Implementing IV Robotics & IV Workflow Systems

Michael J. Freudiger, PharmD, APh, BCPS, BCGP
Disclosure Information

Implementing IV Robotics & IV Workflow Systems
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• I have no financial relationships to disclose.
AND
• I will not discuss off-label use and/or investigational use in my presentation.
Learning Objectives

At the completion of this activity, you will be able to:

• Describe the benefits of IV robotics and IV workflow systems in a hospital compounding program.
• Identify the available hardware and software capabilities from the current manufacturers.
• Describe a plan for implementation and anticipate potential problems.
Questions: IV Robotics & IV Workflow Systems

• What are they?
• Why choose them?
• How do they work?
• How do you operate them?
• How do you decide on one?
• What are the advantages?
• What are the disadvantages?
• How do you implement them?
• How do you maintain them?
Questions: IV Robotics & IV Workflow Systems

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- Why choose them?
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Benefits of IV Robotics & IV Workflow Systems

• Preventable Drug Errors
• ISMP Summary Statements on these Systems

• IV Robotics
  • Advantages
  • Disadvantages
  • Desirable product features

• IV Workflow
  • Advantages
  • Disadvantages
  • Desirable product features
Preventable Errors: Preparation

- Wrong drug
- Expired drug
- Wrong reconstitution diluent
- Wrong final dilution (D5W, NS)
- Wrong concentration
- Wrong final volume
Preventable Errors: Preparation

• **STUDY:** Evaluation of real-time data obtained from gravimetric preparation of antineoplastic agents

• **DESIGN:** Large-scale, multi-center, multinational, retrospective study

• **GOAL:** Detect medication errors with possible critical therapeutic impact

• **RESULTS:** Gravimetric system detected that 7.89% of the 759,060 doses were outside of acceptable tolerance

• **CONCLUSION:** Gravimetric system prevented dosing errors that would not have been recognized by traditional methods
Preventable Errors: Preparation

- Oregon, USA 2014
- Ordered: Fosphenytoin
- Made as: Rocuronium
- Outcome: PATIENT DEATH
• ISMP believes that barcode scanning of base solutions and ingredients should now be considered the minimum requirement for pharmacy IV admixture services.

• Technology solutions (barcode scanning verifications of ingredients, gravimetric verification of drug and diluent volumes, and/or robotic image recognition) should be utilized to augment manual process for preparing and verifying CSPs.
• **CHEMOTHERAPY**: at a minimum, both barcoding and gravimetrics should be used when preparing chemotherapy.

• **PEDIATRICS**: ideally use several semiautomated-manual systems and highly automated robotic systems utilizing barcoding and gravimetrics.
When compounding sterile preparations, perform an **independent verification** to ensure that the proper ingredients (medications and diluents) are added, including confirmation of the proper amount (volume) of each ingredient prior to its addition to the final container.

Specifically, **eliminate** the use of proxy methods of verification for compounded sterile preparations of medications (e.g., the “**syringe pull-back method**,” checking a label rather than the actual ingredients).

**Syringe Pull-Back Method: NO!!!**
Why use GRAVIMETRIC verification systems?

- Gravimetrics provides a quality control step(s) by confirming the expected weight of the ingredients and combined base solution and additives for the individual CSP.
- 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 medications in available.
What is wrong with only VOLUMETRIC (image based) verification systems and barcodes?

• While barcoding does help in documenting that the correct ingredients for admixture are available, and imaging allows visualization of the volumes used for admixing, neither can be used to confirm that the ingredients have actually been added to the correct patient’s IV container in the correct amount.

• Confirmation bias by the pharmacist

• Interpretation errors
Benefits of IV Robotic Systems

Why invest in IV Robotics?

• Increase patient safety (medication safety)
• Standardize products to the hospital’s needs
• Create more reliability in supply of compounded preparations (less need for pre-made products)
• Batch produce high use (high volume) preparations
• Control and reduce costs; reduce waste
• Reduce the workloads from manual (human) compounding
• Record all steps of production process
IV Robotics: Advantages

- Increased efficiency in workflow
  - Bags from 25 – 1000 mL can be produced quickly
  - Syringes from 0.3 – 60 mL can be produced quickly
- Gravimetric checks of stock items with barcodes
- Step-by-step checks during compounding
- Step-by-step photo log of each compounding step
- Internal automated labelling of the final product
- Some robots can compound hazardous drugs
IV Robotics: **Disadvantages**

- Time to prepare products can be slower in some situations
- More employee training involved
- Higher costs (should balance out savings)
- Constant updates to drug libraries
• Compounding robots are not fully automated (yet).
• Technicians are required to constantly:
  • Start the robot
  • Operate the robot
  • Train new drug vial profiles and NDC#s into the robot’s system
  • Load syringes, drug vials, diluents, IVPB, labels, etc.
  • Empty and discard compounding waste
  • Clean the robot
  • Monitor for maintenance
Example Robot at Work

YouTube Video (Freudiger): https://youtu.be/tdQfe0kAtTA
Selecting a Robot (Manufacturer)

- Price of robot, service fees, labour, labels, supplies, stability/sterility testing
- Robot’s size (footprint) in the pharmacy
- Integration of the robot with other systems in place
- Company’s technical support and training of staff
- Robot’s features
- Robot’s throughput (production capacity)
- Internal labelling of bags and syringes
- Non-HD and HD drug compounding
- Gravimetric checks
- Dose type: Batching only? Patient specific doses?
- Product output: Syringes? IVPB? Both?
Manual IV Preparation: So Many Gaps!

Benefits of IV Workflow Systems

Why invest in IV Workflow Systems?

