Safe Injection Practices Patient Safety Brief

Emergency Medicine Patient Safety Foundation

By: Sue Dill Calloway RN MSN JD CPHRM
Ruth Carrico PhD RN FSHEA CIC

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The Centers for Disease Control and Prevention (CDC) says there are 1.7 million healthcare-associated infections in the US every year. Of these, it is estimated that about 99,000 deaths occur as a result. Infection prevention and control is an important issue in today's healthcare environment. It is important to accreditation organizations like the Joint Commission (TJC). The Joint Commission has eight pages of standards in the chapter on Infection Prevention and Control (IC).

Infection prevention and control is also important to the Centers for Medicare and Medicaid Services (CMS). Any hospital that accepts Medicare or Medicaid has to follow the 422 page manual called the Conditions of Participation (CoPs). The CoPs were last updated December 22, 2011 and includes twelve pages of regulations and interpretative guidelines on infection control. CMS recently obtained a $50 million grant to enforce these infection control standards. In 2012, the Department of Health and Human Services will have a billion dollars to help ensure

implementation of appropriate infection prevention and control practices. HHS, as part of this grant, created an important video on preventing healthcare associated infections (HAI) that every healthcare practitioner should see. It is called “Partnering to Heal: Teaming Up Against Healthcare-Associated Infections.” It is available at no charge at www.hhs.gov/ash/initiatives/hai/training/

On October 24, 2011 CMS published a notice to utilize a three surveyor team utilizing a new worksheet for hospitals. CMS issued a revised worksheet on May 18, 2012. One of these worksheets addresses infection prevention and control and includes many of the requirements for safe injection practices set out by the CDC. The worksheet will be used after October 2012 for any hospital having an initial survey, a recertification survey or a validation survey by CMS.

The worksheet also contained a section on systems to prevent the transmission of MDRO (multidrug resistant organisms) and promotion of antibiotic stewardship. There is a section on infection control education and training. The next section is on hand hygiene. There are many other sections such as environmental services, reprocessing of semi-critical equipment, urinary catheter tracer, central venous catheter tracer, and a respiratory and ventilator tracer.

The revised worksheet has a section on injection practices and sharps safety. It contains questions that the surveyors will evaluate and ask staff to ensure compliance. Questions include is the rubber septum disinfected with alcohol before piercing? Are single dose vials, IV bags, IV tubing and connectors used on only one patient? Are needles and syringes used on only one patient? Additional questions asked include the following:

- Are multidose vials dated when opened and discarded in 28 days unless shorter time by manufacturer?
- The surveyor will make sure the expiration date is clear as per P&P.
- If a multidose vial is found in the patient care area, it must be used on only one patient.
- Are all sharps disposed of in resistant sharps container?
- Are sharp containers replaced when fill line is reached?

- Are injections prepared using aseptic technique in an area that has been cleaned and free of visible blood, body fluids, or contaminated equipment?

CMS, in the hospital CoP manual, specifically require hospitals to follow acceptable standards of care and practice. Therefore, CMS can cite a hospital for failure to follow the CDC guidelines on safe injection practices.

There have been more than 35 outbreaks of viral hepatitis in the past ten years associated with unsafe injection practices. This has resulted in the exposure of over 100,000 patients to Hepatitis B (HBV) and Hepatitis C (HCV). Unsafe injection practices includes inappropriate care and maintenance of finger stick devices and glucometers, syringe reuse, contamination of vials or IV bags and failure to utilize general safe injection practices.

Failure to follow safe injection practices can also result in a bacterial infection, including MRSA (methicillin resistant staph aureus). The July 13, 2012 CDC Morbidity and Mortality Report summarized the investigation of two outbreaks of invasive staphylococcus aureus. It occurred in ten patients who were treated in outpatient clinics for pain related problems. In each case, it involved the use of a single-dose or single-use vial (SDV) for more than one patient. Two MRSA-infected patients received epidural steroid injections. Two received contrast for a radiology procedure to guide medication needle placement. The content was drawn up with a sterile needle and syringe. The contents of each syringe was then transferred two vials. One would be used in the morning and the other in the afternoon. Three of the patients with MRSA went to the local emergency department 4-8 days after their outpatient pain procedure. They required admission for severe infections, including acute mediastinitis, bacterial meningitis, epidural abscess, and sepsis. Staff also failed to wear masks when performing spinal injections.

