An assessment of currently available i.v. push medication delivery systems

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In 1999, a consensus conference evaluated the safety, simplicity of use, and cost of available i.v. medication delivery systems and the need for education and training of healthcare providers (HCPs).[1] The medication delivery systems evaluated included pharmacy-based i.v. admixture systems, point-of-care activated systems, augmented i.v. push products, direct i.v. administration products, and manufacturer-prepared products. In 2009, a second consensus development conference convened to reassess the regulatory compliance, cost, ease of use, and patient safety of the available i.v. medication delivery systems, resulting in the development of a tool that could be used to assess the optimal system for a given facility.[2] Considerable differences existed among the various drug delivery systems in terms of their ease of use, cost, applicability to various patient populations, regulatory compliance, and patient safety. Since that time, new methods and devices designed to minimize dosing, compounding, and contamination errors and lower the risk of needle-stick injuries associated with i.v. push administration have evolved. Numerous organizations have published guidelines pertaining to i.v. push medications, and there is a need to evaluate the use of various administration methods with the goal of improving HCP and healthcare system adherence to these recommendations. The Institute for Safe Medication Practices (ISMP) has defined the term ready-to-administer (RTA),[3] but there is a need to identify the characteristics of an ideal RTA device or system to guide future development. Finally, a comparison of the characteristics of currently available i.v. push medication devices to those of an ideal RTA is needed so that decision-makers in healthcare systems can better select devices that improve compliance with best-practice guidelines and ultimately improve patient safety.

Approach

A multidisciplinary expert panel met on June 10, 2015, in Denver, Colorado. The panel selection process is described in the appendix. The objectives of this panel were to (1) assess the risks to patients from i.v. push administration practices, (2) review published guidelines and recommendations on i.v. push medication administration, (3) discuss the complexity of i.v. push medication practices, (4) identify the characteristics of an ideal RTA device or system for i.v. push medications, and (5) evaluate currently available i.v. push delivery devices and methods against the ideal characteristics. The panel also discussed barriers to the extensive use of RTA products.

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Panel discussion

The meeting began with a presentation of the risks associated with i.v.

push medications, including medication errors, infection, variations in potency, and needle-stick risk to HCPs.

Approximately one third of all adverse drug events can be linked to the administration phase of the medication-use process.[5] Intravenous medications are high-risk drugs due to their rapid onset of action, their narrow therapeutic range, and HCPs' limited ability to reverse any adverse effects once administered.[3] Harm from i.v. medications errors is 5 times greater than from medications not administered intravenously.[6] Medication preparation errors, such as deviation from the prescribers' medication order, manufacturers' preparation or administration instructions, or institutional policies, are the most common types of errors associated with injectable medications, occurring in 44–62% of injectable drug errors.[7-9] A 2014 publication from the Pew Charitable Trusts analyzing reports from 2001–13 revealed that more than 25 errors that included compounded or repackaged medications were associated with 1,000 or more adverse events, including 89 deaths.[10] Miscalculations, mistakes in filling the prescriptions, and microbial contamination were the primary errors cited.

Inaccurate medication preparation by HCPs is a potential cause of medication errors. A 2013 study revealed that 29% of 500 prepared unused syringes obtained from an operating room after pediatric and adult surgical procedures had concentrations that varied by more than 10% of the targeted concentration.[11] Of particular concern was that 8% of the syringes' concentrations varied from the targeted concentrations by more than 50% and that 4% had deviations exceeding 100% of the targeted concentrations.

According to the Centers for Disease Control and Prevention, hospital-based HCPs sustain an estimated 385,000 needle-stick and other sharps-related injuries each year.[12] Such injuries have been reported to affect the physical and mental health of HCPs.[13,14] In a survey of healthcare workers in a German university hospital, over 31% reported sustaining at least 1 needle-stick injury within the previous 12 months.[15] Of all occupational groups, physicians reported the highest risk of being injured by needle-sticks (55%), followed by nurses (22%).[15] Needle-stick injuries are a common occupational hazard for HCPs, and the National Institute for Occupational Safety and Health has recommended that employers eliminate the use of needles where safe and effective alternatives are available.[16,17] Nevertheless, vials and syringes continue to be the predominant method used to administer i.v. push medications in hospitals.

