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CDC, CMS targeting vile practices with vials

MRSA infections 'completely preventable'

By **Gary Evans**, Executive Editor

In what is getting to be a familiar, tragic refrain, the improper use of single-dose vials recently resulted in patients at pain clinics in Arizona and Delaware acquiring serious bacterial infections that were "completely preventable," the Centers for Disease Control and Prevention reports.

While such outbreaks are often linked to transmission of blood-borne infections, in this case bacterial infections with susceptible and resistant strains of *Staphylococcus aureus* occurred at the two clinics. Overall, 10 patients at the two pain clinics were hospitalized due to severe infections with MRSA or MSSA that required treatment for conditions such as mediastinitis, bacterial meningitis and sepsis.[1]

In both of the outbreaks, providers were splitting single-dose vials (SDV) designed for one patient into doses for multiple patients. The clinics reported having difficulty obtaining the right vial size, either because of a drug shortage or because the smaller vial size isn't manufactured. Such scenarios do not excuse unsafe practices, says **Michael Bell**, MD, associate director for infection control in the CDC's Division of Healthcare Quality Promotion.

"We are continuing to see the same problems," he says. "It is generally in the same groups of products, related both to [drug] shortages but also more importantly just to the lack of a convenient vial size. I think that there is this one-size-fits-all approach in some cases, and at the bedside that doesn't translate to safe practices very easily — especially when you are talking about contrast material for x-ray procedures that are made in substantially larger volumes."

In the Arizona clinic, the CDC reported that each morning, clinic staff members typically prepared contrast medium in the patient

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procedure room, before the arrival of patients. Two new syringes were used to withdraw 5 mL each from a 10 mL SDV of contrast medium (300 mgI/mL) and a 10 mL SDV of saline solution. The contents from each syringe then were transferred to the alternate vial, resulting in two 10 mL vials of diluted contrast solution, one for use in the morning and one reserved for the afternoon. Among patients receiving contrast solution on the day of the outbreak, six received injections from the morning vial and four from the afternoon vial. Three of the patients who received diluted contrast from the afternoon vial developed MRSA infections.

MRSA not ruled out in one death

The three Arizona patients were eventually hospitalized, with stays ranging from nine to 41 days and additional long-term acute care required for one patient. "The fourth recipient of diluted contrast from the afternoon vial was found deceased at home, 6 days after treatment at the clinic," the CDC reported. "The cause of death was reported as multiple-drug overdose; however, invasive MRSA infection could not be ruled out."

In the Delaware clinic, reuse of SDVs of the anesthetic bupivacaine for multiple patients was the only breach of safe practice identified during the investigation and represented a recent change. Previously, the orthopedic practice had used 10 mL SDVs of bupivacaine for single-patient use. When a national drug shortage disrupted the supply of 10 mL SDVs, office staff members began using 30 mL SDVs of bupivacaine for multiple patients, the CDC reported. The joint injection procedures done in the clinic typically required 1–8 mL of anesthetic, with each injection prepared immediately in advance of the procedure in a separate, clean, medication preparation room. Only one 30 mL vial of bupivacaine was opened at any given time; each vial was accessed over a course of several hours for multiple patients until all contents were withdrawn. Occasionally, an opened 30 mL vial was stored in a medical cabinet for use the next day, the CDC investigators found.

Noting that the infections in both clinics were "completely preventable," Bell says the outbreaks underscore a lack of awareness that such practices put patients at risk. Because injections were prepared with new needles and syringes — and in a separate "clean" prep room in Delaware — the clinicians thought the practices were safe.

On the contrary, the preservative-free medications are not safe for multi-patient use, he emphasized. However, providers do have options, Bell noted. High-quality pharmacies that adhere to standards in United

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States Pharmacopeia General Chapter 797 can be used to safely split doses from SDVs to increase availability, prevent waste, and minimize risk to patients. In addition, some providers are using appropriate alternate medications in times of shortage, he says.

"We have had pharmacies that have been able to split doses safely for a very long time — nothing new there," Bell says. "But that does add to the complexity of care. It is much easier to carry a big vial in your coat pocket and just take some out when you want it. Unfortunately that leads to the risk of contamination and cross infection."

The CDC and other federal agencies have had discussions with drug manufacturers about producing vial sizes that do not lend themselves to inappropriate use.

"That is something we are continuing to explore, but it is not an easy solution it turns out," Bell says. "When you are asking a manufacturer to produce a new vial size, in order to do that they need to go through a great deal of stability testing and what-not for due diligence that can take upwards of a couple of years. It's certainly a financial investment for the manufacturer, so it is not going to be an easy sell necessarily to say that everyone must now start making a wide range of [vial] volumes ."