CMS also issued a survey and certification memo, S&C:12-35-ALL, on June 15, 2012. The name of the memo was “Safe Use of Single Dose/Single Use Medications to Prevent Healthcare-Associated Infections.” This seven page memo does not that there is an exception to the single dose medication rule. Single dose medication vials may be repackaged into smaller doses if it is done by the pharmacist following the USP 797

standards for compounding. This is because the pharmacist can do this under sterile conditions using a laminar hood following the ISO (International Organization Standards) Class 5 air quality conditions within an ISO Class 7 buffer area. This is done to prevent contamination of the medication. Single dose vials typically do not contain a preservative so these safety practices are important. For example, if a nurse in the emergency department opens up a single dose medication vials and administers the content to more than one patient, the hospital will be cited if this practice is detected. There is detailed information on the permissible repackaging of single dose vials under controlled conditions. Every hospital should ensure their pharmacists have a copy of this memo in addition to physicians and nurses. CMS said questions about this memo can be emailed at hospitalscg@cms.hhs.gov. All of the CMS policy memos are located at http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/index.html?redirect=/SurveyCertificationGenInfo/PMSR/list.asp.

The CDC has published information on safe injection practices. Safe injection practice is defined as a set of measures taken to perform injections in an optimally safe manner for patients, healthcare personnel, and others. In other words, safe injection practices are a set of recommendations a nurse or other healthcare provider should follow when an injection is given. A safe injection does not harm the recipient, does not expose the provider to any avoidable risks and does not result in waste that is dangerous for the community. Injection safety includes practices intended to prevent transmission of infectious diseases between one patient and another, or between a patient and healthcare provider, and also to prevent harm such as needle stick injuries.

The CDC has a page on Injection Safety that contains the excerpts from the 2007 CDC Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings. This document summarized ten specific practices for safe injection practices. These have been included in the below mentioned recommendations. CMS has reiterated many of these in their revised hospital infection control worksheet that has been discussed previously. This worksheet would be completed if CMS came to the hospital for a complain survey or validation survey. Hospitals that are not accredited by TJC, DNV Healthcare, or the American Osteopathic Association Healthcare Facility Accreditation Program are supposed to have a CMS survey every three years.

The CDC also issued a six page memo on April 27, 2012. The memo was called “Single-dose/Single-use Vial Position and Messages.” This memo is available at www.cdc.gov/injectionsafety/CDCposition-SingleUseVial.html. The CDC is aware of the recent issue regarding drug shortages and the increased costs to healthcare providers. The CDC reiterated that their guidelines for single dose vial or single use to be used on only one patient is to protect patients from life-threatening infections. They discuss the infectious disease outbreaks that have occurred from this process. In fact, there were at least 19 outbreaks associated with single-dose or single use medication. Unsafe injection practices put at least 130,000 patients at risk for a serious illness. (http://www.oneandonlycampaign.org/news/unsafe-injections-put-least-130000-patients-risk-serious-illness)

Recommendations for Safe Injection Practices

Risk Assessment, Policy Development and Performance Monitoring

- In an emergency department, there may be a variety of medications that are potential hazards with respect to multiple use and contamination opportunities. Lidocaine is one hazard that is easy to recognize. If multiple healthcare personnel utilize a single vial, even if it is labeled as multidose, it is critical that the vial be accessed only with a sterile needle and syringe. If multiple Lidocaine injections are needed for a single patient, the temptation is to reenter the vial with the same needle/syringe. This practice must be prevented. Therefore, policies must be written, implemented and monitored that identify situations of risk and serve to protect the patient from this preventable harm. This situation may require that policy demand that Lidocaine vials are single use only, regardless of the size of the vial or whether or not it is labeled as multidose.
- Every department has the responsibility of identifying risks to the safety of their patient population. The Emergency Department personnel must identify risks such as that involving infection transmission and develop a plan for prevention. Given the fast pace of the ED and the unpredictability of many situations, it is critical that

the workplace and workflow designs be developed with a firm eye toward patient safety.

