Mitigating Risks Associated with Secondary Intravenous Infusions: An Empirical Evaluation of a Technology-based, Training-based, and Practice-based Intervention

by

Katherine Yin-Yee Chan

A thesis submitted in conformity with the requirements for the degree of Master of Health Science in Clinical Engineering

Institute of Biomaterials and Biomedical Engineering
University of Toronto

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Abstract

Secondary infusions is a common method to deliver short infusions of intravenous (IV) drugs and fluids. Errors associated with this infusion method have led to patient safety concerns. This study's objective was to empirically evaluate interventions to mitigate secondary infusion risks. Three interventions, including a technology-based intervention (clamp detector on a smart pump), a training-based intervention (educational module), and a practice-based intervention (use of a separate pump for short infusions), were tested in a simulated inpatient unit. The technology-based intervention significantly decreased secondary clamp errors whereas the training-based intervention reduced complex pressure differential errors. The practice-based intervention was the only intervention that significantly decreased both secondary clamp errors and pressure differential errors, but introduced new risks due to mismanagement of residual volume in IV tubing. Study results highlight the need for a combination of mitigation strategies and can help guide the selection of interventions to reduce secondary infusion errors.
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Special thanks to my family and friends, for your ongoing encouragement and support.

May the completion of this dissertation mark the beginning of a journey in human factors to improve quality and safety.
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Chapter 1

1 Introduction

The intravenous (IV) delivery of multiple drugs and fluids is an important part of the routine care of patients in the clinical setting\textsuperscript{1,2}. The Canadian Adverse Event Study (2004) found that drug and fluid-related events were responsible for 23.6\% of reported adverse events in hospitals, the second most frequent contributor to adverse events after those related to surgical procedures\textsuperscript{3}. More than 34\% of IV medication errors occurred at the patient’s bedside during the administration stage of medication therapy and many of these errors were not intercepted\textsuperscript{4}.

IV medications and fluids can be administered continuously or as a short infusion over a specific amount of time\textsuperscript{1,5,6}. IV medications such as antibiotics\textsuperscript{7,8}, electrolytes\textsuperscript{9}, and chemotherapy\textsuperscript{10–12} are commonly administered to patients as short infusions at repeated intervals throughout the day on an intermittent basis\textsuperscript{5}. An IV infusion technique called secondary infusion, also known as piggyback infusion, is used to deliver short infusions of IV medications and fluids\textsuperscript{13}. This infusion technique facilitates the delivery of a single-dose medication through an established IV access in the patient. A "secondary" IV infusate is connected to an existing infusion line upstream of the patient’s IV access using a y-connector (see Figure 1). Secondary infusions can be delivered with or without the control of an infusion pump\textsuperscript{13}.

![Figure 1. Secondary Infusion Setup (Adapted from Colvin, 2011)\textsuperscript{14}](image-url)
Errors associated with the delivery of secondary infusions have been frequently reported in literature\(^9,13,15–17\). Incident reports from the Institute for Safe Medication Practices Canada (ISMP Canada) database and the United States Food and Drug Administration’s (FDA) Manufacturer and User Facility Device Experience (MAUDE) database demonstrated that secondary infusion errors led to drug and fluid-related adverse events and patient safety risks at the bedside\(^18\). Previous studies in simulated clinical settings also indicate that there is a high frequency of use errors related to the setup and administration of secondary infusions\(^13,17\). Nunnally and Bitan (2006) reported that clinicians were unable to complete secondary infusions successfully in 53% of cases while under observation in a simulated clinical setting\(^13\).

Although errors associated with the administration of secondary infusions have been reported, literature searches revealed little information on the empirical testing of interventions to reduce secondary infusion errors in the clinical setting.

### 1.1 Objectives

The objective of this research was to improve the safety of secondary infusion deliveries by evaluating interventions to mitigate risks associated with this infusion method. Three interventions (a technology-based intervention, a training-based intervention, and a practice-based intervention) were evaluated in a high-fidelity simulation study to assess their effectiveness at reducing secondary infusion errors.

### 1.2 Chapter Outline

In Chapter 2, a background of secondary infusions is presented. It explains the setup of secondary infusions, the hydrostatic principles behind how secondary infusions work, and the common types of errors.

**Chapters 3** provides a review of literature that describes the prevalence of secondary infusion errors and the gaps in current mitigating strategies. It then examines the application of human factors in improving the safety of secondary infusions. It describes the frameworks of developing error mitigation strategies by illustrating the relationship between human performance and error. Finally, it summarizes three potential interventions
that were identified from previous human factors studies on the safety of secondary infusion processes.

**Chapter 4** outlines the research objectives and the approach of using high-fidelity simulation testing as a means of evaluating the interventions. It also presents the research hypotheses for this study. **Chapter 5** presents the methodology, explaining the experiment design, experiment protocol, data collection methods, and data analysis methods.

**Chapter 6** and **Chapter 7** provide the results and discussions of the findings, respectively. Additionally, Chapter 7 discusses new hazards that were identified, particularly the mismanagement of residual volume in IV tubing. **Chapter 8** further explores the under-reported issue of the mismanagement of residual volume and highlights the importance of clearer reporting and process standardization for this issue. Finally, **Chapter 9** concludes with a summary of the key findings from this research, their implications, and the directions of future work.
Chapter 2

2 Background

2.1 Secondary Infusions

Intravenous (IV) medication administration is the process of giving medication directly into a patient's vein. Nurses play primary roles in the administration of IV therapy in the clinical setting\textsuperscript{1,19--22}. IV medications and fluids can be delivered continuously or over a specific amount of time as a short infusion\textsuperscript{1,5,6}. Figure 2A shows the setup of a continuous infusion delivered with an infusion pump. In contrast, short infusions are typically small volumes of medications or fluids (usually 25mL to 250mL)\textsuperscript{23} that are delivered to patients over a short time period (typically 30 minutes to 3 hours)\textsuperscript{6}. These short infusions can be delivered as a single dose or at repeated intervals throughout the day on an intermittent basis. Short infusions can be delivered by connecting a secondary line, often known as a piggyback or intravenous piggyback (IVPB) to an existing IV infusion\textsuperscript{24}. In this setup, the existing IV infusion is referred as the primary infusion. Figure 2B shows the setup of a secondary infusion.

![Figure 2. (A) Primary Infusion Setup (B) Secondary Infusion Setup](Adapted from Colvin, 2011)\textsuperscript{14}
Both primary and secondary infusions can be delivered with or without the control of an infusion device. Infusion devices (e.g., large-volume infusion pumps) are commonly used for intravenous delivery of medications in the clinical setting because they provide greater fluid delivery accuracy and better detection of intravenous cannula infiltration than gravity administration sets.

Secondary infusion is a convenient infusion method because it does not require a new IV access point in the patient. Additionally, in this setup, the primary infusion (typically a maintenance fluid) temporarily stops during the short infusion and automatically resumes upon its completion. The convenience of this automatic return to the primary infusate allows for the unattended delivery of short infusions, which allows nurses to leave the infusion device and address other clinical duties during secondary infusions.

The terms "secondary infusions", "intravenous piggyback", "intravenous short-term infusion", "IVPB" have been used in literature and in clinical practice to refer to the administration of a short infusion or an intermittent infusion via the connection to a primary infusion. In this study, both terms "piggyback infusion" and "secondary infusion" refer to the setup in Figure 2B, where a short infusion is administered via the connection to a primary continuous infusion.

2.1.1 Administration Process of Secondary Infusions

The running of a secondary infusion consists of the following main steps:

1. The connection of secondary (piggyback) line to the primary line
2. The positioning of primary and secondary infusion containers
3. The programming of infusion pump (for infusions delivered with infusion pumps)
4. The opening of roller clamp on secondary IV line
5. Automatic return to primary infusion
1. **The connection of secondary line to the primary line:**

At the beginning of a secondary infusion, the secondary IV line must be primed to avoid delivering air through the lines into the patient. The tubing is primed by holding the end of the IV tubing below the bag and letting the IV solution flow through the tubing to remove air in the line. The primed “piggyback” IV solution is connected to the primary infusion line upstream of the infusion pump at the y-connector of the IV tubing set (Figure 3).

2. **The positioning of primary and secondary infusion containers:**

The position of the primary infusion container must be lower than the secondary infusion container. This is because the height of the fluid level in the container affects the
The hydrostatic pressure in the IV line is dependent on the "head height" of the fluid level above a reference point (e.g., the pump or the patient access point) and the density of the intravenous solution (see Equation 1).

\[ P = \rho g h; \]

where \( P \) = hydrostatic pressure at a reference point, \( g \) = gravitational acceleration, \( h \) = height of fluid level above the reference point, \( \rho \) = density of the intravenous solution.

The secondary infusion container is hung higher than the primary infusion container to establish a greater hydrostatic pressure in the secondary infusion line. This difference in hydrostatic pressure is essential because it closes a back-check valve (see Figure 3) on the primary line and prevents the contents in the primary bag from infusing during secondary infusion. There are different types of IV containers, such as IV bags and glass bottles. The plastic IV bag collapses as the fluid runs out and does not require venting. In contrast, the IV bottle must be vented for air to enter the vacuum of the IV bottle for the fluid to flow out of the container. The IV tubing for glass bottles is equipped with a small air vent above the drip chamber (Figure 5B). For the secondary line using a vented IV bottle, the head height of the fluid level is important for establishing the necessary hydrostatic pressure.
height is the top of the fluid level of the drip chamber (Figure 5B). For IV bag, the head height of the fluid is the top of the fluid level in the bag (Figure 5A).

**Secondary IV Bag**

**Secondary IV Bottle**

![Diagram of Height Differential](image)

**Figure 5. Height Differential**
(Adapted from Colvin, 2011)\(^{14}\)

3. **The programming of infusion pump (for infusions delivered with infusion pumps)**

Secondary infusions can be delivered with or without the control of infusion pumps. Large-volume infusion pumps are programmable pumps that allow users to program the rate of the infusion, as well as the duration or the volume of the secondary infusion to be infused (VTBI).

For most commercially available large-volume infusion pumps, the pump must be switched from "primary mode" to the "secondary mode" to program the secondary infusion. Under the "secondary mode", the volume to be infused (VTBI) and infusion rate of the secondary infusate are entered (see Figure 6). Most pumps are designed so that once the pump delivers the set volume (VTBI) that is programmed under "secondary mode", it automatically resumes delivering fluid at the primary flow rate.
4. The opening of roller clamp of secondary line

After the secondary infusion duration or volume is programmed and the secondary infusion setting is activated, the user must open the roller clamp (see Figure 4) that regulates flow in the secondary line.

![Figure 7. Roller Clamp](image)

When the roller clamp is opened, the greater pressure in the secondary line due to the height differential between the primary and secondary fluid levels will activate the back-check valve located on the primary infusion line (see Figure 3). The flow of the primary infusion will temporarily halt. The pressure in the secondary infusion line will enable the secondary infusate to flow down the tubing into the pump. The back-check valve will
prevent the primary IV infusate from entering the pump as long as there is higher pressure in the secondary IV line (see Figure 8).

Figure 8. Closed Back-check Valve (Adapted from Nettina, 2013) 30:
When the roller clamp on the secondary line is opened, the higher hydrostatic pressure in the secondary line will push the movable diaphragm in check valve upwards, stopping flow from the primary infusate. The primary infusion flow will temporarily halt and only the secondary infusion will continue to flow downstream into the pump.

5. Automatic return to primary infusion

When the secondary infusion is completed, the infusate in the secondary line will drop below the level of the primary infusion. The hydrostatic pressure in the secondary line will decrease, the back-check valve will open and the flow of the primary infusate will automatically resume (see Figure 9).

Figure 9. Open Back-check Valve (Adapted from Nettina, 2013) 30:
When the secondary infusion container is empty or when the roller clamp is closed, there is not enough pressure in the secondary IV line to close the check valve. The check valve will open to allow the primary infusion to resume flow down into the pump.

2.1.2 Limitations of Large-volume Infusion Pumps during Secondary Infusions

Large-volume infusion pumps are programmable pumps that control the rates and volumes of infusions. An infusion pump can have single or multiple infusion delivery channels 25. Most commercially available large-volume infusion pumps rely on gravity to draw fluids
from the IV containers towards the pump. It can draw the infusate from the IV containers as long as the containers are hung above the pump\textsuperscript{5}.

As explained in Section 2.1.1, large-volume infusion pumps often have "primary infusion mode", as well as a "secondary infusion mode" which allow the user to deliver drugs and fluids at two different rates, sequentially. When the user sets the pump at "secondary mode", the pump administers a programmed volume of whichever IV medication is flowing into the pump at the programmed secondary rate. When the remaining volume under "secondary mode" reaches zero, the pump automatically switches to infusing whichever fluid is flowing into the pump, at the programmed primary rate. Importantly, most commercially available pumps cannot detect or control which IV container fluid is delivered from. Therefore, it is the hydrostatic pressure in the infusion lines and not the infusion device that determines which infusion is administered. The actual flow of the primary and secondary infusates into the pump is controlled by the manual setup of the user. Therefore, the understanding of the hydrostatic principles underlying secondary infusions is an important aspect in its accurate administration.

### 2.2 Types of Secondary Infusion Errors

Secondary infusion is a convenient method to administer short infusions because it allows a primary infusion to automatically resume when a short infusion completes. However, the delivery of secondary infusions using infusion pumps is prone to use errors\textsuperscript{13,17}. For example, although the rate and volume can be controlled by the infusion technology, Nunnally and Bitan (2006) found that there were mismatches between the manufacturer’s specified pump operation and users’ practices. Their study reported that clinicians were unable to complete secondary infusions successfully in 53\% of cases in a simulated clinical setting\textsuperscript{13}. Some identified problems included failure to adjust the device correctly and user confusion with the rate and volume of primary and secondary lines\textsuperscript{13}.

The common types of secondary infusion errors are outlined in Table 1.
<table>
<thead>
<tr>
<th><strong>Secondary Infusion Error</strong></th>
<th><strong>Description</strong></th>
<th><strong>Error Detection by pump</strong></th>
<th><strong>Consequence</strong></th>
<th><strong>References</strong></th>
</tr>
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<tbody>
<tr>
<td><strong>Secondary Clamp Errors</strong></td>
<td>Failure to open secondary roller clamp.</td>
<td>No</td>
<td>No flow of secondary medication to patient. Unintentional delivery of the primary infusion at secondary infusion rate.</td>
<td>ISMP Canada (2005)(^9); Trbovich <em>et al.</em> (2010)(^\text{17})</td>
</tr>
<tr>
<td><strong>Connection Error</strong></td>
<td>Secondary infusion line is connected to the primary infusion line downstream of the large-volume infusion pump via a wrong port.</td>
<td>No</td>
<td>The pump cannot control the flow rate of the secondary infusate. The secondary infusate free-flows into patient.</td>
<td>Nunnally &amp; Bitan (2006)(^\text{13}); Trbovich <em>et al.</em> (2010)(^\text{17})</td>
</tr>
<tr>
<td><strong>Pressure Differential Error</strong></td>
<td>Pressure differential errors due to incorrect positioning of IV bags, delivery using large IV bags, or delivery at high secondary flow rates.</td>
<td>No</td>
<td>Mixing and concurrent delivery of the secondary and primary infusate to the patient. Backflow of secondary infusate into the primary line.</td>
<td>Nunnally &amp; Bitan (2006)(^\text{13}); Trbovich <em>et al.</em> (2010)(^\text{17}); Cassano-Piché <em>et al.</em> (2012)(^\text{5})</td>
</tr>
<tr>
<td><strong>Programming Errors</strong></td>
<td>Enter incorrect infusion parameters as a result of drug conversion calculation error or mix-up in programming sequence.</td>
<td>No</td>
<td>Delivery of the primary and/or the secondary infusate at incorrect rate.</td>
<td>Trbovich <em>et al.</em> (2010)(^\text{17}); ISMP Canada (2003)(^\text{16}); ISMP Canada (2003)(^\text{15})</td>
</tr>
<tr>
<td><strong>Lack of back-check valve</strong></td>
<td>No back-check valve on primary IV set.</td>
<td>No</td>
<td>Mixing and concurrent delivery of the secondary and primary drugs to the patient. Backflow of secondary infusion into the primary line.</td>
<td>Cassano-Piché <em>et al.</em> (2012)(^\text{5})</td>
</tr>
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</table>
1) Secondary Clamp Error: Failure to open the roller clamp on secondary IV tubing

After the clinician sets up and primes the secondary infusion line, the secondary IV tubing is usually clamped to prevent spillage of its contents. Once the secondary line is correctly connected to the primary line and the infusion pump is programmed, the roller clamp on the secondary IV tubing needs to be reopened before the secondary infusion can infuse (see Figure 10).

![Figure 10. Closed Secondary Roller Clamp (Adapted from Colvin, 2011)](image)

Consequence of Error: There is no flow of secondary infusate into the pump. Instead, the primary fluid erroneously infuses at the rate of the secondary infusate. The failure to open the roller clamp results in the accidental delivery of the primary infusate when the delivery of the secondary infusate is intended.

2) Connection Error: Connection Downstream of Infusion Pump

When the secondary infusion line is connected to the primary infusion line downstream of the large-volume infusion pump via a wrong port, the pump can no longer control the flow rate of the secondary IV infusate (see Figure 11).

![Figure 11. Connection Downstream of Infusion Pump (Adapted from Colvin, 2011)](image)
Consequence of Error: The secondary infusate free-flows into the patient while the primary infusate is delivered unintentionally by the pump at the secondary rate. Unintentional free-flow of the secondary infusate can lead to unexpected over-infusions.

3) Pressure Differential Errors

During secondary infusions, the secondary IV container must be positioned higher than the primary IV container to establish enough pressure difference between the two IV lines to close the back-check valve on the primary line. The closing of the back-check valve prevents flow of primary infusion during the delivery of secondary infusion.

Common pressure differential error in typical secondary infusions is the incorrect positioning of the IV containers. In the correct setup, the primary IV container should be lowered using an extension hook supplied by manufacturer with the secondary IV tubing set. The use of a hook (which varies between 8 inches to 10 inches depending on manufacturer)\textsuperscript{31,32} for the primary IV container is typically sufficient to establish enough height difference between the primary and secondary infusions to facilitate proper infusion. However, when piggybacking a large secondary IV container or delivering a secondary infusion at a high secondary flow rate (500mL/h or higher), the hook may not be long enough to establish sufficient height and pressure differential and concurrent flow can occur if user does not take additional precautions\textsuperscript{5}. In summary, pressure differential errors include:

- Incorrect positioning of IV containers
- Insufficient pressure differential when piggybacking a large IV container
- Insufficient pressure differential at high secondary flow rate

a) Incorrect Positioning of IV Containers: When the secondary IV container is positioned below or at the same level as the primary IV container, there is not enough pressure difference between the primary and secondary IV line to keep the back-check valve closed (see Figure 12).
b) Insufficient pressure differential when piggybacking a large IV container: 
When using large IV containers, the fluid level may reach the same height as the primary IV infusion as it empties (see Figure 13). Once the fluid level in the secondary container reaches the same height as the fluid level in the primary IV container, there will no longer be sufficient pressure differential in the two IV lines to keep the back-check valve closed and prevent concurrent flow. To prevent concurrent flow, an option is to further increase the height difference between the primary and secondary IV containers (i.e., the pressure differential between the two IV lines).
c) **Insufficient pressure differential at high piggyback flow rate:** A back-check valve is used to prevent flow of primary infusion during the delivery of secondary infusion. However, if the secondary rate is set too high (500mL/h or higher), the back-check valve cannot prevent unintended flow from the primary infusion container\(^{33}\). A high secondary flow rate reduces pressure in the IV line and creates a suction effect on the back-check valve, which may cause it to open. As a result, the primary and secondary infusates will be delivered simultaneously at an indeterminate rate. The detection of concurrent flow relies on the user to notice that the drip chamber on the primary line is active.

Consequence of Errors: When there is insufficient pressure differential in the two lines, the contents in the primary IV container will continue to flow through back-check valve and be delivered to the patient even when the pump is set at the secondary infusion rate. This can lead to the mixing and concurrent delivery of the secondary and primary infusates to the patient, as well as the backflow of secondary infusate into the primary line. Most infusion pumps licensed for use commercially cannot detect this error.

4) **Programming Errors**

Traditional large-volume infusion pumps allow nurses to program an hourly rate (i.e., milliliters per hour) and volume-to-be-infused (VTBI) in milliliters. However, it has been found that many adverse drug events (ADEs) associated with IV infusion devices are due to incorrect parameters manually entered into the pump\(^{34}\). The Institute of Medicine (IOM) in United States (U.S.) estimated that manual programming errors contribute to two-thirds of preventable deaths related to infusion therapy\(^{35}\). Programming errors occur when users enter incorrect infusion parameters into the pump as a result of:

- **confusion in programming sequence:** primary infusion is erroneously programmed using the secondary infusion rate or vice versa, resulting in the delivery of the secondary infusate at the rate of the primary infusate or vice versa\(^{17}\).

- **drug conversion calculation errors:** drug conversion calculations are often required when delivering intermittent infusions on traditional large-volume pump because the
information provided on the physician order, i.e., dose, duration, volume, are not the same as the parameters required by the pump, i.e., rate, volume.

- "**double key bounce**" error: two inputs are entered into device when a single press of the button is intended\(^1\)\(^7\) (e.g., multiple of ten errors such as programming 500ml/h instead of 50mL/h).

Consequence of Error: The infusion rates of the primary and secondary infusions often differ greatly (secondary infusion rates are often higher than the primary rate). Programming errors can result in the over- or under-dosing of either the primary or the secondary infusion. For example, if the secondary infusion volume (VTBI) is programmed lower than actual volume in the secondary IV container, the pump will prematurely switch to the primary rate before all the secondary infusate is delivered. The remaining secondary infusate will be delivered at the primary rate, resulting in under-dosing of the infusate. If the secondary infusion volume (VTBI) is programmed greater than the secondary infusion container volume, the pump will continue to infuse at the secondary rate after all the secondary infusate is delivered. The primary infusate will be delivered at the secondary rate.

5) **The secondary IV tubing is connected to a primary infusion set with no back-check valve**

Back-check valve is essential for ensuring that the secondary infusate is administered as programmed, and does not mix with the primary fluid.

Consequence of Error: Mixing and concurrent delivery of the secondary and primary infusate to the patient, as well as the backflow of secondary infusate into the primary line.

2.3 **Multiple Infusions Using Infusion Pump Technology**

In the clinical setting, patients, especially those in the critical care units, often require numerous different infusions. It is common for a patient in critical care to receive ten or more infusions, which are administered through a combination of primary and secondary infusions using multiple pumps, channels, and IV access points\(^5\).
The presence of multiple infusion lines increases the opportunities for administration errors during the delivery of medications. Kane-Gill et al. reported that patients receiving IV medications had a 3% higher chance of having an adverse drug event for each additional drug that was dispensed\(^{36}\). High frequency of user errors related to secondary IV infusions has been reported and patient safety improvements are needed\(^{13,17}\) (see Section 3.1). However, literature searches revealed little information on empirical testing of interventions to improve the safety of secondary infusion delivery technologies. Thus, the present study empirically evaluated interventions to improve the safety of the administration of secondary infusions.
Chapter 3

3 Review of Literature

3.1 Medication Errors and Prevalence of Secondary Infusion Errors

During intravenous drug therapy, it is important that a patient receives the prescribed amount of medication at a specific time\(^3^7\). The "nine rights of medication administration" are emphasized during the delivery of IV medication: right patient, right drug, right route, right time, right dose, right documentation, right action, right form, and right response\(^3^8\). However, medication administration presents many opportunities for errors because it is a complex process that involves multiple factors including interactions with people, devices, and the environment.

Medication error, in an article by Ferner and Aronson (2006) titled *Clarification of terminology in medication errors: definitions and classifications*, is defined as "a failure in the treatment process that leads to, or has the potential to lead to, harm to the patient"\(^3^9\). Medication errors have led to adverse drug events (ADEs). Approximately 12% are life-threatening\(^3^5(p372)\). In 2000, the United States' Institute of Medicine (IOM) reported that medication errors contributed to 7000 deaths in the United States, annually\(^4^0(p2)\). Medication errors were also associated with high financial costs. It was estimated that one ADE added an average of more than $5,857 to the costs of a hospital stay in North America\(^3^5(p130)\).

Medication errors can occur at any stage in the medication use cycle (i.e., ordering, transcribing, dispensing, administering, monitoring)\(^4^1\). Leape et al. (1995) reported that drug administration errors contributed to the highest rate of medication errors\(^4^2\). IV medication errors, in particular, have led to considerable patient risks\(^4^3\) because they have a fast rate of onset, are difficult to detect, difficult to be intercepted\(^4\), and often involve medications with a narrow therapeutic range\(^3^4,4^4,4^5\). In a joint United Kingdom (U.K.) and German study, Wirtz et al. reported 34% of errors during IV administration\(^4^6\), while Taxis and Barber reported 49% of errors in a U.K. study\(^4^7\).
A systemic search of incident reports from the ISMP Canada Medication Incident Report databases between 2000 and 2010 and from the U.S. FDA MAUDE database for 2008 was conducted by the HumanEra Team (formerly Health Technology Safety Research Team) at the University Health Network, Canada. The ISMP Canada database search returned 424 clinical incidents associated with multiple IV infusions, with 65% related to the administration issues of secondary infusions. The search in FDA MAUDE database from 2008 returned 211 incidents, 39% of which are related to secondary infusion issues. At least 45% of overall multiple IV infusion incidents reported to the FDA MAUDE in 2008 have resulted in patient harm. The percentage of secondary infusions that has led to patient harm is not clear but incidents reported by the Canadian Institute for Safe Medication Practices (ISMP Canada) provide strong evidence that problems exist with secondary infusions.

In 2005, ISMP Canada reported multiple administration errors associated with secondary intermittent IV infusion. In one case, a secondary infusion containing potassium was piggybacked into a primary infusion of insulin. A roller clamp was left clamped on the secondary line, causing the pump to deliver insulin solution from the primary line at the higher secondary infusion rate, leading to patient complications from hypoglycemia.

Secondary infusion errors are highly concerning because they are difficult to detect and have a high potential to cause patient safety risks. Furthermore, medication errors are often underreported. An observational study of the prescription and administration of intravenous medications indicated that self-reporting schemes only reflect a small percentage of the medication errors that occur (i.e., the error iceberg where many errors go unnoticed or errors that are noticed may not be reported because the patient has not come to any harm). Therefore, the actual number of secondary infusion errors can be expected to be more than the number of incidents identified from the FDA and ISMP Canada databases.

Nunally and Bitan (2006) identified that 38% of secondary infusions set up by nurses in a simulation study had pressure differential and connection errors. In another simulation study, Trbovich et al. (2010) found that 9% of secondary infusions set up by nurse participants had secondary clamp errors, 6% had connection errors, 37% had pressure...
differential errors, 28% had programming errors due to drug calculation error, and 19% had programming errors due to confusion in the programming sequence (where the secondary infusate was programmed as the primary infusate or vice versa).