In addition, smaller volume vials may cost more than the same solution in larger quantity vials. "It certainly wouldn't be the first time we saw that pattern where a large volume for one purpose is much less expensive than a tiny volume for another purpose," he said. Likewise, having compounding pharmacies safely split doses – instead of trying to do it in-house – is naturally going to add to a clinic's overhead.

"It's not free," Bell says. "It certainly adds to the costs, but at a certain point it's just doing things properly so the additional cost becomes kind of a false argument. We need to do the right thing. How we go about doing that is still under discussion in the sense that

CMS inspectors will look for safe injection practices

A draft infection control survey by the Centers for Medicare & Medicaid Services (CMS) includes the following provisions on safe injection practices:

- Syringes are used for only one patient (this includes manufactured prefilled syringes and insulin pens).
- Injections are prepared using aseptic technique in an area that has been cleaned and free of visible blood, body fluids, or contaminated equipment.
- Needles are used for only one patient.
- The rubber septum on a medication vial is disinfected with alcohol prior to piercing.
- Medication vials are entered with a new needle. Note - Reuse of syringes and/or needles to enter a medication vial contaminates the contents of the vial making the vial unsafe for use on additional patients. If a surveyor sees needles or syringes being reused to enter a vial to obtain additional medication for the same patient, no citation should be made if the vial is discarded immediately.
- Medication vials are entered with a new syringe. Note - Reuse of syringes and/or needles to enter a medication vial contaminates the contents of the vial making the vial unsafe for use on additional patients. If a surveyor sees needles or syringes being reused to enter a vial to obtain additional medication for the same patient, no citation should be made if the vial is discarded immediately.
- Single dose (single-use) medication vials are used for only one patient.
- Bags of IV solution are used for only one patient (and not as a source of flush solution for multiple patients).
- Medication administration tubing and connectors are used for only one patient.
- Multi-dose vials are dated when they are first opened and discarded within 28 days unless the manufacturer specifies a different *(shorter or longer) date for that opened vial. Note: This is different from the expiration date for the vial. The multi-dose vial can be dated with either the date opened or the discard date as per hospital policies and procedures, so long as it is clear what the date represents and the same policy is used consistently throughout the hospital.
- If multi-dose vials are used for more than one patient, they do not enter the immediate patient treatment area (e.g., operating room, patient room, anesthesia carts). Note: If multi-dose vials are found in the patient care area they must be dedicated for single patient use and discarded after use. ■

we are not saying that pharmacy aseptic handling is the only option. There are also prefilled syringes being produced by compounding pharmacies and that is another option for some of these things."

It goes without saying, that the potential "costs" in human suffering and ensuing liability should certainly give clinics pause before undertaking such practices. Moreover, new regulatory oversight on this issue is also on the horizon.

CMS survey includes injection safety

Infection preventionists should be aware that the Centers for Medicare & Medicaid Services (CMS) is targeting vials and needle injection practices as part of a hospital infection control survey program slated to begin next year. The draft version of the CMS survey includes many provisions looking for signs of reuse of needles, syringes and single-dose vials on multiple patients. (*See box, p. 87.*) This is something of a sensitive issue for the CMS, so they may inspect these measures with particular vigilance. The impetus for the CMS inspections, first in ambulatory care and now in hospitals, was a 2008 hepatitis C virus outbreak at a Las Vegas endoscopy clinic. That outbreak has resulted in at least nine HCV infections and more than 100 suspect cases of people who may have been infected during medical care. As we reported at the time, CMS inspectors had actually been to the Las Vegas clinic while the outbreak was ongoing, but apparently were insufficiently trained in infection control to identify improper practices with syringes and single-dose vials. They are getting up to speed now, and we asked Bell whether CMS oversight could finally make a difference on this longstanding problem.

"I think it already has," he says. "The interesting thing is that none of these recommendations are new. This is a basic standard of care that has been around a long time. We've republished reminders for health care personnel on a couple of occasions in the past couple of years and we didn't really hear any push-back until CMS decided to start incorporating it in their surveys. All of a sudden several parts of the medical community took notice and were not entirely happy. I think they took notice because it is now part of CMS requirements."

