New and Emerging Strategies for Minimizing Errors in I.V. Preparation: Focus on Safety and Workflow Efficiency

Presented as a Midday Symposium at the 48th ASHP Midyear Clinical Meeting and Exhibition

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Orlando, Florida

Planned and conducted by ASHP Advantage and supported by an educational grant from BD
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New and Emerging Strategies for Minimizing Errors in I.V. Preparation: Focus on Safety and Workflow Efficiency

Agenda

11:30 a.m. – 11:35 a.m.  Welcome and Introductions  
Stephen F. Eckel, Pharm.D., MHA, BCPS

11:35 a.m. – 12:00 p.m.  Overview of the Current State of Sterile I.V. Compounding  
Patricia C. Kienle, M.P.A., B.S.Pharm., FASHP

12:00 p.m. – 12:40 p.m.  I.V. Preparation Procedures: Evaluating Processes for Improving Quality and Safety  
Stephen F. Eckel, Pharm.D., MHA, BCPS

12:40 p.m. – 1:15 p.m.  Case Studies: Using Technology to Promote Safety and Minimize Errors in I.V. Preparation  
Kelley M. Reece, Pharm.D.

1:15 p.m. – 1:30 p.m.  Faculty Discussion and Audience Questions

Faculty

Stephen F. Eckel, Pharm.D., MHA, BCPS, Activity Chair
Clinical Associate Professor  
UNC Eshelman School of Pharmacy  
Associate Director  
UNC Hospitals  
Chapel Hill, North Carolina

Patricia C. Kienle, M.P.A., B.S.Pharm., FASHP  
Director, Accreditation and Medication Safety  
Cardinal Health Innovative Delivery Solutions  
Laflin, Pennsylvania

Kelley M. Reece, Pharm.D.  
Assistant Manager  
M.D. Anderson Cancer Center  
Houston, Texas
Disclosure Statement

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The faculty listed below report relationships pertinent to this activity:

- Stephen F. Eckel, Pharm.D., MHA, BCPS, has served as a consultant for BD and Carefusion, has received grants from BD and Yukon Medical, and is principal/part owner of Chemo GLO.
- Patricia C. Kienle, M.P.A., B.S.Pharm., FASHP, is an employee and stockholder of Cardinal Health.

The following faculty and planners report no relationships pertinent to this activity:

- Kelley M. Reece, Pharm.D.
- Angela Cassano, Pharm.D., BCPS, FASHP
- Susan R. Dombrowski, M.S., B.S.Pharm.

ASHP staff has no relevant financial relationships to disclose.
Activity Overview

This educational activity will review traditional and state-of-the-art techniques in the preparation of i.v. drugs. Currently available technologies for sterile compounding will be reviewed on the basis of their potential for improving patient safety and improving workflow processes. The activity will conclude with a discussion of how i.v. technology can be used to minimize waste, decrease costs, and improve efficiency.

Learning Objectives

At the conclusion of this knowledge-based educational activity, participants should be able to

- Review the current environment in i.v. admixture services, including the need for improvements in patient safety and workflow processes.
- Review currently available sterile compounding technology (e.g., bar coding, automated compounders, robots, workflow software, validation software).
- Compare the accuracy of volumetric and gravimetric processes for preparing sterile i.v. preparations.
- Describe the potential effects of i.v. technology on waste, cost, and efficiency.
Continuing Education Accreditation

The American Society of Health-System Pharmacists is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This activity provides 2 hours (0.2 CEUs) of continuing pharmacy education credit (ACPE activity # 0204-0000-13-483-L05-P).

Attendees may print their official statements of continuing pharmacy education credit online after completion of the online evaluation. All statements are available online at the ASHP eLearning portal (http://elearning.ashp.org). For complete activity information, visit www.ashpadvantage.com/ivsafety.

Complete instructions for receiving your statement of continuing pharmacy education credit online are available on the next page. Be sure to record the attendance code beginning with “M” announced during the activity.

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Have ideas about what YOU want to remember to do as a result of what you are learning in this educational session? Use the Action Reminder tool via your smart device, and you will be sent an email reminder from YOURSELF next month.

If you do not have a smart device, access the Action Reminder for this activity at http://www.ashpadvantage.com/ivsafety/remindme.php
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1. Write down the Attendance Code for each session you attend. These codes are announced during each session. If you miss the code, check with the Room Monitor at the session.

2. Log in to ASHP’s eLearning Portal using your username and password. [http://elearning.ashp.org](http://elearning.ashp.org)

3. Click on My Learning Activities. Then click on 2013 – Midyear Clinical Meeting & Exhibition (Orlando, FL) under Conferences.

4. At the bottom of the page is a field for redeeming Attendance Codes (former called CE codes). Enter the Attendance Code(s) from each session, and click Submit.

   Tip: If your code is not redeeming successfully, verify that you have clicked on the title of your conference in order to access the Attendance Code field, not the Enrollment Code field.

5. Each session will be listed under Your Sessions. Click Claim Credit for a session.

6. Click on the name of a session and complete the requirements for the session.

7. Click Claim Credit for your profession. It is important that you select the correct profession.
   - Pharmacists and Pharmacy Technicians: Fill in your NABP eProfile ID and birth month and date. Check the box at the bottom and click Claim. You will see a message advising you whether or not your credits were claimed successfully. Your CPE credit will be reported directly to CPE Monitor.
   - Other (International, Students, etc.): Use ASHP Statement of Completion. Check the box at the bottom and click Claim.

You may print your statement of credit by clicking on Print Statement of Credit. If you require a reprint of a statement of credit, you can return here at any time to print a duplicate.

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1. Login to [www.ashp.org/exhibitorce](http://www.ashp.org/exhibitorce) with your ASHP username and password.

