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

ISMP guidelines that support intravenous drug delivery system safety

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Sterile Compounding Errors and Patient Harm

- Significant patient safety incidents related to sterile compounding have occurred for years and continue to occur.
- Data submitted to the ISMP National Medication Errors Reporting Program (MERP) has repeatedly shown manual inspection of IV admixture ingredients is not a totally effective deterrent in preventing preparation and dispensing errors.
- Eighteen serious events reported to ISMP MERP.
  - Half of these patients died.
Risks and Failure Modes

• Through analysis of error reports, on-site risk assessments and root cause analyses, additional risks for compounding sterile preparation have been identified:

• Lack of standardization
• Lack of use of technology
• Poor environment
• Variability in practices
• Lack of an appreciation for the risk
  • How can that have happened?
  • Don’t you double check?

Image courtesy of Morguefile.com
Risk and Failure Modes

Trends in IV Workflow Automation Adoptions

Pharmacy Purchasing and Products State of Pharmacy Automation 2017
Risks and Failure Modes

• Poor environment

• Insufficient or inadequate workspace
• Counter preparation, staging, verification space
• Number and size of hoods
• Failing to provide adequate segregation of items contributes to mix-ups
• Temperature and lighting also a factor
Risks and Failure Modes

• **Variability in practices**

• Tremendous variation in:
  • Information available
  • Compounding processes
  • Documentation processes
  • Labeling procedures
  • Verification steps
Failure to Appreciate the Risk

• Lack of awareness

• Senior leadership
• Risk managers
• Pharmacists

• People more acutely aware of what they read or hear on the news
Guidelines in Place and Filling the Gaps

• A missing piece needing to be addressed

• ISMP guidelines to address the gaps (IV admixture error prevention)
  • 2016 revision to more strongly address use of emerging technologies
  • Coupled release of the guidelines with a new 2016-2017 ISMP Targeted Medication Safety Best Practices for Hospitals
Core Processes

- Policies and Procedures for Compounding Sterile Preparations
- Order Entry and Verification
- Drug Inventory Storage
- Assembling Products and Supplies for Preparation
- Compounding
- Drug Conservation
- Compounding Performed Outside the Pharmacy IV Admixture Service
- Preparation of Source/Bulk Containers
- Technology/Automation Used for Compounding CSPs
- Automated Compounding (Pumping) Systems
- Quality Control/Final Verification
- Product Labeling
- Staff Management
Compounding Outside the Pharmacy

- *Pharmacy Purchasing and Products 2016 State of Pharmacy Compounding*
  - 57% of facilities that allow nurse compounding have not invested resources into training

- The director of pharmacy is responsible for oversight and ongoing monitoring of CSP preparation occurring in any department within the institution

- Noted *at-risk* behaviors that must be avoided:
  - Preparing IV flush syringes from liter bags of IV solutions
  - Attaching administration sets to IV infusions hours in advance of infusion start time
  - Using prefilled saline flush syringes to reconstitute parenteral drugs, then drawing the medication back up into the prefilled syringe
  - Diluting prefilled syringes containing IV push medication unnecessarily
ISMP Survey on IV Push Medication Practices in Adults

- Conducted between July and August 2018
- 977 respondents
  - 93% nurses, rest advance practice nurses, nurse anesthetists, anesthesiologists, other physicians
- Respondents work in a wide variety of settings
  - Medical/surgical units (31%)
  - Critical care units (24%)
  - Surgical areas (13%)
  - ED (12%)
  - Obstetrics (7%)
  - Outpatient (4%)
  - Oncology (3%)
  - Other (6%)
Selected Survey Results

How often are IV push medications provided in pharmacy-prepared or commercially available ready-to-administer syringes?

- 75% reported less than half of the time
- Given the current drug shortage crisis:
  - 31% agree they have less prefilled, ready-to-use syringes than before
  - 31% agree they see more IV push drugs provided in unfamiliar formulations
  - 34% agree that they are required to prepare more IV push medications at the bedside
  - 38% agree that they are giving more medications via IV push that were previously given as infusions
Selected Survey Results

How often do you withdraw medications from one syringe (or cartridge) to another to administer some or all of an IV push medication dose?

