IV Compounding Automation: Overcoming Challenges to Achieve Benefits

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Objectives

❖ Describe the challenges of implementing IV automation
❖ Identify the strategies used at various practice sites to overcome challenges
❖ Anticipate similar challenges at your own site and adopt strategies described above
❖ Understand considerations and benefits of gravimetrics versus volumetrics when compounding sterile products

Introduction

❖ Why Do We Need Technology?
❖ Robots at BWH
❖ IV Workflow Manager at CHB
❖ IV Workflow Devices at BWH
❖ Desired Features and Gaps
❖ The Debate!

Evidence Demonstrating Concerns about Compounded Sterile Products Prepared by Healthcare Workers

Medication Errors Detected in Infusions

Occurrence and Impact of Unanticipated Variation in Intravenous Methotrexate Dosing
Discrepancies between ordered and delivered concentrations of opioid infusions in critical care
Frequency of Medication Errors with Intravenous Acetylcysteine for Acetaminophen Overdose

Fatal Medication Error

Medication Error → Consequence

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Where's the Heparin?

- Heparin 10,000 units in 500mL NS for use via circuit for procedure in Cath-Angio
- Tested bag – Did NOT contain HEPARIN!
- Patient lost 300 cc of blood

We need to change!

- Visual verification without any safety checks should be a thing of the past!
- We need to use technology to our advantage and do our due diligence to research and utilize resources to make the safest compounds possible!

Brigham and Women’s Hospital

- Partners Healthcare
  - Tertiary Academic Medical Center
  - Harvard Medical School
  - ~800 beds
    - Adults
    - Neonates
    - Inpatient Chemotherapy
- Pharmacy Schools
  - MCPHS
  - Northeastern University (COOP)

Robots Galore!

i.v. Station

- How is it resourced
  - 1 Pharmacy Technician
  - 2 shifts, 7 days per week
  - Batch production
    - PAR level based
    - Scheduled production runs
- Pros/Cons
  - Versatile in final product containers (syringe/bag sizes)
  - Expansive degree of safety features (gravimetric, barcode scanning, visual recognition)
  - Speed and accountability
  - Drug shortages = suboptimal operation due to availability

i.v. Station Opportunity #1

Product Variances
Metrics: Robot vs. Manual

i.v. Station Opportunity #2

<table>
<thead>
<tr>
<th></th>
<th>Made by Robot (Evening)</th>
<th>Made by Hand (Evening)</th>
<th>Made by Hand (Day)</th>
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<th>Total made by Robot</th>
<th>Total made by Hand</th>
<th>Grand Total</th>
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<td>Jan-15</td>
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<td>163%</td>
<td>30%</td>
<td>30%</td>
<td>63%</td>
<td>23%</td>
<td>26%</td>
<td>50%</td>
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<td>Mar-15</td>
<td>0,796</td>
<td>2,099</td>
<td>1,707</td>
<td>3,817</td>
<td>5,016</td>
<td>5,156</td>
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<td>Averages</td>
<td>87%</td>
<td>73%</td>
<td>62%</td>
<td>110%</td>
<td>44%</td>
<td>55%</td>
<td>100%</td>
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i.v. Station Opportunity #3

- Can be very difficult and can be upsetting to staff
  - “I can do it faster!”
  - “Don’t you trust me?”
- Do not underestimate the time and effort required to do this right!

Changing the Work Flow

i.v. Workflow Assist Devices

Boston Children’s Hospital

- 5th largest pediatric hospital in U.S.
  - 22,600 admissions
  - 25,000 surgical cases
  - 400 beds
    - ICUs – 25%
      - 42 medical
      - 33 cardiac
      - 24 NICU

IV Workload at Boston Children’s

- 2015 (extrapolated 6 months)
  - 585,572 doses/yr
    - 1,600 doses/day
    - 67 doses/hr
  - 329,000 products/yr
    - 682 unique (6 months)
    - 900 products/day
- 15 Workstations
- 5 pharmacy locations
  - Main inpatient Rx
  - Emergency department
  - Ambulatory infusion
  - Ambulatory infusion
  - Operating room

