Third Consensus Development Conference on the Safety of Intravenous Drug Delivery Systems

Analysis & Perspectives of the Different Systems and Uncovering Cost Impact of Various Systems

Christopher Fortier, PharmD, FASHP
Chief Pharmacy Officer
Massachusetts General Hospital
Agenda

• Review of IV drug delivery systems
  • Regulatory, quality, safety, operations, and staffing
• What has changed
  • Outsourced compounding
  • IV automation
• Decision-making analysis
  – Financial implications
IV Drug Delivery Systems

- Pharmacy compounded
- Manufacturer ready to use
- Point-of-care activated
- Outsourced ready to use
- Non-pharmacy compounded at point of care
<table>
<thead>
<tr>
<th>Pharmacy Compounded</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Regulatory</strong></td>
</tr>
</tbody>
</table>
| **Quality**         | • Direct control over quality assurance  
                      • Control over personnel hiring to ensure staff is competent |
| **Safety**          | • Human factors, syringe pull back method  
                      • Pediatrics, oncology  
                      • Drug shortages  
                      • High risk compounding  
                      • Healthcare associated infections  
                      • Automation – IV workflow, robotics, smart pumps |
| **Operations**      | • Quick turnaround  
                      • Complexity of preparations  
                      • Inconsistent training between hospitals  
                      • Space limitations  
                      • USP non-compliance  
                      • Hazardous drugs, CSTD  
                      • Live viruses, nano-technology |
| **Staffing**        | • Staffing shortages  
                      • Pharmacist expertise – clinically focused  
                      • Ongoing staff training, USP competencies/testing |
Hazardous Drugs – USP 800

- Chemo and non-chemo hazards
- CSTD
- IV automation
- Multi-disciplinary

[Graph showing the use of closed system transfer devices from 2011 to 2017 with percentages: 41%, 50%, and 65%]

Role of the Pharmacy Technician

- Technician shortage
- Certification
- Accredited training
- Compensation
- Career advancement
- Licensure???
Manufacturer Ready to Use
- Including point-of-care activated

<table>
<thead>
<tr>
<th>Regulatory</th>
<th>Joint Commission, USP 797, CMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality</td>
<td>Provide consistent and high-quality product directly from the drug manufacturer</td>
</tr>
<tr>
<td>Safety</td>
<td>Medications in a dose-specific, ready-to-administer form</td>
</tr>
<tr>
<td></td>
<td>IV smart pumps, BCMA</td>
</tr>
<tr>
<td></td>
<td>Activation errors</td>
</tr>
<tr>
<td></td>
<td>Look-alike bags</td>
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<tr>
<td></td>
<td>Consistent use of one system</td>
</tr>
<tr>
<td>Operations</td>
<td>Product closer to point-of-care</td>
</tr>
<tr>
<td></td>
<td>Quick</td>
</tr>
<tr>
<td></td>
<td>Embedded into pharmacy distribution process</td>
</tr>
<tr>
<td>Staffing</td>
<td>Enable the organization to reallocate resources</td>
</tr>
<tr>
<td></td>
<td>Allocating workload to nursing</td>
</tr>
<tr>
<td></td>
<td>Nursing shortages</td>
</tr>
</tbody>
</table>
## Non-Pharmacy Compounded

<table>
<thead>
<tr>
<th>Category</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory</td>
<td>Joint Commission, USP 797, CMS</td>
</tr>
<tr>
<td>Quality</td>
<td>Provide consistent and high-quality product directly from the drug manufacturer</td>
</tr>
<tr>
<td>Safety</td>
<td>Product not in final dose form</td>
</tr>
<tr>
<td></td>
<td>Provide in a dose-specific, ready-to-administer form</td>
</tr>
<tr>
<td></td>
<td>Utilization of BCMA</td>
</tr>
<tr>
<td></td>
<td>Calculation errors</td>
</tr>
<tr>
<td></td>
<td>Drug information/compatibilities</td>
</tr>
<tr>
<td></td>
<td>Aseptic technique</td>
</tr>
<tr>
<td></td>
<td>Labeling</td>
</tr>
<tr>
<td></td>
<td>Dose manipulations</td>
</tr>
<tr>
<td>Operations</td>
<td>Product closer to point-of-care</td>
</tr>
<tr>
<td></td>
<td>Embedded into pharmacy distribution process</td>
</tr>
<tr>
<td></td>
<td>Syringe pumps</td>
</tr>
<tr>
<td>Staffing</td>
<td>Allocating workload to nursing</td>
</tr>
<tr>
<td></td>
<td>Nurse training</td>
</tr>
</tbody>
</table>
AmerisourceBergen sees Memphis plant back on track by 2019; shares rise
## Outsourcing of Medication Preparation Activities

