The Selection Process for IV Workflow Technology

By Mary-Haston Leary, PharmD, BCPS, and Stephen F. Eckel, PharmD, MHA, BCPS

Photo courtesy of University of North Carolina (UNC) Medical Center

Adverse events caused by compounding errors are a serious public health concern that have prompted increased regulation.[1] We know the risk is significantly greater with compounded IV medications than with oral medications, as oral medications typically receive two checks, from both the dispensing pharmacist and the nurse, prior to administration. Injectable medications administered in the United States are associated with an estimated 1.2 million preventable adverse drug events (ADEs) each year, resulting in $2.7 to $5.1 billion in additional health care costs.[2]

USP <797> has introduced several important safety measures into the IV medication compounding process to ensure a more sterile product,[3] prompting many institutions to significantly redesign their IV compounding procedures and cleanrooms. However, if workflow processes do not change, inefficient or unsafe practice could result. For example, the syringe pullback method of verifying admixtures—wherein the technician injects medication into a container and pulls back the syringe plunger to display the amount added so the pharmacist can verify—is unreliable, per data submitted to the ISMP Medication Errors Reporting Program.[4] With this method, the pharmacist must simply trust that the pharmacy technician accurately added the correct amount of drug to the final product.

The Pharmacist's Responsibility

To ensure medication safety and avoid onerous regulation, pharmacists must be vigilant in ensuring the accuracy and sterility of compounded sterile preparations (CSPs).[1] ISMP recommends the use of bar code scanning and other technologies to assist in verifying the accuracy of IV medications, especially high-alert medications, pediatric/neonatal preparations, pharmacy-prepared source/bulk containers, products administered via high-risk routes of administration (eg, epidural, intrathecal), and other high-risk IV medications.[5] To achieve this goal, some hospitals have implemented IV workflow management systems (WFMS), which automate the processes associated with preparing, verifying, tracking, and documenting IV medications. These systems require bar code scanning of each ingredient for positive identification prior to use in compounding. Additionally, IV WFMS provide support throughout the compounding process, from workflow queue to expiration tracking.[5] Careful evaluation of the various IV WFMS is critical to selecting the system that best fits an organization's needs.

Overall, just 6.5% of all hospitals utilize sterile product workflow management technology for IV preparation, although the trend is significantly higher in larger facilities (>200 beds 15.9%; <200 beds 3.8%). Large, academic medical centers cite a lack of funding, insufficient resources to support implementation, and a dearth of evidence to justify the return on investment as the main

barriers to IV workflow implementation.[6] Nevertheless, 33% of facilities of all sizes plan to implement IV workflow automation moving forward, with the largest hospitals most likely to do so.[7] As adoption of IV WFMS becomes more common, organizations must ask the right questions to identify the system that best suits their specific requirements.

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Questions to Ask in the Selection Process

Workflow

Hospital pharmacies that compound IV medications experience workload stress resulting from order changes, cancellations, and any other actions that require the pharmacy to reproduce and re-dispense an IV medication. Accordingly, IV WFMS are often leveraged to exert greater control over production and distribution.[8] When considering the workflow changes that will occur with the adoption of IV workflow automation, it is important to assess the entire process in a comprehensive manner. Note that while certain steps may require additional time under an automated approach, waste will likely be reduced at other points in the process.

IV WFMS contain several functionalities that improve the workflow within the cleanroom, including standardizing preparation, generating labels, and automating calculations. Moreover, these systems maintain an electronic record of the entire compounding process. From a waste management perspective, certain IV WFMS are capable of assigning beyond-use dates, tracking expiration and lot numbers, and tracking to minimize missing doses.[6]

Key workflow assessment questions to ask when evaluating IV WFMS include[9]:

- How will the system impact current processes?
- What steps will be required to support the new workflow?
- How will the system impact the time required for IV preparation?
- Will the system require an increase or decrease in the number of technicians on staff?
- Will a temporary staff increase be necessary during the implementation period?
- Is the system capable of tracking doses?

Safety Features

IV WFMS provide significant safety benefits, including bar code scanning, gravimetric measuring, and image capture and remote verification.

- **Bar Code Scanning.** By utilizing bar code scanning technology to scan each ingredient prior to compounding, IV WFMS can minimize medication errors by reducing the potential for selecting the wrong drug/IV fluid or wrong dose.
- **Gravimetric Technique.** Traditional compounding utilizes volumetric technique or the syringe pullback method, whereby technicians manually pull back the syringe to indicate the volume used. Conversely, gravimetric technique uses the specific gravity of the medication to compare the ordered dose to the final syringe weight. Gravimetric preparation provides multiple safety benefits versus volumetric technique, including ensuring syringe volume consistency, accurate reconstitution, and allowing the pharmacist to confirm that the correct volume has been added. In addition, gravimetric technique allows for verification of weight prior to addition to the final container, and eliminates the syringe pullback method.