Pharmacy IS

Workflow Manager

1. Dose Originates in Cerner Pharmnet
2. Dose sent to workflow manager via Zebra Printer stream
   1. Print stream info “parsed”
3. Dose Prepared at Workstation by Technician
   1. Products prepared
   2. Dose Prepared
4. Dose reviewed by RPh
   1. Verify or Rework or Reject
5. Dose Sorted by Technician
   1. If verified  to patient
   2. If not  discard or Rework
Safety at Boston Children’s Hospital

- 13 months
  - Jan ’11-Feb ’12
- Error Rates
  - Rework: 0.29%
  - Rejected: 0.39%
- Common Errors
  - Source product expiring soon
  - Blurry/Omitted images
  - Incorrect Volume


IV Workflow Implementation

- Site visits
  - Pharmacists
  - Technicians
- Build
  - Customizing workflows
  - Creating a storyboard
  - Staff feedback
  - Workload & Workflow
  - Testing
- Room Setup
  - Fitting workstations
  - Added fridge to clean room
  - Moved drug vials into room
- Training
- Continuous Evaluation


Building Validation

- Confirmation bias
- Multiple opportunities for build errors
- Good practice


Customizing Product Preparation Scripting

- Enter lot and expiration only for biologicals
  - Albumin / IVIG
  - Clotting factors
  - Vaccines


Customizing Workflows and Procedures

- Building a storyboard
- Avoid over scripting
- Include RPhs and CPhTs
- Combine steps if possible
- Trading productivity with queryable documentation
- Consider value of each step
  - Lot number
  - Expiration
Customizing Dose Preparation Procedures

<table>
<thead>
<tr>
<th>Name</th>
<th>Description</th>
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<tr>
<td>Early Adopters</td>
<td>Implementation allowed laggards to avoid new systems</td>
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<td>Laggards</td>
<td>Decreased productivity initially</td>
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<td></td>
<td>Suffered when batches began</td>
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<tr>
<td>Scripting</td>
<td>Keep language simple</td>
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<tr>
<td></td>
<td>“Capture image” vs “Take picture”</td>
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<tr>
<td></td>
<td>Less is more</td>
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</tbody>
</table>

Implementation Challenges

- Early adopters vs laggards
  - Slow implementation allowed laggards to avoid new systems
  - Laggards
    - Decreased productivity initially
    - Suffered when batches began
- Scripting
  - Keep language simple
  - “Capture image” vs “Take picture”
  - Less is more

Implementation and Maintenance Challenges

- Drug shortages
  - 500 mL and 1000 mL bags
- Clotting factors
  - Inconsistent assay strengths
  - Lot specific products and barcodes
- Multiple vials per dose
  - Reconstitution
  - 10 vials
    - 3 min on paper
    - 15-20 min with workflow “assistance”
  - Fitting all vials in single image

Implementation and Maintenance Challenges

- Barcoding Workarounds
  - Barcode scanning failures
    - Drug shortages and new NDCs
    - Cefepime
      - 14 new NDCs in 7-2 months
    - Inability to make dose with usual product
      - Inappropriate product enforcement
    - Heparin 100 unit/mL
      - 50 mL syringe vs 250 mL bag
  - Bypassing and making on paper
    - Ignore incorrect drug alerts
      - Varicella vs MMR w varicella

Implementation and Maintenance Challenges

- Preparing Multiple vials at once
  - Software designed to reconstitute 1 vial at a time
  - Make all steps optional
  - Ensure only 1 concentration and reconstitution workflow built in system
Repetitive motion hand injuries

Making multiple doses of same drug
  • 1 drug in hood at a time
  • On paper - allowed multiple doses to be drawn up at once and then labeled

Minimizing technician movement in and out of class 100
  • Moved workstation inside hood
  • Smoke testing
  • Particle counts...