<table>
<thead>
<tr>
<th>Outsourced Activity</th>
<th>2017 (n = 674)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any preparation activities</td>
<td>79.6</td>
</tr>
<tr>
<td>Types of preparations or activities*</td>
<td></td>
</tr>
<tr>
<td>Total parenteral nutrition solutions</td>
<td>32.4</td>
</tr>
<tr>
<td>I.V. admixtures and “piggybacks”</td>
<td>33.6</td>
</tr>
<tr>
<td>Patient-controlled and/or epidural analgesia</td>
<td>76.7</td>
</tr>
<tr>
<td>Cardioplegic preparations</td>
<td>14.0</td>
</tr>
<tr>
<td>Oxytocin preparations</td>
<td>60.5</td>
</tr>
<tr>
<td>Syringe-based anesthesia medications</td>
<td>62.3</td>
</tr>
<tr>
<td>High-risk compounded sterile products from nonsterile sources</td>
<td>15.9</td>
</tr>
<tr>
<td>Other</td>
<td>6.7</td>
</tr>
</tbody>
</table>

*Among respondents reporting outsourcing of preparation activities.

*Not surveyed.
Outsourced Ready to Use

- Currently, 73 FDA 503b registered facilities
  - cGMP compliance
- 503A Federal Food, Drug and Cosmetic Act
  - 49% of State Board of Pharmacy require USP 797
- Subject to FDA inspection

# Outsourced Ready to Use

<table>
<thead>
<tr>
<th>Category</th>
<th>Details</th>
</tr>
</thead>
</table>
| Regulatory | • FDA 503b registration/inspection, State Board of Pharmacy, Joint Commission  
• Hospitals responsibility to inspect |
| Quality    | • Consistent and high-quality pharmacy and sterile compounding services, including extended beyond-use-dating  
• Drug shortages  
• FDA 483?  
• cGMP |
| Safety     | • Medications in a dose-specific, ready-to-administer form  
• IV smart pumps, BCMA  
• Labeling, coloring, bar code  
• No longer providing high-risk preparations (i.e. cardioplegia) |
| Operations | • Limited available physical or technological resources  
• Ordering, par level, stocking  
• Time delays  
• Interruptions in service  
• Beyond use dating  
• Decrease waste  
• Inability to perform in-house testing  
• Embedded into pharmacy distribution process  
• Health-system consolidation |
| Staffing   | • Enable the organization to reallocate resources  
• Training |
Could we do this better internally?

- Testing
  - Real-time stability
  - Sterility
- Extended beyond use dating
- Labeling
  - Bar code
  - Color coding
  - Expanded content
  - Tall man lettering
Could outsourcing be safer?

<table>
<thead>
<tr>
<th></th>
<th>SELF-FILLED SYRINGES</th>
<th>PRE-FILLED SYRINGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of cases</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>Process steps</td>
<td>21</td>
<td>19</td>
</tr>
<tr>
<td>System vulnerabilities</td>
<td>21</td>
<td>8</td>
</tr>
<tr>
<td>Medications administered per case</td>
<td>9.6</td>
<td>10.3</td>
</tr>
</tbody>
</table>

Outsourcing Advantages

- Expertise
- Dedicated labor
- Proper facilities and equipment
- Free up pharmacy resources
ISMP Guideline for Safe Preparation of Compounded Sterile Preparations

• Outsourcing the preparation of Compounded Sterile Products (CSPs) is considered as an alternative to in-house compounding when:
  – The frequency of use for certain CSPs is very low, thus making it difficult to maintain staff competency for preparing the product
  – The volume of use for certain CSPs is high, and staff resources are limited, or unavailable and/or infrastructure is limited to prepare the quantity needed
  – The organization does not possess the technological or infrastructure resources to ensure the sterility of compounded products according to USP
  – A COMMERCIALLY-MANUFACTURED product is not available, including product shortages

