A CONTINUING EDUCATION MONOGRAPH FOR PHARMACISTS

Addressing a Trifecta of Overlooked IV Medication Risks

Understanding and Managing IV Container Overfill
Michael R. Cohen, RPh, MS, ScD, FASHP, President, ISMP

Unsafe Intravenous Medication Dilution at the Bedside
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Regulatory and Accreditation Requirements for Syringes, Needles, and Vials
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A ProCE-publication

INSTITUTE FOR SAFE MEDICATION PRACTICES
www.ismp.org

ADDRESSING A TRIFECTA OF OVERLOOKED IV MEDICATION RISKS

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ACTIVITY DESCRIPTION

The causes of intravenous (IV) medication preparation and administration errors are many, but during the past year the Institute for Safe Medication Practices and other healthcare organizations have identified three specific categories of risk that have been largely unnoticed and inadequately addressed by most healthcare organizations. This activity is designed to help participants address: a failure to consider IV container overfill when preparing certain IV drug infusions; unnecessary dilution of IV medications at the bedside; and unsafe use of syringes, needles, and vials. This monograph describes these risky practices, clarifies misperceptions regarding regulatory requirements, and provides practical recommendations to prevent errors.

LEARNING OBJECTIVES

The target audience for this activity is pharmacists in health-system settings. Upon completion of this activity, the reader will be able to:

- Identify conditions that require pharmacists to consider IV container overfill when preparing IV admixtures.
- Describe a standard process that can be implemented for IV admixtures that factors in IV container overfill and produces a label that guides nurses to deliver the correct volume associated with the prescribed dose.
- List three reasons that nurses might dilute adult IV medications unnecessarily before administration.
- Describe strategies to increase awareness of the risks associated with diluting adult IV medications and reduce its occurrence.
- Discuss regulatory and accreditation requirements that promote safe use of vials.
- List three ways that pharmacists can guide nurses to follow safe injection practices.

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Release Date: March 6, 2015
Expiration Date: March 6, 2017

FUNDING

This activity is funded through an educational grant from **Hospira, Inc**.

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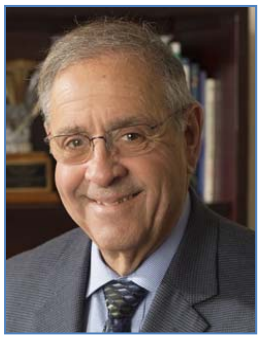

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Dr. Cohen previously served as Vice Chair of the Patient Safety Advisory Group for The Joint Commission (creates the National Patient Safety Goals). He currently serves as a consultant to the FDA and is a member of the Non-prescription Drug Advisory Committee. In 2005, he was recognized as a MacArthur Fellow by the John D. and Catherine T. MacArthur Foundation. In 2008, The Joint Commission and National Quality Forum awarded Dr. Cohen the prestigious John M. Eisenberg Patient Safety and Quality Award in recognition of his life-long professional commitment to promoting safe medication practices. In 2014, he was made an honorary member of the American Society of Health-System Pharmacists.

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INTRODUCTION OF THE TOPIC

By Michael R. Cohen, RPh, MS, ScD

Intravenous (IV) drug administration is often considered the best way to deliver a precise dose of medication quickly, systemically, and in a well-controlled manner. When given intravenously, medications are delivered immediately to the bloodstream and tend to take effect more quickly than medications administered by another route.

SCOPE OF IV MEDICATION ERRORS

Despite its status as a timely and effective route, IV drug administration often poses risks because of its complexity and the multiple steps that are often required to prepare and administer the medication. Studies that have specifically focused on IV medication errors confirm a high rate of occurrence.[1-4] A systematic review and meta-analysis of nine published studies determined an overall probability of 73% for making at least one clinical error with IV medications.[4]

CAUSES OF IV MEDICATION ERRORS

According to a 2011 study, nearly 70% of all IV medications administered had at least one clinical error.[5] Findings from this study suggest that a significant proportion of IV errors were caused by either knowledge/skill deficiencies, or routine violations which were learned workplace behaviors that persisted regardless of clinical knowledge or experience. The former cause of IV errors – knowledge/skill deficiencies – is often associated with the complex preparation of IV medications; for example, chemotherapy admixtures that must account for container overfill. The latter cause of IV errors—routine violations – are often at-risk behaviors where staff unknowingly create risk or believe the risk is insignificant or justified. Examples include unnecessary dilution of medications prior to administration, reuse of a syringe after changing a needle, use of a single-dose vial to provide multiple doses, and other behavioral choices that can result in errors or contamination of medications.

HARM FROM IV MEDICATION ERRORS

The high potential for patient harm and death from IV medication errors is widely recognized.[6-14] The harmful effects may occur more rapidly and be more severe than errors with oral medications, due to the direct administration of the drug into the bloodstream, immediate onset of systemic effect, low therapeutic index of many IV medications, and difficulty reversing pharmacologic effects after IV administration. IV medications are associated with 54% of potential adverse drug events,[15] 56% of medication errors,[16] and between 25%[5] to 61%[14] of very serious, life-threatening, or fatal errors.

THREE PRIORITY AREAS

While the causes and consequences of IV medication errors are many, during the past year, the Institute for Safe Medication Practices (ISMP), along with other healthcare organizations, has identified three specific categories of risk associated with IV medication preparation and administration that have been overlooked and inadequately addressed in healthcare organizations:

1. A failure to factor in IV container overfill when preparing certain IV drug infusions for administration by nurses
2. Unnecessary dilution of IV medications at the bedside
3. Unsafe use of syringes, needles, and vials

During this learning activity, we will explore each of these problems, dispel any misconceptions regarding regulatory requirements for this area of practice, and provide practical recommendations for preventing errors with IV medications. If you have any questions or wish to contact the speakers, please feel free to send an email message to: ismpinfo@ismp.org.

UNDERSTANDING AND MANAGING IV CONTAINER OVERFILL

By Michael R. Cohen, RPh, MS, ScD

Intravenous (IV) drug administration safety is a topic that is near and dear to my heart and has been covered in many of the newsletters published by the Institute for Safe Medication Practices (ISMP). Because ISMP has been concerned about the scope and causes of IV medication errors, we held an important national summit in September 2014 with experts from around the country to examine the circumstances that have led to IV medication preparation and administration errors.[17] One key issue has been incidents in which the volume of overfill in an IV container has not been considered.

IMPACT OF OVERFILL ON CONCENTRATION

When preparing an IV admixture, overfill volumes must be factored in to determine the final concentration of a solution if the final concentration must be exact for dosing purposes. When the final concentration is necessary for dosing, as with chemotherapy and some other complex solutions, not factoring in the overfill can lead to dosing errors because the amount of drug per mL is inaccurate. Thus, patients may receive significantly more or less drug than intended.

If pharmacy staff do not account for the overfill, pharmacy labels on IV admixture products will list only the standard volume (50 mL, 100 mL, 250 mL, 1,000 mL) of the container. Many nurses are unaware of the potential overfill in an infusion bag or bottle. Thus, nurses may set an incorrect volume to be infused when programming an infusion pump. Then, when the pump alarm signals that the stated volume has been infused, the solution left in the bag or bottle due to the overfill may never reach the patient. The extra solution may be misunderstood as pharmacy accommodation for the amount of drug lost in the tubing. Again, if this is an IV medication that must be infused in its entirety to deliver the full dose, serious subtherapeutic doses can be administered.

Reported errors demonstrate that pharmacy staff may ignore the overfill in a container, or account for it incorrectly, believing the concentration is greater than or less than it is. Or, pharmacy staff may account for the overfill inconsistently and prepare IV solutions differently, even within a single pharmacy. You may remember our pharmacy colleague Eric Cropp.[18] He served a prison sentence after a chemotherapy preparation error led to the death of a young child, Emily Jerry. The error was linked to inconsistencies in the way IV admixtures were prepared in the pharmacy.

CASE PRESENTATION: CHEMOTHERAPY ERROR

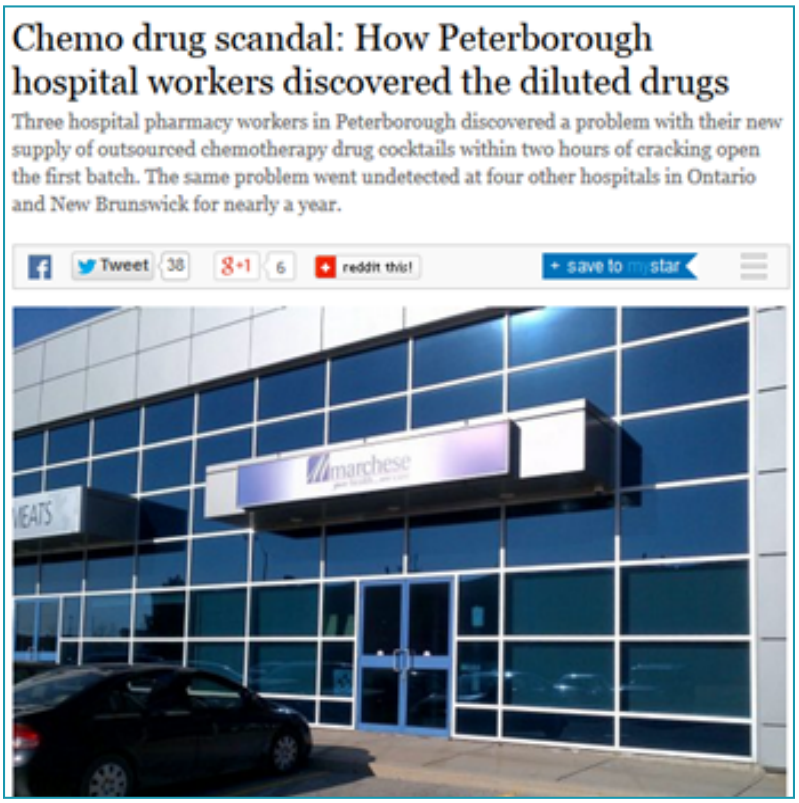
Management of overfill volume may be critical for chemotherapy because dosing is specific to the patient and type of cancer being treated. An error detected in 2013 in which overfill volume was not considered led to more than 1,200 patients receiving less potent chemotherapy than prescribed.[19-21] Larger bags of chemotherapy had been used to prepare smaller individual doses of chemotherapy, but the overfill in the bags used to prepare and administer the chemotherapy was not understood or managed.[19]

Not surprisingly, patients or family members who were contacted about receiving lower chemotherapy doses than prescribed were concerned about the effects of the error. Although it is unknown what, if any, effects the errors had on patients,[19,21] some family members who had recently lost loved ones asked whether the error might have contributed to a premature death; family responses to disclosure of the error

were particularly emotional when the cancer victim was a child.[21] Imagine being a family member and hearing that part of the dose that the patient was supposed to receive was never administered, and that loved one in your family died. It was hard to shake the thought that their loved one had died because they were undertreated.

The highly publicized error happened in Canada and made headline news (**Figure 1**).[22] The event launched several government inquiries reaching all the way up to the Canadian Parliament. The inquiries prompted health ministries to begin to address a lack of oversight of companies that supply sterile compounded preparations to hospitals.

FIGURE 1. Canadian chemotherapy error made headline news. [22]



According to ISMP Canada,[19] a group purchasing organization had recently contracted with a new compounding pharmacy to provide cyclophosphamide and gemcitabine solutions to several hospitals. These drugs were used as part of regimens to treat various solid tumor malignancies, lymphoma, and leukemia in both adults and children. Before the error, hospitals had been using a different company for years without a problem. A discrepancy in the labeling on a gemcitabine preparation between the previous supplier and the new supplier led a hospital pharmacist to ask the compounding pharmacy for clarification.