3.2 Current Mitigation Strategies

As a result of numerous errors associated with secondary infusion, the following approaches and technologies have been proposed as potential mitigation strategies.

1) Policy Change

In response to multiple adverse incidents related to secondary infusions, ISMP Canada recommended the policy that no secondary medication should be connected to a primary infusion that contained a high-alert medication. These high-alert medications are defined by ISMP Canada as “drugs that bear a heightened risk of causing significant patient harm when they are used in error” (e.g., potassium, insulin, narcotics, chemotherapy and heparin)\textsuperscript{9,34,50}.

Other policy changes had also been suggested. In a report called \textit{Nine Recommendations To Prevent Multiple Line Infusion Medication Errors}, published by the Association for the Advancement of Medical Instrumentation (AAMI) Healthcare Technology Safety Institute (HTSI), the policy to administer continuous high-alert medications only as primary IV infusions was recommended\textsuperscript{51}. Another recommended policy was to attach secondary infusions only to primary infusion sets with a back-check valve\textsuperscript{51}. The back-check valve prevents the mixing and concurrent delivery of the primary and secondary infusates, when there is sufficient pressure differential between the primary and the secondary line.

Although several policy changes have been proposed, literature searches revealed little information on studies that demonstrated the effectiveness of these policy changes on the reduction of secondary infusion errors.
2) Education and Training

ISMP Canada also recommended the use of more education and training to improve the safety of secondary infusion administration. For example, ISMP Canada proposed the use of bulletins and education materials to encourage clinicians to perform visual checks (e.g., roller clamp is open, connection is correct, there is activity in both drip chambers) to verify that the correct IV fluid is infusing during secondary infusion. The Medicines and Healthcare Products Regulatory Agency (MHRA) in Great Britain also used a newsletter to highlight secondary infusion issues and encourage clinicians to double-check volume to be infused (VTBI) and the rate for both primary and secondary infusions. This was in response to reports of patient deaths as a result of over-infusion of drugs such as potassium, where dual rate infusion pumps have been used and the secondary rate was unintentionally infused.

In the *Multiple Intravenous Infusions Phase 1b study* report by the HumanEra Team at the University Health Network for the Ontario Health Technology Assessment Series, Cassano-Piché *et al.* (2012) investigated the current nature and comprehensiveness of training of nursing staff around the administration of multiple IV infusions. Based on interviews with nurse educators from 8 colleges and universities in Ontario, it was found that there was no explicit safety training around preventing specific secondary infusion errors. Online searches revealed that nursing staff were using web forums to discuss uncertainties related to the procedures of delivering secondary infusions.

Nurses are commonly trained with rules on how to set up and prepare secondary IV infusions, but are not taught the underlying secondary infusion principles that the rules are based on. For example, Cassano-Piché *et al.* found that many nurses know that a height difference is needed between the primary and secondary IV containers as a result of the effects of gravity. However, many nurses are not taught the basics of hydrostatics so they can understand the reason behind this rule and recognize the source of errors when secondary infusions are not infusing as expected.
In Ontario, the theory and practice of IV medication administration are typically taught in the second year of the Bachelor of Science in Nursing program based on fundamentals in textbook and lectures. In the commonly used nursing textbook, *Potter and Perry’s Fundamentals of Nursing*, only 6 out of 1728 pages of the book provide information on the basic setup and maintenance of all IV infusions. There is limited information on the principles or basic concepts of hydrostatics, and little discussion on potential infusion errors or error prevention strategies. Therefore, the current training and education practices may have been unable to address incorrect behaviours and adequately prevent secondary infusion errors.

Educational programs and training have been used to address errors associated with other medication delivery issues. However, evidence on the impact of training on the reduction of medication errors in the actual clinical setting remains inconsistent. Some studies showed that the implementation of educational interventions led to only small improvement from pre-intervention error rates. For example, Trivalle et al. (2010) investigated the impact of an educational intervention, which involved a physician and nurse providing oral and written recommendations on prescription habits, on the rate of adverse drug events (e.g., excess dose, inappropriate drug, or drug-drug interactions). A significant but small decrease (14%) of adverse drug events were observed in the intervention group in comparison to the control group. Franklin et al. (2006) investigated the use of an internet educational module that focused on patient safety during medication administration. A decrease in non-intravenous medication administration errors was observed but there was no significant decrease in overall error rates. Ford et al. (2010) compared medication administration errors in an intensive care unit before and after the intervention of either a traditional lecture or simulation-based training session. It was found that simulation-based training led to a decrease in overall error rates, while the overall error rates significantly increased after the traditional lecture. Similarly, Mills et al. (2008) reported interventions that focused on training to be negatively correlated with improvement in outcomes.

The use of graphics, animation, sound, and video has also been increasingly used in training instead of traditional instructional approaches, such as textbooks and
lectures. Graphics, animation, sound, and video are alternative methods that provide an interactive learning experience and may lead to better comprehension of the material and improved task performance. Computerized graphics and animation can be used to simplify dynamic information to trainees. Some studies investigated the effectiveness of computerized animation in delivering abstract concepts and presenting complex information within a short timeframe. Schneider et al. (2006) evaluated the effectiveness of an interactive computer training session on errors associated with safe administration practices, medication preparation and administration errors. There was no change in administration errors but the intervention decreased safe administration practice errors.

Although the use of graphics, animation, sound, and video have also been increasingly used in healthcare education, literature searches revealed little information on studies that specifically investigated the use and effectiveness of training and integration of graphics and animation to reduce secondary infusion errors.

3) Infusion Pump Technology

**Smart infusion pumps:** Infusion pumps that incorporate Dose Error Reduction Software (DERS), also known as smart pumps, have been proposed as a promising technology that can increase the safety of IV administration practices at the point of delivery. The DERS software contains a library of drugs and concentrations associated with dosing limits. Clinicians are alarmed (“soft” limit) or prevented (“hard” limit) from starting the infusion if the input exceeds dosing limits. Furthermore, smart pumps have a drug dose calculator which prompts users to select the medication and its concentration, and automatically calculates the correct dosing units and the volume needed to deliver the prescribed dose. The DERS technology and dose rate calculator of smart large-volume infusion can potentially reduce errors associated with dose programming and calculations.

Although current smart pumps are designed to improve the safety of medication delivery, Trbovich et al. (2010) found that the smart pumps did not significantly improve nurses’ ability to successfully deliver secondary infusions in comparison
with traditional large-volume pumps\textsuperscript{17}. Furthermore, drug libraries can be bypassed and soft limit alerts can be overridden by nurses\textsuperscript{71}. When the smart pump drug library is bypassed, the infusion rate and volume are input manually, and the dose error reduction software will no longer be able to function and prevent potential errors. Moreover, many secondary infusion issues, such as incorrect positioning of infusion containers, errors in tubing setup, and the failure to open the roller clamp on secondary IV tubing, cannot be detected or intercepted by the commercially available smart infusion technologies that are commonly used in the clinical setting\textsuperscript{72}. Moreover, some smart infusion pumps do not permit secondary infusions to be programmed with DERS through their drug library\textsuperscript{5}. This limitation affects the ability of smart infusion technologies to mitigate risks related to secondary infusion errors.

One commercially available smart pump technology that can potentially reduce specific risks associated with secondary infusion is the Plum A+ pump developed by Hospira Inc. (Plum\textregistered{} A+ Infusion System, Hospira Inc, Lake Forest, IL)\textsuperscript{73}. The Hospira Plum A+ has a pumping cassette that allows the primary and secondary fluids to be delivered at separate flow rates through a single channel, either concurrently or sequentially\textsuperscript{73}. The delivery rate of each infusion is independent of the fluid container position relative to the pump.

The benefits of the Hospira Plum A+ for the delivery of secondary infusions include:
- No height differential is required between the primary and secondary IV containers
- Unopened clamp on the secondary IV line can be detected
- The secondary infusion cannot back flow into the primary infusion tubing

Currently, the Hospira Plum A+ is the only commercially available large-volume pump that can deliver both the primary and secondary infusions at independent flow rates by a single pump channel and a single access point in the patient. Although the Hospira Plum A+ is a promising technology that can potentially reduce secondary infusion errors, it can also introduce other risks during the administration of
secondary infusions\textsuperscript{5}. For instance, once the user sets the pump to primary or secondary mode, the pump does not display which mode is selected. This increases the likelihood of an undetected mode selection error when the user starts an infusion\textsuperscript{5}. This can lead to user confusion between the rates and volumes of primary and secondary lines, resulting in secondary infusion errors\textsuperscript{5}. Furthermore, the MHRA in Great Britain and Health Canada recently issued medical device alerts and recalls on Hospira Plum A+ infusion pumps due to continuous recycling rebooting problems and failed audible alarms, respectively\textsuperscript{74–76}. These problems may result in a delay or interruption of therapy that can lead to patient harm. Hospira has received reports of failed audible alarms in Canada and has received reports of patient injury due to this failure outside of Canada\textsuperscript{77}. Thus, even though the Hospira Plum A+ is a promising technology that can potentially reduce secondary infusion errors, it may also introduce other risks during the administration of secondary infusions\textsuperscript{5}.

**Dedicated Pressurized Pump for Short Infusions:** For short infusions that are less than 50mL in volume, it was found that some Canadian and American hospitals, in pediatrics and neonatal care, use separate syringe pumps for medication delivery instead of the secondary infusion technique\textsuperscript{5,78,79}. This is because pediatric patients have a lower tolerance for excess fluid volume than adults and inaccuracies in flow rate may lead to patient harm\textsuperscript{5}.

A syringe infusion pump is a pump that generates positive pressure and expels the contents of a syringe by advancing the plunger or the barrel at a controlled flow rate\textsuperscript{80}. Delivery of a short infusion by a separate syringe pump allows for higher accuracy at low flow rates. In Europe, some hospitals also use pressurized pumps (such as syringe pumps) to deliver intermittent infusions of antibiotics for intensive care unit (ICU) adult patients who are fluid-restricted\textsuperscript{81}. Programmable syringe pumps are expensive in comparison to large-volume pumps, and therefore less commonly used for short infusions because they are costly to implement.
In summary, different patient safety improvement strategies and technologies have been proposed (see Table 2). However, there are few data demonstrating changes and improvement of secondary infusion safety in the clinical setting, especially in adult care.

Table 2. Current Mitigating Strategies for Secondary Infusion Errors

<table>
<thead>
<tr>
<th>Secondary Infusion Error</th>
<th>Current Mitigating Strategies</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Connection Error</td>
<td>- Education bulletin</td>
<td>ISMP Canada (2005) (^9)</td>
</tr>
<tr>
<td>3. Pressure Differential Error</td>
<td>- Only one commercially available pump that delivers the primary and secondary infusions at independent flow rates.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- In pediatrics and ICU in Europe, pressurized syringe pumps are used</td>
<td>Claus (et al.) (2012) (^81)</td>
</tr>
<tr>
<td></td>
<td>- Training and Education</td>
<td>Wetterneck (et al.) (2006) (^83)</td>
</tr>
</tbody>
</table>

Currently, to avoid secondary infusion errors using traditional and smart infusion pump technologies, clinicians must still rely on individual vigilance to verify that the secondary roller clamp is opened, the secondary IV line is correctly attached and activated, there is sufficient height differential between the primary and secondary IV containers, the primary IV line has a back-check valve that prevents the back flow of secondary fluid into the primary line, and the maximum secondary infusion rate is not exceeded, to prevent failure. The reliance on practitioner vigilance to ensure appropriate administration adds to their already demanding practice and workload in a fast-paced and complex patient care setting.

3.3 Improving Secondary Infusion Safety using Human Factors Methods

Nunnally and Bitan (2006), in their report on secondary infusion issues in the clinical setting, recommended efforts to improve the secondary infusion process from a human
factors and cognitive systems engineering perspective. Errors can occur because of the characteristics and limitations of the infusion devices or lack of user knowledge, as well as other factors including lack of training and environmental factors, such as physical layout of equipment, noise and distractions in settings.

Human factors is a scientific discipline that studies how people interact with systems, tools, processes, and devices. It studies how the "psychological, social, physical, biological and safety characteristics" of users affect these interactions. Human Factors engineering applies methods to understand and meet the needs of the end user, such as observational studies, task analysis, and usability testing. Basic human factors engineering methodologies facilitate the characterization of mismatches and the development of useful solutions.

The principles and methodologies of human factors can be applied in the healthcare setting to mitigate errors, as well as improve the design of the environment, processes, and policies to improve patient care and safety. As Nunnally and Bitan (2006) pointed out, the improvement to the current setup of secondary infusion delivery requires the understanding of users’ cognition, the nature and flow of work, and the interactions between users and devices. The characterization of human factors issues related to the secondary infusion system may increase the awareness of infusion hazards and lead to design, practice improvement, and interventions that can enhance practitioner operations.

**Simulation Testing**

Simulation testing is a method used in human factors engineering to assess the users' interactions with systems, tools, processes, and devices. It involves the systematic collection of data from users' interactions with the device or the system in realistic situations. Data collection may include direct observation of the interaction and/or subjective user feedback in a simulated environment that mimics the actual environment. This method allows better understanding of how the device, process, or system fits into the environment and its associated risks.
3.3.1 Errors and Mitigations from the Human Factors Perspective

Interventions are methods to manage, mitigate, or eliminate the hazards that can lead to errors\textsuperscript{87}. From the human factors perspective, an understanding of why errors occur is important in the identification or development of appropriate interventions.

The Institute of Medicine (IOM) defined error as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim\textsuperscript{88}. The classification of errors on the basis of underlying cognitive and psychological mechanisms can help identify why errors occur and assist in the identification and development of the interventions to prevent them. Rasmussen (1983) presented the classification of human performance and errors in the context of cognitive control of behavior, known as the Skill, Rule, Knowledge-based (SRK) approach\textsuperscript{89}. Skill-based behaviours are actions conducted automatically and with little conscious attention. Skill-based errors are performances of an action that was not intended. Rule-based behaviours are activities controlled by stored rules or procedures\textsuperscript{89}. Rule-based errors are due to the application of a wrong rule or the incorrect recall of a correct rule. Knowledge-based behaviours are actions that are planned from an analysis of the environment and based on the aims of the person, typically during unfamiliar situations. Knowledge-based errors may be due to incomplete or incorrect knowledge during a decision-making situation\textsuperscript{90}. Based on Rasmussen's approach, Ferner and Aronson (2006) further integrated the classification of errors with other error models by Norman (1988)\textsuperscript{91} and Reason (1990)\textsuperscript{92}, and applied it in the context of healthcare.

Ferner and Aronson's classification system categorizes errors into:

1. **Mistakes\textsuperscript{39}**: Errors in the planning of an action. They can be knowledge-based (errors due to a lack of knowledge) or rule-based (errors due to misapplication of a good rule or the application of a bad rule/the failure to apply a good rule)

2. **Slips\textsuperscript{39}**: Action-based error (a subtype of skill-based error) where there is a mis-execution of a correct procedure and the performance of an action was not what was intended.

3. **Lapses\textsuperscript{39}**: Memory-based error (a subtype of skill-based error) where a required action is omitted (e.g. forgetting to carry out a step in a
procedure). Reason (2002) identified task properties that increase the likelihood of an omission error due to lapse in memory. They include: 1) task steps that require high demand upon short-term memory, 2) procedural steps that are functionally isolated, 3) repeated procedural step, 4) necessary steps at the end of a task sequence, and 5) steps in which the item to be acted upon is concealed\(^3\).

In the context of the administration of secondary infusions, the failure to open secondary clamp can be a lapse where a step in the procedure is omitted. Lapses occur in familiar tasks that require little attention and are errors made by even experienced and well-trained people\(^4\). The task to open the secondary clamp in the secondary infusion setup has many properties that Reason identified for task steps that are easily omitted\(^3\). For instance, the opening of the secondary clamp is a procedural step that is not obviously cued by preceding actions, it is a step in a setting that has a high cognitive load, and it is the last step of setting up a secondary infusion. Steps located near the end of a task sequence are often omitted because users tend to take “premature exits” because of preoccupation with the next task\(^3\).

Similar to the omission to open the secondary clamp, the omission to lower the primary container during secondary infusions can be a lapse. This step is functionally isolated with no cues from the previous step. In addition, the incorrect positioning of the IV containers can also be a slip (the secondary container was accidentally lowered when the lowering of the primary container was intended) or a mistake (a knowledge-based error due to a lack of knowledge of hydrostatic principles or a rule-based error due to the application of a bad rule).

A user connecting the piggyback line to the wrong port of the primary line downstream of the pump (connection error) can be a slip (an action-based error where the performance of an action was not what was intended). It can also be a mistake, as a result of a knowledge-based error due to a lack of knowledge of the correct connection point or a rule-based error due to the application of a bad rule.

Programming error as result of incorrect drug conversion calculations or mix-up in the programming sequence can be a slip. It can also be a mistake (a knowledge-based error if
the user is not knowledgeable of how to perform the correct drug conversion calculation error or a rule-based error if the user misapplies a wrong rule to calculate drug conversion requirements).

An understanding of why secondary infusion errors occur can assist in the identification or development of appropriate interventions to mitigate, control or eliminate the hazards that can lead to errors.

3.3.1.1 Control Measures and Intervention

Ferner and Aronson (2006) and the Health and Safety Executive (HSE: industrial safety regulator in Great Britain) both recommended that error prevention strategies and interventions should consider the type of error based on its psychological classification. Table 3 summarizes the different control strategies and interventions proposed by the HSE for different error types.

Mistakes (knowledge-based or rule-based) take place in situations where the person does not know the correct steps to conduct a task. It may happen because the task is unfamiliar or because the person does not have adequate training or experience. In these scenarios, people may apply rules from similar situations which may not be correct. Ferner and Aronson suggested that these knowledge-based mistakes can be managed by training and computerized decision support, and rule-based mistakes can be addressed by modifications to protocols and guidelines.

Slips commonly occur during simple and frequently performed tasks; lapses are errors that are associated with familiar tasks that require little attention. These types of error can take place in highly trained procedures. Ferner and Aronson (2006) suggested increasing checking systems and checking procedures to detect action-based errors (slips). For lapses, Ferner and Aronson suggested that memory-based lapses may be addressed by increased skill training but the HSE indicated that these errors cannot be easily eliminated by education. Instead, design should be improved to reduce their likelihood and provide a more error tolerant system.
Table 3. Error Types and the Control Measures Recommended by the HSE\textsuperscript{94}

<table>
<thead>
<tr>
<th>Error</th>
<th>Potential Control Measures/Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mistakes</td>
<td>- plan for the relevant ‘what ifs’ (procedures for abnormal and emergency cases)</td>
</tr>
<tr>
<td></td>
<td>- clear displays</td>
</tr>
<tr>
<td></td>
<td>- competence (knowledge and understanding of system; training in decision-making techniques)</td>
</tr>
<tr>
<td></td>
<td>- organizational learning (capture and share experience of unusual events)</td>
</tr>
<tr>
<td>Slips and Lapses</td>
<td>- user-centered design (consistent and intuitive layout of controls and instrumentation)</td>
</tr>
<tr>
<td></td>
<td>- checklists and reminders; procedures with removal of distractions and interruptions</td>
</tr>
<tr>
<td></td>
<td>- warnings and alarms to help detect errors</td>
</tr>
<tr>
<td></td>
<td>- often made by experienced, highly-trained: additional training not valid</td>
</tr>
</tbody>
</table>

**Hierarchy of Effectiveness**

In addition to understanding the causes of errors, the "Hierarchy of Effectiveness" is a rule of thumb framework that serves as a guide for the development of interventions to prevent errors\textsuperscript{96,97}. It ranks the effectiveness of different error mitigating strategies. The hierarchy consists of 6 levels of interventions that range from the most effective intervention (at the top) to the less effective (on the bottom) at preventing errors (see Figure 14).

<table>
<thead>
<tr>
<th>Level</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>1)</td>
<td>Forcing Functions</td>
</tr>
<tr>
<td>2)</td>
<td>Automation and Computerization</td>
</tr>
<tr>
<td>3)</td>
<td>Standardization and simplification</td>
</tr>
<tr>
<td>4)</td>
<td>Warning systems, reminders, checklists, double checks</td>
</tr>
<tr>
<td>5)</td>
<td>Rules and policies</td>
</tr>
<tr>
<td>6)</td>
<td>Education and provision of information</td>
</tr>
</tbody>
</table>

*Figure 14. Hierarchy of Effectiveness*\textsuperscript{96}
The most effective interventions, at the top of the hierarchy of effectiveness are physical changes that force functions and eliminate contributing factors of errors. "Forcing functions" are design features that make it impossible to perform an erroneous act. An example of "forcing function" is the use of an epidural tubing without injection ports, which makes it impossible for clinicians to accidently inject medication into the epidural line. After "forcing functions" on the hierarchy are the automation of repetitive processes and computerization of data entry and retrieval. These are followed by interventions that standardize and simplify key processes to minimize reliance on working memory.

In the hierarchy of effectiveness, the technological interventions (top) are ranked higher than interventions related to human behaviour at the bottom, such as the use of checklists, rules and policies, and education and provision of information. Interventions that depend on human behavior are considered less effective than measures that "force functions" and eliminate the hazard by design.

Although "forcing functions" and system redesigns are usually more effective interventions, they are also more difficult to implement and can be associated with higher costs and automation bias, where users may over-rely on automation "as a heuristic replacement of vigilant information seeking and processing." Furthermore, the rapid release of new medical technologies and the fast-paced nature of healthcare may outpace the feasibility for system redesign. In addition, the application of control measures at the top of the hierarchy of effectiveness may not completely remove all inherent risks in a work system.

When redesign or other interventions high on the hierarchy of effectiveness are not feasible or possible, policies/protocols and training are tools that are commonly implemented to reinforce safe practices to minimize harm. It is important to recognize the limitations of policies/protocols and training (such as requirements for adherence and enforcements, the time commitment required from clinicians, and its low effectiveness in compensating for poorly designed devices or systems), but they are not without value. The purpose of the training is to equip users with the adequate skill and knowledge, as well as understanding of the risks. Since humans are still at the core of making judgments at the point of care, effective policies/protocols and training are needed. For example, Tromp et al. (2009)
found that the implementation of a standardized protocol for preparation and administration of IV drugs in two internal wards of a medical centre in Netherland led to a decrease in preparation and administration errors\textsuperscript{101}. In hospitals that do not have Computerized Physician Order Entry system (CPOE), Navaneethan \textit{et al.} (2005) found that training has increased awareness about appropriate medication use and significantly decreased the risk ratio in the inappropriate prescription rates of metformin, thereby decreasing medication errors.\textsuperscript{102} Thus, procedures and training may supplement and improve system safety, especially in systems where redesign is not possible.

### 3.4 Interventions

#### 3.4.1 Identification of Interventions from Human Factors Perspective

The HumanEra Team at the University Health Network in Toronto uses human factors principles to study and improve the complex conditions under which humans work in healthcare. This research team made use of human factors methods (including literature review, incident database review, technology scan, clinical observations, surveys, and interview with nurse educators) to understand the workflow and risks of secondary infusions (see Figure 15). The findings from these human factors methodologies were used to guide the identification of potential interventions to reduce secondary infusion errors.
3.4.2 Potential Interventions

Three interventions were identified by the HumanEra Team, in consultation with an expert panel made up of nurse practitioners and educators at the University Health Network, Canada. Table 4 shows the three proposed interventions and the specific types of secondary infusion errors that each intervention can potentially mitigate. The proposed interventions include a technology-based, a training-based, and a practice-based intervention:

- **Technology-based**: An automated clamp detector on a smart pump
- **Training-based**: Educational module on key secondary infusion principles
- **Practice-based**: The use of a separate pump for short infusions

These interventions were informed by the situation and practice scans (including literature review, incident database review, technology scan, clinical observations, surveys, and interview with nurse educators) conducted by the HumanEra team\(^5,18\). Mitigations included considerations for interventions that could be implemented at the hospital or hospital-unit level of the system. This is because most hospital organizations will likely continue to use the infusion technology that are already purchased and implemented in their organizations\(^5\).

### Table 4. Proposed Interventions and Targeted Secondary Infusion Errors

<table>
<thead>
<tr>
<th>Secondary Clamp Errors</th>
<th>Connection Errors</th>
<th>Pressure Differential Errors</th>
<th>Programming Errors (drug conversion errors, &quot;slip of finger&quot; errors, mix-up between secondary and primary programming rates)</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: A check mark (✓) indicates the secondary infusion issue being targeted by the intervention.
3.4.2.1 Technology-based Intervention

The clamp detector is a technology-based intervention that can detect upstream occlusions at the start of a secondary infusion. If the roller clamp on the secondary IV line is not opened, the pump will detect and alarm user of the secondary line occlusion. This technology-based intervention can potentially reduce secondary infusion errors due to the omission of opening the secondary roller clamp. The use of a clamp detector to reduce secondary clamp errors was identified by Yue (2012) as a potential intervention based on a Healthcare Failure Mode and Effect Analysis (HFMEA) on the safety of secondary infusions. The clamp detector is a form of an automated detection/alert system. It communicates an alert by sound and by a visual error message. This intervention is an example of a warning system/reminder (an intervention at the middle of the hierarchy of effectiveness). It provides a “just-in-time” warning and reminder that directs the user’s attention to an omission of step, prompts the correct action, and reduces the practitioner’s individual reliance to detect errors (see Figure 16). The Health and Safety Executive (HSE) suggested that increasing checking systems and checking procedures can help detect slips and lapse. This clamp detector feature is not currently commercially available on smart pumps in Canada (see Appendix N for a list of licensed smart pump products in Canada). However, this feature has been patented by its pump manufacturer and will soon be commercially available.

Figure 16. Clamp Detector (Adapted from Colvin, 2011)
Furthermore, the smart pump with the automatic clamp detector is equipped with a Dose Error Reduction Software (DERS). It has a drug dose calculator which prompts users to select the medication and its concentration, and automatically calculates the correct dosing units and the volume needed to deliver the prescribed dose. Based on the hierarchy of effectiveness, this intervention is a form of "automation " which can potentially reduce drug conversion calculation programming errors.

**Potential Limitations:** The implementation of this intervention could lead to an increased cost associated with replacing existing traditional pumps with smart pumps. Also, failure modes due to insufficient container height differential and tubing connection errors are not addressed by this intervention.

### 3.4.2.2 Training-based Intervention

Current training and education on secondary infusions are not focused on teaching the underlying principles behind the setup of secondary infusions or the known failure modes\(^5\). Taxis and Barber (2003) reported that 79% of IV administration errors are due to practitioners’ lack of knowledge and experience with medications and infusion devices\(^47\). Better in-service training is needed to increase practitioners’ awareness of common secondary infusions failure modes and the risk for allowing secondary infusions to run unattended\(^5,13\).

