

Strategies for Minimizing Errors in I.V. Sterile Compounding

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Mr. Churchill received his Bachelor of Pharmacy and Master of Science degrees from Northeastern University, Boston. He is adjunct Clinical Professor of Pharmacy Practice at Northeastern University, Bouve College of Health Sciences. Mr. Churchill also holds an appointment as Visiting Professor at the University of London School Of Pharmacy. Mr. Churchill's main areas of interest and practice include improving the safety and efficiency of medication administration systems, design and implementation of medication safety related technology, robotics, and automation, including the expanding the role of the clinical pharmacy specialist through the use of medication safety technology.

For his efforts in improving medication safety worldwide, Mr. Churchill was awarded the 2007 American Society of Health-System Pharmacists (ASHP) Distinguished Leadership Award. In 2008, he was selected as the Massachusetts Health System Pharmacist of the Year. In 2009, Mr. Churchill was selected by ASHP and Northeastern University as the 25th John W. Webb Lecture Award winner. This annual award recognizes a health-system pharmacy practitioner or educator who has shown extraordinary dedication to fostering excellence in pharmacy leadership. In 2010, Mr. Churchill was awarded the Boston Business Journal's prestigious Healthcare Champion Award for Innovation.

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Strategies for Ensuring the Safe Compounding of IV Medications &

Clinical Pearls: Sterile Compounding Quality and Safety Tips for the Pharmacy Department

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Objectives

- Discuss the need for patient safety-related improvements to current i.v. admixture services.
- Describe the pros and cons of the volumetric and gravimetric processes for compounded sterile preparations (CSP).
- Describe evolving medication safety technologies to support sterile compounding safety.
- Describe types of quality control testing that should be done when implementing a robotic or gravimetrically-based system for CSPs.

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: 1970s vs. 2011 Is it any different?

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



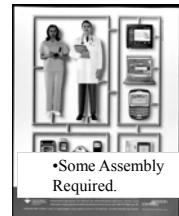
Why is Innovation Needed?

- We must improve the quality of our CSP preparation processes to eliminate sources of error
- We must be able to **guarantee** accuracy of pharmacy-prepared CSPs
- We must improve efficiency and productivity
- We must reduce waste
- We must become more agile and responsive to the changing pharmacy practice environment



Characteristics of Tomorrow's Hospital Pharmacy

- Highly automated with minimal use of labor-intensive processes
- High use of medication safety technology
- All pharmacy staff working at the top of their license
- Pharmacists focused on improving patient outcomes, patient safety, and preventing medication errors
- Technicians highly trained in the use and maintenance of technology-based equipment



•Some Assembly Required.

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Which innovation for tomorrow's pharmacy of the future is most important to our future success?



- A. All staff working at the top of their license.
- B. High use of medication safety technology and automation
- C. Highly trained technicians managing and overseeing the use of drug distribution and preparation equipment
- D. High degree of automation and minimal use of labor-intensive processes

Bar Code Verification in the Sterile Products Suite

- Bar code verification for product selection
- Bar code verification for preparation
- Bar code verification for checking
- Bar code verification for delivery
- Bar code verification for administration



Focus on Use of Safely Labeled and Packaged Products

- Two-dimensional bar code
- Tall man lettering
- Unit dose syringes
- Tamper-evident caps



Rationale for Robotic IV Admixture Preparation

- The medical literature has defined the risks associated with improper preparation of compounded sterile products (CSPs) by humans
- USP Chapter <797> requires sterile product preparation to be completed in an appropriate sterile environment
- The Joint Commission (TJC) requires all non-emergent i.v. admixtures to be prepared by the pharmacy department
- Volumetric process is less accurate than gravimetric process

IV Robotics



Gravimetrics vs. Volumetrics

- Gravimetric process utilizes specific gravity to calculate dose of medication prepared
 - Calculates anticipated weight of bag based on specific gravity of drug, diluents, and carrier fluid
 - Compares anticipated weight of the bag with the weight of the robotically-prepared bag and the established \pm range (5% at Brigham and Women's Hospital)
- Volumetric process relies on accurate drawing up of fluid volumes by pharmacy technicians
 - USP allows \pm 10% for FDA-approved drug products
 - IV fluid bags \pm 10% or minimal fill volume
 - Syringe accuracy \pm 5% at half scale and \pm 4% at full scale
- Which process can be more accurate?

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Issues to Consider Before Selecting a Robotic Device

- **Size of robot and space requirements**
 - **May require renovations**
 - Heating/ventilation/air conditioning (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 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

When considering the acquisition of i.v. robotic equipment, which factor should you consider first?



