ALTERNATE METHODS OF CHEMOTHERAPY PREPARATION
ALTERNATE METHODS OF CHEMOTHERAPY PREPARATION: GRAVIMETRIC TECHNOLOGY-ASSOCIATED WORKFLOW SYSTEMS

Nathan Barnes, PharmD
August 4, 2017
Objectives

• At the conclusion of this presentation, participants should be able to:
  – Understand the importance of a gravimetric workflow for the preparation of high alert medications
  – Describe the challenges faced with the implementation of a Technology-associated Workflow (TAWF) system
What is Gravimetric TAWF?

- Hardware and Software system
  - Camera
  - Barcode Scanner
  - Scale
  - Software Platform
What is Gravimetric TAWF?

- Standardization and streamlining of IV preparation process
  - Safety
  - Efficiency
  - Waste Reduction
Why Gravimetric Preparation?

- Volumetric technique variability
- Syringe inconsistency
- Reconstitution accuracy
- Inability to confirm correct volume added

Assessment of final product dosing accuracy when using volumetric technique in the preparation of chemotherapy

Lindsey B Poppe, Scott W Savage and Stephen F Eckel

Abstract:
Background: Studies have compared gravimetric and volumetric dosing accuracies in chemotherapy agents, finding high accuracy in gravimetric measurements with a mean deviation of ±0.06%, while volumetric measurements had a mean deviation of ±3.02%.

Methods: Chemotherapy doses prepared under a biological safety cabinet containing two weights from the precision scale between 15 December 2010 and 30 March 2011 were eligible for inclusion. Empty syringes attached to a closed-system transfer device were weighed prior to product manipulation. The product was then prepared using the syringe pull-back method (volumetric technique) and the same syringe containing drug was weighed (gravimetric method).

Results: A total of 1156 compounded sterile products were eligible for the study. The mean percent volume difference of preparations included was -0.33% with a range of -4.99% to 9.12% for individual doses. Of the prepared doses, 71.7% were within ±3% and 87.4% were within ±10% of the ordered dose. Secondary outcomes found to be associated with an increased percent volume difference were the pediatric population, tivic volume prepared, drug viscosity,

Why Gravimetric Preparation?

- ISMP Best Practice
- Verification PRIOR TO addition to final container
- Elimination of “syringe pull-back method”
- Use technology to augment manual process

ARS – The Institute of Safe Medication Practices (ISMP) recommends which of the following as a best practice in the preparation and verification of high alert medications?

A. Avoidance of the “syringe pull-back method”
B. Pharmacist verification prior to active drug injection into the final container
C. Use of technology to augment the manual process
D. All of the above
Enhances Safety of Chemotherapy Dispensation

- Manufacturer assistance supplied stock
- New “strength” entered into BD Cato™
- Technician prepared in BD Cato, but inquired about differing volume on EPIC label
- Cato prevented dispensation and administration of 2x ordered dose
- Set-up Tech Workflow
- Drug Lot Tracking
- Vehicle Lot Tracking
Set-up • Preparation • Verification

- Barcode Identification
- Photo Identification
Set-up • Preparation • Verification

- Hard-stops during preparation
- Clear tolerance approvals

- Photo taken. Continue preparation or <F7> Take new photo

  **Too little solution withdrawn**
  Deviation: -18.4%

  Still to withdraw:
  0.9mL solution

  <F2> Vial is empty.

- Photo taken. Continue preparation or <F7> Take new photo

  **Within tolerance**

  Prescribed active ingredient amount: 4mg
  Achieved active ingredient amount: 4.03mg
  Deviation: 0.7%

