Multiple Intravenous Infusions
Phase 1a: Situation Scan Summary Report

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Delivered To
Ontario Health Technology Advisory Committee

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University Health Network

In Collaboration With
Institute for Safe Medication Practices Canada

Funded and Supported By
The Ontario Ministry of Health and Long Term Care
Executive Summary

Patient care, particularly in critical care environments, often requires multiple intravenous (IV) infusions. Minimal research has been found that explicitly addresses the topic of multiple infusion safety, but anecdotal incident reports, related literature and discussions with clinical experts suggest that errors happen frequently, some with the potential to cause serious patient harm or even death.

This report describes the findings of Phase 1a of the Multiple IV Infusions study, aimed at investigating risks associated with administering multiple infusions and mitigation strategies. The following results were found:

• Systematic review of the literature: No literature was found that comprehensively identified the risks or risk mitigating strategies of multiple IV infusions. Mitigating strategies that were uncovered in the literature were not validated.

• Multiple database incident report analysis: A relevant sample of reports from the U.S. Food and Drug Administration’s (FDA) manufacturer and user facility device experience (MAUDE) database and the ISMP Canada medication incident database indicated that patient harm was associated with a high percentage of incidents when multiple IV infusions were involved. Incidents were associated with a wide range of components of the IV system.

• Technology scan: Information from vendors indicated that three major manufacturers dominate the large volumetric IV infusion pump market in Ontario. Increasingly stringent regulations by the FDA, and more popular market demands will likely delay progress on new innovations related to multiple IV infusion safety.

Based on the findings from all three methods, a list of issues and associated mitigation strategies was compiled. The effectiveness of each mitigation strategy has not yet been evaluated.

In summary, the findings to date confirm that multiple IV infusions present numerous risks to patient safety, but further research is required to understand the feasibility and effectiveness of potential mitigating strategies. The research team intends to examine various strategies in detail, in order to determine which are the most effective in reducing risk.

The next report from the study team is estimated to be delivered in March 2011.
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<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
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<tbody>
<tr>
<td>DERS</td>
<td>Dose Error Reduction System</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>GRADE</td>
<td>Grades of Recommendations, Assessment, Development and Evaluation</td>
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<td>HTSRT</td>
<td>Health Technology Safety Research Team</td>
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<tr>
<td>ISMP Canada</td>
<td>Institute for Safe Medication Practices Canada</td>
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<tr>
<td>IV</td>
<td>Intravenous</td>
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<tr>
<td>MAUDE</td>
<td>Manufacturer and User Facility Device Experience</td>
</tr>
<tr>
<td>MAS</td>
<td>Medical Advisory Secretariat</td>
</tr>
<tr>
<td>MOHLTC</td>
<td>Ministry of Health and Long Term Care</td>
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<td>OHTAC</td>
<td>Ontario Health Technology Advisory Committee</td>
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<td>TPN</td>
<td>Total Parenteral Nutrition</td>
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<td>UHN</td>
<td>University Health Network</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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</table>
Background

Patient care, particularly in critical care environments, often requires multiple intravenous (IV) infusions. Clinicians can use several methods to infuse two or more IV drugs or fluids via infusion pumps (Table 1). These methods are often combined as patients may receive as many as 10 to 15 infusions at one time.

### Table 1: Methods of Administering Multiple Line Infusions

| Figure 1: Sequential Infusion | • Also referred to as a “piggyback” or “secondary” infusion  
| | • Two IV fluids are infused through the same channel of an infusion pump  
| | • IV bags are hung at different heights so that the higher bag infuses first  
| | • Only requires single pump and single patient access site  
| | • Can lead to:  
| | o Accidental mixing and concurrently delivering two fluids due to misaligned drug bags and/or no check-valve  
| | o Accidental administration of wrong fluid due to failure to open a roller clamp  
| | o Free-flow infusions due to incorrect tubing setup  
| | • The use of a secondary line to administer a continuous infusion can lead to delays in drug reaching patient upon initiation, or delay in discontinuation and rapid infusion of residual volume once primary infusion initiated |

| Figure 2: Concurrent Infusions On Multiple Pump Channels | • Concurrent infusion using separate channels on the same IV pump  
| | • Each IV fluid has a separate, dedicated channel of one pump unit.  
| | • Setup requires less space than multiple infusion pumps  
| | • Multiple channel or multiple module pump must be available in the hospital  
| | • Can cause wrong drug to be programmed due to a physical mix-up of infusion lines when setting up pumps |

| Figure 3: Concurrent Infusions with Multiple Pumps | • Concurrent infusion using multiple pumps  
| | • Each IV fluid has its own physically separate pump unit  
| | • Provides clinicians with flexibility in the placement of IV pumps  
| | • Requires more space and more pumps than sequential infusions |

Although little research has been explicitly conducted on the topic of multiple infusion safety, some studies have shown a high frequency of potentially serious use errors1,2. Anecdotal
incident reports, indirectly related literature and discussions with clinical experts all support this finding.