It then became apparent that there was a misunderstanding about how the compounded solutions were being used by the hospitals. The new compounding pharmacy thought each full bag of gemcitabine and cyclophosphamide contained a single dose to be administered to a single patient. But that was not the case. The hospitals were using each bag as a multidose product, apportioning the medication from a single bag among several patients. This may not be a common practice with compounded sterile preparations

from outsourcers in the US, but internally in a hospital, pharmacy staff may prepare a sterile product with the intention of using it as a source bag to prepare doses for multiple patients.

With the event in Canada, the compounding pharmacy believed each bag was a single dose and did not account for the volume of overfill in the bag when labeling the concentration of the prepared product. While the full dose in each bag was listed on the label, the actual concentration of the drug (mg per mL) in each bag was lower than stated due to overfill in the normal saline bags used to dilute the medication. The best estimate is that the average actual cyclophosphamide concentration was 10% lower than stated on the label, and the average actual gemcitabine concentration was 7% lower than stated on the label. One thousand patients were under-dosed with cyclophosphamide, and 191 were under-dosed with gemcitabine. Four patients received both oncology medications. Even though the lower doses may not have always been clinically significant, families were distraught.

Although the overall impact on patients was thought to be low, the Ontario Minister of Health and Long-Term Care issued a report,[21] making sweeping recommendations that involved improvements in group purchasing organization-based processes, sterile and non-sterile product preparation processes, and oversight of compounding pharmacies.

Sources of Overfill in Commercial Containers

Some containers used for commercially available sterile preparations may experience a loss of water depending on the storage conditions, specific contents, permeability of the container, and ratio of fluid volume to the container surface area. For example, non-PVC containers experience loss of water through evaporation, making them more concentrated over time. Once the containers have been removed from their overwraps, evaporation is more rapid. This is why we try to maintain the overwrap in place whenever possible. The amount of evaporative fluid loss may vary from one bag to another. Thus, the amount of overfill in any bag at any point in time is variable.

To compensate for fluid loss, manufacturers add overfill to the containers. Although a commercially available bag or bottle of IV solution may be labeled to contain 25, 50, 100, 250, 500, or 1,000 mL, the actual volume is larger because it contains overfill in amounts that are somewhat variable depending on the manufacturer. The volume of overfill is not standardized among various manufacturers, so there is variability in the volume of overfill between manufacturers. There is also variation in the targeted amount of overfill intended in each container based on the manufacturing process.

The three, primary US manufacturers that provide sterile preparations will supply you with estimates of the targeted overfill in various size containers. For example, **Table 1** to the left provides the volume of overfill in sterile preparations by Baxter. For example, in a Baxter 100-mL Mini-Bag Plus container, the volume is 110 mL, plus or minus 5 mL, with a range between 105 mL and 115 mL prior to any evaporation. Larger bags contain more overfill and a wider possible range. For example, a 1,000-mL bag contains 1,050 mL, plus or minus 20 mL, with a range between 1,030 mL and 1,070 mL prior to evaporation.

Table 1. Volume of Overfill in Baxter Sterile Preparations[23]	
Solution Bag Size (mL)	**Manufacturing Fill Specifications (mL)**
25	30 ± 3
50	58 ± 5
50 Pharmaceutical	54.2 + 3.0 54.2 – 2.2
50 Mini-Bag Plus	58 ± 5
100	110 ± 5
100 Mini-Bag Plus	110 ± 5
250	280 ± 15
250 Mini-Bag Plus	275 ± 10
500	547.5 ± 17.5
1,000	1050 ± 20
1500/2000 (Twin Bag)	1565 ± 27
2000 (Single Bag)	2080 ± 40
2000 (Twin Bag)	2065 + 55 2065 – 25
2500/3000	2570 + 70 2570 – 30
3000	3080 – 30 3080 + 70
3000 (TIV)	3080 ± 50
5000	5120 – 45 5120 + 105

Manufacturers periodically test the volume in each bag or bottle after production to be certain that the range of volume is not significantly wide. **Table 2** provides an example from Hospira when testing 1,000 mL containers. The actual volume varies but is within the limits of the targeted amount of 40 mL.

Table 2. Volume Testing for Hospira Sterile Preparations Overfill[24]			
Nominal Volume (mL)	**Batch**	**Average Tested Volume (mL)**	**Overfill (%)**
1000	12024JT	1038	3.8
1000	22031JT	1035	3.5
1000	24056JT	1037	3.7

Overfill is generally not a problem if the entire volume is administered or the medication in the solution is titrated to an effect. Problems arise when an exact dose must be administered, and the infusion is stopped when the volume to be infused has been reached, thus discarding the overfill.

Method of Preparing Drug Infusions Determines Concentration

In general, the preparation of a compounded sterile preparation intended for infusion involves diluting the drug with a diluent and transferring the prescribed amount of drug into a final dosage container. This can be an empty sterile syringe, small volume parenteral solution bag or bottle, or a large volume parenteral solution bag or bottle. In practice, there are several different preparation techniques that practitioners may employ. The preparation method used affects the total volume and concentration of the final product and

determines how to best manage overfill, if it exists. If the method of preparation for a specific product varies, the risk of an error during preparation is higher, and the ability to capture the preparation error during the checking process is lower.

Preparation Technique: Simple Admixture

Pharmacists are familiar with the simple admixture process. The prescribed medication is added to the manufacturer's container of base solution, such as 0.9% sodium chloride, without concern for overfill. This is typically used for the admixture of intermittently administered solutions when the entire bag is intended to be infused to a single patient over a short time (e.g., 30 minutes)—an antibiotic, for example. This method may also be used for continuous infusions where you are titrating a dose to achieve a specific effect. Because the titrated medication is being administered continuously, the actual concentration is not so important. In these cases, the slight difference in per mL concentration may not be as important because the effect of the medication is being continuously monitored. A diltiazem infusion is an example.

With preparations prepared using simple admixture, the total dose and volume of medication added to the container is known, but the concentration can only be estimated. The final container should NOT be labeled with a specific concentration per mL; an admixture label should list the total amount of drug and the total estimated volume in the container.

Preparation Technique: Withdrawal of Drug Volume

The second way of preparing a sterile preparation involves withdrawal of the drug volume from base solution. A volume of the base solution equal to the volume of the medication to be added to the container is withdrawn from the manufacturer's container, without concern about overfill. The medication is then added to the remaining volume in the container. This method is typically used when the volume of medication to be added is exceptionally large relative to the size of the base solution container, such as adding several 50-mL vials to a bag. For example, before adding 150 mL of sodium bicarbonate from a syringe or vial to a 1,000-mL bag of dextrose 5%, a volume of 150 mL of the base solution is withdrawn from the bag and discarded.

With this method, the total dose of the medication is known, but the concentration can only be estimated if the exact volume of overfill is not known. The final container should NOT be labeled with a specific concentration per mL; the label should list the total amount of drug and the total estimated volume in the container.

Preparation Technique: Withdrawal of Drug Volume and Overfill

With this technique, a volume of the base solution equal to the sum of the volume of the medication to be added to the container *and* the estimated volume of overfill is withdrawn from the manufacturer's container. The medication is then added to the remaining volume in the container. This method is typically used when the volume of medication to be added is large relative to the size of the base solution container.

The total dose of medication in the bag is known when using this method. However, the concentration can only be estimated if the exact volume of overfill is not known.

Preparation Technique: 10 Percent Rule

During preparation of infusions, the 10% rule is used by some hospitals to determine whether fluid should be removed from the bulk solution container prior to the addition of the medication. The rule suggests that if the volume of the additive medication(s) is more than 10% of the volume listed on the bulk solution container (without regard to overfill), the volume of the additive, and sometimes the volume of the overfill, will be removed. Unless starting with an empty bag (full sterile compounding), the 10% rule is often applied to all admixtures except small volume intermittent solutions such as antibiotics or other products with manufacturer-specified preparation procedures.

With this method, the total dose of the medication is known, but the concentration can only be estimated if the exact volume of overfill is not known. The final container should NOT be labeled with a specific concentration per mL; the label should list the total amount of drug and the total estimated volume in the container so the nurse can set the volume to be infused with an infusion pump, as applicable.

Preparation Technique: Full Sterile Compounding

This method starts with an empty container, and then both the measured amount of medication and base solution are added to an empty IV bag or other container. This can be accomplished using an automated compounder or manually. With this full sterile compounding method, there is no overfill. This technique may be used when both the total amount of drug in the final container and the concentration of drug need to be precise and must be accurately known, as with cancer chemotherapy. The final container can be labeled with a specific drug concentration (mg/mL) and the total amount of drug and volume in the container.

Note: Only with full sterile compounding can the concentration (mg/mL) be accurately calculated and added to the pharmacy label without the tare weight of the bag, total mass, and specific gravity (Volume=Mass / Specific Gravity). With the other preparation techniques, the total dose of the medication is known, but the concentration cannot be calculated accurately because the volume of overfill in the base solution is not exactly known – it can only be estimated. The final container for these solutions should not be labeled with a specific concentration per mL because of the unknowns. These bags should only be labeled with the total amount of drug in the container and the total estimated volume.

Other Factors That Impact Dose or Strength

Variability associated with equipment, manufacturers, and drug administration practices can also be impacted by overfill and play a role in dosing errors. For example, with equipment, there may be allowable variances in the rate by which the volume is infused by an infusion pump; for manufacturers, the amount of evaporation may vary from one IV bag to another; for drug administration practices, there may be variability among practitioners within a single facility. Many nurses are unaware of the potential overfill in an infusion bag or bottle and may stop the infusion of an intermittent dose of medication as soon as the stated volume (e.g., 150 mL) has been infused, as programmed in an infusion pump. Further, nurses who recognize that overfill might be present in a pharmacy-prepared infusion bag or bottle have often misunderstood the “extra” solution as a pharmacy accommodation for the amount of drug lost in the tubing. Thus, the 20-25 mL of solution in pump tubing sets, which may account for a significant portion of the total dose, will not be received because the bag would not be completely infused.

Overfill in Vials

Some vials of medication contain overfill that can lead to dosing errors if the overfill is not considered and used as intended. Vials of Alimta (**PEME**trexed) are an example. A pharmacist who intended to prepare an 850-mg dose of Alimta thought he needed a total of 34 mL from one 500-mg vial, three 100-mg vials, and half of a fourth 100-mg vial after reconstituting the medication to obtain a final concentration of 25 mg/mL. But the pharmacist was able to obtain 34 mL of Alimta without using the last 100-mg vial of the drug. When contacted, Lilly confirmed that the vials contain overfill, 8.5% in the 100-mg vials, and 2% in the 500-mg vials. Overfill is mentioned in the package insert, but the details are not specified. No mention of the overage is on the carton or vial label (**Figure 2**). In this instance, one vial was wasted, but the patient could have received a larger dose than prescribed.

Another example is with the Docefrez brand of **DOCE**taxel, which is available as a lyophilized powder that reconstitutes to a concentration different than most commercially available **DOCE**taxel products. Instead of a 10 mg/mL or 20 mg/mL concentration, reconstitution results in 24 mg/mL (80-mg vial) or 25 mg/mL (20-mg vial) concentrations. While the final concentration is on the label (**Figure 3**), it has been easily overlooked, leading to overdoses of the drug.

With vials of Torisel (temsirolimus), the concentration of the drug begins at 25 mg/mL (**Figure 4**), but a two-step reconstitution process results in a final concentration of 10 mg/mL (30 mg per 3 mL in the vial). The active drug vial contains 30 mg of the drug in concentrated form in a total volume of 1.2 mL (25 mg/mL). The diluent vial in the kit contains 2.2 mL, and 1.8 mL must be added to the active drug vial. This provides a total volume of 3 mL or 10 mg/mL (30 mg total), which exceeds the typical 25-mg

Figure 2. Vials of Alimta contain overfill, which is not mentioned on the carton (or vial) label.