The proposed training intervention was designed to address the lack of focus on basic principles and known failure modes in previous training materials. The educational module, developed by HumanEra, provided a 10 minute computer-animated video that demonstrated the key principles and rationales behind secondary infusions, including:

- Fluid principles associated with secondary infusion administration (e.g., rationale behind the height differential requirement, principles of hydrostatics, function of the back-check valve)
- Common secondary infusion errors (e.g., unopened secondary clamp, connection errors, pressure differential errors)
The educational module was iteratively reviewed by 7 nursing experts (including critical care nurse educators). This training intervention was different from previous training materials on secondary infusions in terms of its:

- **Emphasis on basic hydrostatics principles:** It provided information on key secondary infusion principles, including the basics of hydrostatics, the rationale behind the height difference requirement between primary and secondary infusion containers. An increase in user's understanding of the underlying principles behind how secondary infusions work could potentially reduce infusion errors due to incorrect setup and could potentially enable clinicians to manage secondary infusion errors.

- **Emphasis on failure modes:** Current training on secondary infusions commonly involves providing clinicians with step-by-step instructions or a general checklist\(^{103}\). Clinicians are rarely explicitly trained on how to prevent specific errors with secondary infusions. However, Arnold *et al.* (1988) reported that errors are highly informative when learners understand why such mistakes occurred and how they could be corrected\(^{104,105}\). Frese *et al.* (1991) suggested that learners trained on the understanding and management of errors performed better than the control group who were instructed how to perform a task without errors\(^{106}\). Therefore, an important aspect of the proposed educational module was to highlight errors and common known failure modes.

- **Visual demonstration of fluid flow:** The abstract concept of hydrostatics behind how secondary infusions work and fluid dynamics can be difficult to teach through traditional instructional approaches, such as textbook and lecture. The colourless and transparent nature of most drugs and fluids makes it difficult to understand the flow of
fluids during the correct and incorrect setup of secondary infusions, even if the training is done in a real clinical setting. The proposed educational module not only showed the definitions and steps to set up secondary infusions, it also presented concepts visually and demonstrated the dynamic flow of processes through the use of graphics, animation, sound, and video.

Thus, the educational module was designed to provide practitioners with a theoretical knowledge base, as well as a better understanding of secondary infusion risks and failure modes. Although training is ranked lower on the hierarchy of effectiveness, it is not without value, particularly when redesign or other interventions high on the hierarchy of effectiveness may not feasible or possible (see Section 0). The educational module was designed to equip practitioners with the adequate skill and knowledge to improve their ability to apply concepts in a variety of situations, so they could safely administer secondary infusions to patients in the clinical setting.

**Potential Limitations**: Training-based intervention does not remove latent deficiencies in the system, tool, process, or device. Its effectiveness is dependent on human behavior and depend on human vigilance. Skill-based errors (lapses and slips) are often committed even by well-trained users, and may not be easily eliminated by training. It requires time commitment from practitioners. Furthermore, the passage of time and the lack of rehearsal of the acquired knowledge or skills may lead to a decline of performance.107

### 3.4.2.3 Practice-based Intervention

This intervention required the short infusion (the "secondary" or "piggyback" infusate in the piggyback infusion setup) to be set up as an independent infusion on a separate infusion pump, just like a primary infusion. This intervention removed the need for user to open a secondary roller clamp or adjust the heights of the IV containers.
The separate infusion is connected to a compatible maintenance infusion at a y-site below infusion pump to share the IV access with the primary infusion. The advantages of this configuration are:

- No height differential is required between the primary and "secondary" IV containers.
- No secondary roller clamp. Occlusions upstream of pump can be detected.
- The "secondary" infusion cannot back-flow into the primary infusion tubing.
- No need for back-check valve on IV sets.

This intervention can potentially eliminate secondary infusion risks due to insufficient height difference between primary and secondary IV containers because there is no height differential requirement. There is no secondary roller clamp, thereby eliminating the error due to unopened roller clamp. The short infusion can be connected to a compatible line at a port downstream of the infusion pump, in a way that is consistent with other infusions using large-volume pumps. The use of secondary lines will be eliminated, reducing connection errors when the secondary line is connected to the primary line at a wrong port. The infusion pump can control the rate of the short infusion directly rather than relying on the back-check valve to prevent concurrent flow. Furthermore, since the primary and secondary infusions are administered separately, this configuration can potentially eliminate the risk of unintended back-flow of secondary infusate in the primary line. This intervention is an example of "forcing functions" (at the top of the hierarchy of effectiveness) where the design of the system makes it impossible to perform a secondary clamp error or pressure differential error.
The use of a separate dedicated pump for short infusions has been debated online by clinicians on internet forums\textsuperscript{108}. Reports in literature also showed that there were incidences where intermittent infusions were delivered as a primary infusion\textsuperscript{81,109}. For instance, in Belgium, Claus \textit{et al.} (2012) reported the antibiotic delivery of Piperacillin-Tazobactam (Piptazo) using its own dedicated pump\textsuperscript{81}. In United States, Weeks (2012) also recommended the use of a separate pump for the short infusion instead the use of secondary infusion setup when the rate of the short infusion is less than that of the prescribed maintenance IV\textsuperscript{109}. The intention is to ensure the patient does not stop receiving prescribed rate of IV maintenance fluids (a temporary discontinuation of the primary infusion always occurs in secondary infusion setup because the flow of primary IV fluid stops until the secondary infusion completes). The receipt of IV maintenance fluids at the prescribed rate and time is particularly important for patients who are being treated for sepsis, are nil per os (NPO: nothing by mouth), or need additional fluids because of dehydration.

In addition, the use of a separate pump to control the delivery of the short infusion independently is similar to the configuration of the Hospira Plum A+, which controls the primary and secondary infusion lines separately. Since most hospital institutions will continue to use the infusion devices already purchased and implemented in their institutions, interventions that are oriented to work practice and relatively low-cost to implement require investigations\textsuperscript{5}. Therefore, instead of empirically testing a brand-specific pump (Hospira Plum A+), the use of a separate pump was tested to evaluate the effectiveness of controlling the "primary" and "secondary" infusates independently on the reduction of secondary infusion errors. This practice-based intervention uses existing pumps that are already available in the hospital and provides a more economical alternative to replacing existing pumps with the Hospira Plum A+.

\textbf{Potential Limitations:} This configuration may require more pumps in the inventory and more physical space, which can be limited at the patient bedside. Also, since each infusion will require a full primary infusion set, there will be a significant increase in the cost of disposables used. There may also be concerns that the setup will increase the time needed to prepare and administer secondary infusions. Furthermore, the additional pump setup will lead to additional flush volume that may be problematic for fluid-restricted patients. Also,
there is no automatic switch from secondary infusion to primary infusion, which may lead to more call-back alarms from the infusion pump after each infusion is finished.
Chapter 4

4 Research Objectives

The main research question is what are the effects of the proposed interventions on reducing secondary infusion errors using large-volume infusion pumps, in comparison to no intervention. The three interventions are:
- An automated clamp detector on a smart pump (Technology-based Intervention)
- An educational module on key secondary infusion principles (Training-based Intervention)
- The use of a separate pump for short infusions (Practice-based Intervention)

Exclusions:
The following infusion systems are not being considered in this research:
- Insulin, elastomeric, ambulatory pumps and magnetic resonance imaging (MRI) compatible IV pumps.
- Pumps designed for non-IV routes (e.g., nasogastric, intrathecal, epidural, patient-controlled analgesic).

4.1 Approach

The effectiveness of the three interventions was evaluated in simulation-based testing. Simulation testing is a method, often applied in human factors engineering, to evaluate the use of a design or a system by end users in an environment that represents the situations where it is used. In this study, nurses, the primary administrators of medications and representative end users, were asked to conduct secondary infusion tasks while under observation in a high-fidelity simulated clinical environment, with and without interventions. The performance under each intervention was quantitatively measured by metrics, such as the types and frequency of errors, as well as level of user satisfaction. The effects of the interventions on the reduction of secondary infusion errors in comparison to no intervention were investigated.
High-fidelity Simulation Study

For a simulation environment, fidelity not only describes the level of accuracy of the devices in the testing but also the level of realism of the context in which the testing is held\(^\text{10}\). Testing in a high fidelity simulated environment can allow the observations of realistic user behavior and interaction with the interventions. To achieve high fidelity, the following aspects were considered and applied in the simulation: equipment fidelity, environmental fidelity, and task fidelity (see Table 5).

Table 5. Types of Fidelity\(^\text{110}\)

<table>
<thead>
<tr>
<th>Types of Fidelity</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equipment Fidelity</td>
<td>The appearance and feel of the devices or systems are replicated</td>
</tr>
<tr>
<td>Environment Fidelity</td>
<td>The physical characteristics of the actual environment are represented</td>
</tr>
<tr>
<td>Task Fidelity</td>
<td>The tasks involved in the real environment are replicated</td>
</tr>
</tbody>
</table>

Evaluation of Training Intervention

In addition, a framework developed by Kirkpatrick (1976, 1994) to evaluate training and its effectiveness, was used to guide the assessment of the training intervention in this study\(^\text{111,112}\). In this framework, Kirkpatrick classified the evaluation of training into 4 levels: reaction, learning, behavioural, results. Table 6 outlines the 4 different levels and the experimental approach used in this study.

Table 6. Kirpatrick's Four Levels of Training Evaluation\(^\text{111,112}\)

<table>
<thead>
<tr>
<th>Levels</th>
<th>Description</th>
<th>Experimental Approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>Learning</td>
<td>Measure of how much trainees retained from the facts, principles, and approaches.</td>
<td>Written performance test before and after training</td>
</tr>
<tr>
<td>Behavioural</td>
<td>Measure of behaviour change because of the training</td>
<td>High-fidelity simulation testing</td>
</tr>
<tr>
<td>Reaction</td>
<td>Measure of how trainee feels about the training program</td>
<td>Post-experiment interview with participant and survey</td>
</tr>
<tr>
<td>Results/Organizational</td>
<td>Measure of the impact that the training has had overall over time, including financial or morale impacts</td>
<td>Longitudinal effect and financial impact was outside the scope of this current study.</td>
</tr>
</tbody>
</table>
4.2 Hypothesis

It was hypothesized that the three interventions would be effective in reducing secondary infusion errors in comparison to no intervention. Table 7 outlines the research hypotheses for each intervention and the targeted secondary infusion errors.

Table 7. Research Hypothesis

<table>
<thead>
<tr>
<th>Hypothesis #</th>
<th>Intervention</th>
<th>Hypothesis</th>
<th>Targeted Error Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Technology-based Intervention</td>
<td>- The clamp detector on the secondary line provides an automated detection/alert system that can reduce errors due to unopened secondary clamps during secondary infusions, in comparison to no intervention.</td>
<td>Secondary Clamp Errors</td>
</tr>
<tr>
<td>2</td>
<td>Technology-based Intervention</td>
<td>- The DERS and the dose rate calculator can reduce programming errors due to incorrect drug conversion calculations and &quot;double key bounce&quot; errors, in comparison to no intervention.</td>
<td>Programming Errors</td>
</tr>
<tr>
<td>3</td>
<td>Training-based Intervention</td>
<td>- The educational module increases the practitioners' understanding of the role of secondary clamp during secondary infusions, which can reduce the occurrence of secondary clamp errors in comparison to no intervention.</td>
<td>Secondary Clamp Errors</td>
</tr>
<tr>
<td>4</td>
<td>Training-based Intervention</td>
<td>- The educational module increases the practitioners' understanding of correct connections practices and common failure modes, which can reduce connection errors in comparison to no intervention.</td>
<td>Connection Errors</td>
</tr>
<tr>
<td>5</td>
<td>Training-based Intervention</td>
<td>- The educational module increases the practitioners' understanding of the basic hydrostatics principles and common failure modes, which can reduce pressure differential errors due to incorrect positioning of IV bags, high secondary flow rate, or large IV bags, in comparison to no intervention.</td>
<td>Pressure Differential Errors</td>
</tr>
<tr>
<td>Hypothesis #</td>
<td>Intervention</td>
<td>Hypothesis</td>
<td>Targeted Error Type</td>
</tr>
<tr>
<td>-------------</td>
<td>-----------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>------------------------------------------</td>
</tr>
<tr>
<td>6</td>
<td>Practice-based Intervention</td>
<td>The delivery of a short infusion using a separate pump as a primary infusion eliminates the possibility of secondary clamp errors because there is no secondary roller clamp on the primary IV tubing.</td>
<td>Secondary Clamp Errors</td>
</tr>
<tr>
<td>7</td>
<td>Practice-based Intervention</td>
<td>The use of the separate pump prevents the incorrect connection of a secondary line to the primary line, since the use of secondary lines will be eliminated.</td>
<td>Connection Errors</td>
</tr>
<tr>
<td>8</td>
<td>Practice-based Intervention</td>
<td>The elimination of secondary infusions and the requirement to deliver a short infusion with separate pump can prevent the unintended delivery of primary infusion when there is an incorrect positioning of infusion containers.</td>
<td>Pressure Differential Errors</td>
</tr>
<tr>
<td>9</td>
<td>Practice-based Intervention</td>
<td>The use of the separate pump can reduce mix-up in the programming of the primary and the short or intermittent infusate in comparison to no intervention because the two infusions are programmed in separate pump interfaces.</td>
<td>Programming Errors</td>
</tr>
</tbody>
</table>
Chapter 5

5 Methods

The technology-based, training-based, and practice-based interventions were evaluated in a high-fidelity simulated inpatient unit at the Human Factors laboratory of the Centre for Global eHealth Innovation, in University Health Network (UHN), Toronto, Ontario. The investigation of these three interventions on secondary infusion errors was part of a large study on Multiple IV Lines by the HumanEra team supported by Health Quality Ontario, where other multiple IV infusion errors were also investigated (i.e., errors associated with the setup and programming of multiple primary continuous infusions, line tracing and identification errors, dead volume errors, and IV pump bolus issues). This thesis focused only on secondary infusion errors. Ethics approval (Ref No: 12-01849-BE) was obtained from the UHN Research Ethics Board for this study.

This chapter describes the methodology in the following sub-sections.
- Participants
- Experimental Setup
- Experiment Design
- Experiment Procedure
- Data Collection
- Data Analysis

5.1 Participants

Forty nurse participants from critical care areas were recruited across the University Health Network in Toronto. A power analysis was conducted using a sample size and power calculator tool. A sample size of 40 participants was required to ensure an 80 percent probability that the study would detect differences between the experimental conditions at a p<0.05 significance level. The recruitment criteria of the participants included registered nurses at UHN who work with large-volume infusion pumps (Graseby™ 500 pump, Smiths Medical, Minnesota, United States) in critical care environments. Other recruitment criteria included the ability to read, speak, and understand English.
5.2 Experimental Setup

The simulation was conducted at the Human Factors Laboratory, which was equipped with ceiling-mounted cameras, audio recording and editing equipment, and an observation room with a one-way observation glass (see Figure 19).

![Human Factors Laboratory Test Environment](image)

Figure 19. Human Factors Laboratory

Test Environment

The laboratory was simulated to replicate the environment of a critical care inpatient unit. The physical setup included patient beds that were equipped with biomedical equipment (such as physiological monitors and ventilators), IV infusion equipment (such as infusion pumps, IV poles, IV tubing, IV bags) and other supplies (such as gloves, alcohol swabs, and hand sanitizer). A mobile computer workstation was set up with a mock computerized physician order entry system that provided the participants with physician medication orders. Figure 20B shows the simulated critical care environment in the Human Factors Laboratory which was replicated from real clinical setups (see Figure 20A).
Figure 20. A) Photos of real clinical setup at a critical care inpatient unit. B) High-fidelity simulation of an inpatient unit at the Human Factors Laboratory.

No real patient or drug was used. A mannequin was set up in each bed to represent the mock patient. The mock patient was set up to receive multiple infusions (see Appendix F for Medication Orders), a total of 11 continuous infusions, including 2 normal saline (NS) infusions. Figure 21 shows the IV access sites setup on the simulated patient. One NS solution was connected to a multiport connector. It served as a “chaser” to help carry other infusions attached to the connector to the patient. The other NS infusion was directly attached to the patient (i.e., clear medication line).
All medication bags, IV tubing sets, and medication labels were the same as those used in real critical care settings. All infusion bags were pre-labeled with appropriate pharmacy labels. No real medications were used; water was used instead in this experiment.

There were four experimental conditions in this study (see Section 5.3). For each experimental condition, there were two scenarios requiring 2 separate short infusions. One infusion had a drug order that specified the drug amount over a period of time (e.g., Vancomycin (1g/50mL) Order: 1 g, Infuse over 1 hour). The other had a drug order that specified the rate and the required duration. All drug orders included the following infusion parameters: drug dose or drug rate, and volume or duration (see Appendix F for Medication Orders).

Table 8 outlines the experimental arrangement that was set up in this study to achieve equipment fidelity, environment fidelity, and task fidelity.
Table 8. High-Fidelity Experimental Setup

<table>
<thead>
<tr>
<th>Description</th>
<th>Experiment Setup</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Equipment Fidelity</strong></td>
<td>The appearance and feel of the devices or systems are replicated</td>
</tr>
<tr>
<td></td>
<td>Patient beds, a computerized physician order entry (CPOE) system, and IV infusion equipment.</td>
</tr>
<tr>
<td><strong>Environment Fidelity</strong></td>
<td>The physical characteristics of the actual environment are represented</td>
</tr>
<tr>
<td></td>
<td>Auditory distractions, including alarms and sounds from the presence of medical devices, staff and patient conversations, and intercom pages.</td>
</tr>
<tr>
<td><strong>Task Fidelity</strong></td>
<td>The tasks involved in the real environment are replicated</td>
</tr>
<tr>
<td></td>
<td>The secondary infusion tasks, medication orders, and scenarios will be designed in collaboration with the hospital pharmacists and nurses to ensure appropriateness of wording and difficulty in the clinical setting. The nurse actor introduced realistic interruptions, adding stress or pressure to the task scenario. For example, they may act highly emotional, ask difficult questions during an important step of the procedure.</td>
</tr>
</tbody>
</table>

5.3 Experimental Design

A within-subjects study was conducted. Participants were asked to perform equivalent secondary infusion tasks under 4 different conditions:

- no intervention (baseline)
- technology-based intervention
- training-based intervention
- practice-based intervention

The order that the conditions were presented to the participants was partially counterbalanced to offset carry-over effects. The detailed counterbalancing table for the conditions are summarized in Appendix G.
**Test Scenario**

At the start of each condition, a confederate nurse (played by an actor) provided the participant with information on the patients’ medical history and physician’s medication orders. For each condition, participants were given two secondary infusion scenarios. In each scenario, the participants were asked to set up, start, discontinue, or titrate two secondary infusions for the mock patient in response to the physician medication orders and instructions from the confederate nurse.

A general description of each condition is as follow:

- **No intervention (Baseline):** The participants were asked to perform 2 secondary infusions and other infusion tasks with no intervention using a traditional large-volume pump (i.e., non-smart pump), as they would in their normal clinical setting.

- **Technology-based Intervention:** The participants were asked to perform 2 secondary infusions and other infusion tasks with the use of clamp detector (on a smart infusion pump).

- **Practice-based Intervention:** The participants were asked to perform 2 short infusion tasks with the use of a separate pump instead of using the secondary infusion method, as well as other infusion tasks.

- **Training-based Intervention:** On a computer, the participants received a 10min educational module on secondary infusions before being asked to deliver 2 secondary infusions and other infusion tasks. The participants were also given a pre-training and post-training knowledge test. The pre-training knowledge test was used to assess the participant’s baseline knowledge of secondary infusion principles. The post-training knowledge test was used to determine knowledge of secondary infusion principles post-training. The test was pilot tested with 7 nursing experts to ensure appropriateness of wording and difficulty. Each test contains 5 multiple-choice questions regarding secondary infusions (see Appendix J). The duration of each test was 10 minutes. The 5 test questions targeted understanding of the following:
  - Role of secondary clamp (1 question)
- Impact of connecting a secondary infusion below the pump (1 question)
- Hydrostatics principles: pressure differential requirements (3 questions)
  o impact of pressure differential (i.e., bag height) on fluid flow
  o impact of pressure differential (i.e., bag height) on function of the back-check valve (1 question)
  o set-up requirements for secondary infusions with a large IV container (i.e., 1000mL) and fast flow rates (i.e., 850ml/h)

5.4 Experimental Procedure

The experimental procedure is summarized in this section. The protocol and script is presented in Appendix H.

1) Consent and Collection of Demographic Information

At the beginning of the experiment, a test facilitator introduced the participant to the lab environment and the process of simulation. Each participant was informed that s/he would be observed and the session would be recorded (both video and audio) for the purpose of documentation and further analysis. Participants were asked to review and complete consent form (see Appendix B) and an electronic demographic questionnaire (see Appendix C).

2) Orientation

Test participants received a brief orientation from the test facilitator on each intervention before they are introduced to the test scenarios in each condition. Table 9 summarizes the topics covered in the orientation before the intervention in each condition.
Table 9. Orientation

<table>
<thead>
<tr>
<th>Condition</th>
<th>Topics covered in orientation (before each condition)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No intervention (Baseline)</td>
<td>None</td>
</tr>
<tr>
<td>Technology-based Intervention</td>
<td>Training on basic functionality of smart pump, clamp detector functionality (approximately 10 minutes)</td>
</tr>
<tr>
<td>Training-based Intervention</td>
<td>10 minute education module</td>
</tr>
<tr>
<td>Practice-based Intervention</td>
<td>Participants were shown how to set up a short infusion on a separate pump and recommended to manually titrate down or pause the connected “primary” infusion. They were also told to flush the residual volume in the primary IV tubing upon infusion completion to ensure complete dose administration.</td>
</tr>
</tbody>
</table>

3) Testing

In each condition, a confederate nurse provided the participant with information on the patients’ medical history and physician’s medication orders. Participants were given two secondary infusion scenarios. In each scenario, the participants were asked to set up, start, discontinue, or titrate two secondary infusions for the mock patient in response to the physician medication orders and instructions from the confederate nurse.

4) Debriefing: Post-experiment Interview

After the experiment, an interview was conducted by the test facilitator with the participants, to gather comments on their overall experience, preferences and concerns related to the interventions being evaluated. In addition, the participants were asked to rate the following on a 4-point Likert scale for each intervention:

1) Effectiveness in reducing secondary infusion errors (1 = very ineffective; 2 = ineffective; 3 = effective; 4 = very effective)

2) Probability of use clinical practice (1 = definitely not use; 2 = not use; 3 = use; 4 = definitely use)

At the end of the study, participants were asked to keep the details of the experiment confidential, to avoid biasing any colleagues who might participate in the future.
5.5 Data Collection

All testing sessions were video and audio recorded. In each session, behind a one-way observation mirror, the observers recorded the type and frequency of errors by logging on a template with metric categories created in Microsoft Excel. Fleiss’ kappa was calculated to assess the inter-rater reliability for the observers based on the categorical data independently collected. The number of observers was reduced to one when an inter-rater reliability of greater than 0.81 between the observers was reached (the agreement between raters is considered as “almost perfect” if the calculated Kappa value is between 0.81 and 1.00 based the Kappa value guideline published by Landis & Koch). When there were discrepancies in the data collected, observers were asked to review the discrepancies and reach a consensus, with a review of the video and audio recordings when needed.

In addition to the categorical metrics, the observer also collected and recorded other qualitative observations. A summary of data collected:
- Demographic questionnaire
- Types of errors and error rates
- Other observations and qualitative observations
- Post-experiment survey

The primary outcome measures were the error rates of secondary clamp errors, connection errors, pressure differential errors, programming errors with and without interventions. Secondary outcome measures were the changes in pre- and post- training test scores, and the responses to post-experiment survey.

5.6 Data Analysis

5.6.1 Analysis of Inter-rater Reliability

Fleiss’ kappa was calculated to determine the inter-rater reliability between the observer who recorded and collected data during the simulation study. The Fleiss' kappa value was calculated based on the metric categories (a total of 181 categories for the entire Multiple IV Lines study). The Kappa value is evaluated based on the Kappa value guideline published by Landis & Koch (1977). A substantial agreement is considered to be reached if
the Kappa value calculated is between 0.61 and 0.80. The agreement is considered as “almost perfect” if the calculated Kappa value is between 0.81 and 1.00.

5.6.2 Analysis of Error Rates

Data analysis was performed using Microsoft Excel and the Statistical Package for the Social Sciences (SPSS, v19). The type and number of errors were compared across the four conditions (i.e., baseline, training intervention, technology-based intervention, practice-based intervention). The secondary infusion tasks were coded as pass or fail based on the criteria listed in Table 10. The calculation method of the error rates and the statistical tests performed for each error type are outlined in Table 11.

Table 10. Error Definitions

<table>
<thead>
<tr>
<th>Error Definition</th>
<th>Pass</th>
<th>Fail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Secondary Clamp Errors</td>
<td>• Roller Clamp is open</td>
<td>• Roller Clamp is closed</td>
</tr>
<tr>
<td>Connection Errors</td>
<td>• Secondary IV tubing is connected to the correct primary line above pump (Except for Practice-based Intervention: Secondary IV tubing is connected to the correct primary line below pump)</td>
<td>• Secondary IV tubing is connected to primary line below pump (Except Practice-based Intervention: Secondary IV tubing is connected to the correct primary line above pump); and/or • Secondary IV tubing is connected to wrong IV line (a line with an incompatible drug or connection to a line that can introduces the risk of unintentional bolus of other drugs)</td>
</tr>
<tr>
<td>Pressure Differential Errors</td>
<td>• Primary IV bag is positioned lower than the secondary IV bag or primary clamp is closed</td>
<td>• Primary IV bag at the same height or higher than the secondary bag</td>
</tr>
<tr>
<td></td>
<td>• Large IV bags: Primary bag is lowered by two hooks or primary clamp is closed</td>
<td>• Large IV bags: Primary bag is lowered by one hook only</td>
</tr>
<tr>
<td></td>
<td>• High flow rate: Primary clamp is closed, or participant indicates that the high flow rate is a problem, or participant makes the decision not to deliver the infusion.</td>
<td>• High flow rate: Primary clamp is open</td>
</tr>
<tr>
<td>Programming Errors</td>
<td>• Rate and volume are programmed within 25% of prescribed value</td>
<td>• Rate and volume are programmed 25% greater or below prescribed value</td>
</tr>
</tbody>
</table>
Table 11. Statistical Tests (by Error Type)

<table>
<thead>
<tr>
<th>Error Type</th>
<th>Number of Secondary Infusion Tasks</th>
<th>Error Rate Calculation</th>
<th>Statistical Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Secondary Clamp Errors</td>
<td>2</td>
<td>Average error rate based on 2 infusion tasks</td>
<td>One-way repeated measures ANOVA test and post hoc test with Bonferroni Correction.</td>
</tr>
<tr>
<td>Connection Errors</td>
<td>2</td>
<td>Average error rate based on 2 infusion tasks</td>
<td>One-way repeated measures ANOVA test and post hoc test with Bonferroni Correction.</td>
</tr>
<tr>
<td>Pressure Differential Errors</td>
<td>2</td>
<td>Average error rate based on 2 infusion tasks</td>
<td>One-way repeated measures ANOVA test and post hoc test with Bonferroni Correction.</td>
</tr>
<tr>
<td>Pressure Differential Errors</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- All Infusions</td>
<td>2</td>
<td>Based on 1 infusion task</td>
<td>Cochran’s Q and pairwise comparisons using McNemar test (threshold p-value was corrected with Bonferroni correction)</td>
</tr>
<tr>
<td>- Common ¹</td>
<td>1</td>
<td>Based on 1 infusion task</td>
<td>Cochran’s Q and pairwise comparisons using McNemar test (threshold p-value was corrected with Bonferroni correction)</td>
</tr>
<tr>
<td>- Complex ²</td>
<td>1</td>
<td>Based on 1 infusion task</td>
<td></td>
</tr>
<tr>
<td>Programming Errors</td>
<td>2</td>
<td>Average error rate based on 2 infusion tasks</td>
<td>One-way repeated measures ANOVA test and post hoc test with Bonferroni Correction.</td>
</tr>
</tbody>
</table>

Notes:
1. Common pressure differential errors due to incorrect positioning of the IV bags
2. Complex pressure differential considerations (related to large IV bags and high secondary flow rate)

For secondary clamp error, connection errors, programming errors, and all pressure differential errors, one-way within-subjects ANOVA tests and post hoc test with Bonferroni correction were conducted. For common pressure differential errors and complex pressure differential errors, non-parametric analyses using Cochran’s Q and pairwise comparisons (McNemar's test) were specifically conducted.