While large volume IV infusion pumps present opportunities for use-error with harmful consequences, they possess a number of advantages compared to gravity infusions (i.e., no pump used) and should continue to be used as the safest form of IV therapy. Infusion pumps offer increased control and accuracy of fluid flow, and possess the ability to detect or prevent other serious errors (e.g., occlusions, air in tubing, free flow). Given the potency of high alert medications and their critical role in maintaining important physiological parameters, the benefits of infusion pumps outweigh the risks of their use.

Scope
This project will investigate risks associated with administering multiple IV infusions on large volumetric IV infusion pumps in the province of Ontario, with the aim of identifying mitigating strategies to reduce the identified risks.

Inclusions:
- Administration of multiple fluids intravenously (e.g., hydration, blood and blood products, total parenteral nutrition, intravenous drugs)
- Large volume IV infusion devices
  - single and multiple channel
  - with and without dose error reduction systems (DERS)
- IV pump-related device accessories (e.g., tubing, clamps, poles)

Exclusions*:
- Epidural, syringe, patient controlled analgesia (PCA), enteral feeding, ambulatory, elastomeric, magnetic resonance imaging (MRI) compatible, or insulin pumps
- Arterial infusions
- Admixture and reconstitution of drugs by nursing staff
- Infusions by gravity
- Creating a specific pump design
- Investigating pharmaceutical interactions and pharmacokinetics

This project is being completed in four phases (Table 2).

<table>
<thead>
<tr>
<th>TABLE 2: PROJECT PLAN</th>
<th>Anticipated Report Completion</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Project Phase</strong></td>
<td><strong>Research Activity</strong></td>
</tr>
<tr>
<td></td>
<td>A systematic review of existing relevant literature.</td>
</tr>
<tr>
<td></td>
<td>Incident databases review.</td>
</tr>
<tr>
<td></td>
<td>Interviews with infusion pump manufacturers (to determine their current and future status with respect to risk mitigation strategies for multiple IV infusions).</td>
</tr>
<tr>
<td><strong>Phase 1b: Practice Scan</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Interviews with nurse educators (to determine the nature and comprehensiveness of education and training of nursing staff around the administration of multiple IV infusions, both in academic institutions and in-service training).</td>
</tr>
<tr>
<td></td>
<td>Ontario-wide field observations (to understand</td>
</tr>
</tbody>
</table>

*If components or topics listed as exclusions are found to influence the administration of IV fluids, they will be investigated in the context of multiple IV infusions.
This report summarizes the findings of Phase 1a: Situation Scan with the aim of:
• Providing an initial overview of the composition, severity and mitigating strategies for multiple IV infusion errors.
• Identifying the key risks and dangers.
• Prioritizing the topics to explore in future phases.

Methods & Results

Literature Review

A systematic review of relevant literature on multiple IV infusions was conducted (Appendix 1: Literature Review Search Terms) to answer three research questions:

1. What risks are associated with the administration of multiple IV infusions?
2. What risk mitigating strategies have been reported or discussed in the literature in regards to multiple IV infusions?
3. What is the effectiveness of the risk mitigating strategies identified in the literature?

Sixteen articles were found in the literature that met the inclusion criteria (Table 3). The literature addressing the first two questions was exploratory in nature and utilized methods such as incident reporting, task observations, and expert consensus. Given the nature of these studies, it was not appropriate to evaluate this body of literature with the GRADE (Grades of Recommendation, Assessment, Development and Evaluation) methodology.

GRADE was used to evaluate studies that addressed the effectiveness of risk mitigating strategies. Only one study was identified and GRADED as low quality evidence due to serious limitations in study quality and sparse data (Appendix 2: Quality of Evidence - GRADE Methodology).
The literature confirms that there are a number of concerns related to the administration of multiple IV infusions. However, no articles addressed the topic of multiple IV infusions in a thorough and systematic manner. Literature often approached the topic tangentially (e.g., misconnections, pump implementation projects, case reports) or addressed limited aspects (e.g., sequential infusions only). In addition, no sources reviewed all risk-mitigating strategies present in the literature.

