

ALTERNATE METHODS OF CHEMOTHERAPY PREPARATION



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August 4, 2017

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



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

Original Article

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

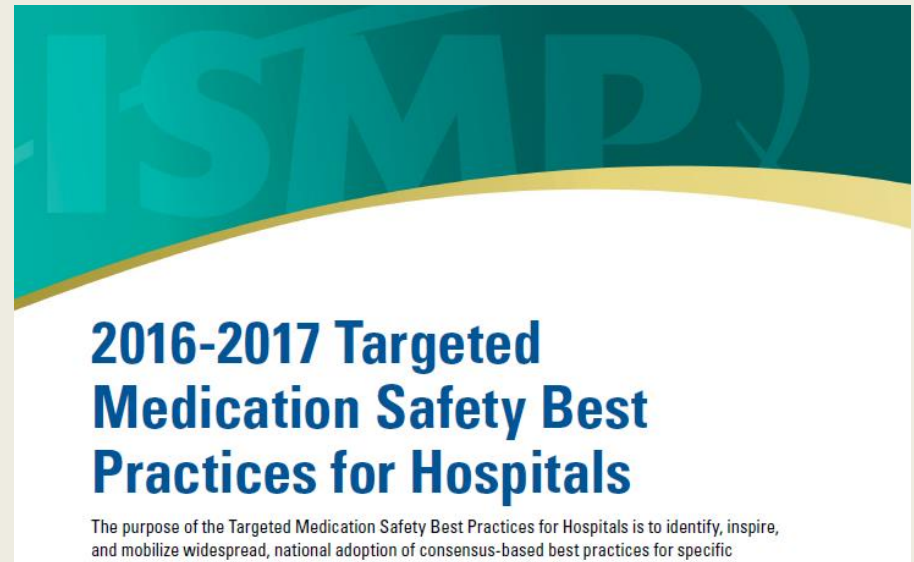
Lindsey B Poppe, Scott W Savage and Stephen F Eckel

Abstract
Background: Studies have compared gravimetric and volumetric dosing accuracies in chemotherapy agents, finding high accuracy in gravimetric measurements with a mean deviation of $\pm 0.06\%$, while volumetric measurements had a mean deviation of $\pm 3.02\%$.
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 -0.53% with a range of -64.9% to 94.22% for individual doses. Of the prepared doses, 71.7% were within $\pm 5\%$ and 87.4% were within $\pm 10\%$ of the ordered dose. Secondary outcomes found to be associated with an increased percent volume difference were the pediatric population, smaller volumes prepared, drugs requiring



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 • Preparation • Verification

- Set-up Tech Workflow
- Drug Lot Tracking
- Vehicle Lot Tracking

Create / Edit Parts List

Planned preparation time: [2/15/2017 2:26 PM](#) Preparation method: Gravimetric Display reminders in all storages


Products

zoledronic acid Solution for injection: **1x 4mg (602070)** 4mg
1x 

Total syringes

1x 5mL

Containers and additional articles (per medication)

Med.# 8892, TESTCATO, NATHAN, for Wed, 2/15/2017 3:00 PM (UNC - HONC3UCA) **1x NaCl 0.9% 100mL Bag PVC Baxter (1234)** 

4mg ZOMETA Solution for injection in 100mL NaCl 0.9%, intravenous

Period: Today (from 02/15/2017)

Unit: (All centers and units)

Pat. no.: Patient:

3 medications in the list Refresh List

	Med. no.	Administration	Product	Patient	Patient number	Unit	
X	8891	2/15/2017 10:00 AM	bendamustine Solution for injection 100mg bolus intravenous	PYXISES BDCATO, UNC	100000409290	UNC - 4ONC-	I
X	8889	2/15/2017 10:00 AM	mesna Solution for injection 356mg ifosfamide Powder for Injection 356mg 500mL NaCl 0.9% Bag intravenous 2 h	PYXISES BDCATO, UNC	100000409290	UNC - 4ONC-	I
	8892	2/15/2017 3:00 PM	zoledronic acid Solution for injection 4mg 100mL NaCl 0.9% Bag intravenous 1	TESTCATO, NATHAN	100000409514	UNC - HONC3UCA	O

zoledronic acid Solution for injection 4mg
 in NaCl 0.9% 100mL Bag PVC Baxter intravenous over 15 min
 TESTCATO, NATHAN d.o.b. 4/26/1990 (26.8 Years) (UNC - HONC3UCA) for 2/15/2017 3:00 PM

