Current Considerations for Meeting the ISMP Standard for Gravimetric Preparation

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Disclosure

Lindsey Amerine
Becton Dickinson: Speaker’s Bureau

All other planners, presenters, and reviewers of this session report no financial relationships relevant to this activity.
Learning Objectives

• Differentiate between volumetric and gravimetric preparation techniques.
• Describe the implementation of gravimetric technique to meet ISMP's best practice recommendation.
• Apply metrics with gravimetric technique that improve accuracy for chemotherapy preparations.
Volumetric Preparation

• Using the measurement of volume
• **Visual** verification of amount of drug in a syringe
Volumetric Preparation

Volumetric

Manual process

Technology

Syringe pull-back

Visual inspection

Camera
Gravimetric Preparation

- Using the measurement of weight
- Verification of amount of drug or fluid by weighing on scale
- Calculation by means of specific gravity
Gravimetric Preparation

Gravimetric process

Manual process

Scale with printed weight

Technology

Integrated software and scale
‘Hybrid’ Model

Volumetric Technology
- Camera

Gravimetric Technology
- Integrated software and scale
Have you considered IV gravimetric technology?

A. Yes, and we have already implemented
B. Yes, but we are still looking
C. No, we implemented volumetric technology (camera)
D. No, not even on our radar
COMING SOON
TO A HOSPITAL
NEAR YOU
ISMP Guidelines

- ISMP National Medication Errors Reporting Program (MERP) showed manual inspection is not effective
- 2016 Revision: Use of barcode scanning and gravimetrics at a minimum for chemotherapy and pediatrics
Implications of ISMP Guidelines

• Plan for funding for technology
• Research available products
• Carefully design a strategy of implementation
Technology lifecycle stages

Stage 1: Establish Need for Change
Stage 2: Select a System
Stage 3: Implementation Planning
Stage 4: Maintenance and Evaluation

Planning a Successful Implementation

• **Ten key considerations** at each stage for a successful implementation of health information technology
• Factors identified in literature:
  – Technical- integration, cost, hardware
  – Social- resistance, “We’ve always done it that way”
  – Organizational- involving leadership outside pharmacy
  – Wider socio-political- professional groups, industry

Stage 1: Do we need change?

- **Consideration**: Clarify the problem technology will solve
  - Map existing processes
  - Assumed benefits
  - How do you quantify patient safety and workflow efficiency?
  - Is technology the answer?

Stage 1: Do we need change?

- *Manual* gravimetric process prior to our implementation
- Failure Modes and Effects Analysis (FMEA) prior to pilot
  - Detailed analysis of workflow
  - What can fail and what are the consequences
  - Deficiencies found in existing processes
Stage 1: Do we need change?

• **Consideration:** Build consensus
  – Buy-in from senior leadership inside and outside pharmacy
  – Don’t forget your end-users

• One year pilot to develop business plan for expansion
  – Gathered data from one pharmacy area
  – Solicited feedback from staff

Stage 2: Selecting a System

- **Consideration**: Consider the options
- **Consideration**: Choose systems that meet needs and are affordable
  - Must be practical and valuable to your end-users
  - Don’t want staff to avoid using the system or create workarounds

Stage 2: Selecting a System

• Our product selection began in 2010
  – Explored options outside of the U.S.
  – Transitioned from manual gravimetric process to gravimetrics with technology
• Explore all options on the market
  – Reach out to other institutions
  – May be limited to current vendors
• Interoperability with pharmacy order entry software
Stage 3: Planning for Implementation

- **Consideration**: Plan appropriately
  - Phased vs big-bang approach
  - Be realistic- avoid “scope-creep”
- Have a plan
- Build your system
  - Master data- checklist and verification
  - User profile and global settings

Stage 3: Planning for Implementation

- **Consideration**: Don’t forget the infrastructure
  - Server capacity
  - Wireless vs wired networks
  - Testing
  - Hardware considerations

Stage 3: Planning for Implementation

• Establish test environments for both systems
• Set up hardware well in advance- consider a test station
• Track test scripts
• Combining testing phases or running concurrently may be more efficient
Stage 3: Planning for Implementation

- Connectivity testing- set up server and test interface
- Mapped record testing
  - Create unique medication identifiers in each system
  - Confirm records map correctly to downstream system
  - Test every medication record
Stage 3: Planning for Implementation

• User acceptance testing- involve end user to test according to workflow
  – Label configuration
  – Hardware functionality