Though injection safety was really the issue that prompted CMS action, the resulting hospital survey includes many areas that generally encourage a culture of safety. These provisions range from non-punitive policies allowing workers to voice concerns about patient safety to stringent provisions on reprocessing equipment. (*See related story, below*)

It is both timely and "forward thinking" for the CMS to emphasize such measures, because sometimes "questioning the status quo is a good thing," says **Ruth Carrico**, PhD, RN, CIC, an associate professor at the School of Public Health and Information Sciences at the University of Louisville, KY. Given current economic conditions, health care workers are inundated with messages to avoid wasteful practices and conserve resources. "Sometimes when we are talking to all staff, we tell them our survival depends upon us making good use of our available resources," she says. "We encourage them to think before they throw things away and not be wasteful. So this [CMS survey] is a way of making sure that the message that we are giving about cost control is being translated appropriately by the frontline staff. With the inclusion of this, I think CMS is recognizing that this can be a problem — the same sort of problem we have seen with our single-dose vials and with some of the drug shortages. Staff are trying to make the best decision that they can, but sometimes it is not the safest decision. They are building some of this in as a patient safety safeguard."

Reference

1. CDC. Invasive *Staphylococcus aureus* Infections Associated with Pain Injections and Reuse of Single-Dose Vials — Arizona and Delaware, 2012. *MMWR* 2012; 61;501-504 ■

Point of emphasis: CDC on single-dose vials

Drug shortages, waste concerns no excuse

In light of recurrent outbreaks linked to misuse of single-dose medication vials, the Centers for Disease Control and Prevention is emphasizing that medications labeled as "single dose" or "single use" are to be used

for only one patient.

In a May 2, 2012, posting (http://ow.ly/c1KE0) the CDC said this practice protects patients from life-threatening bloodborne and bacterial infections that occur when medications get contaminated from unsafe use. The CDC is aware of at least 19 outbreaks associated with single-dose/single-use medications since 2007. Seven of the outbreaks involved bloodborne pathogen infections and 12 involved bacterial infections.

The CDC also addressed common myths about vials in an effort to resolve recurrent confusion about the issue. (*See story, p. 90.)* Regarding concerns that these guidelines and related policies contribute to drug shortages and increased medical costs to health care providers, the CDC said shortages are primarily a result of manufacturing, shipping, and other unrelated issues.

"CDC's priority is protecting patients from harm," the agency stated. "CDC routinely investigates and is apprised of infectious disease outbreaks involving single-dose/single-use vials being used for multiple patients. These outbreaks cause extensive harm to patients, and they are associated with significant health care and legal expenses. Therefore, CDC continues to strongly support its current policies regarding single-dose/single-use vials. It is imperative that drug shortages and drug waste concerns are dealt with appropriately and do not lead to unsafe medical practices that impose increased disease risk on patients. Shortages of some essential medications may warrant implementation of meticulously applied practice and quality standards to subdivide contents of single-dose/single-use vials, as stated in United States Pharmacopeia General Chapter 797 Pharmaceutical Compounding – Sterile Preparations."

Additional CDC points of interest include:

- Vials labeled by the manufacturer as "single dose" or "single use" should only be used for a single patient. These medications typically lack antimicrobial preservatives and can become contaminated and serve as a source of infection when they are used inappropriately.
- Ongoing outbreaks provide ample evidence that inappropriate use of single-dose/single-use vials causes patient harm.
- In times of critical need, contents from unopened single–dose/single–use vials can be repackaged for multiple patients. However, this should only be performed by qualified health care personnel in accordance with standards in United States Pharmacopeia General Chapter 797 Pharmaceutical Compounding — Sterile Preparations. Following the USP standards is imperative, as medication contamination and patient harm can occur when repackaging (e.g. splitting doses) is not done properly.

The CDC listed the following answers to some of the most common questions about this issue.

Can single-dose or single-use vials be used for more than one patient?

No. Vials that are labeled as single-dose or single-use should be used for a single patient and single case/procedure/injection. There have been multiple outbreaks resulting from health care personnel using single-dose or single-use vials for multiple patients. Even if a single-dose or single-use vial appears to contain multiple doses or contains more medication than is needed for a single patient, that vial should not be used for more than one patient nor stored for future use on the same patient. To prevent unnecessary waste or the temptation to use contents from single-dose or single-use vials for more than one patient, clinicians and purchasing personnel should select the smallest vial necessary for their needs when making treatment and purchasing decisions.

Is it acceptable to combine (pool) leftover medication from single-dose or single-use vials?

No. Do not combine (pool) leftover contents of single-dose or single-use vials or store single-dose or single-use vials for later use. Single-dose or single-use vials are intended for use on a single patient for a single case/procedure. There have been outbreaks resulting from pooling of contents of single-dose or single-use vials and/or storage of contents for future use.

In critical situations, is there any option for medication from a single-dose/single-use vial to be used for more than one patient?

