before the procedure, did the house staff:			
Perform a **"time-out"**	☐	☐	
Wash hands (chlorhexidine or soap) immediately prior	☐	☐	**(ask if needed)**
Was hand washing directly observed?	☐	☐	
Place pt in trendelenburg position (< 0 degrees)	☐	☐	to prevent air embolism
Sterilize procedure site (chorhexidine)	☐	☐	☐
Drape entire patient in a sterile fashion	☐	☐	☐
During the procedure, did the house staff:			
Use hat, mask, sterile gown and gloves	☐	☐	☐
Maintain a sterile field	☐	☐	☐
Did all personnel assisting follow the above precautions	☐	☐	☐
Ensure line aspirates blood to prevent hemothorax	☐	☐	
Transduce CVP or estimate CVP by fluid column	☐	☐	
After the procedure:			
Was a sterile dressing applied to the site	☐	☐	☐

	Yes	No
6. Was a correction required to ensure compliance with Safety & Infection control practices? Explain.		

Please return completed form to the designated location in your area

Version 12/2004

Source: Johns Hopkins Hospital, Baltimore.

the years, some of the ICU Initiative activities have become the standard of practice and care at hospitals, and that such standards are, and would be, implemented regardless of the current conduct of the ICU Initiative. Thus it may be the case that hospitals continue to, as a standard of care, implement activities also covered by the ICU Initiative. However, such activities are not being conducted under the ICU Initiative itself, no data are being recorded or collected, and hospitals have been instructed that they may not resume ICU Initiative activities until such time as IRB approval has been gained."

According by **Atul Gawande**, MD, a surgeon at Brigham and Women's Hospital in Boston, the checklist is the primary point of contention. In a recent *New York Times* op-ed piece, he wrote that the OHRP shut the program down because "by introducing a checklist and tracking the results without written, informed consent from each patient and health care provider, they had violated scientific ethics regulations. Johns Hopkins had to halt not only the program in Michigan but also its plans to extend it to hospitals in New Jersey and Rhode Island. . . . The government's decision was bizarre and dangerous."[3]

Contacted by *HIC*, Gawande, declined further comment. The Leapfrog Group seized on the checklist issue in its letter to HHS. "This simple checklist is already proven to save lives," Linscott tells *HIC*. Asked to respond to the charges, **Rebecca Ayer**, a spokeswoman in the HHS Office of Public Health and Science says "the OHRP in no way prohibits hospitals from implementing a checklist and other measures that have been shown to prevent certain hospital-acquired infections. OHRP regulations do not apply when institutions are only implementing practices to improve the quality of care. Recently, some have interpreted the application of these policies differently. We are aware of these concerns and are actively reviewing the facts of this particular case."

Indeed, the HHS strongly encourages hospitals to take steps to improve the quality of care, she adds. "Current research regulations in no way prohibit the adoption of this [checklist] by hospitals whose only goal is to improve the quality of care, "Ayer says.

Move part of larger change

If this all seems a bit confusing, consider that the move to stop the program comes as part of a much larger ongoing effort to draft new human research regulations by the OHRP and its advisors, the Secretary's Advisory Committee on Human Research Protections (SACHRP). A comment period will be allowed after the draft regulations are issued, but the action taken on the

Leapfrog Group urges Leavitt to reverse research ruling

Program similar to fed efforts to cut infections

After a federal health agency cited human research concerns in shutting down a landmark infection prevention effort, the Leapfrog Group strongly criticized the action in a Jan. 2, 2008, letter to Michael Leavitt, Secretary of the U.S. Department of Health and Human Services (HHS). The letter was signed by Karen Linscott, acting CEO of the Washington, DC-based group, which works with both employers and the health care system to promote high-quality care. Edited for style and length, the letter reads as follows:

"We respectfully request to comment on a recent move by the Office for Human Research Protections [OHRP] to shut down a program in Michigan hospitals that uses a checklist to prevent certain hospital infections. As you know, OHRP's reason is that the program violates informed consent regulations.