• Application testing- how do the software features function
  – Use release notes of the software
  – Test each feature that is applicable

• Repeat as necessary for software updates
Stage 3: Planning for Implementation

- Hardware and accessories
  - Computer- cleaning processes, touchscreen vs keyboard
  - Scanners- wired vs wireless, configuration for barcodes
  - Balances- routine and preventative maintenance
  - Label printers- one per IV hood
- IV hood retrofit
  - Cable management
  - Location of computers and printers
Photos courtesy of K. Reece
Stage 3: Planning for Implementation

- **Consideration**: Train the staff
  - Tailor to the end-user roles
  - “Hands-on” setting
  - Schedule training close to implementation
  - Continuous training- weekend and part-time staff

Stage 4: Maintain and evaluate

- **Consideration:** Continuously evaluate progress
  - Elicit and respond to user feedback
  - May be a long term process

- **Consideration:** Maintain the system
  - Hardware and software
  - Interface errors
  - Master data maintenance- new drugs and manufacturers
  - Inventory management

Stage 4: Maintain and evaluate

- **Consideration**: Stay the course
  - Manage expectations
  - Be realistic of timelines and outcomes

‘Failures’ in Implementation

• Rejection by users
• Bandwidth- know your system’s requirements
• Obtain user feedback early on
  – Learning curve expected
• Track the system’s performance

Pearls for your implementation

• Allow users to become familiar with the concept of gravimetrics
• Choose super-users for testing and training
  – Also helps with resistance to change
• Be involved in the technical discussions and hardware decisions
  – Regular team meetings with increasing frequency closer to go-live
• Start slow- no need to change entire workflows at once
Pearls for your implementation

• Provide proper training
  – Technology is NOT an instant fix, workarounds are inevitable
• Monitor errors closely during implementation
• Develop back-up support for “experts”
• Ensure sufficient staff trained to maintain hardware and interfaces
Key Takeaways

• Successful implementation of a gravimetric IV software can be modeled after the technology stages of establishing the need for change, selecting a system, planning, and maintenance and evaluation.

• Testing should be methodical and cover all areas including interfaces.

• Be realistic about goals and listen to your staff to avoid setbacks during implementation.
Which of the following is NOT part of the planning stage?

A. Train staff  
B. Build consensus  
C. Prepare hardware setup  
D. Consider current infrastructure
Which of these factors associated with effective implementation includes hardware cost and integration?

A. Organizational
B. Socio-political
C. Social
D. Technical
UNC Medical Center

- 805-bed academic medical center with a 75-bed community hospital as extension of medical center
### UNC Medical Center Sterile Preparation Areas

<table>
<thead>
<tr>
<th>Hazardous</th>
<th>Non-Hazardous</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Greater than 150 infusion chairs across Medical Center</td>
<td>• Sterile Products Area</td>
</tr>
<tr>
<td>• North Carolina Cancer Hospital</td>
<td>• Pediatric Satellite</td>
</tr>
<tr>
<td>• Five off-site infusion centers</td>
<td>• Operating Room Satellite</td>
</tr>
<tr>
<td></td>
<td>• Investigational Drug Services Satellite</td>
</tr>
<tr>
<td></td>
<td>• UNC Hillsborough Hospital</td>
</tr>
</tbody>
</table>
Impetus for Change: Volumetric Preparation Results in Wide Range of Accuracy

• UNC Study (Poppe et al)
  – Observational study of volumetric accuracy
  – RESULTS:
    • Mean dose = -0.53%
    • 71.7% doses within ±5% of ordered dose

Sterile product preparation at UNC MC traditionally prepared via volumetric method

Volumetric method of preparation measured to syringe demarcation

Visual verification of CSP components by technicians

Product check by a pharmacist using visual verification of volumetric measurement
Solution Selection Process

- **Prioritized EMR implementation first in 2014**
- **Continued RFP post-EMR implementation**

**Sought out solutions starting in 2009**

**Demonstrations**
- **On-site demos to UNCMC leadership and staff of available products**

**Narrowed to two vendors**
- **On-site demos to all Directors of Pharmacy within UNC Health Care System [prior to system pharmacy structure]**
- **Directors, along with feedback from entities, made determination**
UNC Health Care System Selected BD Cato as Gravimetric Solution

- Solution for all hazardous and non-hazardous sterile preparations
Gravimetric-Based Technology-Associated Workflow (TAWF)

