Use of IV Robotic Technology In The Sterile Products Service of the Future

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 many current IV admixture programs in health systems.
- Describe the pros and cons of the volumetric and gravimetric systems for CSP admixture preparation.
- Describe at least two types of quality control testing that should be done when implementing a robotic or a gravimetrically-based system for CSP admixture preparation.
Objectives

- Describe at least two examples of improvements to patient care resulting from the integration of optical scanning and barcode verification into the compounded sterile product (CSP) preparation process.
- Identify at least two steps involved in developing a strategic plan for improving a health system’s’ process for preparing compounded sterile products.

What Keeps us awake at night?

- Many pharmacy directors say….  
  - “what keeps me awake at night is what goes on during the day in my IV room”!
IV Admixture Process 1970’s VS 2011

- Horizontal flow hoods only
- No clean rooms
- No IV robotics
- No end product testing
- No testing of staff
- No testing of environment
- No clean room garb

What’s in these IV Bags?
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


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Evidence Demonstrating Concerns about Sterile IV Admixtures Prepared by Healthcare Workers.

Systematic evaluation of errors occurring during the preparation of intravenous medication

Medication errors in intravenous drug preparation and administration: a multicentre audit in the UK, Germany and France

An observational study of intravenous medication errors in the United Kingdom and in Germany


Why do We Need to Know What’s in Our IV Admixtures

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.
- Volumetric process is less accurate than Gravimetric process
Why is Innovation Needed?

- Need to improve the quality of our health care system and patient outcomes.
- Reduce expenses
- Improve efficiency and productivity
  - Must have the ability to do more with less!
- Increase revenues and funding
- Become more agile and responsive as a department.

The Leader’s Role in Change Management

- Facilitate and enable change.
- Have training in place to get ready for the change
- Celebrate success
  - Recognize employees and when change goals are met
- Do not punish failure!
- Continue to keep line of communication open.
- Adapt, overcome and persevere!
BWH Annual IV Admixture Doses

- BWH pharmacy prepared IV’s 400,000
- Commercially available Premix 700,000
- Outsourced or Robot prepared 375,000
- Urgently needed RN Prepared 25,032
- Require Pharmacy Preparation 41,472
- Total BWH IV admixtures 1,541,504

BWH Strategic Vision for Compounded Sterile Products

- Minimize the number of IV admixture and syringe preparation errors by eliminating human preparation of these products both in the pharmacy in in patient care areas.
- Prepare medications in house that were previously prepared and compounded by outside vendors.
- 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.
**Gravimetrics VS Volumetrics**

- Gravimetric process utilizes Specific Gravity to calculate dose of medication prepared.
  - Ordered dose of Chemo Drug Y = 1000mg in 50mL
  - S.G. of Drug Y 20mg/mL = 1.06g/mL
  - Calculates anticipated weight of bag based on specific gravity of drug, diluents and carrier fluid.
  - Compares anticipated weight of the bag versus the weight of the robotically prepared bag and compares against the established plus/minus range (5% at BWH)

- Volumetric process relies on accurate drawing up of fluid volumes by pharmacy technicians.
  - USP allows plus/minus 10% for FDA approved drug products.
  - IV fluid bags plus/minus 10% or minimal fill volume
  - Syringe accuracy ± 5% at half scale and ± 4% at full scale.

- Which process can be more accurate?

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**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 both IV bags and syringes, centrally located or in high volume hospital areas for on-demand access such as the Emergency Department.
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**
- **Service and training support**
- **Staffing**

Requirements for a Work Horse IV Robot for On-Demand Sterile Product Preparation

- Integration with Pharmacy and eMAR information systems
  - Real time bi-directional interfaces
- Remote verification capability for checking pharmacist
- Medications prepared quickly in ISO class 5 environment
- Documentation available for central data warehouse
- Protection of staff from drug exposure
Staffing and Labor Requirements

- Two full-time certified pharmacy technicians were added to the pharmacy to support the new technology.
- Revised an existing pharmacy manager job description to include oversight of all robotic and medication safety technology operations.
- Re-assignment of one FTE pharmacy technician from TPN preparation to on-demand IV admixture support.