- **Increase patient safety (medication safety)**
- Integrates with CPOE systems: orders are removed from preparation queue as they are changed or discontinued
- Allows pharmacist verification in remote locations
- Live tracking of orders during the dispensing process
- Locate products after dispensing (scanned at delivery steps)
- Waste reduction
IV Workflow Systems: Better Control

- **Workflow** = Automation of “Flow of Work”
- Work is controlled and coordinated by a workflow management system
- Step-by-step process

1 2 3 4
IV Workflow Systems
IV Workflow Systems: Better Control

Automating steps to reduce human error, inefficiency and waste.

- Receipt of medication order
- Pharmacist check
- Order prioritization
- Stock selection
- Dose dispensed
- Pharmacist final check
- Product labeling
- Dose preparation

**Improve medication safety.** Utilize gravimetrics and barcode verification to minimize error.

**Streamline workflow.** Standardize processes using automation to ensure safety checks, enable remote pharmacist verification and remove redundant steps.

**Reduce waste.** Optimize drug inventory to minimize expirations, enable batching, track components and support re-utilization of returned medications.

**Provide an audit trail.** Electronically document every step to support compliance and facilitate analysis of preparation data for productivity and performance improvement.
BD Pyxis IV Prep (Beckton Dickinson)

### GEMcitabine POWDER

<table>
<thead>
<tr>
<th>Lot #</th>
<th>Dilution</th>
<th>Remnant</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>6003328</td>
<td>25ml</td>
<td>1000mg</td>
<td>0.00g</td>
</tr>
<tr>
<td>6003328</td>
<td>25.2ml</td>
<td>1000mg</td>
<td>8.86g</td>
</tr>
<tr>
<td>6003328</td>
<td>25.1ml</td>
<td>1000mg</td>
<td>27.16g</td>
</tr>
</tbody>
</table>

**Med. # 97010: 1700mg GEMcitabine POWDER q.s. to Sodium Chloride 0.9% 250ml Bag PVC IV over 30 min, Patient, Test (TH - Test Unit 3) for 4/25/2014**

- **Achieved:** 1671.26mg
- **AS injected:** 1671.26mg
- **Prescribed:** 1700mg
- **Injected Mass:** 45.7g (44.4ml) (= 1671.26mg AS)
- **Current Amount of Active Ingredient:** 1671.26mg
- **Prescribed Amount of Active Ingredient:** 1700mg
- **Deviation:** -1.7%

**YOU ARE WITHIN TOLERANCE!**
Please remove the Bag from the scale.
BD Pyxis IV Prep (Beckton Dickinson)

Med. # 97029: 1275mg GEMcitabine POWDER q.s. to Sodium Chloride 0.9% 250ml Bag PVC IV over 30 min, Patient, Test (TH - Test Unit 3) for 4/28/2014

Achieved: 1391.18mg  As withdrawn
Prescribed: 1275mg

Attention! You withdrew too much solution.
The deviation of 9.1% is out of tolerance.
Current Amount of Active Ingredient: 1391.58mg
Prescribed Amount of Active Ingredient: 1275mg

Please inject 3.17g (3.07ml) solution back into the vial!

IV Workflow: **Advantages**

- Increased efficiency in workflow
- Gravimetric checks with hard stops
- Eliminates the “syringe pull-back method”
- Error reduction (especially in pediatrics)
  - Step-by-step checks during compounding
  - Step-by-step photo log of each compounding step
- Waste reduction
  - Grouping of similar orders
  - Inventory management
IV Workflow: Disadvantages

• Time to prepare products can be slower
• More equipment installed inside the hood
  • More surfaces to clean
  • More surfaces to hold surface contamination
• More hand movements inside the hood (and outside?)
• Need to have the correct NDC/barcode match the order sent into the system
Comparing IV Robotics & IV Workflow Systems

• IV Robotic Systems
• IV Workflow Systems
IV Robotic Systems: 2018 Marketplace

• APOTECAchemo (Loccioni)
• RIVA (ARxIUM; Intelligent Hospital Systems)
• INTELLIFILL I.V. (Baxter Healthcare) – discontinued
• Equashield Pro (Equashield LLC) *CSTD robot
• KIRO Oncology (Grifols USA)
• i.v.STATION (OmniceLL, Inc.)
• i.v.STATION ONCO (OmniceLL, Inc.)
APOTECChemO (Loccioni)

- Closed system for HD compounding
- Precisions and control through sensors, full documentation and reporting, 100% checks
- Total control over workflow
- Safe waste management

Company Website: [https://www.loccioni.com/en/](https://www.loccioni.com/en/)
YouTube Video: [https://www.youtube.com/watch?time_continue=12&v=FWic3QYzw2Y](https://www.youtube.com/watch?time_continue=12&v=FWic3QYzw2Y)
RIVA (ARxIUM; Intelligent Hospital Systems)

• Fully automated
• Gravimetric checks
• In-process barcode scanning and image capture of ingredients
• Makes IV bags and syringes
• HD or non-HD preparations
• Batch production or patient specific
• Automated final labelling
• Streamlined remote verification

Company Website: https://www.arxium.com/products/iv-room/
INTELLIFILL I.V. (Baxter Healthcare)

- Integrates with pharmacy systems or operated from the console
- Produces syringes from 0.5 mL to 11.5 mL only
- Designed to fill up to 600 syringes per hour and with minimal operator intervention
- Uses INTELLIFILL branded syringes only

Discontinued

Company Website: [http://www.baxtermedicationdeliveryproducts.com/pharmacy-workflow/intellifill.html](http://www.baxtermedicationdeliveryproducts.com/pharmacy-workflow/intellifill.html)
YouTube Video: [https://www.youtube.com/watch?v=gw0PkHhd4Ms](https://www.youtube.com/watch?v=gw0PkHhd4Ms)
Equashield Pro (Equashield LLC)