Reporting Challenges

- Product usage
- Productivity
- Error rates*
  • Rejected doses per Tech
  • Rejected doses per RPh
- Workstations move around

Which implementation strategies should be considered when implementing workflow mangers

- Assessment of expected workload
- Strict build validation procedures
- Site visits should include front line staff
- All of the above

Answer

D. All of the above...

- All of the Above
  - Assessment of expected workload
  - Strict build validation procedures
  - Site visits should include front line staff

i.v. Soft Assist

- Checks human preparation process at each step using
  • Optical scanning
  • Bar code verification
  • Gravimetric checking
- Interface with CPOE system
- Patient specific doses
Remote Pharmacist Verification

Opportunity #1
- "Where the heck am I supposed to put everything?"
  - Individual wrapped syringes vs. tray packs
  - New supply carts
  - Vendor cleaning company

Opportunity #2
- Is it too accurate?
  Meropenem – A Tale of 2 Grams

<table>
<thead>
<tr>
<th>Precise</th>
<th>Inaccurate (imprecision errors)</th>
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</thead>
<tbody>
<tr>
<td>Accurate</td>
<td>Inaccurate (systematic error)</td>
</tr>
</tbody>
</table>

Opportunity #3
- Interface with CPOE System
  - HL7 with Homegrown system (2008)
    - Used BWH Pharmacy label to start process
    - Barcode Scanning by NDC number
    - Table
    - Scanning BWH Label on iv Soft Assist Device
  - HL7 with Epic (2015)
    - Message sent upon pharmacist order approval
    - Based on ERX and Dispense Code
    - Scanning Epic Label on iv Soft Assist Device or Robot (i.v. Station & i.v. Onco)

How We Dealt With It.....
- Lean concepts
- STAFF DRIVEN Tabletop exercises
- STAFF DRIVEN Time and Motion Studies

Potential Concerns with Changing to New Processes for CSP Preparation
- Technology is relatively new and is still developing
  - We are in the early adopter phase
  - The technology is not proven as yet with a multitude of evidenced based studies
  - Potential exists for new kinds of errors to occur due to the introduction of the new technology, new processes and new roles for staff
  - Staff will need additional training to adapt to the additional steps of workflow devices
  - Staff may over-rely on the technology and vigilance may be reduced
Key Lessons Learned

- Incorporate QA measures directly into daily workflow
- Ensure operators, not just super-users continually work with the robot and/or workflow device
- Adaptation of processes & change management.
  - Techs must be first line for improvement recommendations with new technologies
  - What works and what doesn’t work
- A face-to-face “Thank You” is unquantifiable!

Additional Lessons Learned

- It takes time to add and validate new products to the database...patience is key
- Product shortages can greatly impact output volume
- New problems can arise unexpectedly and can be related to:
  - vial sizes
  - drug product composition
  - Hardware
  - Software
  - Human interface issues

Financial Concerns

- Space
  - Ventilation
  - Hood space for workflow devices
- Need to plan for the costs
  - Capital Leasing
  - Monthly Rental
  - Outright Purchase

An IV workflow assist device or robotic device provides which of the following?

- Bar code verification and Optical scanning
- Efficient work flow
- Central Data Storage
- All of the Above

Answer

D. All of the above...and more!

- Bar code verification
- Specific gravity and gravimetrics
- Optical scanning
- Central data storage
- High degree of accuracy and precision
- Efficient work flow
- Workload tracking
- Interfaces

What are potential concerns when changing from a manual process to using a workflow or robotic device?

- The technology is in the “late majority” of the technology adoption phase
- Staff may over-rely on the technology and vigilance may be reduced
- Staff will not need additional training
- You have nothing to worry about!
Answer

B. Staff may over-rely on the technology and vigilance may be reduced

* The technology is in the “early adoption” of the technology adoption lifecycle

* Staff WILL need additional training

Desired Features and Gaps

- Interface with pumps
  - Repeater pump
  - TPN Pump
- Occupational Injuries
  - Repetitive motion hand injuries

The Debate!