### Multiple Database Incident Report Analysis

A review of relevant incident reports from the FDA MAUDE and ISMP Canada Medication Incident Report databases was conducted to:

- Provide a comprehensive survey of clinical incidents involving multiple IV infusions.
- Understand factors that contribute to such incidents.
- Identify relative severity of safety hazards.

Relevant incident reports were filtered using key search terms (Appendix 3: Incident Database Search Terms). Independent teams of researchers analyzed each database. Inter-rater reliability was established so the databases could be divided amongst the individuals of each team (Team 1 kappa = 0.63 and Team 2 kappa = 0.78). Due to the relatively large size of the FDA MAUDE database, the search terms were only run for one year (2008) of incident reports, whereas the entire ISMP Canada database was searched on May 13, 2010, which at the time, spanned incidents occurring from May 2000 to April 2010.

A common coding scheme was used over two passes of the data. The first pass was on the applicability of the cases returned by the search, and the second pass was used to categorize the applicable reports on error type.

The FDA MAUDE 2008 database search returned 3486 incidents, and the ISMP Canada medication incident database returned 1320 incidents with 211 and 424 incidents relevant to multiple IV infusions, respectively. For a direct year to year comparison, ISMP Canada’s database for the year of 2008 returned 215 reports, with 65 being coded relevant. The following analysis utilizes all 10 years of ISMP Canada data, but no major differences were observed when only 2008 data was used (Appendix 4: Comparison of ISMP Canada Incident Report Data between Ten Year Range and 2008 Only)

Analysis of the incidents illustrate that they occur with all methods of administration (i.e., sequential (piggyback), concurrent, and a combination of both; see Figure 4). Errors can also be attributed to all components of the infusion system (e.g., pump, tubing, IV bag, IV access site) (Figure 5). Incidents reported to the FDA MAUDE database highlight that, when incidents occur, patients often experience harm (Figure 6).
FIGURE 4: BREAKDOWN COMPARISON OF ADMINISTRATION METHODS FROM FDA MAUDE AND ISMP CANADA DATABASES

FIGURE 5: BREAKDOWN COMPARISON OF IV COMPONENT CATEGORIES IN FDA MAUDE AND ISMP CANADA DATABASES
To establish the key multiple infusion-related risks, current risk mitigating strategies, and future product development associated with infusion technologies, a technology scan was conducted (Figure 8). It focused on large volumetric IV infusion pumps currently used or for sale in Ontario, and infusion accessories (e.g., IV poles, racks, connectors and lines).

**Technology Scan**
Three major manufacturers (Baxter, Carefusion/Cardinal, and Hospira) dominate the Ontario healthcare market for both traditional and smart infusion pumps. The other manufacturers have a comparatively small amount (B.Braun and Smiths) or no market share (Sigma, distributed by Baxter) (Appendix 5: Large Volume Infusion Pump Use in Ontario Healthcare Organizations).

While large volume IV infusion pumps share the same basic workflow, variations exist in the programming sequence. This variation can influence the degree of complexity of the user-pump interaction. The complexity is magnified when multiple infusions and various therapies (i.e., bolus, secondary, titration) are used. The complexity of different workflows and their impact on use errors will be studied in subsequent phases of the research.

Although all the vendors shared ideas on how the management of multiple IV infusions might be improved, as well as some of their internal research and development targeted towards multiple infusion risks, they indicated that this issue is currently not high-priority enough to warrant focus for upcoming product launches. They indicated that they are currently focused on the new submission requirements from the FDA.

**Summary of Multiple IV Infusion Issues and Mitigating Strategies**

Six categories of risks associated with multiple IV infusions have been identified:

1. Cross Component Mix-ups
2. IV Pole
3. IV Bag
4. IV Tubing
5. IV Pump
6. IV Access Site

These categories correspond with the location in the infusion system where incidents originate, with the exception of the first category which refers to mix-ups between multiple infusion components.
Each issue was assigned a risk rating (Table 4) and was analyzed to determine if it could occur with sequential and/or concurrent infusions (Table 5). Mitigating strategies currently used by some institutions or suggested (as based on the technology scan and literature review) were also identified.

