Current State of IV Workflow Systems and IV Robotics

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Introduction

Despite the fact that errors in intravenous (IV) compounding are among the most likely pharmacy errors to cause patient harm, the typical pharmacy IV room remains one of the last places to be touched by advances in pharmacy automation. However, new IV automation technologies promise to change this. This white paper outlines technologies currently available, offers a list of key questions to consider when evaluating IV automation for your institution, and summarizes early implementation experiences. Please note, TPN compounders are outside the scope of this white paper.
Overview of Available Technologies

Two primary types of automation technologies exist within the IV room: IV robotics and IV room workflow systems. When compared with the traditional method of IV compounding, these technologies offer additional safeguards and advantages that result in decreased errors, decreased waste, operational efficiency, a retrievable electronic audit trail, and even increased employee safety through reduced exposure to hazardous materials.

IV robotic systems are able to compound a combination of IV syringes and/or IV bags depending on the system. In many cases, IV syringes can be compounded in sizes ranging from 0.5 ml to 60 ml. Faster fill rates of up to 600 doses per hour can be achieved if volumes are relatively small (<12ml) and a single syringe size is used. Utilizing a wider range of volumes and syringes will dramatically decrease throughput rates. A broad range of sizes are also possible for IV bags with output ranging from 25-1000 ml per bag and a rate of up 50-60 doses per hour. Production of IV products in an IV robotic system is initiated with validation of stock items through a combination of either gravimetric or volumetric measurement and barcode verification. Following verification, stock items are disinfected and transferred to an IV bag or syringe based on order information collected from the native pharmacy computer system through either an HL7 interface or a print stream interface. Depending on the system, compounded doses are then verified through gravimetric measurement before a final barcoded label is applied to the completed dose for final verification and delivery. With some systems, hazardous materials (e.g. chemotherapy) can be compounded in the IV robotic system thus reducing exposure and subsequently improving employee safety.

IV room workflow systems can be used to compound anything from high-risk, high-cost medications to single-drug antibiotics and even oral medications. IV room workflow systems follow a similar process as described in the previous robotics example but manual steps replace automated steps that were completed by the robot. As orders transfer across from the pharmacy system, they populate into a workflow queue allowing the technician to group and prioritize doses to process. As the technician proceeds with compounding each dose, a compounding label is generated, products are verified via either barcode scan or a gravimetric check, and images are captured of all relevant steps in the compounding process. When doses are ready to be verified, a pharmacist accesses the system reviewing each step the technician took to prepare the product and verifying the images associated with each dose for accuracy. The pharmacist is able to complete this verification process remotely from any workstation with access to the IV workflow system. As doses are verified as correct, a single barcode label is produced and applied to that dose indicating the dose is ready for delivery. Verified doses then can be scanned during subsequent steps of the delivery process which then creates an audit trail and allows pharmacy staff to view status and/or location of the dose during the compounding and delivery processes.
Evaluating IV Workflow Systems and IV Robotics

A detailed comparison of available systems (IV robotics or IV workflow) is a critical first step when these technologies are being considered. While many will share common functionality, the implementation details and vendor approach to sterile compounding operations can vary widely. This comparison can help narrow the list of systems that will potentially satisfy an institution’s needs. Examples of comparison points are listed in Table 1.

Table 1. Points to consider when evaluating IV workflow systems and IV robotics

<table>
<thead>
<tr>
<th>Technology Assessment</th>
<th>Institution Needs</th>
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<tbody>
<tr>
<td>Size and special requirements</td>
<td>Training requirements</td>
</tr>
<tr>
<td>Interface requirements</td>
<td>Staff needs to operate</td>
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<tr>
<td>Workflows supported</td>
<td>Operating costs</td>
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<td>Manufacturer support</td>
<td>Space renovation Need</td>
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<td>Production mode (batch vs. patient specific)</td>
<td>Downtime requirements</td>
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<table>
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<tr>
<th>Law and quality requirements</th>
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<td>State vs. federal laws</td>
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<td>Accreditation/licensure bodies</td>
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<td>Supply needs</td>
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Besides comparing different systems on the market to identify which will serve the institution’s needs, justifying the addition of these technologies is the next step for many institutions. Cost savings, quality improvements, and patient-safety advancements are examples early adopter institutions have utilized in their justifications. Specific patient-safety advantages that have been reported are positive identification of products through barcode technology (both), elimination of contamination sources (IV robotics), and increased accuracy in preparing pediatric patient specific doses (both).