- A. Size and space requirements
- B. Purchase or lease options
- C. Accuracy and quality of the device
- D. Productivity and throughput of the device

Brigham and Women's Hospital IV Station Batch Throughput

- Oxytocin 30 units in 500 mL normal saline
 - Average precision +/- 1.05%
 - Average time to prepare = 1 minute, 48 seconds
- Vancomycin 1 g in 100 mL 5% dextrose in water
 - Average precision +/- 2.07%
 - Average time to prepare = 2 minutes, 34 seconds
- Ondansetron 8 mg in 50 mL dextrose 5% in water
 - Average precision +/- 1.74%
 - Average time to prepare = 1 minute, 37 seconds
- Cefazolin 2 g in 100 mL 5% dextrose in water
 - Average precision +/- 0.9%
 - Average time to prepare = 3 minutes, 14 seconds

Quality Assurance

- Environmental monitoring of syringe robot
 - Weekly tryptic soy broth (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

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



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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 outside laboratory 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
- Integrated end-product bar code verification

Quality Improvement

- Interfacing robotic systems with hospital pharmacy software system
 - Ideal situation would be with a full HL7 interface with the pharmacy information system
 - Eliminates potential transcription errors
 - Monitors productivity and reduces waste
 - Allows use of robot-generated final container labels with the hospital's bar code medication administration (BCMA) system
 - Triages IV room workload

Potential Concerns in Changing to New Processes for CSP Preparation

- We are at the dawn of using this new technology
- The technology is not proven as yet with evidenced-based peer reviewed studies
- Potential exists for the introduction of new sources of error
- Technical staff will need different types of training in their new roles working with robotic technology
- Staff may over-rely on the technology

Examples of IV Room Workflow Software



DoseEdge



IV Soft



ScriptPro
Telepharmacy

Why Use IV Workflow Software?

- Not everyone can afford robots, or they may not have the space required to install a robot
 - However, almost everyone should be able to use i.v. compounding safety tools and workflow software
- Robots cannot make all i.v. admixtures. We need safety tools and software systems to prepare all i.v.s with equal precision
 - Elastomeric infusers
 - Total parenteral nutrition
 - Glass bottles
 - Ampuls
 - IV bags with belly-button ports
 - Cassette-type reservoirs

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Key Components of IV Compounding Safety Tools and Workflow Software

- Must provide a process that uses key safety and productivity tools, devices, and software functionality
 - High degree of accuracy and precision
 - Bar code verification
 - Central data storage
 - Efficient work flow
 - Workload tracking
 - Interfaces to pharmacy software platform

Scriptpro Telepharmacy Workflow

- Technician scans bar code on the vial to match the selected product to the National Drug Code (NDC) of the ordered medication
- Technician takes a picture of the work label, vials, diluent, fluids to be used, and the syringe (prior to injection in the bag) along with the final product
- Pharmacist views these pictures from a check station in the ante room while checking the finished product



Data Slide used with permission from University of Kansas Pharmacy

ScriptPro Telepharmacy Results

- Data collection period – July 2007
 - Use of telepharmacy system for chemotherapy preparation resulted in intervention in 1.1% of doses (4 of 363)
- Ease of use
 - Less than 50 seconds of technician time per dose
- Ongoing maintenance
 - Requires addition of new drugs and NDCs to database

Data obtained from University of Kansas Pharmacy

Dose Preparation-DoseEdge®

1. Select dose
2. Print label
3. Scan bar codes
4. Capture images



Slide used with permission from Baxa

DoseEdge® Pharmacy Workflow Manager

- Real-time status of all doses and the overall pharmacy workload
- No lost or misplaced labels
- Upstream bar code capability
- Dose history
- Clean room policy and procedure support



Slide used with permission from Baxa

Key DoseEdge® Metrics

- 69 Installations
- >10 million doses processed
- >300,000 potential errors prevented with wrong-drug scan alerts (3% error rate)
- 12,000 pharmacist rejected doses

Data obtained from Baxa

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New Direction in CSP End Product Verification: "Drug Fingerprints"

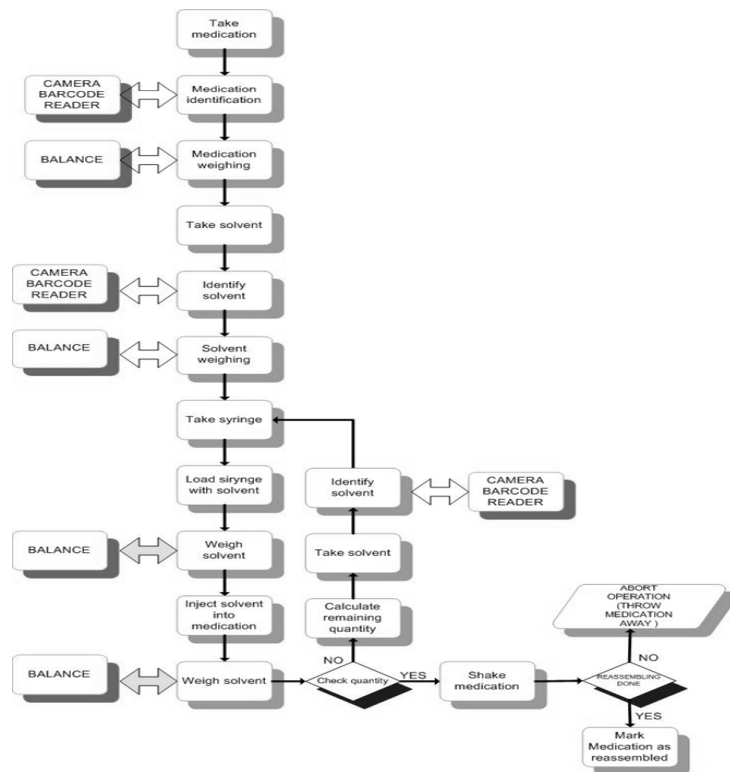
- Current standard of care: pharmacy double check, syringe pull backs
- System and process changes already in process include i.v. robotic devices and i.v. workflow software
- Additional new alternative: ability to instantly measure i.v. contents immediately after compounding using fluid fingerprint technology
 - Instantly generates pattern (fingerprint) for i.v. fluid
 - Fingerprint is unique for each drug, concentration, and diluent
 - Fingerprint is matched to library of fingerprints stored on the device
 - Library continually expands to include more drugs

