ISMP
Safe Practice
Guidelines for
Adult IV Push
Medications



A compilation of safe practices from the ISMP Adult IV Push Medication Safety Summit

Prepared by the Institute for Safe Medication Practices (ISMP)



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Introduction

Intravenous (IV) therapy is considered an

essential component of current healthcare delivery, with over 90% of hospitalized patients receiving some form of infusion therapy. ¹⁻² Errors involving IV medications can occur in all phases of the medication use process and can be particularly dangerous based on the drug's properties and the complexity of its therapeutic action. IV medications are clinically advantageous due to their immediate therapeutic effect and ability to support plasma drug levels that reach an early target effect. At the same time, harm can easily result from IV drug administration due to the immediate bioavailability of intravenously administered drugs, the narrow therapeutic dose range of many IV medications, as well as the limitations in reversing systemic effects after IV administration. ³⁻⁴ Because of their propensity towards serious harm, certain IV medications have been designated as high-alert medications by the Institute for Safe Medication Practices (ISMP). High-alert medications have a narrow margin of safety, and errors with these drugs are associated with a higher risk of patient injury or death. ⁵

The significant risk for patient injury and death related to IV medication errors is well known.^{3-4,6-7} In their 2001 study of pediatric inpatients, Kaushal et al. demonstrated that IV medications are associated with 54% of potential adverse drug events (ADEs).⁸ IV medications were also associated with 56% of preventable ADEs in a five-year retrospective review of medication errors in a United Kingdom pediatric teaching hospital; 59% of these errors occurred during drug administration by nurses, with dosing and concentration mistakes being the most prevalent.⁹ In addition to these studies, over the last several decades, ISMP has received and published numerous IV push-related error reports involving patient injury, which were obtained through its National Medication Errors Reporting Program (ISMP MERP).¹⁰

A 2007 study by the American Nurses Association (ANA) of injectable medication errors reported that 99% of nurses (n = 1,039) believed that the risk to patients is serious if errors occur, and that almost half of the errors (48%) are most likely to happen during preparation and administration of IV medications. Although the literature contains many reports regarding the types and causes of IV medication errors, there are relatively few studies that offer a detailed analysis of the incidence, severity, and proximate causes of IV medication administration errors. In a study on 10 wards in two United Kingdom hospitals, researchers found that IV administration errors occurred in 41.9% of doses observed. A similar study by the same research team showed that errors during IV bolus administration occurred frequently (73%), the most common of which was bolus doses being injected faster than recommended (95%). Latent conditions identified in these studies included inadequate training for preparation and administration of IV medications and lack of dedicated space for medication selection and preparation.

While much emphasis has been placed on the improvement of IV *infusion* safety, there remains a limited amount of published evidence and a lack of established standardized safe practices associated with IV *push* injection safety. With limited research, yet harmful outcomes at stake, ISMP believes it is essential that healthcare practitioners are provided with relevant information to assist them in identifying and managing the inherent risks with this form of parenteral medication administration. This guidance document is intended to identify the risks, examine the current evidence, and make recommendations for safer practices associated with adult IV push injection preparation and administration. In addition, this document will identify and describe a number of unresolved issues that impact the safety of IV push injection practices, which will require additional study and further action by a variety of stakeholders with an interest in safe medication practices.

Factors that Increase the Risk of IV Push Medication Errors in Adults

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the history of IV medication use and the changing role of the nurse as well as other practitioners in the management of this form of therapy. From its early use during the Cholera epidemics in 1852 and 1863 until about the 1930s-1940s, the administration of IV fluids and medications was usually performed by physicians. In fact, in some locations, IV cannulation and IV medication administration remained exclusively a medical role until about the 1970s when roughly 30-40% of patients were receiving some form of IV therapy. However, with the introduction of disposable IV catheters and tubing around that time, an unprecedented growth ensued with IV therapy and associated IV medication delivery by nurses at the bedside, which continued throughout the 1990s. By then, it was estimated that more than 85% of hospitalized patients received some form of IV therapy, with its common use rapidly expanding into non-acute care settings. In patients is important to recognize as well as other practical and the nurse as well as other practical and medication was usually performed by physicians. In the management of the nurse as well as other practical as other practical as other practical as well as other practical as other practical

As IV therapy became commonplace, so did the administration of IV push medications throughout inpatient clinical settings, deeming it essential for nurses to have the education and skill set to manage the challenges associated with IV medication delivery. While the transition to IV medication administration, and specifically IV push administration, has occurred over decades, challenges still exist with teaching IV push medication delivery. Today, most undergraduate professional students have not had much experience with direct IV push injection outside of a classroom or simulation setting, largely due to practice limitations in host facilities.

While organizations typically require competency validation for nurses and other professional staff with IV administration responsibilities, much of this validation focuses on placing and managing vascular access devices. It is not uncommon for graduate nurses to learn much of their IV therapy/IV medication delivery information, and gain most of their experience, from a coworker or preceptor during initial job orientation. The content of such orientation programs is organization-specific, which contributes to variation in knowledge and skill development, as well as a lack of standard practices across all organizations. Given the longitudinal and subtle nature of IV therapy changes over time, it is easy to appreciate why there is currently so much disparity and absence of standardization in IV push preparation and administration practices.

It is important, however, to dispel the assumption that IV injection safety is only a *nursing* issue. In most organizations, a variety of practitioner types (and in some cases unlicensed personnel) have responsibility for preparing and administering IV push medications. ¹⁹ Limited organizational policies and lack of defined clinical expectations that encompass all practitioners involved in IV push medication use increase the chance of variable practices.

In addition, a number of latent system issues contribute to the current variable state of IV injection practices, including the concentrations in which injectable medications are manufactured, how they are packaged for distribution, and the everchanging availability of ready-to-administer injectable products. Stakeholder groups outside of direct care providers can influence or contribute to the safe use of IV push medications by helping to address these issues.