It is optimal for the medication to be used for just one patient. Shortages of some essential medications may warrant implementation of meticulously applied practice and quality standards to subdivide contents of single-dose/single-use vials. In these cases, qualified health care personnel may repackage medication from a previously unopened single-dose/single-use vial into multiple single-use vehicles (e.g., syringes). This should only be performed under ISO Class 5 conditions in accordance with standards in

United States Pharmacopeia General Chapter 797, Pharmaceutical Compounding – Sterile Preparations, as well as the manufacturer's recommendations pertaining to safe storage of that medication outside of its original container.

When should single-dose or single-use vials be discarded?

Medication vials should always be discarded whenever sterility is compromised or questionable. In addition, the following recommendations are made for handling of single-dose or single-use vials:

- If a single-dose or single-use vial has been opened or accessed (e.g., needle-punctured) the vial should be discarded according to the time the manufacturer specifies for the opened vial or at the end of the case/procedure for which it is being used, whichever comes first. It should not be stored for future use.
- If a single-dose or single-use vial has not been opened or accessed (e.g., needle-punctured), it should be discarded according to the manufacturer's expiration date. ■

CDC facts, myths on vials, needle safety

The Centers for Disease Control and Prevention is trying to overcome some stubborn myths and misperceptions about single-dose vials including the following, which the agency refuted with the current facts.

Myth: Improper use of single-dose/single-use vials puts patients at risk of infection with only bloodborne pathogens such as hepatitis C virus.

Fact: Infection risk is not just limited to bloodborne pathogens. Outbreaks from improper use of single-dose/single-use vials have resulted in life-threatening bacterial infections including bloodstream infections, meningitis, and epidural abscesses. Many of these infections have occurred following injection procedures performed in pain remediation clinics.

Myth: Guidance regarding safe handling of single-dose/single-use vials is new and has only been in place since 2010.

Fact: CDC injection safety guidelines are not new. They have been part of Standard Precautions since 2007 (http://www.cdc.gov/injectionsafety/IP07_standardPrecaution.html).

Myth: According to CDC, there is never a circumstance when contents from a single-dose/single-use vial may be used for more than one patient.

Fact: CDC recommends that providers limit the sharing of medications whenever possible. Qualified health care personnel may repackage medication from a previously unopened single-dose/single-use vial into multiple single-use vehicles (e.g., syringes).

This should only be performed under ISO Class 5 conditions in accordance with standards in the United States Pharmacopeia General Chapter 797, Pharmaceutical Compounding – Sterile Preparations, as well as the manufacturer's recommendations pertaining to safe storage of that medication outside of its original container.

Myth: There is no evidence that single-dose/single-use vials used for multiple patients are responsible for infections if "proper infection control measures" are applied.

Fact: Dedicating a single-dose/single-use vial to one patient is, in and of itself, a critical element of proper infection control. CDC continues to see outbreaks in health care settings where providers thought they were preparing and administering injections safely. In the last five years alone, CDC is aware of at least 26 outbreaks due to unsafe injection practices. These outbreaks resulted in more than 95,000 patients being referred for testing after potential exposure to infectious diseases. Nineteen of these outbreaks involved use of single-dose/single-use medications for more than one patient. These and other suboptimal practices are common, as reported by numerous studies about infection control compliance rates. Moreover, infection surveillance is lacking in most outpatient settings; thus it is likely that outbreaks are occurring at a higher frequency, but going undetected.

Myth: CDC's recommendations regarding single-dose single-use vials are flexible. In 2002 the agency issued a communication to the Centers for Medicare & Medicaid Services (CMS) regarding how to safely use contents from single-dose/single-use vials for more than one patient in a dialysis setting. If they allowed use of single-dose/single-use vials for more than one patient in dialysis clinics, why can't it be applied to other patients?

Fact: The current injection safety guidance is part of CDC's 2007 Guideline Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings. This guidance supersedes all other formal and informal guidance on this topic and was

developed to reflect accumulating evidence, including bloodborne pathogen risk, gathered from outbreaks caused by unsafe injection practices. In 2002, an informal communication from CDC to the CMS suggested that certain medications packaged in a single-dose/single-use vial could be used for more than one patient in dialysis settings, assuming that certain criteria were followed. In 2008, CDC issued a formal clarification specifically to dialysis providers stating that the 2007 guidance superseded the 2002 CDC communication to CMS (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5732a3.htm).

Myth: Considerable health care savings could be achieved if less stringent policies were in place.