- 16% reported more than half of the time (always and often)
- Another 20% reported sometimes

<table>
<thead>
<tr>
<th>Reason Why</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Need to dilute the drug</td>
<td>64</td>
</tr>
<tr>
<td>Cannot locate the designated holder</td>
<td>22</td>
</tr>
<tr>
<td>This is how I was taught</td>
<td>15</td>
</tr>
<tr>
<td>Too hard to read dose increments on medication syringe</td>
<td>14</td>
</tr>
<tr>
<td>Syringe has a unremovable needle or does not have needleless connector</td>
<td>14</td>
</tr>
<tr>
<td>Other (e.g., must use 10 mL syringe for central lines)</td>
<td>22</td>
</tr>
</tbody>
</table>
### Selected Survey Results

How often do you dilute medications?

<table>
<thead>
<tr>
<th>Container</th>
<th>Never/Rarely (%)</th>
<th>Sometimes (%)</th>
<th>Often/Always (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SDV</td>
<td>41</td>
<td>37</td>
<td>22</td>
</tr>
<tr>
<td>MDV</td>
<td>79</td>
<td>14</td>
<td>7</td>
</tr>
<tr>
<td>Prefilled syringes</td>
<td>84</td>
<td>11</td>
<td>5</td>
</tr>
<tr>
<td>Pharmacy-prepared syringes</td>
<td>95</td>
<td>4</td>
<td>2</td>
</tr>
</tbody>
</table>
Selected Survey Results

Why do you dilute IV push medications? (select all that apply)

<table>
<thead>
<tr>
<th>Reason</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slow administration; small drug volume</td>
<td>94</td>
</tr>
<tr>
<td>Reduce discomfort at injection site</td>
<td>70</td>
</tr>
<tr>
<td>Afraid of extravasation</td>
<td>33</td>
</tr>
<tr>
<td>Small dose/volume difficult to measure</td>
<td>25</td>
</tr>
<tr>
<td>Other</td>
<td>13</td>
</tr>
<tr>
<td>Examples of Other: Ativan requirements, hospital policy, drug reference recommendation, central lines, how taught, drug shortages (especially NS)</td>
<td></td>
</tr>
</tbody>
</table>
Selected Survey Results

How often do you use a prefilled 0.9% sodium chloride flush syringe to dilute, measure, and administer an IV push medication?

• 56% reported more than 50% of the time (always and often)
• Another 16% reported sometimes

• Three processes
  • Drug drawn directly into NS syringe
  • Drug withdrawn into syringe first, then added to NS syringe
  • Drug and NS (from prefilled syringe) drawn into separate syringe

• Most often, the syringe is not relabeled or labeled
Selected Survey Results

How often do you label IV push syringes that you prepare away from the patient’s bedside?

- 28% reported **less than 10% of the time**
- Only **50% reported always**
- Lot of “labeling” appears to be taping of vial to syringe

<table>
<thead>
<tr>
<th>Reason Why</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not necessary if preparing just 1 drug</td>
<td>51</td>
</tr>
<tr>
<td>Not necessary if preparing just 1 syringe</td>
<td>45</td>
</tr>
<tr>
<td>Emergency</td>
<td>39</td>
</tr>
<tr>
<td>Too time consuming</td>
<td>20</td>
</tr>
<tr>
<td>No labels</td>
<td>20</td>
</tr>
<tr>
<td>Not an expectation in my facility</td>
<td>12</td>
</tr>
<tr>
<td>Can distinguish by appearance/location</td>
<td>7</td>
</tr>
</tbody>
</table>
## Selected Survey Results

How do you distinguish between two or more unlabeled syringes?

<table>
<thead>
<tr>
<th>Method</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Know what the syringes contain because they have different volumes</td>
<td>76</td>
</tr>
<tr>
<td>Use different size syringes</td>
<td>40</td>
</tr>
<tr>
<td>Separate syringes in hands or use different clothing pockets</td>
<td>24</td>
</tr>
<tr>
<td>Place syringes on tray or sterile field a certain way</td>
<td>16</td>
</tr>
<tr>
<td>Mark one of the syringes with a marker</td>
<td>12</td>
</tr>
<tr>
<td>Other</td>
<td>36</td>
</tr>
<tr>
<td>Examples of Other: Visual appearance such as color, needle differences, color-coded tape</td>
<td></td>
</tr>
</tbody>
</table>