While the prescribing, preparation, and administration of IV push medications has become exceedingly commonplace as part of a therapeutic standard of care, the lack of oversight and guidance for administration practices has led to significant variability, not only among organizations, but within organizations; even among individual clinical units. These common risks, as they relate to IV push medications for adult patients, can best be described using the ISMP conceptual model of the Key Elements of the Medication Use System^{M.5}

Risks Associated with Lack of Patient Information

• Lack of essential patient information necessary for the safe prescribing, preparation, administration, and monitoring of selected IV push medications (e.g., age, metric height and weight, laboratory values)

Risks Associated with Lack of Drug Information

- A frequent lack of direction for the rate of IV push administration from drug information resources (either because the reference does not indicate if there is a rate for administration or it uses ambiguous terminology such as IV push, IV bolus, "slow" or "fast" IV push, leading to the need for personal interpretation)
- A lack of direction or confusing, ambiguous directions in drug information resources regarding whether a medication
 can or must be diluted prior to IV push administration (either because references are vague, suggest that all
 medications may be diluted prior to administration unless contraindicated in official prescribing information, or do not
 include such information unless it appears specifically in the medication's official prescribing information)
- Lack of awareness that an adjustment is needed in the dose or administration frequency of the IV medication when required by the patient's clinical status or drug bioavailability
- Lack of administrative policies/protocols/guideline development for IV injections, so the expectation for safe practices is undefined and left solely to each individual's and/or the department's preferences

Risks Associated with Communication of Drug Information

- Ambiguous and undefined terminology such as "IV push," "IV," "IV bolus," "IV over X minutes," and "slow IV push"
- Failure to distinguish orders for "IV" medications as IV injection (push) or IV infusion, leaving the decision open to interpretation by the pharmacist and/or nurse
- Failure to provide a rate of administration with orders for "IV" medications, leaving the decision open to interpretation by the pharmacist and/or nurse
- Medication administration records (MARs) that do not provide easy to read and/or readily-accessible instructions on dilution, reconstitution, or the safe rate of administration of IV push medications

Risks Associated with Drug Labeling, Packaging, and Nomenclature

- IV medications that are prepared in empty sterile syringes, but left unlabeled
- IV push medications that are prepared (diluted, reconstituted) in commercially available syringes of 0.9% sodium chloride flush solution and remain mislabeled as containing only 0.9% sodium chloride
- Pre-labeling empty syringes prior to use
- Misleading/confusing pharmacy or manufacturer labeling and packaging
- Excessive use of organization-applied auxiliary label warnings that become "white noise," with the warning no longer being noticed

Risks Associated with Drug Storage, Stock, Standardization, and Distribution

- IV push drug dosages that need to be manipulated (e.g., vial-to-syringe transfer, syringe-to-syringe transfer, dilution, the need to use a partial vial or ampule, or more than one vial or ampule to prepare a dose)
- Reconstitution of a medication on the unit for IV push administration using the incorrect type and/or amount of diluent (mis-selection) and/or random choices or assumptions by practitioners regarding the use of diluent type and amount
- Use of commercially available 0.9% sodium chloride flush syringes to prepare (dilute, reconstitute) a medication and then administer the resultant product
- Use of commercially available prefilled syringes as single- or multiple-dose vials from which to withdraw a dose
- Preparation of IV flush syringes for one or more patients from a common-source IV infusion bag of 0.9% sodium chloride outside of the pharmacy
- Limited incentive for manufacturers to provide common concentrations in ready-to-administer packaging, often due to lack of standardization

Risks Associated with Device Use

- Variability in practice with the use of IV syringe pump devices to administer an IV push medication
- Vendor design flaws in IV medication delivery pumps, administration sets and associated tubing, and syringes that lead to erroneous assumptions, misinformation, unwarranted reliance on equipment, and human error during IV medication preparation and administration
- Insufficient staff education and training about new IV infusion devices, contributing to variability in practice for the administration of medications via IV syringe pump devices
- Lack of available Carpuject[™] holders to use with prefilled Carpuject[™] cartridges, and lack of knowledge about proper use of Carpuject[™] cartridges

Risks Associated with Environment, Staffing, and Workflow

- Lack of dedicated locations for aseptic IV medication preparation that must be performed outside of the pharmacy
- Lack of financial resources, human resources, or technology for safe pharmacy preparation of IV medications and/or purchase of commercial ready-to-administer products

Risks Associated with Staff Education and Competency

- Wide variability in preparation and administration procedures; no delineated procedures for clinical unit preparation of IV doses; and lack of practice standards and expectations for IV drug preparation and administration
- Learned workplace practices for IV push medications without sound scientific evidence; unsafe, unsubstantiated practices become the "norm" (normalization of deviance)
- Pharmacists with limited knowledge and understanding as to how medications may be manipulated by clinical staff prior to administration and how IV push medications are administered
- Lack of training and experience with the IV push route of administration for undergraduates in professional nursing programs due to constraints placed on student drug administration by the school or clinical practice site
- Lack of a detailed review of safe IV injection practices during new hire orientation

Risk Management and Quality Improvement Challenges

- IV push medications that are selected, prepared, and administered by a single practitioner with limited or no safeguards to protect the patient/caregiver
- Failure to follow appropriate infection control standards associated with IV injection preparation and administration
- At-risk behaviors associated with IV push medications (e.g., unlabeled syringes), either due to a faded perception of the risk associated with the behavior, or times when staff believe the risk is insignificant or justified
- Lack of a defined process to monitor IV injection practices or associated adverse effects after IV push drug administration

Current Practices withIV Injectable Medications

n 2010, more than 800 participants responded to an ISMP survey regarding the impact of the US economic crisis on medication safety. Despite Joint Commission standards that encourage pharmacy dispensing of ready-to-administer medications, about a quarter of pharmacists reported long delays in dispensing pharmacy-prepared parenteral solutions or nurses preparing or manipulating more drugs than ever before on the clinical unit.²⁰

A second ISMP survey in 2012 reviewed the practices of 540 nurses when using a cartridge-type syringe (Carpuject[™]). Initially designed to look at the practices associated with syringe overfill, the survey uncovered that many nurses were not concerned with overfill because they used the medication cartridge like it was a vial. That is, nurses reported removing the needleless adapter on the Carpuject[™] (or removing the drug cartridge from the Carpuject[™] system) and withdrawing doses through the rubber diaphragm. Some of the primary reasons that nurses did not use the prefilled cartridge as designed included the unavailability of syringe holders, or lack of knowledge of how to use them; the inability to see the volume markings when the product is in the syringe holder; and/or the desire to dilute the medication prior to administration. Nurses also admitted that they may use a single Carpuject[™] syringe for small incremental doses of medication for the same patient over time, instead of repetitively wasting part of the product with each dose.²¹