"The Leapfrog Group urges OHRP to reverse its decision, quickly. The checklist program consists of five steps that are proven to reduce the incidence of infection in intensive care units. While it can be argued that the program does not adhere to the specific language in the informed consent regulations, it cannot be argued that the checklist poses a danger to 'subjects'; on the contrary, the checklist has been proven to save scores of lives quickly and efficiently. The checklist is a far cry from an experimental drug for which informed consent is crucial. It is in fact consistent with your efforts related to the [HHS] Four Cornerstones, with the Centers for Medicare & Medicaid Services progress towards true value-based purchasing, and with the significant progress led by the Centers for Disease Control and Prevention to reduce hospital-acquired infections.

"The second major benefit of the checklist program is that it reveals which hospital staff members are not following basic infection-prevention procedures. This sort of reporting system is critical to the success of the overarching goal of increased public reporting and transparency. . . . We hope that you will support a speedy reversal of the OHRP decision. Lives depend on it." ■

CR-BSI prevention project may be a strong indication of which way the wind is blowing. Citing concerns among both the public health and health care epidemiology communities, Schaffner would like to see open hearings with expert testimony before the draft is completed.

"In my opinion, these well-intentioned people [at OHRP and SACHRP], unfortunately, are not very aware of the extraordinary diversity of current public health practice at the state and local level," he says. "Nor are they attuned to issues regarding quality assurance activities — which very much include infection control activities within the health care system. Speaking personally, it is my impression that because they are unacquainted with this large background of activity, they are 'overcalling' what is research."

As a result, traditional public health and infection control activities such as case control studies of outbreaks may be undermined, Schaffner warns. "If a case control study was used to investigate a disease problem this guidelines group might view that as a research methodology," he says. "You would have to put it through an IRB and give individuals informed consent. The whole notion of how you do your work becomes curtailed. You become much less effective, much less incisive. We won't be able to respond as quickly."

While the strong reaction to the incident makes it something of a test case, it remains to be seen whether the OHRP guidelines will ultimately give infection prevention more leeway or codify the view that some of its activities are subject to human research requirements. If it's the latter, there could be a "profound change" in the way infection control has traditionally been practiced, Schaffner warns.

"Infection control has traditionally done a variety of things using techniques that a committee such as this [may view as research]," he says. "The activities being undertaken in Michigan are quality assurance activities. It has nothing to do with research. This is a huge potential issue that has all kinds of insidious ramifications."

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UTIs create a danger field, but they get no respect

Catheters go unchecked, infections not reported

Though they are the most common infectious complication in hospitals, urinary tract infections (UTIs) get no respect.

"UTIs are the Rodney Dangerfield of nosocomial infections," says **Sanjay Saint**, MD, MPH, Professor of Medicine at the University of Michigan Health Systems in Ann Arbor.

Before we explore the reasons for this historical apathy, it should be noted that it is all about to change. The Centers for Medicare & Medicaid Services' (CMS) recent decision to halt payment on additional costs generated by UTIs and two other infections (mediastinitis, catheter-related vascular infections) is getting the respectful attention of many a hospital administrator. Arguments against the CMS changes note that not all infections are preventable and cite the possibility of unintended consequences such as increased testing and possible inappropriate treatment for hospital patients on admission.

However, Saint is the lead author of a recent study that could scarcely be more damning to hospitals with regard to UTI prevention.[1] In findings that bolster the CMS contention that many UTIs are preventable, Saint and colleagues found that urinary catheters — a well-established risk of infection if not removed as soon as possible — are not even monitored at a large number of hospitals. In a particularly striking finding, one-third of hospitals surveyed did not conduct any type of UTI surveillance. "If you don't track the infection, how will you know that you are reducing it or preventing it?" he tells *Hospital Infection Control*. "It does indirectly bolster [the CMS] argument that hospitals need to do more to prevent nosocomial UTIs. I think it will further incentivize hospitals to focus on prevention of catheter-related [CR-]UTIs."

No standardized prevention method

The researchers surveyed infection control professionals in 719 U.S. hospitals asking about their current practices to prevent UTIs. The overall survey response rate was 72%. Overall, 56% of

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Hib vaccine lots recalled, production stopped

CDC: Shortage predicted

Recall of a dozen lots of two *Haemophilus influenzae* type b (Hib) vaccines and suspension of production by a major manufacturer will result in a national shortage that could put children at risk and will certainly trouble physicians and parents in the short run, **Julie Gerberding**, MD, MPH, director of the Centers for Disease Control and Prevention, warns.