**TABLE 4: ISSUE RISK RATING LEGEND**

<table>
<thead>
<tr>
<th>Issue Risk Rating</th>
<th>Definition</th>
<th>Total number of issues identified</th>
</tr>
</thead>
<tbody>
<tr>
<td>🚨 High</td>
<td>Issues that have direct patient safety impact. Note: this includes situations when users are unaware of the infusion pump status (e.g., whether the infusion is running or stopped).</td>
<td>11</td>
</tr>
<tr>
<td>🔄 Medium</td>
<td>Issues that have a potential indirect patient safety impact. That is, these issues need to be combined with other errors to impact patient safety.</td>
<td>8</td>
</tr>
<tr>
<td>🅿️ Low</td>
<td>Issues that led to user frustration and/or inefficiencies but will have a small likelihood of patient safety impact.</td>
<td>6</td>
</tr>
</tbody>
</table>
### Table 5: Issues with Multiple Infusions

<table>
<thead>
<tr>
<th>Issue</th>
<th>Multiple Infusions</th>
<th>Potential Mitigating Strategies*</th>
</tr>
</thead>
</table>
| 1. Cross Component Mix-Ups                                             | ✓ ✓                | • Use bar code enabled pumps to verify correct patient, drug, concentration and programming parameters  
• Use pumps that detect repeated programming of same drug on multiple channels (e.g., duplicate drug, alarm)  
• Use pumps that can verify if IV bag is connected to correct channel by detecting back pressure when the user squeezes the desired IV bag  
• Use channel labels on pump channels  
• Use pumps that alarm when tubing is misloaded  
• Colour code infusion lines or coloured labels  
• Drug labels on tubing above and below the pump  
• Use pumps that are coloured differently depending on their function  
• Distinguish pump type by where it is placed near the patient (e.g., at feet or at head). This also implies that IV tubing is routed in directions standard directions based on where pumps are typically placed.  
• Use Tubing Separators  
• Use different pumps for different infusion types  
• Use a single pump model for each infusion type (e.g., large volume and syringe)  
• Avoid removing tubing from pump unless necessary  
• Program multiple pumps or multiple channels in a sequence that reduces confusion (e.g., left to right rather than randomly) |
| 1.1 IV drug may not be infused properly due to system mix-up error (e.g., wrong tubing/bag, channel, or pump) | ✓ ✓                | • Use pumps that detect repeated programming of same drug on multiple channels (e.g., duplicate drug, alarm)  
• Colour coded infusion lines or coloured labels  
• Use coloured tubing and coloured connectors to facilitate connector to connector matching  
• Use pumps that are coloured differently depending on their function  
• Distinguish pump type by where it is placed near the patient (e.g., at feet or at head). This also implies that IV tubing is routed in directions standard directions based on where pumps are typically placed.  
• Use different pumps for different infusion types  
• Instruct non-clinicians to not reconnect lines  
• Avoid buying equipment that can connect to IV systems, despite being intended for dissimilar purpose (e.g., avoid adapters, or connectors that mate with other connectors that they should not be attached to) |
| 1.2 IV bag is the wrong medication/fluid due to bag mix-ups.           | ✓ ✓                |                                  |
| 1.3 IV bags and tubing may be                                        | ✓                  | • Use Tubing Separators          |

*All mitigating strategies listed in Table 5 (pages 14 to 17) represent strategies identified in the literature review and technology scan. They have not been validated and do not represent recommendations by the research team. Further research to identify and validate appropriate mitigating strategies is needed.
<table>
<thead>
<tr>
<th>Issue</th>
<th>Multiple Infusions</th>
<th>Potential Mitigating Strategies*</th>
</tr>
</thead>
<tbody>
<tr>
<td>misaligned to pumps/channels.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| **1.4 ▶ IV tubing is connected to other tubing incorrectly, or to tubing it should not be connected to.** | ✓                  | • Connectors with distinct physical appearances  
• Connectors with locking mechanisms  
• Use pumps that can verify that IV bag is connected to the correct channel by detecting back pressure when the user squeezes the desired IV bag |
| **2.1 ▶ IV pole may be unstable when multiple pumps/modules are attached** | ✓                  | • Clear feedback provided to users when pumps are mounted on pole correctly  
• Consider context of use when designing device orientation  
• Purchase IV pole based on the pump’s unique form factor  
• Purchase IV pole based on unique clinical area needs  
• Use IV stands/poles that are designed to support IV pump equipment, rather than gravity infusions. |
| **2.2 ▶ Numerous IV pump power and communication cords clutter clinical environments and may contribute to pump power and communication problems and/or cause tipping hazards** | ✓                  | • Use IV poles which provide power sockets on the pole |
| **3.1 ▶ IV bag is labeled incorrectly causing misinterpretation of bag contents and/or dose rate.** | ✓                  | • Integrate CPOE and BCMA information systems to allow verification of barcode information against doctor’s original order |
| **3.2 ▶ Insufficient pressure differential between the primary IV infusion container and secondary infusion container.** | ✓                  | • Use pumps that allow administration of sequential infusions without a differential in bag height  
• Use pumps that prompt users to lower primary IV bag and open clamp when administering sequential infusions |
| **4.1 ▶ IV tubing clamps may be in the wrong position (e.g., open, closed, or partially open).** | ✓                  | • Use pumps that can verify that IV bag is connected to the correct channel by detecting back pressure when the user squeezes the desired IV bag  
• Double check the status of clamps |
<table>
<thead>
<tr>
<th>Issue</th>
<th>Multiple Infusions</th>
<th>Potential Mitigating Strategies</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.2</td>
<td>❌</td>
<td>❌</td>
</tr>
<tr>
<td>4.3</td>
<td>❌</td>
<td>❌</td>
</tr>
<tr>
<td>4.4</td>
<td>❌</td>
<td>❌</td>
</tr>
<tr>
<td>4.5</td>
<td>❌</td>
<td>❌</td>
</tr>
<tr>
<td>4.6</td>
<td>❌</td>
<td>❌</td>
</tr>
</tbody>
</table>