Studies on errors that occur during the preparation and administration of parenteral medications suggest up to 49% of IV medication errors involve the reconstitution process.²²⁻²³ A 2014 ISMP survey that was completed by 1,773 practitioners providing care to adults gave insight into the disparate and often risky dilution practices. Over 83% of nurse respondents reported that they further dilute IV injectable medications, which may be dispensed or already available as a unit dose item. Dilution occurred most frequently with single-use vials or ampules, followed by multiple-dose vials, commercial prefilled syringes, and pharmacy-prepared syringes.²⁴

The most commonly diluted medications included opioids and antianxiety/antipsychotics, followed by antiemetics and anticonvulsants. Respondents suggested that certain factors influenced a nurse's decision to dilute a parenteral medication, including the desire to maintain patient comfort, to follow standard practice with vesicants to avoid extravasation, the need to control the rate of administration using additional solution volume. Some respondents believed it was safer to dilute all IV push medications in order to administer them slowly and monitor the patient's response. In some cases, nurses reported administering a piggyback infusion of saline concurrently with an IV push medication to avoid having to dilute the medication — a practice that may not be appropriate without a prescriber's order.²⁴

Forty-nine percent of respondents said that the volume of diluent used to prepare an IV push medication was variable; in fact, many of the respondents reported different personal formulas for determining the final dilution. Some referred to a formula of 1 mL of diluent for every minute needed to safely administer an IV injectable drug; however, no respondents actually described a process of dilution that would result in a specific concentration. Forty-three percent of respondents reported having specific policies or guidelines on dilution; whereas 44% were unsure whether their organization had a policy or procedure. Of particular note, 54% of respondents reported that they use a commercially available prefilled "flush" syringe to dilute medications.²⁴ This practice frequently results in a mislabeled syringe, as the labeled flush syringe (0.9% sodium chloride) also contains the diluted medication.

Developing Consensus Guidelines for Adult IV Push Medications



o begin addressing the numerous and extensive concerns uncovered by the ISMP surveys as well as unsafe practices and at-risk behaviors observed during onsite consultations at acute care and outpatient locations across the US, ISMP obtained an educational grant from BD to hold a national summit of expert stakeholders. The purpose of the Adult IV Push Medication Safety Summit was to develop a compendium of safe practices for adult IV push administration by a cross section of healthcare experts from around the country.

The summit objectives were:

- Identify and gain consensus on the most common risks associated with IV push administration of medications to adults
- 2. Standardize and simplify the safe administration of parenteral medications to adults through the IV push administration route
- 3. Develop and communicate safe practices associated with the use of IV push medications for adults
- 4. Establish a minimum level of knowledge and competency associated with the administration of IV push medications to adults, regardless of a clinician's healthcare discipline

Fifty-six participants, representing a range of frontline providers, professional organizations, regulatory bodies, and product vendors from across the US, attended the two-day facilitated summit in September 2014. A framework of recommended safe practices with adult IV push preparation and administration was established by ISMP summit staff, and then a pre-meeting survey of participants was conducted to identify early consensus on these practices as well as top safety challenges for discussion. Breakout sessions focused on adult IV injection preparation and administration practices, reconstitution and flush practices, as well as the use of prefilled syringes for medication compounding on the clinical units. Consensus was reached on a variety of safe practices, which are presented below. Evidence-based research was used as available to support the development of the guidance statements; however, as with many patient safety or medication safety-related issues, controlled clinical trials have rarely, if ever, been done, nor would they be ethically possible in many cases. As such, this guidance document relies on the synthesis of the best evidence available at the time of publication, including clinical articles and other published literature, along with expert consensus. Regulatory evidence is also acknowledged and included as appropriate. Additional topics for further research and inquiry were developed based on group discussion and ISMP staff insight, and are listed in the section entitled Future Inquiry.

Safe Practice Guidelines

raft guidelines were developed by ISMP staff following the summit meeting, and all participants were given an opportunity to comment. These guidance statements were then shared on the ISMP website for public comment, and feedback was solicited through newsletter articles, website announcements, and email blasts. ISMP received a significant number of comments over a six-week period. Each comment was carefully reviewed and considered by ISMP summit staff. In addition, these comments were reviewed by ISMP professional staff members in order to finalize safe practices.

Each guidance statement that follows represents consensus for safe practice associated with IV push medication preparation and administration in adults. Additional discussion is provided for clarity purposes as indicated after each safe practice statement.

1. Acquisition and Distribution of Adult IV Push Medications

1.1 To the greatest extent possible, provide adult IV push medications in a ready-to-administer form (to minimize the need for manipulation outside of the pharmacy sterile compounding area).

<u>Discussion</u>: Medication errors associated with the administration of the wrong dose and/or wrong concentration are believed to be more prevalent when frontline practitioners are provided with a parenteral product that requires additional manipulation (partial doses, reconstitution, or dilution) at the bedside. In one study of IV medication administration errors, four error types (wrong diluent mixture, wrong diluent volume, wrong "bolus" rate, and drug incompatibility) accounted for over 91% of the errors; 27% of these errors were considered serious.²⁵ Although not confirmed in the Westbrook study, McDowell and colleagues reported that, of the procedural failures associated with IV administration, medication reconstitution was the most error prone. The study concluded that the use of prepared injections may help to eliminate errors.²³

To avoid the unnecessary, error-prone complexity of IV push medication preparation and administration, and to avoid the risk of contamination and personnel exposure that accompanies manipulation of IV push parenteral products, all stakeholders should re-evaluate current products administered by IV push and standardize as much as possible to ready-to-administer formulations and concentrations. This strategy was also described as a priority IV medication safety practice during a 2008 joint summit held by the American Society of Health-System Pharmacists (ASHP), ASHP Research and Education Foundation, United States Pharmacopeia (USP), Infusion Nurses Society (INS), The Joint Commission, National Patient Safety Foundation (NPSF), and ISMP. Expert panelists in this early summit included all disciplines and major stakeholders involved in IV therapy.³ The use of commercially available prefilled syringes or pharmacy-prepared syringes compared to routine provider-prepared medications has also been endorsed as a safer practice by the Anesthesia Patient Safety Foundation during their Medication Safety Conference held in 2010.²⁶

Concerns have been expressed about perceived barriers to achieving this strategy, including the unavailability of pharmacy 24-7 to prepare solutions, the cost and shortages of commercially available products, and the lack of approved stability data. However, it is important that this safety strategy continue to guide organizational strategic planning efforts for all parenteral medication acquisition, distribution, preparation, administration, and storage.