"This is not an immediate health threat, but we do need to do everything we can to restore effective vaccine coverage in the long run because children are at risk for [HIB] disease if we don't solve this problem over the next several months," she said at a recent press conference. "We anticipate that the short-term shortages are going to be very inconvenient and very messy to sort out."

The recall affects about 1 million of the 14 million doses annually distributed in the United States. Though downplaying any immediate risk, Gerberding emphasized that the shortage hits a very important vaccine. "It helps protect children from meningitis, from pneumonia, from severe throat infections and other serious blood stream infections caused by Hib," she said. "Before this vaccine was licensed and used, we experienced about 20,000 cases of HIB disease in the United States, and about 1,000 children died every year from this infection. But thanks to these vaccines that have been around for the last decade or so, there are fewer than 100 documented cases of HIB disease in the entire United States each year, a reduction of more than 99%. So obviously, this is an extremely effective vaccine that has saved the lives of many, many children."

The recommended vaccination schedule for Hib vaccine is a primary series (consisting of two or three doses, depending on the formulation) administered beginning at two months and a booster dose at age 12-15 months. Because of the short-term reduction in available doses of Hib-containing vaccines, CDC recommends that providers temporarily stop the routine Hib vaccine booster dose except to children in high-risk groups.[1] Providers should register and track children for whom the booster dose is deferred in order to recall them for vaccination when supply improves. The action is not likely to result in an increased risk for Hib disease because of continued protection of children with the primary series and the low level of carriage and transmission currently in the United States, the CDC noted.

Children considered at high risk for Hib disease include those with asplenia, sickle cell disease, malignant neoplasms, HIV and other immunodeficiency syndromes. The CDC recommends that providers continue to vaccinate these children with available Hib conjugate vaccines according to the routinely recommended schedules, including the 12-15 month booster dose. American Indian/Alaska Native (AI/AN) children also are at increased risk for Hib disease, particularly in the first six months of life. Before the use of Hib conjugate vaccines, the incidence of Hib disease among young AI/AN children in AI/AN communities was approximately 10 times higher than among children of comparable age in the general population.

"I think the most important priority group in this country is Alaska Native/American Indian children," **Anne Schuchat**, MD, director of the CDC's national center for immunization and respiratory diseases, said at the press conference. "They have much higher rates of Hib disease than others do. They have been a special population for Hib from the beginning. In fact, many of the vaccine studies were done in that population. It's also a fairly small group of children. I think we've already made the decision that we've prioritized our stockpile vaccine for the American Indian/Alaska Native children."

Bacillus cereus *found on equipment*

On Dec. 13, 2007, Merck & Co. in West Point, PA, announced a voluntary recall of certain lots of two *Haemophilus influenzae* type b (Hib) conjugate vaccines, PedvaxHIB® (monovalent Hib vaccine) and Comvax® (Hib/hepatitis B vaccine). **(See lots, p. 19.)** Providers are being asked to return unused vaccine from these recalled lots

using procedures outlined on the Merck web site (www.merckvaccines.com/PCHRecall.pdf).

Merck, which produces roughly half of the Hib conjugate vaccines used in the United States, has suspended production of the vaccine and does not expect to resume distribution until the fourth quarter of 2008, the CDC reports. Merck took the steps as a precautionary measure because potential contamination in the specific lots was identified as part of the company's standard evaluation of its manufacturing processes. In routine testing of the vaccine manufacturing equipment used to produce the vaccines, the company found *Bacillus cereus*, a gram-positive enteric pathogen typically associated with food poisoning. Sterility tests of the vaccine lots themselves have not found any contamination. No adverse reactions in vaccinated children had been reported as this issue went to press, but parents of children recently vaccinated with recalled vaccine should watch for any signs of infection (such as redness and swelling at the injection site) and contact their providers if such reactions occur. Vaccine potency was not affected, so children who were immunized with the affected vaccines do not need to be revaccinated.