Consolidated Service Center

- 503A
- Health system consolidation
- Deliver from central location
New Model – Centralized Compounding
New Model – Centralized Compounding
### Automation and Technology Used During Sterile Product Preparation - 2017

<table>
<thead>
<tr>
<th>Prevalence of Use and Types of Technology Used</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>No technologies used for sterile product preparation</td>
<td>64.0%</td>
</tr>
<tr>
<td>Barcode scanning to verify ingredients</td>
<td>29.6%</td>
</tr>
<tr>
<td>Gravimetric to verify dose, amount, and/or volume</td>
<td>5.5%</td>
</tr>
<tr>
<td>Robotic IV compounding device for non-hazardous agents</td>
<td>2.3%</td>
</tr>
<tr>
<td>Robotic IV compounding for hazardous agents</td>
<td>0.9%</td>
</tr>
<tr>
<td>IV workflow management software</td>
<td>12.8%</td>
</tr>
<tr>
<td>Pictures or video of compounding process</td>
<td>12.5%</td>
</tr>
</tbody>
</table>

IV Automation Considerations

- Workflow integration
- Production times
- Reduce staffing needs
- Space
- Regulatory compliance
- Interoperability

- Unintended consequences
- Capital funding
- Implementation costs
- Technology limitations
- No best practices
IV Workflow Systems

- The automated workflow management system intercepted 72.27% of the identified errors (mainly errors involving the use of an incorrect drug or diluent), with the remaining 27.73% detected by pharmacists.
- 49 self-reported versus 1,126 software-detected errors, demonstrating that reliance on human detection of errors is not sufficient.
- The average time spent per preparation was 14.2% higher when using the automated method compared with manual preparation.
- Study demonstrated a 37% reduction in pharmacist check time and 34% reduction in technician production time.

IV Workflow “Near Miss” Results

- Incorrect Drug
- Concentration Mismatch
- Product Is Expired
- Exact Drug Required
- Incorrect Diluent

Chart showing trends from December to April.
BEST PRACTICE 11:

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).
- Except in an emergency, perform this verification in all locations where compounded sterile preparations are made, including patient care units.
- At a minimum, perform this verification for all high-alert medications (including chemotherapy and parenteral nutrition), pediatric/neonatal preparations, pharmacy-prepared source/bulk containers, products administered via high-risk routes of administration (e.g., intrathecal, epidural, intraocular), and other compounded sterile preparations that the organization believes are high-risk.
- Use technology to assist in the verification process (e.g., barcode scanning verification of ingredients, gravimetric verification, robotics, IV workflow software) to augment the manual processes. It is important that processes are in place to ensure the technology is maintained, the software is updated, and that the technology is always used in a manner that maximizes the medication safety features of these systems.
IV ROBOTICS
IV Robotics

- Had a limited efficiency impact in practice. This solution, with its numerous limitations and technical difficulties, is not yet mature enough for universal adoption.
- Many mechanical or software failure events associated with robotic preparation that were not potentially harmful to patients but did affect workflow and resulted in some wasted medications.
- Provide a completely traceable product with known rather than assumed accuracy, and integrated in-process checks.


SMART INFUSION PUMPS
Smart Infusion Pumps

• The mean number of keystrokes needed to program an infusion was reduced from 15 to 2 (an 86% decrease) with system interoperability.
• During the study period, the overall rate of user compliance with the safety software was 78%.
• 97% of the errors resulted from user programming of doses or infusion rates above the hard limits defined in the smart pump drug library.
• Drug library update delays during the study period were substantial, with delay medians ranging from 22 to 192 days.