1.2 Use only commercially available or pharmacy-prepared prefilled syringes of appropriate IV solution to flush and lock vascular access devices.

<u>Discussion</u>: In support of the Safe Injection Practices initiative from the Centers for Disease Control and Prevention (CDC), this strategy is intended to reduce the potential for product, syringe, or needle contamination caused by unnecessary manipulation of the product outside of the pharmacy prior to use. Outbreaks related to unsafe injection practices indicate that, for a number of reasons, some healthcare personnel are unaware of, do not understand, or do not adhere to what are considered basic principles of infection control and aseptic technique. This has led to unnecessary vial contamination and public health outbreaks of infectious diseases such as hepatitis B and hepatitis C. In a large study of US healthcare providers in 2010, a significant number of practitioners reported engaging in a variety of unsafe injection practices, including using a single-dose vial for more than one patient, or reusing syringes to obtain additional doses from the same multiple-dose vial.²⁷

In instances when commercially available prefilled syringes are unavailable, the CDC recommends the proper use of single-dose vials over multiple-dose vials.²⁸

2. Aseptic Technique

- 2.1 Use aseptic technique when preparing and administering IV push medications, flush/locking solutions, and other parenteral solutions administered by direct IV injection. Aseptic technique includes:
 - 2.1a Hand hygiene prior to and after preparation and administration of the medication or solution
 - 2.1b Disinfection of the medication access diaphragm on a vial or the neck of an ampule prior to accessing the medication or solution
 - 2.1c Disinfection of the IV access port, needleless connector, or other vascular access device (VAD) prior to administration of the medication or solution
 - 2.1d The use of personal protective equipment (PPE) if contact and exposure to blood or bodily fluids are possible when administering the medication or solution

<u>Discussion</u>: According to CDC guidelines (IV.H.1), the use of aseptic technique when preparing and administering IV push medications, flush/locking solutions, or other parenteral solutions administered by direct IV injection is necessary to avoid contamination of sterile injection equipment.²⁸

Aseptic technique includes appropriate hand hygiene, the use of PPE when exposure to bodily fluids is possible, disinfection of the vial access diaphragm or ampule neck with an appropriate solution, and disinfection of all IV access ports, needless connectors, or other vascular access devices (VADs) with an appropriate solution prior to administration.^{18, 28}

Practitioners may not be aware that the "pop-off" vial caps from manufacturers are considered "dust covers" and are not intended to maintain sterility of the vial diaphragm or access point. Thus, the diaphragm must always be disinfected after removing the cap of a new vial. According to the Association for Professionals in Infection Control and Epidemiology (APIC) Safe Injection, Infusion, and Medication Vial Practices in Health Care, practitioners should disinfect vials by cleansing the access diaphragm "using friction and a sterile 70% isopropyl alcohol, ethyl alcohol, iodophor, or other approved antiseptic swab." Organizational standards for infection control in each facility should identify which disinfectant to use. It is also important to wait at least 10 seconds to allow the diaphragm to dry before inserting any device into the vial or accessing the medication. 29-30

At-risk behaviors that breach aseptic technique require coaching and education, as well as continued monitoring by organizational leadership.

3. Clinician Preparation

3.1 Withdraw IV push medications from glass ampules using a filter needle or straw, unless specific drugs preclude their use.

<u>Discussion</u>: Although controversial, this practice was supported by a consensus of summit participants after careful consideration of its impact on safety and its ability to be implemented in most healthcare organizations.

3.2 Only dilute IV push medications when recommended by the manufacturer, supported by evidence in peer-reviewed biomedical literature, or in accordance with approved institutional guidelines.

<u>Discussion</u>: Dilution of medications prior to IV push administration may be required by the manufacturer, and whenever possible, this should occur in the pharmacy before dispensing the medication. Unnecessary dilution adds complexity to the drug administration process and introduces a needless risk of making medication errors and contaminating sterile IV medications or solutions. A recent ISMP survey of nurses suggests that further dilution of IV push medications happens frequently, even with medications provided in prefilled syringes or pharmacy-dispensed syringes that contain a patient-specific dose.²⁴ An earlier study found that errors related to dilution most frequently included using the wrong diluent.²² ISMP has also received reports of errors related to the administration of the wrong medication or solution due to unlabeled or mislabeled syringes of diluted medications.¹⁰

3.3 If dilution or reconstitution of an IV push medication becomes necessary outside of the pharmacy sterile compounding area, perform these tasks immediately prior to administration in a clean, uncluttered, and functionally separate location using organization-approved, readily-available drug information resources and sterile equipment and supplies.

<u>Discussion</u>: Special procedures including the use of a dedicated workspace are considered essential to maintain asepsis when IV push medications are prepared for immediate use in less than an ISO Class 5 environment. APIC suggests that, in addition to a clean, and dry workspace, parenteral medication preparation must be performed away from obvious contamination sources (e.g., water, sinks).²⁹ Advance preparation of immediate use syringes or IV infusions (the night before or even hours before) outside of an ISO Class 5 environment is considered a controversial issue, and this practice is not supported by APIC, USP <797>, INS, or ISMP.

3.4 Provide instructions and access to the proper diluent when reconstitution or dilution is necessary outside of the pharmacy sterile compounding area.

<u>Discussion</u>: In the event that reconstitution or dilution of a medication is necessary, take steps to provide ready access to the proper diluent and instructions for reconstitution or dilution to support safe practice. In some facilities, this consists of "pharmacy-prepared kits," while in other facilities, this information is available in an electronic medication administration record (eMAR) in an expanded view as part of the MAR entry.

3.5 Do NOT withdraw IV push medications from commercially available, cartridge-type syringes into another syringe for administration.

<u>Discussion</u>: Carpuject[™] syringes were introduced to the marketplace to save time and reduce the potential for medication errors by limiting the number of steps required for preparation of an injectable medication. With easy-loading cartridges, their use may also help avoid delays in drug administration. Over the years, nurses have adopted an unsafe practice of using the prefilled syringe cartridges as single-dose or multiple-dose vials by withdrawing the medication from the cartridges.²¹ Using the cartridges as vials can lead to contamination, given that the cartridges were not intended to be used in this manner. This unsafe practice also can lead to dosing errors, drug mix-ups, and other types of medication errors, particularly because the prepared syringes are often unlabeled. Utilizing the cartridges as vials is also not economical when comparing the cost of prefilled syringes to vials of the same medication.

