Improving the Safety of IV Drug Delivery:
Interpreting Current Standards To Improve Practices

Various recommendations are available to help health systems improve their intravenous (IV) drug delivery processes. One of the more significant guidelines came out of the Second Consensus Development Conference on the Safety of Intravenous Drug Delivery Systems, held in August 2008, which reflects the standards put forth in the United States Pharmacopoeia (USP) Chapter <797> guidelines and the Joint Commission’s medication management standards. These recommendations, which were highlighted in the previous articles in this series, establish a framework to assist institutions in improving the safety of IV drug delivery. However, many health systems continue to struggle over how to implement some of these recommendations. This article discusses some factors to consider during the implementation of, and compliance with, the consensus recommendations and current standards.

Streamlined Systems

Pharmacy IV admixture programs can involve a variety of product types, including manufacturer-prepared, premixed (ready-to-use) products; outsourced ready-to-use products, point-of-care activated products, pharmacy-compounded products, and products compounded at the point-of-care (Table). Specific delivery vehicles can include syringes, mini-bags, frozen premix products, and other premixes.

Many health systems have 6 or 7 different IV drug delivery systems using an assortment of the aforementioned products. Although a single system would be ideal, there is no single system that can meet all the possible needs related to different patient and disease-state parameters. Minimizing the disparity of systems used may improve efficiency by reducing waste and allowing reuse of a greater number of products. With that in mind, the best approach may be for facilities to set up 1 major system, with 1 or 2 minor systems in place to cover unusual circumstances.

Making the Choice

Facilities should determine which 2 or 3 drug delivery system options are best suited for them. These systems can differ with respect to cost, safety, ease of use, regulatory compliance, and applicability to various patient populations.

Although the Joint Commission has not recommended a specific drug delivery system, it has established specific goals with regard to standardized concentrations of solutions. These recommendations, identified as medication management standards, support the use of premixed or manufacturer-prepared products. Such products ensure enhanced quality and system integrity for a defined period of time. Outsourced products offer many of the same attributes but may require shorter dating and increased pharmacy oversight in contracting, etc. The combination of these 2 methods along with some pharmacy compounding may fit into many workflow plans. Facilities may choose to use vial-attached systems such as Vial-Mate, ADD-Vantage, or Mini-Bag Plus to avoid compounding directly when possible. Determining which IV drug delivery system is best requires a thorough evaluation of the net cost of each product type before settling on a particular approach. Pure product acquisition costs are not the only costs to consider when choosing IV drug delivery systems. There are time, safety, and risk costs, as well as additional expenses related to handling, waste, and medication errors that should be factored into the analysis. For example, although premix drug delivery systems may have a higher acquisition cost, they also can allow pharmacy resources to be used more efficiently (ie, having a decentralized clinical pharmacists or pharmacy technicians admixing only necessary compounds). Individual health systems must determine the best way to balance all of these factors in order to meet their particular needs, which can vary widely based on patient demographics, institution type, size of pharmacy staff, available storage space, budgets, group purchasing contracts, and other financial considerations. Still, prevention of medication errors whenever possible should be a primary goal of any major system. IV compounding has a large potential for errors to occur. The MEDMARX Data Report, which focused on a database of more than 400 hospital systems nationwide, cited 11,239 perioperative errors reported voluntarily to the system between 1998 and 2005. Of the errors reported to

| Table 1. Common Issues Associated With IV Drug Delivery Systems |
|-------------------|---------------------|-------------------|
| **PRODUCT TYPE** | **BENEFITS** | **PROBLEMS** |
| Non–pharmacy-compounded at point of care | Can customize dose for each patient, immediate availability | High potential for error, low compliance with regulatory requirements, labeling typically handwritten or absent, risk for contamination |
| Pharmacy-compounded | Can customize dose for each patient, significant quality control, labeled in accordance with hospital standards | Risk for contamination, significant operational requirements related to USP Chapter <797> |
| Point-of-care activated | Works well with automated cabinets, longest expiration date | Products not available for special patient populations, cost analysis recommended, risk for inactivation errors |
| Outsourced ready-to-use | Can customize dose for each patient, low risk for contamination | Cost analysis recommended, requires advance planning and storage |
| Manufacturer ready-to-use | Low risk for contamination, ease of use and dispensing, longest expiration date | Products not available for special patient populations, lack of pharmacoeconomic data, frozen products require thawing |

IV, intravenous; USP, United States Pharmacopoeia

Adapted from the Second Consensus Development Conference on the Safety of Intravenous Drug Delivery Systems.
Gearing Up for Implementation

Once the drug delivery systems are chosen, they must be implemented the way they are intended to provide their full benefits. Efficient use of these systems will result in optimal cost savings and patient safety improvements. Clearly delineating how the systems will be used and the specific roles of the various staff in the process will greatly assist in the program’s implementation.

The components of implementation include purchasing all required products and addressing storage needs. Training staff is a mandatory step in this process that is often overlooked. Errors may occur when the staff uses a new drug delivery system without fully understanding the features of the system. Certain aspects of implementing a new drug delivery system may discourage staff as unfamiliar steps may be required. These areas need to be discussed and resolved before the system is implemented.

Staff Training and Documentation

Additional regulations and technical requirements are involved when admixtures are compounded in the pharmacy. USP Chapter <797> defines the processes that are required to provide a high-quality environment and the appropriately trained personnel to accomplish the compounding of IV solutions in each practice setting. When a pharmacy prepares admixtures it must be done using specific policies and procedures to operate with a high degree of quality. System-specific training is required for all personnel using the IV delivery system. Appropriate space and additional equipment are required to make certain the system does not encounter unnecessary obstacles.

In addition, there are specific requirements with respect to the design of appropriate clean rooms and anterooms, the use of gowns and gloves, as well as monitoring and reporting. A published gap analysis tool is available from the American Society of Health-System Pharmacists (ASHP) to help evaluate pharmacy-compounding programs. Several recent market introductions of training modules, (ie, a CD-ROM from ASHP and an online program from Baxter Healthcare) also are available to assist in the training and documentation of pharmacy staff.

Optimizing Pharmacy Processes

Consulting groups can assist health systems in evaluating the best approaches. One such group is Baxter Healthcare’s pharmacy services group. This group will consult with a facility and use several analysis and implementation tools to maximize the effectiveness and efficiency of the institution’s IV delivery system. They can also evaluate staffing components, available space and equipment, and policies and procedures already in place, and make specific suggestions.

Another option is to use Lean Six Sigma principles and statistics to analyze current processes and compare with desired future state. Defining the process, collecting and analyzing the data, and identifying opportunities will assist in developing and presenting the justification for the drug delivery system chosen by identifying variables and results to support the decision.

Conclusion

IV delivery systems are a major consideration with regard to patient safety. Institutions must ensure policies and procedures match the actual use of product and that all involved staff are properly trained on the use of the system being implemented. This reevaluation process should take into account changes in technology as well as new products that may offer increased efficiency and/or safety.

References