4. IV Pump

| 5.1   | ❌ | ❌  | • Pumps can be programmed with the wrong infusion type on one channel. |
| 5.2   | ❌ | ❌  | • Use pumps that allow switching between infusion modes in an appropriate fashion. For example, the mode switch key should not share functionality with other commonly used functions (e.g., "confirm"). |
| 5.3   | ❌ | ❌  | • Use separate single channel pumps for high alert drugs |
| 5.4   | ❌ | ❌  | • Use pumps that do not allow information mismatches between primary and secondary infusion modes |

• Modular or multiple channel pumps may experience a single point of failure affecting all infusions running.
<table>
<thead>
<tr>
<th>Issue</th>
<th>Multiple Infusions</th>
<th>Potential Mitigating Strategies*</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.5</td>
<td><img src="/checkmark" alt="Checkmark" /></td>
<td>• Pump histories display volume history by drug infused</td>
</tr>
<tr>
<td>5.6</td>
<td><img src="/checkmark" alt="Checkmark" /></td>
<td></td>
</tr>
<tr>
<td>5.7</td>
<td><img src="/checkmark" alt="Checkmark" /></td>
<td></td>
</tr>
<tr>
<td>5.8</td>
<td><img src="/checkmark" alt="Checkmark" /></td>
<td></td>
</tr>
</tbody>
</table>
| 6.1   | ![Checkmark](/checkmark) | • Use pumps that are coloured differently depending on their function  
• Distinguish pump type by where it is placed near the patient (e.g., at feet or at head). This also implies that IV tubing is routed in directions standard directions based on where pumps are typically placed.  
• Use clinical advisories in smart infusion pumps to remind users of the correct IV access site to use based on the infusion therapy  
• Label the catheter (e.g., epidural, intrathecal, arterial etc.)  
• Use different pumps for different infusion types  
• Instruct non-clinicians to not reconnect lines  
• Avoid buying equipment that can connect to IV systems, despite being intended for dissimilar purpose (e.g. avoid adapters, or connectors that mate with other connectors that they should not be attached to)  
• Don’t use catheters that have injection ports |
| 6.2   | ![Checkmark](/checkmark) | • Positive pressure mechanical valves |
| 6.3   | ![Checkmark](/checkmark) | • Connectors with distinct physical appearances  
• Connectors with locking mechanisms |
Recommendations

The findings presented in this report highlight that the administration of multiple infusions poses serious patient safety risks. Risk stems from all components of the system and all methods of administration. Eleven serious safety issues were identified and a wide range of mitigating strategies for all the issues described is available. However, the extent to which each mitigating strategy has been implemented in Ontario, and the effectiveness, availability, and associated costs has not been studied.

The recommendations to OHTAC based on this phase of the research are to further investigate:

1. The factors contributing to the issues identified in this report.

2. The level of implementation, effectiveness, availability, and costs of known mitigating strategies.

3. New mitigating strategies where current mitigating strategies prove to be inadequate.

Until the above questions are addressed, there are no specific recommended actions for Ontario health care organizations to reduce the risks associated with multiple IV infusions.
References


Appendix 1: Literature Review Search Terms

The systematic literature review was a comprehensive literature search for peer-reviewed journal studies, meta-analyses, literature reviews, review papers, patents, news articles, and accredited websites, blogs, and discussion boards using a specific set of search terms.