- It is recommended that all hospital departments have a policy and procedure that clearly addresses safe injection practices and their relevance to work performed in the given department
- It is recommended that the emergency department include information regarding safe injection practices during the orientation of any new nurse or other healthcare personnel who may have medication administration as part of their job responsibility
- All hospital infection preventionists and ED nurse managers should review the revised CMS infection control worksheet. Information on the infection control worksheet should be shared with the ED physicians and staff during staff meetings
- To help ensure that staff understand and adhere to safe injection practices designate someone in the ED department to provide ongoing oversight for infection control issues and to conduct performance improvement assessments

Hand Hygiene

- Performance of hand hygiene (alcohol-based hand rub or hand washing) must be performed prior to medication preparation and medication administration.
- Perform hand hygiene before accessing IV supplies, handling vials and IV solutions as well as preparing medications

Medication Preparation

- Prepare medications in clean work areas. Avoid preparing medication in patient rooms or other areas that may promote contamination
- Make sure contaminated items are not placed near the medication preparation area
- All medication should be mixed, compounded, or diluted in designated areas such as the Pharmacy. In the pharmacy environment, medications are prepared under special conditions that

include use of laminar air flow hoods, protective equipment, and meticulous attention to environmental disinfection. Pharmacy staff must conform to acceptable standards as outlined in the USP 797.

- Medications should be stored in a manner and location that prevents tampering
- Do not keep medication in the immediate patient treatment area as that places the medication out of the immediate control of the healthcare worker and tampering/contamination may occur

Needle and Syringe Use

- Needles and syringes are single use devices and should never be used for than one patient or reused to draw up additional medications
- Manufactured prefilled syringes are single use and most do not contain a preservative. Once opened, use immediately and discard any that is left.
- A needle or other device should never be left inserted into a medication vial septum for multiple uses as this provides a direct route for microorganisms to enter the vial and contaminate the fluid

Single Dose/ Single Use Vials

- Single dose/ single use vials can only be used on one patient and not multiple patients. They have no preservative and no protection from microbial growth once accessed.
- Never combine left over contents of a medication vial for later use.
- If medication is available in a single dose vial it is recommended that the hospital purchase that option.
- If a pharmacist is going to separate a single dose vial into more than one dose, the pharmacist should follow the USP 797 guidelines covered in the June 15, 2012 CMS memo discussed above.

Multidose Vials

- Multidose vials contain a preservative that helps to inhibit microbial growth; however, poor technique can certainly lead to contamination and patient harm.

- If the drug is only available as a multidose vial it is ideal to confine its use to one patient
- All vials, single or multidose, must be accessed in a manner that protects the contents from contamination. Always use meticulous technique when piercing the septum with the needle or other access device by cleaning off the top of the vial with a sterile alcohol swab using friction for at least 15 seconds. Let the septum dry before entering the vial as contact with alcohol may be detrimental to the contents of the vial.
- Always use a new sterile needle and syringe used to access the medication vial, regardless of whether it is single use or multidose
- When a multidose vial is first opened be sure to mark the expiration date on the vial. The expiration date is usually 30 days from the date of first use.

Intravascular Devices

- An IV bag can only be used for one patient, never multiple patients
- Do not spike an IV bag until you are ready to use it
- Do not utilize an IV bag as a source for drawing multiple flushes (community bag).
- Staff should be aware of the 2011 CDC recommendations outlined in the revised “Guidelines for the Prevention of Intravascular Catheter-Related Infections” which set for the standards on how to disinfect the skin in preparation for insertion of a peripheral or midline intravenous catheter, PICC line or central line; care of those insertion sites; safe methods for accessing the devices; and strategies for early removal.

Glucose Meters, Fingerstick Devices, Insulin Pens

- Glucosemeters must be cleaned and disinfected between each patient use.
- Do hand hygiene and wear gloves during fingerstick blood glucose monitoring and other procedures involving potential exposure to blood or body fluids.
- Items contaminated with blood may not be immediately visible, but the opportunity for bloodborne pathogen transmission may still be present.
- Fingerstick devices (including the lancing device or the lancet itself) should never be used on more than person.

- Insulin pens must never be used for more than one patient, even if the needles are changed.
- CMS issued memo S&C: 12-30-ALL, on May 18, 2012 regarding the subject of “Use of Insulin Pens in Healthcare Facilities.” CMS had received reports of the use of an insulin pen on more than one patient. Insulin pens are intended to be used by a single patient only.