Collect medications same products <F6> per patient <F8> Set up for: Gravimetric preparation Volumetric preparation Set Up Preparation

Stock solution Stock batch production



Set-up • Preparation • Verification

zoledronic acid Solution for injection

4mg (Lot # 602070)
Used: 0/1 Blocked: 0
In use: # 1
Remainder: 4mg (5.0mL)

Med. # 8892: **4mg zoledronic acid Solution for injection** in NaCl 0.9%
100mL Bag PVC Baxter **intravenous over 15 min**, TESTATO, NATHAN (UNC
- HONC3UCA) for 2/15/2017 3:00 PM

Achieved: 0m; Act. Ingr. withdrawn (zoledronic acid Solution for injection) escribed: 4mg

0%

Scan barcode:
1st vial zoledronic acid 4mg (Lot: 602070)

<F1> Transfer solution directly
<F2> Do not use vial
<F3> Skip medication



- Barcode Identification
- Photo Identification

Med. # 8892: **4mg zoledronic acid Solution for injection** in NaCl 0.9%
100mL Bag PVC Baxter **intravenous over 15 min**, TESTATO, NATHAN (UNC
- HONC3UCA) for 2/15/2017 3:00 PM

Achieved: 0m; Act. Ingr. withdrawn (zoledronic acid Solution for injection) escribed: 4mg

0%

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

Withdrawal: 5.0mL

Additionally on the scale:
5mL Syringe (Empty)

<F1> Transfer solution directly
<F3> Skip medication



Set-up • Preparation • Verification



Med. # 8892: 4mg zoledronic acid Solution for injection in NaCl 0.9%
100mL Bag PVC Baxter intravenous over 15 min, TESTCATO, NATHAN (UNC
- HONC3UCA) for 2/15/2017 3:00 PM

Achieved: 3.26 Act. Ingr. withdrawn (zoledronic acid Solution for injection) prescribed: 4mg
84.6%

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

- Hard-stops during preparation
- Clear tolerance approvals



Med. # 8892: 4mg zoledronic acid Solution for injection in NaCl 0.9%
100mL Bag PVC Baxter intravenous over 15 min, TESTCATO, NATHAN (UNC
- HONC3UCA) for 2/15/2017 3:00 PM

Achieved: 4.03r Act. Ingr. injected (zoledronic acid Solution for injection) prescribed: 4mg
100.7%

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

Within tolerance

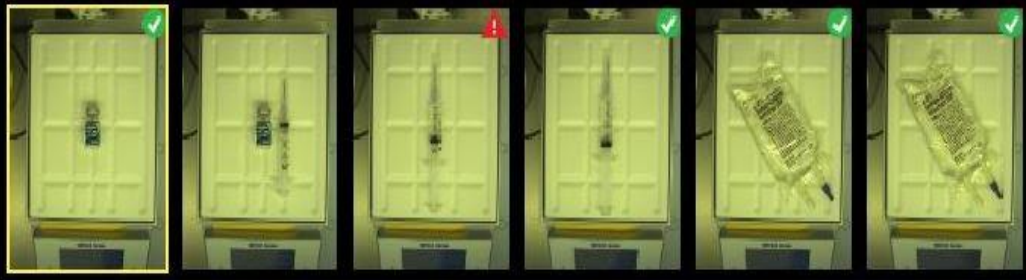
Prescribed active ingredient amount: 4mg
Achieved active ingredient amount: 4.03mg
Deviation: 0.7%