  With gravimetric analysis, the known specific gravity or density of each ingredient is used to confirm the accuracy of the additives and base solution in a product based on its measured weight. During each step of the process, solutions are weighed on an electronic balance and the results are compared to the expected weight stored in the system's database. This verifies the accuracy of the prepared volume and ensures that it falls within an acceptable margin of error. One challenge with gravimetric analysis is the limited availability of known specific gravities for non-hazardous medications, limiting its use for these drugs.[10] As additional technologies that rely on specific gravities enter the market, it is expected that the availability of this information will increase.
- **Image Capture and Remote Verification.** Image capture and positive photo identification help ensure accurate product selection and preparation during each step of the compounding process. Image capture provides real-time electronic images of infusion bags, drug and diluent vials, and syringes throughout the verification process. In addition, image capture facilitates remote verification by the pharmacist (in states where remote verification is permitted), an additional workflow benefit. Finally, image capture creates an archived record of the preparation, should the need arise to validate what was dispensed to a patient.

Critical safety feature assessment questions include:

- Does the system provide bar code scanning?
- Does the system utilize image capture, gravimetric analysis, or both? What does your institution value in safety features?
- Is your institution interested in implementing an IV workflow management system for hazardous compounding, non-hazardous sterile IV compounding, or both?
- Does the system facilitate identification and correction of errors prior to pharmacist verification?

System/Vendor Comparison Factors

Implementation of an IV workflow management system requires significant engagement with the vendor. Considerations include the cost of the system relative to the safety and workflow capabilities offered, and the level of customer support provided to the organization.

Important questions to ask a potential vendor include[9]:

- What level of automation repair and replacement will be available? What is the expected turnaround time for equipment repair/replacement?
- How long will project development, testing, and implementation take?
- What level of project support will the vendor provide?
- Does the vendor provide sample policies, procedures, or quality assurance best practices?
- Is onsite training offered? If so, what does it entail?
- What lessons have been learned from early adopters of IV automation?

As adoption of IV WFMS becomes more common, organizations must ask the right questions to identify the system that best suits their specific requirements.

Interoperability

Introducing technology with the capability to interact with the electronic health record (EHR) requires an increased focus on integration and interoperability. IV WFMS access the EHR to build a work queue of medications to be compounded. Additional advantages of these systems include a status dashboard indicating where each dose is in the preparation process, as well as reporting capabilities.

Key interoperability questions include[9]:

- Does the system integrate/interface with the institution's current EHR system?
- Can the system use active authorization accounts (eg, for technician and pharmacist login), or is a separate login required?
- Will the IV WFMS system require information system (IS) enhancements?
- Does the vendor provide interface development, or does this responsibility lie with the institution?

Choosing a System

When assessing the available automation systems, it is important to evaluate the effectiveness of the workflow management system while also reviewing any integrated technology that assists in improving the accuracy and/or precision of IV production. Most systems utilize a queuing system with bar code verification to ensure the correct ingredient is chosen and to promote efficient workflow; some systems offer additional tools to ensure dose accuracy. Descriptions of some of the available IV WFMS, including DoseEdge,[11] BD Pyxis IV Prep (formerly BD Cato),[10] Phocus Rx,[12] Dispense Prep/Dispense Queue,[13] and IVX Workflow,[14] are included below.

Features of specific IV WFMS include:

DoseEdge

DoseEdge from Baxter interfaces with the PIS to automate routing, preparing, inspecting, tracking, and reporting on IV and oral liquid doses, reducing opportunities for compounding errors and improving the efficiency of sterile and nonsterile workflow. A stationary camera captures digital images that allow a pharmacist to verify products throughout drug preparation remotely. The system utilizes automatic calculations, bar code scanning, and IV Workload Management Solutions software (which provides a pharmacist work queue). DoseEdge offers an optional gravimetric system to verify dose weight during compounding; if gravimetrics are incorporated, the organization can opt to either use or not use gravimetric verification for each dose, which facilitates efficient preparation of lower-risk products. DoseEdge includes lot number and expiration date tracking, and helps identify errors prior to admixture, to reduce the number of rejections and remakes. Reporting functions facilitate analyzing compounding error rates, workload trends, and productivity measures.[11]

BD Pyxis IV Prep (formerly BD Cato)