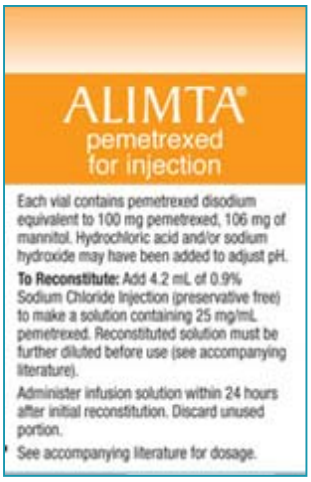


Figure 3. When reconstituted, the 80 mg vial of Docefrez actually contains 96 mg. The concentration of 24 mg/mL is different than other docetaxel products (20 mg/mL)

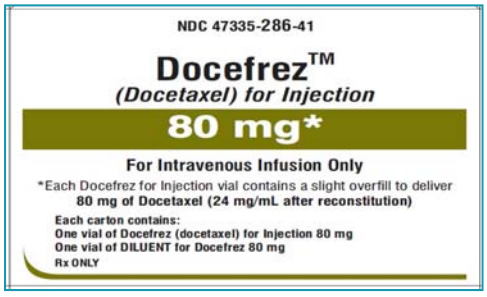
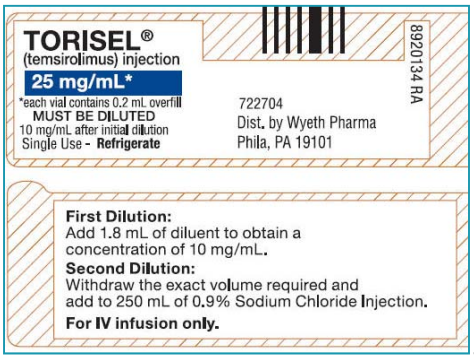


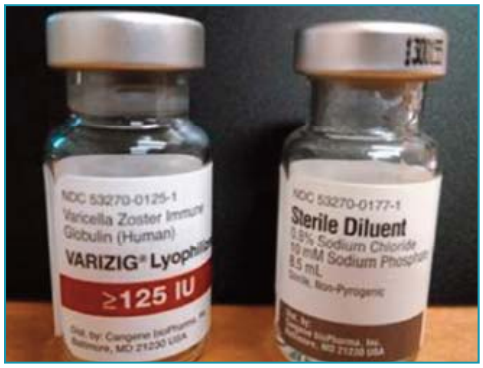
Figure 4. Torisel vials contain overfill. The active drug begins at 25 mg/mL, but reconstitution results in a final concentration of 10 mg/mL.



dose. This 20% overfill is meant to accommodate withdrawal of the medication from the vial. However, practitioners may not realize that the resultant solution is no longer 25 mg/mL but now 10 mg/mL. Both overdoses and underdoses have occurred.

The final example involves overfill of the diluent used with the Varicella zoster immune globulin, Vari**ZIG** (**Figure 5**). The product is available as a kit that contains 125 units of lyophilized powder and a single-dose vial of diluent (8.5 mL). For a single IM dose, only 1.25 mL of diluent should be used to reconstitute 125 units of lyophilized drug. Unfortunately, the entire vial of diluent has been used, and the resulting solution drawn up and administered in separate IM injections. In one recent event, a full vial of diluent (8.5 mL) was used to prepare a dose of 125 units a child who needed 125 units of the immune globulin, which required three IM injections to administer the full dose. We could also foresee a situation where the entire diluent is used to reconstitute the powder, and the practitioner assumes this provides the labeled 100 units per mL concentration, which would lead to a subtherapeutic dose.

FIGURE 5. Only 1.25 mL of the 8.5 mL of diluent in the vial is needed to prepare a dose.



A WORD ABOUT THE SYRINGE PULL-BACK METHOD OF VERIFICATION

Some pharmacies use the syringe pull-back method to verify prepared solutions. After injecting the medication into the container, the syringe plunger is pulled back to display the amount of medication or diluent that was added to the container. This is accompanied by the actual drug or diluent container that was supposed to be added to the container. The syringe pull-back method is unreliable, particularly since it relies on memory to recreate the volume of solution added to containers, and it may be unclear which syringe goes with which vial. An error report we received earlier this year serves to illustrate one of the problems with this checking system.

Magnesium sulfate 135 mg was ordered to be infused IV over 4 hours for a neonate. The pharmacy production label correctly stated that 135 mg of magnesium sulfate 50% (0.27 mL) should be added to 5.13 mL of 0.9% sodium chloride injection, which would provide a total volume of 5.4 mL. Due to a shortage of magnesium sulfate, the pharmacy did not have 2-mL vials, so 50-mL vials were used to prepare the dose. A pharmacy technician transposed the directions and mixed 0.27 mL of 0.9% sodium chloride with 5.13 mL of magnesium sulfate 50%, which was available from the 50-mL vial. The pharmacy always used the syringe pull-back method for checking all admixtures, but in this case, the method did not identify this serious error. When checking the two syringes, one was drawn back to 0.27 mL and one was drawn back to 5.13 mL. The magnesium vial and the 0.9% sodium chloride vial were placed near the syringes. But the placement of the syringes did not make it clear which syringe was associated with which vial. The pharmacist who checked the product reversed the syringes and thought the correct amount had been pulled back for each.

RECOMMENDATIONS

Healthcare organizations must develop standardized preparation methods appropriate for various clinical situations. There is no single, standard method appropriate for all infusions in all hospitals, particularly given the variability in environmental conditions, staff expertise, and technology among health providers. However, consider the following points when designing processes in your hospital for admixture and sterile compounding.

- **Clearly define the processes.** Choose the most appropriate method of preparing each medication infusion according to whether or not the volume (and therefore the concentration) is critical. Start by developing a list to identify medications and situations for which added accuracy in dose or concentration is needed and the level of accuracy required. This list will help determine which preparation method should be used for specific drugs. Also, obtain a list of overfill amounts of commonly used products from vendors for reference as necessary.

Whatever method is chosen for preparing sterile preparations, it is critical to be consistent within your organization. In particular, variability in admixture practices within a single hospital and among the same drug infusions can result in dosing inconsistencies and errors – as it did in the tragic death of Emily Jerry, whose chemotherapy was prepared using one method but assumed to be prepared using another method.[4]

- **Continuous infusions.** Medications administered by continuous IV infusion are often titrated to a desired effect (e.g., pain relief with opioids, blood pressure control with vasopressors, anticoagulation with heparin). Thus, the key strategy with these infusions is to ensure consistency in the preparation process in order to avoid variations in concentration and inconsistencies with the dose delivered. In these instances, a standard process for simple admixture may be all that is needed to ensure consistency from bag to bag and the desired therapeutic effect.

- **Intermittent single doses.** For a single dose drug infusion, the most critical aspect of the process is ensuring that the entire dose in the container is administered. Thus, the product label must be explicit regarding how to deliver the entire dose, which is dependent on the preparation process. For example, if 160 mg of **CARBO**platin (10 mg/mL) has been added directly to the IV bag without withdrawal of any solution before admixing, the label should read as follows:

CARBOplatin 160 mg (16 mL) +
0.9% Sodium Chloride (100 mL) +
OVERFILL (7 mL) = 123 mL total
Infuse entire contents for full dose

For infusions in which the dose remaining in the tubing must also be infused to deliver the entire dose (e.g., chemotherapy, neonatal medications), the product label should specify that the tubing should be flushed with a particular diluent and volume. When the rate of administration is critical, as for some IV medications given intermittently by infusion pump, ensure that information about the rate of administration and flush is built into relevant protocols and smart infusion pumps.

- **Preparations intended for multiple doses.** The preparation of medications for multiple doses (e.g., bulk preparation) ideally requires full sterile compounding of the product. Bags containing the manufacturer's base solution contain a variable amount of overfill, and specific concentrations of drugs can be prepared only by starting with an empty bag or other container. Keep in mind that an error

occurring early in the process (e.g., during medication reconstitution) may have an impact on the dose of medication received by multiple patients. Therefore, pharmacies that prepare IV medications intended for multiple doses should proactively evaluate their processes and take necessary precautions to mitigate identified risks.[25]

- **Guide the processes.** Develop protocols that specify how drug infusions should be prepared. Consider using compounding worksheets to guide the procedures for making common infusions. (In the United Kingdom, for example, a predesigned worksheet is used to ensure admixtures are prepared to exact specifications, thus standardizing the processes. This also provides documentation of compounded products.)

- **Specify on labels.** Design labels with the end user in mind. In situations where either the dose or the timeframe over which the dose is to be administered is critical, the information about dose, total volume, and concentration that appears on the label should be designed to guide the processes for administration, including the use of infusion pumps. These labels should include the total amount of drug in the total volume of solution. If the entire contents of the container must be administered to provide the specified dose, the label should also include a reminder: **INFUSE ENTIRE CONTENTS FOR FULL DOSE.**

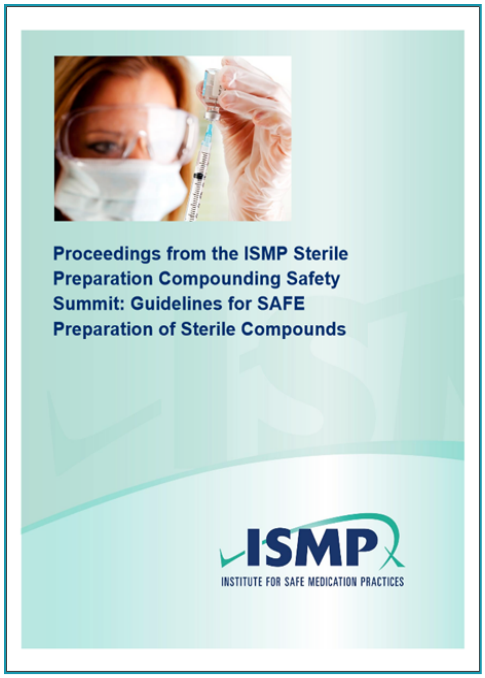
- **Avoid syringe pull-back checking method**. ISMP strongly discourages use of the syringe pull-back method of verification of IV admixtures, and it should never be used in the preparation of chemotherapy, complex or pediatric/neonatal solutions, or compounded sterile products (CSPs) with high-alert medications. For these admixtures, the base solution and additives should be verified before mixing.

- **Employ technology.** Employ pharmacy workflow technology that utilizes barcode scanning and other strategies such as imaging and automatic calculations to verify the components of preparations. Products like ScriptPro and DoseEdge, for example, come to mind. Too few health providers are actually using technology like this.

- **Use ISMP guidelines to assess practices.** Proceedings from the ISMP Sterile Preparation Compounding Safety Summit: Guidelines for SAFE Preparation of Sterile Compounds[25] are available to serve as a resource and assess current practices associated with sterile compounding (**Figure 6**).

- **Manage vial overages.** For medications that come in vials with overages that could lead to clinically significant overdoses, include warnings on medication packages, work labels, and computer systems.

FIGURE 6. Guidelines can be found on the ISMP website: www.ismp.org/Tools/guidelines/IVSummit/IVCGuidelines.pdf.[25]



UNSAFE INTRAVENOUS MEDICATION DILUTION AT THE BEDSIDE

By Judy L. Smetzer, BSN, RN, FISMP

Nurses frequently dilute intravenous (IV) medications – a practice that might be necessary depending on the drug, but also one that may unnecessarily result in repackaging of prefilled syringes or other containers provided by the pharmacy. This practice often leads to unlabeled or mislabeled syringes, potential contamination of sterile IV medications, dosing errors, and other types of drug administration errors. Gaining a nursing perspective on why medication dilution happens, how that process is carried out, and how it can result in errors or other adverse drug events can be helpful to pharmacists who want to understand the practice and facilitate changes to promote patient safety.

VIGNETTE: NURSING DILUTION

To start, consider the vignette, "A Nurse's Perspective," which depicts a few hours in the life of a nurse as she works in a critical-care setting and administers IV push medications to adults. It is a fictional glimpse into nursing practice, but it is typical of the actions and thought processes that are common among nurses who work in a fast-moving clinical setting.