2. Click on the Get Started button.

3. Select the 48th ASHP Midyear Clinical Meeting & Exhibition from the dropdown menu.

4. Select your Exhibiting Company from the list of exhibitors. From here, follow the instructions above.

ASHP is now using the eLearning Portal ([http://elearning.ashp.org](http://elearning.ashp.org)) for CE Processing, which allows ASHP to report pharmacy credits via CPE Monitor. For more information, visit [www.ashp.org/CEtransition](http://www.ashp.org/CEtransition)

Pharmacists and Pharmacy Technicians: To process your CE on the eLearning Portal, you must enter your NABP e-Profile ID and birth month and date. After you have entered this information once it is saved for future CE processing. You may obtain your eProfile ID at [www.nabp.net](http://www.nabp.net).

There may be different directions for workshops and review courses.

| Date of Activity: Monday December 9, 2013 | Attendance Code: M_ _ _ _ _ | CPE Hours: 2.0 |

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• A web-based activity based on today’s live symposium will provide an opportunity to review today’s presentations
  
  o For your colleagues who missed the live symposium, this on-demand activity will offer 2 hours of CPE
  
  o Please note that individuals who claim CPE credit for the live symposium are ineligible to claim credit for the web-based activity

  www.ashpadvantage.com/ivsafety
New and Emerging Strategies for Minimizing Errors in I.V. Preparation:
Focus on Safety and Workflow Efficiency

Patricia C. Kienle, M.P.A., B.S.Pharm., FASHP
Director, Accreditation and Medication Safety
Cardinal Health Innovative Delivery Solutions
Laflin, Pennsylvania

Patricia C. Kienle, M.P.A., B.S.Pharm., FASHP, is Director of Accreditation and Medication Safety for Cardinal Health Innovative Delivery Solutions. She is a member of the United States Pharmacopeial Convention (USP) Expert Committee on Compounding and Chair of the Subcommittee and Expert Panel on Hazardous Drugs.

Ms. Kienle received her Bachelor of Science in pharmacy degree from the Philadelphia College of Pharmacy and Science and Master of Public Administration from Marywood University in Scranton, Pennsylvania. She completed an Executive Fellowship in Patient Safety from Virginia Commonwealth University and is an Adjunct Associate Professor at Wilkes University in Wilkes-Barre, Pennsylvania.

Ms. Kienle is an American Society of Health-System Pharmacists (ASHP) Fellow, Pennsylvania Society of Hospital Pharmacists (PSHP) Pharmacist of the Year, and recipient of the Distinguished Achievement Award in Hospital and Institutional Practice from the American Pharmaceutical Association Academy of Pharmacy Practice and Management.


Ms. Kienle has served on the ASHP Board of Directors and as PSHP President. She has also served as a member of the Pharmacotherapy Specialty Council of the Board of Pharmaceutical Specialties, Hospital Professional and Technical Advisory Committee of the Joint Commission, and Board of Governors of the National Patient Safety Foundation.
Current State of Pharmacy Compounding

Patricia C. Kienle, M.P.A., B.S.Pharm., FASHP
Director, Accreditation and Medication Safety
Cardinal Health Innovative Delivery Solutions
Laflin, Pennsylvania

Learning Objectives

• Review the current environment in i.v. admixture services, including the need for improvements in patient safety and workflow processes.

• Review currently available sterile compounding technology (e.g., bar coding, automated compounders, robots, workflow software, validation software).

• Compare the accuracy of volumetric and gravimetric processes for preparing sterile i.v. preparations.

• Describe the potential effects of i.v. technology on waste, cost, and efficiency.
What is your primary job position?

A. Director of Pharmacy  
B. Associate or Assistant Director of Pharmacy  
C. Clinical Coordinator or Other Supervisory Role  
D. Staff Pharmacist  
E. Clinical Pharmacist  
F. Medication Safety Coordinator  
G. Informatics/Technology Specialist  
H. Faculty

Who says what we have to do?

- Regulatory agencies  
- Accreditation organizations  
- Professional guidelines

Regulatory Agencies

- National  
  - Food and Drug Administration (FDA)  
  - United States Pharmacopeia (USP)  
- State  
  - Board of Pharmacy  
  - Department of Health
USP

- Nonsterile compounding – Chapter <795>
- Sterile compounding – Chapter <797>
- Hazardous drugs – Coming soon

Accreditation Organizations

- The Joint Commission
- Det Norske Veritas (DNV) Healthcare
- Healthcare Facilities Accreditation Program
- Center for Improvement in Healthcare Quality
- Ambulatory Accreditation Organizations

Best Practices

- ASHP
- American Society for Parenteral and Enteral Nutrition (ASPEN)
- Oncology Nursing Society (ONS)
- Physician organizations
- Nursing organizations

Photo courtesy of ASHP
ASHP’s New Compounding Sterile Preparations Guidelines

Is your practice contemporary?