RTA i.v. bolus preparations. According to various publications (as well as panel members' observations of practices in their own institutions), clinicians' adherence to guideline recommendations for the administration of i.v. medications is suboptimal.[3,18-29] The expert panel reviewed regulatory and professional guidelines issued by various organizations regarding the use of RTA systems or devices. The guidelines reviewed included information regarding the safe use, labeling, packaging, dispensing, storage, and administration of single-use, single-dose, and multidose i.v. push medications. While the individual guidelines and recommendations differ in scope, virtually all recommend using single-use syringes or vials, not pooling or combining leftover contents for later use or to obtain a full dose, and not administering medicines from single-dose vials, syringes, or ampules to multiple patients, even if a cannula or needle is changed.[3,18,19,25,27,29] These guidelines also recommend that all preparations should be labeled with the medication's name, dose, and concentration and that provider-prepared preparations be avoided whenever possible.[3,20,22-25,27] The products purchased or dispensed should be in the most RTA form possible to minimize the risk of error and contamination. Ideally, these products should be in unit doses that are manufacturer-prepared under current Good Manufacturing Practices (cGMPs) or compounded by a licensed outsourcing facility subject to cGMPs to reduce compounding and labeling errors and minimize the risk of contamination.[3,20-23,25,30]

It is the opinion of the expert panel that the use of single-use-only i.v. bolus preparations can potentially reduce the risk of contamination and medication errors and allow for faster medication administration and symptom relief (by reducing the time needed to assemble the required supplies). The use of such systems may also improve the pharmacy workflow and assist the pharmacy department in becoming more compliant with regulatory guidelines. In addition, the use of manufacturer-prepared products (prepared under conditions that conform to cGMPs) will help ensure the administration of a high-quality product. Eliminating the need to transfer drugs from a vial to a syringe or any other device for administration should reduce the risk of contamination and HCP injury. The ideal RTA system should be cost-effective, be available in standardized doses to minimize waste and diversion, have a sufficiently long expiration date, and need no additional manipulation at the point of use.

Characteristics of an ideal RTA system. The expert panel identified 7 characteristics of an ideal RTA i.v. push medication system. A scoring matrix was then used to evaluate the 6 i.v. push medication delivery systems currently available. The 7 characteristics identified by the panel included

- Prefilled standard single dose,
- Manufacturer-prepared under cGMPs,
- Single-patient-use only,
- No assembly required (i.e., no needles, plunger, or labeling needed at the point of care),
- No drug manipulation required (e.g., no need for further dilution),

- Labeling information consistent with ISMP labeling requirements (including clear, easily understood, readable, and unobscured labels and easy-to-read gradations showing best contrast [vertical gradations preferred]), and
- Label and barcode on outside of tamper-evident package.

The ideal RTA system should be a single-dose prefilled syringe to prevent use on multiple patients. Manufacturer-prepared syringes were considered ideal since preparation using cGMPs is the optimal means to meet sterility, potency, shelf-life, and other established standards, thereby minimizing the issues of potential contamination and altered potency. Recently, the Food and Drug Administration (FDA) implemented the Drug Quality and Security Act, which requires that facilities that perform anticipatory compounding or repackaging of large volumes of sterile products register with FDA and adhere to cGMPs.[31] This suggests that prefilled syringes compounded by registered 503B outsourcing facilities may satisfy the characteristics listed for an ideal RTA system, provided that these facilities are regulated and monitored as meeting cGMPs by FDA.

According to the panel members, the ideal RTA system would require no assembly or dose manipulation. It should be noted that such characteristics would preclude the use of RTA devices in patients who require customized dosing based on age, weight, laboratory test values, or other patient-specific criteria.

Assessment of current delivery systems. The panel recognized that RTA i.v. unit-of-use push medication delivery systems may help HCPs adhere to the guidelines while minimizing the number of steps required for preparation and administration of i.v. drugs, thus limiting the opportunities for errors associated with i.v. medication administration. Several such systems have been in use or have recently become available and include a broad spectrum of devices including pharmacy-prepared syringes, compounding pharmacies' or 503B outsourcing facilities' prefilled syringes, and, more recently, manufacturer-prefilled syringes and prefilled cartridge systems.[32-35]