The vignette elucidates why nurses might choose to dilute medications and how their reasoning reflects a desire to meet patient needs and keep patients safe. Dilution often happens as a means of overcoming barriers in the task of IV drug administration. Nurses are diluting medications for what might be perceived, in that moment, as the right reasons. Nurses face various challenges, and they solve problems with actions that, in retrospect, may not be the safest choice but are clearly a practical choice. This is an example of first-order problem solving – making quick fixes to satisfy the immediate patient care need.

A NURSE'S PERSPECTIVE

I am an experienced registered nurse working in a critical care unit, with two patients assigned to my care during my 7 p.m. to 7 a.m. shift. One is a fresh post-operative patient who had cardiac complications during orthopedic surgery, and the other is a recently admitted trauma patient involved in a motor vehicle accident.

Shortly after report from the day-shift nurse, the post-operative patient requests pain medication, experiencing 8 on 10-point pain scale. He has an order for morphine 2 mg IV every 3-4 hours. In the automated dispensing cabinet (ADC) I find 5 mg/1 mL single-use vials and 4 mg/1 mL prefilled syringes of morphine. The new post-operative orders have not yet been reviewed by a pharmacist. I remove the 4 mg/1 mL prefilled morphine syringe via override.

Given that only 0.5 mL is needed for the 2-mg dose, I plan to dilute the medication to make it easier to administer by slow IV push, which is my typical practice. I check my Intravenous Medications drug reference quickly, which recommends dilution with 5 mL of sterile water for injection (SWFI) or normal saline (NS). Since the prefilled syringe only has gradation marks to the 2.5-mL mark, I dilute the morphine with just 1 mL of normal saline from a single-dose vial (20 mL). I draw the diluent directly into the prefilled syringe. I leave the vial of sterile saline on the counter in the medication room, intending to use it for dilution of additional morphine doses throughout my shift since I don't want to waste the remaining 19 mL.

I then administer 1 mL of morphine (2 mg) slow IV push via a distal port in IV tubing connected to a peripheral IV line. After administering the drug slowly, I wonder

whether I should have used a more proximal port since the peripheral infusion is running at 150 mL/hour. I lose that thought as another nurse enters the room with critical lab values for my patient.

Finding no one nearby to witness the disposal of the remaining 2 mg of morphine in my prefilled syringe, I decide to hold onto the syringe in anticipation of the next dose requested by the patient. I look for a suitable blank label for the syringe but find none. Since I can't put the syringe back in the ADC, I keep it in my pocket given that it's a controlled substance and cannot be left unsecured.

My trauma patient has been agitated since admission and is awaiting surgery in a few hours to repair fractures of the left femur and tibia. Anesthesia orders a single 4-mg dose of IV **LOR**azepam to reduce the agitation. A pharmacist has reviewed the order, and the drug is available in the ADC. I remove a 4-mg prefilled syringe of lorazepam and administer it, not noticing the note on the label that says it must be diluted. Given that the drug is in a prefilled syringe, I have no reason to believe it is not in a ready-to-administer form. Too rapid administration of the undiluted drug leads to heavy sedation of the patient.

The critical lab values called to the unit show that the trauma patient's hemoglobin and hematocrit are dropping rapidly, and I call the patient's doctor who prescribes diagnostic tests and blood transfusions. Before the blood transfusions can be started, the patient develops a rigid abdomen, tachycardia, and hypotension. When he goes into cardiac arrest, one of the medications requested by the lead physician is phenylephrine 100 mcg IV push. The pharmacist who typically attends codes during the evening has not yet arrived. I find a 1-mL vial of phenylephrine in the code cart labeled "single dose vial." In my haste, I misread the 10 mg as 100 mcg and draw the entire 1-mL dose (100 mg) into the syringe. The pharmacist arrives and notices the error immediately as I am drawing the medication into a syringe. She quickly takes over the task, dilutes the medication, and prepares the dose correctly. My patient is resuscitated, and I am now preparing him for emergency surgery

When my post-operative patient asks for a dose of pain medication 3 hours later, I am busy with my trauma patient and ask another nurse to administer the dose. Remembering that I have a syringe in my pocket, I quickly hand her the syringe as I am wheeling my patient out of the unit to the OR. The covering nurse reads the label on the prefilled syringe and believes it contains 4 mg given its 1-mL fill. This nurse does not typically dilute the medication first, so she administers just 0.5 mL (1 mg) of the morphine, leading to uncontrolled pain. The nurse follows protocol for witnessing disposal of the remaining medication; however, the narcotic count is off since the same syringe of medication was used to administer 2 doses.

In the vignette, dilution of adult IV medications represents a nursing challenge for which there is little guidance and low recognition of the risks associated with the practice. One of the nurses wanted to dilute the morphine to make it easier to administer a small volume of drug very slowly via IV push. The medication was not available in the exact dose for the patient. Practices regarding dilution were variable; one nurse typically diluted IV-push opioid doses, and the other did not. Dilution led to unsafe practices, including reuse of a single-dose vial and a mislabeled syringe.

The nurse in the vignette was also presented with a medication in a prefilled syringe that required further dilution despite its appearance as a ready-to-use medication, and another drug without prominent labeling regarding the need to dilute the medication. The manufacturer's misleading labeling and packaging led to administration of **LOR**azepam without the required further dilution, and a near miss with phenylephrine that could have further harmed the patient. Reuse of the unlabeled syringe of diluted morphine led to another dosing error when the second nurse administered only half of the remaining volume.

Risks When Diluting IV Push Medications

These and many other issues frequently arise when a nurse believes dilution of a medication is necessary. So why are we concerned about dilution at the bedside? First, manipulation of the drug and dose is required when diluting medications. Carried out in a medication room or at the bedside, the procedure is vulnerable to errors and invites contamination.

Unknown to nurses, specific diluents may be necessary. Studies suggest that between 11% and 49% of drugs diluted at the bedside are prepared using the wrong diluent.[26,27] While many of these errors are not serious, harm could happen if a precipitate forms and the drug is administered. The labeling of syringes prepared on patient care units is often limited, absent, or incorrect. Other factors that increase the vulnerability of errors during dilution include lack of dedicated space in patient care units for preparation of the IV push medications[28] and training, knowledge, or skill deficiencies.[5,28]

Also, wide variability exists regarding when and how nurses prepare, dilute, and administer IV push medications.[28] During professional training, nurses rarely have an opportunity to gain practical experience with these skills – IV push medications are typically off-limits for many professional student nurses. The first experiences with these important tasks are during the initial employment of a graduate nurse. Thus, dilution practices are based on tradition handed down from one nurse to another, with no sound or scientific basis.[5,29] As a result, individual practices are widely variable and based on how each nurse was taught by an individual predecessor. Most of these on-the-job training sessions begin with the statement, "This is how I do it." These learned workplace behaviors persist even when nurses gain experience or new knowledge, particularly because they don't perceive the risks associated with dilution practices.[5] Thus, dilution practices are hard to change.

The last two points underscore how vulnerable dilution of IV push medications is to errors. Graduate registered nurses who are coming out of training programs do not have a lot of practical experience with IV push medications. So they are typically learning about this from other nurses who are handing down what they learned from their predecessor. Once the practices are learned, it is hard to change them, particularly if nurses do not fully understand the risks. When a problem with dilution leads to an error, safeguards are rarely in place to detect the error before it reaches the patient.

Scope of Medications Diluted

In April and May 2014, ISMP conducted a survey of registered nurses who administer IV push medications to adults to learn about dilution practices prior to IV push drug administration.[30] The survey was completed by 1,773 respondents, mostly staff-level (82%) nurses. Overall, 83% of nurses responding to our survey reported that they further dilute certain IV push medications for adult patients prior to administration.[31]

Pertaining to the containers in which IV medications are provided, medications available in single-dose vials or ampules were most often diluted (**Table 3**), as anticipated. But we were surprised by how often a manufacturer's prefilled syringes and pharmacy dispensed syringes that supposedly provide the correct dose for the patient are being further diluted before being administered. At least a quarter of nurses often or always diluted medications provided in manufacturer's prefilled syringes (e.g., Carpuject syringe, others). Pharmacists may believe that the syringe of medication containing a patient-specific dose will be administered exactly as dispensed. However, *20% of the nurses told us they further diluted even*

pharmacy-prepared medications – 12% "often" and another 8% "sometimes." Further dilution of adult IV push medications is common practice in patient care units.

Table 3. Frequency of further dilution of adult medications prior to IV push administration, by container type[31]

	Never 0%	Rarely 1-10%	Sometimes 11-40%	Often 41-95%	Always >95%
Single-dose vials and ampules	9	14	35	28	14
Multiple-dose vials	36	15	23	15	11
Manufacturer's prefilled syringes	42	15	18	15	10
Pharmacy-dispensed syringes	63	17	8	7	5

When asked about the dilution of specific drugs, opioids and antianxiety/antipsychotic medications were most frequently diluted (**Table 4**). For opioids alone, more than a quarter of respondents reported always diluting the drug before administration, and another 21% diluted the drug often. Almost half of all respondents reported they often or always dilute antianxiety/antipsychotic medications prior to IV push administration. More than 1 in 3 respondents often or always dilute antiemetics, and almost 1 in 5 respondents often or always dilute anticonvulsants or cardiovascular medications prior to IV push administration. The frequency of diluting opioids, antianxiety medications, anticonvulsants, and antiemetics was likely higher than reported, as survey respondents also included these agents under the category of "other" medications diluted, particularly **HYDRO**morphone and other "narcotics" in the opioid category, **LOR**azepam and other "benzodiazepines" in the antianxiety category, promethazine in the antiemetic category, and various barbiturates found in the anticonvulsant category. Many of these drugs are high-alert medications and can cause serious consequences to the patient if an error happens.

Table 4. Frequency of further dilution of adult medications prior to IV push administration, by type of medication[31]

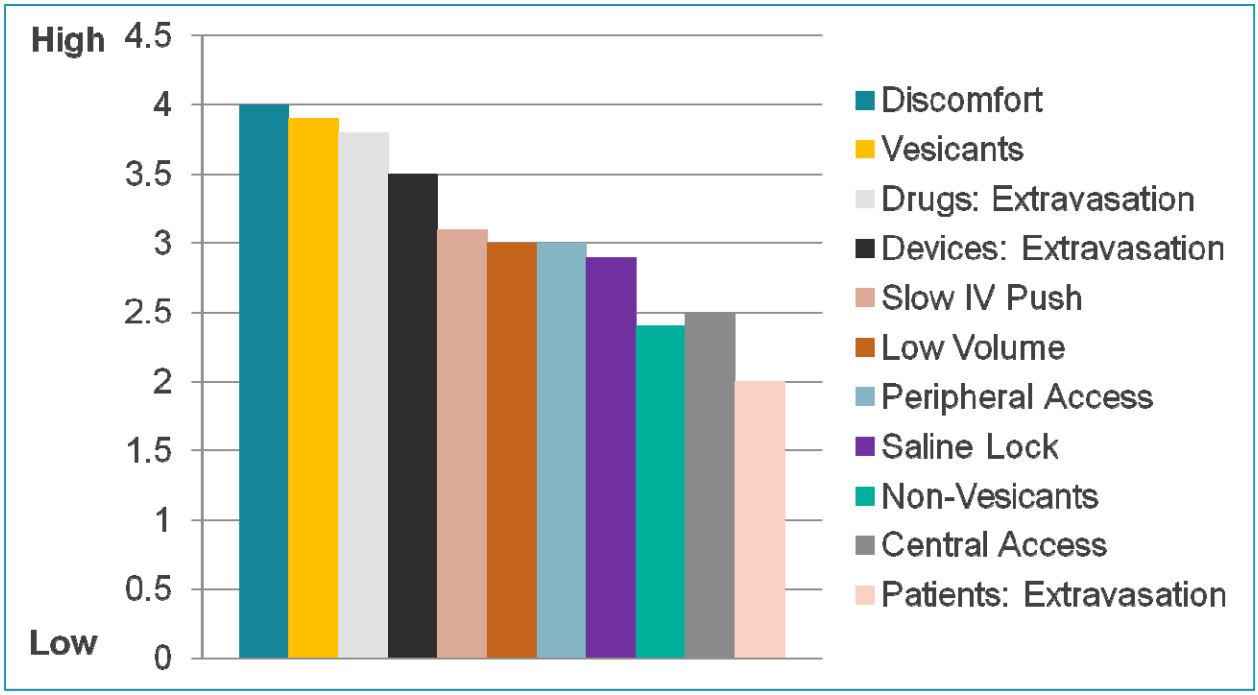
	Never 0%	Rarely 1-10%	Sometimes 11-40%	Often 41-95%	Always >95%
Opioids	20	13	19	21	27
Antianxiety/antipsychotic	22	14	18	23	24
Antiemetics	29	16	19	18	18
Anticonvulsants	58	11	10	9	11
Cardiovascular drugs	58	13	12	8	10
Naloxone	74	6	4	4	13
Flumazenil	81	6	4	3	6
Insulin	85	6	2	2	5
Heparin	91	6	1	1	1

Nurses also reported diluting medications not specifically included in the survey, including drugs that may cause pain, irritation, or injury at the site during injection (e.g., corticosteroids, diphenhydr**AMINE**); medications that must be administered very slowly (e.g., ketorolac); medications for which manufacturers recommend dilution and immediate or timely use after dilution (e.g., famotidine, levothyroxine); and antibiotics. The reversal agents, naloxone (which can be diluted) and flumazenil, along with bolus doses of insulin and heparin, were least often diluted.

