Strategic Planning for the Implementation of the Sterile Products Service of the Future

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Objectives

• Identify key components of a strategic plan for implementing a sterile product service
• Describe the role of IV robotic devices can play in implementing a sterile product service
• Describe key components of a Quality Assurance Program for a sterile product service

Disclosures

I do not have any financial relationships or interests with any proprietary entity discussed in this program.

Questions?

• How many people currently feel they have a USP 797 compliant clean-room?
• How many people currently use a barcode scanning system during sterile product preparation?
• How many people currently use some form of robotic technology to prepare sterile products?

What’s in these IV Bags?

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

Ex-Cleveland pharmacist gets 6 mos. in fatal chemo dose

By Associated Press

POSTED: 12:11 p.m. EDT, Aug 14, 2009

CLEVELAND, A former Ohio pharmacist has been sentenced to six months in jail and six months of house arrest in the death of a toddler given an incorrect tumor treatment.

At Friday’s sentencing in Cleveland, 41-year-old Eric Cropo also was ordered to tell professional groups about his case as part of 400 hours of community service when he leaves jail.

Cropo pleaded no contest in May to involuntary manslaughter in the 2008 death of 2-year-old Emily Jerry. Prosecutors said Cropo was responsible because he oversaw the mixing of the girl’s chemotherapy at Rainbow Babies and
Evidence Demonstrating Concerns about Sterile IV Admixtures Prepared by Healthcare Workers.

**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**


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 and 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.

Rationale for Robotic IV Admixture Preparation

- USP <797> requires sterile product preparation to be completed in an appropriate sterile environment.
- The Joint Commission, require all non-emergent IV admixtures to be prepared by the Pharmacy department.
- Medical literature has defined the risks associated with improper preparation of Compounds Sterile Products (CSP) by humans.

Questions?

- How many people currently use a compounding pharmacy (Ameridose, CAPS, PharMedium, etc.) for sterile product production?
- How many people still prepare TPN solutions within the Pharmacy Department?
- How many people send weekly samples of sterile products prepared for microbiologic testing?

The Annual IV Admixture Doses

- BWH pharmacy prepared IVs 400,000
- Commercially available Premix 700,000
- Outsourced or Robot prepared 375,000
- Urgently needed RN Prepared 25,032
- Require Pharmacy Preparation 43,472
- Total potential BWH IV admixtures 1,541,504
Action Plan: Equipment

- The Cytocare Robot is designed for preparing chemotherapeutic agents.
- The Intellifill syringe robot is designed to prepare bulk batches of ready-to-use syringes for Anesthesia and Nursing staffs.
- The Health Robotics IV Station can prepare patient specific IV bags and syringes.

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.

BWH Quality Assurance Program

The Specific Gravity (S.G.) Lynch Pin
- Current robotic technology uses gravimetric measures to ensure dose is made accurately.
- 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.

Quality Improvement

Robotic vs. Human Accuracy
- Utilize S.G. to back-calculate dose of medication prepared
  - Ordered dose of Chemo Drug Y = 1000mg in 50mL
  - S.G. of Drug Y 20mg/mL = 1.06g/mL
  - Weight of Robot prepared bag = 52.90g
  - Weight of Human prepared bag = 49.20g
- 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)
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 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

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

Enhanced Photometric Spectroscopy

- Table top spectroscopy machine (ValiMed) used to validate medication identity and concentration
- Sample taken of drug reservoir used to validate contents of source bag prior to robotic preparation of syringes
- Enhances medication safety by validating drug entity and concentration
- Testing drug reservoir as source bag prior to robotic preparation of syringes increases operational efficiency by preventing re-work and decrease waste by catching potential reservoir preparation error

Validation Protocols of Chemotherapy Robot

- Cross Product Contamination
- Accuracy/Precision Testing
- Correct Vial Recognition
- Correct Bag Recognition
- Final Container Labeling

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

• Cytocare 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 institutions BCMA system
• IV Station Robot will use same interface engine from pharmacy system to robot.

Quality Improvement: Bar Code Verification in Sterile Products Suite

• Bar code verification for product selection and setup
• Bar code verification for preparation
• Bar code verification for checking
• Bar code verification for delivery
• Bar code verification for administration.

Patient Specific Prep Label Prints

Scan Patient Label

Verify the Medications

Final Patient IV Label

• Bar Code scanned at eMAR
• Order and Expiration information in data matrix bar code
Sterile Preparation & Distribution

- Dynamic tracking system display

IV Preparation & Administration

6 Critical “Patient Safety Points”

<table>
<thead>
<tr>
<th>Central Pharmacy - IV Room</th>
<th>Nurse Station</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>IV Robotics</strong></td>
<td><strong>Manual</strong></td>
</tr>
<tr>
<td>Bar code verified</td>
<td>Bar Code scanned + RFID + Camera</td>
</tr>
<tr>
<td><strong>Drug Identification</strong></td>
<td><strong>Manual</strong></td>
</tr>
<tr>
<td>Weight base verified</td>
<td>Smart Bar Codes RFID + Drug picture</td>
</tr>
<tr>
<td><strong>Drug Preparation</strong></td>
<td><strong>Drug Information &amp; administration Procedures</strong></td>
</tr>
<tr>
<td>Package verification at all steps</td>
<td>Computer Screen information + procedures + Weight / scales</td>
</tr>
<tr>
<td><strong>Packaged Labeling</strong></td>
<td><strong>Enhanced Labeling Premixed standard concentration</strong></td>
</tr>
<tr>
<td>Packaged and labeled to institution's standards</td>
<td>Syringes &amp; bags</td>
</tr>
<tr>
<td><strong>Package Verification</strong></td>
<td><strong>Bar code Scanned RFID</strong></td>
</tr>
<tr>
<td>Patient - IV line &amp; route</td>
<td>Smart Pumps (patient / drug &amp; route)</td>
</tr>
</tbody>
</table>

The Future?

The Gold Standard for IV Admixture Service

Medication Compounding Process of the Future

Hospital Clinic Barcelona - Gravimetrics

- Weight control scales and software

Compounding preparation process
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.

Learning Assessment

• Why do we need a strategic plan for the preparation of sterile products?

• How does current sterile product technology ensure the dose has been made accurately?

• What are the 6 critical safety points in sterile product preparation and administration?