Safety

Efficacy ↔ Cost

Patient Safety

• Facilities
  – Rooms
  – Devices
  – Equipment
• Personnel
• Environmental monitoring
• Beyond-use dates
Hazardous Drugs

Patient Safety

Worker Safety

Containment

Medication Use System

Order

Dispense

Administer

Store

Select

Monitor

Repeater Pump

Photo courtesy of Baxter
Closed System Transfer Devices

• A drug transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drugs or vapors outside the system

Automated Compounding Device

Photo courtesy of Baxter
Workflow Software

Evolution

Workflow Methods

• Develop workflow methods to support quality practices
  – Existing practices: 1970s → 2013
  – Contemporary standards: USP Chapter <797> and others
  – Contemporary guidance: ASHP and others
Our Goal

- Decrease errors
  - Standardization
  - Streamline workflow
- Increase safety
- Increase efficiency
New and Emerging Strategies for Minimizing Errors in I.V. Preparation:
Focus on Safety and Workflow Efficiency

Selected References


Self–Assessment Questions

1. What is the United States Pharmacopeia Chapter that will be dedicated to hazardous drugs?
   a. Chapter <795>
   b. Chapter <797>
   c. Chapter <800>
   d. There are no plans for a chapter on Hazardous Drugs

2. Which of the following is NOT a goal of best practices?
   a. Increase safety and efficiency
   b. Increase chaos
   c. Decrease errors
   d. Streamline workflow

3. Which of the following influence the practice of pharmacy?
   a. Regulatory agencies
   b. Professional guidelines
   c. Accreditation organizations
   d. All of the above

Answers

1. c
2. b
3. d
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Associate Director of Pharmacy
UNC Hospitals
Chapel Hill, North Carolina

Stephen F. Eckel, Pharm.D., MHA, BCPS, is Associate Director of Pharmacy and Director, Pharmacy Residency Programs at UNC Hospitals in Chapel Hill, North Carolina. Dr. Eckel is also Clinical Associate Professor and Vice Chair, Graduate and Post-Graduate Education in the division of practice advancement and clinical education at the University of North Carolina Eshelman School of Pharmacy.

Dr. Eckel received his Bachelor of Science and Doctor of Pharmacy degrees from the University of North Carolina at Chapel Hill. Following completion of a pharmacy practice residency at Duke University Medical Center, he worked as a clinical pharmacist at the University of North Carolina Hospitals. Dr. Eckel also completed a Masters of Health Care Administration degree from the UNC School of Public Health. He is a board-certified pharmacotherapy specialist.

Dr. Eckel is known as an innovator and entrepreneur within the pharmacy profession. Whether it is his leadership in UNC Pharmacy Grand Rounds, ChemoGLO, or as editor of the health-system edition of Pharmacy Times, he is a passionate supporter of the role of the pharmacist in patient care. He conducts and publishes research and is frequently asked to speak around the world on these issues.

Dr. Eckel also leads and develops a dynamic group of patient care providers at UNC Hospitals. He has also mentored almost 200 residents, instilling in them the passion to practice and to be involved in the profession.
I.V. Preparation Procedures: Evaluating Processes for Improving Quality and Safety

Stephen F. Eckel, Pharm.D., MHA, BCPS
Clinical Associate Professor
UNC Eshelman School of Pharmacy
Associate Director
UNC Medical Center
Chapel Hill, North Carolina

Objectives

• Review currently available sterile compounding technology (e.g., bar coding, automated compounders, robots, workflow software, validation software).
• Compare the accuracy of volumetric and gravimetric processes for preparing sterile i.v. preparations.

Overview of I.V. Technology

• Robotics
  – Apoteca: APOTECAchemo
  – Health Robotics: i.v. STATION ONCO
  – Intelligent Hospital Systems: Riva
  – Baxter: IntelliFill i.v.
  – ICU Medical: Diana
• I.V. workflow systems
  – Baxter: DoseEdge
  – BD: Cato
Which i.v. robotics technology is being used within your organization?

A. No i.v. robotic technology is being used
B. Apoteca: APOTECAschemo
C. Health Robotics: i.v.STATION ONCO
D. Intelligent Hospital Systems: Riva
E. Baxter: IntelliFill i.v.
F. ICU Medical: Diana
G. Not applicable

Which i.v. workflow system is being used within your organization?

A. No i.v. workflow systems are being used
B. Homegrown i.v. workflow system
C. Baxter: DoseEdge
D. BD: Cato
E. Not applicable

Steps in Preparing a Medication

Enlarged slide on page 41.
Benefits of Automation

APOTECAnx
• Currently only compounds chemotherapy
• Prepares syringes, i.v. bags, and elastomeric pumps
• Uses both gravimetric and volumetric check
• 12-40 preparations per hour
• Uses barcode, size and shape of vial, and label scan for product identification
• One published study describing implementation

www.apotecausa.com
Implementation of APOTECAdemo

- Description of the implementation and experience at Cleveland Clinic
- 7,384 doses over 13 months
- Performance issues categorized
  - Dose issues: 1.2% were manually modified
  - Mechanical issues: 155 documented
  - Human error: 12 instances
  - Interface / IT issues
- Does not prepare syringes for them
- They did not reduce full-time equivalents (FTEs)


Riva

- Currently compounds chemotherapy and non-chemotherapy items
- Prepares both syringes and i.v. bags
- Uses gravimetric check
- I.V. bags: 12–28 per hour
- Syringes: 29–60 per hour
- UV sanitation of vials and bags
- No published studies of effectiveness

www.intelligenthospitals.com

Used with permission from Intelligent Hospital Systems
Impact of Robotics on Chemotherapy Preparation

• Utilized direct observer technique

• Results

<table>
<thead>
<tr>
<th></th>
<th>Baseline (n=4,422)</th>
<th>Intervention (n=722)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication errors</td>
<td>9 (0.7%)</td>
<td>7 (0.7%)</td>
<td>NS</td>
</tr>
<tr>
<td>Staff safety events</td>
<td>73 (5.1%)</td>
<td>28 (2.9%)</td>
<td>P=0.007</td>
</tr>
<tr>
<td>Intended consequences</td>
<td>–</td>
<td>45 (4.6%)</td>
<td></td>
</tr>
<tr>
<td>Medication accuracy</td>
<td>23 (12.5%) of 184</td>
<td>1 (0.9%) of 110</td>
<td>P=0.002</td>
</tr>
<tr>
<td>Workflow – overall</td>
<td>7 min 24 sec</td>
<td>10 min 51 sec</td>
<td>P=0.009</td>
</tr>
<tr>
<td>Costs – personnel</td>
<td>$5.22</td>
<td>$5.10</td>
<td></td>
</tr>
<tr>
<td>Costs – ancillary materials</td>
<td>$13.36</td>
<td>$6.44</td>
<td>P&lt;0.001</td>
</tr>
</tbody>
</table>