Fact: Any potential savings from stretching the contents of single- dose/single-use vials by health care providers can be quickly offset by the costs associated

with viral hepatitis, bloodstream infections, meningitis, epidural abscesses and other infectious complications. These costs are primarily borne by patients and their families. In addition, clinicians could face legal costs and potentially lose their medical licenses if basic safe practices are not followed and patients are harmed. ■

CMS survey could boost central services departments

'Show me' is a phrase you can expect to hear

A Centers for Medicare & Medicaid Services draft infection control survey expected to be finalized for use in hospitals next year could lead to increased support and appreciation for the challenges faced by central services departments, says **Rose Seavey**, RN, BS, MBA, CNOR, CRCST, CSPDT, President/CEO of Seavey Healthcare Consulting, Inc., in Arvada, CO.

A specialist in reprocessing issues, Seavey notes that the CMS survey includes important and potentially problematic areas like endoscope reprocessing. For example, the CMS survey requires that such "items are thoroughly pre-cleaned according to manufacturer instructions and visually inspected for residual soil prior to high-level disinfection. For lumened instruments (e.g., endoscopes), pre-cleaning must include all device channels and lumens with cleaning brushes appropriate for size of instrument channel or port."

"They are spelling it out — you must use the appropriate size brushes," Seavey says. "Facilities may be tempted to save money on brushes, and that can lead to situations where the wrong-size brush is being used to clean equipment."

This could be a problem for equipment like endoscopes if you cannot pass the brush all the way through the lumen, she adds.

"You can't just go up one side and down the other or you are going to just pack it in," she says. In addition, forcing a brush into a piece of equipment could damage the interior surface, creating a possible breeding ground for bacteria.

"Once you harm the surface of a lumen it is a good place for biofilm to start going," she says. "Or if the brush is not big enough, you may not be doing a good enough job of cleaning. So you have to have the appropriate size brushes."

The CMS survey also addresses "immediate use sterilization procedures," requiring that any equipment subjected to them is used "immediately and handled in a manner to prevent contamination during transport from the sterilizer to the patient." Formerly termed "flash sterilization," immediate-use sterilization has been a confusing issue subject to some differing definitions. One abiding general principle is that if you must rapidly sterilize an instrument — usually in an effort to return it to the sterile field — you must immediately use it.

"If you do everything that you are supposed to — and that is a big if — remove the bioburden, get off all the blood and the tissues, rinse it off properly and sterilize it according to the recommended sterilization cycle of the instrument — it's sterile," says **Patti Grant**, RN, BSN, MS, CIC, an infection preventionist in Addison, TX. "The challenge with immediate-use sterilization is getting the sterile instrument from the autoclave to the patient's OR suite without bumping into anybody, without air currents putting stuff on it, somebody sneezing on it. The trick is in the transport."

In that regard, Seavey says the CMS should consider adding more detailed language in the transport of immediate-use items.

"I would really like to see them be a little more specific about that, like saying that it should be covered with a rigid container — the product is put in there before it is sterilized," Seavey says. "That is what the AORN recommends."

Other survey areas apply to reprocessing

The CMS survey dedicates seven pages to

reprocessing issues but there are also other aspects of the survey that apply to central services. One example is the CMS survey's overall emphasis on "non-punitive" policies protecting workers who express concerns regarding patient safety and infection control.

"If you have a process failure — a positive biological [indicator] for example — that you think is unsafe it is important to be able to report it without fear of recrimination," Seavey says. For example, there can be logistical problems with "loaner" instrumentation that imperil patient safety.

"If we don't get those in time to adequately reprocess them and run biological indicators — then it might be 'guess work,'" she says. "We're in a hurry to turn them over, but we should have the authority — and not be punished — to say to the surgeon and the OR: 'Listen, I am not going to be able to get those instruments to you in time because I did not get them in time. I wasn't given, for example, 48 hours.'"

In addition, the CMS section on personal protective equipment (PPE) certainly applies to central services workers, she emphasizes. The hazards of exposure to body fluids and chemicals are clear, but that does not always translate to the workers being provided with the proper equipment and trained in its appropriate use.

"Who needs PPE more than somebody working in sterile processing," Seavey says. "But often times it is not adequately worn or they don't have the right PPE like extra-heavy duty gloves and fluid-resistant face masks — not just surgical masks."

To meet this need, it is important to have someone from central services on the hospital product evaluation committee. "That's where infection preventionists can help. Make sure that there is a representative from sterile processing," she says.

Likewise, the length of time that a given product will take to reprocess is critical, as that could affect labor and staffing needs. The time to address this is "before you actually purchase the devices, when you have the clout to make sure that this happens," she says.

It is also important to remember the CMS survey includes non-critical medical equipment and other possible vectors for contamination and potential infection. "It is not just sterile instruments, but also patient care equipment like pumps and other [medical equipment]," Seavey says.

