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ISMP 25 YEARS ADVANCING MEDICATION SAFETY

Acute Care
ISMP Medication Safety Alert!®
Educating the Healthcare Community About Safe Medication Practices

IV push Gap Analysis Tool (GAT) helps uncover national priorities for safe injection practices

In January 2019, the **ISMP Gap Analysis Tool (GAT) for Safe IV Push Medication Practices** (www.ismp.org/node/1188) was launched to help hospitals, long-term care facilities, and outpatient centers identify and manage targeted risks associated with the use of intravenous (IV) push medications in adults. The GAT, which reflects the 2015 **ISMP Safe Practice Guidelines for Adult IV Push Medications** (www.ismp.org/node/97), was made available at no charge, thanks to support from the Baxter Healthcare Corporation. The tool consists of 50 items designed to help evaluate adult IV push medication systems and practices associated with the acquisition and distribution of these medications; practitioner preparation, including aseptic technique and labeling; administration; drug information resources; competency assessment; and error reporting.

The open enrollment period for participation in the GAT was between January and April 2019 during which organizations could anonymously submit their GAT findings to ISMP to receive a GAT score. Recently, participating facilities received access to a workbook with aggregate data and worksheets that could be used to compare their experiences to that of demographically similar facilities and to plan improvements within their own organization (www.ismp.org/node/1188). Now, ISMP is sharing some of the key findings with the healthcare community to identify challenges and ongoing national priorities with safely administering adult IV push medications.

Participant Profile

A total of 243 US healthcare facilities participated in the GAT and submitted their findings to ISMP through a confidential database. Most participants (n = 233) were from inpatient facilities, primarily hospitals. Data from the few participating outpatient facilities has been excluded from this analysis. The demographics of participating US hospitals were similar with respect to all US hospitals, although participants were more likely to be larger, rural, non-profit facilities providing general medical and surgical services.

Scoring Methodology

Each best practice item had four possible assessment choices: A = no activity (0 points), B = considered but not implemented (1 point), C = partially implemented (3 points), and D = fully implemented (5 points). The percent of facilities that reported no implementation (A and B), partial implementation (C), or full implementation (D) of the best practices was calculated. Then, the mean percent score for each item, each GAT section, and the entire GAT was calculated by dividing the average score achieved by facilities by the maximum possible score, and multiplying by 100. The mean percent score allows for the evaluation of collective performance within a familiar "report card" context.

Results

Overall Scores

The maximum score for the entire GAT was 250, and the mean score achieved by participating facilities was 196, resulting in an overall mean percent score of 78%. Differences were noted in the overall mean percent score based on facility demographics:

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URGENT REQUEST for action

Confirmed mix-ups between Prolia and Udenyca syringes

ISMP has learned of two serious medication errors involving the administration of **UDENYCA** (pegfilgrastim-cbqv; Coherus BioSciences) instead of **PROLIA** (denosumab; Amgen). Udenyca is a biosimilar leukocyte growth factor associated with the reference pegfilgrastim product, **NEULASTA**, and Prolia is an osteoporosis drug. Both of these errors were reported to the US Food and Drug Administration (FDA). Prior to these cases, ISMP had received 13 reports of concerns about potential mix-ups or close calls in which the wrong product had been dispensed or retrieved from stock; however, until now, the errors never reached the patient.

Figure 1. Package similarity has led to serious medication errors.

In the first case, an 80-year-old male patient with osteoporosis accidently received Udenyca instead of Prolia. Barcode scanning did not occur when retrieving the medication from the refrigerator or before administration. Although the patient appeared to be fine after receiving the wrong drug and was sent home, 1 day after the error, the patient experienced chest pain and presented to the emergency department. The patient's troponin increased from 0.07 ng/mL to 0.25 ng/mL in 8 hours and his white blood cell count had gone from

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- Facilities that were part of a larger health system had a higher mean percent GAT score than single facilities (80% vs. 75%)
- Facilities with more than 25 licensed beds had a higher mean percent GAT score than facilities licensed for 25 beds or less (79% vs. 74%)
- Facilities located in urban settings had a higher mean percent GAT score than facilities located in rural settings (80% vs. 76%)
- For-profit facilities reported a higher mean percent GAT score than non-profit or government facilities (86% vs. 77%)
- Facilities that had a pharmacist present on site, around the clock, had a higher mean percent GAT score than facilities without a pharmacist on site, around the clock (80% vs. 76%)

Minor or no differences were noted in mean GAT scores based on location (Midwest, Northeast, West, South) or whether the facility served as a site for nursing students.