The manufacturer-prefilled delivery systems, as well as pharmacy-outsourced prefilled syringes from 503B-registered outsourcing facilities, are prelabeled, barcoded, and compliant with several published guidelines. However, some prefilled cartridge systems require an injection device or manipulation of the prefilled needle-free device before they can be administered at the point of care.[33,34] Therefore, the expert panel proposed a new phrase, "near ready to administer" (NRTA), to differentiate these devices from prefilled syringes that are truly RTA without any additional assembly. The panel also discussed the results of a survey conducted by ISMP in 2012, which indicated that nurses were using prefilled cartridge systems as single-dose or multidose vials, removing the needleless adapter and puncturing the rubber diaphragm with a needle attached to a syringe instead of using the syringe holder that was included as part of the delivery system.[36] According to the nurses, this approach was used for various reasons, including lack of awareness about the availability of syringe holders, unfamiliarity with how to use the syringe holders, difficulty viewing the volume gradations once the cartridge was placed inside the syringe holder, desire to prevent wastage of drugs during shortages, difficulty in administration due to occasional cartridge slippage, incompatibility of syringe holders with some needleless i.v. connectors, and risk of breaking the glass cartridges.[36] The survey results highlight the need to design i.v. unit-of-use push delivery systems that improve patient safety, minimize manipulation at the point of care, and minimize the potential for use that is inconsistent with best-practice recommendations.

The panel members assessed the following 6 i.v. drug delivery systems: (1) HCP-prepared single-dose injectables, (2) HCP-prepared multidose injectables, (3) pharmacy-prepared single-dose injectables, (4) repackaged or outsourced injectables,[35] (5) manufacturer-prepared NRTA delivery systems,[34,35] and (6) manufacturer-prepared RTA delivery systems.[32] The HCP-prepared multidose injectable preparations did not meet any of the characteristics for an ideal RTA delivery system established by the panel. The HCP-prepared single-dose injectables met only 1 of the characteristics (i.e., single use). Panel members noted that this method is the most commonly used method of i.v. push administration today in U.S. hospitals. The pharmacy-prepared and repackaged or outsourced injectables met 5 characteristics (prefilled, single use, requires no assembly, requires no manipulation of the drug, and follows ISMP labeling guidelines); however, the repackaged or outsourced injectables were considered superior to the pharmacy-prepared preparations when prepared using cGMPs. The panel did not consider injectable products prepared by a 503A-type compounding facility since they do not meet the rigorous cGMP standards and are intended for patient-specific compounding only. The manufacturer-prepared NRTA methods and devices met 6 of the 7 characteristics (prefilled, single use, manufactured under cGMPs, requires no manipulation of the drug, follows ISMP labeling guidelines, and has label and barcode on outside of tamper-evident package). The manufacturer-prepared RTA devices met all 7 characteristics. The manufacturer-prepared NRTA devices ranked lower than the RTA methods and devices because some assembly or manipulation is required at the point of administration. Results of the ISMP survey suggest that some NRTA devices are not being used as intended.[35] When used as a single-dose or

multidose vial, the NRTA method or device meets fewer of the ideal characteristics as set forth by the panel.

Scoring matrix

A scoring matrix was developed by 1 of the panel members to evaluate other aspects of the available i.v. push administration systems. All panel members reviewed the tool and had the chance to comment before its use. The matrix included 6 domains: (1) procurement, (2) dispensing, (3) safety, (4) usability, (5) efficiency, and (6) compliance with regulatory standards and best practices. The categories were weighted equally. The criteria for each of the 6 domains are described below. Panel members used a 7-point Likert scale to rate each domain for each system. Before applying the matrix, the panelists were given the opportunity to interact with each of the different systems. The criteria for each domain are listed below.

Procurement: cost of drug acquisition, cost of additional supplies, cost of waste from unused drugs, cost of waste from expired drugs, and cost associated with shortages.

Dispensing: inventory storage in pharmacy, storage at point of dispensing, availability of standard concentrations, identification of high-alert medicines to prevent dispensing errors, and ease of auditing for controlled drugs.

Safety: prefilled, prelabeled, and barcoded medication delivery system, risk for needle-stick injury, safe disposal, preparation in a sterile environment, dosing and administration accuracy, and risk of harm to patients and HCPs.

Usability: easy to use, prepare, and administer in the safest manner and improve HCPs' ability to recognize potential medication errors and correct such errors.

Efficiency: time required to gather all required materials, prepare the medication, manipulate the drug, and assemble the device.

