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A Note about Pharmacy Settings

While the use of aseptic technique when preparing and administering injectable medications is applicable to all healthcare settings, including pharmacy areas, these FAQs are not intended to reflect the standards and recommended practices for handling medication vials and related products in pharmacy settings—these should be determined in accordance with the state boards of pharmacy, the United States Pharmacopeia (USP), the **Drug Enforcement Agency** (DEA), and the Food and Drug Administration (FDA). Please visit http://www. cdc.gov/injectionsafety/ providers/provider_faqs. html for updates or additional information. Published March 1, 2011.

FAQs

FREQUENTLY ASKED QUESTIONS (FAQs) REGARDING SAFE PRACTICES FOR MEDICAL INJECTIONS

Background

Injection safety, or safe injection practices, is a set of measures taken to perform injections in an optimally safe manner for patients, healthcare personnel, and others.

The Standard Precautions section of the <u>2007 Guideline for Isolation Precautions</u> provides evidence-based recommendations for safe injection practices and reflects the minimum standards that healthcare personnel should follow to prevent transmission of infections in healthcare settings.

Despite these recommendations, outbreaks and patient notifications resulting from healthcare personnel failing to adhere to Standard Precautions and basic infection control practices continue to be reported. Unsafe injection practices that have resulted in disease transmission have most commonly included:

- Using the same syringe to administer medication to more than one patient, even if the needle was changed or the injection was administered through an intervening length of intravenous (IV) tubing 1.2;
- Accessing a medication vial or bag with a syringe that has already been used to administer medication to a patient, then reusing contents from that vial or bag for another patient³⁻⁶;
- Using medications packaged as single-dose or single-use for more than one patient⁷⁻⁹;
- Failing to use aseptic technique when preparing and administering injections 10-12

For these reasons, CDC reminds healthcare personnel of the following practices that are critical for patient safety:

- Follow proper infection control practices and maintain aseptic technique during the preparation and administration of injected medications (e.g., perform hand hygiene).
- Never administer medications from the same syringe to more than one patient, even if the needle is changed.
- · Never enter a vial with a used syringe or needle.
- · Do not use medications packaged as single-dose or single-use for more than one patient.
- Do not use bags of intravenous solution as a common source of supply for more than one patient.
- · Limit the use of multi-dose vials and dedicate them to a single patient whenever possible.
- Always use facemasks when injecting material or inserting a catheter into the epidural or subdural space.

The following FAQs summarize inquiries received by CDC from healthcare personnel regarding safe use of needles, syringes, and injectable medications in patient care settings. Wherever possible we have attempted to provide examples of outbreaks or patient notification incidents that support the guidance offered in these FAQs. An extensive reference list is included at the end of this document.

These FAQs are not intended as a comprehensive resource for all safe injection practices and additional considerations may be necessary for certain clinical scenarios or settings. Healthcare personnel are encouraged to consult the Standard Precautions section of the 2007 Guideline for Isolation Precautions to ensure that their practices adhere to the basic principles of infection control and aseptic technique. Additional information applicable to specific clinical settings or procedures may be available from professional organizations.



GENERAL QUESTIONS

1. What is injection safety?

Injection safety, or safe injection practices, is a set of measures taken to perform injections in an optimally safe manner for patients, healthcare personnel, and others. 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 (e.g., through inappropriate disposal of injection equipment)¹³. 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 harms such as needlestick injuries.

2. What is aseptic technique?

In this context, aseptic technique refers to the manner of handling, preparing, and storing of medications and injection equipment/supplies (e.g., syringes, needles and IV tubing) to prevent microbial contamination. See additional FAQs below for details on aseptic technique.

3. What are some of the unsafe injection practices that have resulted in transmission of pathogens?

The most common practices that have resulted in transmission of hepatitis C virus (HCV), hepatitis B virus (HBV) and/or other pathogens include:

- Using the same syringe to administer medication to more than one patient, even if the needle was changed or the injection was administered through an intervening length of intravenous (IV) tubing^{1,2};
- Accessing a medication vial or bag with a syringe that has already been used to administer medication to a patient, then reusing contents from that vial or bag for another patient³⁻⁶;
- Using medications packaged as single-dose or single-use for more than one patient⁷⁻⁹;
- Failing to use aseptic technique when preparing and administering injections¹⁰⁻¹².

4. What are some procedures that have been associated with unsafe injection practices?

Unsafe injection practices that put patients at risk for HBV, HCV and other infections have been identified during various types of procedures. Examples include:

- Administration of sedatives and anesthetics for surgical, diagnostic, and pain management procedures;
- Administration of IV medications for chemotherapy, cosmetic procedures, and alternative medicine therapies;
- · Use of saline solutions to flush IV lines and catheters;
- · Administration of intramuscular (IM) vaccines.

The medications used in these procedures were in single-dose or single-use vials, multi-dose vials, and bags. What they had in common was the vials or bags were used for more than one patient and were entered with a syringe that had already been used for a patient; or the syringe itself was used for more than one patient.