3.6 Do NOT dilute or reconstitute IV push medications by drawing up the contents into a commercially-available, prefilled flush syringe of 0.9% sodium chloride.

<u>Discussion</u>: Commercially available prefilled syringes of saline and heparin are regulated by the US Food and Drug Administration as *devices*, not as medications. These devices have been approved for the flushing of vascular access devices, but have NOT been approved for the reconstitution, dilution, and/or subsequent administration of IV push medications. Such use would be considered "off label" and not how manufacturers intended these products to be used, nor have prefilled flush syringes been tested for product safety when used in this manner.

Warnings intended to limit the use of prefilled syringes for medication preparation and administration appear on some syringe barrels, clearly stating "IV flush only." Some manufacturers have also limited or removed the gradation markings on the prefilled flush syringes in order to prevent measurement of a secondary medication in the flush syringe. When prefilled syringes are used in an off-label manner, the practitioner and employer bear the legal liability for any adverse events occurring from this practice.³¹

The mislabeling that occurs when medications are added to a prefilled syringe and a secondary label is not applied creates significant risk for errors. In many cases, the manufacturer's label is permanently affixed to the syringe barrel and contains product codes and a barcode as well as specific information about the fluid and its volume. When another medication is added to this syringe, there is no adequate method to amend the manufacturer's label, without covering the current information.³¹ Thus, the syringe frequently remains labeled as 0.9% sodium chloride, when it also contains the diluted or reconstituted medication.

Although this unsafe practice is widespread, and many who use it mistakenly believe the risk of an error is insignificant—a belief clearly reinforced during public comment regarding this guidance statement—summit participants arrived at a consensus that the practice must be eliminated.

3.7 When necessary to prepare more than one medication in a single syringe for IV push administration, limit preparation to the pharmacy.

<u>Discussion</u>: Combinations of more than one medication in a single syringe for IV push use is seldom necessary and error prone, and it could result in unwanted changes in the medications due to incompatibilities. Unless required for immediate use, compounding more than one drug in a single syringe should be carried out in the pharmacy, in a USP <797> compliant cleanroom.

3.8 NEVER use IV solutions in containers intended for infusion, including mini bags, as commonsource containers (multiple-dose product) to prepare IV flush syringes or to dilute or reconstitute medications for one or more patients in clinical care areas.

<u>Discussion</u>: IV infusion bags are labeled by the manufacturer as *single dose containers*, and as such, are intended for administration as a single dose for use promptly after the container is opened, and any unused portions dicarded.³² APIC standards also suggest never to use IV solution containers (e.g., bags, bottles) to obtain flush solutions, diluents, or for any other purpose for more than one patient.²⁹ Examples in the literature can be found in which the use of common-source infusion bags has resulted in the administration of contaminated injection solution. Respondents to an ISMP survey erroneously suggested this practice was safe because they discarded the solution after 24 hours. However, limiting use to 24 hours does not prevent disease transmission if the bag becomes contaminated.³³ CDC Safe Injection Practices (IV.H.8) also indicate that practitioners should not use bags or bottles of IV solution as a common-source of supply for multiple patients.²⁸ If the solution becomes contaminated, it can impact disease transmission for a large group of patients (www.cdc.gov/injectionsafety/IPO7_standardPrecaution.html).²⁸

4. Labeling

- 4.1 Appropriately label all clinician-prepared syringes of IV push medications or solutions, unless the medication or solution is prepared at the patient's bedside and is immediately administered to the patient without any break in the process.
 - 4.1a If the clinician needs to prepare and administer more than one syringe of medication or solution to a single patient at the bedside:
 - Prepare each medication or solution separately, and immediately administer it before preparing the next syringe or
 - If preparing several IV push medications at a time for sequential IV push administration, label each syringe as it is being prepared, prior to the preparation of any subsequent syringes.
 - 4.1b Alternatively, if a practitioner prepares one or more medications or solutions away from the patient's bedside, immediately label each syringe, one at a time, before preparing the next medication or solution.
 - 4.1c Bring only one patient's labeled syringe(s) to the bedside for administration.

<u>Discussion</u>: Medications or solutions in unlabeled syringes are unidentifiable and have been mistaken for different medications or solutions and administered to the wrong patient, in the wrong dose, and/or by the wrong route. Many errors associated with unlabeled containers have resulted in serious patient harm or death.

It is not safe to prepare a syringe away from the patient's bedside and carry it unlabeled to the bedside, even if the intent is to administer it immediately. Clinicians have been unexpectedly interrupted or distracted while carrying an unlabeled syringe to the bedside, thus prone to a mix-up.⁵ Also, The Joint Commission National Patient Safety Goal (03.04.01) requires practitioners to "Label all medications, medication containers (for example, syringes, medicine cups, basins), or other solutions on and off the sterile field."³⁴

Group consensus determined that completing an entire sequence of preparing, scanning, and administering a drug for IV push injection prior to the preparation of a second parenteral medication will limit the possibility of error due to syringe swap. If more than one syringe must be prepared, then completing the preparation and labeling of one syringe at a time is the safer approach.

4.2 Provide clinical units with blank or printed, ready-to-apply labels, including sterilized labels where needed, to support safe labeling practices.

<u>Discussion</u>: An ANA study identified that the top reasons nurses do not label syringes included concerns that the labels may cover the measurement gradation on the syringe barrel, impairing the ability to accurately check the dosage, and lack of a suitable label. Preprinted, ready-to-apply labels, including available sterilized labels where needed, can support safe labeling practices.¹¹

4.3 Immediately discard any unattended, unlabeled syringes containing any type of solution.

<u>Discussion</u>: Unlabeled syringes should always be considered unidentifiable unless prepared at the bedside and administered immediately by the preparer. Administration of an IV push medication from an unlabeled syringe, even if the practitioner "thinks" that they know what the unlabeled syringe contains, carries high risk and has resulted in severe patient harm and even death.⁵

4.4 Never pre-label empty syringes in anticipation of use.

<u>Discussion</u>: Errors have occurred when a pre-labeled syringe was mistakenly selected and the wrong medication or solution was drawn into the syringe. Instead, label each syringe immediately after being prepared, one at a time.