FACTORS THAT INFLUENCE DILUTION

In the 2014 survey,[31] we also asked nurses why they diluted medications before IV push administration. **Figure 7** summarizes the findings, which clearly show that nurses dilute medications to protect patients from adverse outcomes and harm, including discomfort at the injection site, extravasation of vesicant or irritant, and the adverse effects of rapid administration or dosing errors.

FIGURE 7. Factors that Influence a Decision to Dilute[31]



Note: 1= low influence and 5 = high influence.

Respondents also told us they are more likely to dilute a medication that will be administered through a peripheral venous access site rather than a central venous access device. They were also more likely to dilute a medication administered via a saline lock or intermittent access site rather than an access port with a continuous infusion. A decision to dilute a specific medication was also influenced by a prescriber's order or by a recommendation from a drug or device manufacturer, the pharmacy, an IV drug reference, or a hospital policy.

Additionally, numerous respondents provided reasons for diluting medications that may not be clinically necessary. Several respondents suggested it was safer to dilute all medications before IV push administration so that the drugs are always administered slowly, thus enabling more careful patient

monitoring. Others felt there was no way to know how the patient would respond to a medication or if it would cause discomfort, so it was best to dilute all medications.

Multiple respondents reported the oft-unnecessary practice of withdrawing a medication from a vial or prefilled syringe then further diluting the medication in a larger syringe size or diameter if patients have an implanted port or a peripherally inserted central catheter. Some vascular access devices require lower injection pressures during flushing to avoid the risk of catheter damage if the line is clotted. A 10-mL syringe or a smaller syringe with the same 10-mL diameter delivers its contents under lower pressure than a 3-mL or smaller syringe. Thus, catheter manufacturers may recommend the use of a 10-mL syringe during a saline flush to confirm patency. What is not understood, however, is that once patency has been confirmed, experts on nursing standards of practice agree that a smaller-diameter syringe can be used to administer a medication.[32]

Several respondents reported simply hanging a piggyback of normal saline to administer concurrently with an IV push medication to circumvent the need to dilute a medication—a practice that may not be appropriate without a prescriber's order. In addition, a few respondents reported diluting medications for which the manufacturer specifically warns against dilution (e.g., darbepoetin alfa).

Determination of Diluent Volume

For those who diluted medications, the survey asked nurses whether they used a standard volume of diluent every time for each specific medication. The response was nearly split with just a little less than half (49%) indicating that the volume of diluent was variable, even for a single drug. These nurses diluted medications based on what was available to them at the time.

Nurses were also asked to describe how they determined the volume of diluent to use. Again, the responses were highly variable. For example, respondents reported personal practice preferences that included diluent volumes anywhere from 1 mL to 10 mL, equal parts drug and diluent (1:1 ratio), or drug-diluent ratios between 1:½ and 1:¾ of the drug volume. Those who diluted to a total of 10 mL using a 10-mL syringe reported difficulty withdrawing the medication from a prefilled syringe, sometimes fearing they had lost some of the actual drug. A small number of respondents reported that they:

- Had a list of diluents and standard volumes available in a medication room.
- Used a standard formula of diluting with 1 mL of diluent per minute of time needed to slowly administer the drug (e.g., 2 mL of diluent added to a drug to be administered over 2 minutes).
- Had a standard volume of diluent to use if administration was via a peripheral vein vs. a central vascular device.

None of the nurses described a dilution process that would result in a specific concentration (e.g., add 4 mL of diluent to 1 mL of drug to equal xx mg/5 mL). As suggested by the variability of dilution methods and volumes, less than half of respondents (43%) reported organizational policies or guidelines on dilution. Most of the remaining respondents (44%) were unsure whether their organization had such policies or guidelines. Most of these nurses were diluting IV push medications despite uncertainty regarding organizational policies or guidelines.

How Dilution Occurs

When nurses were asked about how dilution occurs, some described a process that starts with a common bag of diluent in the medication room each morning from which nurses withdraw the diluent when needed. Many nurses had a good faith but mistaken belief that this process was safe as long as a new bag of diluent was used every 24 hours.

Dilution often involves vial-to-syringe transfers, or syringe-to-syringe transfers, which do not occur in a sterile, distraction-free environment. Nurses reported that syringe-to-syringe transfers are difficult and have sometimes resulted in spillage of the drug. Nurses can be pretty creative about getting the medication out of one syringe and into another—either from the top part of the syringe or by pulling out the plunger and looking for a way to access that drug through the bottom part of that syringe. But they told us they often feel that some of the medication has dripped out during the process, and they do not end up with the full medication dose in the final syringe. Potential contamination of the medication is also a risk.

In lieu of diluting an IV push medication in a syringe, we heard from some nurses that they simply hang a piggyback of normal saline and let it flow in fast as they are administering an IV medication. However, nurses did not mention whether they obtained a physician's order for the IV saline solution.

Mislabeled Syringes

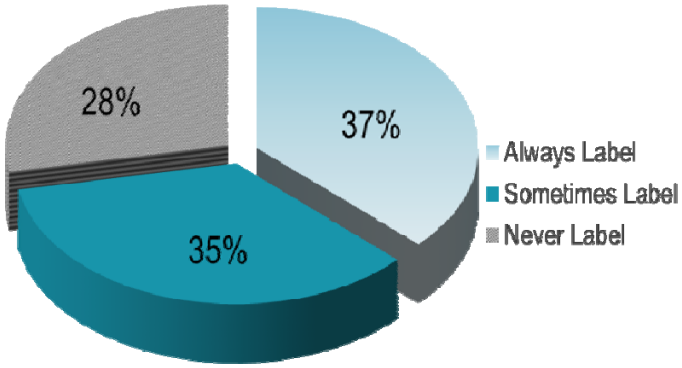
Most concerning, more than half (54%) of nurses told us that they withdraw an IV push medication directly into a manufacturer's prefilled and prelabeled flush syringe containing 0.9% sodium chloride. Nurses will determine how much medication they want to draw into the flush syringe to dilute it, squirt out that much flush solution, and then draw the medication into the flush syringe so the resulting volume will be about 3 mL again. This practice results in a syringe mislabeled as containing only the diluent (0.9% sodium chloride) but actually containing the diluent and medication. If the medication is not administered immediately and the syringe is put down, it could be mistaken as a syringe containing the diluent alone and be used to flush an IV line.

Unlabeled Syringes

Unlabeled syringes are a significant risk associated with preparation of IV push medications in clinical areas. Several years ago, the American Nurses Association released the results of an online survey about the challenges of labeling syringes that contain injectable medications.[33] The survey results from more than 1,000 nurses across the U.S. were quite dramatic.

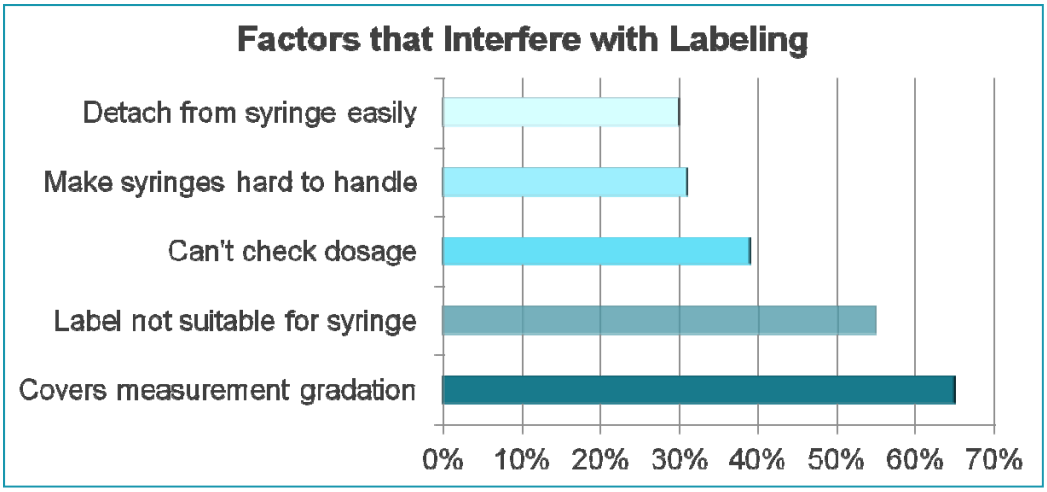
The survey found that nurses were worried about medication errors, and two-thirds (68%) believed medication errors could be reduced with more consistent syringe labeling. Nearly half (44%) of the nurses said they inject medications via a syringe more than five times each shift, and one-third (37%) administer injectable medications at least one time per shift. However, only one-third (37%) of the nurses surveyed reported that they *always* label syringes (**Figure 8**). Equally concerning, the study suggested that more than one in four (28%) nurses *never* label syringes when administering medications.

FIGURE 8. Frequency of Labeling Nurse-Prepared Syringes[33]



The reasons nurses cited for not labeling syringes included the label's obstruction of the measurement markings on the syringe barrel and the lack of suitable labels that do not interfere with dosage and volume verification (**Figure 9**). Nurses who label syringes often use tape or IV solution labels, which are big and bulky, making the syringe hard to handle and the measurement marks on barrel hard to see. Nurses also reported that the labels they apply detach easily, especially if they place the label on the syringe like a flag. Those who tried to use a flag-type label so that they could see the markings on the syringe complained that the label falls off before they can administer the medication. About 68% of the surveyed nurses believed that errors could be reduced with more consistent syringe labeling. Of course, that leaves 32% of nurses who did not see any relationship between errors and unlabeled syringes.

FIGURE 9. Factors the Interfere with Labeling, Cited by Nurses Who Do Not Label Syringes[33]



RECOMMENDATIONS

ISMP recommends serious consideration of the following actions to reduce the risk of medication errors or other adverse patient outcomes associated with dilution of adult medications prior to IV push administration. (Similar issues may exist with pediatric IV push medications; thus, these recommendations may be applicable to the pediatric population, also.)

- **Poll the nursing staff.** Conduct a nursing survey (similar to the ISMP survey[30]) or focus group to learn the extent and variability of dilution of adult IV push medications. Find out:
  - What drugs are most often being diluted?
  - What types of containers are these drugs being dispensed in?
  - What methods are nurses using to dilute medications?

