The Impact of IV Robotics on Improving Safety, Efficiency and Workflow

William W. Churchill MS, R.Ph.
Chief of Service
Department of Pharmacy
Brigham and Women’s Hospital
Boston MA

Objectives

- Discuss the need for patient safety-related improvements to our current IV admixture services.
- Describe the pros and cons of the volumetric and gravimetric systems for CSP admixture preparation.
- Describe two examples of improvements in pharmacy workflow resulting from the integration of IV Robotic systems and Work Flow Assist systems into the (CSP) preparation process.
- Identify several examples of potential problems or new sources of errors associated with implementation of IV admixture technology.

Disclosures

- Mr. Churchill has no conflicts of interest to disclose.

Why do We Need to Know What’s in Our Compounded Sterile Products?

Meningitis Outbreak: Pharmacy Inspection Reveals Drug-Safety Lapses

Meningitis Outbreak Highlights Hazards of Drug Compounding

Pols back new rules in wake of NECC flap

Evidence Demonstrating Concerns about Sterile IV Admixtures Prepared by Healthcare Workers

Occurrence and Impact of Unanticipated Variation in Intravenous Methotrexate Dosing

Medication Errors Detected in Infusions

Discrepancies between ordered and delivered concentrations of opiate infusions in critical care
Frequency of Medication Errors with Intravenous Acetylcysteine for Acetaminophen Overdose


Rationale for Robotic IV Admixture Preparation

- The medical literature has defined the risks associated with improper preparation of Compounded Sterile Products (CSP) by humans.
- USP <797> requires sterile product preparation to be completed in an appropriate sterile environment.
- The Joint Commission, requires all non-emergent IV admixtures to be prepared by the Pharmacy department.
- Use of specific gravity and gravimetric verification process is far more accurate than standard volumetric checking.1

Pharmacy Practice Model Initiative

ASHP PPMI Objectives
- Identify Emerging Technologies
  - Identify the available technologies to support implementation of the practice model, and identify emerging technologies that could impact the practice model.
- Implement Change
  - Identify specific actions pharmacy leaders and staff should take to implement practice model change including determination of the necessary staff (pharmacy leaders, pharmacists, and technicians) skills and competencies required to implement this model.

Pharmacy Practice Model Initiative
- In most hospitals and health systems, improvements in technology will be required for pharmacy departments to fully achieve optimal deployment of pharmacist and pharmacy technician resources.
- The following technology solutions in hospitals and health systems are important enablers in the development of optimal pharmacy practice models:
  - Use of bar-code technology during the inventory, preparation, compounding, and dispensing processes.
  - Automated dispensing
  - Robotic devices

Current State of the World and the practice of Pharmacy are changing

- New technologies are available that will change the standard of practice.
  - Bar-code verification, IV workflow assist software
  - Robotic Technology
- The roles of Pharmacy Technicians are changing to include more responsibility for drug preparation and dispensing as well as roles in med rec and medication history obtainment.
- The roles of the pharmacist will be changing dramatically to be more patient care focused and less product focused.

Strategic Vision for Designing the Ideal Process for Compounding Sterile Products

- Minimize the number of potential and actual compounded sterile product preparation errors by:
  - Including state of the art medication safety technology such as bar code verification and optical scanning, and gravimetric measurement.
  - Minimize human interaction with actual drug preparation.
  - Utilize the quality and safety features of IV robotic devices to insure that all products are made with the highest degree of accuracy, sterility, and safety.

Volumetrics vs. Gravimetrics

Gravimetric processes utilize S.G. to back-calculate dose of medication prepared
- Ordered dose of Chemo Drug Y = 1000mg in 50mL
- S.G. of Drug Y = 1.06g/mL
- Weight of Robot prepared bag = 52.90g

- Volumetric process relies on accurate drawing up of fluid volumes by pharmacy technicians.
  - Weight of Human prepared bag = 49.97g
- “Who” is more accurate?
  - Theoretical weight = 1.06g/mL x 50mL = 53.0g
  - Robot variance = 52.90g + 53.0g x 100 = 99.8%
  - Human variance = 49.20g + 53.0g x 100 = 92.83%
  - Robot is programmed with a pass/fail variance setting of 5%
  - Which dose of chemo would you rather get?
    - 998mg (Robot) vs. 928mg (Human)

Robots, Robots, Robots!
Robots Provide Us With:

- Bar code verification
- Specific gravity and gravimetric verification
- Optical scanning
- Central data storage
- High degree of accuracy and precision
- Efficient work flow
- Workload prioritization and tracking
- Interfaces
- Limits human involvement in the compounding process
  - **NOTE**: we are the primary source of contamination!