- Uses CSTDs in the compounding of hazardous drugs
- Has proprietary safety systems and design elements that prevent exposure and cross-contamination
- Cameras identify vials and bags
- Items tracked continuously
- Photo report for each compound
- No compounding arms: uses movement in X, Y, Z axis along the work station
- Compounds up to 8 doses simultaneously
- Compact machine requires small footprint

Company Website: [http://www.kirogrifols.com/](http://www.kirogrifols.com/)
YouTube Video: [https://www.youtube.com/watch?v=Zq11bb1_Or0&feature=youtu.be](https://www.youtube.com/watch?v=Zq11bb1_Or0&feature=youtu.be)
Equashield Pro (Equashield LLC)

Company Website: https://www.equashield.com/
YouTube Video: https://www.youtube.com/watch?v=8mL-xJUexjw
KIRO Oncology (Grifols)

- Gravimetric verification at all stages of compounding
- In-process barcode readers
- Image capture at all steps
- Automatic error rejection and reporting
- BUD is automatically calculated and tracked for multi-dose vials
- Meets USP 800 requirements
KIRO Oncology (Grifols)

Company Website: [http://www.kirogrifols.com/](http://www.kirogrifols.com/)
YouTube Video: [https://www.youtube.com/watch?v=YVRmRuGScKo](https://www.youtube.com/watch?v=YVRmRuGScKo)
KIRO Oncology (Grifols)

Company Website: [http://www.kirogrifols.com/](http://www.kirogrifols.com/)
YouTube Video: [https://www.youtube.com/watch?v=YVRrnRuGScKo](https://www.youtube.com/watch?v=YVRrnRuGScKo)
i.v.STATION (Omnicell, Inc.)

- Fully automated
- Gravimetric checks
- In-process barcode scanning and image capture of ingredients
- Makes IV bags and syringes
- Non-HD preparations only
- Batch production or patient specific
- Automated final labelling
- Streamlined remote verification

Company Website: https://www.omnicell.com/Products/IV_Solutions/ivSTATION_Non-Hazardous_Compounding_Robot.aspx
i.v.STATION ONCO (Omnicell, Inc.)

• Fully automated
• Gravimetric checks
• In-process barcode scanning and image capture of ingredients
• Makes IV bags and syringes
• Designed for HD preparations
• Batch production or patient specific
• Automated final labelling
• Streamlined remote verification

Company Website: https://www.omnicell.com/Products/IV_Solutions/ivSTATION_ONCO_Hazardous_Compounding_Robot.aspx
Comparing IV Robotics & IV Workflow Systems

• IV Robotic Systems
• IV Workflow Systems
IV Workflow Systems: 2018 Marketplace

- **BD Pyxis IV Prep** (Becton Dickinson) – formerly BD Cato
- **IVX Workflow** (Omnicell)
- **i.v.SOFT Assist** (Omnicell)
- **DoseEdge** (Baxter)
- **DoseEdge TPN** (Baxter)
- **Dispense Prep** (Epic)
- **PharmacyKeeper** (Grifols)
- **Diana** (ICU Medical)
- **Sterile Room Medication Preparation SRMP** (ScriptPro)
## IV Workflow System Desired Features: Scorecard

<table>
<thead>
<tr>
<th>Y/N</th>
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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Gravimetric verification</strong></td>
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<td><strong>Barcode scanning and automation</strong></td>
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<td></td>
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<tr>
<td></td>
<td>• Records identity of compounding</td>
</tr>
<tr>
<td></td>
<td><strong>Dose tracking</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Integration with other systems (check website)</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Extras:</strong></td>
</tr>
</tbody>
</table>
BD Pyxis IV Prep (Beckton Dickinson)

• Guided transfer, dilution, and reconstitution of powdered and concentrated drugs
• Camera, barcode scanner, scale, software
• Allows for remote verification
• Hard-stops the technician if dose is out of range and approves doses within tolerances set by the organization
• Identification of errors in real time
• Tracks partial vials, drug waste, reports
<table>
<thead>
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<td>YES</td>
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<tr>
<td></td>
<td>• Records identity of compounder</td>
</tr>
<tr>
<td>YES</td>
<td><strong>Dose tracking</strong></td>
</tr>
<tr>
<td>YES</td>
<td><strong>Integration with other systems (check website)</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Extras:</strong> tracks inventory to reduce waste</td>
</tr>
</tbody>
</table>

### BD Pyxis IV Prep (Beckton Dickinson)

#### Set Up Preparations

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>Unit: (All Centers and Wards)</td>
<td>Delivery time:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pat. no.</th>
<th>Patient</th>
<th>Delivery time:</th>
</tr>
</thead>
</table>