- Software and hardware interfaced with the pharmacy information system utilizing hard stops to guide CSP preparation
  - **Gravimetric measurement of components**
  - Barcode verification of components
  - Lot number and inventory management
  - Photographic documentation of steps
  - Partial vial waste management
Gravimetric-Based TAWF

- Software guides technician through one-piece flow CSP preparation
  1. Pick list
  2. Barcode scan
  3. Preparation
  4. Accuracy check
  5. Label Print
Screen Shots for Technician Set-up

- Set-up Tech Workflow
- Drug Lot Tracking
- Vehicle Lot Tracking
Screen Shots of Technician Preparation

- Barcode Identification
- Photo Identification
System Will Not Allow Technician to Move Forward Until Tolerance is Met

Hard stop with directions on correcting the step before allowed to move forward
Pharmacist Verification of Product Visual Inspection and Gravimetric Validation

- Verification without all vial/syringe components
- Visual Checking Process
- Detailed Preparation Log
Pharmacist Verification of Product Visual Inspection and Gravimetric Validation

1 - Transfer of 4mg ZOMETA Solution for injection

Identification of vial before withdrawal
Identification successful
Expected weight: 12.03 g, Determined weight: 12.03 g, Deviation: 0%

Preparation log

<table>
<thead>
<tr>
<th>Date</th>
<th>Information text</th>
</tr>
</thead>
<tbody>
<tr>
<td>2:27:35 PM</td>
<td>PREPARATION No. 9508 INITIATED ON 2/15/2017 AT 2:27 PM (BD Cato VERSION: 2.38 G1.1)</td>
</tr>
<tr>
<td>2:27:35 PM</td>
<td>Assigned vials: 1x zolendronic acid 4mg. Nominal volume: 5mL, actual volume: 5mL, Density: 1.02g/mL, UID: 270965.</td>
</tr>
<tr>
<td>2:27:35 PM</td>
<td>Gravimetric Preparation:</td>
</tr>
<tr>
<td>2:27:35 PM</td>
<td>Computer name: MGMA24R1BCAT01, Prep. Person: Brannam, 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. #8892: 4mg zolendronic acid Solution for injection in NaCl 0.9% 100mL Bag PVC Baxter intravenous over 15 min, TESTGCAT, NTHAN (UNC - HON3UCA) for 2/15/2017 3:00 PM</td>
</tr>
<tr>
<td>2:27:35 PM</td>
<td>MESSAGE: “Scan barcode: 1x vial zolendronic acid 4mg (Lot: 602070) F1 Transfer solution directly F2 Do not use vial F3 Skip medication”</td>
</tr>
<tr>
<td>2:28:16 PM</td>
<td>IDENTIFICATION OK: 1x vial zolendronic acid 4mg (Lot 802073) has been identified with barcode: 0100325021801666</td>
</tr>
<tr>
<td>2:28:16 PM</td>
<td>MESSAGE: “On the scale: 1x vial zolendronic acid 4mg (Lot 602076) F1 Transfer solution directly F2 Do not use vial F3 Skip medication”</td>
</tr>
<tr>
<td>2:28:16 PM</td>
<td>MESSAGE: “On the scale: 1x vial zolendronic acid 4mg (Lot 602076) F1 Transfer solution directly F2 Do not use vial F3 Skip medication”</td>
</tr>
</tbody>
</table>
Streamlined Waste Management through Printed Labels of Partial Vials after Preparation is Complete

- Proactively selects remainder vials for the technician to use
- Auto populates remainder labels
- Generates waste reports
Master Data Build Process

• Administrator Designation [system builders]
  – Assigned existing staff to build database
  – Four primary individuals (2 from Sterile Products Area, 2 from the Cancer Hospital) plus area managers

• Information Collection
  – Product and Stability Information
  – Preparation Details

• External site visit
Build Drugs According to Type of Drug and Preparation Method

- Build “like” drugs (e.g. reconstituted drugs being pushed into a final bag or straight drug being dispensed in a syringe)
- Build a few, test a few
- Conduct weekly calls with IT Department and vendor to ensure all issues found within testing are being resolved quickly
Training Process

• Vendor on-site support to train staff
• Train staff within a simulated environment using real drug
  – Setup workstation in the cleanroom
  – Super users/administrators push through practice orders
  – Used real drug (less costly agents with smaller vial sizes)
Phased Implementation Started in Cancer Hospital