The electronic databases searched (search terms described in footnotes) included Ingenta Connect (1993-2010), INAHTA.org (2000-2010), EMBASE (2000-2011), OVID MEDLINE (1950-2010), CINAHL (1982 to 2010), Cochrane, ACP Journal Club, Database of Abstracts of Review of Effects (DARE), Health Business (1933-2010), Google Scholar, Google, ISMP Canada, ISMP U.S., and PubMed. The bibliographic references of particular studies were also searched. After a review of the title and abstracts, relevant studies were obtained and the full report evaluated. All studies were filtered through inclusion and exclusion criteria to determine which would be retained.

Inclusion and Exclusion Criteria

All items returned from the search (e.g., Meta-analysis/research studies/Lit reviews/review articles/medical websites/patents) were reviewed. Studies that contained discussion regarding the following themes were retained:

1) Multiple infusions or IVs
2) Piggyback
3) Secondary infusion or IV
4) Secondary line
5) Multiple lines

However, reports that solely focused on the topics below and failed to possess a component of any of the inclusion criteria categories listed above were excluded.

1) Medication error
2) Single infusion or IV
3) Primary line
4) General infusions or IV safety or education

---

1 (piggyback OR "secondary line" OR "multiple infusion" OR "secondary infusion") AND error
2 Eight search phrases were individually searched: "piggyback infusion", "piggyback IV", "multiple infusion", "multiple i.v.", "secondary line", "secondary infusion", "multiple lines", "infusion error"
3 "piggyback infusion" OR "secondary line" OR "secondary infusion" OR "infusion error" OR "multiple infusion" OR "multiple line" OR "multiple i.v.",
4 Seven search phrases were individually searched: "piggyback infusion", "multiple infusion", "multiple i.v.", "multiple lines", "secondary infusion", "secondary i.v.", "infusion error"
5 Four search phrases were individually searched: "piggyback infusion", "multiple infusion error", "multiple IV error", "secondary infusion error"
6 Manual Search
Appendix 2: Quality of Evidence - GRADE Methodology

One study was found in the literature that addressed the effectiveness of a risk mitigating strategy and was therefore appropriate to be rated by GRADE. The quality of the study was evaluated using the GRADE Working Group criteria in which quality refers to factors such as the strength of the study design (i.e., effective randomization, allocation concealment, sample size, blinding etc.) and consistency of results across multiple studies[^20].

The GRADE Working Group uses the following definitions in grading the quality of the evidence:

- **High**: Further research is very unlikely to change confidence in the estimate of effect.
- **Moderate**: Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.
- **Low**: Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate.
- **Very Low**: Any estimate of effect is very uncertain.

While outcomes of interest are typically determined by the research questions in advance of the literature review, this was not possible as the study team relied on the literature to establish what outcomes were relevant. As such, outcomes of interest were not selected until after the research team had found what risk mitigating strategies had been studied.

One study was identified that tested the effectiveness of a colour coded labeling method in a simulated environment on several measures. These outcomes of interest included the time to:

1. Identify a syringe with a specific drug and dosage from among several on a table.
2. Label an IV bag and its tubing and connect it to a simulated patient (mannequin).
3. Identify the correct syringe pump to change a dosage.
4. Identify a peripheral vein.
5. Identify and describe all drugs and tubing associated with the simulated patient.
6. Detect a mismatch between the pump label and tubing label.

Given the lack of additional studies on the outcomes above, and serious methodological limitations, the quality of evidence is rated low (Table 6), which indicates that the estimate of effect is uncertain.

<table>
<thead>
<tr>
<th>Number of Studies</th>
<th>Design</th>
<th>Limitations</th>
<th>Consistency</th>
<th>Directness</th>
<th>Imprecision</th>
<th>Other Modifying factors</th>
<th>Overall Quality of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>RCT (crossover)</td>
<td>Serious Limitations*</td>
<td>N/A</td>
<td>No serious indirectness</td>
<td>Serious limitations†</td>
<td>None</td>
<td>Low</td>
</tr>
</tbody>
</table>

* lack of blinding, lack of allocation concealment, randomization issues, no power calculation and small study size, confounding (due to learning effect between control and intervention beds)