#### Preparations Table

<table>
<thead>
<tr>
<th>Med. No.</th>
<th>Order number</th>
<th>Administration</th>
<th>Product</th>
<th>Patient</th>
<th>Patient Number</th>
<th>Date of delivery</th>
</tr>
</thead>
<tbody>
<tr>
<td>X 009999</td>
<td>173</td>
<td>4/25/2014</td>
<td>Fluor/PACIL INJ 525mg 50mL Sodium Chloride 0.9% DOE, Jane</td>
<td>1001065</td>
<td>TH - Test Unit 1</td>
<td></td>
</tr>
<tr>
<td>X 009990</td>
<td>175</td>
<td>4/25/2014</td>
<td>CycloPHOS/PAMIDE POWDER 25mg 100mL Sodium Chloride 0.9% DOE, Jane</td>
<td>1001068</td>
<td>TH - Test Unit 2</td>
<td></td>
</tr>
<tr>
<td>X 009995</td>
<td>176</td>
<td>4/25/2014</td>
<td>Fluor/PACIL INJ 400mg 25mL Sodium Chloride 0.9% DOE, John</td>
<td>1001069</td>
<td>TH - Test Unit 1</td>
<td></td>
</tr>
<tr>
<td>X 009986</td>
<td>73</td>
<td>4/25/2014 12:30 PM</td>
<td>GEGalamab INJ 300mg</td>
<td>Interal Bag</td>
<td>4h</td>
<td>DOE, John</td>
</tr>
<tr>
<td>X 059780</td>
<td>180 - 10050093286</td>
<td>4/25/2014</td>
<td>BEVAC/ZUMAB INJ 35mg</td>
<td>100mL Sodium Chloride 0.9%</td>
<td>PATIENT RUPERT</td>
<td>101648</td>
</tr>
<tr>
<td>X 059782</td>
<td>181 - 10050093286</td>
<td>4/25/2014 11:00 AM</td>
<td>Trastuzumab INJ 140mg</td>
<td>50mL DSW</td>
<td>Bag</td>
<td>1 x 30 min</td>
</tr>
<tr>
<td>X 059784</td>
<td>182 - 10050093286</td>
<td>4/25/2014 11:00 AM</td>
<td>Trastuzumab INJ 40mg 25mL Sodium Chloride 0.9%</td>
<td>PATIENT RUPERT</td>
<td>101648</td>
<td>TH - Test Unit 3</td>
</tr>
<tr>
<td>X 070100</td>
<td>136 - 100500971507</td>
<td>4/25/2014</td>
<td>GEMLCABINSA POWDER 1780mg</td>
<td>25mL Sodium Chloride 0.9%</td>
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<td>3396885</td>
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<td>GEMLCABINSA POWDER 1725mg</td>
<td>25mL Sodium Chloride</td>
<td>PATIENT Test</td>
<td>3396885</td>
</tr>
</tbody>
</table>

#### Preparation Details

- **Preparation Place:** I
- **Approval:** Approv. & Not Approv.
- **Delivery time:**

ABATACEPT (same as ORENCIA) powder for injection 750mg q.s. to NORMAL SALINE (NS) 100mL bag VIAFLEX Baxter intravenous over 30 min for 7/13/2018 11:00

i.v.SOFT Assist (Omnicell)

• Guided transfer, dilution, and reconstitution of powdered and concentrated drugs
• Integrated gravimetrics to enhance accuracy
• Barcode scanning and visual recognition for identification and recording of drugs
• Auto printing of customized labels to track every preparation.

Company Website: https://www.omnicell.com/Products/IV_Solutions/IVX_Workflow.aspx
## i.v.SOFT Assist (Omnicell)

<table>
<thead>
<tr>
<th>Y/N</th>
<th>Desired Features Scorecard</th>
</tr>
</thead>
</table>
| YES | **Gravimetric verification**  
  • Real-time identification and correction of errors before final pharmacist verification |
| YES | **Barcode scanning and automation**  
  • Detects incorrectly selected drug, diluent, container |
| YES | **Electronic documentation for remote verification**  
  • Photographs and saves each preparation step  
  • Records identity of compounder |
| YES | **Dose tracking (integrated with other systems)** |
| YES | **Integration with other systems (check website)** |
| Extras: | prints customized labels |

Company Website: [https://www.omnicell.com/Products/IV_Solutions/IVX_Workflow.aspx](https://www.omnicell.com/Products/IV_Solutions/IVX_Workflow.aspx)
IVX Workflow (Omnicell)

- Gravimetrics, volumetrics, barcode scanning, advanced image recognition, photo documentation, label printing
- Guides technicians in set compounding protocols for each preparation
- Antimicrobial screen eliminates buttons and mouse clicking, less removal of hands from the compounding hood
- Remote pharmacist checking
- Can integrate with Simplifi797

Company Website: https://www.omnicell.com/ivxworkflow
### IVX Workflow (Omnicell)

<table>
<thead>
<tr>
<th>Y/N</th>
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</tr>
<tr>
<td></td>
<td>• Records identity of compounder</td>
</tr>
<tr>
<td>YES</td>
<td><strong>Dose tracking (integrated with other systems)</strong></td>
</tr>
<tr>
<td>YES</td>
<td><strong>Integration with other systems (check website)</strong></td>
</tr>
</tbody>
</table>

**Extras:** integrates with Simplifi797

Company Website: [https://www.omnicell.com/ivxworkflow](https://www.omnicell.com/ivxworkflow)
DoseEdge (Baxter)

• Gravimetrics, volumetrics, barcode scanning, advanced image recognition, photo documentation
• Guides technicians in set compounding protocols for each preparation
• Automatic calculations
• Identifies errors prior to admixture
• Use unexpired returned doses
• Remote pharmacist checking

Company Website: http://www.baxtermedicationdeliveryproducts.com/pharmacy-workflow/doseedge.html
<table>
<thead>
<tr>
<th>Y/N</th>
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<tbody>
<tr>
<td>YES</td>
<td><strong>Gravimetric verification (add-on feature)</strong></td>
</tr>
<tr>
<td></td>
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</tr>
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<tr>
<td>YES</td>
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</tr>
<tr>
<td></td>
<td>Extras: lot number, expiration date tracking</td>
</tr>
</tbody>
</table>

Company Website: [http://www.baxtermedicationdeliveryproducts.com/pharmacy-workflow/doseedge.html](http://www.baxtermedicationdeliveryproducts.com/pharmacy-workflow/doseedge.html)
Dispense Prep (Epic)

- Part of the Epic EMR
- Bar code scanning to match correct product to expected product at order verification
- Image capture for remote verification of IV preparations
- No gravimetrics or volumetrics
- Reduces waste as orders are removed from IV prep list as they are discontinued