Poppe L, Eckel S. Evaluating an approach to improving the adoption rate of wireless drug library updates for smart pumps. Am J Health Syst Pharm. January 2011, 68 (2) 170-175
### IV Smart Pumps


<table>
<thead>
<tr>
<th>No. Staffed Beds</th>
<th>Smart Infusion Pumps Used</th>
<th>Smart Pumps Autopopulated With Prescribed Order and Patient Information From Electronic Health Record, Eliminating Need to Manually Select Drug and Infusion Rate During Setup</th>
<th>Wireless Pump Updates</th>
<th>Documentation Practices</th>
<th>Continuous Quality Improvement Logs Used</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>% Hospitals</td>
<td>n</td>
<td>% Hospitals</td>
<td>n</td>
</tr>
<tr>
<td>&lt;50</td>
<td>219</td>
<td>75.8</td>
<td>163</td>
<td>3.7</td>
<td>164</td>
</tr>
<tr>
<td>50-99</td>
<td>104</td>
<td>95.2</td>
<td>99</td>
<td>7.1</td>
<td>99</td>
</tr>
<tr>
<td>100-199</td>
<td>150</td>
<td>93.3</td>
<td>136</td>
<td>11.0</td>
<td>138</td>
</tr>
<tr>
<td>200-299</td>
<td>84</td>
<td>91.7</td>
<td>76</td>
<td>6.6</td>
<td>76</td>
</tr>
<tr>
<td>300-399</td>
<td>56</td>
<td>100</td>
<td>56</td>
<td>19.6</td>
<td>56</td>
</tr>
<tr>
<td>400-599</td>
<td>49</td>
<td>98.0</td>
<td>48</td>
<td>14.6</td>
<td>48</td>
</tr>
<tr>
<td>≥600</td>
<td>21</td>
<td>100</td>
<td>21</td>
<td>19.0</td>
<td>21</td>
</tr>
<tr>
<td>All hospitals—2017</td>
<td>683</td>
<td>88.1*</td>
<td>599</td>
<td>8.9*</td>
<td>602</td>
</tr>
</tbody>
</table>
Pharmacy Compounded

- GPO/340b pricing
- Disposables
- Labor investment
- Facilities
- Waste
- Testing costs
  - Product
  - Environmental
Manufacturer Ready to Use

- Including point-of-care activated

- GPO/340b pricing
- Shortages
- Ability to reuse
- Operational limitations (i.e. frozens)
- Staff training
  - Point of care activated
Non-pharmacy Compounded at Point of Care

- GPO/340b pricing
- Provider training
- Product shortages
- Error potential
Outsourced Ready to Use

• Associated costs
  – Material costs
  – Labor costs
  – Overhead costs
  – Safety costs
  – Compliance costs

• More expensive to do internally
  – Testing
  – Labeling
  – Medication safety/liability
  – Regulatory compliance
# Waste Reduction

<table>
<thead>
<tr>
<th></th>
<th>Phase I (baseline)</th>
<th>Phase II (PFS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Cases</td>
<td>154</td>
<td>171</td>
</tr>
<tr>
<td>Case w/ waste</td>
<td>110 (71%)</td>
<td>66 (38%)</td>
</tr>
<tr>
<td>Drug waste (mL)</td>
<td>3284.2 mL</td>
<td>1266.3 mL</td>
</tr>
<tr>
<td>Avg. waste per case</td>
<td>21.3 mL</td>
<td>7.4 mL</td>
</tr>
</tbody>
</table>

TOTAL WASTE REDUCTION WITH THE USE OF PFS

61%
Decision Analysis

- **Operational**
  - Preparation time
  - Storage requirements
  - Training
  - Beyond use dating
  - Administration time

- **Financial**
  - Cost
  - Waste
  - Facility remodeling

- **Staffing**
  - Reallocate resources
  - Labor shortages

- **Availability**
  - Drug shortages

- **Regulatory**
  - Compliance
  - Employee safety

- **Medication Safety**
  - Safety event
  - Look alike
  - Dose specific, ready to administer

- **Location**
  - Point of care
  - Geographic limitations

- **Shared risk**
Closing it Out

• **Is there a reliable role for IV automation?**
  – Pump interoperability, IV workflow, IV robotics

• **Financial decision-making**
  – Data & analytics
  – Would we make different decisions if pressed to cut costs
Closing it Out

• Top of mind
  – Pharmacy leadership, medication-use system specialists
  – Strategic priority for department

• Take to next level
  – Pharmacy technicians
  – IV automation