5. Can some of these unsafe injection practices also result in transmission of bacterial infections?

Yes. These unsafe injection practices put patients at risk for bacterial, fungal, viral, and parasitic infections.

6. Is it acceptable to visually inspect syringes to determine whether they are contaminated or can be used again?

No. Just because blood or other material is not visible in a used syringe or IV tubing does not mean the item is free from potentially infectious agents. Pathogens including HBV, HCV, and human immunodeficiency

virus (HIV) can be present in sufficient quantities to produce infection in the absence of visible blood. Similarly, bacteria and other microbes can be present without clouding or other visible evidence of contamination. All used injection supplies and materials are potentially contaminated and should be discarded.

7. How can healthcare personnel ensure that injections are performed correctly?

To help ensure that all healthcare personnel understand and adhere to safe injection practices, we recommend the following:

- 1. Designate someone to provide ongoing oversight for infection control issues;
- 2. Develop written infection control policies;
- 3. Provide training;
- 4. Conduct quality assurance assessments



MEDICATION PREPARATION QUESTIONS

1. How should I draw up medications?

Parenteral medications should be accessed in an aseptic manner. This includes using a new sterile syringe and sterile needle to draw up medications while preventing contact between the injection materials and the non-sterile environment. Proper hand hygiene should be performed before handling medications and the rubber septum should be disinfected with alcohol prior to piercing it.

2. Where should I draw up medications?

Medications should be drawn up in a designated clean medication area that is not adjacent to areas where potentially contaminated items are placed. Examples of contaminated items that should not be placed in or near the medication preparation area include: used equipment such as syringes, needles, IV tubing, blood collection tubes, needle holders (e.g., Vacutainer® holder), or other soiled equipment or materials that have been used in a procedure. In general, any item that could have come in contact with blood or body fluids should not be in the medication preparation area.

3. Is it acceptable to leave a needle inserted in the septum of a medication vial for multiple medication draws?

No. A needle should never be left inserted into a medication vial septum for multiple uses. This provides a direct route for microorganisms to enter the vial and contaminate the fluid.

4. Is it acceptable to leave a needle inserted in the septum of a medication vial for multiple medication draws?

The safest practice is to always enter a medication vial with a sterile needle and sterile syringe. There has been at least one outbreak attributed to healthcare personnel using a common needle and syringe to access multiple multi-dose vials for the purpose of combining their contents into a single syringe¹⁴. If one vial becomes contaminated, this practice can spread contamination to the others, prolonging presence of the pathogen and increasing the potential for disease transmission. Syringe reuse in this fashion may also have been a factor in additional outbreaks⁹.

While it is not recommended to use the same needle and syringe to enter more than one medication vial because of the risks described above, there are circumstances where more than one vial may need to be entered with the same syringe and needle (e.g., when reconstituting medications or vaccines). In these circumstances, aseptic technique must be followed and reconstitution should be performed in a designated clean medication area that is not adjacent to areas where potentially contaminated items are placed.



MEDICATION ADMINISTRATION QUESTIONS

1. Is it acceptable to use the same syringe to give an injection to more than one patient if I change the needle between patients?

No. Once they are used, the syringe and needle are both contaminated and must be discarded. Use a new sterile syringe and needle for each patient.

2. Is it acceptable to use the same syringe to give an injection to more than one patient if I change the needle between patients and I don't draw back before injecting?

No. A small amount of blood can flow into the needle and syringe even when only positive pressure is applied outward. The syringe and needle are both contaminated and must be discarded.

3. If I used a syringe only to inject medications into an IV tubing port that is several feet away from the patient's IV catheter site, is it acceptable to use the same syringe for another patient?

No. Everything from the medication bag to the patient's catheter is a single interconnected unit. All of the components are directly or indirectly exposed to the patient's blood and cannot be used for another patient. A syringe that intersects through ports in the IV tubing or bags also becomes contaminated and cannot be used for another patient. Separation from the patient's IV by distance, gravity and/or positive infusion pressure does not ensure that small amounts of blood are not present in these items.

4. Is it acceptable to reuse a syringe and/or needle to enter a medication vial for the same patient if the medication vial and the syringe will be discarded at the end of the procedure and not used for subsequent patients?

The safest practice is to always enter a medication vial with a sterile needle and sterile syringe, even when obtaining additional doses of medication for the same patient. This adds an extra layer of safety in case, for some reason, the medication vial is not discarded at the end of the procedure as it should be and is inadvertently used on a subsequent patient.

There have been multiple outbreaks resulting from healthcare personnel reusing syringes to access medications for a single patient and then using contents from that vial or bag for subsequent patients³⁻⁴. In some of these outbreaks, healthcare personnel believed that they were being careful and their intention was to discard the vial or bag at the end of the procedure; however, this did not always occur and contents from the vial or bag were inadvertently used for subsequent patients⁵.

5. Is it acceptable to use the same syringe and/or needle to administer multiple injections to the same patient (e.g., in the case of numbing a large area of skin or to provide incremental doses of intravenous medication)?