Section Scores

The lowest and highest scoring GAT items within each section of evaluated systems and practices are provided in **Table 1** (page 6). The following is a brief description of key findings within each of these sections.

Acquisition and distribution. This section of the GAT evaluated the purchase and dispensing of ready-to-administer medications and flush solutions. Overall, the average mean percent score for this section was 76%. While most participating facilities use commercially available or pharmacy-prepared prefilled syringes for flushing and locking vascular access devices (94% mean percent score, 86% full implementation), fewer facilities reported dispensing adult IV push medications in a ready-to-administer form to minimize the need for manipulation and product relabeling outside the pharmacy (61% mean percent score, 22% full implementation). In fact, 16% of participating facilities reported that they never dispense adult IV push medications in a ready-to-administer form, and 61% reported that they do not always purchase ready-to-administer medications even when they are commercially available.

Aseptic technique. This section of the GAT evaluated hand hygiene, disinfection of vial diaphragms and access ports, and use of personal protective equipment. Participating facilities scored the highest in this section, achieving a mean percent score of 87%. Facilities with 25 beds or fewer achieved a mean percent score higher than larger facilities for several aseptic processes, including vial disinfection procedures (84% vs 80%) and using a new syringe (and needle as necessary) for every IV push injection (98% vs. 94%), but lower mean percent scores regarding hand hygiene prior to (78% vs. 87%) and after (77% vs. 84%) drug preparation and administration. However, it is concerning that 11% of participating facilities reported no or only partial implementation of the best practice to use a new syringe for every IV push medication.

Practitioner preparation. This section of the GAT evaluated dilution and reconstitution of IV push medications, the use of a filter needle when appropriate, proper use of cartridge-type syringes, and inappropriate use of common-source containers (containers of solution used to prepare multiple doses of a drug or flush solution for multiple patients). Participants also scored high in this section, achieving a mean percent score of 80%. The highest scoring GAT items included using a filter needle or straw to withdraw IV push medications from a glass ampule when appropriate (93% mean percent score); diluting/reconstituting IV push medications immediately prior to use if it becomes necessary to prepare outside the pharmacy (88%); using sterile equipment and supplies (91%); having reliable drug information resources available (89%); and never using IV solutions in bags as a common source container outside the pharmacy sterile compounding area (89%).

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4,700/mm^3 to 25,800/mm^3. The patient was subsequently admitted to the hospital with a diagnosis of non-ST segment elevated myocardial infarction (non-STEMI).

In the second case, a patient at a general infusion center received a single dose of Udenyca instead of the prescribed Prolia. The error was identified when a different patient in the infusion center was to receive Udenyca, and the nurse realized that she still had a carton of Prolia in stock, but not the needed Udenyca. The patient was subsequently contacted and made aware of the error. The patient reported experiencing bone pain following the Udenyca injection but had no other complaints. During Udenyca clinical trials, the most common adverse reactions were bone pain and pain in the extremities.

ISMP previously alerted readers to the potential for mix-ups in the May 23 and July 18, 2019, issues of the *ISMP Medication Safety Alert!* Both medications look similar with green and white packaging, and the concentration is listed in a green circle in the same location (**Figure 1**, page 1). Each carton holds one single-dose, prefilled syringe, and both medications are intended for subcutaneous administration. The Prolia 1 mL syringe contains 60 mg, and the Udenyca 0.6 mL syringe contains 6 mg. Once the carton is opened, the syringes look different. Prolia and Udenyca are likely to be dispensed to the same outpatient oncology centers and infusion centers. Both are refrigerated items and may be near one another, especially if stored alphabetically by brand name.

Earlier, ISMP discussed the risk of mix-ups with Coherus BioSciences and FDA, and we understand that packaging changes are actively being pursued. ISMP urges pharmacists and other healthcare practitioners to ensure that inventories of these products are stored away from one another and that barcode verification occurs whenever possible before dispensing and administering the drugs. Pharmacy staff are also urged to apply a prominent auxiliary label to the outer carton that warns against confusion. Pharmacists should also consider circling (with a permanent marker) the drug name on the carton to draw attention to it.