Don't rely on policies and procedures for dilution that you may have in place to inform actual practice. In our 2014 survey,[31] almost half of all nurses did not know if their organization had policies or procedures on dilution, yet they diluted IV push medications.

Use the survey results to inform the organization about potentially unsafe dilution practices, and to establish standard practice expectations and guidelines for drugs that require dilution based on the manufacturer's instructions.

- **Encourage reporting.** Encourage nurses to report challenges that lead to a decision to dilute IV push medications. This information can help identify IV push medications that need to be diluted in the pharmacy prior to dispensing, as well as mistaken beliefs regarding the need for further dilution.

- **Consider risk-benefit ratio.** IV push medications, including prefilled syringes, should NOT be diluted unless recommended by the manufacturer. For drugs that may require dilution to improve patient comfort, reduce the risk of extravasation, increase the accuracy of measuring the dose, or allow for slow IV push administration, research the safety of dilution in the absence of manufacturers' recommendations. If appropriate, seek approval for dilution from the pharmacy and therapeutics committee. For medications that carry a high risk of extravasation and injury during IV administration – for example, promethazine (**Figure 10**) – have the pharmacy and therapeutics committee determine if safer medication alternatives exist. This may not be possible for chemotherapy vesicants but should be a serious consideration if still using IV promethazine as an antiemetic, which ISMP highly discourages.

FIGURE 10. Promethazine extravasation caused gangrene in a 19-year-old woman's fingers. She was hospitalized for 30 days, during which her thumb, index finger, and top of her middle finger had to be amputated.[34]

- **Pharmacy dilution.** To the fullest extent possible, IV push medications should be available to nurses in a ready-to-administer form. Pharmacy should prepare any IV push medications that must be diluted according to the manufacturer's guidelines or hospital policy. The syringe of diluted medication should be labeled for each patient with the patient's name, drug name, strength, dose, directions for administration (e.g., slow IV push over 2 minutes), and expiration date/time.

- **Establish guidelines**. Organizations should establish and approve standardized IV push medication preparation and administration guidelines for all practice locations. The proceedings from ISMP's National Summit on Safe Practices Associated with IV Push Medications: Consensus Statements[17] can help inform this process. Include frontline nurses in the development of the guidelines, and be sure nurses find them practical in the real world and believe they can successfully carry them out.

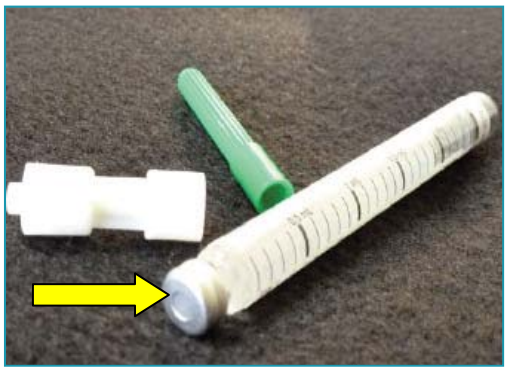
- **Nursing dilution.** If stability requires drug dilution immediately prior to IV push administration, it should be performed in a designated location using readily available drug information resources and guidelines. Provide nurses with exact directions for dilution via written or electronic guidelines or checklists that include standard diluent and diluent volumes, resulting concentrations, dilution instructions, and rate of IV push administration. Be sure directions for measuring the patient's dose and proper labeling is also included (see labeling recommendation that follows). Nurses should not dilute IV push medications according to personal practice habits. It should be part of a thoughtful process with all nurses following the same standard practice. Provide dilution instructions on the medication administration record or other document readily accessible during drug administration. It might be an abbreviated set of directions, but be sure to include the diluent and the diluent volume, the resulting concentration, any special instructions about the dilution, and the rate of IV push administration.

If a dose calculation is required after dilution, require an independent double check of the dose before administering the drug. Encourage nurses to always reference the hospital's standard guidelines when diluting medications, and to call the pharmacy with questions (as commercial drug references may provide less specific recommendations than hospital guidelines).

- **Promote proper labeling.** Syringes of medications diluted in clinical areas should be properly labeled unless prepared at the patient's bedside (e.g., in an emergency or during a bedside procedure) and immediately administered to the patient. Protocols should specify the elements that must be included on the label and how to apply it to ensure it is secure and will not limit the handling of the syringe. Provide clinical units with labels that are appropriate for syringes and which allow the nurse to view the measurement markings and the volume of medication in the syringe.

- **Prohibit unsafe dilution practices.** Medications should never be diluted by drawing up the contents of a commercially available, prefilled flush syringe of 0.9% sodium chloride. If dilution must occur in a clinical unit, pharmacy must dispense and/or stock the unit with single-use vials of diluent. Also, IV push medications should never be withdrawn from commercially available cartridge-type syringes, which are not intended for use as single-dose or multiple-dose vials (**Figure 11**). It is not how manufacturers envisioned their

FIGURE 11. Nurses have removed medication from cartridges via the rubber diaphragm.



products being used. Yet, there is a whole generation of nurses who do not know there is a holder for the syringe cartridges, and that the cartridge is intended to be used as a syringe itself. They have never seen the holders, and they believe that the cartridges are just a different form of a single-dose or multiple-dose vial.

- **Educate nurses.** If the nursing survey in your organization identifies episodes of dilution not supported by the official drug labeling or other reliable source, conduct educational programs to dispel myths and help nurses see the risks associated with these practices. For example, an update may be in order based on the Infusion Nurses Society guidelines that note it is safe to administer an IV push medication via a central line using a 3-mL syringe as long as patency has been verified using a 10-mL (or 10-mL diameter) syringe to flush the line.[32]

Teach nurses to avoid the unsafe practice of drawing medications directly into a prefilled syringe containing a diluent, by heightening their perceptions of the risks associated with an unlabeled or mislabeled syringe. Be sure nurses understand the need for a prescriber's order to hang and infuse a small-volume parenteral solution, even though it serves as a means to "dilute" an IV push medication and is administered in small quantities. Dispel any misunderstandings regarding the safety of diluting all adult IV push medications prior to administration.

During orientation of new nurses, review the IV push medication guidelines and ensure the nurses understand the risks associated with further dilution of medications. Be clear about any medications that will require nurses to dilute and how that should be accomplished. For new graduate nurses, assign a preceptor to teach each nurse the standard processes to be used if dilution is necessary on the clinical unit. Pharmacists should work with nurses to develop a standard competency evaluation that includes observation of actual or simulated practices, and nurses should be provided with feedback about their performance in the area of IV push medications.

REGULATORY AND ACCREDITATION REQUIREMENTS FOR SYRINGES, NEEDLES, AND VIALS

By Darryl S. Rich, PharmD, MBA, FASHP

Alarming lapses in the proper use of syringes, needles, and vials have been revealed in various healthcare practitioner surveys, headline news of disease transmission, and preventable adverse drug event reports. Regulatory, accrediting, and safety agencies such as the U.S. Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), the Centers for Medicare & Medicaid Services (CMS), and The Joint Commission have stepped up activities to bring awareness to this crucial topic and to establish regulatory and accreditation requirements to promote safe use. The lapses in proper use go far beyond documentation issues that can easily be fixed with checklists, forms, and templates. The regulatory and accrediting requirements associated with proper use of syringes, needles, and vials are intended to improve practice and to approach the problem from a patient safety perspective.

The Joint Commission, CMS, and CDC requirements have recently focused on four areas related to the safe use of syringes, needle, and vials: labeling of syringes, beyond-use dating of multiple-dose vials, IV administration competencies and training, and safe injection practices.

LABELING OF SYRINGES

The Joint Commission has a National Patient Safety Goal that requires all medications in containers (e.g., syringes, bowls) to be labeled in the perioperative setting or other areas where procedures are performed. The Joint Commission also has a Medication Management Standard that requires labeling of medication containers, including syringes, in all settings. The only exemption with either the goal or standard is for *immediate use* of the drug. The Joint Commission defines *immediate use* as meaning there are no intervening steps between the preparation of the drug and administration to the patient. A phrase coined by Joint Commission surveyors explains it this way: “If it hits the table, it needs a label.” This definition of *immediate use* differs from the United States Pharmacopeial Convention (USP) definition of *immediate use* pertaining to exemptions to USP <797> preparation standards for certain sterile products. To qualify for an *immediate use* exemption to USP <797>:[35]

- Only simple, aseptic measuring and transfer is required.
- Only three or less of the compounded sterile preparations are prepared.
- No hazardous drugs are involved.
- No delays or interruptions in preparation occur.
- No contact contamination of ingredients or critical sites occurs.
- Administration must begin within 1 hour after the start of preparation, or the dose must be discarded.

BEYOND-USE DATING OF MULTIPLE-DOSE VIALS

The Joint Commission requires multiple-dose vials (except vaccines) to be labeled with a beyond-use date of 28 days after opening, or the expiration date, whichever is shorter. The date required is not the date the product was first opened but rather the last date the product can be used.[36] Compliance with this is much improved, particularly with insulin vials, but not so much with other vials of medication such as lidocaine or labetalol.

IV Administration Competencies and Training

CMS has prescriptive interpretive guidelines regarding the training of health professionals who administer IV medications. The required components for training include:[37]

- Venipuncture techniques
- Safe medication administration practices applying to all types of medications and practices concerning IV tubing and infusion pumps, including:
  - Tracing invasive lines and tubes prior to administration to ensure the proper route
  - Avoiding forcing connections when the equipment offers clear resistance
  - Verifying proper programming of infusion devices
- Maintaining fluid and electrolyte balance
- Patient assessment of risk related to IV medications and appropriate monitoring, including documentation and frequency
- Early detection and intervention for IV opioid-induced respiratory depression in post-operative patients
- Blood components
- Blood administration procedures based on hospital policy, state law, best practices
- Process for verification of the right blood product for the right patient
- Identification and treatment of transfusion reactions

While most nursing departments are in compliance, other clinical areas with staff who administer IV medications, such as radiology technologists, may not be included in the training.

Safe Injection Practices

The CDC Safe Injection Practices comprise 9 recommendations within Standard Precautions in the Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings (2007).[38] Because the Safe Injection Practices guidelines are a matter of intense national focus, the CDC maintains a separate webpage for the guidelines,[39] where an excerpt of the guidelines can be found.[40] The CDC also maintains a set of Frequently Asked Questions about the guidelines on the topic.[41]

Four large outbreaks of hepatitis B virus and hepatitis C virus in the U.S. more than a decade ago identified the need to define and reinforce the nine safe injection practices. [42] The outbreaks occurred in two private physician's offices, a hematology/oncology clinic, and a pain clinic. Reuse of a needle and/or syringe to administer IV medications to patients and reinsertion of used needles in multiple-dose vials of medications or solution containers were the primary breaches in safe injection practices. These and many other outbreaks could have been prevented if the following nine safe injection practices had been followed.

1. Practice Aseptic Technique

- **Use aseptic technique to avoid contamination of sterile injection equipment.**

This practice is well known to healthcare professionals. In this context, aseptic technique refers to the manner of handling, preparing, and storing of medications and injection equipment/supplies (e.g., syringes, needles, IV tubing) to prevent microbial contamination.[41] Yet breaches in aseptic technique have been especially pervasive with injections into IV administration sets, specifically:[43]

- A failure to place a sterile cap on the end of a reusable IV administration set, saline lock, or catheter hub, leaving the tip exposed to contaminants that can lead to infection when the tubing is reconnected to the patient's IV access
- A failure to properly disinfect the injection port when accessing needle-free valves with syringes or connectors, risking the entry of contaminants into the patient's IV access

It is possible that the implementation of a needleless system has contributed to the problem.[44] The need for aseptic technique was never far from mind when a needle was used at the end of temporary tubing or to inject medication into the IV access line. However, there are no visual cues anymore to remind nurses that aseptic technique is still crucial when accessing needle-free valves with syringes.