In terms of inspections in general, the main phrase to keep in mind, whether it is a CMS survey, a Joint Commission visit or an in-house risk assessment: "Show me."

"Show me the written recommendations, the policy on that — don't just take people's word for it," she emphasizes. "That is what the CMS is going to do because now the biggest emphasis is on the manufacturer's instructions for use. You've got to have those. So if they are going to track something, if they are going around and interviewing, they are going to ask, 'Well, how do you know how that instrument set is cleaned? Show me those instructions for use.'"

The instructions for use, proper cleaning and sterilization must be provided by every manufacturer in order to get clearance by the Food and Drug Administration, she reminds.

By the same token, CMS surveyors will be looking for the manufacturer's instructions for the appropriate use and proper disposal of detergents and cleaning solutions — an area that could be overlooked, she said. "So many times we go into facilities and they may be using the right type of detergent, but are they using the right concentration?" Again, the prescriptive nature of the CMS survey could lead to a surveyor saying, "Show me. How do you know that is the right type of detergent for that kind of equipment?" Seavey says.

Log it now to avoid headaches later

Another important area is use of a log for recording each procedure specific to the scope or similar equipment, pieces of information that may be critical to avoid the massive headache of huge follow-up programs if the potential for contamination is discovered.

"You may not have always identified the specific endoscope that was used on that specific patient, but that's what you need to do," she says. "Each one has a serial number, so you should be identifying that [scope with the specific patient.]"

If some concern arises about inadequate processing or possible transmission of infection surfaces, "you don't have to alert 20,000 patients. You just alert the patients that particular scope was used on," she says.

Similarly, if you have five basic tonsillectomy instrument sets for OR use, they each should be clearly labeled with their respective numbers so you know which set was used on which patient, Seavey says.

A "hot button" issue that may come up during a CMS survey is the proper use and processing of laryngoscopes, she adds.

"Laryngoscopes need to be either sterilized or high-level disinfected because they touch mucous membranes," Seavey says. "Too many times they aren't. Even if they are high-level disinfected between patients, they may be [inappropriately] stored in a box containing a bunch of them. You really should be packaging them individually."

The CMS survey places appropriate emphasis on implantable items, with clear requirements for use of a biological indicator in processing, see adds. While prosthetics and other implantables have a well-known risk of infection, it is just as important to emphasize an area that can easily be overlooked: routine maintenance.

"So many times our equipment is not maintained the way it should be," she says. "It just like our cars, if we want them to run right we have to make sure that they are maintained. So I'm glad to see that they are mentioning that and requiring that the records be actually available." ■

Hospital program leads to dramatic drop in CAUTIs

Four-fold focus includes removal protocol

Looking for a quality improvement (QI) project targeting catheter-associated urinary tract infections (CAUTIs)? Here's one that produced dramatic results, including a 68% decline in the CAUTI rate and a 20% reduction in the use of indwelling urinary catheters. Also, 90% of the nursing staff completed a nursing indwelling urinary catheter skills competency.

Overall, the hospital-acquired CAUTI rate decreased from 3.09 to 0.99/1000 IUC days.

"Our goal was to improve the safety at our facility and we did that in a pretty rapid manner," says **Elaine Flynn**, RN, MSN, CIC, Infection Preventionist for Moss Rehab, which is part of Albert Einstein Healthcare Network in Philadelphia, PA.

A catheter-associated UTI can extend a patient's hospital stay by one to two days and increase the cost of their care by some $750-$1500. In many cases, Medicare and other insurers regard CAUTIs as a preventable condition. CMS may not reimburse the hospital for the additional costs associated with treating the infection.

Flynn and colleagues compared their hospital's urinary catheter practices to those identified in the 2008 Compendium of Strategies to Prevent Healthcare-Associated Infections published by the Society for Healthcare Epidemiology of America (SHEA). The SHEA guidelines outline best practices to prevent catheter-associated urinary tract infections (CAUTI) in hospitals.[1]

The UTI Prevention team found areas where the hospital could improve its practices, so they decided to tackle the initiative as a multidisciplinary team project. A team of health care providers including physicians and nurses volunteered to participate on the CAUTI Prevention Team, adopting the Plan–Do–Study–Act quality model for the process.