Safe Sharps Disposal

- Make sure every ED patient room/bay has a sharps container that is readily available at the point of sharps use
- Discard used needles and syringes in the sharps container immediately after use.
- Have a process in place that prevents overfilling of sharps containers and supports rapid replacement when the fill line is approached.

Other Safe Injection Practices

- Any procedure that involves use of a needle or syringe is part of safe injection practice. Commonly overlooked practices include lumbar puncture or spinal injection
- Any clinician performing a spinal injection procedure or lumbar puncture must wear a mask
- Use of a mask prevents inadvertent contamination of the injection device/supplies and transmission of infection (e.g., respiratory flora of the clinician) to the patient.

EMPSF is one of more than 27 organizations who have endorsed the CDC’s position on safe injection practices. A possible drug shortage or a perception about medication being wasted is not an excuse for unsafe injection practices.

Resources and Toolkits

- There are free posters and resources available from the CDC at http://www.cdc.gov/Features/InjectionSafety.
- The One & Only Campaign is a CDC public health campaign that aims to eradicate outbreaks resulting from unsafe injection practices.

More about this campaign is available at http://www.oneandonlycampaign.org/

- Safe Injection Practices toolkit is available at no charge at http://www.oneandonlycampaign.org/content/healthcare-provider-toolkit
- ASC Quality Collaboration has free toolkits on safe injection practices and point of care devices. The toolkits contain training material, sample policies, CMS expectations, monitoring tools, workplace reminders, evidence based guidelines from leading authorities and more. The toolkits are available at http://ascquality.org/advancing_asc_quality.cfm
- All of the CMS CoPs are located at www.cms.hhs.gov/manuals/downloads/som107_Appendicestoc.pdf
- The proposed and revised May 18, 2012 CMS worksheet on infection control is available off the CMS surveyor and certification website at www.cms.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopOfPage
- Information on the incidence and cost of Healthcare-associated infections (HAI) is available on the CDC's HAI website at http://www.cdc.gov/hai/
- For information about outbreaks of viral hepatitis see the APIC Position Paper: Safe Injection, Infusion, and Medication Vital Practices in Healthcare authored by Susan Dolan, Gwenda Felizardo, et al. The paper can be found in the American Journal of Infection Control 201:38;167-172. More information is also available. at www.apic.org
- The CDC safe injection practices are contained in the CDC 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings. The guideline is available at http://www.cdc.gov/hicpac/2007IP/2007isolationPrecautions.html
- CDC Frequently Asked Questions regarding Safe Practices for Medical Injections is located at http://www.cdc.gov/injectionsafety/providers/provider_faqs.html
- Infection Prevention during Blood Glucose Monitoring and Insulin Administration at http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html
- The CDC Guidelines for the Prevention of Intravascular Catheter-Related Infections 2011 is located at www.cdc.gov/hicpac/pdf/guidelines/bsi-guidelines-2011.pdf

- Information on the federal regulation USP 797 can be accessed at www.usp.org. The entire standard is available for purchase
- APIC Key Talking Points on Safe Injection Practices at http://apic.informz.net/apic/archives/archive_272235.html
- IP Tools, a wonderful website for information sharing among infection preventionists at http://www.infectionpreventiontools.com/home
- AORN 2012 Perioperative Standards and Recommended Practices Recommended Practices for Medication Safety (recommends against multi-dose vials and IV solutions should be punctured as close as possible to the time of use)
- The CDC Position on SDVs (single dose vials) is located at http://www.cdc.gov/injectionsafety/CDCposition-SingleUseVial.html and CDC Outbreaks in Outpatient Settings at http://www.cdc.gov/HAI/settings/outpatient/outbreaks-patient-notifications.html
- The ASHP Foundation (American Society of Hospital Pharmacist) offers a tool for assessing contractors who provide sterile products which healthcare facilities may find useful. See http://www.ashpfoundation.org/MainMenuCategories/PracticeTools/SterileProductsTool.aspx and click on "Start using Sterile Products Outsourcing
- Invasive *Staphylococcus aureus* Infections Associated with Pain Injections and Reuse of Single-Dose Vials — Arizona and Delaware, MMWR Weekly, July 13, 2012, at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6127a1.htm?s_cid=mm6127a1_w
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meningitis. Atlanta, GA: US Department of Health and Human Services, CDC; 2011. Available at http://www.cdc.gov/injectionsafety/spinalinjection-meningitis.html