With Bonferroni correction, for six comparisons, a P value of p < 0.0083 was required to reach significance at the 0.05 level (0.05/6). With Bonferroni correction, for five comparisons, a P value of p < 0.01 was required to reach significance at the 0.05 level (0.05/5).
Furthermore, 2 (years of experience: less than 10 years vs. greater than 10 years) x 3 (error type: secondary clamp error vs. connection error vs. pressure differential error) mixed-factors ANOVA with repeated measures on the last factor was conducted to determine if the years of experience of the participants have any effect the error rates for the different error types. For this analysis, the participants were divided into two groups (less than 10 years of critical care experience and greater than 10 years of critical care experience).

5.6.3 Analysis of Pre- and Post-training Tests

There were two different but equivalent knowledge tests, Test A and Test B. Twenty nurses completed Test A prior to the education module (pre-training test) and Test B after the module (post-training test); 20 nurses completed Test B prior to the module and Test A after the module.

An independent sample t-test was conducted to determine the equivalency of Test A and B (see Appendix J). A one-way within-subjects ANOVA test was conducted to determine if there was any significant change in test scores before and after the training intervention. Each test contained 5 multiple-choice questions covering three topics related to secondary infusions: role of secondary clamp, impact of connecting a secondary infusion below the pump, and hydrostatics principles. Table 12 shows the statistical tests conducted to assess if there was any significant change in test score for each topic.

<table>
<thead>
<tr>
<th>Question Category</th>
<th>Number of Questions</th>
<th>Statistical Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Secondary Clamp Errors</td>
<td>1</td>
<td>Cochran’s Q</td>
</tr>
<tr>
<td>Connection Errors</td>
<td>1</td>
<td>Cochran’s Q</td>
</tr>
<tr>
<td>Pressure Differential Errors</td>
<td>3</td>
<td>One-way repeated measures ANOVA test</td>
</tr>
<tr>
<td>All Topics (Total)</td>
<td>5</td>
<td>One-way repeated measures ANOVA test</td>
</tr>
</tbody>
</table>

5.6.4 Post-experiment Survey

Responses from the post-experiment survey were analyzed with the Cochran's Q test to determine if there was any significant differences.
Chapter 6

6 Results

6.1 Demographics

The demographic information collected from the participants in this study are summarized in Table 13. There was no significant difference in error rates between participants who had less than 10 years of critical care experience and participants who had greater than 10 years of critical care experience (p>0.05).

Table 13. Demographics of Participants

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Frequency (n=39)¹</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
</tr>
<tr>
<td>Role</td>
<td>Staff nurse</td>
</tr>
<tr>
<td>Gender</td>
<td>Female</td>
</tr>
<tr>
<td></td>
<td>Male</td>
</tr>
<tr>
<td>Age range</td>
<td>18 to 29 years</td>
</tr>
<tr>
<td></td>
<td>30 to 39 years</td>
</tr>
<tr>
<td></td>
<td>40 to 49 years</td>
</tr>
<tr>
<td></td>
<td>50 to 64 years</td>
</tr>
<tr>
<td>Years critical care experience</td>
<td>&lt;1 year</td>
</tr>
<tr>
<td></td>
<td>1 to 3 years</td>
</tr>
<tr>
<td></td>
<td>4 to 10 years</td>
</tr>
<tr>
<td></td>
<td>&gt; 10 years</td>
</tr>
<tr>
<td>Clinical care area</td>
<td>Cardiovascular ICU</td>
</tr>
<tr>
<td></td>
<td>Coronary ICU</td>
</tr>
<tr>
<td></td>
<td>Medical surgical ICU</td>
</tr>
<tr>
<td>Average shift(s) per week</td>
<td>&lt; 1 shift</td>
</tr>
<tr>
<td></td>
<td>3 to 4 shift</td>
</tr>
<tr>
<td></td>
<td>&gt; 4 shifts</td>
</tr>
<tr>
<td>Completed post-graduate studies</td>
<td>Critical care nursing core program</td>
</tr>
<tr>
<td></td>
<td>Full critical care nursing certificate</td>
</tr>
<tr>
<td></td>
<td>C.N.A. specialty credential in critical care nursing</td>
</tr>
<tr>
<td></td>
<td>Additional IV therapy courses at education institution (did not specify)</td>
</tr>
</tbody>
</table>

Notes:
1. Demographics for one participant were missing (One participant did not complete the demographics survey, but the performance of all forty participants were analyzed in the study).
6.2 Inter-rater Reliability

The inter-rater reliability for the three raters was found to be Kappa = 0.95. Based on Landis and Koch's (1977) guideline\textsuperscript{113}, this indicates "almost perfect agreement" on categorical observations between the raters (data observers).

6.3 Pre- and Post-Test for Training Intervention

Pre- and post-training knowledge tests were completed before and after the training-based intervention. The average test scores for the post-training knowledge test (mean: 75\%) were significantly higher than test scores on the pre-training test [mean: 46\%; F(1,39) = 59, p < 0.001]. Table 14 shows the average test scores on each type of secondary infusion questions. The training-based intervention led to a significant increase in scores for questions related to pressure differential requirements (p<0.001), and correct IV line connections (p=0.013). However, it did not lead to a significant increase in knowledge scores for questions related to secondary clamp errors (p=0.317).

![Figure 22](image.png)

Figure 22. Overall test scores (mean % ± SEM) in the pre-training and post-training knowledge tests.
### Table 14. Pre- and Post-Training Test Scores (by Question Categories)

<table>
<thead>
<tr>
<th>Secondary Infusion Question</th>
<th>Average Test Score (n=40)</th>
<th>Within-subjects p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre-training Test (Baseline)</td>
<td>Post training Test</td>
</tr>
<tr>
<td>Secondary roller clamp</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>- Role of secondary clamp (i.e., clamp error)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Connection</td>
<td>63%</td>
<td>85%</td>
</tr>
<tr>
<td>- Impact of connecting a secondary infusion below the pump (i.e., connection error)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pressure differential (Average for all 3 questions)</td>
<td>22%</td>
<td>65%</td>
</tr>
<tr>
<td>- Impact of pressure differential (i.e., bag height) on fluid flow</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Function of the back-check valve</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Set-up requirements for secondary infusions with a large IV container (i.e., 1000mL) and fast flow rates (i.e., 750mL/h)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall score (Average for all 5 questions)</td>
<td>46%</td>
<td>76%</td>
</tr>
</tbody>
</table>

### 6.4 Error Rates

Four secondary infusion error types were analyzed: secondary clamp errors (Section 0), connection errors (Section 6.4.2), pressure differential errors (Section 6.4.3), and programming errors (Section 6.4.4). A summary of the mean error rates (by error type) under each condition is shown in Table 15. The types and numbers of errors by participant under each condition are shown in Figure 23.

### Table 15. Mean Error Rates (by Error Type)

<table>
<thead>
<tr>
<th>Error Type</th>
<th>Mean Error Rates (% ± SEM)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>Technology-based Intervention</td>
</tr>
<tr>
<td>Secondary Clamp Errors</td>
<td>11% ± 4</td>
<td>0% ± 0</td>
</tr>
<tr>
<td>Connection Errors</td>
<td>5% ± 4</td>
<td>6% ± 4</td>
</tr>
<tr>
<td>Pressure Differential Errors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Common ¹</td>
<td>35% ± 8</td>
<td>43% ± 8</td>
</tr>
<tr>
<td>- Complex ²</td>
<td>88% ± 5</td>
<td>100% ± 0</td>
</tr>
<tr>
<td>Programming Errors ³</td>
<td>--</td>
<td>--</td>
</tr>
</tbody>
</table>

Notes:
1. Common pressure differential errors due to incorrect positioning of the IV bags
2. Complex pressure differential considerations (related to large IV bags and high secondary flow rate)
3. Programming errors could not be assessed
Figure 23. The types and numbers of errors (by participant) under each condition.
6.4.1 Secondary Clamp Errors

The omission to open the secondary roller clamp during secondary infusion will prevent the delivery of the secondary infusate. The pump will infuse the primary drug or fluid to the patient at the rate of secondary infusate. Figure 24 shows the error rates of secondary clamp errors (mean error rates % ± SEM) across the 4 experimental conditions.

<table>
<thead>
<tr>
<th>Conditions</th>
<th>Mean Error Rate (%)</th>
<th>SEM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline (No intervention)</td>
<td>11 %</td>
<td>4</td>
</tr>
<tr>
<td>Training-based Intervention</td>
<td>15 %</td>
<td>5</td>
</tr>
<tr>
<td>Technology-based Intervention</td>
<td>0 %</td>
<td>0</td>
</tr>
<tr>
<td>Practice-based Intervention</td>
<td>0 %</td>
<td>0</td>
</tr>
</tbody>
</table>

A one-way within-subjects ANOVA was conducted to compare the effect of interventions on error rates of secondary clamp errors across the four experimental conditions. There was a significant effect of intervention type, $F(3,117) = 7.518, p < 0.001$. 

Figure 24. Secondary Clamp Error Rates (mean %±SEM)
Pairwise comparisons with Bonferroni correction were conducted (see Table 17). There were significant decreases in the error rates under the technology-based intervention (smart pump with the clamp alarm) and practice-based intervention (separate pumps setup), in comparison to no intervention and the training-based intervention. However, the training-based intervention did not lead to a significant decrease in secondary clamp error rates in comparison to baseline. No other significant differences were found across conditions.

Table 17. Statistical Comparison of Condition Groups*

<table>
<thead>
<tr>
<th>Conditions</th>
<th>Baseline (No Intervention)</th>
<th>Technology-based Intervention</th>
<th>Training-based Intervention</th>
<th>Practice-based Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline (No Intervention)</td>
<td>--</td>
<td>p = 0.01</td>
<td>p = 0.41</td>
<td>p = 0.01</td>
</tr>
<tr>
<td>Technology-based Intervention</td>
<td>--</td>
<td>--</td>
<td>p &lt; 0.01</td>
<td>n.a**</td>
</tr>
<tr>
<td>Training-based Intervention</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>p &lt; 0.01</td>
</tr>
<tr>
<td>Practice-based Intervention</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
</tbody>
</table>

* Using Bonferroni correction for 5 comparison, a P value of ≤ 0.01 is significant at the 0.05 level.
**n.a = not applicable

Specifically, under the technology-based intervention, each participant completed 2 secondary infusions using the smart pump with a clamp detector. In 20 out of 80 infusions, the participants initially forgot to open the roller clamp. For all 20 infusions, the smart pump with the clamp alarm successfully alerted the participants to open the clamp in 100% of instances. The alarm significantly reduced potential secondary roller clamp errors (p<0.05).

Thus, the technology-based and practice-based interventions significantly decreased secondary clamp errors in comparison to baseline (no intervention), while the training-based intervention did not.
6.4.2 Connection Errors

Table 18 and Figure 25 show the connection error rates (mean% ± SEM) under the 4 experimental conditions. A one-way within subjects ANOVA was conducted to compare the effect of interventions on number of connection errors across the four experimental conditions. Connection error rates did not vary significantly as a function of intervention type, F (3,117) =3.40, p = 0.797.

<table>
<thead>
<tr>
<th>Conditions</th>
<th>Mean Error Rate (%)</th>
<th>SEM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline (No Intervention)</td>
<td>5%</td>
<td>4</td>
</tr>
<tr>
<td>Training-based Intervention</td>
<td>3%</td>
<td>3</td>
</tr>
<tr>
<td>Technology-based Intervention</td>
<td>6%</td>
<td>4</td>
</tr>
<tr>
<td>Practice-based Intervention</td>
<td>5%</td>
<td>4</td>
</tr>
</tbody>
</table>

![Figure 25. Connection Error Rates (mean%±SEM)](image)

A total of 320 secondary infusions were set up during the experiment because each participant (n=40) was asked to deliver 2 secondary infusions under each condition (4 conditions). Although connection error rates did not vary significantly as a function of intervention type, a total of 15 (4.7%) connection errors were observed (see Table 19). In 6 infusion tasks, one participant incorrectly connected the secondary line connection to the primary infusion line downstream of the pump (via a wrong port). For this participant, the
practice-based intervention was the only intervention out of all the interventions that prevented the connection error.

In addition to the incorrect connection of the secondary infusion line to the wrong port of the primary infusion line, other connection errors that could affect patient safety during the delivery of secondary infusion were observed. These errors included the connection to the wrong primary line, including the connection of the secondary infusate to the normal saline "chaser" on a multi-port connector and to the peripheral IV line (PIV) carrying rate-sensitive medications of heparin and humulin R (see "Connection to wrong primary line" in Table 19). Since participants have different practices of labeling and identifying the medication lines and pumps during multiple IV infusions, it was not possible to assess the impact of the three proposed interventions in this study on reducing these specific types of connections errors to wrong medication lines. A discussion of these types of connection errors and their consequences are in Appendix L.

<table>
<thead>
<tr>
<th>Table 19. Types of Connection Errors</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of Connection Errors</strong></td>
</tr>
<tr>
<td>1. Connection to wrong port (6 Instances)</td>
</tr>
<tr>
<td>2. Connection to wrong primary line (9 Instances)</td>
</tr>
</tbody>
</table>

Thus, none of the interventions led to a significant decrease in connection errors.
Figure 26. Incorrect connection of secondary infusate to the "chaser" line on a multi-connector port: IV chasers are usually connected last in a series of infusions on the connector. It is used to provide fluid volume, to ensure IV line patency, or to “push” other medication connected downstream on the multi-connector port.

Figure 27. Incorrect connection to peripheral IV line that is delivering heparin and humulin R
6.4.3 Pressure Differential Errors

The mixing and concurrent flow of the primary and secondary infusates can take place when the IV containers are not positioned correctly to establish enough pressure differential between the two IV lines to close the back-check valve. Concurrent flow can also occur when piggybacking a large secondary IV container or delivering a secondary infusion at a high secondary flow rate if the user does not take additional precautions (see Pressure Differential Errors in Section 2.2) Table 20 and Figure 28 show the error rates of pressure differential (mean error rates % ± SEM) across the 4 experimental conditions.

<table>
<thead>
<tr>
<th>Conditions</th>
<th>Mean Error Rate (%)</th>
<th>SEM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline (No Intervention)</td>
<td>61%</td>
<td>5</td>
</tr>
<tr>
<td>Training-based Intervention</td>
<td>34%</td>
<td>6</td>
</tr>
<tr>
<td>Technology-based Intervention</td>
<td>71%</td>
<td>4</td>
</tr>
<tr>
<td>Practice-based Intervention</td>
<td>0%</td>
<td>0</td>
</tr>
</tbody>
</table>

Figure 28. Pressure Differential Error Rates (mean %±SEM)

A one-way within subjects ANOVA was conducted to compare the effect of interventions on the error rates of pressure differential errors across the four experimental conditions. There was a significant effect of intervention type, F (3,37) = 118.615, p < 0.005.
Pairwise comparisons with Bonferroni correction were conducted (see Table 21). The smart pump with the clamp detector (technology-based intervention) did not significantly reduce pressure differential errors. Both the practice-based intervention and the training-based intervention significantly decreased pressure differential errors in comparison to both the baseline with no intervention and the technology-based intervention. For the reduction of pressure differential errors, the practice-based intervention led to a significantly greater reduction in pressure differential errors than the training-based intervention.

### Table 21. Statistical Comparison of Condition Groups*

<table>
<thead>
<tr>
<th>Conditions</th>
<th>Baseline</th>
<th>Training-based Intervention</th>
<th>Technology-based Intervention</th>
<th>Practice-based Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline (No Intervention)</td>
<td>--</td>
<td>p &lt; 0.008</td>
<td>p = 0.058</td>
<td>p &lt; 0.008</td>
</tr>
<tr>
<td>Training-based Intervention</td>
<td>--</td>
<td>--</td>
<td>p &lt; 0.008</td>
<td>p &lt; 0.008</td>
</tr>
<tr>
<td>Technology-based Intervention</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>p &lt; 0.008</td>
</tr>
<tr>
<td>Practice-based Intervention</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
</tbody>
</table>

* Using Bonferroni correction for multiple comparison, a P value of ≤ 0.008 is significant at the 0.05 significance level.

Thus, both the training-based and the practice-based intervention significantly decreased overall pressure differential errors.

However, in Section 2.2, two subtypes of pressure differential errors were described:

1) Common pressure differential error in typical secondary infusions (i.e., incorrect positioning of the IV containers)

2) Infusions that require complex pressure differential considerations (i.e., errors when piggybacking a large secondary IV container or delivering a piggyback infusion at a high secondary flow rate)

Therefore, to pinpoint the effect of the interventions on different subtypes of pressure differential errors, the error rates for the two subtypes of infusion tasks were further analyzed separately.
Common pressure differential error in typical secondary infusions

Common pressure differential error in typical secondary infusions is the incorrect positioning of the IV containers. In the correct setup, the primary IV container on the IV pole should be lowered using a hook provided by manufacturer. In each experimental condition of the study, one of the two infusion tasks was a typical secondary infusions that require common pressure differential considerations (i.e., lower the primary infusion to establish sufficient pressure difference) Figure 29 shows the error rates of this type of pressure differential errors (mean error rates % ± SEM) across the 4 experimental conditions.

![Common Pressure Differential Error Rates](image)

**Figure 29. Common Pressure Differential Error Rates (mean%±SEM)**

The mean error rates were 35% (SEM = 8) under no intervention, 18% (SEM = 6) under training-based intervention, 43% (SEM = 8) under technology-based intervention, and 0% (SEM = 0) under practice-based intervention. With a Cochran's Q test, it was found that there was significant difference in mean error rates among the interventions, Q(3) = 30.529, p < 0.005. Pairwise comparisons using McNemar's tests with Bonferroni correction (see Table 22) indicated that the mean error rate under practice-based intervention was significantly lower than no intervention, the technology-based intervention, and nearly significantly lower than the training-based intervention. The mean error rate under the
training-based intervention was also significantly lower than under the technology-based intervention.

However, there was no significant difference in mean error rates between baseline (no intervention) and training-based intervention or between baseline (no intervention) and the technology-based intervention.

### Table 22. Statistical Comparison of Condition Groups*

<table>
<thead>
<tr>
<th>Conditions</th>
<th>Baseline</th>
<th>Training-based Intervention</th>
<th>Technology-based Intervention</th>
<th>Practice-based Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline (No intervention)</td>
<td>--</td>
<td>p = 0.039</td>
<td>p = 0.508</td>
<td>p &lt; 0.008</td>
</tr>
<tr>
<td>Training-based Intervention</td>
<td>--</td>
<td>--</td>
<td>p &lt; 0.008</td>
<td>p = 0.016</td>
</tr>
<tr>
<td>Technology-based Intervention</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>p &lt; 0.008</td>
</tr>
<tr>
<td>Practice-based Intervention</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
</tbody>
</table>

* Using Bonferroni correction for multiple comparison, a P value of ≤ 0.008 is significant at the 0.05 level.

A noteworthy observation was that some participants had the habit of closing the clamp (see Figure 30) on the primary IV tubing, instead of lowering the primary IV container, to prevent flow from the primary infusion. The smart pump in the technology-based intervention did not have a clamp on the primary line, and therefore some participants failed to adjust the bag heights when the primary clamp was unavailable, resulting in concurrent flow.

![Figure 30. Lack of slide clamp on primary IV tubing for smart pump](image)

Thus, only the practice-based intervention significantly decreased common pressure differential errors. The training-based intervention did not significantly reduced common pressure differential errors in typical secondary infusions.
Infusions that require complex pressure differential considerations

Complex pressure differential considerations are needed when piggybacking a large secondary IV container or delivering a piggyback infusion at a high secondary flow rate. In each experimental condition, one of the two infusion tasks was a secondary infusion that require more complex pressure differential considerations. It involved piggybacking a large secondary IV container or delivering a piggyback infusion at a high secondary flow rate. Figure 31 shows the error rates of this type of pressure differential errors (mean% ± SEM) cross the 4 experimental conditions.

![Complex Pressure Differential Error Rates](image)

**Figure 31. Complex Pressure Differential Error Rates(mean%±SEM)**

The mean error rates were 88% (SEM = 5) under no intervention, 50% (SEM = 8) under training-based intervention, 100% (SEM = 0) under technology-based intervention, and 0% (SEM = 0) under practice-based intervention. With a Cochran's Q test, it was found that there was significant difference in mean error rates among the interventions, Q(3) = 83.63, p < 0.005.
Pairwise comparisons using McNemar’s tests with Bonferroni correction revealed that the mean error rate under both the practice-based intervention and the training-based interventions were each significantly lower than no intervention and the technology-based intervention. The mean error rate under the practice-based intervention was significantly lower than the training-based intervention. There was no significant difference in mean error rates between no intervention and the technology-based intervention.

Table 23. Statistical Comparison of Condition Groups

<table>
<thead>
<tr>
<th>Conditions</th>
<th>Baseline</th>
<th>Training-based Intervention</th>
<th>Technology-based Intervention</th>
<th>Practice-based Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline (No intervention)</td>
<td>--</td>
<td>p &lt; 0.008</td>
<td>p = 0.063</td>
<td>p &lt; 0.008</td>
</tr>
<tr>
<td>Training-based Intervention</td>
<td>--</td>
<td>--</td>
<td>p &lt; 0.008</td>
<td>p &lt; 0.008</td>
</tr>
<tr>
<td>Technology-based Intervention</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>p &lt; 0.008</td>
</tr>
<tr>
<td>Practice-based Intervention</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
</tbody>
</table>

* Using Bonferroni correction for multiple comparison, a P value of ≤ 0.008 is significant at the 0.05 level.

In comparison to no intervention, the technology-based intervention did not lead to a significant decrease in mean error rates for infusions that require complex pressure differential considerations, similar to the effect of technology-based intervention on common pressure differential errors.

The practice-based intervention significantly reduced the mean error rates for pressure differential errors that were due to large IV bags and high secondary flow rate, in comparison to no intervention, the training-intervention, and the technology-based intervention.

Thus, both the practice-based and the training-based interventions significantly decreased complex pressure differential errors in comparison to baseline (no intervention). However, only the practice-based intervention decreased common differential errors.
### 6.4.4 Programming Errors

The programming error rates under the different intervention could not be compared against the baseline (no intervention) due to an unexpected bias observed in the baseline condition. It was observed that 14 out of 40 participants (35%) made the same mistake of programming twice the prescribed rate or greater (>100mL/h instead of 50mL/h) for vancomycin. The error rate of this "doubling" mistake was significantly smaller in all other interventions, leading to investigation of the reason behind this. A nurse educator was consulted and it was discovered that many nurses at UHN often use a larger bag (100mL) with a concentration of 1g/100mL to deliver vancomycin. Although the drug order for vancomycin requires a rate of 50mL/h and volume of 50mL, 35% of nurses may have entered 100ml/h for the rate and 100mL for the VTBI by routine. This bias in the baseline was unexpected. The high error rates in the baseline can lead to an over-estimation of the effectiveness of the other interventions. Thus, the error rates under the different intervention cannot be compared against the baseline (no intervention).

**Table 24. Programming Errors**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Drug Infusion</th>
<th>Percentage of Participants (n=40)</th>
<th>Greater than prescribed rate by &gt;25%</th>
<th>Lower than prescribed rate by &gt;25%</th>
</tr>
</thead>
<tbody>
<tr>
<td>No intervention</td>
<td>Vancomycin&lt;sup&gt;b&lt;/sup&gt;</td>
<td>&lt;sup&gt;35&lt;/sup&gt; % (14 out of 40)&lt;sup&gt;g&lt;/sup&gt;</td>
<td>2.5 % (1 out of 40)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Clinical Trial Drug&lt;sup&gt;c&lt;/sup&gt;</td>
<td>0 % (0 out of 40)</td>
<td>2.5 % (1 out of 40)</td>
<td></td>
</tr>
<tr>
<td>Technology-based</td>
<td>Ceftriaxone&lt;sup&gt;d&lt;/sup&gt;</td>
<td>12.5 % (5 out of 40)</td>
<td>10 % (4 out of 40)</td>
<td></td>
</tr>
<tr>
<td>Intervention&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Sodium Bicarbonate&lt;sup&gt;e&lt;/sup&gt;</td>
<td>0 % (0 out of 40)</td>
<td>0 % (0 out of 40)</td>
<td></td>
</tr>
<tr>
<td>Training-based</td>
<td>Piptazo&lt;sup&gt;f&lt;/sup&gt;</td>
<td>5 % (2 out of 40)</td>
<td>5 % (2 out of 40)</td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>Sodium Bicarbonate&lt;sup&gt;e&lt;/sup&gt;</td>
<td>0 % (0 out of 40)</td>
<td>0 % (0 out of 40)</td>
<td></td>
</tr>
<tr>
<td>Practice-based</td>
<td>Piptazo&lt;sup&gt;d&lt;/sup&gt;</td>
<td>7.5 % (3 out of 40)</td>
<td>0 % (0 out of 40)</td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>Clinical Trial Drug&lt;sup&gt;c&lt;/sup&gt;</td>
<td>0 % (0 out of 40)</td>
<td>2.5 % (1 out of 40)</td>
<td></td>
</tr>
</tbody>
</table>

**Notes:**

a. The smart pump with the clamp detector has a DERS software and drug library that allows practitioner to program the duration of the infusion by default.

b. Vancomycin (Correct Rate = 50mL/h, Correct Volume =50mL)

c. Clinical Trial Drug (Correct Rate = 750mL/h, Correct Duration = 20 min, Correct Volume = 250mL/h)

d. Ceftriaxone (Correct Rate = 50mL/h, Correct Duration = 60 min)

e. Sodium Bicarbonate (Correct Rate = 250mL/h, Correct Volume =1000mL)

f. Piptazo (Correct Rate = 100mL/h, Correct Volume =50mL)

g. 14 out of 40 participants (35%) programmed twice the prescribed rate or greater (>100mL/h instead of 50mL/h)
6.5 New Observations

6.5.1 Inconsistent Management of Residual Volume under Practice-based Intervention

Specifically during the use of a separate pump for short infusions (practice-based intervention), it was observed that 75% (30 of 40) of participants did not appropriately manage the residual medication (approx. 25mL) in the tubing at the end of the infusion. A summary of issues related to residual volume management are outlined in Table 25.