Company Website: https://www.epic.com/services
<table>
<thead>
<tr>
<th>Y/N</th>
<th>Desired Features Scorecard</th>
</tr>
</thead>
<tbody>
<tr>
<td>NO</td>
<td>Gravimetric verification</td>
</tr>
<tr>
<td></td>
<td>• Real-time identification and correction of errors before final pharmacist verification</td>
</tr>
<tr>
<td>YES</td>
<td>Barcode scanning and automation</td>
</tr>
<tr>
<td></td>
<td>• Detects incorrectly selected drug, diluent, container</td>
</tr>
<tr>
<td>NO</td>
<td>Electronic documentation for remote verification</td>
</tr>
<tr>
<td></td>
<td>• Photographs and saves each preparation step</td>
</tr>
<tr>
<td></td>
<td>• Records identity of compounding</td>
</tr>
<tr>
<td>YES</td>
<td>Dose tracking</td>
</tr>
<tr>
<td>YES</td>
<td>Integration with other systems (check website)</td>
</tr>
<tr>
<td>YES</td>
<td>Notes: great for checking non-compounded products</td>
</tr>
</tbody>
</table>
PharmacyKeeper (Grifols)

• Barcode scanning, image capture of final products, tracks lot#, expiration dates.
• Facilitates remote pharmacist verification and documentation of IV compounding
• Integrates with EMR to enhance workflow for patient-specific and batch preparations
• 2 options for hardware setup:

Company Website: http://www.grifolsusa.com/en/web/eeuu/hospital/-/product/pharmacykeeper
PharmacyKeeper (Grifols)

• 2 options for hardware setup:
  1. Compact cameras in cleanroom ceilings with medical grade touch screen computers supported by arms at work stations
  2. Embedded work station with cameras and computers enclosed within the laminar flow hood or BSC.

<table>
<thead>
<tr>
<th>Y/N</th>
<th>Desired Features Scorecard</th>
</tr>
</thead>
<tbody>
<tr>
<td>NO</td>
<td><strong>Gravimetric verification</strong></td>
</tr>
<tr>
<td></td>
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</tr>
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<td>YES</td>
<td><strong>Barcode scanning and automation</strong></td>
</tr>
<tr>
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<td>• Detects incorrectly selected drug, diluent, container</td>
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<tr>
<td>YES</td>
<td><strong>Electronic documentation for remote verification</strong></td>
</tr>
<tr>
<td></td>
<td>• Photographs and saves each preparation step</td>
</tr>
<tr>
<td></td>
<td>• Records identity of compounder</td>
</tr>
<tr>
<td>YES</td>
<td><strong>Dose tracking</strong></td>
</tr>
<tr>
<td></td>
<td>(integrated with other systems)</td>
</tr>
<tr>
<td>YES</td>
<td><strong>Integration with other systems (check website)</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Notes:</strong> uses commercially available devices</td>
</tr>
</tbody>
</table>
Diana (ICU Medical)

- No gravimetrics involved
- Automated volumetrics
- Imaging of each step
- Barcode scanning
- Remote pharmacist verification of each preparation


YouTube Video: [https://www.youtube.com/watch?v=p5oR1xPV6RU](https://www.youtube.com/watch?v=p5oR1xPV6RU)
## Desired Features Scorecard

<table>
<thead>
<tr>
<th>Y/N</th>
<th>Feature Description</th>
</tr>
</thead>
</table>
| **NO** | Gravimetric verification *(automated volumetric)*  
• Real-time identification and correction of errors before final pharmacist verification |
| **YES** | Barcode scanning and automation  
• Detects incorrectly selected drug, diluent, container |
| **YES** | Electronic documentation for remote verification  
• Photographs and saves each preparation step  
• Records identity of compounder |
| **NO** | Dose tracking *(none found)* |
| **??** | Integration with other systems *(check website)* |

**Extras:**

Sterile Room Medication Preparation (ScriptPro)

- Designed for chemotherapy
- Barcode scanning and image capture
- Uses both video and audio during verifications steps, errors are caught before medication is injected into the bag
- “Allows pharmacist to remain outside the cleanroom while inspecting the preparation of the drug via images taken of the medication, physician’s order, vials, and pullback syringe”.

Company Website: https://www.scriptpro.com/Products/Pharmacy-Workflow-Systems/Sterile-Room-Medication-Preparation/
## Sterile Room Medication Preparation (ScriptPro)

<table>
<thead>
<tr>
<th>Y/N</th>
<th>Desired Features Scorecard</th>
</tr>
</thead>
<tbody>
<tr>
<td>NO</td>
<td><strong>Gravimetric verification</strong></td>
</tr>
<tr>
<td></td>
<td>• Real-time identification and correction of errors before final pharmacist verification (VISUAL)</td>
</tr>
<tr>
<td>YES</td>
<td><strong>Barcode scanning and automation</strong></td>
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<tr>
<td></td>
<td>• Detects incorrectly selected drug, diluent, container</td>
</tr>
<tr>
<td>YES</td>
<td><strong>Electronic documentation for remote verification</strong></td>
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<tr>
<td>NO</td>
<td><strong>Dose tracking</strong></td>
</tr>
<tr>
<td>YES</td>
<td><strong>Integration with other systems (check website)</strong></td>
</tr>
</tbody>
</table>

**Notes:** primarily for use in telepharmacy

Company Website: [https://www.scriptpro.com/Products/Pharmacy-Workflow-Systems/Sterile-Room-Medication-Preparation/](https://www.scriptpro.com/Products/Pharmacy-Workflow-Systems/Sterile-Room-Medication-Preparation/)
IV Workflow: Prepare a Plan for Implementation

- Review pharmacy sterile products workloads
- Identify your needs based on your patient population
- Formulate a plan for starting with a few high volume use products and do a gradual “go-live” with the systems
- Coordinate with IT (networking) department
- Consider extra staff during the implementation period
IV Workflow: Barriers to Success

- Constant drug shortages: always new NDC# and barcodes to add into the system
- IV workflow management system fails to interface with existing CPOE system
- Failure to reach ROI
- Unexpected costs:
  - Maintenance, Cleaning, Upgrades
  - Staff training shifts, ongoing training
  - Extra compensation for increased skillsets
  - Construction costs for installations
IV Robot: Prepare a Plan for Implementation

• How will the compounding robot be utilized?
  • Batch production of common preparations? (which ones?)
  • Patient-specific doses?