Health Robotics Evaluation

- Monoclonal antibodies are difficult to reconstitute
  - Foaming hampers drawing correct doses into syringes
  - Aggregates associated with immune reactions
- Robotic reconstitution and compounding are similar to manual process
- Manual compounding can cause upper limb disorders (ULD)
- Automated compounding was associated with a lower ULD risk than manual processes


IntelliFill i.v.

- Only prepares syringes
- Range of volume is from 0.5 mL to 11.5 mL
- While it can make up to 600 syringes per hour, a usual rate is 360 per hour
- Requires the use of special syringes
  (IntelliFill i.v. banded syringes)
- No published studies of effectiveness

Used with permission from Baxter
Diana

- User controlled (as opposed to robotic)
- Requires the use of a closed system transfer device during compounding
- Can prepare i.v. bags, syringes, and elastomeric pumps
- Two channels
  - Low volume: <20 mL
  - High volume: up to 50 mL
- No published studies of effectiveness

DoseEdge

- Pharmacy workflow manager
- Can assist with preparation of more than i.v. doses (TPN, oral syringes)
- Utilizes bar-code scanning of product
- Volumetric method (camera) for checking
- Allows for remote order verification
- Assists in compliance with preparation best practices
- Can be used within a glove box
- No published studies of effectiveness

www.baxtermedicationdeliveryproducts.com/pharmacy-workflow/doseedge.html
DoseEdge

Cato
- Information system that allows for physician order entry (regimens / protocols), pharmacy order verification and preparation, and nursing administration
- Pharmacy workflow manager
- Guides the technician when preparing a product
- Gravimetric method (balance) for checking – organization sets the tolerance
- Can be used within a glove box
- No published studies of effectiveness

www.chemocato.com

Cato
Major Concerns / Issues
With Chemotherapy Dispensing
Efficiency
Safety

What is your usual chemotherapy turnaround time?
A. >60 minutes
B. 45-60 minutes
C. 30-45 minutes
D. 15-30 minutes
E. <15 minutes

Using Lean Principles to Improve Adult Outpatient Chemotherapy Preparation Turnaround Time in a Large Cancer Hospital Infusion Pharmacy
Matt Lamm, Pharm.D., MS, BCPS
Lindsey Poppe, Pharm.D., MS, BCPS
Stephen F. Eckel, Pharm.D., MHA, BCPS
Background

- Opened new cancer center pharmacy in August, 2009
  - Consolidation of two dispensing sites
- 42% total growth in chemotherapy volume since opening
  - 51% increase in outpatient chemotherapy
- 215 total chemotherapy preparations per day
- Minimal change to staffing (5 pharmacists; 6 technicians)

Chemotherapy Wait Time

- 2011 – anecdotal data of 1 hour total turnaround time
- 2012 – interim goal of 45 minutes
- 2013 – final goal of <30 minutes
- Turnaround time includes
  - Primary verification and order entry into the pharmacy system by a pharmacist
  - Preparation by a chemotherapy pharmacy technician
  - Secondary verification by a pharmacist located inside the infusion cleanroom
  - Delivery to the patient by a pharmacy technician

Study Initiation

- Phase 1 – gathered baseline data for chemotherapy turnaround time for Adult Infusion Clinic patients
- Phase 2 – implemented various experiments using Lean principles in an effort to decrease chemotherapy preparation turnaround time
Phase 1

• Data collected between January 14th and January 25th, 2013 (9 days)
• Orders were separated into three main categories
  – Preapproved orders in advance (processed 48 hours in advance)
  – On-demand
  – Investigational Drug Service

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean ± S.D. Total Time per Preparation (min)</th>
<th>Median Total Time per Preparation (min)</th>
<th>Maximum Total Time per Preparation (min)</th>
<th>Minimum Total Time per Preparation (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Turn-Around Time</td>
<td>44 ± 18</td>
<td>42</td>
<td>140</td>
<td>9</td>
</tr>
<tr>
<td>Automated Dispensing Cabinet (ADC) to Prep Table</td>
<td>12 ± 11</td>
<td>11</td>
<td>85</td>
<td>0</td>
</tr>
<tr>
<td>Prep Table to Technician Start</td>
<td>9 ± 10</td>
<td>6</td>
<td>72</td>
<td>0</td>
</tr>
<tr>
<td>Technician Preparation</td>
<td>6 ± 5</td>
<td>5</td>
<td>43</td>
<td>0</td>
</tr>
<tr>
<td>End of Tech Preparation to Pharmacist Check</td>
<td>8 ± 7</td>
<td>6</td>
<td>35</td>
<td>0</td>
</tr>
<tr>
<td>Pharmacist Check</td>
<td>2 ± 1</td>
<td>2</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>Pharmacist Check to Delivery</td>
<td>6 ± 4</td>
<td>5</td>
<td>30</td>
<td>0</td>
</tr>
</tbody>
</table>