Table 25. Issues related to Residual Volume Management

<table>
<thead>
<tr>
<th>Residual Volume Management</th>
<th>Number of Participants</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Residual volume was given at the start of the next medication after possible drug degradation</td>
<td>11</td>
<td>- 3 participants switched empty secondary bag with a saline flush bag and flushed tubing at a rate that matched the rate of the prescribed medication and at the same volume as the residual volume (25mL ±20 %)</td>
</tr>
<tr>
<td>2. Incomplete administration of full dose of medication</td>
<td></td>
<td>- Too much volume: 4 participants switched empty secondary bag with a saline flush bag and flushed a volume more than double the residual medication</td>
</tr>
<tr>
<td>• Residual medication discarded with a change in IV tubing</td>
<td>19</td>
<td>- At too high a rate: 1 participant switched empty secondary bag with a saline flush bag and flushed at a high rate (999mL for 30mL)</td>
</tr>
<tr>
<td>• Residual medication was discarded (i.e., flushed) into garbage can</td>
<td>1</td>
<td>- At too low a rate: 1 participant switched empty secondary bag with a saline flush bag and flushed at a low rate (100mL for 3mL)</td>
</tr>
<tr>
<td>3. Residual Volume was fully delivered to patient</td>
<td>9</td>
<td>- 3 participants switched empty secondary bag with a saline flush bag and flushed tubing at a rate that matched the rate of the prescribed medication and at the same volume as the residual volume (25mL ±20 %)</td>
</tr>
</tbody>
</table>


In summary, it was found that:

1. 25% (11 out of 40) of participants did not adequately flush the residual fluid prior to reusing the same IV tubing for the subsequent medication.

2. 50% (20 out of 40) participants disposed of residual medication.

In total, 22.5% (9 of 40) of participants infused the full dose of infusion by delivering the residual medication in the tubing to the patient. However, only 3 participants accurately delivered the residual medication in the tubing at a rate that matched its prescribed rate and the residual volume (25mL ±20%). The other 6 of 9 nine participants delivered the full dose of medication but:
   - 4 participants delivered more than double the residual volume (Too much volume)
   - 1 participant flushed at high rate of 999mL for 30mL (Rate is too high)
   - 1 participant flushed at low rate of 100mL for 30mL (Rate is too low)

In addition, inconsistent practices of flushing to manage residual volume were observed. It was observed that 7 out of 40 participants attempted to deliver the residual volume but did not adequately flush the line:
   - 2 participants set the flush volume too low to clear the residual volume
   - 3 participants injected a flush syringe(5cc -10cc) at y-site above the pump (see Figure 32)
   - 2 participants flushed the maintenance line that was connected downstream of the pump delivering the short infusion. The residual medication in "short infusion line" above the connection point remained in the IV line after flushing.

Figure 32. Y-site (Injection location of flush syringe)

Thus, mismanagement of residual volume in the IV lines was observed during the use of a separate pump for short infusions.
6.5.2 Variations in the Management of the "Primary" Infusion during the Practice-based Intervention

When a short infusion is set up using a separate pump, both the short infusion and the primary infusion that it is connected to are delivered concurrently. In contrast, during secondary infusions, the primary infusion (typically a maintenance fluid) temporarily stops until the secondary infusion finishes. This difference between the two setups was highlighted in the orientation before participants were asked to set up a short infusion of antibiotics using a separate pump. In the orientation before the practice-based intervention condition (see Table 9), all participants were shown how to pause or titrate down the rate of the connected “primary” infusion. Table 25 shows the number of participants who did and did not reduce the rate of the "primary" infusion that the short infusion was connected to, when delivering the short infusion using a separate pump.

Table 26. Management of "Primary" Infusion Rate

<table>
<thead>
<tr>
<th>Observations</th>
<th>Number of Participants (n=40)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did not reduce the rate of the primary infusion that the short infusion was connected to</td>
<td>29</td>
</tr>
<tr>
<td>Reduced the rate of the primary infusion that the short infusion was connected to</td>
<td>9</td>
</tr>
<tr>
<td>Paused the primary infusion that the short infusion was connected to</td>
<td>2</td>
</tr>
</tbody>
</table>

Thus, there was a variation in the management of the "primary" infusion during the practice-based intervention. The majority of participants did not reduce the rate of the primary infusion that the short infusion was connected to. Only 11 out of 40 participants titrated down the rate or stopped the primary line that the short infusion was connected to.
6.6 Post-experiment Questionnaire

At the end of the experiment session, participants were asked to rate the effectiveness of each intervention on the reduction of secondary infusion errors (1=very ineffective; 4=very effective), as well as the probability of use of each intervention on the clinical units (1= definitely not use; 4 = definitely use).

Table 27 shows the average rating and general comment themes for each intervention.

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Effectiveness at reducing secondary infusion errorsa</th>
<th>Likelihood of using intervention in clinical practiceb</th>
<th>General Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technology-based Intervention</td>
<td>3.7</td>
<td>3.8</td>
<td>important feature to improve patient safety</td>
</tr>
<tr>
<td>Training-based Intervention</td>
<td>3.6</td>
<td>3.6</td>
<td>increased my understanding of IV principles</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>would be useful for new hires and should be added to the hospital’s annual re-certification program</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>module was too long to be viewed while at work</td>
</tr>
<tr>
<td>Practice-based Intervention</td>
<td>2.7</td>
<td>2.0</td>
<td>required more time to set up (e.g., prime primary line)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>increased workload upon infusion completion (practitioners are called back by an infusion alarm to the bedside to an end of infusion and need to flush the residual infusate in the IV tubing)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>required at least one more pump at the bedside where space is already limited, pump shortages are common, and contribute to line identification confusion</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>financial and environmental costs of using more primary IV tubing and flush IV mini-bags</td>
</tr>
</tbody>
</table>

aFour point scale: 1=very ineffective; 2= somewhat ineffective; 3= somewhat effective; 4= very effective
bFour point scale: 1= definitely not use; 2= probably not use; 3= probably use; 4= definitely use
Figure 33 summarizes the results from participant's feedback on the effectiveness and usefulness of the interventions, in the post-experiment questionnaire. When asked to rate the perceived effectiveness of the interventions at reducing secondary infusion errors, responses by participants were statistically different between the types of interventions, $F(2,80)=23.608$, $P<0.001$. The rating of the practice-based intervention ($M=2.7$) was significantly lower than the technology-based intervention ($M=3.7$, $P<0.001$) and the training intervention ($M=3.6$, $P<0.001$).

When asked to rate the probability of use of each intervention, responses by participants were also statistically different between the types of interventions, $F(2,78)=43.98$, $P<0.001$. Participants rated the likelihood of using the practice-based intervention ($M=2.0$) significantly lower than the technology-based intervention ($M=3.8$, $P<0.001$) and training-based intervention ($M=3.6$, $P<0.001$).

Thus, the perceived effectiveness and the probability of use of the practice-based intervention was the lowest in comparison to the technology-based intervention and the training-based interventions.
Chapter 7

7 Discussion

The occurrence of errors and patient harm during secondary infusions have been demonstrated by incident reports from ISMP Canada and FDA databases. Three interventions (a technology-based, a training-based, and a practice-based intervention) to reduce secondary infusion errors were tested in a high-fidelity simulated clinical environment. The three interventions included: i) the use of clamp detector on a smart pump (technology-based), ii) an educational module (training-based), and iii) the use of a separate pump for short infusions (practice-based intervention). The effects of these interventions on four common secondary infusion error types were analyzed: secondary clamp errors (Section 0), connection errors (Section 6.4.2), pressure differential errors (Section 6.4.3), and programming errors (Section 6.4.4).

The baseline (no intervention) results from this present study were consistent with findings reported by Trbovich et al. (2010) who investigated the frequency of different types of secondary infusion errors in a simulated inpatient unit with 24 nurse participants from multiple clinical areas (e.g., cardiac intensive care unit, emergency, general internal medicine). The mean error rates of secondary clamp errors (11%), connection errors (5%), and common pressure differential errors (35%) in the baseline of this present study (no intervention) were found to be similar to the error rates reported by Trbovich et al., which were 9%, 6%, and 37%, respectively. However, the error rates of specific types of secondary infusion errors in actual clinical settings have not been reported in literature.

No significant difference in secondary infusion error rates was observed in the present study between participants who had less than 10 years of critical care experience and participants who had greater than 10 years of critical care experience. This is consistent with findings by Statistics Canada, reported by Wilkins et al. (2008), who found that the likelihood of medication error was not significantly related to number of years as a nurse. The effects of the interventions on the different types of secondary infusion errors are discussed from Sections 7.1 to 7.3.
7.1 Effects of the Technology-based Intervention

The clamp detector on the smart pump (technology-based intervention) was effective in significantly decreasing secondary clamp error rates in comparison to baseline (no intervention) and the training intervention.

Based on Ferner and Aronson's (2006)\textsuperscript{39} classification of errors which was adapted from Rasmussen's SRK (Skills, Rules, Knowledge) model\textsuperscript{89}, secondary clamp errors (the omission to open the secondary clamp) can be considered as a memory-based error, where a step is omitted due to a lapse in memory during a skill-based task (i.e., tasks conducted automatically and with little conscious attention).

The high average test scores on the secondary clamp question in the pre-training test suggests that nurse participants in this study had the adequate knowledge base to complete this task correctly and that this error was not a result of knowledge gap. Instead, these lapses were likely occurring during highly routine activities, which the user had been appropriately trained in\textsuperscript{93}. The task to open the secondary clamp in the secondary infusion setup has many factors that Reason (2002)\textsuperscript{93} identified for task steps that are easily omitted: 1) it is a procedural step that is not obviously cued by preceding actions; 2) it is a step in a setting that has a high cognitive load, and 3) it is a step near the end of setting up a secondary infusion where users tend to take “premature exits” because of preoccupation with the next task. In the present study, the clamp detector, an automatic detection and alert technology, provides a more effective mitigation strategy against this memory-based error than baseline (no intervention) or the training intervention. This finding is consistent with Health and Safety Executive’s (HSE) guidelines that memory-based errors (lapses) cannot be eliminated by training\textsuperscript{95}, thereby require interventions higher up on the hierarchy of effectiveness. The hierarchy of effectiveness framework ranked interventions that are less dependent on human behavior to be higher in effectiveness than training\textsuperscript{96}.

Overall, participants rated this technology-based intervention to have a high level of effectiveness in reducing errors and probability of use (see Figure 33). Over 75\% of the participants rated the technology-based intervention to be very effective. However, contrary to its perceived effectiveness, the smart pump did not significantly reduce connection errors or pressure differential errors. These findings were consistent with results...
reported by Trbovich et al. (2010), who demonstrated that smart pumps with DERS (with no clamp detector) did not significantly decrease secondary infusion errors in comparison to traditional pumps and barcode pumps. Husch et al. (2005) pointed out that “smart” pump technology is often expected to be capable of reducing IV medication errors associated with IV pumps because IV pump errors are often assumed to be programming errors in literature. However, in a study that investigated the preventability of IV errors by smart pump technology, Husch et al. showed that 97.3% of "IV rate deviation" errors found in their study were rated unlikely to be prevented by smart pump technology. The assumptions that "smart" pump technology can reduce all IV errors may allow undetected weaknesses in medication delivery system to persist and can lead to patient safety risks.

Literature searches did not reveal studies that evaluated the use of clamp detector or similar automated detection/alert system for secondary infusions. However, the use of electronic alerts and warnings have been reported for clinical systems that are used during other stages of the medication use cycle, such as the Electronic Patient Medication Record (ePMR) systems during medication order entry. Some Electronic Patient Medication Record (ePMR) systems can generate visual alerts for users when there are clinical hazards and errors during order entry. Systematic review by Ojeleye et al. (2013) demonstrated that the use of alerts and warnings in ePMRs was effective in reducing the dispensing of critically interacting, contraindicated drugs based on age or pregnancy, adverse drug events related to hyperkalaemia and medication errors.

Although the results in the study indicate that the automated clamp detector (technology-based intervention) was effective in reducing secondary clamp errors, the long-term effectiveness of the clamp detector could not be assessed in this short-term study. The introduction of the clamp detector alarm could lead to increased noise, divert attention from other clinical alarms, or lead to alarm fatigue (where staff become overwhelmed by the number of alarm signals, which results in alarm desensitization and delayed response or missed alarms). In the present study, the participants responded to the clamp alarm in 100% of instances when it detected an error. There was no missed alarm and the clamp detector significantly reduced potential close calls of secondary clamp errors. Furthermore, there was no evidence that the clamp detector diverted attention from other clinical alarms. However, the long-term effects need to be investigated over a longer period of time.
Thus, as hypothesized, the clamp detector on the smart pump was effective in significantly decreasing secondary clamp error rates in comparison to baseline and the training intervention. The clamp detector (a technology-based intervention) targeted at reducing secondary clamp errors but other interventions are needed to reduce other error types such as connection errors and pressure differential errors.

7.2 Effects of the Training-based Intervention

Kirkpatrick's evaluation model of training is a framework to determine the effectiveness of training\textsuperscript{111,112}. Applications of Kirkpatrick's model have been used to evaluate the effectiveness of nursing training programs\textsuperscript{116–120}.

The training-based intervention for secondary infusions was assessed based on an adaptation of Kirkpatrick's evaluation model, focusing on learning, behaviour, and reaction.

7.2.1 Learning

To measure the learning (theoretical knowledge) that the participants gained from the educational module, they were asked to complete a written test on secondary infusion principles and failure modes before and after the training intervention. The mean test scores for the overall post-training knowledge test were significantly higher than mean test scores on the pre-training test. The improvement of test scores in the post-training tests indicates that the training intervention resulted in a gain of overall knowledge in secondary infusion principles/failure modes.

To date, there has been no empirical study that evaluated the theoretical knowledge gained from computer-based training on the reduction secondary infusion errors. However, the improvement in mean test scores in the post-training knowledge test of the present study was consistent with the findings reported by Ford et al. (2010), who observed an increase in post-training quiz scores after the use of traditional lecture-based training and simulation-based training on the reduction of medication administration errors in two intensive care units\textsuperscript{57}. 
The pre- and post-training knowledge tests covered important concepts related to secondary infusion principles and known failure modes. There were three main categories of questions which addressed different types of secondary infusion errors: 1) role of secondary clamp, 2) correct IV line connections, and 3) pressure differential requirements (impact of pressure differential on fluid flow and function of the back-check valve, setup requirements for secondary infusions with a large IV container and high flow rates). Based on the pre- and post-training tests, the training intervention did not lead to a significant increase in test scores for questions related to secondary clamp errors. This suggests that nurse participants had adequate knowledge to successfully complete this task prior to the training and that this error was not a result of knowledge gap. However, the educational module led to a significant increase in scores for questions related to pressure differential requirements and correct IV line connections, suggesting that this educational module addressed an existing knowledge gap related to these error types.

Thus, the results from the pre- and post-training tests indicate that the educational module led to a gain in overall knowledge of secondary infusion principles/failure modes, particularly pressure differential requirements and correct IV line connections. However, there was no theoretical knowledge gained related to secondary clamp errors.

7.2.2 Behaviour

The performance and error rates in the high-fidelity simulation were used to measure behaviour change as a result of training using the educational module.

Secondary Clamp Errors

For secondary clamp errors, the educational module did not lead to significant reductions in secondary clamp errors in the simulated setting. This is consistent with the findings from the written knowledge test, further suggesting that the nurse participants have an adequate knowledge base related to this task. This observation supports that the omission to open the secondary clamp may not be a result of knowledge gap, but instead, a memory-based error where a step is omitted due to a lapse in memory (see Sections 7.1 and 7.2.1). These lapses tend to occur during highly routine activities even when users are well-trained. This is consistent with
Health and Safety Executive (HSE) recommendations that additional training is not the most appropriate response to lapses which are memory-based errors. The clamp detector (Section 7.1) and the use of a separate pump (Section 7.3), which were interventions higher up on the hierarchy of effectiveness, were more effective than the training intervention in reducing the omission errors of opening secondary clamps. Previously, May et al. (2009) suggested that training intervention can improve the understanding of the context and implications of actions, and thereby reduce incidences of omissions being made by individuals or teams. However, Henriksen et al. (2006) indicated that additional training for lapses during skill-based tasks is of little value since care providers are already performing these routine tasks at asymptotic levels. Therefore, the results of the present study are consistent with Henriksen et al. and suggest that the advantages of training intervention are of less value with skill-based tasks than with knowledge-based tasks that are more cognitively demanding.

**Connection Errors**

Although the mean test scores on questions related to the correct IV line connection (see Table 14) were significantly higher in the post-training than the pre-training written test, the educational module did not significantly reduce actual connection errors in the simulated clinical environment as hypothesized. This observation was consistent with the results reported by Ford et al. (2010), who did not observe a decrease in error rates in medication administration errors after the use of traditional lecture-based training.

Thus, the educational module may have increased theoretical knowledge about connection errors but this theoretical knowledge did not appear to translate to reduction of error.

**Pressure Differential Errors**

The training-based intervention, as hypothesized, led to a significant decrease in complex pressure differential errors (errors related to high secondary flow rates and height difference requirements for large IV bags). This is consistent with the
improved performance on the post-training tests for questions related to hydrostatic principles and pressure differential. The result suggests that the educational module led to increased knowledge of basic hydrostatic principles, enabling participants to better manage infusions that have complex pressure differential considerations. When a deficiency of knowledge leads to an error (knowledge-based error), training may help address the knowledge gap and reduce errors, as seen in the case of complex pressure differential errors. This is consistent with literature that showed training improves outcomes.\textsuperscript{123} Ross and Loke (2009) systematically reviewed 11 controlled trials of educational intervention aimed at improving prescribing practices by medical students or junior doctors\textsuperscript{124}. They reported that 10 out of 11 studies indicated a decrease in prescribing errors after a training intervention.

Although the educational module was effective against complex pressure differential errors in the present study, it did not significantly reduce common pressure differential errors, as hypothesized. In the literature, the effects of training intervention have not always been shown to decrease errors. Some investigators, such as Schneider \textit{et al.} (2006) and Franklin \textit{et al.} (2006) reported positive effects of training\textsuperscript{59,63}, but others, such as Mills \textit{et al.} (2008) and Ford \textit{et al.} (2010) have found that training did not always improve outcomes\textsuperscript{57,58}. The effect of training may be impacted by the underlying cognitive mechanisms contributing to the error.

Health and Safety Executive (HSE) indicated that training is not the most appropriate response to skill-based errors, such as slips and lapses\textsuperscript{95}. Common pressure differential errors may be a combination of mistakes (knowledge-based or rule-based error), slips (the lowering of a wrong IV container when the correct one was intended) and lapses (the omission to lower the primary container). The educational module may have been an insufficient intervention to reduce common pressure differential errors that were due to slips and lapses (skill-based errors). As previously mentioned, Henriksen \textit{et al.} (2006) indicated that additional training for lapses during skill-based tasks are of little value because users are already performing these routine tasks at asymptotic levels\textsuperscript{122}. On the contrary, infusions that require complex pressure differential considerations are less routine tasks in the clinical setting. A larger proportion of complex pressure differential errors seen in
the present study may have been due to knowledge-based errors than in common pressure differential errors. This may account for why the educational module was effective for complex pressure differential errors and not common pressure differential errors. Further studies are required to characterize the types of underlying errors involved in these secondary infusion tasks.

Overall, the educational module tested was different from previous training materials for secondary infusions because of its emphasis on basic underlying principles of secondary infusions, common error types and failure modes, and the use of computerized graphics and animation to provide visual demonstration of fluid flow and hydrostatics during secondary infusions. Improving the understanding of the context and implications of actions can be important in complex clinical environments because a finite set of step-by-step procedures may not be sufficiently robust to meet the changing circumstances in healthcare\textsuperscript{122}. Computerized graphics and animation have been used to simplify dynamic information to improve understanding of abstract concepts\textsuperscript{60,61}. In this present study, the educational module, a form of training intervention, significantly decreased complex pressure differential errors that require a basic understanding of the dynamics of fluid flow and hydrostatic pressure, as hypothesized. This is consistent with findings by Madar et al. (2011), who reported positive effects of animation on training outcomes. Therefore, designing secondary infusion training materials that educate users on the principles of hydrostatics and possible errors and failure modes may be more effective than prescribing step-by-step instructions and the use of computer graphics and animation may be an effective modality to teach these abstract concepts. However, the findings related to the training-based intervention may be specific to the educational module tested in this study. Therefore, further studies are required to delineate the most effective training format and modality to address cognitive processes underlying secondary infusion errors.

7.2.3 Reaction

The responses to the post-experiment interview and survey were used to measure reaction (how participant felt about the training program). In the post-experiment interview, many participants commented that this educational module was effective in increasing their understanding of IV principles and should be included in routine nurse training. Some
participants commented that they found the module too long to be viewed while at work. However, some participants commented that it would be useful for new hires and should be added to the hospital’s annual re-certification program. Accreditation Canada implemented a standard that requires nurses to be re-certified every year on infusion pump technology. This type of training that emphasizes basic underlying principles of secondary infusions, common error types and failure modes, and uses computerized graphics and animation to provide visual demonstration of fluid flow may be useful during these re-certifications.

Thus, the educational module, a form of training intervention, was effective in reducing pressure differential errors for infusions that require complex pressure differential considerations. It did not significantly reduce connection errors or common pressure differential errors due to incorrect positioning of IV containers. The long-term effectiveness of the training-based intervention, however, could not be assessed in this study that took place over the period of three hours.

7.3 Effects of the Practice-based intervention

This intervention required the short infusion (the "secondary" or "piggyback" infusate in the piggyback infusion setup) to be set up as an independent infusion, just like a primary infusion. This intervention removed the need for user to open a secondary roller clamp or adjust the heights of the IV bags.

Figure 34. Practice-based Intervention: Use of Separate Pump for Short Infusions
(Image by Colvin, 2011)
As hypothesized, this intervention significantly reduced both pressure differential errors and secondary clamp errors. Under the practice-based intervention, the secondary clamp error rates were significantly lower than no intervention (baseline) and the training intervention. The use of a separate pump for short infusions in this intervention eliminated the need for practitioners to remember to open a secondary roller clamp. The effectiveness of this intervention in reducing the omission of opening the secondary clamp (memory-based error) is consistent with Byrne and Bovair’s (1997) recommendation that the most appropriate solution to address omission errors (i.e., lapses) is to avoid building the step into the setup of the interaction.26

This was also the only intervention out of the three interventions in this study that led to a significant reduction of risks related to pressure differential errors, which could be due to a combination of memory-based, knowledge-based, and rule-based errors. The use of a separate pump for short infusions in this intervention eliminated the need for practitioners to adjust the heights of the IV bags. This intervention is an example of "forcing functions" (at the top of the hierarchy of effectiveness) where the design of the system makes it impossible to perform a secondary clamp error or pressure differential error. The effectiveness of the practice-based intervention against secondary clamp error and pressure differential error is consistent with the effectiveness reported for the use of forcing functions other clinical domains. Coded locking systems have been implemented to reduce bedside identification errors during blood transfusions.25–27 This design, based on a forcing function concept, did not allow a blood unit to be accessed and transfused without matching a barcode that could be found only on the patient’s wristband. Mercuriali et al. (1996) reported that this forcing function design detected and avoided four potentially fatal errors in a 2-year study. Bernardello et al. (2009) also reported its effectiveness in reducing patient misidentification errors during transfusions after its implementation in a 1-year study. In addition to the coded locking system, Luria et al. (2006) also reported that a Computerized Physician Order Entry (CPOE) system that integrated a forcing function when opiate medications were prescribed. It defaulted to a stool softener ordering screen and required physicians to document reason if they chose to opt out, leading to a decrease in opiate related constipation. These examples of forcing functions in clinical setting support the use of forcing functions that led to improvement in patient safety and outcome.
In agreement, the use of a separate pump in this practice-based intervention, based on a forcing function concept, had a high level of effectiveness against secondary clamp errors and pressure differential errors.

However, out of the three interventions, the perceived effectiveness and the probability of use of this practice-based intervention were found to be the lowest in comparison to the other interventions. Some participants commented that this intervention:

- increased workload upon infusion completion (i.e., call-back alarm from pump at the end of infusion, the need to flush the residual medication in the IV tubing)
- was perceived to require more time for setup
- required at least one more pump at the bedside where space was already limited, pump shortages were common
- would lead to higher financial and environmental costs (more primary IV tubing and flush IV mini-bags were needed)

Furthermore, it was observed that the use of a separate pump introduced new risks to the delivery of short infusions. These new risks include:

- residual volume mismanagement
- excess fluid

**Residual volume mismanagement**

The delivery of a short infusion using a “separate pump” requires a separate and longer primary IV tubing than the secondary IV tubing used for secondary infusions. The primary IV tubing used in this present study had a priming volume of 25mL (Smiths Medical, US LOT21-0442-25), which was almost 4 to 5 times greater in volume than the 6mL secondary IV administration set (Baxter International Inc, Illinois, US, LOT JC7453).

Inconsistent practices of managing residual volume were observed when participants were asked to use a separate pump to deliver a short infusion.

The mismanagement of residual medication in the IV line can lead to an under-infusion or an over-infusion of medication. Residual medication from the IV container can remain in the IV tubing (as high as the priming volume of the IV set) after the delivery of the short infusion using a separate pump. Since the sizes of IV bags for short infusions are typically
small (25 - 250mL), a large proportion of the medication or fluid can remain in the residual volume of the IV tubing. The mismanagement of residual volume can lead to an over-dose of the short infusion. If the residual volume is given at the start of the next medication and the medication runs at a higher rate than the previous medication, there is a risk of giving the patient an extra dose inadvertently. It can also lead to under-dosing of the short infusion. If the old IV tubing is disposed before the residual medication is infused to the patient, the patient does not receive the full dose of medication.

In this study, 25% (11 out of 40) of participants did not adequately flush the residual fluid prior to reusing the same IV tubing for the subsequent medication. When the IV tubing is not flushed prior to being reused, the residual fluid from the initial "secondary" medication will be unintentionally delivered to the patient during the subsequent infusion (at the rate of the subsequent medication). Since, the volume of the primary IV tubing is 4-5 times greater than the typical secondary IV tubing, there is a risk of a greater volume of residual volume being delivered unintentionally. The risks include:

- **Residual volume is given at the start of the next infusate after possible drug degradation:** Some drugs (such as vancomycin) may degrade and lose significant potency after being left out at room temperature for an extended period of time. A degraded medication in the residual volume may be delivered to the patient unintentionally if the IV line was reused. Previously, the residual volume may have been considered to be clinically insignificant due to the small residual volume of the secondary IV line. The increase in residual volume due to the longer primary IV set may lead to more clinically apparent effects on the patient. The presence of the residual medication in the tubing may also lead to the formation of precipitates if the drugs are not compatible.