Unload scale



Set-up • Preparation • Verification

1 - Transfer of 4mg ZOMETA Solution for injection



- Remote Verification
- Visual Checking Process
- Detailed Preparation Log

Identification of vial before withdrawal

Identification successful

Expected weight 12.63 g; Determined

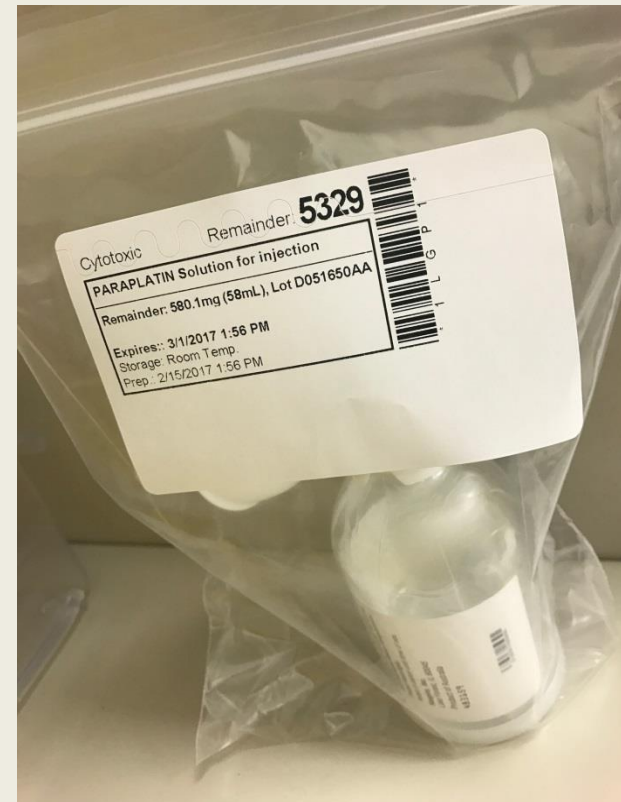
Preparation log

Date	Information text
2:27:35 PM	PREPARATION No. 9508 INITIATED ON 2/15/2017 AT 2:27 PM (BD Cato VERSION: 2.38.1.17)
2:27:35 PM	Assigned vials:
2:27:35 PM	1st vial zoledronic acid 4mg; Nominal volume: 5mL, actual volume 5mL, Density: 1.02g/mL, UID: 270665
2:27:35 PM	Gravimetric Preparation
2:27:35 PM	Computer name: MCMAIGRIBDCAT01, Prep. Person: Barnes, Nathan (NEB)
2:27:35 PM	Preparation settings: Default
2:27:35 PM	Visual documentation is used for this preparation.
2:27:35 PM	Med. # 8892: 4mg zoledronic acid Solution for injection in NaCl 0.9% 100mL Bag PVC Baxter intravenous over 15 min, TESTCATO, NATHAN (UNC - HONC3UCA) for 2/15/2017 3:00 PM
2:27:35 PM	MESSAGE: "Scan barcode: 1st vial zoledronic acid 4mg (Lot: 602070) F1 Transfer solution directly F2 Do not use vial F3 Skip medication"
2:28:16 PM	IDENTIFICATION OK: 1st vial zoledronic acid 4mg (Lot: 602070) has been identified with barcode: 0100325021801666
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"