Categorized Chemotherapy Preparations Results – Phase 1

<table>
<thead>
<tr>
<th></th>
<th>Advance Preparations</th>
<th>On-Demand Preparations</th>
<th>Investigational Drug Service Preparations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Turnaround Time</td>
<td>39 ± 16</td>
<td>48 ± 10</td>
<td>57 ± 22</td>
</tr>
<tr>
<td>ADC to Prep Table</td>
<td>5 ± 2</td>
<td>8 ± 2</td>
<td>12 ± 2</td>
</tr>
<tr>
<td>Prep Table to Technician Start</td>
<td>10 ± 10</td>
<td>8 ± 10</td>
<td>9 ± 13</td>
</tr>
<tr>
<td>Technician Preparation</td>
<td>6 ± 5</td>
<td>6 ± 4</td>
<td>7 ± 4</td>
</tr>
<tr>
<td>End of Tech Preparation to Pharmacist Check</td>
<td>8 ± 6</td>
<td>7 ± 7</td>
<td>10 ± 7</td>
</tr>
<tr>
<td>Pharmacist Check</td>
<td>1 ± 1</td>
<td>2 ± 2</td>
<td>2 ± 2</td>
</tr>
<tr>
<td>Pharmacist Check to Delivery</td>
<td>6 ± 5</td>
<td>5 ± 3</td>
<td>7 ± 4</td>
</tr>
</tbody>
</table>
Phase 1 Results

Mean Turnaround Time vs Doses Received per Hour

Phase 2

- Implemented a Kaizen event (used A3 model)
- Formed 4 different groups to evaluate functions
  - Outside the cleanroom (CR) checking pharmacist
  - CR technicians
  - CR pharmacist
  - Supplies management

Phase 2

- Suggested changes to the process evaluated
  - Moving the double check of chemotherapy orders from the CR pharmacist to a pharmacist outside the cleanroom
  - Having the CR pharmacist focus on final product checking instead of performing a second clinical check
  - Changing technician product preparation from batch processing to 1-piece flow
  - Remove excess products from the supply room
Phase 2 Results

**Turnaround Times Pre- and Post-Kaizen**

Do you use the syringe pull back method?
A. Yes  
B. No  
C. Not sure

Does your i.v. preparation process utilize a gravimetric method to evaluate accuracy?
A. Yes  
B. No  
C. Not sure
Assessment of dosing accuracy when using volumetric technique in the preparation of chemotherapy

Lindsey Poppe, Pharm.D., MS, BCPS
Scott Savage, Pharm.D., MS
Stephen F. Eckel, Pharm.D., MHA, BCPS

Objectives

• Primary outcome – determine the accuracy of volumetric measurements in the preparation of chemotherapy by using the gravimetric method
• Secondary outcome – evaluate the accuracy of volumetric measurements based on volumes prepared, syringe size used, patient age, preparations requiring reconstitution, drug prescribed, and technicians preparing the agents

Background

• Conducted at the UNC Cancer Hospital
• Approximately 160 chemotherapy doses prepared per day
• 10 different pharmacy technicians are employed there
• All technicians are trained and tested on chemotherapy preparation competencies
• At the time of this study, utilized the syringe pull-back method
Methodology

- Placed an electronic balance in one hood
- All technicians that were scheduled to work there participated in the study
- Data collected between December 15, 2010, and March 30, 2011
- Doses excluded if no specific gravity, agent given via non-i.v. route, or data transcription incorrect

Methodology

- Empty syringe with a closed system transfer device (CSTD) was weighed
- Medication prepared using the typical process with the syringe pull back method (volumetric technique)
- Full syringe with the drug to be dispensed was weighed
- Drug was dispensed in syringe or transferred to an i.v. bag
- No change was made to the pharmacist checking process

Calculation of Primary Outcome

- Percent volume difference for the dose dispensed compared to the dose prescribed
  - Weight of drug in syringe (full weight minus empty weight)
  - Reduction based upon estimated residual volume
  - Divided by the specific gravity to determine volume dispensed
  - Compared to the prescribed amount to determine difference
Few Considerations

- Concerns with over-dosing and under-dosing of chemotherapy
- Inherent inaccuracies in the current process
  - Percent label strength of the parent product
  - Issues associated with reconstitution
  - Syringe tolerance variability
- Nurse need for and reliance on syringe markings for double check

Results

Enrollment

1560 Chemotherapy Doses Dispensed

<table>
<thead>
<tr>
<th>409 Excluded</th>
</tr>
</thead>
<tbody>
<tr>
<td>402 no specific gravity, 6 inaccurate gravimetric measurement</td>
</tr>
<tr>
<td>1156 Included</td>
</tr>
</tbody>
</table>
### Percent Volume Difference of Drugs Prepared

<table>
<thead>
<tr>
<th>Drug prescribed</th>
<th>Sample Size</th>
<th>Mean % Volume Difference</th>
<th>Median % Volume Difference</th>
<th>Range (Min, Max)</th>
<th>Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>165</td>
<td>7.07%</td>
<td>5.76%</td>
<td>(-2.34%, 19.22%)</td>
<td>(-0.06, 0.207)</td>
</tr>
<tr>
<td>B</td>
<td>122</td>
<td>1.47%</td>
<td>-0.74%</td>
<td>(-8.17%, 10.1%)</td>
<td>(-0.06, 0.092)</td>
</tr>
<tr>
<td>C</td>
<td>57</td>
<td>-0.99%</td>
<td>-0.62%</td>
<td>(-14.08%, 2.02%)</td>
<td>(-0.045, 0.025)</td>
</tr>
<tr>
<td>D</td>
<td>50</td>
<td>0.52%</td>
<td>-1.22%</td>
<td>(-1.15%, 12.62%)</td>
<td>(-0.07, 0.047)</td>
</tr>
<tr>
<td>E</td>
<td>55</td>
<td>-3.46%</td>
<td>-2.15%</td>
<td>(-7.9%, 1.88%)</td>
<td>(-0.081, 0.039)</td>
</tr>
<tr>
<td>F</td>
<td>58</td>
<td>2.01%</td>
<td>-2.50%</td>
<td>(-11.00%, 1.78%)</td>
<td>(-0.025, 0.004)</td>
</tr>
<tr>
<td>G</td>
<td>53</td>
<td>-1.24%</td>
<td>-0.60%</td>
<td>(-10.05%, 1.05%)</td>
<td>(-0.045, 0.018)</td>
</tr>
<tr>
<td>H</td>
<td>58</td>
<td>2.01%</td>
<td>-2.50%</td>
<td>(-11.00%, 1.78%)</td>
<td>(-0.025, 0.004)</td>
</tr>
</tbody>
</table>