The safest practice is for a syringe and needle to be used only once to administer a medication to a single patient, after which the syringe and needle should be discarded. This practice prevents inadvertent reuse of the syringe and protects healthcare personnel from harms such as needlestick injuries.

However, when this is not feasible (e.g., when administration of incremental doses to a single patient from the same syringe is an integral part of the procedure), reuse of the same syringe and needle for the same patient should occur as part of a single procedure with strict adherence to aseptic technique. In such situations it is essential that the syringe never be left unattended and that it be discarded immediately at the end of the procedure.

There have been situations of disease transmission and recent patient notification events in the setting of unintentional syringe reuse after a syringe was not immediately discarded following use on a patient^{2,15}. Please visit http://www.cdc.gov/injectionsafety/providers/provider_faqs.html for updates or additional information. Published March 1, 2011.

QUESTIONS ABOUT SINGLE-DOSE/SINGLE-USE VIALS

1. What is a single-dose or single-use vial?

A single-dose or single-use vial is a vial of liquid medication intended for parenteral administration (injection or infusion) that is meant for use in a single patient for a single case/procedure/injection. Single-dose or single-use vials are labeled as such by the manufacturer and typically lack an antimicrobial preservative.

ONE NEEDLE, ONE SYRINGE, ONLY ONE TIME. Safe Injection Practices Coalition www.ONE and ONLY campaign.org

2. 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 healthcare personnel using single-dose or single-use vials for multiple patients^{3,6-9}.

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, healthcare personnel should select the smallest vial necessary for their needs when making purchasing decisions.

3. How many times may individual single-dose or single-use vials be entered for a single patient?

The safest practice is to enter a single-dose or single-use vial only once so as to prevent inadvertent contamination of the vial and infection transmission. Single-dose or single-use vials should be used for a single patient and a single case/procedure/injection. Therefore, they should require only a single entry into the vial.

However, in certain situations, healthcare personnel may believe that drawing the entire contents of the vial into a single syringe will not allow for safe and accurate titration of dosage (e.g., pediatric dosing during a surgical procedure). In these circumstances, healthcare personnel must consider the risk of repeated entry into a single-dose or single-use vial for that single patient/procedure.

If the single-dose or single-use vial will be entered more than once for a single patient as part of a single procedure, it should be with a new needle and new syringe, and the vial must be discarded at the end of the procedure and not stored for future use.

4. 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 use⁸.

5. 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. Please visit http://www.cdc. gov/injectionsafety/providers/provider_faqs.html for updates or additional information. Published March 1, 2011.



QUESTIONS ABOUT MULTI-DOSE VIALS

1. What is a multi-dose vial?

A multi-dose vial is a vial of liquid medication intended for parenteral administration (injection or infusion) that contains more than one dose of medication. Multi-dose vials are labeled as such by the manufacturer and typically contain an antimicrobial preservative to help prevent the growth of bacteria. The preservative has no effect on viruses and does not protect against contamination when healthcare personnel fail to follow safe injection practices.

2. Can multi-dose vials be used for more than one patient? How?

Multi-dose vials should be dedicated to a single patient whenever possible.

If multi-dose vials must be used for more than one patient, they should not be kept or accessed in the immediate patient treatment area. This is to prevent inadvertent contamination of the vial through direct or indirect contact with potentially contaminated surfaces or equipment that could then lead to infections in subsequent patients. If a multi-dose vial enters the immediate patient treatment area, it should be dedicated to that patient only and discarded after use.

3. What are examples of the "immediate patient treatment area"?

Examples of the immediate patient treatment area include patient rooms or bays, and operating rooms.

4. When should multi-dose vials be discarded?

Medication vials should always be discarded whenever sterility is compromised or questionable.

In addition, the United States Pharmacopeia (USP) General Chapter 79716 recommends the following for multi-dose vials of sterile pharmaceuticals:

- If a multi-dose has been opened or accessed (e.g., needle-punctured) the vial should be dated and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial.
- If a multi-dose vial has not been opened or accessed (e.g., needle-punctured), it should be discarded according to the manufacturer's expiration date.

The manufacturer's expiration date refers to the date after which an unopened multi-dose vial should not be used. The beyond-use-date refers to the date after which an opened multi-dose vial should not be used. The beyond-use-date should never exceed the manufacturer's original expiration date.

For information on storage and handling of vaccines please refer to the CDC Vaccine Storage and Handling Toolkit: http://www2a.cdc.gov/vaccines/ed/shtoolkit/ or the manufacturer's recommendations for specific vaccines.

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The Safe Injection Practices Coalition (SIPC) is a partnership of healthcare-related organizations led by the Centers for Disease Control and Prevention. The SIPC developed the *One & Only Campaign*—a public health effort to eliminate unsafe medical injections by raising awareness of safe injection practices. For a list of SIPC Partners, more information about the Campaign, and to view additional resources including videos and other materials, please visit:

OneandOnlyCampaign.org





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