• Do you have enough extra employees?

• Coordinate with other departments: IT, engineering, electrical, etc.

• Do you need more than one robot?
IV Robot: Prepare a Plan for Implementation
IV Robot: Prepare a Plan for Implementation

• Ongoing budgets for:
  • Robot
    • Maintenance and replacements parts
    • Calibration of equipment
    • Cleaning of machinery
  • Personnel
    • Workload and shifts
    • Training of new employees
    • Training of robot for new drug vials
Who is going to train the hospital employees?

• Company engineer will give onsite operations training.
• Allow a few hospital technicians to work dedicated shifts for all robot processes and become your experts.
• New hospital expert technicians will:
  • Manage the robot and train others after implementation.
  • Train the robot (enter each new drug compounding process into the system).
IV Robot: Planning the Daily Workload
IV Robot: Barriers to Success

- Not enough space to install the robot
- Not enough staff members to operate the machine
- Not enough employee education or support
- Unanticipated costs
- Too many machines, not enough staff
- Inability to integrate the robot into other hospital systems
- IV Robot only able to produce syringes and not IVPB
- Implementation project runs out of money
- Always adding new NDC# and barcodes into the system
IV Robot & IV Workflow: Other Considerations

• Plan for downtimes in each system
  • IV Robots go down, IV Workflow Systems go down (failures)
  • Compounding cleanrooms go down (cleanings, failures)

• Have a backup plan and location to compound

• Consider starting with one robot then scaling from there

• Constantly monitor CSPs being made compared to what is being used to avoid waste.

• Produce CSPs in smaller batches more frequently rather than large single batches.
Compounding Program Elements

- Employee Education
- Employee Safety
- Compounding Process
- Quality Assurance
- Regulatory Compliance

Patient Safety
Compounding Program Elements & IV Robot

- Employee Education
- Patient Safety
- Quality Assurance
- Regulatory Compliance
- Compounding Process
- Employee Safety
- Robot Operations
- Workload Management
IV Robot: Employee Education

• Robot Operations (documented, ongoing assessment)
  • Training the robot
  • Loading of materials
  • Cleaning
  • Maintenance
  • Environmental sampling

• Workload Management
  • Batch run times
  • Planning for patient-specific dose production
Compounding Program Elements & IV Robot

- Employee Education
- Compounding Process
- Employee Safety
- Regulatory Compliance
- Patient Safety
- Quality Assurance
- Environmental Sampling CSP Recall Process
**IV Robot: Environmental Sampling**

Sampling is performed before weekly or monthly full clean, or more frequently depending on sample growth trends.

<table>
<thead>
<tr>
<th>Day</th>
<th>Swab</th>
<th>Plate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sunday</td>
<td>S1</td>
<td>P1</td>
</tr>
<tr>
<td>Monday</td>
<td>S2</td>
<td>P6</td>
</tr>
<tr>
<td>Tuesday</td>
<td>S3</td>
<td>P2</td>
</tr>
<tr>
<td>Wednesday</td>
<td>S4</td>
<td>P3</td>
</tr>
<tr>
<td>Thursday</td>
<td>S5, S6</td>
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<tr>
<td>Friday</td>
<td>S7</td>
<td>P4</td>
</tr>
<tr>
<td>Saturday</td>
<td>S8</td>
<td>P5</td>
</tr>
</tbody>
</table>

www.ivpnsymposium.org
Compounding Program Elements:
IV Robot & IV Workflow

- Employee Education
- Quality Assurance
- Employee Safety
- Compounding Process
- Patient Safety
- Regulatory Compliance

- Calibration, Maintenance Certification, Documentation

www.ivpnsymposium.org
IV Robot & IV Workflow: Regulatory Compliance

- Routine calibration and certification of equipment is performed and documented, including balances
- Preventative maintenance performed; software is current
- Equipment is properly cleaned at appropriate frequency
- Staff members trained in all functions (training documented)
- Final check of the CSP is completed prior to dispensing by a pharmacist possessing training and experience in the technology
- All of the above is described in the SOP

ISMP Guidelines for Safe Preparation of Compounded Sterile Preparations 2016
Compounding Program Elements & IV Robot

- Employee Education
- Quality Assurance
- Regulatory Compliance
- Employee Safety
- Patient Safety
- Compounding Process

- Review Master Formulas
- Train Robot to Formulas
- CSP Recalls in Systems
How do you train a robot?
IV Robot: Compounding Process

How do you train a robot?