Over an 18-month period the CAUTI Prevention team identified key evidence-based practices to prevent the infections. They broke the mission into four key areas, which were in turn targeted by four work groups:

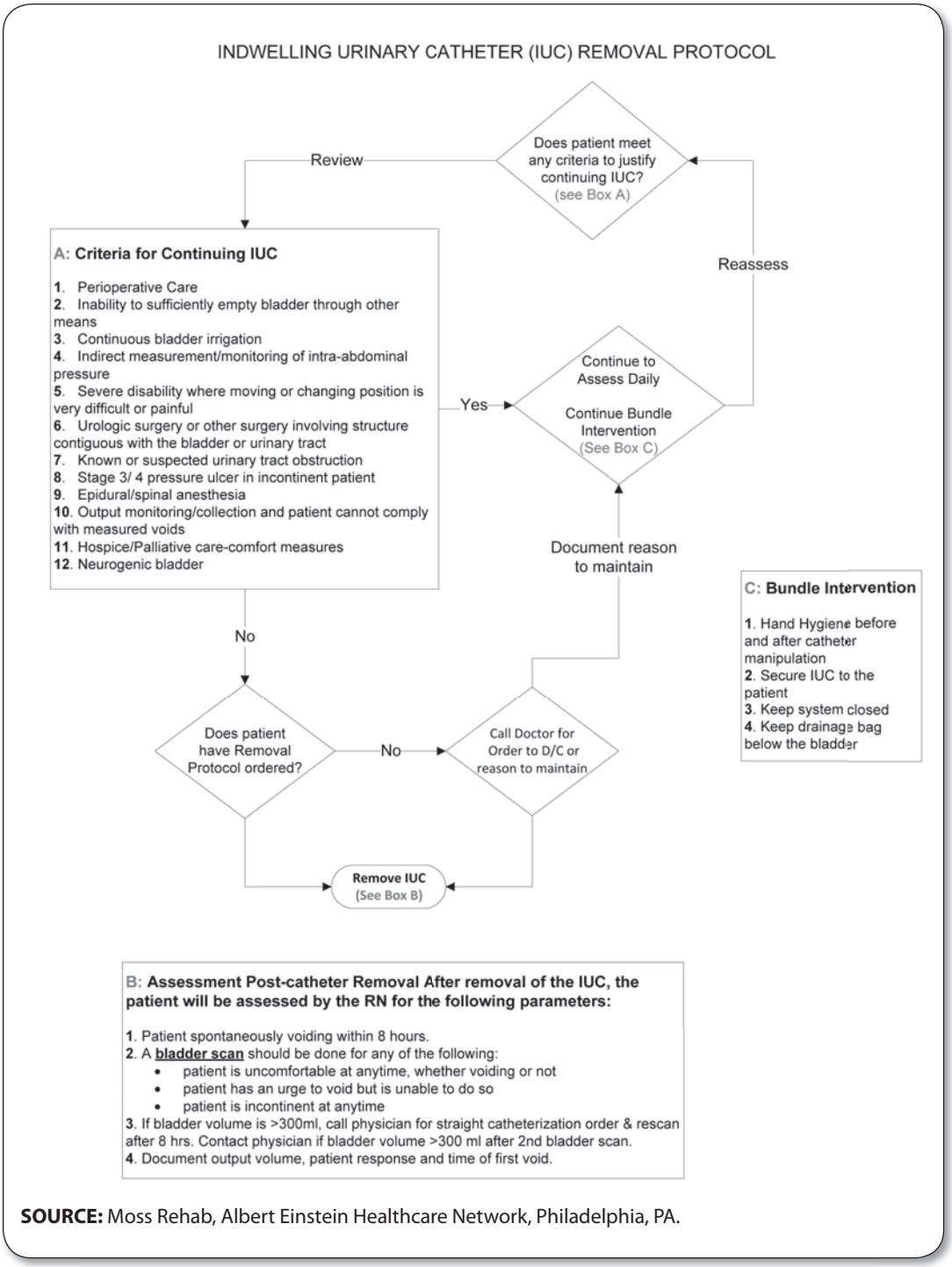
1. Develop written guidelines for urinary catheter insertion and maintenance. Clinicians armed with guidelines or a checklist based on clinical indications often have better compliance and better outcomes, Flynn notes. The bladder management work group identified evidenced-based practices for insertion and maintenance of indwelling urinary catheters. These included performing hand hygiene before and after insertion, aseptic technique, using the smallest size urinary catheter that is appropriate, using a closed system catheter, securing the catheter and placing the drainage bag below the bladder.

Process measures to monitor catheter maintenance include:

- Is there a written clinical indication for the catheter?
- Is urinary catheter stabilized?
- Is the urinary drainage system closed?
- Is the urinary drainage bag below bladder?
- On rounds, reassess clinical indication for the catheter.

2. Document guidelines and order sets. "We created an order set that physicians use to identify patients and the clinical indications," Flynn says. "There's a medical form used as a checklist to ensure patient safety."