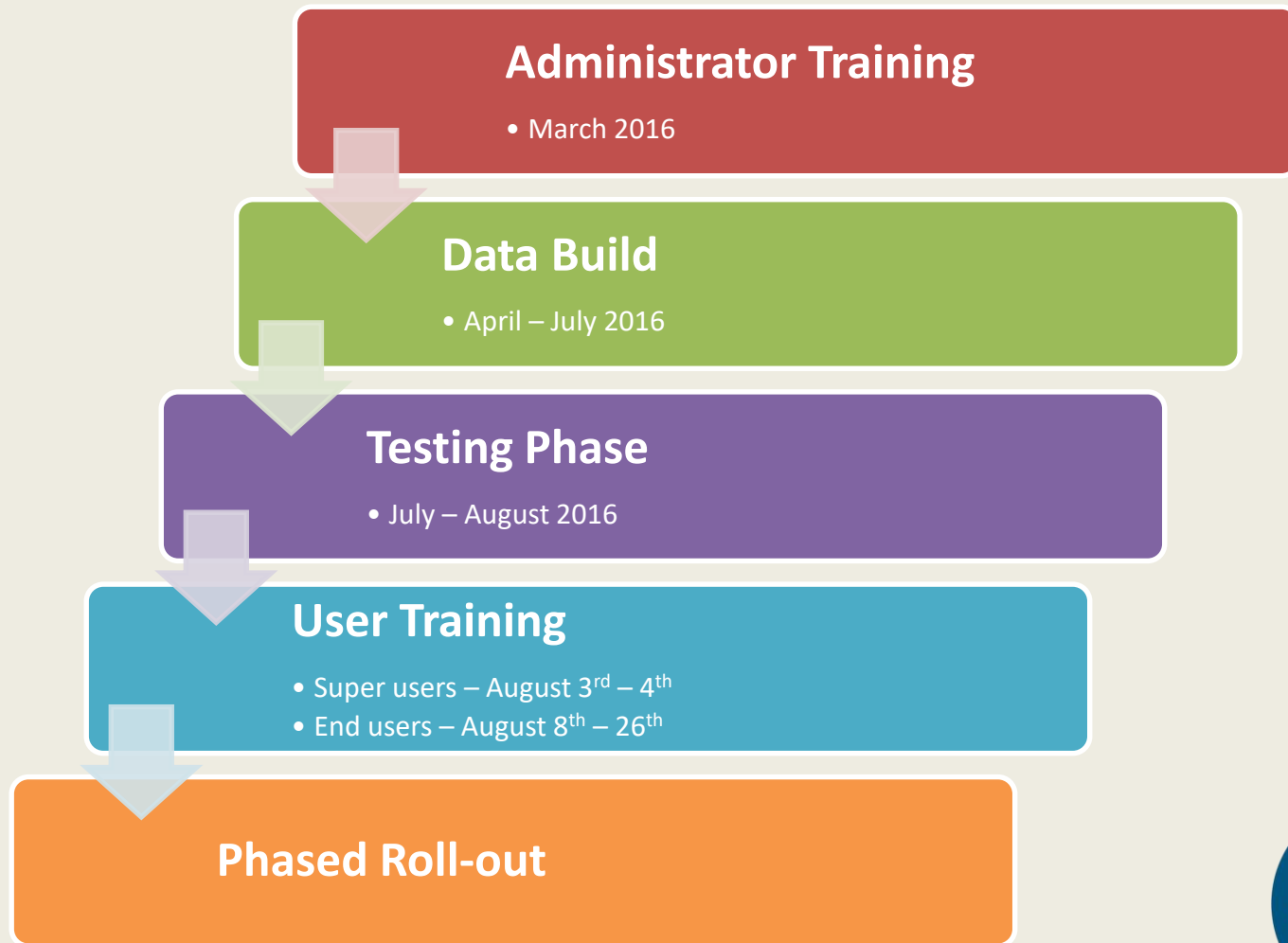


Waste Management

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



Implementation Timeline



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

	Volumetric Preparation (n=643)	Gravimetric Preparation (n=728)	P-value
Technician Preparation Median time, minutes [IQR]	7.42 [4.55-9.25]	5.97 [4.12-8.28]	0.006
Pharmacist Check Median time, minutes [IQR]	0.75 [0.53-1.13]	0.32 [0.23-0.65]	<0.001



Evaluation

- Improved accuracy of preparations within $\pm 5\%$ by 27.7%

	No. of Preparations	Range of % Difference	% within $\pm 5\%$ of ordered dose
Volumetric Pre-Period (Historical Study)	1156	-64.9 to 94.2	71.9
Gravimetric Post-Period	3156	-12.5 to 5.4	99.6



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

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ALTERNATE METHODS OF CHEMOTHERAPY PREPARATION: GRAVIMETRIC TECHNOLOGY- ASSOCIATED WORKFLOW