Volumetrics vs. Gravimetrics

Team Tom vs. Team Caryn

Team Caryn

- A gravimetric measurement process utilizes Specific Gravity to weigh and verify the accuracy of all components used to prepare a Compounded Sterile Product (CSP)
  - Technology using gravimetric assessment can have accuracy parameters set for each specific drug depending on accuracy needed.
  - A volumetric measurement process relies on the ability of a pharmacy technician to accurately reconstitute, measure and draw up all components used to prepare a CSP. Precision accuracy in a manually prepared CSP is impacted due to the variability in the products used:
    - IV bags are frequently overfilled by 10%
    - Medication vials have an accuracy range of +/- 10%
    - Syringes are accurate +/- 5%
    - Human variability

Team Caryn

“In the baseline phase, there were a total of 23 failed preparations (12.5%) and one failed preparation (0.9%) in the intervention period (P < .002) using our cutoff point of more than 5% variance.

On secondary analysis using the industry standard of more than 10% variance, eight preparations (4.3%) failed in the baseline and none failed when robotically prepared.”

Team Caryn

- Cameras and pictures are better than nothing at all
- No benefit than having a pharmacist stand over a technician and watch their every move
- Want to know exactly what is in final product
- Barcode scanning and weighing is the way to go to ensure a safe final product

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Team Tom

- Gravimetrics use is not new
  - TPN pumps
  - Robotics
  - BCH – used for chemotherapy diluents since 1990s
- Increases production time
  - Observed ceftriaxone mini bag prep exceed 12 minutes
- Every change comes with an opportunity for new error types
  - Are errors with potential for patient harm decreased in practice?
- Technologies fails to improve safety when no optimized
  - CPOE, smart pumps, EMAR

Gravimetric vs Volumetric

- Gravimetric
  - Confirms volume
  - Does not confirm drug
- Volumetric
  - Repeated syringe measurements are within 5% 2
  - No published data showing gravimetric measurements decrease errors when using
    - barcoding
    - images
    - automated calculations

Gravimetrics – Where is the Evidence

- Jean-Monnet Hospital – France
  - 325 beds, 7200 preparations/yr (80% oncology)
- Weighing inside isolator
  - 577 preparations
    - 3 errors found by gravimetrics (5% variance)
    - Weight before and after injection
- Weighing outside isolator
  - 577 preparations
    - 34 errors found by gravimetrics (6%)
    - Injected solution
    - Bag of solvent, infusion set, laser lock stopper, etc
    - Rinse bag prior to removing from isolator
- Variation in workflow lead to variation of results.

Gravimetrics – Where is the Evidence

- UNC Cancer Hospital
  - 8 FNP/10 techs
  - 160 preparations/day
  - Closed system transfer device (CSTD)
  - [(Medication X pcn/CSTD) – (pcn/CSTD)] * residual estimate = mL drug dispensed
    - specific gravity
  - Unclear methods didn’t include weighing final container
  - Limits ability to draw conclusions
  - Most egregious errors and larger % difference associated with smaller volumes measured.
  - Could this be due to using scales in turbulent laminar environments.

Gravimetrics – Where is the Evidence

- UNC study cont’d
  - 1156 doses evaluated
    - 71.7% within 5% ; 87.4% within 10%
    - Most egregious errors – likely caught on pharmacist check
      - Mitomycin – 40 mL vs 14.04 mL weighed
      - Mitomycin – 20 mL vs 13.96 mL weighed
      - Altemuzumab – 0.1 mL vs 0.18 mL weighed
      - Vincristine – 1.3 mL vs 2.53 mL weighed
    - Secondary outcomes associated with increased variance
      - Pediatric doses
      - Smaller measured volumes
      - Preparations requiring reconstitution

What do we know, what don’t we know

- BCH using gravimetrics since 1990s
  - mostly for larger diluent volumes
  - Have we already overcomplicated the process with images
    - Will adding even more time in the hood increase errors
    - Is there a net benefit if there are images?
      - Dexamethasone 1 mg/mL 3 mL syringe
    - Is “Judicious Use of Gravimetrics” the answer?
      - Use when it’s inconvenient to measure in syringes
      - Start with volume > 180 mL