If the patient comes in with an indwelling urinary catheter the history and physical must reflect that they have one and why. They have to list the clinical indication. The physician also has to order an indwelling urinary catheter on an order set. Nurses have to make a daily review and document the



SOURCE: Moss Rehab, Albert Einstein Healthcare Network, Philadelphia, PA.

continued clinical indication for the urinary catheter.

"Our goal was to avoid unnecessary urinary catheter insertions," Flynn says. "Each day that a urinary catheter is in place there's an increased risk for a urinary tract infection."

The documentation guidelines/order set work group developed a nurse-driven protocol that will allow nurses to remove indwelling urinary catheters that are not indicated clinically. Also, there is a reminder embedded in the electronic medical record for catheter removal when it is no longer clinically indicated.

Nurses can refer to a catheter removal flow chart, which outlines the steps to take given different scenarios. (*See diagram on this page.*)

Outcomes data, including number of HA-CAUTIs per 1,000 device days and catheterization utilization rates, are provided to the shared governance council, the physician group, and the nursing unit each month. The report explains the device utilization rate and the HA-CAUTI rate.

3. Provide urologic equipment. The hospital switched from having nurses collect four packages to create the urinary indwelling catheters to having all the pieces in one kit.

"We had urinary indwelling catheters that would be in one package, while another package had the bag, another one had the stabilization device, and still another the insertion tray," Flynn says.

In addition, the various packages often were not stored in the same area or available at the same time. This complex process increased the risk for contamination and infection, so the hospital switched to a closed urinary catheter system, which has the catheter pre-attached to the drainage bag with a stabilization device within it.

"So when nurses go into the clean utility room to get the catheter, they pull out one package with all of those products in it," Flynn

says. "This means there is better compliance and less risk of contamination."

Plus it saves nurses time because they can pick up one box at one location, only needing to decide what size to select, she adds.

"It costs more, but the return on investment is reduced hospital-acquired infections, which is important for patient safety and provides better care," Flynn says.

Another equipment change was to have ultrasound bladder scanners added to each area. When patients no longer have clinical indications for catheters they are removed, and nurses monitor patients to make certain they could urinate. If there is no evidence of the patient urinating, nurses use the scanner to see if the bladder is empty. If so, no further catheterization is necessary.

"We did an assessment of how many bladder scanners were available and made a request to purchase additional ones to make certain every nurse had access to one," she adds.

4. Educate to ensure competency in all areas. Physician members of the CAUTI prevention team presented an education program to medical staff and residents in the various specialties, including departments of surgery, internal medicine, geriatrics, and others. The program focused on UTI prevention, implementation of the clinical indication for insertion and documentation requirement, and the daily documentation of the need for a catheter.

Nurses were trained on the procedure of inserting catheters and evidence-based practices to ensure prevention of UTIs. These were self-learning modules for both licensed nurses and non-licensed staff. Licensed staff were trained on all UTI prevention strategies, including utilization documentation and how to insert urinary catheters. Nonlicensed staff were trained on maintenance features, including hand hygiene and CAUTI prevention.

"We created an education group and education plan and competency for our nursing staff," Flynn says. "It was an education module with a test at the end."

REFERENCES

1. Lo E, Nicolle L, Classen D, et al. Strategies to Prevent Catheter-Associated Urinary Tract Infections in Acute Care Hospitals. *Infect Con Hosp Epi* 2008;29(supl 1):S41-S50. ■

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%.
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5. Once the completed evaluation is received, a credit letter will be e-mailed to you instantly. ■

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. ■

COMING IN FUTURE MONTHS

- The coming impact of health care reform on infection prevention
- Never-ending story? Discontinuing contact isolation
- The expanding IP role in patient education
- The IP and social networking
- The new focus on reducing HAIs in dialysis patients

CNE/CME Questions

1. Which of the following was an infecting pathogen in two pain clinic outbreaks linked to improper use of single-dose vials?
   A. hepatitis C virus
   B. HIV
   C. hepatitis B virus
   D. Methicillin-resistant *Staphylococcus aureus*

2. According to the Centers for Disease Control and Prevention, there is never a circumstance when contents from a single-dose/single-use vial may be used for more than one patient.
   A. true
   B. false

3. According to reprocessing consultant **Rose Seavey**, RN, BS, MBA, using the wrong size brush to clean an endoscope could damage the interior surface, leading to possible:
   A. leakage during cleaning
   B. inability to use the scope on more than one patient
   C. biofilm growth
   D. all of the above

4. A project targeting catheter-associated urinary tract infections included which of the following process measures for monitoring catheter maintenance?
   A. written clinical indication for the catheter
   B. closed urinary drainage system
   C. urinary drainage bag below patient bladder
   D. all of the above