† Sparse data as only one study
Appendix 3: Incident Database Search Terms

<table>
<thead>
<tr>
<th>IV Therapy (Part 1)</th>
<th>IV Equipment or Material (Part 2)</th>
<th>Incident descriptors (Part 3)</th>
<th>Primary Keywords</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;* IV *&quot;</td>
<td>&quot;* LABEL &quot;</td>
<td>&quot;* DOSE *&quot;</td>
<td>&quot;* INFUSIONS *&quot;</td>
</tr>
<tr>
<td>&quot;* I.V *&quot;</td>
<td>&quot;* BAG *&quot;</td>
<td>&quot;* ERROR *&quot;</td>
<td>&quot;* PIGGYBACK *&quot;</td>
</tr>
<tr>
<td>&quot;* INTRAVENOUS *&quot;</td>
<td>&quot;* PORT *&quot;</td>
<td>&quot;* ENTER *&quot;</td>
<td>&quot;* DRIPS *&quot;</td>
</tr>
<tr>
<td>&quot;* INFUS *&quot;</td>
<td>&quot;* PUMP *&quot;</td>
<td>&quot;* LABEL *&quot;</td>
<td>&quot;* IVS *&quot;</td>
</tr>
<tr>
<td>&quot;* PIV *&quot;</td>
<td>&quot;* SET *&quot;</td>
<td>&quot;* RATE *&quot;</td>
<td>&quot;* TUBINGS *&quot;</td>
</tr>
<tr>
<td>&quot;* PCA *&quot;</td>
<td>&quot;* CATHERETER *&quot;</td>
<td>&quot;* SET *&quot;</td>
<td>&quot;* PUMPS *&quot;</td>
</tr>
<tr>
<td>&quot;* VTBI *&quot;</td>
<td>&quot;* CONNECT *&quot;</td>
<td>&quot;* INJ *&quot;</td>
<td></td>
</tr>
<tr>
<td>&quot;* PCEA *&quot;</td>
<td>&quot;* TUBING *&quot;</td>
<td>&quot;* INJECT *&quot;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&quot;* LINE *&quot;</td>
<td>&quot;* CONNEXT *&quot;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&quot;* FLUID *&quot;</td>
<td>&quot;* INCIDENT *&quot;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&quot;* CHANNEL *&quot;</td>
<td>&quot;* FLOW *&quot;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&quot;* BOTTLE *&quot;</td>
<td>&quot;* PRIMARY *&quot;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&quot;* PICC *&quot;</td>
<td>&quot;* SECONDARY *&quot;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&quot;* CLAMP *&quot;</td>
<td>&quot;* SPINAL *&quot;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&quot;* POLE *&quot;</td>
<td>&quot;* CHANNEL *&quot;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&quot;* CVAD *&quot;</td>
<td>&quot;* CENTRAL *&quot;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&quot;* CVL *&quot;</td>
<td>&quot;* CONTINUOUS *&quot;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&quot;* MODULE *&quot;</td>
<td>&quot;* 2ND *&quot;</td>
<td></td>
</tr>
</tbody>
</table>

"* TUBING *"         | "* INCIDENT *"                   | "* BOLUS *"                 |
|                     |                                 | "* MAINT *"                 |
|                     |                                 | "* VOLUME *"                |
|                     |                                 | "* PRIMARY *"               |
|                     |                                 | "* SECONDARY *"             |
|                     |                                 | "* SPINAL *"                |
|                     |                                 | "* CENTERAL *"              |
|                     |                                 | "* CONTINUOUS *"            |
|                     |                                 | "* 2ND *"                   |

"* BOTTLE *"         | "* DOSE *"                       | "* BOLUS *"                 |
|                     |                                 | "* MAINT *"                 |
|                     |                                 | "* VOLUME *"                |
|                     |                                 | "* PRIMARY *"               |
|                     |                                 | "* SECONDARY *"             |
|                     |                                 | "* SPINAL *"                |
|                     |                                 | "* CENTERAL *"              |
|                     |                                 | "* CONTINUOUS *"            |
|                     |                                 | "* 2ND *"                   |

"* TUBING *"         | "* INCIDENT *"                   | "* BOLUS *"                 |
|                     |                                 | "* MAINT *"                 |
|                     |                                 | "* VOLUME *"                |
|                     |                                 | "* PRIMARY *"               |
|                     |                                 | "* SECONDARY *"             |
|                     |                                 | "* SPINAL *"                |
|                     |                                 | "* CENTERAL *"              |
|                     |                                 | "* CONTINUOUS *"            |
|                     |                                 | "* 2ND *"                   |