Compliance: presence of required labeling and barcoding; availability as a unit-dose, prefilled, RTA prepa-

Table 1. Mean Scores of I.V. Push Methods and Devices[a]

Variable	HCP-Prepared Single-Dose Injectables	HCP-Prepared Multidose Injectables	Pharmacy-Prepared Single-Dose Injectables	Repackaged or Outsourced Injectables	Manufacturer-Prepared NRTA Delivery Systems	Manufacturer-Prepared RTA Delivery Systems
Procurement	3.19	3.44	3.57	2.89	2.86	2.68
Dispensing	4.93	4.59	5.54	5.43	5.52	5.59
Safety	3.25	2.98	5.36	5.78	6.07	6.50
Usability	3.25	3.00	4.91	5.69	4.80	5.80
Efficiency	2.75	2.69	6.09	6.36	5.31	6.75
Compliance	3.12	2.82	5.86	5.84	6.00	6.43
Total score	20.49	19.52	31.33	31.99	30.56	33.75

[a]Each domain was scored by using a 7-point Likert scale. The scales were as follows, by domain: procurement (1 = extremely low and 7 = extremely high), dispensing (1 = extremely impossible and 7 = extremely possible), safety (1 = extremely dangerous and 7 = extremely safe), usability (1 = extremely difficult and 7 = extremely easy), efficiency (1 = extremely inefficient and 7 = extremely efficient), and compliance (1 = fosters total noncompliance and 7 = fosters total compliance). HCP = healthcare provider, NRTA = near ready to administer, RTA = ready to administer.

ration; potential for diversion; and potential for use past the beyond-use date.

The mean score obtained for each device is shown in Table 1. The pharmacy-prepared single-use injectables, repackaged outsourced injectables, manufacturer-prepared NRTA delivery systems, and manufacturer-prepared RTA delivery systems all scored numerically higher than the HCP-prepared single-dose or multidose preparations in the dispensing, safety, usability, efficiency, and compliance categories. Not all panel members responded to all criteria under various domains; if a panel member did not feel knowledgeable in assessing a domain, then he or she abstained from rating that attribute.

The panel members noted that the RTA devices have not been widely adopted in hospitals and healthcare systems. One of the primary barriers recognized by the panel was the cost associated with these newer methods and devices. Panel members believed that when a hospital or healthcare system evaluates the available i.v. push options, it is critical to consider the safety and sterility characteristics, the cost of additional supplies needed, and the time required by nurses to manipulate and label the non-RTA devices.

Another barrier identified by the panel was the availability of storage space, as the RTA devices provide challenges related to storage space in automated dispensing cabinets. Finally, the panel believed that the common practice of nurses diluting i.v. push medications is a key barrier in the optimal use of RTA devices. Results from a recent ISMP survey revealed that 83% of 1,773 respondents diluted i.v. push medications before administration.[37] The reasons reported for this dilution predominantly centered around protecting the patients from perceived adverse events or harm associated with rate of administration, potential irritation, and i.v. access duration. However, there is little evidence that this extra manipulation of the drug before administration improves safety.

RTA devices can help improve patient safety because they require fewer manipulations, thereby minimizing the risk of contamination and other medication errors.[3,4] RTA devices have been reported to help save nurses time and improve their workflow, thus allowing them to focus on other activities related to patient care and clinical work, resulting in improved nurse satisfaction.[4] From the perspective of the health system, RTA devices improve standardization, as they are labeled and barcoded, and may reduce training requirements for medication administration and variability in administration practices.[4]

Summary

A small panel of experts reviewed the current evidence and guidelines regarding the administration of i.v. push medications and the adherence of HCPs and health systems to those recommendations. The panel noted that significant variation from best-practice guidelines exists in current practice. Panel members believed that barriers to the use of more ideal i.v. push drug delivery systems should be addressed by healthcare organizations, and HCPs and healthcare leaders should become more familiar with the risks and benefits of such systems and strive to move practice toward optimal and safer administration practices. The opinions and recommendations of the expert panel are limited by the small number of panel members, and similar assessments by a larger group of stakeholders should be conducted to validate the views of the panel. Finally, panel members recognized that, as newer devices evolve, there is a need to reevaluate the systems periodically to ensure that appropriate modifications are made to the characteristics for an ideal RTA administration system.

Disclosures

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Appendix—Selection of the multidisciplinary expert panel

This multidisciplinary expert panel was identified by a committee that included the chairperson of the 2008 Second Consensus Development Conference on the Safety of Intravenous Drug Delivery Systems[2], a nursing executive, and a patient safety expert.

Panel members from the previous consensus conference were invited to attend. Those who could not attend were asked to nominate physicians, pharmacists, nurses, medication safety officers, and human factors researchers with extensive knowledge of i.v. push medication administration and patient safety.

Panel members were vetted by reviewing their publications, leadership roles in relevant positions, and interests.

Selected expert panel members consisted of pharmacists, nurses, human factors experts, quality experts, patient safety experts, medication safety experts, and a critical care–emergency medicine physician, representing a variety of practice settings.

All expert panel members were aware that the meeting and the subsequent publication of the group commentary were funded by an unrestricted educational grant from BD Rx.