ARS Question 1

When considering the acquisition of IV Robotic equipment, which factor is most important to consider?

A. Size and space requirements
B. Purchase or lease options
C. Accuracy and quality of the device
D. Productivity and throughput of the device
E. Ability to protect staff from drug exposure

Issues to Consider Before Selecting a Robotic Device

- Size of robot and space requirements
  - May require renovations
    - HVAC
    - Electrical
    - Doors
- Clean Room required?
  - Yes/no
- Cost
  - Purchase
  - Lease
  - Fee per use
- Interface requirements
- Quality and accuracy of product produced
- Service and training support
- Staffing

BWH Action Plan: Equipment

- Implement the use of a robotic device for preparing chemotherapeutic agents and other hazardous drugs.
- Implement the use of a robotic device to prepare bulk batches of ready-to-use syringes for intra-operative use.
- Implement a modular work horse robotic device that can prepare patient specific IV bags and syringes, centrally located or in high volume hospital areas for on-demand access such as the Emergency Department.

The Gold Standard for A Compounded Sterile Products Service

Meet Our BWH Robots!
i.v. Station

- How is it resourced?
  - 1 Pharmacy Technician
  - 2 shifts, 7 days per week
  - Batch production
    - PAR level based
    - Scheduled production runs

- PROS
  - Versatile in use of final product containers (syringe/bag sizes)
  - Expansive degree of safety features (gravimetric, barcode scanning, optical scanning)
  - Relatively small physical footprint
  - Fully interfaced via “Worklist” software

- CONS
  - Drug shortages = suboptimal operation due to lack of drug availability
  - Database setup and maintenance

IV Station Onco

- Installation date May 2014

- How will it be resourced?
  - 1 Pharmacy Technician Specialists (7d/week)
    - Drug Inventory
    - Robot supplies
    - Logging production/producing reports
    - Lead technician for cleaning and basic PM Program

- Pros
  - Highly accurate and efficient production
  - Protects staff from cytotoxic exposure
  - Interfaced as part of robotic software workflow platform.

- Cons
  - Takes longer than manual compounding
  - May not be efficient enough to manage high volume outpatient infusion service without multiple robots

Other IV Robotic Technologies

Riva

- Highly accurate and efficient production
- Protects staff from cytotoxic exposure
- Interfaced as part of robotic software workflow platform.

Centralized Electronic Data Storage and Database Management

- We need the capability to electronically store all data associated with the preparation of CSPs:
  - Date/time
  - Source of preparation (Human/Robot)
  - All ingredients with lot numbers and exp. Date
  - Accuracy of final product
  - Production time for efficiency

- We need the capability to analyze and utilize the data to continuously improve the process and staff proficiency.
Central Database Tracking of all Gravimetrically Prepared CSPs - Production by Shift

<table>
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Central Database Tracking of all Gravimetrically Prepared CSPs - Accuracy Rate by Drug

<table>
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<tr>
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<tr>
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<td>B</td>
<td>90%</td>
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<td>C</td>
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<td>15%</td>
</tr>
<tr>
<td>D</td>
<td>80%</td>
<td>20%</td>
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ARS Question 2

When considering the benefits of electronic data storage what report would be most valuable to pharmacy size and space requirements:

A. Hour by hour breakdown of IV workflow volume of activity
B. Pass failure rate for each compounded sterile product
C. Productivity for each of the robotic devices
D. Accuracy rate for each pharmacy technician on manually compounded admixtures

Changing the work flow

- Can be very difficult and can be upsetting to staff.
- Do not underestimate the time and effort required to do this right!

Changing the Workflow

- In the beginning…some resistance:
  - “Replacing humans with robots has made it to healthcare!”
  - “I can do it faster.”
  - “Are pharmacy technicians going to have to know how to make a sterile product anymore?”
  - “Don’t you trust us?”
How We Dealt with it....

- Lean concepts
- STAFF DRIVEN Tabletop exercises
- STAFF DRIVEN Time and Motion Studies

Sample Process Flow Map for Intellifill Robot

Remote Pharmacist Verification

Key Learning Points

- Set expectations early & mobilize commitment
- Daily huddles during implementation and weekly check-in during sustain phases
- Encourage input from all SPR staff
  - All ideas will be considered
  - Some parts of the process are negotiable, others are not – speak up proactively
  - Focus on the positive
- Be able to "operate" the process as well as "administrate"
  - A huge win for staff acceptance and buy-in

Key Learning Points

- Incorporate QA measures directly into daily workflow.
- Ensure operators, not just super-users continually staff the robot shift.
- Adaptation of processes & change management.
  - Continuously assess need for change post-implementation.
- Techs must be first line for improvement recommendations with new technologies.
  - What works and what doesn’t work.
- A face-to-face “Thank You” is unquantifiable!