*Drugs with sample size > 50

---

### Percent Volume Difference from Prescribed Chemotherapy Dose (n = 1,155)

- **<sup>*<sup>** ± 3% 73.4% of all doses
- **<sup>*<sup>** ± 10% 88.9% of all doses

---

### Percent Volume Difference Based on Syringe Size

---

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---

---
Percent Volume Difference Based on Technician Preparing the Drug

<table>
<thead>
<tr>
<th>Tech #</th>
<th>Sample Size</th>
<th>Mean % Volume Difference</th>
<th>Median % Volume Difference</th>
<th>Range (Min, Max)</th>
<th>Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>51</td>
<td>2.91%</td>
<td>-1.28%</td>
<td>(-12.77%, 94.22%)</td>
<td>(-0.013, 0.073)</td>
</tr>
<tr>
<td>2</td>
<td>5</td>
<td>-0.05%</td>
<td>-0.68%</td>
<td>(-1.86%, 3.09%)</td>
<td>(-0.128, 0.111)</td>
</tr>
<tr>
<td>3</td>
<td>441</td>
<td>-0.07%</td>
<td>-0.52%</td>
<td>(-13.48%, 12.68%)</td>
<td>(-0.003, 0.006)</td>
</tr>
<tr>
<td>4</td>
<td>39</td>
<td>-0.16%</td>
<td>-1.41%</td>
<td>(-11.47%, 30.2%)</td>
<td>(-0.019, 0.051)</td>
</tr>
<tr>
<td>5</td>
<td>202</td>
<td>-0.45%</td>
<td>-1.32%</td>
<td>(-23.74%, 79.09%)</td>
<td>(-0.013, 0.051)</td>
</tr>
<tr>
<td>6</td>
<td>94</td>
<td>-1.67%</td>
<td>-1.21%</td>
<td>(-15.67%, 10.57%)</td>
<td>(-0.026, 0.007)</td>
</tr>
<tr>
<td>7</td>
<td>31</td>
<td>-1.73%</td>
<td>-1.45%</td>
<td>(-10.21%, 6.92%)</td>
<td>(-0.038, 0.040)</td>
</tr>
<tr>
<td>8</td>
<td>131</td>
<td>-2.10%</td>
<td>-2.00%</td>
<td>(-16.05%, 31.72%)</td>
<td>(-0.034, 0.051)</td>
</tr>
<tr>
<td>9</td>
<td>60</td>
<td>-2.80%</td>
<td>-1.92%</td>
<td>(-64.9%, 11.21%)</td>
<td>(-0.051, 0.005)</td>
</tr>
<tr>
<td>10</td>
<td>12</td>
<td>-4.76%</td>
<td>-2.79%</td>
<td>(-28.34%, 5.76%)</td>
<td>(-0.084, 0.065)</td>
</tr>
</tbody>
</table>
Evaluation of Final Product

- One limitation with study is use of syringe pull-back method
- Classified data on whether dispensed as syringe or i.v. bag

<table>
<thead>
<tr>
<th></th>
<th>Number</th>
<th>Mean % Volume Difference</th>
<th>Median % Volume Difference</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>1,156</td>
<td>-0.53%</td>
<td>-1.27%</td>
<td></td>
</tr>
<tr>
<td>Bags</td>
<td>915 (79%)</td>
<td>-1.80%</td>
<td>-1.69%</td>
<td>-28.34% to 76.09%</td>
</tr>
<tr>
<td>Syringes</td>
<td>241 (21%)</td>
<td>4.27%</td>
<td>3.68%</td>
<td>-64.90% to 94.22%</td>
</tr>
</tbody>
</table>

Conclusions

- Continued development of new technology to aid in preparation of chemotherapy
  - These have both differences and similarities
- Limited literature evaluating their impact and effectiveness
- Need for continued research into current processes and systems
- Focus on enhancing efficiencies while maintaining safety in chemotherapy preparation
Steps in Preparing a Medication

Used with permission from Intelligent Hospital Systems
Benefits of Automation

Used with permission from Intelligent Hospital Systems
New and Emerging Strategies for Minimizing Errors in I.V. Preparation: Focus on Safety and Workflow Efficiency

Selected References


Online Resources

Apoteca

BD

Baxter

Chemocato

Intelligent Hospitals

Health Robotics
Self–Assessment Questions

1. When comparing the accuracy of the volumetric method to the gravimetric method, what is the rate found in the study of chemotherapy drugs outside of the 10% range?
   a. 4%
   b. 10%
   c. 14%
   d. 18%

2. What was the average decrease in turnaround time of i.v. products after the implementation of Kaizen at UNC Hospitals?
   a. 10%
   b. 25%
   c. 50%
   d. 75%

3. All of the following contribute to variability in volumetric dosing EXCEPT?
   a. Volume of the dose
   b. Viscosity of the liquid
   c. Color of the liquid

Answers

1. c
2. c
3. c
Kelley M. Reece, Pharm.D.
Assistant Manager
M.D. Anderson Cancer Center
Houston, Texas

Kelley M. Reece, Pharm.D., is Assistant Manager at M.D. Anderson Cancer Center in Houston, Texas. Dr. Reece earned her Doctor of Pharmacy degree at the University of Texas at Austin College of Pharmacy. After graduation, she completed a pediatric pharmacotherapy residency at Texas Children’s Hospital in Houston, Texas.