- Cancer Hospital GO-LIVE – August 31, 2016
- Rollout Method (example of first 4 phases):
  - Phase 1 – 4 drugs (August 2016)
  - Phase 2 – 6 drugs (September 2016)
  - Phase 3 – 10 drugs (October 2016)
  - Phase 4 – 25 drugs (November 2016)
Phased Implementation Followed in Non-Hazardous Area

• Sterile Products Area GO-LIVE – May 2017
• Rollout method:

Phase 1 – 5 drugs (May 2017)
Phase 2 – 10 drugs (June 2017)
Phase 3 – 19 drugs (September 2017)
Continue to roll out based on type of preparation
RESULTS OF GRAVIMETRIC-BASED TAWF IMPLEMENTATION
Implementation Results Studied in Cancer Hospital

- Pre-post study conducted in phases using mixed-methods
- Results studies
  - Accuracy
  - Production time – technicians
  - Production time – pharmacists
  - Staff satisfaction
Hazardous Drug Preparation More Accurate with Gravimetric TAWF

<table>
<thead>
<tr>
<th></th>
<th>Volumetric Preparation</th>
<th>Gravimetric TAWF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doses (n)</td>
<td>1,156</td>
<td>3,156</td>
</tr>
<tr>
<td>Accuracy range</td>
<td>-64.9% ± 94.2%</td>
<td>-12.5% ± 5.4%</td>
</tr>
<tr>
<td>Doses within ± 5% of ordered dose</td>
<td>71.7%</td>
<td>99.6%</td>
</tr>
</tbody>
</table>

38.9% increase in accuracy of chemotherapy and hazardous sterile products
Hazardous Drug Preparation Faster for Technicians at 90 Days

• Production Times Measured Pre- and Post-Implementation
• Measured from time technician began obtaining components for the preparation to the time at which they completed their compounding actions
• Statistically significant decrease in production time
  – Technician preparation time: 7.42 minutes versus 5.98 minutes (p<0.001)
Hazardous Drug Preparation Faster for Pharmacist Check at 90 Days

• Production Times Measured Pre- and Post-Implementation
• Measured from time pharmacist began product check to time pharmacist finished check (prior to placing in delivery bin)
• Statistically significant decrease in production time
  – Pharmacist check time: 45 seconds versus 19 seconds (p <0.01)
Potential Reasons for Faster Hazardous Drug Preparation

**Technicians**

- Reduction of time for documentation of lot numbers per product
- Standardized workflow for each preparation

**Pharmacists**

- Reduced number of checking steps
- Standardized workflow to check each preparation
Increased Staff Satisfaction with Gravimetric TAWF

Methodology
- Surveys conducted online through Qualtrics at pre-implementation, 30 days post-implementation, and 90 days post-implementation

Perception of Safety and Accuracy
- Perception of safety and accuracy were maintained in agreement through the pre-period and the post-period

Value of skills and abilities
- Believed hospital valued their skill and ability to compound/check and dispense sterile products accurately and safely through each time period

Perception of Production Time
- Speed compounding with the TAWF as slower initially, however recovered that perception at the end of the post-period
Increased Staff Satisfaction with Gravimetric TAWF

- Prefer to use the gravimetric-based TAWF system to compound CSPs over traditional volumetric preparation
Prevented Dispensation of Double the Ordered Dose

- System automatically caught a potential error with a manufacturer assistance replacement stock vial
  - Docetaxel 10 mg/mL is our standard
  - Manufacturer replacement program sent Docetaxel 20 mg/mL that was put into the inventory
  - New strength entered into the system, then technician inquired about differing volumes
Data Collection for Results in Non-Hazardous Area In Progress

- Data being collected:
  - Error Rates – types and frequencies
  - Production time – technicians
  - Production time – pharmacists
  - Staff Satisfaction
Limitations

- Low volumes
- Complex preparations difficult to incorporate
- Density information availability
- Variability in EMR creates inherent challenges
Key Takeaways

• Implementation of gravimetric-based TAWF occurred in a phased approach for all hazardous and non-hazardous sterile preparations
• Resulted in faster and more accurate hazardous sterile preparations
• Staff prefer to use the gravimetric system over volumetric compounding
Audience Response Question

• Which of the following is true of a gravimetric-based technology associated workflow solution?

A. Is slower than volumetric preparation methods
B. Is less accurate than volumetric preparation methods
C. Cannot be used for chemotherapy
D. Enhance medication safety for preparations
Implementation of New Sterile Compounding Practices for Chemotherapy to Meet ISMP’s Standards for Gravimetric Preparation

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