5. Clinician Administration

5.1 Perform an appropriate clinical and vascular access site assessment of the patient prior to and following the administration of IV push medications.

<u>Discussion</u>: An appropriate clinical assessment includes an evaluation of the prescribed therapy for the patient's age and condition (reason for drug treatment), the drug name, dose, route, rate of administration, and frequency. The practitioner should assess the patient for therapy indications and contraindications, have knowledge of the size and type of catheter, confirm that the vascular site is functional (i.e., aspirate for positive blood return and encounter no resistance when manually flushing the VAD), and verify that the patient is clinically suited for the ordered IV push medication.¹⁸

As with any medication, the practitioner administering an IV push medication should carefully review the vial or syringe label; confirm accuracy of the patient, drug, dose/strength, route, and timing by comparing the drug label against the order or MAR; confirm the integrity of the container (intact; no leaks), check for any visible contamination (precipitate, clarity); verify the potency (within the beyond-use date); and validate that any special storage conditions have been met.^{5, 18}

Before, during, and post administration, practitioners should assess the patient for any signs of infiltration or extravasation, and monitor the patient for potential adverse effects and reactions, being prepared for appropriate interventions should an adverse event occur.^{5, 18}

5.2 Unless its use would result in a clinically significant delay and potential patient harm, use barcode scanning or similar technology immediately prior to the administration of IV push medications to confirm patient identification and the correct medication.

<u>Discussion</u>: Use of approved automation and other technology to confirm the patient and drug prior to IV push administration is a more efficient and effective error-reduction strategy than a manual check performed by a practitioner. Even in emergencies, some automated dispensing cabinet (ADC) systems can aid in the accurate selection of medications by requiring barcode scanning at the ADC once a medication is selected from the ADC screen. This can be accomplished even if an order has yet to be entered into the electronic health record.

5.3 Administer IV push medications and any subsequent IV flush at the rate recommended by the manufacturer, supported by evidence in peer-reviewed biomedical literature, or in accordance with approved institutional guidelines. Use an appropriate volume of the subsequent IV flush to ensure that the entire drug dose has been administered.

<u>Discussion</u>: Rates for IV push medication administration listed as "slow" or "fast" are considered ambiguous and should be clarified. In some cases, the speed at which a practitioner administers a medication makes a therapeutic difference, or may contribute to an untoward adverse reaction. Practitioners who administer IV push medications without a watch or second hand tend to underestimate the time that has passed, often administering medications at a rate faster than recommended. Therefore, practitioners who administer IV push medications over a period of seconds to minutes must have immediate access/view of a watch or clock with a second hand or with a digital display of minutes and seconds. Since not all locations where IV medications are administered will have a viewable wall clock, it is suggested that the practitioner wear a watch.

The rate and volume of the subsequent flush can also result in unintended rapid or delayed administration of a drug. The medication left in any dead space in tubing or catheters will be flushed into the vascular system at the same rate that the flush or associated compatible IV solution is being administered.

5.4 Assess central line patency using at a minimum, a 10 mL diameter-sized syringe filled with preservative-free 0.9% sodium chloride. Once patency has been confirmed, IV push administration of the medication can be given in a syringe appropriately sized to measure and administer the required dose.

<u>Discussion</u>: Care should be taken when assessing for central line patency to avoid possible catheter rupture. Manufacturers recommend using at a minimum, a 10 mL diameter-sized syringe for assessing patency because a syringe of this size generates lower injection pressure. After patency has been established, however, medications can be administered in a syringe appropriately sized for the dose of the IV push medication required. Many facilities have created policies stipulating that a 10 mL syringe be used for all procedures involving a central line, when in fact, it is not necessary to introduce risk through a syringe-to-syringe transfer in order to administer medications.

5.5 When administering IV push medications through an existing IV infusion line, use a needleless connector that is proximal (closest) to the patient, unless contraindicated in current evidence-based literature, or if the proximal site is inaccessible for use, such as during a sterile procedure.

<u>Discussion</u>: Access points closest to the patient are preferable for use during IV push medication administration and subsequent flushing procedures, as they allow the medication to reach the patient as soon as possible, with a minimal amount of flushing required. Medications administered IV push in a distal port (away from the patient) may linger in the IV tubing of an existing line, and thus may actually be administered at a later time based on the rate of the existing IV fluids, or may not actually be administered at all if the IV line is dislodged or discontinued before the medication reaches the patient. The use of distal ports for IV medication administration has resulted in occasional patient harm, if the patient was no longer being monitored when the full dose of medication finally reached the patient.⁵

On occasion, the proximal port may be unavailable when a patient is situated under sterile drapes for a procedure. In this case, using the next proximal port to the patient is appropriate. When using a more distal site, staff need to be aware of and account for the dead space in the tubing after IV push medication administration to ensure that the entire dose has been administered at the intended rate of injection.

6. Drug Information Resources

6.1 Standardized, facility-approved IV push medication resources are readily available at the point of care to guide the safe practice of IV push medication administration. Resources should include any special considerations for the preparation and administration of IV push medications and for unique practice locations where medications may be administered IV push to ensure effective patient monitoring.

<u>Discussion</u>: With thousands of prescription medications available in the US, and more being added each year, frontline practitioners need ready access to reliable drug information in order to safely administer IV push medications. While most organizations provide online access to drug information resources, instructions regarding drug dilution and IV push administration procedures, including the rate of administration, may be lacking, difficult to find, or variable between resources. Ideally, readily available, point-of-care guidance for IV push medications should be provided on the MAR.

The term "IV" as a route without stating IV *continuous infusion*, IV *intermittent infusion*, or IV *push* is ambiguous, and may lead to variation in interpretation and unreliable practice. Clear administration instruction should be included as part of the original order for IV medications or solutions, clarified with the prescriber if unlisted, and confirmed as part of preapproved organizational protocols. In some cases, IV push medications may not be approved for use in all practice locations or by all clinician types.

7. Competency Assessment

7.1 Competency assessments for IV push medication preparation and administration are standardized across disciplines within healthcare organizations and validated through an initial assessment and on an ongoing basis.