"* TUBING *"         | "* INCIDENT *"                   | "* BOLUS *"                 |
|                     |                                 | "* MAINT *"                 |
|                     |                                 | "* VOLUME *"                |
|                     |                                 | "* PRIMARY *"               |
|                     |                                 | "* SECONDARY *"             |
|                     |                                 | "* SPINAL *"                |
|                     |                                 | "* CENTERAL *"              |
|                     |                                 | "* CONTINUOUS *"            |
|                     |                                 | "* 2ND *"                   |
Appendix 4: Comparison of ISMP Canada Incident Report Data between Ten Year Range and 2008 Only

No major differences were observed in the composition and characteristics of incident reports from the ISMP Canada database when the date range of incident reports retrieved was altered. As the figures below indicate, ten years of ISMP Canada data (2000 – 2010) is similar to data retrieved from 2008 only. The FDA MAUDE data presented in this study relies on a single year of data from 2008. Given the similarity of the figures below, there is minimal risk that the usage of ten years of ISMP Canada data impacted its relevance when being compared to a single year of FDA MAUDE data.

Figure 10: Breakdown Comparison of Administration Methods from ISMP Canada Database (2000-2010 vs. 2008)

Figure 11: Breakdown Comparison of IV Component Categories from ISMP Canada Databases (2000-2010 vs. 2008)
**Figure 12: Composition of Patient Impact in ISMP Canada Database (2000-2010)**

- **No Harm**: 73%
- **Unknown**: 6%
- **Harm**: 11%
- **Hazardous**: 3%
- **Near Miss**: 7%
- **Mild Harm**: 7%
- **Moderate Harm**: 1%
- **Death**: 3%

**Figure 13: Composition of Patient Impact in ISMP Canada Database (2008)**

- **No Harm**: 81%
- **Harm**: 11%
- **Hazardous**: 3%
- **Near Miss**: 5%
- **Mild Harm**: 9%
- **Death**: 2%
## Appendix 5: Large Volume Infusion Pump Use in Ontario Healthcare Organizations

### Table 8: Dominant Large Volume Infusion Pump Use in Ontario Healthcare Organizations

<table>
<thead>
<tr>
<th>Vendor</th>
<th>Product Name</th>
<th># of channels</th>
<th>Date first licensed in Canada</th>
<th>Approx # pumps in Ontario</th>
<th>Approx # Ontario Orgs</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baxter Healthcare Corp.</td>
<td>Colleague</td>
<td>1 or 3</td>
<td>Dec 1998</td>
<td>Not provided</td>
<td>3400</td>
<td>Not provided</td>
</tr>
<tr>
<td></td>
<td>Flo-Gard</td>
<td>1 or 2</td>
<td>Sept 1999</td>
<td>Not provided</td>
<td>--</td>
<td>Not provided</td>
</tr>
<tr>
<td></td>
<td>Sigma International: Spectrum</td>
<td>1</td>
<td>Oct 2008</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>B.Braun</td>
<td>Space infusion system - infusomat space</td>
<td>1</td>
<td>Nov 2006</td>
<td>0</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td></td>
<td>Outlook safety infusion system/Horizon</td>
<td>1</td>
<td>Feb 2002 (Horizon: Sept 1999)</td>
<td>0</td>
<td>200</td>
<td>200</td>
</tr>
<tr>
<td>Carefusion/Cardinal Health</td>
<td>Alaris SE</td>
<td>1 or 2</td>
<td>Sept 1999</td>
<td>430</td>
<td>370</td>
<td>800</td>
</tr>
<tr>
<td></td>
<td>Alaris patient care system</td>
<td>Upto 4</td>
<td>Sept 1999</td>
<td>0</td>
<td>2700</td>
<td>2700</td>
</tr>
<tr>
<td>Hospira Inc.</td>
<td>Plum A+, 1.6 and XL.</td>
<td>1 or 3</td>
<td>Apr 1999</td>
<td>2400</td>
<td>3100</td>
<td>5500</td>
</tr>
<tr>
<td></td>
<td>Symbiq infusion system</td>
<td>1 or 2</td>
<td>Mar 2007</td>
<td>0</td>
<td>880</td>
<td>880</td>
</tr>
<tr>
<td>Smiths Medical</td>
<td>Graseby</td>
<td>1</td>
<td>Oct 1999</td>
<td>1450</td>
<td>--</td>
<td>1450</td>
</tr>
</tbody>
</table>

Notes:
1. Information collected from spring 2008 to 2010 and rounded to two significant digits
2. “—” indicates that this pump is not sold as a smart pump
3. Pumps that are not actively licensed for sale or have insignificant market share are not included (e.g., Sigma 6000 and B.Braun Vista)