- **If the subsequent medication runs at a higher rate than the previous medication, there is a risk of giving the patient an extra dose inadvertently:** The administration of the flush at a rate greater than that recommended for the medication can be problematic. This flush rapidly forces a bolus of medication into the blood stream. This may result in speed shock and increase the risk of side-effects. For example, if vancomycin is infused too rapidly (above a rate of 10mg/min, or at a concentration above 500mg in 100ml) in adults, the patient may experience thrombophlebitis, rash,
facial and neck flushing accompanied by pruritus, muscle pain and/or hypotension, which can induce cardiovascular collapse or cardiac arrest. Furthermore, 50% (20 out of 40) participants disposed of the old IV tubing without appropriately infusing the residual medication to the patient. In these instances, the patient may not have received the full dose of medication. Suboptimal antibiotic dosages may lead to treatment failure and encourage emergence of antibiotic-resistant bacteria.

Mismanagement of residual volume during the use of a separate pump for short infusions may affect the safety of the patient. The inconsistent practices of flushing and residual volume management have been reported in literature. Even though the flushing of IV lines is a common nursing procedure, the meaning of the term "flushing" is ambiguous and ill defined in literature and clinical practice. The term "flush" often implies a volume of water that is sent quickly for the purpose of cleansing. Different practices of flushing are reported in literature. Flushes may be infused by pump or be manually pushed at a different rate than the medication infused. The Intraavenous Nurse Society and the Royal College of Nursing in London (2010) suggested that the volume of the flush should be twice the amount of the volume capacity of the cannula and the add-on devices. Vail (1987) recommended that the flush should be injected at the rate prescribed for the medication. Due to the ambiguity of the term flush, instructions to simply "flush the line after the infusion completes" is not a sufficient direction. Incorrect flushing will result in the patient not receiving the full dose of prescribed medication at the prescribed time. Mismanagement of residual volume can lead to under-dosing or over-dosing of the short infusion. The effect of infusion methods on the amount of drug remaining in the infusion set affects the quantity of drug delivered to the patient. The issues of mismanagement of residual volume are further discussed in Chapter 8.

**Excess Fluid**

In the secondary infusion setup, the primary infusion (typically maintenance fluid) temporarily stops when the secondary infusion is infusing until it finishes. On the other hand, when a short infusion is set up using a separate pump, both the short infusion and the primary infusion that it is connected to are delivered concurrently. This difference between the two setups was highlighted in the orientation before participants were asked to set up a
short infusion of antibiotics using a separate pump. In the orientation before the practice-based intervention condition (see Table 9), all participants were shown how to manually pause or titrate down the rate of the connected “primary” infusion.

However, in the experiment, when asked to deliver the short infusion using a separate pump, only 9 out of 40 participants titrated down the rate of the primary line maintenance fluid that the short infusion was connected to. Two participants stopped (turned off) the pump infusing the maintenance line. If the practitioner did not stop or lower the rate of the primary fluid during the short infusion, the amount of fluid delivered to the patient can be expected to be higher when delivering using a separate pump in comparison to the secondary infusion method. In addition, another risk could be introduced if the user forgets to reset the original rate of the connected primary infusion back to the original rate upon completion of the short infusion. This may result in insufficient fluid for patients who are being treated for sepsis, are N.P.O., or need additional fluids because of dehydration. Of course, the decision whether or not to titrate down the primary infusion depends on the patient population and the nurse's clinical judgment. However, to minimize variations in practices, flushing practices should be more clearly standardized.

Thus, the use of a separate pump for short infusions eliminated the need for practitioners to open a secondary roller clamp or adjust the heights of the IV bags. This intervention was an example of "forcing functions" where the design of the system made it impossible to perform a secondary clamp error or pressure differential error. As hypothesized, this intervention had a high level of effectiveness against secondary clamp errors and pressure differential errors. However, it was observed that the use of a separate pump introduced new risks to the delivery of the "secondary" infusate. These new risks include residual volume mismanagement and excess fluid. To deliver short infusions safely using a separate pump, flushing practices and management of residual medication should be carefully considered and more clearly standardized to prevent possible over-dosing or under-dosing of the short infusion.

7.4 Summary

The overall aim of this study was to assess the effectiveness of the clamp detector (technology-based intervention), the training intervention, and the use of a separate pump
for short infusions (practice-based intervention) on the reduction of secondary infusion errors. Table 28 provides a summary of the hypotheses and indicates whether or not the hypothesis was confirmed. The research hypotheses for each intervention were presented in Chapter 4 Section 4.2.

Table 28. Summary of Intervention Effectiveness (Confirmation or rejection of specific hypotheses)

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Targeted Error Type</th>
<th>Hypothesis</th>
<th>Was intervention effective at reducing the error type (i.e, was hypothesis confirmed?)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technology-based Intervention</td>
<td>- Secondary Clamp Errors</td>
<td>1</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>- Programming Errors</td>
<td>2</td>
<td>Could not be assessed</td>
</tr>
<tr>
<td>Training-based Intervention</td>
<td>- Secondary Clamp Errors</td>
<td>3</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>- Connection Errors</td>
<td>4</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>- Pressure Differential Errors</td>
<td>5</td>
<td>Yes (Common Secondary Infusions)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>No (Complex Secondary Infusions)</td>
</tr>
<tr>
<td>Practice-based Intervention</td>
<td>- Secondary Clamp Errors</td>
<td>6</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>- Connection Errors</td>
<td>7</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>- Pressure Differential Errors</td>
<td>8</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>- Programming Errors</td>
<td>9</td>
<td>Could not be assessed</td>
</tr>
</tbody>
</table>

Results from this empirical study provided insights into the effects of the three proposed interventions. The following key findings were observed:

1. The clamp detector (technology-based intervention) was effective in detecting secondary clamp errors and alarming users to open the clamp when this step was omitted due to a lapse in memory. This type of memory-based error (lapse) tends to occur during highly routine activities when attention is diverted from a task. It was found that the training intervention was not effective in reducing secondary clamp errors and was not the most appropriate responses to this type of memory-based error. The use of the clamp detector, an automated warning system that can detect an error and alert user (an intervention that is higher on the hierarchy of effectiveness), was more effective than training in minimizing secondary clamp risks.

2. In addition to the clamp detector, the use of a separate pump for short infusions (practice-based intervention) also significantly reduced secondary clamp errors. Furthermore, this practice–based intervention also significantly reduced pressure differential errors. It was the only intervention that reduced both secondary clamp
errors (memory-based errors) and pressure differential errors (skill-based errors, knowledge-based errors, rule-based error). The use of a separate pump for short infusions in this intervention eliminated the need for practitioners to open a secondary roller clamp or adjust the heights of the IV bags. This intervention was an example of "forcing functions" where the design of the system made it impossible to perform a secondary clamp error or pressure differential error. As hypothesized, this intervention had a high level of effectiveness against secondary clamp errors and pressure differential errors.

However, under this practice-based intervention, it was observed that many participants did not appropriately manage the residual fluid in the IV tubing at the end of a short infusion on a separate pump. This mismanagement can lead to an over-dose or under-dose of the prescribed medication. Furthermore, out of the three interventions, the perceived effectiveness and the probability of use of this practice-based intervention were found to be the lowest in comparison to the other interventions.

3. None of the interventions significantly decreased connection errors.

4. For the training-based intervention, the average test scores for the post-training knowledge test were significantly higher than test scores on the pre-training test. This indicates overall theoretical knowledge gained from the educational module. However, in the simulated clinical environment, the educational module did not lead to significant reductions in secondary clamp errors (memory-based error) and connection errors due to a slip (action-based error) or mistake (knowledge-based or rule-based error). However, the educational module significantly decreased pressure differential flow errors that were related to high secondary flow rates and height differences requirements for large IV bags.
7.5 Limitations of Study

This study had several limitations, which include:

1) Limitations of simulation experiments

Hawthorne Effect: A simulated clinical environment was used to evaluate the effectiveness of the interventions. A limitation of simulation-based experiment was that the behaviours and performances of the participants might have altered because of their awareness of being observed. This effect is known as the Hawthorne effect. This might have led to increased vigilance in participants, resulting in better performance and a decrease in observed errors. An under-estimate of the actual error rate might have been observed. To reduce the Hawthorne effect, all observations were conducted behind one-way mirror in this study. The validity and reliability of this observational method for studying medication administration errors were previously investigated by Dean and Barker (2001)\(^ {134}\). They found that there was no significant decrease in medication error rates when nurses were under observation, suggesting that the close observation of participants in simulation might not have a large effect on their behaviour. Furthermore, in this within-subjects study, the performance of the participants (measured by error rates) was evaluated in comparison to their baseline performance (which served as the control condition). A participant who was more vigilant or was more careless as result of being observed would likely be affected by the Hawthorne effect similarly across all four experimental conditions.

Limitations in the Simulation Fidelity of "End-of-Infusions": The interventions investigated in this study were focused on targeting errors related to the physical setup at the beginning of secondary infusions. Therefore, the fidelity of the simulation was focused on replicating the initial setup and the activation of a secondary infusion. In each experimental condition, the participants were asked to set up and program the infusions as prescribed in the medication order and based on volumes and rates indicated on the label of the medication bags. However, due to restrictions in time, each medication bag was already spiked with the IV set and the IV lines were pre-primed. Also, the duration that the secondary medication infused was all artificially shortened in the simulation. For example, a 100mL IV medication running at 50mL/h would require 2 hours of infusion in reality. In
the simulation, the infusion bag was switched to an empty infusion bag and the remaining VTBI on the pump was lowered to mimic the end of an infusion at an earlier time so the participant can proceed to the next infusion task. There might have been discrepancies in the simulated setup from the actual setup in the real setting at the end of the infusion. In the real setting, for example, when delivering a short infusion using dedicated pump, an air-in-line alarm may have stopped an infusion pump in the middle of an infusion or the pump may have stopped prematurely before the full dose is delivered if the participant did not take into account the priming volume of IV tubing when programming the infusion (refer to Section 8 for discussion of residual volume management).

In this study, the issue related to residual volume came to light when inconsistent practices of flushing and residual volume management were observed. The assessment of residual volume management was not the original goal of this study. It was acknowledged that the discrepancies in the setup of secondary infusion at the end of an infusion from the real setting might have led to changes from a participant's real behaviour. A high fidelity simulation of the setup at the end of a short infusion is needed to gather more representative information on flushing behaviours and residual volume management. Nonetheless, the inconsistent practices of flushing and management of residual volume observed in this study highlighted the variability in nurse's practices. These inconsistencies and variability in residual volume management can have impact on infusion safety and are further discussed in Chapter 8.

2) Partial Counterbalancing: The order that the experimental conditions were presented to the participants was partially counterbalanced to offset order effects. The training intervention was presented last in all sessions because of possible carryover effects after training, in this within-subjects study. The advantage of the within-subjects design was that the variability in measurements was more likely due to differences among conditions than to behavioural differences between participants. A participant who was more meticulous or more careless would likely exhibit the behaviour consistently across the experimental conditions. In spite of the reasoning for the design of this study, it was nonetheless limited by the presentation of the training intervention as the last condition in all sessions. The pre- and post-tests before and after the training intervention attempted to monitor transfer of knowledge. Furthermore, this limitation was considered in the assessment of the
For example, if there was a carryover effect, a significant decrease in error rates should have been observed across all error types in the last condition under training intervention. However, this was not seen.

3) Generalizability of Intervention: The effects of the educational module designed for this study may not be generalizable to other training programs or other educational modules. The findings related to the training-based intervention may be specific to the educational module tested in this study. Further studies are needed to determine if other formats or modalities of training intervention can lead to similar effects as the educational module tested. Also, additional studies are required to delineate the most effective training modality or format to address cognitive processes underlying secondary infusion errors.

Similarly, the effects of the clamp detector (technology-based intervention) and the use of the separate pump (practice-based intervention) may not be generalizable to other technology-based intervention and practice-based intervention, respectively.

4) Homogenous sample population: The simulation data was collected at a single institution from nurses with critical care background. An advantage of a homogeneous sample population was that it increased the representativeness of the sample, however the findings might not be generalized to practitioners from all nursing backgrounds.

5) Longitudinal Effect: The experiment in this study took place over the course of three hours in one session. It was acknowledged that this study could not assess the long-term results of the interventions, particularly the training intervention, on the reduction of secondary infusion errors. A longitudinal study over a longer period of time will be needed to determine the long-term results of the interventions.
Chapter 8

8 Residual Volume Issue

In Section 7.3, the mismanagement of residual volume in the IV tubing during the use of a separate pump for a short infusion was highlighted. The mismanagement of residual volume can lead to under-dosing or over-dosing of short infusions. Inaccurate and incomplete administration of prescribed dosages may lead to suboptimal treatment outcomes or other adverse effects for the patient\(^\text{129}\).

To date, there is little information in literature on the issue of residual volume when short infusions are delivered as secondary infusions or primary infusions using pumps. A couple of clinical articles in literature reported the use of higher doses of medication, higher solution volumes, and the use of expensive pressurized pump in response to the loss of medication due to residual volume. Based on the few but limited number of reports on this issue, it is believed that the incomplete administration of the drug due to residual volume may be well-known in clinical practice but not a well-researched and well-reported issue, especially for non-pediatric populations\(^\text{135}\).

This chapter first describes the effect of infusion method (i.e., use of a separate pump for short infusions and pump-controlled secondary infusions) on residual volume. It then discusses the effect of IV bag overfill and the clinical responses to residual volume in literature. (e.g., the use of higher doses of medication, higher solution volumes, use of expensive pressurized pump).

8.1 Effect of infusion methods on residual volume

Different infusion methods have different effects on the amount of residual medication in the infusion set and affect the overall quantity of medication delivered to the patient\(^\text{136}\).

This section discusses the residual volume during the delivery of short infusions as 1) pump-controlled primary infusions and 2) secondary infusions by large volume IV pumps.
Residual Volume for Short Infusion Delivered as a Primary Infusion

At the beginning of a primary infusion, all IV lines are primed to avoid delivering air through the lines. The tubing is primed by holding the end of the IV tubing below the bag and let the IV solution flow through the tubing to remove air in the line. The priming volumes of primary IV administration sets vary by manufacturers.

After priming, the volume in the IV bag is the total drug volume minus the priming volume. For example, for a 50mL IV infusion with an IV set of a priming volume of 25mL, the volume in the IV bag above the pump is approximately 25mL after priming (Figure 35B). Therefore, approximately after 25mL is delivered, the infusion line above the pump would be empty, and the infusion pump with a programmed VTBI of 50mL will stop when there is no fluid upstream of pump. The remainder of the medication (residual medication) in the IV line from the pump to the patient access will remain unless it is appropriately managed (see Figure 36).

Figure 35. A) Before priming B) After priming
Secondary infusion: Dead Volume and Residual Volume

During secondary infusion, the secondary infusate is connected to a primary infusion line at a y-site upstream of the pump. Instruction from pump manufacturers is to set the secondary VTBI value to equal the secondary bag volume.

However, this does not prevent residual amounts of the secondary container from infusing at primary flow rates. There can be substantial delay before the secondary infusate reaches the patient. This is because the volume in the IV tubing between the y-site for the secondary line and the end of the primary tubing can be large. This volume between the point where the secondary line and primary line are connected and the patient’s vein is the dead volume. When the secondary infusion is started, the pump is in fact delivering the dead volume of primary infusate in the line (see Figure 37).
The dead volume in the IV set varies based on manufacturer. The dead volume for a secondary infusion connected to a Smiths Medical primary IV administration set and Alaris® CareFusion (California, United States) IV administration set are approximately 23mL and 13mL, respectively. For example, for a secondary infusion that is programmed to run at 50mL/h, there is a delay of almost 30 min before the secondary infusate can reach the patient if the Smiths Medical primary IV administration set is used. (At the beginning of secondary infusion, the primary infusate in the dead volume of the tubing will be pushed into the patient at the secondary rate. If the secondary rate is significantly higher than the primary rate, the dead volume bolus of primary infusate could cause patient harm if it is a high-alert primary medication).

When the pump delivers the programmed secondary VTBI, the volume of the secondary infusate has not been completely administered and some infusate will remain in the tubing. When the pump automatically switches to primary infusion rate, the residual volume of secondary infusate in the tubing will be delivered at the primary rate. Therefore, even if the user set the secondary VTBI value to equal the secondary bag volume, as indicated by pump manufacturers, residual amounts of the secondary container will infuse at primary flow rates.

A common practice at the end of secondary infusions is to "back-prime" the primary IV fluid into the empty IV secondary container. The secondary line is cleared by flushing the primary IV fluid into the empty secondary container. The old secondary container is then disconnected, discarded and a new IV container is hung. The residual in the secondary
tubing would be discarded with the secondary IV container and would not be infused. This practice of back-priming is very common and some institutions have indicated that it is their preferred method of managing IV secondary tubing.\textsuperscript{137}.

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{backpriming_diagram.png}
\caption{Backpriming}
\end{figure}

8.2 Effect of IV bag overfill

To compensate for the possible loss of drug due to tubing residual, the question whether or not the overfill of IV solution bags or drug powder by manufacturers is a solution has been discussed controversially\textsuperscript{6}. During the preparation of most short infusions, a drug (often in lyophilized powder form) is added to a commercially available IV bag prefilled with IV solution (such as Normal Saline, D5W) by the clinician. The common manufacturing practice of including an overfill volume of solution in commercially available IV bags does not address the possible loss of drug in the residual volume. The amount of the “overfill” can be up to 16\% of the labeled volume of the IV bag\textsuperscript{138}. Depending on the volume of the overfill, the concentration of the medication in the IV bag after the addition of the drug may differ. However, Plagge \textit{et al.} (2010) reported that medicinal products marketed as powders for infusion are not generally overfilled by the manufacturer, therefore, the total amount of drug present in the IV bag prepared in this format is the same\textsuperscript{6}. Thus, the entire
volume of the IV bag, regardless of the overfill, must be given to the patient to ensure accurate dose delivery. In an environment scan on pediatric intravenous administration of drugs and fluids by the Canadian Agency for Drugs and Technologies in Health, one of the hospitals (Children’s Hospital at Health Sciences Centre Winnipeg) indicated that the management of imprecise overfill volume in mini-bags to ensure that all of the medication is infused and the IV lines flushed are ongoing challenges\textsuperscript{139}.

### 8.3 Clinical Responses in Literature

In literature, management of residual volume is often considered to be an issue related to dead-space volume replacement. Few articles discussed the issue of residual volume during the secondary method by volumetric pumps or the use of dedicated pump as a primary infusion.

In one report, Claus \textit{et al.}(2010) identified residual volume to be a potential reason of under-dosing when a new antibiotic protocol for piperacillin/tazobactam (pitazo) was implemented without considering the priming volume\textsuperscript{81}. Claus \textit{et al.} reported that the replacement of the infusion line could lead to a 40\% loss of the prescribed antibiotic dose when the infusion line was not cleared with a compatible solution after the antibiotic infusion. Claus \textit{et al.} pointed out that dead-space volume replacement is a critical issue that needs to be addressed when the dead space exceeds 10\% of the infused volume.

In response to the issue of residual volume, several clinical response strategies (non-standardized) have been reported:

- **The use of higher doses of medication**: Higher doses of medication have been given to patients to compensate for the loss of medication in residual volume during the infusion of Piperacillin-Tazobactam. In a protocol where the patients require a minimum of 3.375 gm over four hours, the dosage was increased to 4.5 gm IV in a volume of 100mL to compensate for a loss of medication\textsuperscript{135}.

- **The use of higher solution volumes (for non-ICU patients)**: Claus \textit{et al.} described that the infusions of piperacillin-tazobactam (3.375 g) were initially reconstituted in 50mL of 0.9\% saline and infused over 3–4 hours\textsuperscript{81}. Due to the loss of medication in the tubing residual (a total of 24mL which accounted for
approximately 40% of the antibiotic dose), the infusions were reconstituted in at least 250mL of solution to compensate for the loss (this use of higher solution volumes was not used for patients in the intensive care units). Similarly, Xamplas et al. (2010) also described the increase of the volume of piperacillin-tazobactam 3.375g from 50mL to 100mL to minimize the percentage of medication remaining in intravenous tubing after administration of extended-infusion piperacillintazobactam\textsuperscript{140}.

The purpose of increasing infusion volumes is to decrease the concentration of medication being infused, therefore the amount of drug left in tubing residual and lost can be minimized. However, Lam et al. (2013) demonstrated that reconstituting 3.375g into larger volumes may still result in significant loss of drug (there is a 30% loss of dose, i.e, 1.01g, when 3.375g of medication is reconstituted into 100mL solution)\textsuperscript{135}.

- **The use of expensive pressurized pump (for ICU patients and patients with fluid restrictions):** Claus et al. described the use of pressurized pumps with infusion dead space of less than 1mL when delivering short infusions for ICU patients and patients with fluid restrictions\textsuperscript{81}. However, the use of pressurized pumps are costly to implement hospital-wide across all patient populations.

- **Continuous infusion of antibiotics:** The delivery of medications continuously may remove the issues related to the loss of medication during short infusions. The continuous delivery of common intermittent antibiotic infusions (such as piptazo) have been reported in literature\textsuperscript{141,142}. However, Lam et al. pointed out that this option may not be practical for all patient populations because of limited intravenous access and the numerous antibiotics the patient may need\textsuperscript{135}.

- **Injection of the total volume of the short infusion into the dead volume:** In some pediatric and neonatal settings, intermittent medications are delivered by injecting the total volume of the intermittent infusion into the dead volume between the lower port of the drug tubing and the IV catheter\textsuperscript{5}. The medication does not
reach the patient immediately because the dose is small and will remain in the dead volume space without until it is pushed through with a primary infusion (i.e., manually with IV syringe or by infusion pump at a secondary rate).

- **Flushing:** The use of flushing to deliver the residual medication in the IV tubing to the patient is a method to ensure the full amount of drug is delivered. Furthermore, as discussed in Section 7.3, the meaning of the term "flushing", is ambiguous and ill defined in literature and clinical practice even though the flushing of IV lines is a common nursing procedure. Flushes may be infused by pump or be manually pushed at a different rate than the medication infused. Variations in flushing practices can lead to over-dosing or under-dosing of the medication. If the residual volume flushed too fast (greater rate than the prescribed medication), it could lead to a bolus or an over-dose. If the residual volume is flushed too slow, the patient would receive the medication too slowly, still leading to suboptimal treatment outcome. If too much volume is flushed, it may lead to a delivery excess fluid in fluid-restricted patient. If too little volume is flushed, residual medication may remain in the line and given at the start of the next medication after possible drug degradation if the line is reused. Most articles on flushing only cite its importance for the purpose of maintaining IV line patency and preventing drug incompatibilities. Internationally or nationally recognized guidelines related to the management of residual volume to prevent under-dosing and over-dosing for intermittent infusions do not appear to exist.

In addition to the aforementioned response strategies, a new type of infusion bag called Self-flushing Infusion Bag (Laboratoire AGUETTANT®, Lyon France), patented in 2005, offer an alternative system to facilitate the flushing of residual medication at the end of a short infusion. These self-infusing bags have two chambers, one containing the drug and the other containing the flushing solution. These bags are designed so that when the chamber containing the medication becomes a vacuum when it empties, the flushing solution is drawn into the medication chamber and infused. For the delivery of the short infusion as a primary infusion, the automatic switch to the flushing solution can remove the
need to manually switch to a flush bag and adjust programmed VTBI to deliver the full dose of medication.

These self-flushing infusion bags also has the potential to remove the reliance on clinicians to remember to intervene at the end of the infusion and remove the variability in flushing practices for short infusions. It reduces the time needed to attend to the infusion to make sure the complete dose is administered. There is also no change of the current infusion protocol. Currently, the use of self-flushing bags for the delivery of short infusions as a primary infusion has not been reported. It is not clear if it can be used with pumps or by means of gravity only. More in-depth investigation of the human factors around the use of these IV bags is needed to determine their effectiveness.

**8.3.1.1 Impact of Residual Volume Management on Patients**

At the moment, the impact of residual volume mismanagement is still a theoretical problem which has not yet been reported in literature to affect patient safety directly. However, during IV drug therapy, it is important that patients receive the specified amount of drug at the prescribed time. The inaccurate and incomplete administration of prescribed dosages due to mismanagement of residual volume may lead to suboptimal treatment outcomes or other adverse effects for the patient. The administration of intravenously short infusion with inaccurate and incomplete delivery does not agree with the nine rights of drug delivery.

The lack of standardized approach on how to deal with residual volume is problematic because the over-dose and under-dose of medications can occur as a result of mismanagement of residual volume even when the clinician sets up and programs the short infusion as per instructions by pump manufacturers.

As discussed, the loss of medication in residual volume also prompted various clinical responses that are non-standardized (e.g., higher doses of medication, higher solution volumes). The effects of these approaches have not been fully investigated. Currently, the management of residual volume relies on the vigilance of individual institutions and individual practitioners. More standardized approach or best practices recommendations
are needed both for short infusions that are delivered as a separate infusion and as a secondary infusion.

The results from this study add to the literature by highlighting that there is great variations in the management of residual volume and flushing practices, which are particularly important consideration when short infusions are set up as independent primary infusions. Previously, the variability in serum concentration of drugs in patients receiving the same intravenous doses have been attributed to inter-patient variation in physiology. However, perhaps some of the inter-patient variation may actually be due to inter-infusion variations and incomplete dose delivery during drug administration, as suggested by Sherwin et al. (2009)\(^{136}\). Therefore, awareness of the potential problem over- and under-dosing due to mismanagement of residual fluid during the use of a dedicated pump or piggyback method are needed to stimulate further research into this problem.
Chapter 9

9 Conclusion

Three interventions (a technology-based, a training-based, and a practice-based interventions) to mitigate secondary infusion risks were tested in a high-fidelity simulated clinical environment. The three interventions were identified based on a human factors approach and included: i) the use of clamp detector on a smart pump (technology-based), ii) a educational module (training-based), and iii) the use of a separate pump (practice-based).

In a within-subjects study, forty nurse participants from critical care performed equivalent secondary infusion tasks under 4 different conditions (no intervention, technology-based intervention, training-based intervention, and practice-based intervention). The error rates of common secondary infusion errors across the 4 conditions were compared. Specifically, the types of common secondary infusion errors evaluated were secondary clamp errors, connection errors, pressure differential errors, and programming errors.

The clamp detector on the smart pump (technology-based intervention) significantly decreased secondary clamp errors in comparison to the baseline (no intervention) and the educational module (training-based intervention). However, the technology-based intervention did not have a significant effect on the reduction of connection errors or pressure differential errors.

The educational module (training-based intervention), in comparison to no intervention, led to a significant decrease in pressure differential errors for secondary infusions that require complex understanding of hydrostatics. Due to a bias in the baseline condition, the effects of the interventions on programming errors could not be evaluated. Further improvements are needed to mitigate risks associated with connection errors.