<u>Discussion</u>: While the basics of IV therapy are taught within accredited nursing programs and other professional schools, the curriculum is variable and often does not require/allow the student to practice IV push administration as a part of their clinical rotations or simulated learning. Nurses and other practitioners typically learn IV push medication procedures "on the job," either firsthand through a preceptor or possibly through a course to confirm venipuncture competency.² Because a nationally approved curriculum does not exist, a wide range of practices can be found, many of which are unsafe, but unrecognized as such by those who use them and teach them to new staff.

Competency validation should occur for all practitioners, regardless of profession, who are required to safely perform IV push medication administration as a part of their role. In addition, periodic validation of competency should be performed.

8. Error Reporting

8.1 Report adverse events, close calls, and hazardous conditions associated with IV push medications internally within the healthcare organization as well as in confidence to external safety organizations such as ISMP for shared learning.

<u>Discussion</u>: Healthcare providers and safety agencies use error and adverse event reporting programs to learn about actual and potential safety risks and the underlying system and behavioral circumstances that lead to human errors. The goal of learning from events is to create reliable systems and enhance the ability of staff to make safe behavioral choices. It is also important to share close call events in order to improve the design of systems within the organization.³⁵

Federally-certified Patient Safety Organizations (PSOs) such as ISMP create a secure external environment where clinicians and healthcare organizations can report errors and close calls, and receive expert assistance in analyzing individual events and aggregate data, thus identifying and helping to reduce the risks associated with patient care and improving quality. Sharing errors and close calls with an external PSO such as ISMP allows the entire healthcare community to benefit from lessons learned.

8.2 Use internal and external information about adverse events, close calls, and hazardous conditions associated with IV push medications for continuous quality improvement.

<u>Discussion</u>: By addressing common, preventable adverse occurrences, a healthcare organization has the opportunity to become safer, thereby enhancing the quality of care delivered. Using internal sources of error information helps staff identify risks in their own setting. It also creates the expectation that all staff within the organization has the obligation to be safety minded and to be committed to speaking up when risk is known. Using external sources of risk identification and error stories (such as from the *ISMP Medication Safety Alert!*) prompts the evaluation of similar risks within an organization where they otherwise may have been be hidden for years before becoming evident, often in the form of an adverse patient outcome.³⁶

Future Inquiry

he topics below represent a number of unresolved safety issues from the ISMP Adult IV Push Medication Safety Summit. Many of these topics were briefly discussed, but not in enough detail in the time allotted to gain consensus on associated safe standard practices. The following statements are provided to encourage future studies and further discussion when looking to enhance the safety of IV push medication preparation and administration practices.

- Standardize the terminology associated with the safe use of IV push medications among professional organizations, accrediting bodies, and regulatory agencies to promote safe practice (e.g., "IV push," "IV," "IV bolus," "IV over X minutes," and "slow IV push").
- Under what circumstances is it safe to draw up more than one dose or use a single syringe that contains more than one dose of IV push medication for a single patient?
- Consider if some IV push medications should be administered via smart syringe pump technology. If yes—which ones and why?
- Consider the use of other bedside devices/technologies to enhance the safety of IV push medication procedures.
- What is the best manner to provide inter-professional education and competency evaluation for IV push medication administration?

Conclusion

he use of IV push medications, when performed without full knowledge and understanding of the error potential or infection control hazards, or without defined policies, procedures, standard practice guidelines, and demonstrated competency validation, carries a significant risk to patients. The challenges of improving the safety of IV push medication use does not belong only to the frontline practitioner, but rather to a variety of stakeholders in healthcare, including manufacturers, regulators, academicians, and professional organizations, as well as individual organizations that must adopt and operationalize safe practices.

As a starting point, organizations are asked to enhance current orientation and clinical educational models to include the safety of IV push medication therapy. Educators and healthcare leaders are asked to observe and monitor practice, and coach at-risk behaviors. Manufacturers are asked to provide IV products in the most ready-to-administer form as possible, and to design devices and technology that will promote the safe administration of IV push medications. Academicians are asked to look for novel ways to introduce IV push medication safety into the curriculum, and to ensure student understanding of all safety principles for IV push medication therapy before graduation. Researchers are asked to take on the unanswered questions regarding IV push medication safety, leading the healthcare community to a better understanding of what places patients at risk and the corresponding evidence-based risk-reduction strategies that have proven to be the most successful. Frontline practitioners are asked to adopt and promote safe practices, to avoid risky behavioral choices that bypass basic safety and infection control practices, and to report any system barriers making it difficult to maintain best practices. Through dedicated commitment to the use of standardized safe practices with IV push medication use and continued further inquiry into the associated unanswered challenges, patient outcomes with this mode of therapy will be optimized, and the risk of harm significantly reduced.

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Definitions

Term(s)	Definitions	
Admixture	The preparation of a pharmaceutical product which requires the measured addition of medications or a combination of one or more sterile products	
Common- source container	A container of solution used to prepare multiple doses of a drug or flush solution for multiple patients	
Compatible	Capable of being mixed and administered without undergoing undesirable chemical and or physical changes or loss of therapeutic action	
Dilution	To add a diluent (e.g., normal saline, sterile water) to a solution of medication in order to make it less concentrated or to provide additional solution for ease of administration and titration, or to decrease the tissue irritation of a medication	
Extravasation	The inadvertent administration of a vesicant solution or medication into the tissue surrounding a vessel	
Flushing	The act of moving fluids, medications, blood and blood products out of a vascular access device into the bloodstream, ensuring delivery of those components and verifying patency	
Infiltration	Inadvertent leakage of a nonvesicant IV fluid into the tissue surrounding a vessel	
Intravenous push or IV push	Direct manual administration of a medication using a syringe, usually under pressure, connected to an IV access device; this may include a manually administered IV "bolus" dose in an emergency	
IV bolus	A discrete dose of medication or solution given rapidly over a short period of time	
Locking	The instillation of a solution into a vascular access device to maintain device patency during periods of non-use	
Preparation	Includes dilution, reconstitution, and measurement of drugs and doses in a clean, uncluttered, and functionally separate environment	
Ready-to-administer	An injectable product containing the active drug in solution at the required concentration and volume, presented in the final container (syringe, infusion bag, or elastomeric device), and ready to be administered to the patient	
Ready-to-use	An injectable product containing the active drug in solution at the required concentration and volume in a vial. The injectable product is transferred to a final container (syringe, infusion bag, or elastomeric device) for administration to the patient	
Reconstitute	The act of adding diluent to a powder to create a solution	
Single dose container	A single dose container is a single unit container intended for parenteral administration only. A single dose container is labeled as such. Examples of single-dose containers include prefilled syringes, cartridges, fusion-sealed containers, and closure-sealed containers when so labeled	
Vascular Access Device (VAD)	Catheters, tubes, or devices inserted into the vascular system including arteries, veins, and bone marrow	

Several definitions modified from INS Standards of Practice (2006, 2013); ISMP Medication Safety Self-Assessment $^{\circ}$ for Hospitals (2004), USP General Notices, and Medication Errors (2007).