• Measurements of drug vials
  • Height (with cap, without cap)
  • Weight (dry, diluted)
  • Diameter (all areas of vial)
• Initial and final concentration
• Specific gravity
• Appropriate shaking speed during reconstitution
• Appropriate size syringes to use
• Other parameters: vial barcode, bag size (mL), bag port puncture limits, etc.
### IV Robot: Training Medications into the System

<table>
<thead>
<tr>
<th>Anesthesia/Controlled</th>
<th>Antibiotic/Antiviral</th>
<th>Cytotoxic</th>
<th>Critical Care</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>atropine</td>
<td>acyclovir</td>
<td>bendamustine*</td>
<td>acetaminophen</td>
<td>dexamethasone</td>
</tr>
<tr>
<td>bupivacaine*</td>
<td>amikacin*</td>
<td>bevacizumab</td>
<td>acetaZOLAMIDE*</td>
<td>dextrose</td>
</tr>
<tr>
<td>cisatracurium</td>
<td>ampicillin</td>
<td>bleomycin</td>
<td>alleplase</td>
<td>diphenhydrAMINE</td>
</tr>
<tr>
<td>clonIDine*</td>
<td>ampicillin sulbacam</td>
<td>bortezomib</td>
<td>aminocaproic acid*</td>
<td>fenoldipine</td>
</tr>
<tr>
<td>dexmedetomidine</td>
<td>azithromycin</td>
<td>CARBOplatin</td>
<td>amiodarone*</td>
<td>fluorococin*</td>
</tr>
<tr>
<td>diazepam</td>
<td>aztreonam*</td>
<td>CISplatin</td>
<td>caffeine</td>
<td>folic acid</td>
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<td>ePHEDrine</td>
<td>bacitracin</td>
<td>cyclophosphamide</td>
<td>calcium gluconate</td>
<td>gadobutrol</td>
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<tr>
<td>fentanyl</td>
<td>ceFAZolin</td>
<td>DOCEtaxel</td>
<td>chlorothiazide*</td>
<td>heparin</td>
</tr>
<tr>
<td>glycopyrrolate</td>
<td>cefepime</td>
<td>DOXOrubicin</td>
<td>diltiazem</td>
<td>ipamidol</td>
</tr>
<tr>
<td>HYDROMorphine</td>
<td>ceFOTAxime</td>
<td>EPIrubicin</td>
<td>DOPIamine</td>
<td>iron sucrose*</td>
</tr>
<tr>
<td>ketamine</td>
<td>ceFOXitin</td>
<td>etoposide</td>
<td>EPINEPhrine</td>
<td>Latius™ insulin*</td>
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<tr>
<td>lidocaine</td>
<td>ceTRIAxone</td>
<td>fluorouracil</td>
<td>furosemide</td>
<td>levETIRacetam</td>
</tr>
<tr>
<td>lidocaine w/epi*</td>
<td>ceUROxime</td>
<td>ganciclovir</td>
<td>labetalol</td>
<td>lidocaine Buffered</td>
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<tr>
<td>LORazepam*</td>
<td>chlormycin</td>
<td>gemcitabine</td>
<td>metoprolol</td>
<td>magnesium sulfate</td>
</tr>
<tr>
<td>methadone</td>
<td>colistimethate*</td>
<td>irinotecan</td>
<td>milrinone</td>
<td>metoclopramide*</td>
</tr>
<tr>
<td>midazolam</td>
<td>gentamicin</td>
<td>luvocorin</td>
<td>naloxone</td>
<td>methylPREDNISolone</td>
</tr>
<tr>
<td>morphine</td>
<td>imipenem</td>
<td>methotrexate</td>
<td>nifCARdipine</td>
<td>omeprazole</td>
</tr>
<tr>
<td>nalbuphine</td>
<td>levofloxacin*</td>
<td>mycophenolate</td>
<td>nitroglycerin*</td>
<td>ondansetron</td>
</tr>
<tr>
<td>neostigmine</td>
<td>meropenem</td>
<td>oxaliplatin</td>
<td>nitroprusside</td>
<td>oxytocin</td>
</tr>
<tr>
<td>pancuronium</td>
<td>nafcilin</td>
<td>PACItaxel</td>
<td>norepinephrine</td>
<td>pantoprazole</td>
</tr>
<tr>
<td>PENTobarbital</td>
<td>oxacillin</td>
<td>pamidronate</td>
<td>vasopressin*</td>
<td>potassium chloride</td>
</tr>
<tr>
<td>PHENYLEphrine</td>
<td>penicillin</td>
<td>PEMEtrexed</td>
<td></td>
<td>potassium phosphate</td>
</tr>
<tr>
<td>propofol</td>
<td>piperacillin/tazobactam</td>
<td>riTUXImab</td>
<td></td>
<td>ranitidine</td>
</tr>
<tr>
<td>remifentanil*</td>
<td>tigecycline*</td>
<td>vinBLAStone</td>
<td></td>
<td>sodium bicarbonate</td>
</tr>
<tr>
<td>rocuronium</td>
<td>tobramycin</td>
<td>vinCRISTine</td>
<td></td>
<td>sodium chloride</td>
</tr>
<tr>
<td>ropivacaine</td>
<td>vancomycin</td>
<td>vinorelbine</td>
<td></td>
<td>sodium citrate</td>
</tr>
<tr>
<td>succinylcholine</td>
<td>voriconazole*</td>
<td>zoledronic acid</td>
<td></td>
<td>sterile water</td>
</tr>
<tr>
<td>thiopental</td>
<td>zidovudine*</td>
<td></td>
<td></td>
<td>tromethamine</td>
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<tr>
<td>vecuronium</td>
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<td></td>
<td></td>
<td>TSB</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>valproate sodium*</td>
</tr>
</tbody>
</table>

These are limited only by your imagination!
VCH: Utilization of RIVA Compounding Robot

• Mostly antibiotics
• Mostly batch production
• Some patient-specific doses (depends on orders)