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The lowest scoring GAT items in this section suggest ongoing unsafe practices associated with dilution and reconstitution of adult IV push medications. Only about a third (31%) of participating facilities reported that IV push medications are never diluted or reconstituted by drawing up the contents into a commercially available, prefilled flush syringe. Another third (30%) suggested that this unsafe practice is allowed and perhaps is widespread (58% mean percent score). Only 34% reported that dilution and reconstitution always occur in a clean, uncluttered, and functionally separate location. Furthermore, less than half (48%) of the facilities were fully confident that IV push medications for adults are diluted only when recommended by the manufacturer, supported by evidence in peer-reviewed literature, or in accordance with approved institutional guidelines.

Less than half of participating facilities (47%) reported that IV push medications prepared outside of the pharmacy are never withdrawn from commercially available, cartridge-type syringes into another syringe for administration, and only 64% were fully confident that associated syringe cartridge holders to support proper use are readily available.

Labeling. This section of the GAT evaluated IV push medication syringe labeling and availability of blank or preprinted labels. Overall, the average mean percent score for this section was 78%. The highest scoring GAT items in this section were related to a ban on pre-labeling of IV push medication syringes (87% mean percent score), and immediately discarding unattended, unlabeled syringes containing any type of solution (86% mean percent score), although it is concerning that only 77% and 70% of facilities, respectively, reported full compliance with these best practices. The lowest scoring GAT items were associated with making sure blank or preprinted labels are provided to clinical units to support safe labeling practices (71% mean percent score) and preparing and labeling just one syringe at a time when multiple medications or solutions are prepared away from the bedside (73% mean percent score). Less than half of facilities (49% and 46%, respectively) reported full compliance with these best practices.

Practitioner administration. This section of the GAT evaluated assessment of the access site and patient, barcode scanning prior to administration, IV push medication administration and flushing practices, and availability and permitted use of emergency rescue agents. Participants achieved a mean percent score of 80% for this section.

Barcode scanning of IV push *flush* solutions was the lowest scoring GAT item in this section (57% mean percent score), with 31% reporting that flush solutions were never scanned, and 31% reporting that flush solutions were always scanned prior to administration. Many more facilities reported barcode scanning of IV push *medications* prior to administration (78% mean percent score, 41% partial, and 53% full implementation). Another low-scoring GAT item dealt with including directions in protocols and/or coupled order sets that permit the emergency administration of rescue agents (67% mean percent score, 42% full implementation), although most facilities reported that antidotes and rescue agents are readily available where IV push medications are administered (85% mean percent score, 70% full implementation). Only about half of participating facilities (58%) reported that all IV push medications and any subsequent flush solutions are administered at the rate recommended by the manufacturer, supported by evidence in peer-reviewed literature, or in accordance with internal guidelines.

The highest scoring GAT items in this section, each achieving a mean percent score of 88%, involved conducting a clinical and vascular access site assessment prior to IV push medication administration, using a proximal connector to administer the medication through an existing IV infusion line, and flushing the line with an appropriate volume to ensure the entire medication has been administered. However, clinical and vascular access site assessment *following* the administration of IV push medications scored lower than assessment *prior* to administration (78% vs. 88% mean percent score).

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SAFETY briefs

Reduce the risk of phenol-related burns. A 15-year-old patient was undergoing a routine outpatient procedure on his scrotum. The surgeon requested a bottle of collodion skin adhesive (flexible collodion) for use in closing the surgical wound, but was accidentally handed a bottle of liquified phenol, which is approximately 89% phenol. It is believed that the two bottles, which look nearly identical (**Figure 1**), were stored near each other. The surgeon proceeded to apply a thin film of the phenol to the surgical wound and noted immediate blanching of the skin. The error was quickly identified, and the wound was irrigated with water and polyethylene glycol for more than 30 minutes. The event was

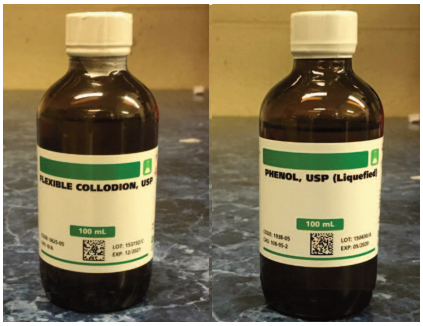

Figure 1. Similar looking 100 mL bottles (flexible collodion, left; phenol, right) resulted in error.

reported to a local poison control center. The patient was observed in the post-anesthesia care unit (PACU) for 6 hours and, fortunately, the blanching around the wound resolved and the patient experienced no systemic symptoms. Given the look-alike labeling of the Medisca phenol and flexible collodion bottles, it is unsafe to keep these anywhere near one another, especially in patient care areas.