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Appendix A



ISMP Safe Practice Guidelines for Adult IV Push Medications

1. Acquisition and Distribution of Adult IV Push Medications

- **1.1** To the greatest extent possible, provide adult IV push medications in a ready-to-administer form (to minimize the need for manipulation outside of the pharmacy sterile compounding area).
- **1.2** Use only commercially available or pharmacy-prepared prefilled syringes of appropriate IV solution to flush and lock vascular access devices.

2. Aseptic Technique

- **2.1** Use aseptic technique when preparing and administering IV push medications, flush/locking solutions, and other parenteral solutions administered by direct IV injection. Aseptic technique includes:
- **2.1a** Hand hygiene prior to and after preparation and administration of the medication or solution
- **2.1b** Disinfection of the medication access diaphragm on a vial or neck of an ampule prior to accessing the medication or solution
- **2.1c** Disinfection of the IV access port, needleless connector, or other vascular access device (VAD) prior to administration of the medication or solution
- **2.1d** The use of personal protective equipment (PPE) if contact and exposure to blood or bodily fluids are possible when administering the medication or solution

3. Clinician Preparation

- **3.1** Withdraw IV push medications from glass ampules using a filter needle or straw, unless specific drugs preclude their use.
- **3.2** Only dilute IV push medications when recommended by the manufacturer, supported by evidence in peer-reviewed biomedical literature, or in accordance with approved institutional guidelines.
- **3.3** If dilution or reconstitution of an IV push medication becomes necessary outside of the pharmacy sterile compounding area, perform these tasks immediately prior to administration in a clean, uncluttered, and functionally separate location using organization-approved, readily-available drug information resources and sterile equipment and supplies.
- **3.4** Provide instructions and access to the proper diluent when reconstitution or dilution is necessary outside of the pharmacy sterile compounding area.
- **3.5** Do NOT withdraw IV push medications from commercially available, cartridge-type syringes into another syringe for administration.
- **3.6** Do NOT dilute or reconstitute IV push medications by drawing up the contents into a commercially-available, prefilled flush syringe of 0.9% sodium chloride.
- **3.7** When necessary to prepare more than one medication in a single syringe for IV push administration, limit preparation to the pharmacy.
- **3.8** NEVER use IV solutions in containers intended for infusion, including mini bags, as common-source containers (multiple-dose product) to prepare IV flush syringes or to dilute or reconstitute medications for one or more patients in clinical care areas.

4. Labeling

4.1 Appropriately label all clinician-prepared syringes of IV push medications or solutions, unless the medication or solution is prepared at the patient's bedside and immediately administered to the patient without any break in the process.

- **4.1a** If the clinician needs to prepare and administer more than one syringe of medication or solution to a single patient at the bedside:
- Prepare each medication or solution separately and immediately administer it before preparing the next syringe or
- If preparing several IV push medications at a time for sequential IV push administration, label each syringe as it is being prepared, and prior to the preparation of any subsequent syringes.
- **4.1b** Alternatively, if a practitioner prepares one or more medications or solutions away from the patient's bedside, immediately label each syringe, one at a time, before preparing the next medication or solution.
- **4.1c** Bring only one patient's labeled syringes to the bedside for administration.
- **4.2** Provide clinical units with blank or printed, ready-to-apply labels, including sterilized labels where needed, to support safe labeling practices.
- **4.3** Immediately discard any unattended, unlabeled syringes containing any type of solution.
- **4.4** Never pre-label empty syringes in anticipation of use.

5. Clinician Administration

- **5.1** Perform an appropriate clinical and vascular access site assessment of the patient prior to and following the administration of IV push medications.
- **5.2** Unless its use would result in a clinically significant delay and potential patient harm, incorporate barcode scanning or similar technology immediately prior to the administration of IV push medications to confirm patient identification and the correct medication.
- **5.3** Administer IV push medications and any subsequent IV flush at the rate recommended by the manufacturer, supported by evidence in peer-reviewed biomedical literature, or in accordance with approved institutional guidelines. Use an appropriate volume of the subsequent IV flush to ensure that the entire drug dose has been administered.
- **5.4** Assess central line patency using at a minimum, a 10 mL diameter-sized syringe filled with preservative-free 0.9% sodium chloride. Once patency has been confirmed, IV push administration of the medication can be given in a syringe appropriately sized to measure and administer the required dose.
- **5.5** When administering IV push medications through an existing IV infusion line, use a needleless connector that is proximal (closest) to the patient, unless contraindicated in current evidence-based literature, or if the proximal site is inaccessible for use, such as during a sterile procedure.

6. Drug Information Resources

6.1 Standardized, facility-approved IV push medication resources are readily available at the point of care to guide the safe practice of IV push medication administration. Resources should include any special considerations for the preparation and administration of IV push medications and for unique practice locations where medications may be administered IV push to ensure effective patient monitoring.

7. Competency Assessment

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8. Error Reporting

- **8.1** Report adverse events, close calls, and hazardous conditions associated with IV push medications internally within the healthcare organization as well as in confidence to external safety organizations such as ISMP for shared learning.
- **8.2** Use internal and external information about adverse events, close calls, and hazardous conditions associated with IV push medications for continuous quality improvement.

Disclosure

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About ISMP

The Institute for Safe Medication Practices (ISMP) is an independent, nonprofit charitable organization that works closely with healthcare practitioners and institutions, regulatory agencies, consumers, and professional organizations to provide timely investigation, analysis and education about medication errors and their prevention. ISMP represents almost 40 years of experience in helping healthcare practitioners keep patients safe, and continues to lead efforts to improve the medication use process. ISMP is a federally certified patient safety organization (PSO).

For more information on ISMP, or its medication safety alert newsletters and other tools for healthcare professionals and consumers, visit www.ismp.org.

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ISMP's mission is to advance patient safety worldwide by empowering the healthcare community to prevent medication errors.



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