  Unload scale
Set-up ● Preparation ● Verification

- Remote Verification
- Visual Checking Process
- Detailed Preparation Log

### Preparation log

<table>
<thead>
<tr>
<th>Date/Time</th>
<th>Information text</th>
</tr>
</thead>
<tbody>
<tr>
<td>2:27:35 PM</td>
<td>PREPARATION No. 8508 INITIATED ON 2/15/2017 AT 2:27 PM (BD Cato VERSION: 2.38.1.17)</td>
</tr>
<tr>
<td>2:27:35 PM</td>
<td>Assigned vials:</td>
</tr>
<tr>
<td>2:27:35 PM</td>
<td>1st vial zoledronic acid 4mg: Nominal volume: 5mL, actual volume 5mL, Density: 1.02g/mL, UID: 270985</td>
</tr>
<tr>
<td>2:27:35 PM</td>
<td>Gravimetric Preparation</td>
</tr>
<tr>
<td>2:27:35 PM</td>
<td>Computer name: MCM2GR/BDB0701, Prep. Person: Barnes, Nathan (NEB)</td>
</tr>
<tr>
<td>2:27:35 PM</td>
<td>Preparation settings: Default</td>
</tr>
<tr>
<td>2:27:35 PM</td>
<td>Visual documentation is used for this preparation.</td>
</tr>
<tr>
<td>2:27:35 PM</td>
<td>Med. # 888; 4mg zoledronic acid Solution for injection in NaCl 0.9% 100mL Bag PVC Baxter intravenous over 15 min, TESTCATO, NATHAN (UNC - HON3UCA) for 2/15/2017 3:00 PM</td>
</tr>
<tr>
<td>2:27:35 PM</td>
<td>MESSAGE: &quot;Scan barcode: 1st vial zoledronic acid 4mg (Lot: 602070) F1 Transfer solution directly F2 Do not use vial F3 Skip medication&quot;</td>
</tr>
</tbody>
</table>
| 2:28:16 PM | IDENTIFICATION OK: 1st vial zoledronic acid 4mg (Lot: 602070) has been identified with barcode: 01000325021801666 | **Note:** The barcode verification step is not visible in the figure.
| 2:28:16 PM | MESSAGE: "On the scale: 1st vial zoledronic acid 4mg (Lot: 602070) F1 Transfer solution directly F2 Do not use vial F3 Skip medication"          |
| 2:28:16 PM | MESSAGE: "On the scale: 1st vial zoledronic acid 4mg (Lot: 602070) F1 Transfer solution directly F2 Do not use vial F3 Skip medication"          |
Waste Management

- Cato proactively selects remainder vials for the technician to use
- Auto populates remainder labels
- Cato will generate waste reports
Implementation Timeline

- Administrator Training: March 2016
- Data Build: April – July 2016
- Testing Phase: July – August 2016
- User Training:
  - Super users – August 3rd – 4th
  - End users – August 8th – 26th
- Phased Roll-out
Required Resources

• Database builds and Testing
  – Lead Technician
  – Lead Pharmacist
  – Pharmacist Operations Specialist

• System Maintenance
  – 0.5 FTE Dedicated
Master Data Build Process

• Information Collection
  – Stability Information
  – Product Information
  – Preparation Details
  – Pharmacy Information System Formulary Information

• System Entry

• Order/ADT Testing
Implementation & Expansion

- Hazardous Drug Go-Live – August 31, 2016
- Rollout Method
  - Phase 1 – 4 drugs (August 31, 2016)
  - Phase 2 – 6 drugs (September 12, 2016)
  - Phase 3 – 10 drugs (October 10, 2016)
  - Phase 4 – 25 drugs (November 1, 2016)
- Expansion
  - Non-hazardous IV Room – June 2017
  - Infusion Centers – Summer 2017
**Evaluation**

- Statistically significant reduction in production times seen at 90-days post-implementation

<table>
<thead>
<tr>
<th></th>
<th>Volumetric Preparation (n=643)</th>
<th>Gravimetric Preparation (n=728)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Technician Preparation</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pharmacist Check</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median time, minutes [IQR]</td>
<td>0.75 [0.53-1.13]</td>
<td>0.32 [0.23-0.65]</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
Evaluation

• Improved accuracy of preparations within ±5% by 27.7%

<table>
<thead>
<tr>
<th></th>
<th>No. of Preparations</th>
<th>Range of % Difference</th>
<th>% within ± 5% of ordered dose</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Volumetric Pre-Period</strong></td>
<td>1156</td>
<td>-64.9 to 94.2</td>
<td>71.9</td>
</tr>
<tr>
<td>(Historical Study)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Gravimetric Post-Period</strong></td>
<td>3156</td>
<td>-12.5 to 5.4</td>
<td>99.6</td>
</tr>
</tbody>
</table>
Limitations

• Low Volumes
• Complex preparations difficult to incorporate
• Specific gravity information availability
• Variability in Pharmacy Information System (EPIC, etc.) builds can present a challenge
ARS – True/False: Despite the safety benefits of an automated gravimetric IV workflow, the extra steps introduced typically result in a sustained increase in production time.

A. True
B. False
Summary

• A gravimetric workflow increases product accuracy while reducing production times.
• Gravimetric TAWF enhance patient and medication safety.
• Implementation involves an extensive time commitment.
Acknowledgements

• Lindsey Amerine, PharmD, MS, BCPS
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• Ashley Paruscio, CPhT
• Patricia Roberts, PharmD, MS, BCPS
ALTERNATE METHODS OF CHEMOTHERAPY PREPARATION: GRAVIMETRIC TECHNOLOGY-ASSOCIATED WORKFLOW
How do robotics make you feel?