**Key Questions to Consider**

The following sections suggest key questions in several categories that pharmacy leadership should consider and answer. This careful evaluation and planning will help determine the best path to improving the quality and safety of intravenous product preparation. These categories include:
- Workflow impact
- Financial impact
- Project management requirements
- Vendor assessment and service level agreements
- Requirements for new quality control measures
- Integration and interoperability with existing information systems and technology

**Workflow Impact**

The impact of IV preparation automation on workflow is generally anticipated to have a positive impact by increasing productivity, decreasing potential product contamination and assuring accuracy during routine preparation of medications. To have the best impact on workflow, new IV preparation automation technology should be easy to learn and manage. Key workflow questions include:

- How will automation of IV preparation change current processes?
- What is the new workflow?
- Does the new workflow make the process lean or add extra steps?
- How does the new technology impact the time to perform the task?
- Will there be a need to adjust other preparation or distribution workflows to enable incorporation of the new technology into daily, weekly or off-shift use?
- Does the new workflow require an increase or decrease in number of technician and/or pharmacist staff during automation operations?
- Will the pharmacy department be able to repurpose staff assignments as result of implementation of the new technology?

A key point regarding workflow assessment is to consider the entire process. Some steps in the process might take more time, but reduce wasted time at other points in the process. Defining the workflow analysis too narrowly (i.e. only focusing on technician compounding time) may produce misleading results.

**Financial Impact**

Pharmacy department leaders must manage their financial resources with skill and assist in meeting the decisions of their institutions. The cost of IV preparation automation and other new technologies to improve medication safety and productivity must be evaluated with the organization’s financial goals, along with objectives and other strategic plans in mind. Key financial questions include:

- What is the return on investment?
- What are the annual costs to maintain?
- What are the supply costs associated with the automation?
- What infrastructure, set-up and operating costs will be incurred?
- Will the volume of currently outsourced manufactured products be able to be reduced because the cost reduction associated with the new technology is significant?
- Are there other products that may be considered to be prepared by the new technology for additional future savings?
- Will new staff compensation levels be required for increased skill sets?
- What are the construction and/or remodeling costs associated with the installation of the technology? Will new heating/ventilation/air conditioning (HVAC) or electrical modifications be required?
- What will be associated costs (upgrades, product improvements, etc.), if any?

**Project Management**

Successful implementation of IV preparation automation is the result of contributions of the right department staff with the right combination of skills, coordination of many tasks, and requires sufficient resources to meet goals. Key questions related to project management include:

- How long will the project development, testing and implementation take?
- What has been learned from early adopters of IV automation? How can these lessons be applied to current automation project?
- What criteria will be used to determine staff participation in the project and eventual users of the new technology?
- How will you approach change management for your staff? Will a temporary staffing increase be necessary? How long might it take to reach a ‘new normal’ with the new system?
- What level of project support will be provided by the vendor?
- Does the vendor provide sample policies, procedures, or quality assurance best practices?
- Will there be necessary training to any users outside pharmacy?
- Is on-site training offered and what does it entail? Evening and Night shifts?
- Who is in charge of making the final decisions (director vs. administration, etc.)?