Meet Our BWH Robots!
Issues with using Gravimetics

The Specific Gravity (S.G.) Lynch Pin

- Pharmaceutical manufacturers often do not have S.G. information readily available for customers
- If S.G. is available, many will not share in writing
- Outside testing labs can do test
  - Need to send product from inventory
  - Testing can be expensive
- Gravimetric Method
  - Utilization of laboratory grade volumetric pipette and scale for manual calculation of S.G.

Accuracy of Robotic IV Preparation
Tolerance level of Plus/Minus 5%

CytoCare Throughput- Pass/Fail

(Week Beginning)
Robot Failures by Percent Error

Failures by Percent Error
July 2010-September 2010

Total IV's Prepared
752

- 6,32%
- 5,28%
- 3,17%
- 2,11%
- 1,6%

50% of Robot failures are within acceptable USP range.

± 5.1% to ± 5.9%
± 6 % to ±10%
±10.1% to ± 20%
± 20.1% to ± 50%
± 50.1% to ±100%
> ±100%

50% of Robot failures are within acceptable USP range.

Quality Assurance

- Continuous assurance of robotic scale accuracy
  - Verification of scale sensitivity using apothecary grade weights
  - Record values in log to monitor trending
Quality Assurance

- Environmental monitoring of syringe robot
  - Weekly TSB media paddle testing
    - Air Sampling
      - 4 samples day 1 prior to cleaning robot
      - 4 samples day 1 after cleaning robot
    - Surface Sampling
      - 7 samples day 1 prior to cleaning robot
      - 7 samples day 2 after cleaning robot
  - Weekly TSB media syringes
    - Ten x 5mL TSB media syringes prepped 2x/week before and after cleaning
    - All air/surface paddles and TSB syringes checked daily for contamination

Quality Assurance

Microbiological Monitoring of Chemotherapy Robot

- Microbiological Testing
  - Surface monitoring using contact plates (TSA and SAB)
  - Testing done monthly
- Sterility of the Compounded Solution
  - Full runs of all manufacturing processes with TSB
- Sterility of Partially Used Vials
  - Use of TSB vials
Quality Assurance

Validation Protocols of Chemotherapy Robot
- Cross Product Contamination
- Accuracy/Precision Testing
- Correct Vial Recognition
- Correct Bag Recognition
- Final Container Labeling

Quality Assurance

- End product testing for extended Beyond Use Dating (BUD)
  - Testing performed by Dynalab with customer receipt of certified results
    • Potency/purity via HPLC
    • Sterility <USP 71>: aerobic/anaerobic/fungal
    • Endotoxin <USP 85>
    • Particulate matter <USP 788>
    • pH testing
Quality Improvement

Integrated end-product bar code verification

- Barcode produced by the robot is integrated with BWH bar-code validation systems
  - Automated dispensing cabinets
  - Anesthesia dispensing cabinets
  - Pharmacy drug storage Carousels
  - Pharmacy distribution barcode verification systems
  - Point of care administration systems
- Barcode on the syringes is also used by the robot as internal verification of the end-product during robot syringe preparation

Quality Improvement

Interfacing Chemotherapy Robot with Hospital’s Medication Use System

- Chemo robot has full HL7 interface with the BWH Pharmacy Information System
  - Eliminates potential transcription errors
  - Monitor Inventory usage and reduce waste
  - Use of robot generated final container label with the hospital’s BCMA system
- Workhorse robot will use same HL7 interface engine from pharmacy system.
Financial Implications

- BWH did not spend any capital dollars to acquire robots.
- Use of robotic devices in place of IV outsourcing expend to yield $1 million dollars in savings when fully deployed.
- No jobs were lost due to implementation of IV robotics.

IV Syringe Productivity

[Graph showing cumulative syringe production by month]
Intellifill Robot - Cumulative Net Savings by Month

The Future?
What About CSPs that Can’t be made in a Robot?

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

The Gold Standard for IV Admixture Service

The solution: Closed Loop I.V. Admixture

With permission of Health Robotics
Remote Pharmacist Verification

With permission of Health Robotics

Future System for Gravimetric preparation

With Permission of Health Robotics
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.