Aseptic technique can also be compromised if medications are not drawn up in a designated clean area away from potentially contaminated items. For example, parenteral medications should not be prepared with nearby used equipment such as blood collection tubes, sharps containers, or soiled equipment used during a procedure. Leaving a needle or other device inserted into a medication vial is another way that microorganisms can enter the vial.

2. Do Not Reuse Syringe, Needle, or Cannula

- **Do not administer medications from a syringe to multiple patients, even if the needle or cannula on the syringe is changed. Needles, cannulae, and syringes are sterile, single-use items; they should not be reused for another patient or to access a medication or solution that might be used for a subsequent patient.**

The second safe practice may seem obvious to many health professionals, but apparently, it isn't. There have been many instances in which otherwise competent health professionals have reused these devices. Some reuse can be linked to human error in which a syringe, needle, or cannula was inadvertently reused. For example, a multiple-dose vial of lidocaine may be reentered inadvertently if a patient requires further numbing around a wound. This becomes a problem if the vial is used for another patient. But most instances of reuse are caused by a mistaken belief that syringes can be reused if the needle is changed, or if the needle is changed *and* the plunger is not drawn back, or if the syringe is used to access a needle-free valve in intravenous access tubing. Yet, a small amount of blood can flow into the needle and syringe even when only positive pressure is applied. In these instances, because there is no *visible* blood contamination, health practitioners have mistakenly thought that the syringe itself has not been contaminated.

For example, the professional staff at a male reproductive center were using an injection that contained papaverine to treat impotence. Throughout the entire day, the staff used the same syringe for the injections, changing only the needle between patients. When a pharmacist discovered this practice, he learned that even the physicians in the center incorrectly believed that blood never entered the syringe and only the needle was contaminated.

The same issue has been observed with insulin pens, which are designed to be used multiple times for a single patient using a new needle with each injection. Pens should never be used for more than one patient (**Figure 12**). Regurgitation of blood into the insulin cartridge can occur after injection, creating a risk of pathogen transmission if the pen is used for more than one person, even if a new needle is used. Older studies have found squamous, epithelial, and red blood cells; hemoglobin; and macrophages in up to 58%

of insulin cartridges in used pens.[45,46] With newer models of insulin pens introduced since then, a 2013 study found 5.6% of the cartridges in used pens contaminated.[47]

FIGURE 12. Poster created by the Safe Injection Practices Coalition to remind healthcare providers that insulin pens should never be shared.

ISMP first warned healthcare providers about insulin pen sharing in early 2008. Since then, ISMP and others have chronicled large-scale, potential exposures to bloodborne pathogens such as hepatitis B, hepatitis C, and human immunodeficiency virus (HIV) caused by using insulin pens for multiple patients after changing the needle, including:[48-52]

- 2,114 patients at a Texas Army medical center in 2009
- 2,345 patients at a Wisconsin clinic in 2011
- 716 patients at a New York Veterans Affairs medical center in 2013
- 1,915 patients at a New York general hospital in 2013
- 3,149 patients at a Connecticut hospital in 2014

While the level of biologic contamination is believed to occur in quantities enough to transmit bloodborne pathogens, to date, there is no clear evidence of pathogen transmission from pen sharing.[53] Yet, it can't be stated enough that pen sharing could lead to such an adverse outcome.[45-47,53]

Unfortunately, "wrong patient" errors have continued to occur, even when every nurse knows that pens should not be shared, and when patient- and order-specific barcode scanning at the bedside occurs with compliance rates above 99% and a hard stop if the wrong pen is scanned.[54] These events have been linked to human error—using a discharged patient's pen left in a medication drawer for a new patient in the same room, or carrying two patient's pens in a pocket and using the wrong pen to administer insulin. Yes, a barcode scanning system will capture these errors, but when nurses believe they have the correct pen in hand, they have administered the insulin and manually entered drug administration in the electronic record. These experiences have pulled back the curtain to view a crack in the armor of barcode scanning to ensure correct pen use.

3. Do Not Reuse Fluid Infusion/Administration Sets

- **Use fluid infusion and administration sets (i.e., intravenous bags, tubing, and connectors) for one patient only and dispose appropriately after use. Consider a syringe or needle/cannula contaminated once it has been used to enter or connect to a patient's intravenous infusion bag or administration set.**

The first part of this safe practice has been followed regularly with relatively few reported breaches. In fact, it would be highly unusual for an intravenous bag or administration set to be removed from one patient and used for another patient. A rare report of this type of breach involved a small volume piggyback medication that had been accidentally started on the wrong patient and, when noticed, removed and reconnected to the correct patient and administered.

It is the second part of the safe practice that has been breached more often. There are numerous reports of using a syringe to administer medication or another solution (e.g., flush) to more than one patient. One of the four cases that evoked the need to define and reinforce the nine safe injection practices involved a certified registered nurse anesthetist (CRNA) who used a single needle and syringe to administer three sedation medications to up to 24 patients at each clinic session.[42] These medications were administered through intravenous tubing or heparin locks. A total of 100 hepatitis B or hepatitis C virus infections were identified that were linked to the clinic. The CRNA stopped this unsafe practice after a nurse filed a complaint, after which no evidence of disease transmission was associated with the clinic.

4. Use Single-Dose Vials

- **Use single-dose vials for parenteral medications whenever possible.**

While there are some parenteral medications that are only available in multiple-dose vials, single-dose or single-use vials (or prefilled syringes) should always be used whenever available (**Figure 13**). The use of multiple-dose vials should be limited to single patients, aseptic pharmacy compounding, and very expensive medications prepared in the pharmacy, as an extra barrier of protection against unrecognized syringe reuse or other means of unintended vial contamination. The relatively inexpensive drugs and solutions that often require multiple entries into the vial (e.g., sodium chloride injection 0.9%, bacteriostatic water, lidocaine) should not be saved for use with other patients. These should be provided in single-use containers that are discarded after first use.

Figure 13. Use single-dose or single-use vials.

5. Do Not Reuse Single-Dose Vials

- **Do not administer medications from single-dose vials or ampules to multiple patients or combine leftover contents for later use.**

This best practice appears to be self-evident, but compliance has been a challenge amid an unprecedented volume of drug shortages. For example, during each of the propofol shortages, health practitioners have used the same, single-dose vial to remove doses for multiple patients. Contrast media is another product available in single-dose vials that have been used as multiple-dose vials. When single-dose vials are used for multiple patient doses in clinical areas, the patient is at risk for infection.

Strict compliance with USP <797> provides a safer solution to ease drug shortages by permitting the repackaging of medications in single-dose vials. Qualified pharmacy personnel can repackage medication from a previously unopened single-use/single-dose vial into multiple single-use syringes if the process is performed under ISO Class 5 conditions in accordance with USP <797> and the manufacturer's recommendations pertaining to safe storage of that medication outside of its original container. This process should be used by pharmacy to dispense medications in short supply, rather than allowing non-pharmacy staff to withdraw doses in an environment that does not meet USP <797> standards.

Another reason for misuse of single-dose vials entails a misconception that reuse depends on the vial size, reflecting the mistaken belief that a large volume of medication alone makes it suitable for multiple patients. Single-dose or single-use vials typically lack an antimicrobial preservative. Only a single dose should be removed for a single case/procedure/injection, and the vial and its remaining contents should be disposed.

6. Use Sterile Equipment to Access Multiple-Dose Vials

- **If multiple-dose vials must be used, both the needle or cannula and syringe used to access the multidose vial must be sterile.**

Reuse of a syringe to withdraw a medication or solution from a multiple-dose container may not be overt; rather, this unsafe practice is probably engaged in without much thought when multiple doses of the medication (e.g., lidocaine) or solution (e.g., saline) are required during a single procedure. If syringes are deliberately reused after changing the needle, practitioners may erroneously believe that any residual pathogens will be halted by the bacteriostatic or preservative agents in the multiple-dose vials. While common preservatives used in multiple-dose vials may be bacteriostatic, they will not destroy all bacteria, they do not have antiviral or antifungal activity, and they do not protect against contamination. Even if the preservative effectively stops bacteria from reproducing, there's about a 2-hour window during which contaminating organisms may remain viable in a multiple-dose vial before the preservative fully exerts its effect.[55]

7. Keep Multiple-Dose Vials Out of Patient Treatment Areas

- **Do not keep multidose vials in the immediate patient treatment area and store in accordance with the manufacturer's recommendations; discard if sterility is compromised or questionable.**

This is probably the least followed of all the CDC safe injection practices. The practice prohibits storage of a multiple-dose vial in an immediate patient treatment area, meaning a multiple-dose vial should not enter a patient's room. This is to prevent inadvertent contamination of the vial through direct or indirect

contact with potentially contaminated surfaces or equipment.[41] For example, a multiple-dose vial of insulin used to prepare doses for more than one patient must remain out of the room or patient care area. This includes emergency department bays and operating rooms or post-anesthesia patient care unit bays. Insulin doses must be prepared outside of the patient's room.

For organizations with barcode scanner attached to computers on the wall in immediate patient care areas, the practice is challenging. It's also challenging for anesthesia staff, who should discard all multiple-dose vials entered during a procedure. But vials can become contaminated when in close contact with patients.

8. Avoid Common Source Bags

- **Do not use bags or bottles of intravenous solution as a common source of supply for multiple patients.**

A bag or bottle of IV solution (e.g., saline) used as a common source of flushes or drug diluents for multiple patients has been seen frequently in procedural areas such as the cardiac catheterization lab, interventional radiology, or nuclear medicine. The solution is used as a flush before or after administration of contrast media. Some health professionals erroneously suggested this practice is safe because they discard the solution after 24 hours. However, limiting use to 24 hours does not prevent disease transmission if the bag becomes contaminated. Further, use of a contaminated solution for large groups of patients can result in widespread disease transmission.

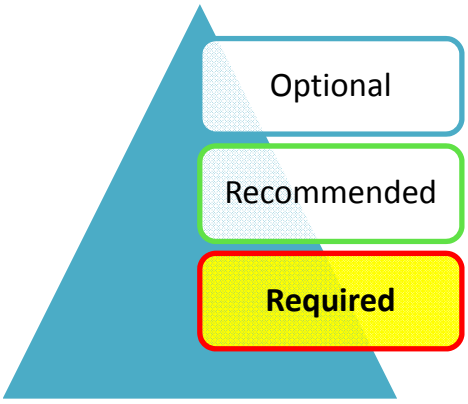
9. Wear Mask During Spinal Procedures

- **Infection control practices for special lumbar puncture procedures: Wear a surgical mask when placing a catheter or injecting material into the spinal canal or subdural space (i.e., during myelograms, lumbar puncture and spinal or epidural anesthesia.)**

In 2004, the CDC investigated eight cases of post-myelography bacterial meningitis.[38,56] Blood and/or cerebrospinal fluid of all eight cases yielded *Streptococcus* species consistent with nasal and oropharyngeal flora. Equipment and products used during these procedures (e.g., contrast media) were excluded as probable sources of contamination. Procedural details determined that antiseptic skin preparations and sterile gloves had been used. However, none of the clinicians wore a face mask, giving rise to the speculation that droplet transmission of nasal and oropharyngeal flora was the most likely explanation for these infections.

In October 2005, the Healthcare Infection Control Practices Advisory Committee (HICPAC) reviewed this evidence as well as cases of bacterial meningitis and epidural abscesses previously reported in the literature.[56] HICPAC concluded that there is sufficient evidence to warrant the additional protection of a face mask worn by the individual placing a catheter or injecting material into the spinal or epidural space.[38] Thus, the CDC recommends wearing a mask when carrying out these procedures, including myelograms and lumbar punctures. The decision by HICPAC and CDC to recommend wearing a mask was based in large part on evidence that face masks are effective in limiting the dispersal of oropharyngeal droplets[57] and are currently recommended as an evidence-based practice for the placement of central venous catheters.[58-60] Although not required by the CDC, some labor and delivery units also require staff assisting with a spinal procedure and within 50 cm of the procedural tray to wear a mask.[61]

RECOMMENDATIONS OR REQUIREMENTS?