BD Pyxis IV Prep comprises a camera, a bar code scanner, a scale, and a software platform. The system utilizes bar code scanning, image capture, gravimetric preparation, and remote verification. As a part of the gravimetric system, the system hard-stops the technician if a dose is out of range and approves doses that are within tolerances set by the organization. For example, an institution may determine that it will accept doses within +/-10% of the ordered dose. The bar code scanning functionality, in combination with gravimetric functionality, facilitates identification of errors in real time. From a waste management perspective, the system selects remainder vials for the technician to use before removing an unopened vial. BD Pyxis IV Prep also auto-populates remainder labels for vials for drug remaining after use, and generates waste reports for unused medications.[10]

Phocus Rx

Phocus Rx from Grifols facilitates remote pharmacist verification and documentation of IV compounding processes. The system integrates with the EHR to enhance workflow for patient-specific and batch preparations. Phocus Rx provides two hardware solutions: an adapted hardware, in which compact cameras are placed in cleanroom ceilings, with medical-grade touchscreen computers supported by arms located at workstations; and an embedded solution, in which the cameras and computer are enclosed within the laminar airflow hood or biological safety cabinet. Phocus Rx utilizes bar code scanning to confirm the correct medication is used in each preparation, includes image capture capabilities for visualization of final products and remote verification, and tracks lot and expiration date.[12]

Dispense Prep/Dispense Queue

Dispense Prep/Dispense Queue is an IV workflow management system module within the Epic EHR. With this system, each patient's dose enters an electronic queue within the EHR, where the pharmacy technician manually selects the order to print the label for compounding. The EHR validates the scanned bar code, matches the order, and alerts the technician if an incorrect medication was selected. Dispense Prep/Dispense Queue helps to reduce waste, as the EHR automatically removes orders from the electronic queue as they are discontinued or if the patient is discharged.[13]

IVX Workflow

IVX Workflow is a sterile compounding workflow solution available from Omnicell. The system incorporates integrated bar code scanning, the option of either gravimetric or volumetric verification, image capture and photo documentation, and label printing. IVX Workflow allows for remote pharmacist verification and also has the capability for reporting and analytics to improve workflow optimization and efficiency. The module is designed for placement within laminar airflow hoods. It supports aseptic technique by providing

step-by-step instructions to guide technicians in preparing IV doses according to set protocols, and requires minimal screen contact. The system is powered through the Omnicell IVX Cloud, Web-based software that supports workflow and formulary management. The cloud technology also provides safety features, such as specific gravities and BUD studies. The IVX Cloud integrates with Wolters Kluwer's Simplifi 797 to support USP <797> and <800> compliance.[14]

In addition to the technologies described, additional workflow systems and devices to improve the precision and accuracy of IV medications will soon be introduced to the market. Establishing clear goals and a specific strategy for integration and optimization of the technology, as well as an accurate understanding of the features offered by each system, is necessary to select the technology that will be the best fit for your organization. **ONLINE TABLE 1** includes features to consider when choosing an IV workflow management system.[10]

Conclusion

IV WFMS are an important tool to enhance safety in sterile IV compounding. As with all new technologies, institutions must assess the impact of these systems and prepare for significant change management associated with their implementation. Determining your organization's goals for the technology, as well as investing the time up front for system selection, will ensure the selected automation meets your needs. Moreover, implementing an IV workflow management system provides pharmacy peace of mind that patients' IV medications are accurate and safely compounded. ■

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Apoteca USA
Baxter Healthcare Corporation
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Envision Telepharmacy
Grifols USA
ICU Medical, Inc
MedKeeper
Omnicell, Inc
RxScan, Ltd
ScriptPro

UNC Hospitals discloses that it has received a grant from BD to study specific gravities for medications in IV workflow automation.

Mary-Haston Leary, PharmD, BCPS is a PGY2 Administration/MS Resident at the University of North Carolina (UNC) Medical Center in Chapel Hill and UNC Eshelman School of Pharmacy. She received her pharmacy education at the University of Mississippi School of Pharmacy. Mary-Haston's professional interests include transition of care services, practice advancement and pharmacy practice models, and practice-based outcomes research.

Stephen F. Eckel, PharmD, MHA, BCPS, is an associate director of pharmacy at UNC Hospitals, as well as a clinical associate professor and interim chair in the division of practice advancement and clinical education. He oversees the 2-year MS in pharmaceutical sciences with a specialization in health-system pharmacy administration, and is also the associate dean for global engagement. Stephen received both his BS and PharmD from the UNC Eshelman School of Pharmacy and his MHA from the UNC Gillings School of Global Public Health.