Liquified phenol can cause severe burns if accidentally applied to the skin. A *Safety Brief* in our April 5, 2018, newsletter detailed a case involving a 17-year-old patient for whom phenol was being used to destroy part of the nail matrix (matricectomy) in conjunction with nail removal for treatment of an ingrown toenail. An unlabeled bowl of what was thought to be saline solution was used to cleanse the patient's foot, but it actually held phenol. The patient experienced a burning sensation which led to the realization that phenol solution was in the bowl. Although first aid was provided, and

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Drug information resources. This section of the GAT evaluated the availability of drug references and defined key terms associated with IV push medications. Overall, the mean percent score for this section was 75%. Defining "IV bolus" and "IV push" in facility policies scored lowest in this section (50% mean percent score), and the availability of facility-approved IV push medication resources (85% mean percent score) and resources free of error-prone abbreviations (91% mean percent score) scored highest.

Competency assessment. This section of the GAT evaluated privileging for preparation and administration of IV push medications, competency verification upon hire and ongoing, and feedback about errors and how to avoid them. Overall, participants scored the lowest in this section, achieving a mean percent score of only 67%. For-profit facilities scored much higher in this section than non-profit or government facilities (82% vs. 64%), as did facilities that were part of a larger system compared to single facilities (70% vs. 60%). Defining which practitioners can prepare (75% mean percent score) and administer (87% mean percent score) IV push medications scored highest in this section. The lowest scoring GAT items were related to competency assessments for IV push medication preparation and administration at the time of hire (59% mean percent score) and ongoing (44% mean percent score). Almost half of facilities (49%) reported no validation of IV push medication preparation and administration competencies on an ongoing basis, and almost one-third (32%) failed to validate competencies upon hire. Furthermore, only 42% of facilities consistently provide practitioners who prepare, dispense, or administer IV push medications with ongoing information about associated risks and errors that have occurred in the facility and have been reported by external organizations, as well as strategies to minimize these risks and errors.

Error reporting. This section of the GAT evaluated internal and external reporting and use of the information for improvement. Participating facilities achieved a mean percent score of 78% for this section. Scores tended to rise as bed size increased (73% for the smallest facilities, 83% for the largest facilities). Reporting of adverse events, close calls, and hazardous conditions associated with IV push medications *internally* within the facility was the highest scoring GAT item in this section (88% mean percent score), while reporting these events to *external* safety organizations such as ISMP for shared learning was the lowest scoring item (60% mean percent score).

Conclusion

While the results of the GAT suggest adherence to some of the best practices in the **ISMP Safe Practice Guidelines for Adult IV Push Medications**, the results also point out significant opportunities for improvement. The following 10 best practices, which scored low on the GAT, represent key national priorities that should be assessed and considered for improvement in all US healthcare facilities:

1) Purchase or prepare and dispense IV push medications in a ready-to-administer form as much as possible.
2) Only dilute IV push medications when recommended by the manufacturer, supported by evidence in peer-reviewed literature, or in accordance with approved institutional guidelines.
3) Never dilute or reconstitute an IV push medication by drawing the contents into a commercially available prefilled flush syringe of 0.9% sodium chloride.
4) Never withdraw IV push medications from commercially available, cartridge-type syringes into another syringe for administration.
5) Barcode scan all IV push *flush* solutions prior to administration. (While it may seem unnecessary to scan a saline flush syringe, given that it contains no active medication, there may be look-alike prefilled syringes that do contain active medications that may harm the patient.)
6) Include directions in protocols and/or coupled order sets that permit the emergency administration of rescue agents.

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poison and drug information services were contacted, the condition worsened and required additional care at a tertiary healthcare facility with a burn center.

If phenol is stored and/or used in your facility, determine why it is being used (e.g., matricectomy, nerve ablation) and whether alternatives are plausible. Many hospitals stock bottles of phenol for use in matricectomy; however, a better alternative is to use prepackaged phenol applicators that contain a small amount of phenol for use during procedures. These prepackaged applicators are much safer than bottles of liquid phenol and reduce staff exposure to phenol. If bulk bottles of liquid phenol must be used, keep them in the pharmacy and consider repackaging in small applicator bottles with auxiliary label warnings to dispense to areas outside the pharmacy.