Dr. Reece has served in a number of different roles, including Pediatric and Critical Care Pharmacist at The University of Texas Medical Branch in Galveston, Texas, and Pediatric Critical Care Pharmacist at Texas Children’s Hospital in Houston. Dr. Reece has worked in the Ambulatory Treatment Center at M.D. Anderson Cancer Center for the past 7 years and is responsible for USP Chapter <797> compliance, hazardous drug safe handling, and implementation of the i.v. room software system.

Dr. Reece has presented at local and state conferences, including the 2013 Health Care Symposium at The University of Texas at Austin.
Using Technology to Promote Safety and Minimize Errors in I.V. Preparation

Kelley Reece, Pharm.D.
Assistant Manager
MD Anderson Cancer Center
Houston, Texas

Objectives

• Describe the potential effects of i.v. technology on waste, cost, and efficiency.

MD Anderson Cancer Center (MDACC)
Division of Pharmacy

• 557 Pharmacists and Technicians
• 14 Production Areas
• Ambulatory Treatment Center (ATC) prepares 225,000 chemotherapy doses/yr.
Chemotherapy Preparation Risks

- High-risk patient population
- Narrow therapeutic range drugs
- Sound-alike/look-alike drugs

Where do you see the most risk for error during compounding?

A. Drawing up diluent
B. Final concentration calculation
C. Bag labeling
D. Pharmacist verification

I.V. Chemotherapy Preparation Errors Exploratory Study

- Field observations at six Canadian cancer centers
- Five critical process steps
  - Staging
  - Reconstitution
  - Mixing
  - Verification
  - Labeling

I.V. Chemotherapy Preparation Errors Exploratory Study

- Reconstitution (2 sites)
  - No diluent verification
- Mixing (5 sites)
  - Multiple preparations in the biological safety cabinet (BSC)
- Labeling (3 sites)
  - Patient-specific label not paired with bag


I.V. Chemotherapy Preparation Errors Exploratory Study

- Dispensing errors range <0.1% up to 65%
- Methods of detection unreliable
  - Chart review
  - Self-reporting
  - Direct observation


MDACC Reported Medication Related Errors

- Patient Safety Net reviewed between September 2011 to February 2013
- 27 reports including
  - Wrong amount of vehicle (n=15)
  - Wrong amount of drug (n=2)
  - Wrong drug (n=1)
  - Wrong bag type (n=1)
MDACC Cost of Chemotherapy Preparation Errors

<table>
<thead>
<tr>
<th>Types of errors</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrong amount of vehicle (n=8)</td>
<td>$21,609.39</td>
</tr>
<tr>
<td>Wrong vehicle (n=8)</td>
<td>$7,501.25</td>
</tr>
<tr>
<td>Calculation/Math error (n=2)</td>
<td>$5,083.96</td>
</tr>
<tr>
<td>Expired drug vial (n=5)</td>
<td>$2,727.50</td>
</tr>
<tr>
<td>No drug vial to check (n=2)</td>
<td>$2,491.53</td>
</tr>
<tr>
<td>Wrong amount of drug (n=9)</td>
<td>$2,151.69</td>
</tr>
<tr>
<td>Reconstitution error (n=2)</td>
<td>$2,034.00</td>
</tr>
<tr>
<td>Wrong drug (n=3)</td>
<td>$1,688.57</td>
</tr>
<tr>
<td>Unexpected mixing error (n=17)</td>
<td>$1,222.61</td>
</tr>
<tr>
<td>No weight slip included (n=5)</td>
<td>$1,110.76</td>
</tr>
<tr>
<td>Missing expiration info on bag</td>
<td>$94.86</td>
</tr>
<tr>
<td>Missing error in string (n=11)</td>
<td>$18.60</td>
</tr>
<tr>
<td>Total errors (n=61)</td>
<td>$48,858.94</td>
</tr>
</tbody>
</table>

Total doses: 49,910
Error rate: 0.12%

Analysis of I.V. Preparation Process

Photo courtesy of K. Reece

Failure Mode and Effects Analysis for I.V. Preparation Steps

- Process steps – detail, detail, detail
- Failure modes – What could go wrong?
- Failure effects (Severity)
- Causes (probability)
- Controls (detectability)
- Process improvement / recommended actions
MDACC FMEA Process Summary

<table>
<thead>
<tr>
<th>I.V. Process Steps</th>
<th># of Steps</th>
<th># of Failure Modes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Review Label</td>
<td>4</td>
<td>19</td>
</tr>
<tr>
<td>2) Gather Components</td>
<td>8</td>
<td>28</td>
</tr>
<tr>
<td>3) Preparation Plan</td>
<td>8</td>
<td>24</td>
</tr>
<tr>
<td>4) Vehicle Bag Preparation</td>
<td>13</td>
<td>49</td>
</tr>
<tr>
<td>5) Vial Preparation</td>
<td>23</td>
<td>106</td>
</tr>
<tr>
<td>6) Final Product Preparation</td>
<td>12</td>
<td>58</td>
</tr>
<tr>
<td>* Vinca Alkaloids Process</td>
<td>15</td>
<td>19</td>
</tr>
<tr>
<td>* Intrathecal Process</td>
<td>14</td>
<td>31</td>
</tr>
<tr>
<td>Total</td>
<td>97</td>
<td>334</td>
</tr>
</tbody>
</table>

334 Potential Failures x 170 doses/day = 56,780 chances for error in one day

FMEA = failure mode and effects analysis

I.V. Management System Implementation

- Initiated pilot in October 2012
- Involvement from pharmacy, informatics, and software vendor
- 28 drugs currently in production
- Over 12,000 products prepared

Hardware Components

- Computer
- Barcode scanner
- Balance
  - Accuracy ±0.01 g
  - Verification of drug volume based on actual concentration and density of drug
- Label printer
Software Features

- Dose management queue
- Standardizes process steps
- Documents preparation steps
- Prints patient label with correct beyond-use date (BUD)
- Manages vial inventory
- Records drug waste
- Generates reports including productivity and inventory management

What is your main concern with i.v. technology?