The use of a separate pump for short infusions (practice-based intervention), in comparison to no intervention, significantly reduced both secondary clamp errors and pressure differential errors. It was the only intervention that significantly reduced both secondary clamp errors and pressure differential errors. The study revealed, however, that the use of a
separate pump for secondary infusions introduced new patient safety risks related to inappropriate management of residual volume in IV tubing.

Prior to this study, there has not been an empirical evaluation of interventions to reduce secondary infusion errors. Results from this study may provide healthcare organizations, policy makers, and manufacturers with empirical evidence on potential interventions that can reduce secondary infusion errors. The clamp detector (technology-based intervention) may reduce secondary clamp errors but does not appear to have an effect on the reduction of other common secondary infusion errors. The educational module (training-based intervention) may enable users to manage secondary infusions that require complex understanding of hydrostatics. Out of the three interventions, the use of a separate pump (practice-based intervention) was the only intervention that significantly reduced both secondary clamp errors and pressure differential errors. The delivery of short infusions using a separate pump is effective against error types that could not be mitigated by other interventions, however, standardization of flushing practices is needed to ensure there is no under-dosing or over-dosing of medications due to mismanagement of residual volume.

The present work evaluated the effectiveness of the interventions in a controlled simulation environment. Further research is needed to investigate the effect of the interventions on secondary infusions in real clinical settings. Future studies can involve participants from nursing backgrounds outside of critical care and from other institutions. Moreover, to determine the long-term effectiveness of the interventions on reducing secondary infusion errors, a study over a longer period of time will be needed. Additional studies are also required to delineate the most effective training modality to address cognitive processes underlying secondary infusion errors. Furthermore, additional research is needed to design and evaluate appropriate interventions for the reduction of programming and connection errors during secondary infusions. In particular, this study adds to the literature by highlighting that there are great variations in the management of residual volume and flushing practices. The delivery of short infusions using a separate pump is effective against error types that could not be mitigated by other interventions. However, further research and standardization of flushing practices are needed to ensure there is no under-dosing or over-dosing of medications.
In summary, results from this study provide healthcare organizations, policy makers, and manufacturers with empirical evidences on potential interventions that can mitigate secondary infusion risks. Results of the present study highlighted the need for a combination of mitigation strategies to reducing secondary infusion errors. This work may guide the selection of interventions to reduce secondary infusion errors in the clinical setting.
References


27. Rosdahl CB. *Textbook of Basic Nursing*. Lippincott Williams & Wilkins; 2008:858.


71. ISMP. *Proceedings From the ISMP Summit on the Use of Smart Infusion Pumps*.; 2009:1–19.


78. Loorand-Stiver L. *Pediatric Intravenous Administration of Drugs and Fluids*. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2011:1–8.


89. Rasmussen J, Member S. Skills, Rules, and Knowledge; Signals, Signs, and Symbols, and Other Distinctions in Human Performance Models. 1983;(3):257–266.


108. IV-therapy.net. Secondary bag for antibiotic infusion vs primary bag for antibiotic infusion. Available at: http://iv-therapy.net/node/3304.


Appendices

Appendix A  Research Ethics Approval

University Health Network
Research Ethics Board
10th Floor, Room 1050
700 University Ave
Toronto, Ontario, M5G 1Z5
Phone: (416) 581-7849

Notification of REB Initial Approval

Date: June 13th, 2012
To: Dr. Patricia Trbovich
Room 425, 4th Floor S, Toronto General Hospital
200 Elizabeth St. Toronto Ontario, Canada M5G 2C4

Re: 12-0184-RE
Mitigating Risks Associated with Multiple IV Infusions: Phase 3 - Simulation Lab Experiment

REB Review Type: Expedited
REB Initial Approval Date: June 13th, 2012
REB Expiry Date: June 13th, 2013

Documents Approved:
- Protocol Version date: March 5th, 2012
- Consent Form - Main Version date: May 3rd, 2012
- Semi-Structured Interview Themes Received on: May 11th, 2012
- Questionnaire - Background Version date: March 5th, 2012
- Questionnaire - Final Version date: March 5th, 2012


Best wishes on the successful completion of your project.

Sincerely,

Anna Gagnard, PhD
Co-Chair, University Health Network Research Ethics Board
Appendix B  Consent Form

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title:  Mitigating Risks Associated with Multiple IV Infusions

Investigator:  Dr. Patricia Trbovich 416-340-4800 x7180

Sponsor:  Health Quality Ontario

Introduction:

You are being asked to take part in a research study. Please read this explanation about the study and its risks and benefits before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish. Participation in this study is voluntary.

Purpose

Researchers at the University Health Network (UHN) are investigating the effectiveness of various infusion-related technologies and work practice changes on minimizing risks associated with administering multiple IV infusions. Your participation helps us to determine whether or not these approaches could improve safety and also any unanticipated side effects they may initiate.

Procedures

If you agree to participate in the study your demographic information (e.g., age, sex, years nursing experience) will be collected and you will be asked to complete a series of clinical tasks in a simulated clinical environment. In other words, you will be in a laboratory facility with clinical equipment and scenarios but no real patients or patient care. You will be taught how to use any infusion-related devices not in routine use on your unit prior to starting the simulations. After training you will be oriented to the simulated environment, and asked to perform various multiple IV-related tasks to a simulated patient (mannequin and/or actor). After each scenario, we will ask you for your feedback relevant to the interventions being tested in the scenario to further understand the risks and benefits of the various approaches being tested. We will also be assessing the impact of education on multiple IV infusion management and will ask you to complete an education questionnaire before and after we provide specific infusion-related training. The session will last no more than 3 hours, and will be videotaped for later analysis. Your
performance/competency is NOT being evaluated in a way that will impact your employment, but rather the results of this study will be used to better understand issues relating to delivering multiple IV infusions and the effectiveness of various interventions to improve safety and reduce errors.

**Risks**

There are no anticipated or known medical risks associated with this study. You may experience discomfort in sharing your opinions with the researchers. You only have to share as much about your opinions as you wish. Your participation will have NO impact on your employment at UHN.

**Benefits**

You may or may not receive direct benefit from participating in this study. Information from this study may help to increase your knowledge about managing multiple IV infusions.

**Voluntary Participation**

Your participation in this study is voluntary. You can choose not to participate or you may withdraw at any time prior to January 2013, when the study findings will be finalized. Whether you choose to participate or not has no impact on your employment at UHN. In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities. You do not give up any of your legal rights by signing this consent form.

**Confidentiality**

All information obtained during the study will be held in strict confidence. You will be identified with a subject number only. No names or identifying information will be used in any reports, publication or presentations that may come from this study. No information identifying you will be transferred outside the investigators of this study. If the videos from the research are shown outside the research team, your face will be blurred and all identifying information will be made anonymous. However, despite best efforts, there is a very small possibility that you may still be identified. Data from the study (e.g., videotapes, paper records) will be kept for a minimum of two years, and a maximum of seven years, after the completion of the study. Any personal identifiable information will be stored and protected on secured servers or kept in a locked filing cabinet and then destroyed by shredding of paper or erasing of digital information. The University Health Network Research Ethics Board may look at the study records for auditing purposes.

**Reimbursement**

You will receive monetary compensation in the amount of $200 for your participation in this study.

**Conflict of Interest**
The sponsor of this study will pay the hospital and researcher for the costs of doing this study. All of these people have an interest in completing this study. Their interests should not influence your decision to participate in this study.

Questions

If you have any questions, concerns or would like to speak to the study team for any reason, please contact the Principal Investigator Patricia Trbovich at (416) 340-4800 x 7180 or the Study Co-ordinator Sonia Pinkney at (416)-340-4800 x 4766.

If you have any questions about your rights as a research participant or have concerns about this study, call the Chair of the University Health Network Research Ethics Board (REB) or the Research Ethics office number at 416-581-7849. The REB is a group of people who oversee the ethical conduct of research studies. These people are not part of the study team. Everything that you discuss will be kept confidential.

Consent

This study has been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree to take part in this study.

Study participant’s name (please print)          Participant’s Signature          Date

(You will be given a signed copy of this consent form)

My signature means that I have explained the study to the participant named above. I have answered all questions.

Name of person obtaining consent          Signature          Date
Appendix C  Demographic Questionnaire

1. What best describes your role in the hospital?
   - [ ] Staff nurse
   - [ ] Nurse manager
   - [ ] Clinical trials nurse
   - [ ] Advanced practice nurse
   - [ ] Other:

2. What age range are you in:
   - [ ] 18 – 29 years old
   - [ ] 30 – 39 years old
   - [ ] 40 – 49 years old
   - [ ] 50 – 64 years old
   - [ ] 65 years old and over

3. Are you:
   - [ ] Male
   - [ ] Female

4. How long have you worked as a registered nurse on a critical care unit?
   - [ ] Less than a year
   - [ ] 1-3 years
   - [ ] 4-10 years
   - [ ] greater than 10

5. Have you completed the following post-graduate programs? Please check all that apply.
   - [ ] Completed a college-based Critical Care Nursing Program (e.g., core fundamentals orientation program)
   - [ ] Obtained the full Critical Care Nursing Certificate from a college-based program
     (includes Coronary Care Level II & Neuro courses)
   - [ ] Obtained the additional specialty certification credential in critical care nursing offered by the Canadian Nurses Association (CNA)
   - [ ] Completed additional courses offered by an educational institution that focused exclusively on IV therapy principles (e.g. IV therapy course) and is separate from the critical care nursing program curriculum. Please specify in “other” category box below
   - [ ] Not required to complete the college-based core fundamentals orientation program (#1) as have experience in a critical care unit from another hospital upon hire
If you selected #4 “additional courses”, please list course name and educational institution in the box below:

6. How often do you work in the critical care units, on average?
   - Less than once a week
   - 1 to 2 times a week
   - 3 to 4 times a week
   - More than 4 times a week

7. Which critical care unit (ICU) do you work at? Please check all that apply.
   - Medical surgical ICU (MSICU)
   - Cardiovascular ICU (CVICU)
   - Coronary ICU (CICU)
   - Other (please specify)

8. What best describes your role in the hospital?
   - Staff nurse
   - Nurse manager
   - Clinical trials nurse
   - Advanced practice nurse
   - Other:

9. What age range are you in:
   - 18 – 29 years old
   - 30 – 39 years old
   - 40 – 49 years old
   - 50 – 64 years old
   - 65 years old and over

10. Are you:
    - Male
    - Female

11. How long have you worked as a registered nurse on a critical care unit?
    - Less than a year
    - 1-3 years
    - 4-10 years
    - greater than 10

12. Have you completed the following post-graduate programs? Please check all that apply.

    - Completed a college-based Critical Care Nursing Program (e.g., core fundamentals orientation program)
    - Obtained the full Critical Care Nursing Certificate from a college-based program
(includes Coronary Care Level II & Neuro courses)

☐ Obtained the additional specialty certification credential in critical care nursing offered by the Canadian Nurses Association (CNA)

☐ Completed additional courses offered by an educational institution that focused exclusively on IV therapy principles (e.g. IV therapy course) and is separate from the critical care nursing program curriculum. Please specify in “other” category box below.

☐☐ Not required to complete the college-based core fundamentals orientation program (#1) as have experience in a critical care unit from another hospital upon hire

If you selected #4 “additional courses”, please list course name and educational institution in the box below.

13. How often do you work in the critical care units, on average?
   ☐ Less than once a week
   ☐ 1 to 2 times a week
   ☐ 3 to 4 times a week
   ☐ More than 4 times a week

14. Which critical care unit (ICU) do you work at? Please check all that apply.
   ☐ Medical surgical ICU (MSICU)
   ☐ Cardiovascular ICU (CVICU)
   ☐ Coronary ICU (CICU)
   ☐ Other (please specify)
Appendix D  Demographics

Participant characteristics for 39 of the 40 nurse participants are shown. Participants had no prior experience with the interventions tested.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Frequency (n=39)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Role</td>
<td></td>
</tr>
<tr>
<td>Staff nurse</td>
<td>39 100</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>37 95</td>
</tr>
<tr>
<td>Male</td>
<td>2 5</td>
</tr>
<tr>
<td>Age range</td>
<td></td>
</tr>
<tr>
<td>18 to 29 years</td>
<td>8 21</td>
</tr>
<tr>
<td>30 to 39 years</td>
<td>14 36</td>
</tr>
<tr>
<td>40 to 49 years</td>
<td>8 21</td>
</tr>
<tr>
<td>50 to 64 years</td>
<td>9 23</td>
</tr>
<tr>
<td>Years critical care experience</td>
<td></td>
</tr>
<tr>
<td>&lt;1 year</td>
<td>3 8</td>
</tr>
<tr>
<td>1 to 3 years</td>
<td>3 8</td>
</tr>
<tr>
<td>4 to 10 years</td>
<td>18 46</td>
</tr>
<tr>
<td>&gt;10 years</td>
<td>15 38</td>
</tr>
<tr>
<td>Clinical care area</td>
<td></td>
</tr>
<tr>
<td>Cardiovascular ICU</td>
<td>12 31</td>
</tr>
<tr>
<td>Coronary ICU</td>
<td>6 15</td>
</tr>
<tr>
<td>Medical surgical ICU</td>
<td>32 54</td>
</tr>
<tr>
<td>Average shift(s) per week</td>
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</tr>
<tr>
<td>&lt;1 shift</td>
<td>1 3</td>
</tr>
<tr>
<td>3 to 4 shift</td>
<td>21 54</td>
</tr>
<tr>
<td>&gt;4 shifts</td>
<td>17 44</td>
</tr>
<tr>
<td>Completed post-graduate studies</td>
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<tr>
<td>Critical care nursing core program</td>
<td>36 92</td>
</tr>
<tr>
<td>Full critical care nursing certificate</td>
<td>17 44</td>
</tr>
<tr>
<td>C.N.A. specialty credential in critical care nursing</td>
<td>11 28</td>
</tr>
<tr>
<td>Additional IV therapy courses at education institution (did not specify)</td>
<td>1 3</td>
</tr>
</tbody>
</table>

Note:

1) Demographics for one participant were missing (One participant did not complete the demographics survey, but the performance of all forty participants were analyzed in the study).
Appendix E  Mock Patient Setup

A mannequin was set up in each bed to simulate the mock patient. At the beginning of each condition, the mock patient was set up to receive a total of 11 continuous infusions, including 2 normal saline (NS) infusions.

Central triple lumen: 9 infusions (8 medications and 1 normal saline)

Peripheral IV line: 2 infusions

Distal line (i.e., brown line) of triple lumen catheter: medication line

proximal lumen (white), middle lumen (blue), distal lumen (brown)
Appendix F  Medication Orders

There were four experimental conditions in this study. For each experimental condition, there were two scenarios requiring 2 separate short infusions.

- 1st Infusion Task: Participants were provided with a pre-mixed IV container with the drug that is attached to primed IV tubing
- 2nd Infusion Task: Participants were provided with a pre-mixed IV container. Participants could choose to re-use the tubing or use a new tubing set.

One infusion had drug order that specified the drug amount over a period of time (e.g., Vancomycin (1g/50mL) Order: 1 g, Infuse over 1 hour). The other infusion had drug order that specified the rate and the required duration). All drug orders included the following infusion parameters: drug dose or drug rate, and volume or duration.

<table>
<thead>
<tr>
<th></th>
<th>1st Secondary Infusion</th>
<th>2nd Secondary Infusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>Vancomycin (1g/50mL)</td>
<td>Clinical Trial Drug (100mg/250mL)</td>
</tr>
<tr>
<td></td>
<td>Order: 1 g, Infuse over 1 hour</td>
<td>Order: 750ml/h, Infuse over 20 min</td>
</tr>
<tr>
<td>Training Intervention</td>
<td>Piptazo (4.5g/50mL)</td>
<td>Sodium Bicarbonate (150mmol/1000mL)</td>
</tr>
<tr>
<td></td>
<td>Order: 4.5g. Infuse over 30 min.</td>
<td>Order: inj IV-cont 250mL/hr</td>
</tr>
<tr>
<td>Technology-based Intervention</td>
<td>Ceftriaxone (1g/50mL)</td>
<td>Sodium Bicarbonate (150mmol/1000mL)</td>
</tr>
<tr>
<td></td>
<td>Order: 1 g, Infuse over 1 hour</td>
<td>Order: inj IV-cont 250mL/hr</td>
</tr>
<tr>
<td>Practice-based Intervention</td>
<td>Clinical Trial Drug (100mg/250mL)</td>
<td>Piptazo (4.5g/50mL)</td>
</tr>
<tr>
<td></td>
<td>Order: 750ml/h, Infuse over 20 min</td>
<td>Order: 4.5g. Infuse over 30 min.</td>
</tr>
</tbody>
</table>
Appendix G  Counterbalance Orders

In the simulation experiment, participants were asked to perform equivalent secondary infusion tasks under 4 different conditions: no intervention (baseline), technology-based intervention, training-based intervention, and practice-based intervention. The order that the conditions were presented to the participants was partially counterbalanced to offset order effects. (Limitation: The training intervention was presented last in all sessions because of possible carryover effects after training. To address this limitation, a pre-training and post-training test was given to the participant to assess baseline knowledge prior to training. This limitation was also acknowledged in the assessment of the experimental data.)

<table>
<thead>
<tr>
<th>Group</th>
<th>1st</th>
<th>2nd</th>
<th>3rd</th>
<th>4th</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Technology-based Intervention</td>
<td>Baseline</td>
<td>Training-based Intervention</td>
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<tr>
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<td>Baseline</td>
<td>Practice-based Intervention</td>
<td>Training-based Intervention</td>
</tr>
<tr>
<td>C</td>
<td>Baseline</td>
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<td>Technology-based Intervention</td>
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</tr>
<tr>
<td>D</td>
<td>Practice-based Intervention</td>
<td>Baseline</td>
<td>Technology-based Intervention</td>
<td>Training-based Intervention</td>
</tr>
<tr>
<td>E</td>
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<td>Practice-based Intervention</td>
<td>Baseline</td>
<td>Training-based Intervention</td>
</tr>
<tr>
<td>F</td>
<td>Baseline</td>
<td>Technology-based Intervention</td>
<td>Practice-based Intervention</td>
<td>Training-based Intervention</td>
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</tbody>
</table>
To assess the effect of the order of presentation, one-way between-subjects ANOVA were conducted to determine the effect of the order of presentation on the error rates of different types of secondary infusion errors (i.e., secondary clamp errors, connection errors, pressure differential errors) in the baseline. There was no significant difference in error rates for all these types of errors between the orders that the condition was presented (i.e., there was no significant difference in error rates whether the baseline was presented first, second, and third).
Appendix H  Experiment Script

Please note that this study was part of a large research study on Multiple IV Lines by the HumanEra team, University Health Network, Toronto, where other multiple IV infusion errors were also investigated (i.e., errors associated with the setup and programming of multiple primary continuous infusions, line tracing and identification errors, dead volume errors, line change and IV pump bolus issues). The sample script provided in Appendix H is an excerpt of the secondary infusions section from the full Multiple IV Lines Study.

In addition, there were 6 different orders that the experimental conditions were presented in this study (see Appendix G). The script provided in Appendix H is a sample of the script for where the technology-based intervention for secondary infusions was presented first, followed by the practice-based intervention, the baseline (no intervention), and training.
1.0 Pre-experiment Script

1. Introduction to the study and the lab

Location: Main office area and innovation lab hallway

[Facilitator] “Hi ______________________ , welcome to the centre! My name is _______________ and I’m one of the study coordinators for the multiple IV infusion study. [Name of Participant], this center was created to improve healthcare for people through safe, usable and effective technologies and processes. A key component of our work is to conduct usability simulation studies on new medical technologies and processes so we can understand potential safety and usability issues prior to roll-out. We often require the help of frontline nurses because it is your issues we want to learn about! By understanding your needs we can hopefully create technologies and processes that effectively support you and improve patient.”

But before we do, I want to stress that the purpose of this study is not to assess your skills and will in no way affect your position at TGH. And I am going to repeat this numerous times as a reminder this morning! If you encounter any problems during the scenario, it is not a reflection on your skills but rather an indication to me that something requires improvements. We regard you as the expert and we are here to learn from you. Our approach is that any issue you encounter, is reflective of poor design and is not unique to you, but rather something many of your colleagues would also experience.”

2. Explanation of consent form and signing of the consent form

[Facilitator] “OK – the first thing we should do is review the consent form.

- Paraphrase key pieces of info
  - Purpose: Today we will be looking at how infusion-related technologies, tools, and processes affect the ability of nurses to efficiently and safely administer iv medications to patients.
  - Procedure: I will provide more details later, but essentially you will be performing various IV tasks while using various new tools and processes in this simulated environment, while I observe behind this one-way mirror, which prevents me from distracting you when you are completing the tasks.
  - Voluntary participation: your participation is voluntary and may withdraw at any time
  - Confidentiality: All information obtained will be held strictly confidential and we will only report on the data collected at an aggregate level. This session will be videotaped and audio taped just in case I miss anything after the session is completed. If we share your video clips, for example in a presentation, your face will be blurred.
  - Reimbursement: You will receive $200 to compensate you for you time in participating in this study

- Do you have any questions?
- Participant and Coordinator signs two copies
- One copy to participant and another for coordinator
- Put on microphones and lab coats (participant and you)

3. Background Questionnaire

[Facilitator] “Okay, now that all the paper work is taken care of, I would like you to complete a short background questionnaire.”

- Participant completes background questionnaire

4. Overview of Scenario

[Facilitator] “So now I will give you more details about the study and the scenarios. The study is structured so you will be delivering IV infusions to four patients, each in a separate scenario. Before each scenario starts, you will receive training on various new tools and/or processes and then be asked to perform various IV-related tasks with these new tools or processes. Once the scenario is completed, you will receive training on another completely different set of tools and/or processes and then asked to perform more IV-related tasks
on a different patient. After all four scenarios are completed, you will be asked to complete a questionnaire for your feedback on the tools and processes. So there are a few things I want to highlight:

First, we are not accessing your skills but rather the new tools and processes at helping you manage multiple IV infusions. Second, I want to stress that the scenarios are meant to be as realistic as possible, and you should try to practice your nursing as you regularly would (for instance, ensuring the five-rights, flushing your lines, talking to the patients, infection control practices). But there are a few areas where things will not be entirely realistic (show participant an example, if possible)

There will be an actor playing the role of the charge nurse. She will guide the scenarios. Feel free to ask her questions, but she may not directly answer them and this isn’t because she is trying to be difficult or patronizing, but because we want to understand what you would do in this situation. Also, you will find that the charge nurse will micro manage your work more than normal to help guide the scenarios. In addition, when she is orienting you to a new patient, she will give you less information than you are used to since she will just focus on the information relevant to the study scenarios.

At Bedside:
- There will be mannequins playing the role of patients. Each patient has a PIV and a central line.
- None of the patients have allergies.
- There will be no real drugs used.
- All IV bags will be given to you pre-mixed and labelled so you are not responsible for this task and you can assume it is mixed properly according to the label.
- In the interest of time, IV lines will be pre-primed.
- Also, you may find that time artificially flies in this study. That is, we will not be actually running infusions over the true length of time that they would run. However, we have tried to reflect the before and after situations as accurately as possible. Therefore, please ensure before and after an episode of accelerated time that you perform all your usual tasks as normal.
- For IV pushes, however, please do it over the prescribed time or for the duration that you would normally administer the drug.
- All patients are ventilated, but you will notice that the ventilators are not on as we don’t have air up here and we don’t want them alarming all the time and they won’t be needed for our scenarios.
- As much as possible, please don’t change the physical setup of the scenarios (e.g., move pumps, untangle the IV lines, move IV poles, label the pumps and lines, move the IV bags). We need to ensure that each nurse who comes to do this study has the same physical setup for experimental control. However, please let me know if there is something you would normally do (and this goes for everything in the study).
- Normally you would reference the cardex and other documentation for patient information. In this study, only the dose rate information will be provided in this sheet here, which we have created. Please assume that the drug orders and instructions from charge nurse are correct.
- At the foot of each bed are supplies for flushing your lines, if needed. They are both syringes and bags.
- You are not responsible for any documentation. You don’t have to check off the items in Nursing inbox in MOE/MAR (show MOE/MAR). Your orders will be in a MOE/MAR that we have recreated but it is not the real system so has limited functionality so you can only see the orders in this view (show MOE/MAR) and scroll up and down using these buttons.
2.0 Experiment Protocol

Patient 1- Mr. Matthew Ward (Technology-based Intervention)

1. Setup

Control Room
- Control Room Data Collection: Synch time on laptops with camera recording time
- Dim Lights in control room

Nurse Actor
- Ensure that collection bags are not full
- Prepare flushing supplies (syringes and two 50cc Normal Saline bags) at bedside
- Bring MOE/MAR cart to bedside. Pulls up Matthew Ward’s MOE/MAR orders

2. Patient 1 - Intervention Orientation

[Facilitator] In the following scenario, you will be using a different infusion pump, called the Alaris pump. I’m not going to give you a full in-service, but just give you the information you need today.

It is a multi-channel infusion pump that supports up to four infusions at once on either side. Most of your interactions will be with the central “brain” which is used to control the channels.

The Alaris pump is a smart pump, which means it contains a hospital defined library of drugs with your unit’s specific appropriate concentrations, and it will also be set with dose limits for each drug to prompt users to potential programming or dosing errors.

If you look at the face of the brain, you’ll see these arrows pointing to the screen. These are soft keys or soft buttons. Much like an ATM, they will point to options that will change depending on your task. In contrast, these lower keys are called “hard” keys because their meaning is always the same.

Among the hard keys, the cancel key will usually back you out of whatever you’re doing, and the clear key will clear the number you are working on; if you hit a 2 instead of a 1, you can hit clear to start over.

The silence key is over here.

Okay, so I have an infusion running right now and you can notice that:
- Normal Saline is infusing on channel A
- The VTBI is also on the home screen.
- Channel A is labelled with the letter “A”
- The flow rate and the name of the drug is also displayed on the pump channel
- The channel has a green light at top (indicates that the infusion is running). Note that if the light is yellow or red, like a traffic light, that means something is not working properly.

I also want to mention that if we had 3 other channels, we would simply have channels A, B, C or D, but they always go in sequence. So the channel farthest to the left is channel A.

Let’s say we want to administer a secondary infusion on top of our normal saline. In order to use channel A, you have to physically touch the channel you want to use, by pressing the channel select button. If you touch the soft key, nothing will happen.

Select “secondary”

Select your drug. Let’s say we want to do ampho B.

Select the appropriate concentration: let’s do 50/250
You’ll notice that the pump has automatically filled in the VTBI for you because it knows what the standard concentrations are. You’ll also notice that VTBI and duration have boxes around them, but rate does not. Only parameters with a box around them are programmable, so at the moment, you cannot enter a flow rate. You can enter duration if you have it, or you can also press this soft key at the bottom to swap the boxes and make flow rate programmable instead.