Dangerous abbreviation: IT. The abbreviation "IT" was seen recently in conjunction with an investigational drug for use by ear, nose, and throat (ENT) specialists. This abbreviation is sometimes used for intratympanic injection. The website **MEDABBREV.com** (http://medabbrev.com/) mentions that IT has been used for "intrathecal, intra-tracheal, intra-tumor, intratympanic, and inhalation therapy" and, therefore, is a dangerous abbreviation for routes of administration. While the abbreviation may be well understood by ENT specialists, who knows if it might be confused in a way that could lead to mix-ups between other routes of administration, including intrathecal injection, which might be fatal. It should be on every organization's "Do not use" list and will be added to **ISMP's List of Error-Prone Abbreviations, Symbols, and Dose Designations** during the next update. Spell out these routes of administration to be sure communication is clear.

LevETIRAcetam premix strengths hard to tell apart. Dr. Reddy's premixed bags of levETIRAcetam 1,000 mg per 100 mL (10 mg/mL) and levETIRAcetam 500 mg per 100 mL (5 mg/mL) were erroneously mixed together in storage bins in the central pharmacy cleanroom as well as in a satellite pharmacy at the same hospital. The premixed levETIRAcetam bags, which

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7) Administer all IV push medications and any subsequent flush solutions at the rate recommended by the manufacturer, supported by evidence in peer-reviewed literature, or in accordance with internal guidelines.
8) Assess practitioner competency for IV push medication preparation and administration at the time of hire and on an ongoing basis.
9) Provide practitioners who prepare, dispense, or administer IV push medications with ongoing information about associated risks and errors (internal and external), and strategies to minimize these risks and errors.
10) Report errors, close calls, and hazardous conditions associated with IV push medications to *external* safety organizations such as ISMP for shared learning.

While the period for participation in our recent national assessment of adult IV push medication systems and practices has concluded, a PDF version of the **ISMP Gap Analysis Tool (GAT) for Safe IV Push Medication Practices** will remain available on our website (www.ismp.org/node/1188) for use by facilities. We encourage inpatient and outpatient facilities to use the GAT to identify facility-specific opportunities for improvement.

Table 1 appears on page 6—IV push GAT >

ISMP welcomes four new Fellows

ISMP welcomes two new **2019-2020 Safe Medication Management Fellows**, **Yashar Rafi, PharmD**, supported by Baxter International Inc., and **Benedicta (Benny) Asamoah, PharmD**, supported by Express Scripts Foundation.

Yashar had recently been working in a community pharmacy in California. He became interested in medication safety while obtaining his Doctor of Pharmacy degree at Jefferson College of Pharmacy, Philadelphia, PA, after attending lectures on medication safety presented by ISMP staff.

Benedicta completed her Doctor of Pharmacy at the University of Maryland Baltimore and a PGY-1/2 pharmacy residency in Health-System Pharmacy Administration and Leadership at the University of Pittsburgh Medical Center in Pittsburgh, PA. Medication safety has long been an interest.

ISMP also welcomes two international Fellows, **Nistha Shah, PharmD**, our **2019-2020 International Medication Safety Management Fellow**, supported by Novartis, Name Creation & Regulatory Strategy; and **Allison Hanson, PharmD, BCPS**, our **2019-2021 International Medication Safety Management Fellow,** supported by Baxter International Inc.

Originally from India, **Nistha** completed her Doctor of Pharmacy at Temple University, Philadelphia, PA, and completed a PGY-1 pharmacy residency at Nazareth Hospital in PA. Her interest in global safety initiatives grew when she participated in a mission trip to Guatemala as a pharmacy student and from personal experiences growing up in India. She will spend 1 year at ISMP.

Allison most recently practiced as a clinical pharmacist with Michigan Medicine. Prior to that, she completed a PGY-1 pharmacy residency with Froedtert & the Medical College of Wisconsin. Allison's enthusiasm for global medication safety sparked in pharmacy school. She participated in the International Pharmaceutical Students' Federation Student Exchange Program in Israel and interned with the International Pharmaceutical Federation in the Netherlands. She also attended the World Health Assembly in Switzerland. Allison will spend 2 years at ISMP.