Joseph Bonkowski, PharmD, MHA, MS

August 4, 2017

IV ROBOTICS IN HAZARDOUS DRUG PREPARATION



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

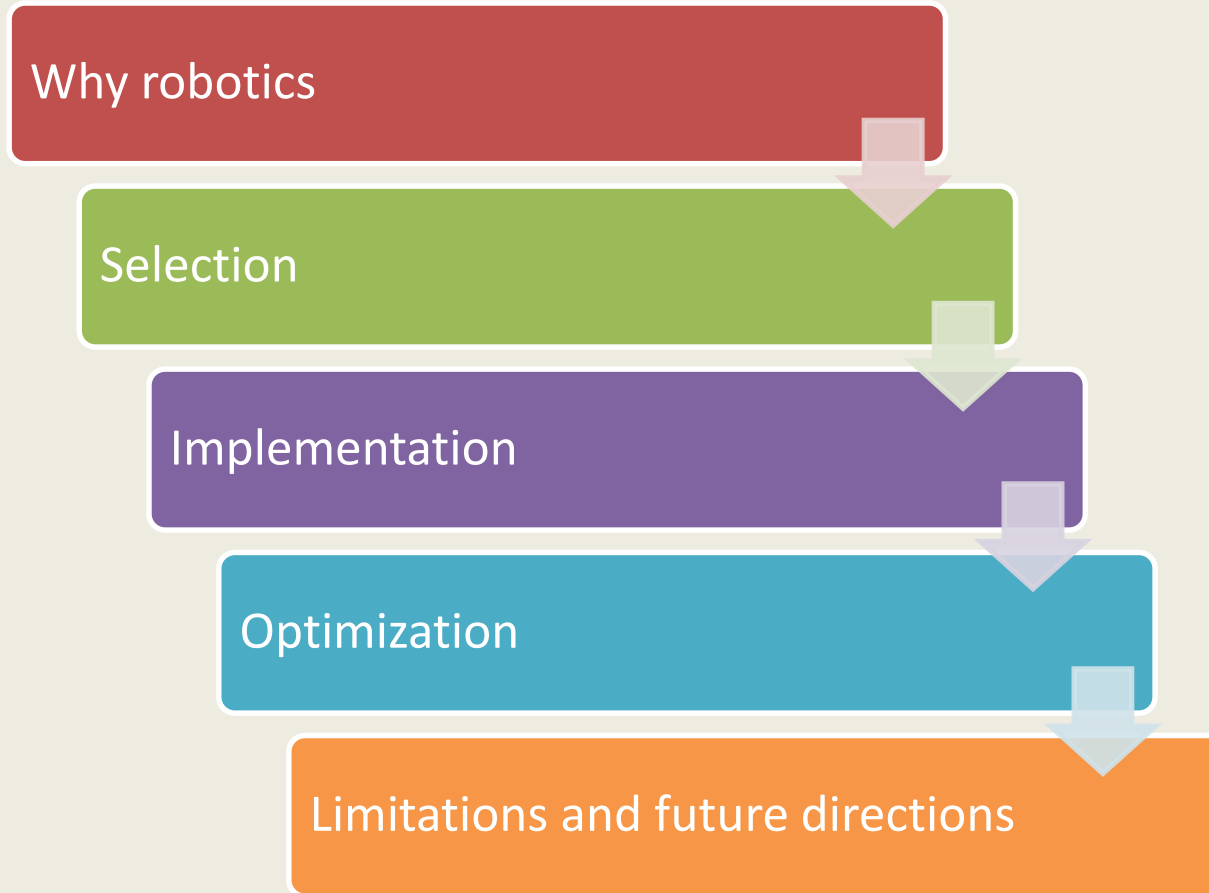
Objectives

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 implement robotics in IV chemotherapy compounding?