Two other shots available

Two other Hib conjugate vaccines manufactured by Sanofi Pasteur (Swiftwater, PA) are currently licensed and available for use in the United States. However, Sanofi Pasteur likely will not be able to immediately provide adequate Hib vaccine to vaccinate fully all children for whom the vaccine is recommended. The CDC is working with manufacturers to address the issue and expects to draw from its own emergency stockpile of Hib vaccine as the shortage unfolds. "We know that a portion of our stockpile will also be affected by this recall, so the flexibility and future ability to backfill for shortages and so forth has been lost by this change," Gerberding said.

Fortunately, current immunization rates in the United States for Hib vaccine are high. In 2006, about 94% of U.S. children 19-35 months of age were vaccinated against Hib. "We have very low disease rates and very low carriage rates in our population, so we would not expect any meningitis outbreaks for many months because our population is so highly immune," she said. At the same time, the CDC is taking the situation very seriously because experience has shown that when immunization rates fall affected populations are susceptible to increases in disease occurrence. "CDC will be continuing our close surveillance for *Haemophilus* disease in children, and we will be heightening our attention in some of our special programs that we use to give a sentinel look at invasive disease," she added.

[Editor's note: Any adverse events that are potentially vaccine-related should be reported to the Vaccine Adverse Event Reporting System (VAERS) at (800) 822-7967 or online at http://www.vaers.hhs.gov.]

Reference

1. Centers for Disease Control and Prevention. Interim Recommendations for the Use of *Haemophilus influenzae* Type b (Hib) Conjugate Vaccines Related to the Recall of Certain Lots of Hib-Containing Vaccines (PedvaxHIB® and Comvax®) *MMWR* 2007; 56(Dispatch):1-2. ■

Which lots of vaccine are being recalled?

Merck & Co. has initiated a voluntary recall in the United States for 10 lots of PedvaxHIB® [Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate)] and two lots of COMVAX® [Haemophilus b Conjugate (Meningococcal Protein Conjugate) and Hepatitis B (Recombinant) Vaccine]. The affected doses were distributed in the United States starting in April 2007. The lots that are being recalled are:

Description

- PedvaxHIB® 0677U 11 January 2010;
- PedvaxHIB® 0820U 12 January 2010;
- PedvaxHIB® 0995U 16 January 2010;
- PedvaxHIB® 1164U 18 January 2010;
- PedvaxHIB® 0259U 17 October 2009;
- PedvaxHIB® 0435U 18 October 2009;
- PedvaxHIB® 0436U 19 October 2009;
- PedvaxHIB® 0437U 19 October 2009;
- PedvaxHIB® 0819U 09 January 2010;
- PedvaxHIB® 1167U 10 January 2010;
- COMVAX® 0376U 05 January 2010;
- COMVAX® 0377U 08 January 2010. ■

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hospitals did not have a system for monitoring which patients had urinary catheters placed, and 74% did not monitor catheter duration. Despite the strong link between urinary catheters and subsequent UTI, the authors found no strategy that appeared to be widely used to prevent hospital-acquired UTIs. The most commonly used practices — bladder ultrasound and antimicrobial catheters — were each used in fewer than one-third of hospitals, and urinary catheter reminders, which have proven benefits, were used in less than 10% of U.S. hospitals, they concluded. "It points out that hospitals don't have a standardized approach to preventing the most common nosocomial infection," Saint says.

UTIs can be deadly

The conventional wisdom is that UTIs rarely lead to serious or fatal infections, but the Michigan Health & Hospital Association's Keystone Center for Patient Safety & Quality estimates that 5% of all deaths caused by health care-associated (HAI) infections are from CR-UTIs. That's 5,000 fatal infections if one uses the typical ballpark figure of 100,000 HAI deaths annually. In addition, the sheer number of UTIs is overwhelming with indwelling urinary catheters ("Foleys") being placed into 15%-25% of patients admitted to acute care hospitals. On an annual basis in U.S. hospitals there are some 5 to 9 million indwelling urinary catheters placed into patients during their admission, the Keystone Center estimates.