Quality Assurance and Quality Control
Beyond Use Date Certification

- Increase expiration dating to decrease cost of waste and increase operational efficiency.
- End product testing of robot preparations.
  - Testing performed by outside lab at designated time points with customer receipt of certified results.
    - Stability - potency/purity via HPLC
    - Sterility <USP 71>: aerobic/anaerobic/fungal
    - Endotoxin <USP 85>
    - Particulate matter <USP 78>
    - pH testing
  - Examples:
    - Succinylcholine 100mg/5mL: 60 days room/temperature
    - Cefazolin 2g/100mL D5W: 90 days refrigerated

Environmental Monitoring

- Hired Quality Assurance specialist to oversee IV compounding Q/A program.
  - Individual is microbiologist by degree and training.
- Contracted with outside testing agency
  - Robots are tested similar to IV hoods:
    - Every 6 months
    - Certified as ISO Class 5 devices
    - Air volume and velocity profile
    - HEPA filter integrity/leak test
    - Airflow patterns and pressure differential
    - Particle count monitoring
    - Temperature and relative humidity monitoring

Environmental Monitoring of Robots:
- In-house weekly microbial monitoring
  - Air test paddles
  - Surface contact paddles

<table>
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<tr>
<th>Date</th>
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Continuous Quality Assurance

- Testing is performed by an outside laboratory.
- Robot and human prepared products sent to outside lab weekly for test of end product sterility.
  - An appropriate number of bags or syringes as dictated by USP regulations is pulled from each batch and sent for quality testing.
- Robot prepared products are also sent every six months for sterility and potency evaluation.
  - Different medications sent on a rotating basis
  - Tests performed (previous slide)
- Staff - aseptic sterile product technique tested twice yearly with growth medial fill.

Continuous Quality Assurance

- Pharmacy Technician Specialist enters sample info into vendor lab web site and ships product.
- Next step is to hire Quality Assurance coordinator.
  - Degree in Microbiology or chemistry
E-Mail Notification of Test Completion

The following results are available online at...

Real Time Online Results

Continuous Quality Assurance

Monthly Summary Report

What About CSPs that Cannot be made in a Robot?

- Must provide a consistent process that uses same tools and functionality as robot:
  - Bar code verification
  - Specific gravity and gravimetric verification
  - Remote pharmacist verification
  - Optical scanning
  - Central data storage
  - High degree of accuracy and precision
  - Workflow prioritization

Workflow Assist Technologies

DoseEdge®

l.v.soft Assist®
i.v. Soft Assist

- Checks human preparation process at each step using gravimetric checking.
- Fully interfaced via "Worklist".
- Efficiency (1.5 – 3.5 minutes per dose).
- Not as product dependent as robotics.
- Patient specific doses.
- Vials/materials that do not meet robot specification.
- Non-standard, non-premade doses.

ARS Question 3

What is the most important safety feature of IV Workflow assist software systems?
A. Bar code verification
B. Centralized data storage
C. Workflow prioritization
D. Gravimetric weighing of products
E. All of the above

Potential Concerns with Changing to New Processes for CSP Preparation

- Technology is relatively new and we are in the early adopter phase.
- The technology is not proven as yet with evidenced based studies.
- Potential exists for new kinds of errors to occur due to the introduction of the new technology, processes and roles for staff.
- Staff will need additional training to adapt to their new roles working with robotic technology.
- Staff may over-rely on the technology.

Lessons Learned

- It takes time to add and validate new products to the robot's database. Patience is key!
- Product shortages can greatly impact robotic output volume.
- New problems can arise unexpectedly and can be related to:
  - vial sizes
  - drug product composition
  - Hardware
  - Software
  - Human interface issues
- Not everything needs to be prepared by the robots. Select your products based on your individual hospital needs and the capabilities of the robots.

Lessons Learned

- You must have clearly written implementation and validation protocols.
- You must also have clear change management protocols for when hardware or software are upgraded.
- Training of both the pharmacist and technical staff is a key success driver.
- Establish a partnership with your vendor to keep in constant contact during implementation and expansion periods.

Conclusions

- It’s time for the old process of volumetric preparation and visual checking to be retired.
- Innovative technology is now available that will allow for precise and accurate IV admixture preparation.
- Pharmacy leaders need to embrace the change and lead their departments into the future.