**Vendor assessment and service level agreements**

Implementation of new technologies like robotic IV preparation or workflow management tools requires a successful engagement with the technology vendor. The pharmacy department and institution will need to set realistic, appropriate vendor performance expectations and establish operational responsibilities to implement the technology. Key vendor assessment and service level agreement related questions include:

- Based on the department’s experience or experience from other institutions, how good of an implementation partner is the vendor?
- Who will maintain the productive operation of the automation – vendor, pharmacy department, biomedical department?
- What is expected from the vendor over the next three years regarding product improvements, updates, upgrades or new features?
- What is the experience of vendor staff providing customer support? Is there a problem triage process in place at the vendor’s customer support?
• What are the hours of customer support?
• What level of customer support will be agreed on?
• What level of automation repair and replacement will be available from the vendor? What will the expected turn-around time for technology equipment replacement?
• What will be the role of the pharmacy department or the institution in repair and replacement of the automation?
• What will be agreements associated with level of automation productivity?
• What will be considered extraordinary downtime or significant automation failure requiring financial penalty or rebates from the vendor?
• How much involvement will be needed by the institution’s IT department?

Quality Control Measures
Introducing new IV preparation technology will require new quality control processes and measures to assure the accuracy and safety of the products being distributed to patients. Validation of robot operation and end product testing requires new training for technical staff and integration into the staff’s daily or weekly workflows. Key questions for new quality assessments programs include:

• Is there any evidence-based data supporting the use of the new technology?
• What regulatory or quality standards can be addressed by implementing the new technology?
• What new quality assurance procedures will be required to monitor accuracy of the new technology? How often will quality control measure be required – daily, weekly, monthly, etc.?
• Will new methods and/or equipment be required to assess accuracy, e.g., spectroscopy, refractometry?
• What record keeping will be required to meet regulations associated with implementing the new technology?
• Will stability and sterility testing be necessary to meet USP 797 requirements?
• Does new technology impede/enhance the ability to maintain USP 797 compliance?
• What additional process and procedural assessments or validations will be required because of new technology use?
• What is the automated system’s reporting capabilities on performance?

Integration and Interoperability
Introduction of any new technology that includes use of information systems usually requires new levels of integration and interoperability between systems, while hoping to maintain flexibility in practice and workflows. Key questions in IV workflow systems allow for standardization and automation of the IV preparation by technicians. The systems create a work queue that produces a priority list controlled by either the pharmacist or technician. The standardization of this automation prevents technicians from falling into bad habits, i.e. preparing multiple doses at the same time. This technology also gives pharmacists the advantage of remote verification of products, preventing them from being confined to the sterile preparation areas. Other advantages of these systems include a status board that indicates
where each dose is in the preparation process, returned-dose scanning which alerts technicians when there is a dose with appropriate expiration dating that can be re-used for a new dose, and extensive reporting capabilities.

- How does the new system handle user login information? Can it use current active pharmacy authorization accounts, or is separate system independent login required?
- What new information system enhancements will be required, e.g., interfaces to practitioner order entry or pharmacy information systems?
- What will be the vendors interface development responsibility? What will be the expected level of institution involvement in interface development?
- Does the new technology interface/integrate with current EHR systems?

Early Implementation Experiences
As institutions gain experience with IV robotics they have reported issues surrounding the use of such technologies. Examples from University Health-System Consortium (UHC) include volume left in tubing, label appearance differing from other production labels, volumes have greater accuracy than previous human production, and lack of supplies that comply with protect from light standards. One institution reported that there was extensive database build prior to implementation and recommended institutions consider this when planning the implementation timeline. This same institution experienced issues with the robot puncturing pieces of the vial stopper into the solution due to multiple needle insertions into the same site. Remedies for this issue include switching product manufacturers and utilizing different needle types in the robot.

A challenge with implementing IV workflow technology has been staff push back and resistance to change. One institution observed this when they implemented an IV workflow system. Just because a project has obvious patient-safety improvements and/or workflow efficiency improvements doesn’t mean staff will be in support immediately. Working with the frontline staff and gaining their trust before implementation is vital to the success of the new automation. There will be challenges but if you have your frontline staff support those challenges can be easier to work through.

Conclusion
IV robotics and workflow systems offer long awaited solutions to enhance patient safety sterile products compounding. As with all new technologies, institutions must carefully assess the impact of these systems and plan for the substantial change management efforts associated with their implementation.
Works Cited


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