1. Excited, I always have the latest and greatest electronics
2. Fearful, they are replacing jobs and changing how we live
3. Inevitability, everything will be augmented by technology in the future
Objectives

At the conclusion of this activity, participants should be able to:

• Identify key reasons for implementing hazardous IV compounding robotics

• Predict potential challenges in implementing hazardous IV compounding robotics in their practice
Outline

Why robotics

Selection

Implementation

Optimization

Limitations and future directions
Why implement robotics in IV chemotherapy compounding?

- Patient safety
- Employee safety
- Workflow efficiency and reliability
- Data capture
- Supply cost reduction

Selecting a Solution

**Company**
- Customers
- Company reputation and goals

**Capabilities**
- Safety mechanisms including barcode scanning, gravimetric measurement and picture validation
- Impact on workflow and role of staff
- Flexibility of solution
- Hazard containment

https://www.arxium.com/index.php
p/iv-compounding/
Selecting a Solution

Financial
• Cost of robot
• Cost of consumables
• Financing options

Technical Support
• Implementation support
• Downtime support
• Technology refresh

https://www.omnicell.com/Products/IV_Solutions/ivSTATI ON_ONCO_Hazardous_Compounding_Robot.aspx
Selecting a Solution

Facility Requirements
- HVAC
- Electrical
- Footprint

IT Integration
- Data storage
- Interfaces

http://www.kirogrifols.com/
Wake Forest Baptist Health Experience

- NCI Comprehensive Designation
- Over 150 inpatient cancer beds
- 7 infusion clinics with over 100 chairs
- Over 38,000 doses of chemotherapy per year
Wake Forest Baptist Health Experience

- Implemented robot outpatient in June 2012
- Partnered to create guided prep technology in May 2014
- Implemented robot inpatient in March 2016
Implementation

Installation

• Place to receive
• Pathway for delivery
• Facility involvement
Implementation

Mechanical Assembly
• Robot training
• Component calibration
• Certification
• Redundant compounding space

IT Integration
• Interface development
• Database
Implementation
Implementation

- Staff training and ownership
- Workflow development
- Risk assessment
- Board of Pharmacy involvement
Self Assessment Question 1

What is a reason for implementing robotics into hazardous IV compounding practice?

A. Robotics replaces the need for any closed system transfer device
B. Robotics eliminates the need for any technician involvement in compounding
C. Robotic preparation reduces the risk of repetitive hand motion injuries
D. Currently robotics can compound any final preparation
Optimization

Adding or changing drugs and base fluids to formulary

- Vial dimensions
- Specific gravity
- Label and barcode
- Minibag clamps

http://www.medstandard.uz/en/content/glass-vials-medicaments
Optimization

Improving Efficiency

• Queue development
• Coordinated workflow with guided preparation device
• Addition of inpatient robot allowing load shifting
• Interdisciplinary team education
Optimization

Vendor collaboration
• Weekly phone calls
• Annual national user group meeting
• Biannual international user group meeting
• Standardization across users
Optimization

Cycle Time Improvements

- Cycle Time (min)
- Preps per week

2013: 6.66
2014: 6.12
2015: 5.98

2013: 122
2014: 153
2015: 189
Optimization

Error Rate Improvements

- **Error Rate**
- **Total Preparations**
Functional Limitations

- Multi-drug preparations
- Investigational drugs
- Small volume doses
- Speed
- Formulary design
Future Developments

Bidirectional interface

• Send NDC and waste back to electronic record

Advanced preparation for outreach clinics

• About 50% of outpatient preparations off main campus

Consolidate robots

• Allow for complementary configuration
USP<800> Implications

• Work surface of the primary engineering control (hood) must be decontaminated between compounding of different hazardous drugs (HD)

• Closed system transfer device (CSTD) should be used when compounding HDs when the dosage form allows

• CSTDs must be used when administering anti-neoplastic HDs when the dosage form allows
Self Assessment Question 2

What is an unintended consequence of implementing IV compounding robotics?

A. New compounding data was made available that wasn’t possible with manual processes
B. Drug waste increased early due to process failures in the robot
C. Pharmacist effort in checking the final preparation decreased
D. Staff immediately accepted the technology
Summary

- IV robotics adds value to the compounding process
- Selecting and implementing a robotic solution is a multidisciplinary process
- Leadership is needed to continue to advance IV robotics
Joseph Bonkowski, PharmD, MHA, MS
August 4, 2017

IV ROBOTICS IN HAZARDOUS DRUG PREPARATION