Essentially, bacteria use the catheter as a gateway to the bladder, meaning the longer it is left in place the greater the risk of infection. **(See Figure 1, above right.)** About 900,000 patients develop a UTI annually. Even though the infection may be asymptomatic, almost 80% of patients with an indwelling urinary catheter will receive an antibiotic, the center reminds. In many instances, this selects for a multidrug-resistant organism that may be more difficult to treat and also creates a reservoir of resistant bugs that can be transmitted to other patients. UTIs result in a burden of morbidity and expense, even considering the relatively low treatment cost of $500 to $1,000 per infection. If a secondary bacteremia develops the cost per episode increases to $2,800, the Keystone Center reports. The Keystone project has developed a "bladder bundle" of preventive strategies to help ICPs reduce these infections. **(See related story, p. 21.)**

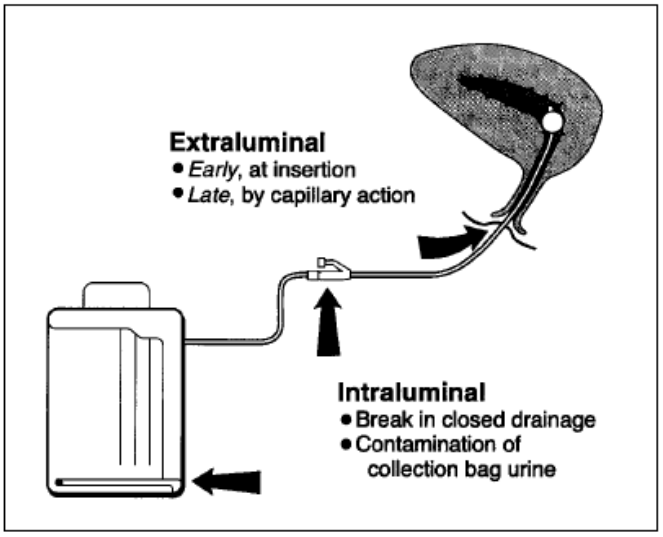

Figure 1. Routes of entry of uropathogens to catheterized urinary tract.

Source: Maki DG. Michigan Health & Hospital Association's Keystone Center for Patient Safety & Quality. *Emerg Infect Dis* 2001; 7:1-16.

"The bladder bundle [recommends] several things, including appropriate indications for urinary catheter use and proper aseptic techniques during insertion to prevent any infection from occurring," Saint says. "Once the patient has a urinary catheter, [it recommends] some type of a reminder system to remove it. [Clinicians] should also consider alternatives to indwelling catheterization. One alternative would be the use of portable bladder ultrasound scanning to avoid indwelling catheterization in the first place."

Reminders make it a systems problem

Saint is a strong advocate of using catheter reminder systems that prompt clinicians to remove the devices in a timely fashion. "One of the simplest and most cost-effective approaches — that has high validity in some studies — would be the use of a urinary catheter reminder, whether it is computerized, nursing-based, or a written reminder,"[3-5] he says.

Such a reminder system should be aimed at both physicians and nurses, who must work in collaboration to prevent UTIs. "I think physicians just take for granted that this has more to do with nursing care than something they should be invested in," he says. "This isn't just a nursing issue or doctors' issue. This is more of a systems issue. That's why I have been very supportive of some type of a urinary catheter reminder system, rather than just relying on overworked clinicians to remember that the patient has a urinary catheter. The system can

help us do the right thing."

Why hasn't the right thing already been done — why do UTIs get no respect?

"I think the perception is that that they are relatively easy and straightforward to treat and the morbidity is less [compared to infections such as] ventilator-associated pneumonia (VAP) and catheter-related bloodstream infections (CR-BSIs)," Saint says. "Based on the data that I've seen, UTIs do seem easier to treat and do not have as much morbidity as VIPs and CR-BSIs, but it is still substantial given the high number of patients who have urinary catheters. The fact is that a third to one-half of the days that a patient has a urinary catheter, it meets no medically justified indication. A third of doctors are unaware that their own patients have a urinary catheter in place."

Noninfectious factors

While no infection may result from this neglect, there are noninfectious factors that make the patient's stay all the more miserable — and the healing more difficult.

"It is just as important to emphasize the noninfectious complications of urinary catheter use," Saint says. "Patients find urinary catheters uncomfortable, painful, and restrictive of their activities of daily living. If you couple both the infectious and noninfectious consequences of urinary catheters — when they may not even be serving a medical purpose — it heightens the importance of preventing urinary catheter-related problems."