A. Increased preparation time
B. Increased cost
C. Increased waste
D. Complex process
I.V. Management System
Pilot Evaluation

Productivity
Waste
Safety

The Office of Performance Improvement
Miguel Lozano
Sr. Quality Engineer

Cycle Times

Cost Savings

Non-Value Added Indirect Labor Costs
$47,430/year
Eliminated manual process steps

Direct Labor Costs
$110,628/year
Decreased mixing and checking time
Cost of Opened Vial Waste

**CYCLOPHOSPHAMIDE Vial Waste**

<table>
<thead>
<tr>
<th>Month</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-12</td>
<td>$0.00</td>
</tr>
<tr>
<td>Dec-12</td>
<td>$200.00</td>
</tr>
<tr>
<td>Jan-13</td>
<td>$400.00</td>
</tr>
<tr>
<td>Feb-13</td>
<td>$600.00</td>
</tr>
<tr>
<td>Mar-13</td>
<td>$800.00</td>
</tr>
<tr>
<td>Apr-13</td>
<td>$1,000.00</td>
</tr>
<tr>
<td>May-13</td>
<td>$1,200.00</td>
</tr>
<tr>
<td>Jun-13</td>
<td>$1,400.00</td>
</tr>
<tr>
<td>Jul-13</td>
<td>$1,600.00</td>
</tr>
<tr>
<td>Aug-13</td>
<td>$1,800.00</td>
</tr>
</tbody>
</table>

Potential Risk Reduction

<table>
<thead>
<tr>
<th>I.V. Process Steps</th>
<th># of Failure Modes</th>
<th>% of Failure Modes with I.V. software</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Review Label</td>
<td>19</td>
<td>16</td>
</tr>
<tr>
<td>2) Gather Components</td>
<td>28</td>
<td>14</td>
</tr>
<tr>
<td>3) Preparation Plan</td>
<td>24</td>
<td>20</td>
</tr>
<tr>
<td>4) Vehicle Bag Preparation</td>
<td>49</td>
<td>24</td>
</tr>
<tr>
<td>5) Vial Preparation</td>
<td>106</td>
<td>25</td>
</tr>
<tr>
<td>6) Final Product Preparation</td>
<td>58</td>
<td>44</td>
</tr>
<tr>
<td>* Vinca Alkaloids Process</td>
<td>19</td>
<td>13</td>
</tr>
<tr>
<td>* Intrathecal Process</td>
<td>31</td>
<td>19</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>334</td>
<td>175</td>
</tr>
</tbody>
</table>

52% of Failure Modes Impacted by I.V. Technology

Detection of Preparation Errors

<table>
<thead>
<tr>
<th>Preparation Failures detected during drug weighing</th>
<th>11/1/12 - 1/23/13 (Immediately following pilot)</th>
<th>1/23/13 - 3/25/13</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doses prepared</td>
<td>1560</td>
<td>1242</td>
</tr>
<tr>
<td>Doses over tolerance</td>
<td>36</td>
<td>19</td>
</tr>
<tr>
<td>Doses under tolerance</td>
<td>46</td>
<td>28</td>
</tr>
<tr>
<td>Percentage out of tolerance</td>
<td>5.26%</td>
<td>3.78%</td>
</tr>
</tbody>
</table>
The Joint Commission Sentinel Event Alert

- Warning issued about technology-related adverse events
- Suggested actions
  - Assess workflow processes
  - Careful planning and implementation
  - Staff training programs
  - Monitor continuously

Challenges

- Reluctance by pharmaceutical companies to provide drug density (g/mL)
- Non-standardized barcodes
- Acceptance by staff of new processes

Summary

- System uses gravimetric validation method
- Eliminates manual processes
- Provides step-by-step documentation
- Improves accuracy
- Allows barcode scanning for drug and vehicle
- Provides more efficient pharmacist verification process
New and Emerging Strategies for Minimizing Errors in I.V. Preparation:  
Focus on Safety and Workflow Efficiency

**Selected References**


New and Emerging Strategies for Minimizing Errors in I.V. Preparation: 
Focus on Safety and Workflow Efficiency

Self–Assessment Questions

1. Which of the following is not a risk associated with i.v. chemotherapy preparations?
   a. High risk patients
   b. Wide therapeutic window drugs
   c. Sound-alike/Look-alike drugs
   d. High toxicity of therapy

2. I.V. technology can decrease your overall risk by__?
   a. Increasing detectability
   b. Decreasing detectability
   c. Decreasing severity
   d. Increasing probability

3. When implementing technology an organization should perform all of the following EXCEPT?
   a. Train end users
   b. Make a project timeline
   c. Reduce resources due to increased productivity
   d. Assess workflow prior to implementation

4. Which of the following is the most reliable way to detect errors in i.v. preparation?
   a. HPLC studies
   b. Directly observing staff
   c. Chart reviews
   d. Incident reports

Answers

1. b
2. a
3. c
4. a