(Management Case Study)
Implementation and Evaluation of a Sterile Compounding Robot in a Cancer Center Pharmacy

Sunny Bhakta, Pharm.D., M.S. Candidate
Pharmacy Administrative Resident

A. Carmine Colavecchia, Pharm.D., Ph.D., BCPS
Pharmacy Administrative Specialist
Houston Methodist Hospital
Houston, Texas
Disclosure

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

• Explain the fundamental safety features of automated robotic compounding technology (ARCT) in chemotherapy compounding.
• Describe important features related to the implementation of IV automation into pharmacy workflow.
• Identify potential benefits of utilizing ARCT in chemotherapy compounding.
Self-Assessment Question 1

ARCT offers many safety features to enhance patient safety, which of the following is NOT a feature utilized with this technology?

A. Gravimetric weight checking to ensure accurate dosage and volume transfer
B. Photovalidation of components such as syringes and vials
C. Barcoding capabilities on drug vials and IV bags
D. Proxy verification methods such as syringe pull back or writing volumes on the IV label
Self-Assessment Question 2

(True or False) Key aspects of an IV automation implementation plan involves a multi-disciplinary effort, change management, training, and education.
Self-Assessment Question 3

Which of the following is a benefit of ARCT when used for hazardous drug compounding?

A. Guaranteed return on investment in 3 to 5 years
B. Advanced safety features such as barcoding, gravimetrics, interfacing, containment, and photovalidation to ensure patient and staff safety
C. Improved efficiency in preparation and turnaround time by at least 10 minutes
D. Increased patient satisfaction scores
Houston Methodist

1,119 licensed beds
67 operating rooms
265 pharmacy staff
Institutional Growth

CANCER CENTER PHARMACY PATIENT VOLUMES

OP NON HEME ONC INFUSION: Outpatient Non-Hematology/Oncology Infusion
IP ONCOLOGY: Inpatient Oncology
BMT: Bone Marrow Transplant
OP HEME ONC INFUSION: Outpatient Hematology/Oncology Infusion
Grand Total
Institutional Growth

CANCER CENTER PHARMACY DISPENSE VOLUMES

<table>
<thead>
<tr>
<th>YEAR</th>
<th>DOSES</th>
</tr>
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<tbody>
<tr>
<td>2014</td>
<td>41,997</td>
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<tr>
<td>2015</td>
<td>44,911</td>
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<tr>
<td>2016</td>
<td>59,714</td>
</tr>
</tbody>
</table>

Dispense Volume
Hazardous Preparations
Focus on Quality and Safety

“For hospitals and other IV admixture locations that regularly provide parenteral cancer chemotherapy, or ideally, where pediatric patients are treated, gravimetrics should be used when information about specific gravity of ordered medication is available.”

– 2016 ISMP Guidelines for Safe Preparation of Compounded Sterile Preparations
# Key Safety Features of ARCT

## Barcoding
- During loading
- Vials
- Bags
- Lot/Expiration Information loaded on web interface

## Gravimetrics
- High sensitivity balance
- Dose thresholds (± 5%)
- Bag and vial weight thresholds

## Photovalidation
- Vials against validation library
- Provides tertiary check
- Syringe and needle type

## Containment
- Dual chamber positive pressure
- Internal negative pressure
- Vented externally
- CACI equivalent
Key Considerations for Robotics

• Business case
• Plans for efficiency measurement and optimization
• IT costs, interface testing
• Cleanroom footprint
• Training and education
• Return on capital expenditure
Improve patient safety
Improve production capacity and decrease disposables
Decrease risk of repetitive motion injury
Minimal space requirement
Network of hospitals maintain drug library
Reporting features

Cost of ARCT
Build of drugs not in drug library
Requires a technician to operate and maintain machine
Can only prepare products in the form of a syringe or bag

SWOT

Absorb increase in order volume
Ability to prepare batches
Minimization of waste
Improve turn-around time of medications
Expand pharmacist clinical responsibilities due to decreased time to verify dose

ARCT malfunctions
ARCT becomes obsolete
Employee resistance to change
Employees worried about taking his or her position
Previous Operations State

Extensive growth due to addition of new service lines, requiring increased resources to meet the outpatient treatment needs

Lack of technology in high alert drug compounding (chemotherapy)

Infusions nearly doubled from 2013 to 2014 (35/day → 70/day) and subsequent 41% increase in dispense volume from 2014 to ~60,000 in 2016

11 FTEs; 5 Pharmacists and 6 Technicians
Robotics Implementation Analysis

- **Pre-implementation**
  - Collected TAT and preparation times from IV workflow system
  - 14 weeks

- **Robot GO LIVE**
  - Collected TAT and preparation time data
  - 1 week washout period

- **Post-implementation**
  - Post-implementation TAT and preparation time
  - 20 weeks

- **Analysis**
  - Time-segmented regression analysis (pre-post) for TAT and preparation time
  - Return on investment (ROI)
Efficiency Monitoring Plan

• Quantify the impact on preparation time and turnaround time compared to i.v. workflow management system (IVWFM) alone
• Statistical approach: interrupted time series for initial four oncologic agents
• Supply cost savings: closed-system transfer device utilization reduction
• Monitor deviation trends, robot preparation failures, downtimes
Evaluation of Efficiency

Initial Four Oncologic Agents:
- Cyclophosphamide
- Cisplatin
- Carboplatin
- Oxaliplatin

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Slope Pre-robot (min)</th>
<th>Difference (min)</th>
<th>Slope Post-robot (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TAT, mean ± std</td>
<td>-0.5(^a)</td>
<td>-9.2 ± 3.7(^b)</td>
<td>0.5(^a)</td>
</tr>
<tr>
<td>Prep time, mean ± std</td>
<td>-0.4(^a)</td>
<td>-6.3 ± 2.6(^b)</td>
<td>0.4(^a)</td>
</tr>
</tbody>
</table>

\(^a\) p > 0.05
\(^b\) p = 0.01
IT Considerations

• Interface testing
• Product mapping: many to many relationship table created
  – HL7 standards for interface messaging with EHR
• New product addition and configuration
  – Specific gravities, NDC for product mapping
• EHR default dispensing to ARCT during operational times
  – ARCT as a dispense location
Realized (current) State

- Additional production stream in OPC
- Addition of compounding barcode scanning standards, gravimetric dose validation, and photovalidation compounding accuracy and safety
- Automated in-process validation
- A reduction in pharmacy compounding supply costs
- Operational efficiencies gained in both TAT and preparation times
- FTE Neutral
- Robot went live in September 2016
- 10 drugs configured in robot
Lessons Learned

- Change management
- Robotic downtime: cleaning, maintenance, spills, ventilation errors
- Preparation rejections: alignment issues, bag withdrawal system issues, partial vials
- Spill management: policy and procedures
- IT possibilities: many to many relationships via HL7 interface
Key Takeaways

• Key Takeaway #1
  – Create a business case that incorporates implementation timelines, and estimated impacts on safety, costs, and efficiency

• Key Takeaway #2
  – Robotic implementations must identify key operational metrics and conduct effective technology assessments utilizing appropriate statistical techniques

• Key Takeaway #3
  – Engage IT stakeholders early to optimize interfacing with EHR and assistance with troubleshooting
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