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are available in three different concentrations (500 mg, 1,000 mg, and 1,500 mg per 100 mL), look nearly identical (**Figure 1**) and have the concentration printed in a way that is difficult to readily identify. A dispensing error was avoided when a pharmacist was checking an intravenous (IV) lev**ETIRA**cetam premixed bag and realized the wrong concentration was in hand. We have communicated with Dr. Reddy's to request a label revision and have notified the US Food and Drug Administration (FDA). Premixed solutions of lev**ETIRA**cetam from other manufacturers are available with better labeling. If you must use the Dr. Reddy's products, consider alerting staff about the issue and placing auxiliary labels on the bags and wherever the products are stored to help differentiate them. Always scan the barcode when selecting the product for dispensing and before administering the product at the bedside.

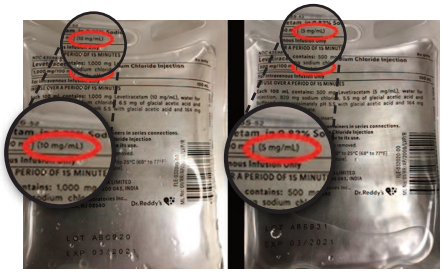

Figure 1. Dr. Reddy's infusion bags of lev**ETIRA**cetam 1,000 mg per 100 mL (left) and 500 mg per 100 mL (right) can be easily confused because they look remarkably similar, with the drug name and concentration listed in small print.

Special Announcement

Accepting Cheers Awards nominations

You still have time, until **September 6**, to submit a nomination for this year's prestigious ISMP **Cheers Awards**! To submit a nomination, please visit: www.ismp.org/node/1036.

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Report medication and vaccine errors to ISMP: Please call 1-800-FAILSAF(E), or visit our website at: www.ismp.org/MERP or www.ismp.org/VERP. ISMP guarantees the confidentiality of information received and respects the reporters' wishes regarding the level of detail included in publications.

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Table 1. Low- and High-Scoring GAT Items in Each Section

Low-Scoring GAT Item	Percent (%)				High-Scoring GAT Item	Percent (%)			
	Mean	Implementation				Mean	Implementation		
		None	Partial	Full			None	Partial	Full
ACQUISITION AND DISTRIBUTION OF ADULT IV PUSH MEDICATIONS									
Adult IV push medications are dispensed in a ready-to-administer form (to minimize the need for manipulation and product re-labeling outside of the pharmacy sterile compounding area).	61%	16%	62%	22%	Only commercially available or pharmacy-prepared prefilled syringes of an appropriate IV solution are used to flush and lock vascular access devices.	94%	0%	14%	86%
ASEPTIC TECHNIQUE									
The medication access diaphragm on a vial or neck of an ampule is disinfected with facility-defined disinfectant solution and allowed to air dry prior to accessing an IV push medication or solution.	81%	6%	34%	60%	A new syringe (and needle as necessary) is used for every IV push injection.	95%	1%	10%	89%
PRACTITIONER PREPARATION									
IV push medications are NOT diluted or reconstituted by drawing up the contents into a commercially available, prefilled flush syringe of 0.9% sodium chloride.	58%	30%	39%	31%	IV push medications are withdrawn from glass ampules using a filter needle or straw, unless specific drugs preclude their use.	93%	2%	14%	84%
LABELING									
Blank or printed, ready-to-apply labels, including sterilized labels, are provided to clinical units where needed, to support safe labeling practices.	71%	18%	33%	49%	Empty syringes are never prelabeled in anticipation of use.	87%	7%	16%	77%
PRACTITIONER ADMINISTRATION									
Barcode scanning or similar technology is used immediately prior to the administration of IV push *flush solutions* to confirm identification of both the patient and the solution, unless its use would result in a clinically significant delay and potential patient harm.	57%	31%	38%	31%	An appropriate, facility-defined, clinical and vascular access site assessment of the patient is performed *prior* to the administration of IV push medications.	88%	5%	17%	78%
DRUG INFORMATION RESOURCES									
Internal facility policies define IV bolus and IV push terms.	50%	45%	18%	37%	Facility-approved IV push medication resources are free of error-prone abbreviations and dose expressions.	91%	5%	11%	84%
COMPETENCY ASSESSMENT									
Competency assessments for IV push medication preparation and administration are standardized across disciplines within the facility and validated *on an ongoing basis*.	44%	49%	28%	23%	The facility has clearly defined which practitioners have privileges to perform IV push medication *administration*.	87%	7%	16%	77%
ERROR REPORTING									
Adverse events, close calls, and hazardous conditions associated with IV push medications are reported in confidence to external safety organizations such as ISMP for shared learning.	60%	31%	29%	40%	Adverse events, close calls, and hazardous conditions associated with IV push medications are reported internally within the facility.	88%	2%	26%	72%