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



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/>

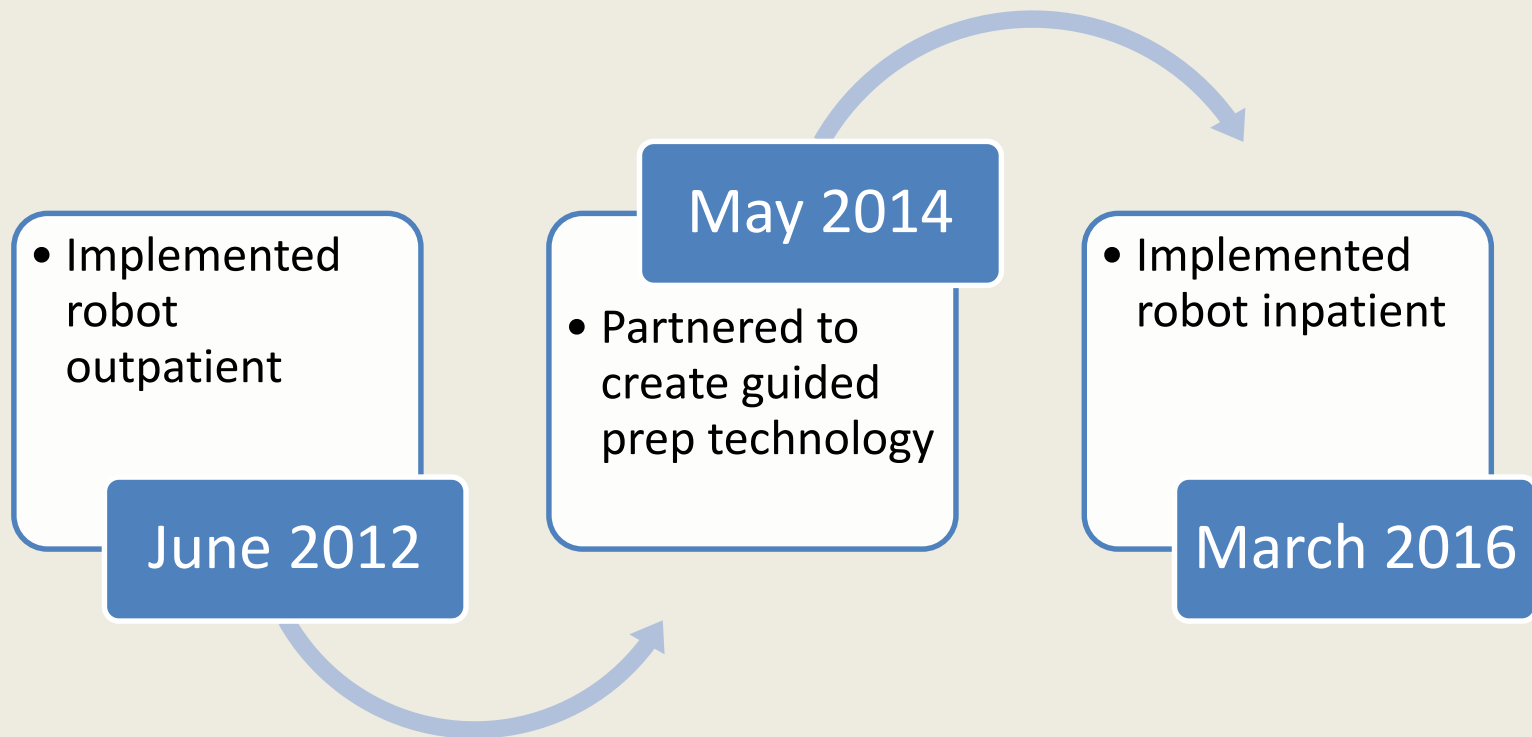


Wake Forest Baptist Health Experience

- 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



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?

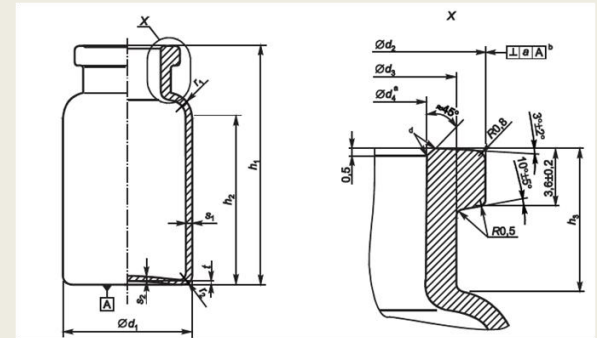
- A. Robotics replaces the need for any closed system transfer device
- B. Robotics eliminates the need for any technician involvement in compounding
- C. Robotic preparation reduces the risk of repetitive hand motion injuries
- D. Currently robotics can compound any final preparation