• Cefazolin 500 mg/25 mL D5W
• Cefazolin 1,000 mg/50 mL D5W
• Cefepime 500 mg/25 mL D5W
• Cefepime 1,000 mg/50 mL D5W
• Ceftriaxone 1,000 mg/25 mL D5W
• Ceftriaxone 2,000 mg/50 mL D5W
• Clindamycin 300 mg/25 mL D5W
• Clindamycin 600 mg/50 mL D5W
• Piperacillin/Tazo 3.375 Gm/50 mL NS
• Vancomycin 250 mg/50 mL D5W
• Dextrose 5% in Water / 25 mL
• Compounding of intermediate bag
VCH: Utilization of RIVA Compounding Robot

1. Compounding of intermediate bag

2. Make batched syringes from intermediate bag, or patient specific doses
VCH: Utilization of RIVA Compounding Robot

1. Compounding of intermediate bag

2. Make batched syringes from intermediate bag, or patient specific doses

3. Make patient specific doses with IV workflow system from batched syringes
VCH: Pharmacist Sign-Off and CSP Tracking

**RIVA Intermediate Bag**
**Piperacillin/Tazobactam 60 mg/mL NS**

DESCRIPTION: this template task is used to document RIVA compounding.

PRODUCTS TO CHECK: Zosyn 4.5 Gm vials; NS of available size (50 mL, 100 mL, 250 mL, or 500 mL).

PHARMACIST PRE-CHECK: Prior to taking medications into the IV room for a batch run, the RIVA technician will gather all necessary products for the pharmacist to check (drug vials, bags, expiration dates, etc.)

EXPIRY (BUD) DATE @ TIME: enter this for the FIRST and LAST compounded product.

PHARMACIST SIGN-OFF: A signature in this field gives approval to all RIVA compounded prefilled syringes in this batch.

**RIVA Prefilled Syringe**
**Piperacillin/Tazobactam 3.375 Gm/50 mL NS**

DESCRIPTION: This template task is used to document RIVA compounding of prefilled syringes from compounded intermediate bags.

PHARMACIST SIGN-OFF: A signature in this field gives approval to all RIVA compounded prefilled syringes in this batch.
CSP Recall Process with Multiple Systems

EMR
CSP Recall Process with Multiple Systems
CSP Recall Process with Multiple Systems

Archived paper records.

Other system for compounding records patient identifiers.
CSP Recall Process with Multiple Systems

CSP Components

ROBOT records lot #s of all components w/ images available in database, quality control check-off recorded in alternate (web-based) program.
CSP Recall Process with Multiple Systems

CSP Components

ROBOT records lot #s of all components w/ images available in database, quality control check-off recorded in alternate (web-based) program

ROBOT Stock Bag Lot#

Patient Specific Doses
(recorded in IV workflow system)
CSP Recall Process with Multiple Systems

CSP Components

ROBOT records lot #s of all components w/ images available in database, quality control check-off recorded in alternate (web-based) program

ROBOT Stock Bag Lot#

IV WORKFLOW: Patient Specific Doses

IV WORKFLOW records source product images and lot #s (vials, solution bags, ROBOT stock bags, ROBOT stock syringes), then generates an IV WORKFLOW lot # which is then tied to each specific patient profile.

ROBOT Stock Syringe Lot#

Patient Specific Doses (recorded in IV workflow system)
CSP Recall Process with Multiple Systems

**CSP Components**

**ROBOT**

ROBOT records lot #s of all components w/ images available in database, quality control check-off recorded in alternate (web-based) program

**IV WORKFLOW**

IV WORKFLOW: Patient Specific Doses

IV WORKFLOW records source product images and lot #s (vials, solution bags, ROBOT stock bags, ROBOT stock syringes), then generates an IV WORKFLOW lot # which is then tied to each specific patient profile.

**WEB-BASED**

Web-Based Program: records of compounding for many miscellaneous small batch products.

**ROBOT Stock Syringe Lot#**

**IV WORKFLOW**

Patient Specific Doses (recorded in IV workflow system)
CSP Recall Process with Multiple Systems

CSP Components

ROBOT

ROBOT records lot #s of all components w/ images available in database, quality control check-off recorded in alternate (web-based) program

IV WORKFLOW: Patient Specific Doses

IV WORKFLOW: Patient Specific Doses (recorded in IV workflow system)

IV WORKFLOW

IV WORKFLOW

IV WORKFLOW

ROBOT Stock Syringe Lot#

Patient Specific Doses

(Recorded in IV workflow system)

Web-Based Program:
records of compounding for many miscellaneous small batch products.

STAT Compounding Record (paper records saved and searched on recall)
IV Robot: Opportunity for Extended BUD

- Robots can produce regular and precisely measured compounded preparations.
- Compounding is performed inside the ISO-5 environment within the robot.
- Less variability between each preparation
- Less chance for contamination (removing the human)
- Samples can be taken for sterility testing per USP 71; batch can be quarantined until sterility tests are clear.
- **LIMITATION**: drug chemical/physical stability
Compounding Program Elements & IV Robot

- Safe Operations Policy & Procedures
- Employee Safety
- Compounding Process
- Patient Safety
- Employee Education
- Quality Assurance
- Regulatory Compliance

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Conclusion

• Many workflow and automations options exist, it is important for you to work closely with your staff to determine which is going to be the best fit for your pharmacy.

• Understand the systems ahead of go-live implementation to help prevent unexpected workflow failures that could impact patient care.

• Ensure your selection of programs and systems improves patient care, workloads, safety, costs, and time involved.
References

- ISMP Medication Safety Alert 2014;19[25]:1-4
- ISMP Guidelines for Safe Preparation of Compounded Sterile Preparations 2016
- Wild, D. Making the Switch to IV Workflow. Pharmacy Practice News 2016
- ASHP Current State of IV Workflow Systems and IV Robotics 2018
- Company specific product references (see slide footnotes)
Questions?

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michaelfreudiger@gmail.com