An accompanying editorial underscoring Saint's findings emphasized that "to optimize patient safety, documentation of the use and duration of any invasive device that carries a risk to the patient is necessary. There seems no reasonable argument against expecting facilities to collect, distribute, and act on this information for indwelling urethral catheters."[5] The editorial's author — **Lindsay E. Nicolle**, MD, a professor in the department of internal medicine and medical microbiology at University of Manitoba Health Sciences Centre in Winnipeg, Canada — elaborated on her position in an interview with *HIC*.

"We are still in a transition phase from when people didn't pay a lot of attention to invasive procedures in terms of monitoring them and moving to a period of time when probably all this will be monitored," she says. "Perhaps because they are not causing as much death or prolongation of stay as the other common nosocomial infections, people tend to ignore them."

In that regard, Saint's paper and the coming CMS changes should send an unmistakable message that the days of benign neglect toward UTIs are coming to an end.

"Here we have a risk procedure — putting in a urinary catheter — and we aren't monitoring it," she says. "We aren't measuring how many people we are doing this to or for how long. [Electronic monitoring] should make it easy to do this, but in fact we don't do that and most places can't do that. I am hoping this is going to be a stepping stone toward institutions acknowledging that they need to start doing this and moving in that direction."

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Keystone provides keys to preventing UTIs

'Bladder bundle' team includes ICPs

The Michigan Health & Hospital Association's Keystone Center for Patient Safety & Quality has created a "bladder bundle" of measures to prevent urinary tract infections. Some of the key recommendations for implementation of the bundle are summarized as follows:

- **Step 1:** Identify and enlist a nurse champion to lead this bundle. The nurse champion could be a case manager, nurse coordinator, clinical nurse specialist. The major focus of this bundle is on processes of care with an emphasis on continual assessment and removal of the catheter as soon as

possible — especially those for which there is no clear indication. The underlying reasons are that:

i) Over 80% of hospital-associated UTIs are caused by an indwelling urinary catheter;

ii) Studies that have looked at indications for catheters in place have found that only about 46% are appropriate;

iii) The insertion, care, and maintenance of the indwelling catheter falls entirely on the nursing staff.

• **Step 2:** Identify and organize the bladder bundle team. This likely will include nurse(s), physician(s) (consider a hospitalist if available or other medical director), education coordinator, infection control professional, patient care assistants, performance improvement coordinator, social worker, etc.

Step 3: Identify the unit(s) targeted for implementation of the bladder bundle.

i) Obtain urinary catheter utilization data from your facility's purchasing department to determine which units are high volume.

ii) It may be more challenging to get buy-in from ICU personnel even though utilization of catheter is likely high. Consider instead an inpatient medicine, surgery or even a progressive care unit. If the facility has a limited number of beds this may require enrolling the entire medical/surgical unit.

• **Step 4:** Baseline assessment: Structure and crude frequency of positive urine cultures.

i) In collaboration with your facility's ICP ask the microbiology laboratory or key contact with the laboratory your facility uses to create a report that provides:

a. All urine cultures that were positive more than 48 hours after the patient's date of admission

b. If possible, see if this can be sorted by unit, frequency, pathogen, and cumulative susceptibility profile for all of these positive cultures.

• **Step 5:** Point prevalence study of appropriateness of urinary catheterization —

A) Baseline Point Prevalence: If unit-specific catheter utilization data are not readily available, do a single day point prevalence survey of all medical/surgical inpatient units to determine which have the highest utilization of urinary catheters.

B) Identify target unit(s)

C) Collect pre-intervention phase: Baseline data (e.g. assess 5 days/week 1)

a. If possible, have target unit begin collecting urinary catheter days, e.g., on each day, tabulate total number of patients with an indwelling urinary catheter on a device utilization log.

b. Calculate unnecessary catheterization rate

CNE/CME instructions

Physicians and nurses participate in this CE/CME program by reading the issue, using the provided references for further research, and studying the questions. Participants should select what they believe to be the correct answers, then refer to answer key to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing the semester's activity, you must complete the evaluation form that will be provided and return it in the reply envelope to receive a credit letter. ■