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



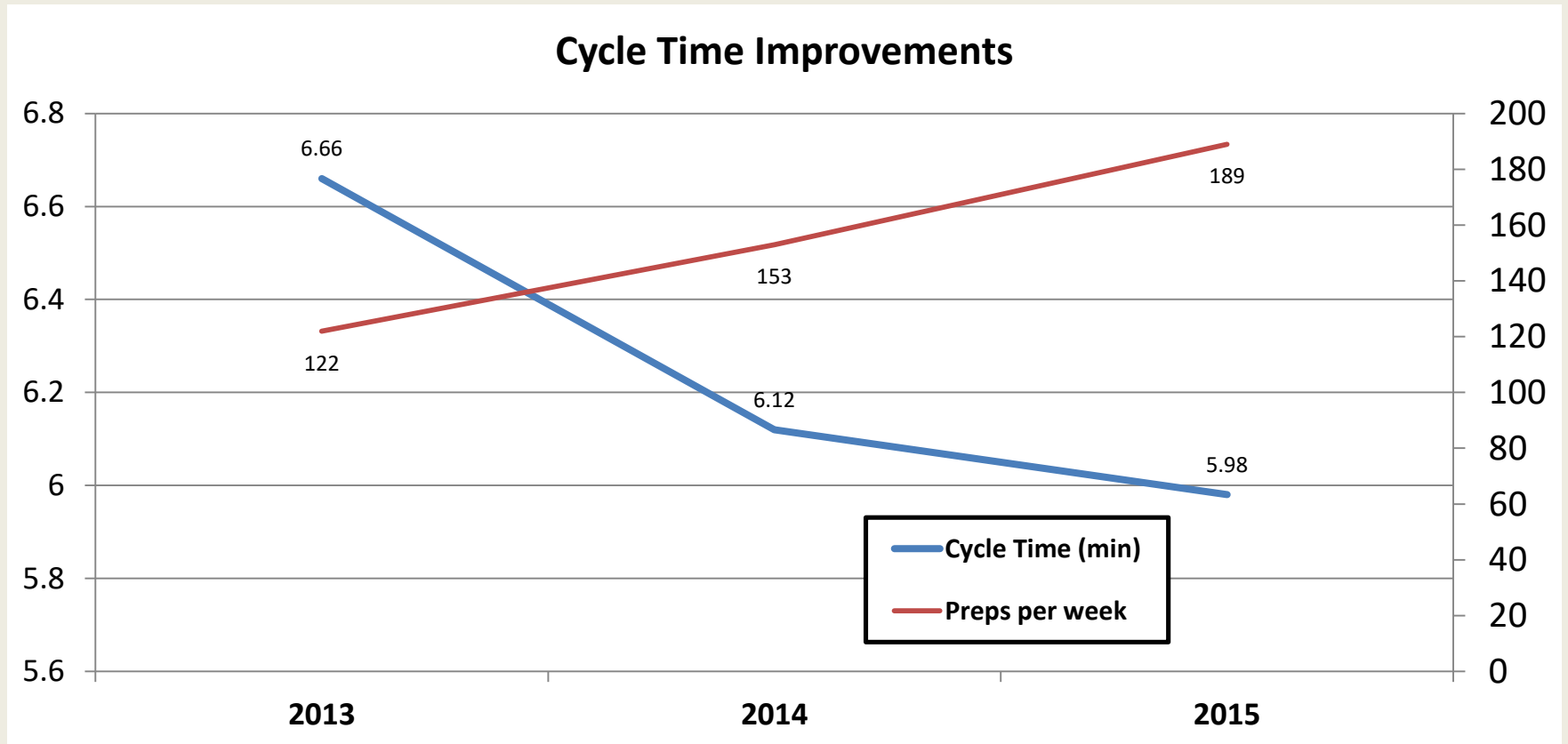
Optimization

Vendor collaboration

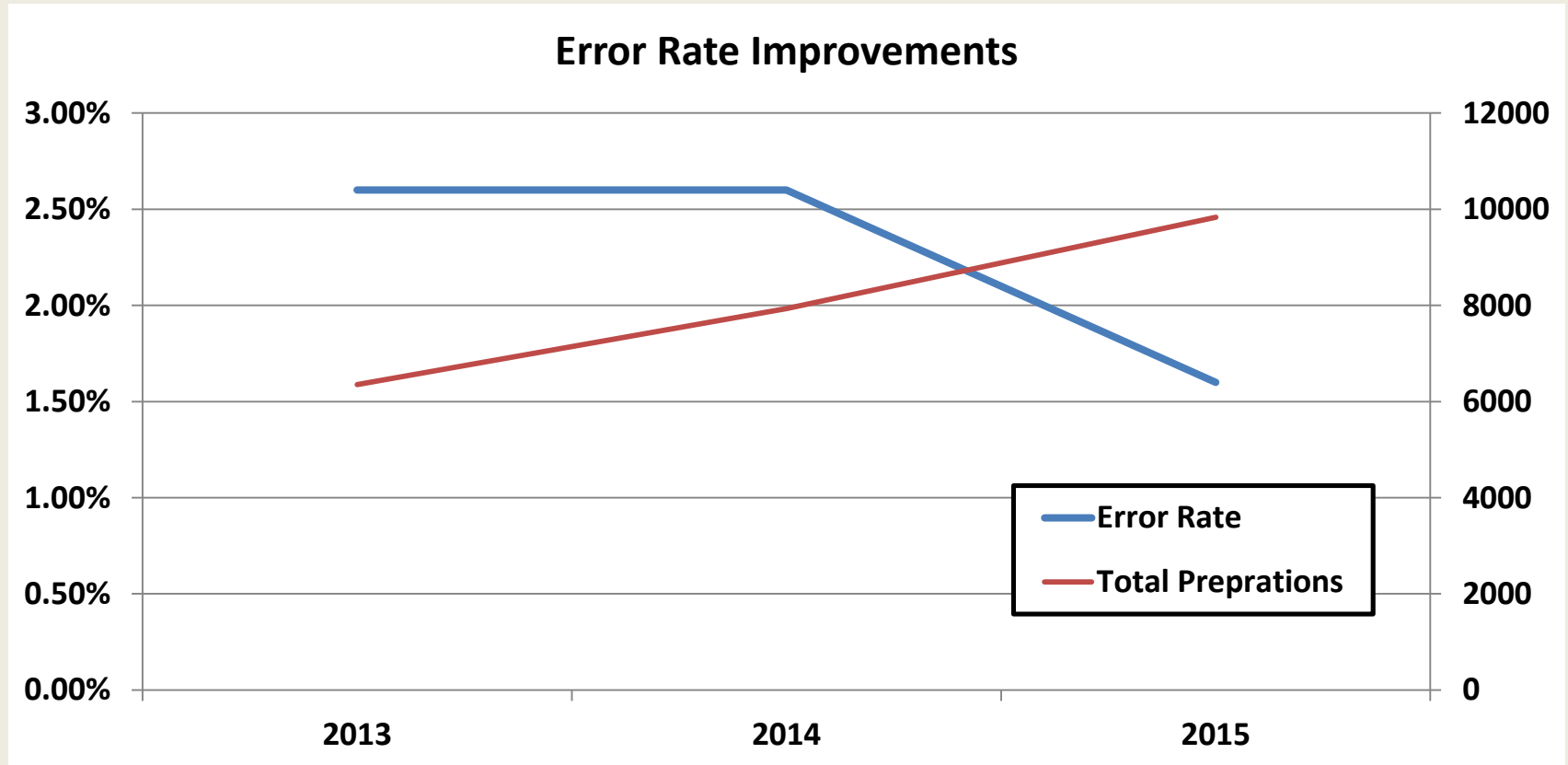
- Weekly phone calls
- Annual national user group meeting
- Biannual international user group meeting
- Standardization across users



Optimization



Optimization



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

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