Although the CDC is one of the major operating components of the Department of Health and Human Services, the CDC Safe Injection Practices are not laws or regulatory requirements in and of itself. CMS and The Joint Commission make them requirements. CMS Conditions of Participation (COP) [§482.23(c)] require healthcare providers to prepare and administer drugs and biologicals in accordance with accepted standards of practice. The standard specifically cites the CDC evidence-based practice guidelines and recommendations on medication preparation and administration designed to reduce the risk of infection associated with these activities. The COP [§482.42(a)] also require risk mitigation measures to control communicable diseases and again cites adherence to nationally recognized infection prevention and control precautions, such as current CDC guidelines and recommendations.

Likewise, The Joint Commission has Standards [IC.01.05.01, IC.02.01.01] that require accredited healthcare providers to develop infection prevention and control activities using evidence-based national guidelines and standard precautions, specifically referencing the CDC guidelines in a footnote. The Joint Commission also published an edition of *Perspectives* to clarify its safe injection practice standards, noting: "All Joint Commission accredited organizations (ambulatory care, behavioral healthcare, critical access hospital, home care, hospital, laboratory, long-term care, and office-based surgery programs) are *required* to follow relevant scientific guidelines for infection prevention per IC.01.05.01, EP1."[62] Again, the CDC guidelines are specifically referenced. Safe injection practices are also a key component of standard precautions *required* per IC.02.01, EP2.

Examples of unsafe injection practices commonly cited during recent Joint Commission surveys include:

- Administration of propofol in single-dose vials to multiple patients by anesthesia professionals during surgery, especially during a drug shortage. (During a shortage, pharmacy can prepare multiple doses from a single-dose vial, packaged in labeled syringes, while adhering to USP <797>.)
- Administration of lidocaine from a single-dose vial to multiple patients in the emergency department and outpatient clinics.
- Using an IV bag as a source of flush/diluent in cardiac catheterization laboratories, interventional radiology suites, procedural areas, and operating rooms. (Surveyors are required to visit every procedural area in a hospital or health system.)

SURVEY OF SAFE INJECTION PRACTICES

In 2010, the Association for Professionals in Infection Control and Epidemiology conducted an online survey of 5,446 clinicians who prepare and/or administer parenteral medications.[63] Respondents were mostly registered nurses (89.5%) who worked in hospitals.

The survey showed some disturbing results:

- Nearly 1% of respondents admitted to sometimes or always reusing a syringe for more than one patient after only changing the needle.

- About 6% of respondents admitted to sometimes or always using single-dose/single-use vials for multiple patients.
- More than 15% of respondents reported using the same syringe to re-enter a multiple-dose vial numerous times; of this group, about 7% reported saving these multiple-dose vials for use with other patients.
- About 9% of respondents sometimes or always use a common bag or bottle of IV solution as a source of flushes and drug diluents for multiple patients.

In the US, between 2000 and 2011, there have been at least 49 outbreaks attributed to unsafe injection practices.[64] Twenty-one involved transmission of hepatitis B or hepatitis C virus. The other 28 involved bacterial infections. The outbreaks required notification of an estimated 150,000 patients and identification of more than 600 who became infected. Approximately 90% of these known outbreaks occurred in outpatient settings; yet, more recent outbreaks due to insulin pen reuse have included hospitals.

Examples of Recent Outbreaks

In 2012, two outbreaks of invasive *Staphylococcus aureus* infection were confirmed in 10 patients being treated for pain in outpatient clinics.[65] In both clinics, the use of single-dose or single-use vials for more than one patient was associated with infection transmission. In both clinics, healthcare professionals reported difficulty obtaining the medication type or vial size needed for the procedures. Thus, appropriately sized single-dose vials were unavailable.

In one of the outbreaks, clinic staff began the day by preparing contrast media by withdrawing 5 mL each from a 10-mL single-dose vial of contrast media and a 10-mL single-dose vial of saline. The contents of each syringe were then injected back into the opposite vial. Each of the resulting vials of diluted contrast media was used throughout the day to prepare patient doses. Clinicians also failed to wear face masks when performing spinal injections. Three patients with methicillin-resistant *Staphylococcus aureus* were hospitalized for severe infections, including acute mediastinitis, bacterial meningitis, epidural abscess, and sepsis.

In the other outbreak, orthopedic practice staff members had previously used 10-mL single-dose vials of bupivacaine for single-patient use during joint injections. But due to a national drug shortage of 10-mL vials of bupivacaine, the practice was forced to use 30-mL single-dose vials, which they incorrectly used for multiple patients. Seven patients were admitted to the hospital with septic arthritis or bursitis, all requiring debridement. Three additional patients who received bupivacaine injections on the same days developed symptoms suggestive of infection and were treated as outpatients. Nasal swabs confirmed that two clinicians who prepared injections were colonized with *S. aureus*, one of whom had a strain that was identical to the outbreak strain.

Recommendations

- **Conduct ongoing risk assessments.** Visit clinical units regularly and, through observation and discussion, determine whether clinicians are following CDC's nine Safe Injection Practices. Observe how clinicians are using single-dose and multiple-dose vials, insulin pens, fluid administration sets, and syringes and needles. Watch for aseptic technique. Ask nurses how they are handling any multiple-dose vials on the unit and whether there are any barriers to safe injection practices. Go into

medication preparation areas to look for inappropriate use of intravenous bags, storage of multiple-dose vials, reuse of single-dose vials, and contaminated equipment and supplies. Be sure to visit procedural areas, radiology, clinics, and the emergency department. Share the results with the infection preventionist, and use the results of these assessments to plan improvements in safe injection practices, focusing on what pharmacy can do to support these practices.

- **Work with an infection preventionist to monitor and educate.** Pharmacists should be one of numerous interdisciplinary participants who establish and review policies and procedures regarding safe injection practices, and who plan and deliver educational programs for clinical staff. Both the American Society of Health-System Pharmacists[66] and the CDC[67] have developed very useful tools and resources to help educate both clinicians and patients about safe injection practices, including videos, posters, slide presentations, continuing education activities, and Frequently Asked Questions, and the Safe Injection Practices Coalition, a CDC-led partnership of healthcare-related organizations, have developed materials to support its One & Only Campaign.[68] Take the time to tell staff about the human toll of unsafe injection practices by sharing specific stories of infection transmission or the stress of possible infection transmission (e.g., HIV).

- **Minimize multiple-dose vial use.** Pharmacists are among the most influential health professionals when it comes to whether single-dose or multiple-dose vials are utilized. To the greatest extent possible, single-dose vials should be stocked. If very few multiple-dose vials are in use, consider treating them the same as single-dose vials so a single standard of one use for one injection can be applied system-wide.

- **Repackage large-volume vials.** In the pharmacy under USP <797> specifications, break down large volume single-dose vials and any multiple-dose vials into individual doses dispensed in labeled, single-use syringes (especially during a drug shortage).

- **Reevaluate the use of insulin pens.** Even with barcode scanning and other strategies considered best practices, health systems are still vulnerable to pen sharing. While we can't call for an all-out moratorium on using insulin pens in hospitals, ISMP still leans toward their use in hospitals only under special circumstances, such as the use of pens that may become available for concentrated U-200, U-300, and U-500 insulin.

- **Affix reminders about single use.** Consider affixing a warning label to problem-prone, single-dose or single-use products, or building alerts for electronic medication administration records and/or automated dispensing cabinet screens, to remind staff to avoid sharing pens or to discard single-dose vials and any remaining content after a single entry.

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ADDRESSING A TRIFECTA OF OVERLOOKED IV MEDICATION RISKS

POST-TEST

1. **When preparing an IV admixture, overfill volumes must be factored in to determine the final concentration of a solution if the final concentration must be exact for dosing purposes.**

   a. True
   b. False

2. **According to the "10% rule," if the volume of an additive medication is more than 10% of the volume listed on the bulk solution container (without regard to overfill), the volume of the additive, and sometimes the volume of the overfill, will be removed.**

   a. True
   b. False

3. **All of the following statements are true about "full sterile compounding" EXCEPT:**

   a. You start with an empty container
   b. You add measured amounts of the medication and the base solution to the empty container
   c. The final container **SHOULD** be labeled with a specific drug concentration (mg/mL) and total amount of drug and volume in container
   d. Full sterile compounding should be used for products in which the total amount of the drug and the concentration of the solution can be estimated

4. **Regarding the syringe pull-back method for verifying IV admixture accuracy, all of the following are true EXCEPT:**

   a. The syringe pull-back method allows a second individual the ability to accurately check the syringe contents after preparation of the admixture
   b. The syringe plunger is pulled pack to the same additive volume used
   c. The pull-back method is particularly unsafe when used with high-alert drugs
   d. Syringes should be labeled if verification is not completed shortly after drawing the solution into the syringe

5. **When preparing an infusion of a single dose of a drug, such as 160 mg of CARBOplatin (10 mg/mL), and the drug has been added directly to the IV bag without withdrawal of any of the base solution (0.9% sodium chloride), which volume(s) should be listed on the product label?**

   a. No volume needed, just the dose of the **CARBO**platin
   b. **CARBO**platin and the base solution
   c. **CARBO**platin, the base solution, and overfill in base solution
   d. **CARBO**platin added to the base solution

6. **All medications must be diluted and transferred to a 10-mL syringe (or a syringe with the same diameter as a 10-mL syringe) prior to IV administration via a peripherally inserted central catheter.**

   a. True
   b. False

7. **During the process of diluting IV push medications, what is a common practice that often leads to mislabeled syringes and potential misadministration of the drugs?**

    a. Using a common bag of IV solution as a diluent for parenteral medications for all patients on the unit
    b. Drawing medication into a manufacturer's prefilled "flush" (0.9% sodium chloride) syringe to dilute it
    c. Hanging a piggyback of normal saline to administer concurrently with IV push medication to further dilute it
    d. All of the above

8. **What is the most effective way to prevent errors that occur when nurses dilute medications on the unit?**

    a. Rely on nurses to follow policies and procedures that prohibit dilution on the unit
    b. Educate nurses to avoid dilution of drugs on the unit
    c. Provide multiple-dose vials of diluent to be used on the unit
    d. Dispense IV push medications from the pharmacy in a ready-to-administer form

9. **Dilution practices are typically based on tradition handed down from one nurse to another, with no sound or scientific basis.**

    a. True
    b. False

10. **Which of the following is not a risk associated with diluting medications on clinical units?**

    a. Contamination and infection transmission
    b. Using the wrong diluent
    c. Administering the drug by the wrong route of administration
    d. Administering a diluted medication to the wrong patient if the syringe is not labeled

11. **The Joint Commission does not require compliance with the Centers for Disease Control and Prevention Safe Injection Practices guidelines.**

    a. True
    b. False

12. **It is acceptable to use a single-dose vial for multiple patients on a patient care unit if there is a shortage, provided a new needle and syringe are used for each penetration, and proper aseptic technique is used to withdraw and administer the medication.**

    a. True
    b. False

13. **It is acceptable for an anesthesiologist to keep a multiple-dose vial on the anesthesiology cart for use in multiple cases, as long as the vial is discarded after 28 days from the date of opening.**

    a. True
    b. False

14. **Which of the following is NOT one of the 9 CDC Safe Injection Practices?**

    a. Do not use IV bags or bottles as a common source of supply for multiple patients
    b. Wear a mask during spinal procedures
    c. Wear sterile gloves when administering any IV push medication
    d. Do not keep multiple-dose vials in any immediate patient treatment area

15. **Administration of insulin from the wrong patient's pen can be avoided if barcode scanning of the patient and the pen occur consistently, *and* if the system has a hard stop when the wrong patient's pen is scanned (i.e., the nurse cannot proceed unless the dose is manually documented).**

    a. True
    b. False

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