CNE/CME *questions*

5. The federal Office for Human Research Protections (OHRP) took action to stop a catheter-related bloodstream infection prevention program that includes:
A. avoiding the femoral insertion site.
B. removal of unnecessary catheters.
C. a checklist for proper catheter insertion.
D. All of the above

6. The action was taken as OHRP and its advisors continue the process of drafting new human research regulations.
A. True
B. False

7. Recall of a dozen lots of two *Haemophilus influenzae* type b (Hib) vaccines and suspension of production by a major manufacturer will result in a national shortage. Which of the following is among the infections the vaccine is designed to prevent?
A. Skin and soft tissue
B. Rotavirus
C. Influenza
D. Meningitis

8. In a study of urinary tract infections (UTIs), what proportion of hospitals did not conduct any type of UTI surveillance?
A. One-fourth
B. One-third
C. Half
D. Three-quarters

c. Calculate proportion of unnecessary catheters.

d. Provide training on prevention of catheter-related UTIs to personnel, including list of appropriate indications for catheter utilization.

e. Report baseline findings to personnel

D) Intervention Phase (weeks 2 & 3):

a. Convene daily patient rounds, aka "catheter patrol."

b. During rounds, assess patients for presence of a catheter and if present documentation in chart on reason(s) for insertion and unit where inserted.

c. Implement RN-based discontinuation protocol (if physician leadership for involved unit approves protocol) or reminders to patient's physician if use is not appropriate.

d. Recollect catheter utilization ratio, unnecessary catheter utilization rate, and proportion of unnecessary catheters.

e. Report findings periodically to personnel.

E) Post-Intervention Phase (weeks 4-7): No specific intervention; continue to collect weekly indicators and report findings to personnel.

F) Post-Intervention Phase (week 8): Collect data to assess the effect of the intervention, compare results over the project phases, & report findings to personnel.

a. Ask laboratory to provide a repeated uropathogen distribution report. Have ICP analyze this for any notable changes and report findings. ■

CNE/CME answers

5. D; 6. A; 7. D; 8. B.

CNE/CME objectives

After reading each issue of *Hospital Infection Control*, the infection control professional will be able to do the following:

• identify the particular clinical, legal, or educational issue related to epidemiology;

• describe how the issue affects nurses, hospitals, or the health care industry in general;

• cite solutions to the problems associated with those issues, based on guidelines from the federal Centers for Disease Control and Prevention or other authorities, and/or based on independent recommendations from clinicians at individual institutions. ■

In body or mind? CDC studying mystery disease

Morgellons subject of research project

The Centers for Disease Control and Prevention in conjunction with Kaiser Permanente's Northern California Division of Research will formally investigate an unexplained but persistently reported skin condition known as Morgellons.

People who suffer from the condition report a range of symptoms, including nonhealing skin lesions associated with the emergence of fibers or solid material from the skin, abnormal skin sensations (such as stinging and biting or pins and needles) and noncutaneous symptoms such as difficulty concentrating and short-term memory loss.

Patients who report Morgellons are often thought to be suffering psychiatric illness (e.g., delusional parasitosis), but the CDC study indicates some infectious etiology or other disease origin is not being ruled out. Indeed, some observers have previously speculated that the condition could be linked to fungi or bacteria of plant origin. Lead investigator in the project is Michele Pearson, MD, a medical epidemiologist at the CDC's national center for infectious diseases.

Kaiser's research division in Oakland, CA, was awarded a $338,000 contract to assist the CDC in the investigation because many self-reported cases are in the geographic area and already in the Kaiser system. CDC also is bringing in the Armed Forces Pathology Institute. The primary goals of the investigation are to better

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■ Complete coverage of SHEA in Orlando

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■ New CDC guidelines on UTI prevention

describe the clinical and epidemiological features of the condition and possible risk factors.

The investigation may take a year or longer to complete. Initially, investigators will identify and recruit participants and collect detailed information on participants' symptoms and potential factors that may contribute to the condition. Later, eligible participants will undergo detailed clinical evaluations, including a general medical examination, dermatologic examination, mental health examination, skin biopsies, and multiple blood tests.

A message line with prerecorded messages [(404) 718-1199] has been established and will provide updates about the investigation and new information as it becomes available. The CDC has also set up a web site to provide information at www.cdc.gov/unexplaineddermopathy. ■

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