Conclusions

- It's time for pharmacy practitioners to use innovation and technology to change the current process for preparing CSPs
- Medication safety technology is now available that will allow for safe and accurate preparation of CSPs
- Pharmacy leaders must be committed to eliminating drug preparation errors by the pharmacy department

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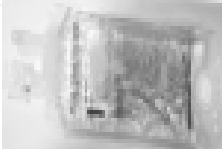
i.v.SOFT uses Robotic Logic and Accessories



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i.v.SOFT CheckOut

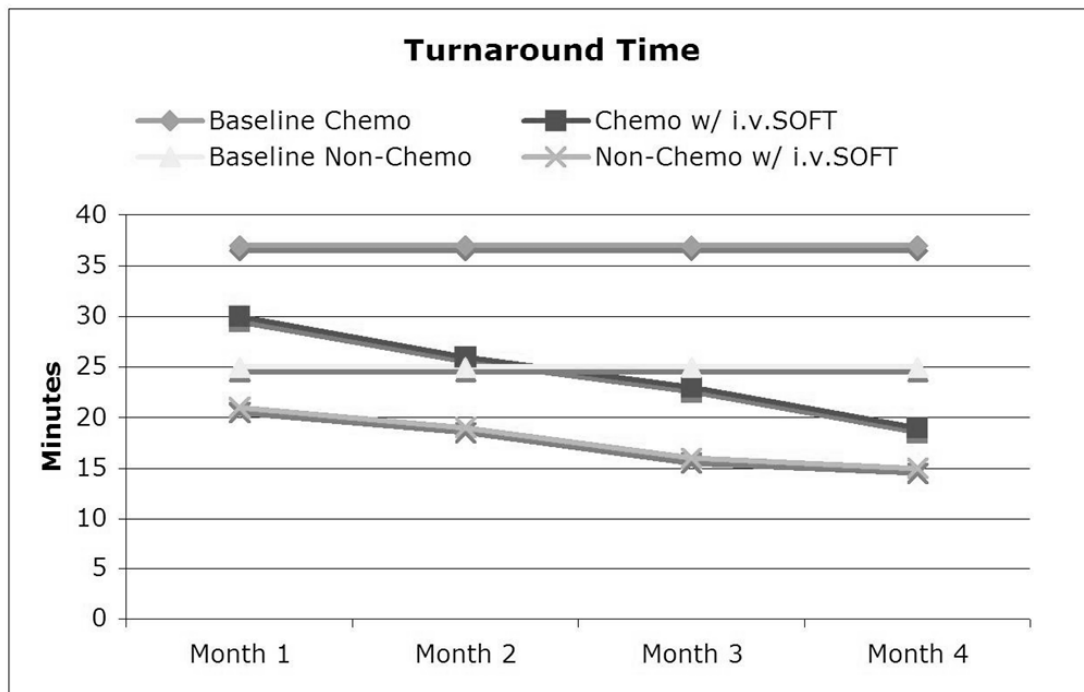
Patient Information	
TESTERICA (05/27/1980)	ID: 80106685 Sex: F Unit: Physician:
Status Information	
Status:	Confirmed
Preparation Summary	
Main Drug	Active Principle: Ofatumumab
	Requested dose/volume: 200 mg/10 mL
	Actual dose/volume: 194.30 mg/9.71 mL
	Deviation from request: -2.85 % (acceptable deviation +/- 5%)
Final Container	Bax Via NS 100mL
Requested Carrier Volume	90 mL
Carrier Volume	89.97 mL (acceptable deviation +/- 10%)
Total Volume	99.68 mL
Barcode	0000000031905
Preparation details	
Main Drug	
	Genmabs 416 20g/ml
	Concentration: 20 mg/ml
	Dose/volume drawn from this vial: 101.85 mg/5.08 mL
	Loaded by: Master
	Loading datetime: 07/19/2011 12:10:42
	Genmabs 416 20g/ml
	Concentration: 20 mg/ml
	Dose/volume drawn from this vial: 89.70 mg/4.49 mL
	Loaded by: Master
	Loading datetime: 07/19/2011 12:10:42

i.v.SOFT CheckOut enables the Pharmacy Supervisor to safely and efficiently release the IV Admixture for delivery and administration, including thorough verification of final label and audit trails of the Sterile Compounding process, including bar-code, pictorial, and gravimetric controls.

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i.v.Soft Assist European Study Results: Turnaround Time



Data provided by Health Robotics