Let’s infuse this over an hour, and press start.
You have now hit a soft limit alert
The drug library is set-up so that any flow rate higher than 125ml/h for this drug alerts you to make sure this is what you intend to give. This is called a soft limit and you can override it whereas if you hit a hard limit, your only option is to go back to the reprogramming screen. You can just press “yes” for now to start the infusion.

You would then also unclamp your secondary line.
So let’s say that we had to use this channel for a continuous IV drip of heparin when the secondary is done. Since it is currently associated with normal saline and ampho b, we need to clear it and start over. *(have participant do steps with your guidance)*

If there are other channels running, this is easy, you just press and hold channel off for a moment and then let go. BUT, because this is the only channel running on the pump, you have to hit any key to prevent it from powering down the central brain too.

Okay, on to our continuous infusion of heparin.

Again, select your channel, and now, because you are programming a drug, you will go into guardrails drugs. “Guardrails” means that those safety limits are available, so please use those libraries.

Find and select heparin and pick your concentration of 25000/250mL.

Then review your selection and confirm. You can now program. Note that unlike the Graseby, which has just rate and volume, this screen has dose in units/h, flow rate and VTBI. All three are programmable because they have boxes around them.

Use a flow rate of 12mL/hr and a VTBI of 250mL. Notice that when you program rate, dose is automatically calculated based on the concentration you selected earlier. If you start with dose, the opposite will occur. Go ahead and press start.

So just by looking:
- Where would you find the dose-rate information? [Answer: scrolling marquee on pump channel].
- Is the pump running? [Answer: yes, because green light is on]
- Where can you find the VTBI? [Answer: Home screen]
- And finally, where is the drug name? [Answer: Home screen and pump channel].

One last thing, some drugs also have the bolus feature enabled. For example, if you are just starting heparin, you might see that there’s a loading bolus for 8000 units.

Select channel
Press soft key for “bolus”.
Enter the bolus dose, in this case 8000 units
Enter duration. Let’s use 10 minutes. There is also a “Rapid Bolus” soft key to the right here [point this out], which will deliver at the maximum flow rate allowable for that drug based on how the hospital has setup the drug library. Press start and the bolus will begin.

So that’s it! Just a quick primer on how to use the pump. You will only need basic functionality today, so this should give you everything you need. Do you have any questions?
3. Introduction to Patient 1

[Nurse Actor] “Hi (Participant’s Name). It is so good to see you. I’m sorry that your patient, Mr. Tickner passed away, but since he did, I am going to ask you to be our float nurse today.

I’d like to introduce you to Mr. Matthew Ward. Miranda was attending this patient, but she has just been called away to get the smart pump training, so she should be back momentarily. So it is great that you can cover for her. She apologizes for leaving things in a mess, but she’ll fix it up when she is back.

I am being pulled in every direction today managing these new initiatives so have to run off soon, but first let me tell you about this patient. So, this is Matthew Ward. He is 47 years old and he is suffering from acute respiratory distress syndrome. His dry weight is 100 kg and here is a quick overview of his drips:

He is on Amiodarone because he was experiencing rapid atrial fibrillation (rapid afib). The doctor also suspects that he has a pneumonia infection. He is currently sedated with 1.5 mg/h of Midazolam. He is also receiving 125 mcg/h of fentanyl for pain and 0.4 mg/kg/h of Rocuronium, a muscle relaxant. He is also on 6 units/hour of Humulin R and 1800 units/h of heparin. He’s also receiving 0.171 mcg/kg/min of norepinephrine, 0.171 mcg/kg/min of epinephrine, and 0.54 mcg/kg/min of dopamine to stabilize his blood pressure. The flow sheet is in the binder.

I have to go, but a resident will be putting in a chest tube for Mr. Ward momentarily, but should be back soon. Until then take some time to assess your lines.”

4. Infusion Tasks

Task 1: Pump-controlled Bolus Task

Task 2: Secondary Infusion Task (under Technology-based Intervention)

[Nurse Actor] “Thank you so much for your help earlier. It looks like the doctor has ordered Ceftriaxone for Matthew Ward. I have the bag and primed tubing here. The information is in the MOE/MAR. Could you give Mr. Ward the medication now because I have to go back to that other patient?”

➢ Nurse Actor hands IV bag and leaves.

➢ Participant sets up and programs secondary infusion.

➢ DISTRACTION: Before the participant presses RUN to start secondary infusion, Nurse Actor returns and prompts participant to talk:

[Nurse Actor] “Oh Geez….it has been a long day – I’m dropping everything. How is Ms. Chur doing? Her daughter just called and said she’ll be coming to visit her again tomorrow. I think Ms. Chur will be happy to see her.”

Task 3: Line Identification Task (Dopamine Line Disconnection)

Task 4: Line Identification Task

Task 5: Manual IV Push Task (Furosemide)

Task 6: Secondary Infusion Task (under Technology-based Intervention)

[Nurse Actor] “I just checked Mr. Ward’s lab report on the computer. Results from his blood gas analysis indicate that he is going through uncompensated metabolic acidosis. Could you set up the sodium bicarbonate for Mr. Ward as a secondary infusion? I think the previous secondary infusion is done and he doesn’t have any other scheduled meds coming up so it is fine to give this as a secondary.”

➢ Nurse Actor hands IV bag and leaves.

➢ If participant asks for new secondary IV line, provide a new secondary IV line.
- Participant sets up and programs secondary infusion.
- DISTRACTION: Before the participant presses RUN to start secondary infusion, Nurse Actor returns prompts participant to talk:

  [Nurse Actor] "I think we have some new training for you soon. Let me know when you are done and I’ll let Sonia (or whoever was doing training) know. She will be here to give you some training."
Patient 2 - Ms. Susan Chur (Practice-based Intervention)

1. Setup

Control Room
- Control Room Data Collection: Sync time on laptops with camera recording time
- Dim Lights in control room

Nurse Actor
- Make sure grasby pumps are NOT bolus-enabled
- Bring cell phone to bedside
- Bring MOE/MAR cart to bedside
- Ensure that collection bags are not full
- Prepare flushing supplies (syringes and two 50cc Normal Saline bags) at bedside
- Make sure IV poles are aligned with markings on floor

2. Patient 2 - Intervention Orientation

[Facilitator] "For the next scenario, there is a hospital policy that secondary infusions must be setup using a separate infusion pump. That is, all secondary infusions now must be delivered as a primary infusion."

So instead of having a piggyback setup as normal (show), why don’t we just talk through the steps together:
- you would hang the secondary bag but use a primary infusion set instead.
- You would then prime the line
- Use a new pump and program it as a primary infusion
- Connect to the injection port of a compatible line
- Start the pump....and pause or titrate down the primary infusion, if necessary, since it will continue to run while the intermittent is running.
- When it is done
  o since the intermittent infusion is now being run as a primary, you will get an end of infusion alarm once complete.
  o If you paused or titrated down the medline, you would need to restart or titrate it back up
  o Since the priming volume of the line is now much larger, depending on the drug and situation, you will need to flush the residual fluid in the secondary line.

3. Introduction to Patient 2

[Nurse Actor] "Good to see you again. Debbie, the nurse who was taking care of Ms. Susan Chur has just been called way, she should be back momentarily. Please cover this patient for her while she is away, but she should be back soon. Let me give you a quick update on Ms. Susan Chur’s condition.

She came to the ICU from the Emergency Department two days ago. She is 64 years old and her dry weight is 70 kg. She was unwell for 2 weeks and was brought in by her family as she was becoming increasingly weak. I have to run, but I will quickly go over her drips:

At the moment, she is sedated with Midazolam (Versed) at 1.5 mg/h and also on 3mg/h of morphine. She’s also receiving 1200units/h of heparin, and 39.6mg/h of Amiodarone because she was experiencing rapid afib (rapid atrial fibrillation) earlier. Her last blood sugar level an hour ago was 18.2 (mmol/L) and she’s receiving Humulin R at 4units/hour. Debbie will be back in a few minutes so she’ll take the next accucheck reading.
Her blood culture test for E.Coli was positive, so she is on scheduled IV antibiotics.

To stabilize her blood pressure, she is getting 0.183 mcg/kg/min of norepinephrine and 0.95 units/h of vasopressin. Her dopamine has been titrated down over the night; it’s now at 0.57 mcg/kg/min. Her vitals are good at the moment. The flow sheet is in the binder."
We have just implemented a new policy that all secondary infusions must be delivered as a primary infusion on a separate pump.

I have to go -- I just got an urgent page -- but take a few minutes to orient yourself and play with the light linking system if you want to help trace your lines.

4. Infusion Tasks

Task 1: Secondary Task (under Practice-based Intervention)

[Nurse Actor] “Debbie just called and said she completely forgot to give Ms. Chur an infusion because of all the other infusions running. She is part of a clinical trial at our ward, called RNAD, which is an experimental antibiotic for the treatment of sepsis. So let me show you the clinical trial documentation. It’s in the binder. Although this is an intermittent infusion and would normally be given as a piggyback infusion, can you please set it up as a separate infusion on a separate pump as per the new policy? And there’s the extra pump for the secondary medication?”

Oh dear – I have to run, but I’ve already add-mixed it for you and primed the line. It is not compatible with most drugs but is compatible with normal saline.....Oh and remember you can use the Light Linking System to trace the injection port of your primary line.

- Nurse Actor hands IV bag and leaves.
- Participant programs secondary infusion
- DISTRACTION: Before the participant presses RUN to start secondary infusion, control room calls cell phone. Cell phone rings loudly and Nurse Actor returns.

[Nurse Actor] “Oh no, I think one of the family members left this. What a ridiculous ringtone. I never really understood the need for ringtones; they always seem to go off at the wrong times. I always put mine on vibrate – I don’t know, what do you think?”

Task 2: Line Identification (Disconnection of Amiodarone Line)

Task 3: Bolus Task

Task 4: Line Identification

Task 5: Secondary Task (under Practice-based Intervention)

[Nurse Actor] “Thanks! It’s look like she is more stable now. What a busy day! I just remembered that there is a piptazo order for her. And since we have this new policy, please deliver it on a separate pump as a primary infusion. The order for Piptazo is on the MOE/MAR. Thanks a lot!”

- Nurse Actor hands IV bag and leaves.
- If participant asks for new primary IV line, provide a new primary IV line.
- Participant delivers secondary infusion
- DISTRACTION: Before the participant presses RUN to start secondary infusion, Nurse Actor returns and prompts participant to talk:

[Nurse Actor] Can you remind me later on, when we have time, that we have to turn Mrs Chur. Mrs. Chur had some very bad bed sores in the past. I always find it tough to turn the patient. I have a really bad back and it hurts a lot. I guess we do have a “lift” here on the unit. I guess they really help.”
1. **Setup**

   **Control Room**
   - Control Room Data Collection: Synch time on laptops with camera recording time
   - Dim Lights in control room

   **Nurse Actor**
   - Ensure that collection bags are not full
   - Prepare flushing supplies (syringes and two 50cc Normal Saline bags) at bedside
   - Bring MOE/MAR cart to bedside
   - Remember to set up pump Alarm a secondary infusion task (Use training pumps to make the sound)

2. **Introduction to Patient 3**

   [Nurse Actor] “How are you doing? It’s good to have you as our float nurse. I’d like to introduce you to Mr. Thomas Sim. His nurse, Jenny, had to help with a new patient admission. Could you fill in for Jenny until she comes back?

   He is 72 years old and his dry weight is 80 kg. He had surgery for a small bowel obstruction 3 weeks ago. He developed pneumonia 4 days after his operation. He was treated and sent home. Three days ago, he was admitted at the ER because he was experiencing dyspnea and severe shortness of breath.

   Since you were last on shift, this unit has decided to implement the nursebuddy, pre-printed labels and horizontal rake pole top. Also, you would not need to deliver secondary medications as a primary infusion on a separate pump.

   Let’s quickly review Mr Sim’s drips. He is currently sedated with 1.5 mg/h of Midazolam. He is also receiving 125 mcg/h of fentanyl and 0.4 mg/kg/h of rocuronium. He is getting 0.5 units of Humulin R. His blood pressure is being maintained by 0.173 mcg/kg/min of Norepinephrine, 1 unit/h of Vasopressin, and 2 mcg/kg/min of Dopamine. The doctor has also ordered a drip of pantoprazole, which is running at 8mg/h. The flow sheet is in the binder.”

   [Control Room] Calls simulation lab.

   [Nurse Actor] “I’m going to go take that call. Please feel free take a few minutes to orient yourself. I’ll be right back.”

3. **Infusion Tasks**

   **Task 1: Secondary Task (under no intervention/baseline)**

   [Nurse Actor] “His nurse, Jenny, just called to tell us that she forgot to give Mr. Sim’s his Vancomycin before she left to help with that new admission. She said there’s an order for him in the MOE/MAR. Can you set it up? I just need to check something for another patient.

   ➢ Nurse Actor hands IV bag and leaves.
   ➢ Participant delivers secondary infusion
   ➢ DISTRACTION: Before the participant presses RUN to start secondary infusion, Nurse Actor creates noise by moving sink.

   [Nurse Actor] “Sorry this sink is leaking. I put in a work order but for now I have to move it to the other room. By the way, do you find it too cold in here? I’m always freezing! One of the family members was complaining about the room being too cold this morning as well.”
Task 2: Line Identification Task (Humulin R Line Disconnection)

Task 3: Secondary Task (under no intervention-baseline)

[Nurse Actor] “Did I tell you earlier that Mr. Sim is also part of the clinical trial study at this ward? This is an experimental antibiotic for sepsis patients. Could you give him this clinical trial medication as a secondary infusion? Come over here and I’ll show you the paper documentation.”

- Nurse Actor hands IV bag and leaves.

  If participant asks about the compatibility of the clinical trial drug
  [Nurse Actor] “It’s compatible with Normal Saline, of course, but not compatible with any of the other drugs since it hasn’t been fully studied yet.”

  If participant is concerned about the clinical trial drug
  [Nurse Actor] “We have been running this drug for Mr. Sim for the past couple of days. Don’t worry, we will do the lab work for him later.”

  If participant asks for new secondary IV line, provide a new secondary IV line.
  [Nurse Actor] “Here’s the secondary IV line that you asked for. I just took it out from a new package, you can assume that it is sterile.

- DISTRACTION: Before the participant presses RUN to start secondary infusion, Nurse Actor returns and prompts participant to talk:

  [Nurse Actor]”The doctor was just here on rounds and he asked to see if there’s anything new happening with Mr. Sim. I told him that Mr. Sim is doing pretty well. His vitals are pretty good at the moment. As you know, jenny didn’t have a chance to write down the fluid balance before she left. I’m just going to check the urine output from the foley catheter. Now where’s that urine bag. Do you mind if I can just take a look here?”

Task 4: Line Identification Task

Task 5: Dead Volume Task

Task 6: Line Change Task
Patient 4 - Mr. Calvin Madee (Training Intervention)

1. Setup

**Control Room**
- Control Room Data Collection: Synch time on laptops with camera recording time
- Dim Lights in control room

**Nurse Actor**
- Make sure there are at least 2 hooks on IV poles
- Prepare flushing supplies (syringes and two 50cc Normal Saline bags) at bedside
- Bring MOE/MAR cart to bedside

2. Orientation/Educational module

[Facilitator] “Before we introduce you to your final patient, we would like to present an education tool to you. This education tool is focused on principles of IV infusions. But before you begin, please complete this pre-training questionnaire on the computer. Have you used survey monkey before? (If participant has not used survey monkey before, show participant how to navigate the survey.) Please do not go back to previous questions as you fill out the questionnaire.

- Remind Participant not to press back button (and show them mouse)
- Participant completes pre-training questionnaire
- Open education module files on computer.
- Participant receives training on education tool.
- Give Dead Volume Tip Sheet

“Before we proceed to the next patient, please take a moment to fill out this questionnaire on the computer."

- Participant completes post-training questionnaire
- Give Laminated Questionnaire Sheet. Make sure it is for the right version.

3. Introduction to Patient 4

[Nurse Actor] “Janet, the nurse for this patient was asked to help with taking a very sick patient next door down to CT. Can you cover for her and look after things until she comes back?

While you were away, the hospital decided not to use the smart pumps. However, we are trialing this new Light Linking System. And we also have a new bolus feature on our Graseby pumps.

Calvin Madee is 62 years old and his dry weight is 90kg. He was admitted with septic shock to the ICU 2 days ago. He was on the surgical floor post op after his colectomy procedure. We suspect there is a leak from the surgery. So here are his drips:

He’s sedated with 1.5 mg/h of midazolam and 12.5 mg/h of ketamine. He’s also on 125mcg/h of fentanyl. He is on 1600 units/h of heparin and he is also on 8 units/h of Humulin R at the moment for his high blood sugar. His sugars have been a little high, around 16 to 20. He is also receiving 0.178 mcg/kg/min of epinephrine and 0.178 mcg/kg/min of norepinephrine to maintain his blood pressure. He is also on 1 unit/h of vasopressin.

The flow sheet is in the binder.

I just need to check a few things in the next room. I’ll let you have a few minutes to orient yourself. I’ll be right back.”
4. Infusion Tasks

Task 1: Line Identification Task (Disconnection of Ketamine)

Task 2: Secondary Infusion Task (after training intervention)

[Nurse Actor] “I just remembered. Before Janet left, she said there is an order of Piptazo for Mr. Madee that she didn’t have a chance to get to. Could you administer it to him?”

- Nurse Actor hands over IV bag and leaves.
- DISTRACTION: Before the participant presses RUN to start secondary infusion, Nurse Actor returns and prompts participant to talk:

[Nurse Actor] “Pump alarming. Oh Gosh, not again. I think there’s something wrong with this pump. Don’t worry of it, I’ll take care of the alarms this time. It’s been beeping for no reason all day. It’s funny; sometimes I wake up in the middle of the night hearing IV pump alarms.”

Task 3: Line Identification Task

Task 4: Bolus Task

Task 5: Manual IV push task (Furosemide)

Task 6: Dead volume task

Task 7: Secondary Infusion Task (after Training Intervention)

[Nurse Actor] “Mr. Madee’s lab results just arrived and showed that he is experiencing uncompensated metabolic acidosis. Could you give him sodium bicarbonate as a secondary infusion?”

- Nurse Actor hands over IV bag and leaves.
- If participant asks for new secondary IV line, provide a new secondary IV line.
- DISTRACTION: Before the participant presses RUN to start secondary infusion, Nurse Actor returns and prompts participant to talk:

[Nurse Actor] “I completely forgot to tell you that Janet called and asked to leave early because her daughter is really sick again – that poor kid. Since she’s not coming back, could you take over for her...and unfortunately that means you have to do the line change for Mr. Madee. Could you let me know when you are done the secondary infusion. The good news is that as you may recall, only the white line has to be done”

Task 8: Line Change
3.0 Post-Experiment Debriefing

1. Post-experiment Survey

After the experiment, an interview was conducted by the test facilitator with the participants, to gather comments on their overall experience, preferences and concerns related to the interventions being evaluated. In addition, the participants were asked to rate the following on a 4-point Likert scale for each intervention:

1) Effectiveness in reducing secondary infusion errors (1 = very ineffective; 2 = ineffective; 3 = effective; 4 = very effective)
2) Probability of use clinical practice (1 = definitely not use; 2 = not use; 3 = use; 4 = definitely use)

[Facilitator] “Here is a summary of all the different interventions that you used today.”

- Go over summary with participant and complete paper questionnaire
- Nurse’s general study feedback
  - How did you find the simulation?
  - Was there anything you found challenging in managing the patient(s)?
  - Are there any other strategies that you use to help manage multiple IV infusions?
- Explore observed nurse’s actions
  - Why did you/did you not perform a task a particular way?
  - What are the potential risks associated with an observed issue?
- Intervention feedback
  - What are your thoughts on the interventions?
  - Would you use the interventions in your routine practice?
  - How would you improve the interventions?
- Do you work on behalf of an agency?

2. Cheque Requisition

[Facilitator] “Thank you again for participating in this study... Because there is a possibility that your co-workers will participate in this study, please don’t discuss this experiment with others.”

- Participant is escorted outside of lab area.
- Remind participant not discuss with colleagues
- Return to normal TGH practices when next work!
Appendix I  Data Collection Log

### Multiple IV Infusion Data Collection  (GROUP E)

**PATIENT 1**

<table>
<thead>
<tr>
<th>Participant ID</th>
<th>Date</th>
</tr>
</thead>
</table>

Press <control> + "t" to timestamp

<table>
<thead>
<tr>
<th>Task</th>
<th>Timestamp</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>INTRO</td>
<td>Introduction to Mr. Matthew Ward</td>
<td></td>
</tr>
<tr>
<td>Trace Lines</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Task 1: Mr. Matthew Ward - Pump-controlled Bolus Task</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Midazolam</td>
<td>Control Room Resident puts in chest tube. Increase Mr Ward’s Heart Rate and Blood Pressure on Sim Man Monitor</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Identify Med Line</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Use Smart Pump Labels to Locate Pump</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Manually Trace Midazolam Line to Locate Pump</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Press Channel Select</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Press Rapid Bolus Button on Smart Pump</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Enter Bolus Dose (5 mg)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Enter Bolus Duration (1 min)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Press Run</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Distraction (Start)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Distraction (End)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bolus Ends</td>
<td></td>
</tr>
<tr>
<td></td>
<td>[Control Room] Return heart rate and blood pressure on Sim Man monitor.</td>
<td></td>
</tr>
</tbody>
</table>

| Task 2: Mr. Matthew Ward - Secondary Infusion Task (under Technology-based Intervention) | | |
| Ceftriaxone | Verify drug label against computer order | |
| | Walk to Mr. Ward’s bedside | |
| | Check patient’s armband | |
| | Identify Med Line | |
| | Spike IV Bag | Prime (Start) |
| | | Prime (End) | |
| | Hang secondary bag | |
| | Lower primary bag (Normal Saline on Med Line) | |
| | Connect Ceftriaxone to primary above pump | |
| | Press Channel Select and Secondary infusion button | |
| | Enter Ceftriaxone VTBI (50 mL) | |
| | Enter Ceftriaxone Duration (1 h) | |
| | Distraction (Start) | |
| | Distraction (End) | |
| | Press Run | |
| | Open clamp | |
| | Secondary Line Clamp Infusion Detector Alarms | |
| | Acknowledge Line Clamp Alarm and Open Clamp | |
| | Acknowledge Line Clamp Alarm and DO NOT Open Clamp | |

| Task 3: Mr. Matthew Ward - Line Identification Task | | |
| Dopamine Line | Use Smart Pump Label to Trace Dopamine Line | |
| | Manually Trace Dopamine Line | |
| | Stop Dopamine Flow on pump/Turn off pump | |
| | Disconnect Dopamine Line from Bridge of Proximal Line (White) | |
| | [Control Room] Calls Simulation Lab. Confederate Nurse exchanges secondary bag | |

| Matthew Ward - End of Secondary Infusion | | |
| Ceftriaxone | Secondary Line Clamp Infusion Detector Alarms | |
| | Acknowledge Line Clamp Alarm and Open Clamp | |
| | Acknowledge Line Clamp Alarm and DO NOT Open Clamp | |

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### Task 4: Mr. Matthew Ward - Line Identification Task

- **Rocuronium**
  - Use Smart Pump Label to Trace Rocuronium Line
  - Manually Trace Rocuronium Line
  - Identify that Rocuronium is running on Medial Line of Triple Lumen Catheter (Blue)
  - Identify Amiodarone
  - Identify Midazolam (Versed)
  - Identify Normal Saline

- **Furosemide**
  - Identified Med Line
  - Start Push (Record which port was used - should be medline)
  - End Push
  - **Flushing**
    - Syringe Flush
      - Start Flush
      - End Flush
    - Pump Flush
      - Enter Rate (Record Rate)
      - Enter VTBI (Record Volume)
      - Start Flush (Press Run)
      - End Flush
  - **Pull Tab on Pressure Transducer**

### Task 5: Mr. Matthew Ward - Manual IV Push Task

- **Sodium Bicarbonate**
  - **Verify drug label against computer order**
  - **Walk to Mr. Ward’s bedside**
  - **Check patient’s armband**
  - **Identify Med Line**
  - **Flushing**
    - Flush Primary IV line with 50 cc Normal Saline bag (Start)
    - Flush Rate (Record)
    - Flush Volume (Record)
    - Flush Primary IV line with 50 cc Normal Saline bag (End)
  - **Spike IV Bag**
  - **Priming**
    - **(Option 1)** Use same IV set: Prime tubing (Start)
    - Use same IV set: Prime tubing (End)
    - **(Option 2)** Use different IV set: Prime line (Start)
    - Use different IV set: Prime line (End)
  - **Hang secondary bag**
  - **Lower primary bag on (Normal Saline on Med Line) with 2 Hooks**
  - **Connect Sodium Bicarbonate to primary above pump**
  - **Press Channel Select and Secondary infusion button**
  - **Enter Sodium Bicarbonate VTBI (1000 mL)**
  - **Enter Sodium Bicarbonate Rate (250 mL/h)**
  - **Enter Sodium Bicarbonate Duration (4 h )**
  - **Distraction (Start)**
  - **Distraction (End)**
  - **Press Run**
  - **Open clamp**
  - **Secondary Line Clamp Infusion Detector Alarms**
    - Acknowledge Line Clamp Alarm and **Open Clamp**
    - Acknowledge Line Clamp Alarm and **DO NOT Open Clamp**

### Task 6: Mr. Matthew Ward - Secondary Infusion Task (under Technology-based Intervention)

- **Verify drug label against computer order**
- **Walk to Mr. Ward’s bedside**
- **Check patient’s armband**
- **Identify Med Line**
- **Flushing**
  - Flush Primary IV line with 50 cc Normal Saline bag (Start)
  - Flush Rate (Record)
  - Flush Volume (Record)
  - Flush Primary IV line with 50 cc Normal Saline bag (End)
- **Spike IV Bag**
- **Priming**
  - **(Option 1)** Use same IV set: Prime tubing (Start)
  - Use same IV set: Prime tubing (End)
  - **(Option 2)** Use different IV set: Prime line (Start)
  - Use different IV set: Prime line (End)
- **Hang secondary bag**
- **Lower primary bag on (Normal Saline on Med Line) with 2 Hooks**
- **Connect Sodium Bicarbonate to primary above pump**
- **Press Channel Select and Secondary infusion button**
- **Enter Sodium Bicarbonate VTBI (1000 mL)**
- **Enter Sodium Bicarbonate Rate (250 mL/h)**
- **Enter Sodium Bicarbonate Duration (4 h )**
- **Distraction (Start)**
- **Distraction (End)**
- **Press Run**
- **Open clamp**
- **Secondary Line Clamp Infusion Detector Alarms**
  - Acknowledge Line Clamp Alarm and **Open Clamp**
  - Acknowledge Line Clamp Alarm and **DO NOT Open Clamp**
### Patient 2: Mrs. Susan Chur

<table>
<thead>
<tr>
<th>Task</th>
<th>Timestamp</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>INTRO</strong></td>
<td></td>
<td>Introduction to Mrs. Susan Chur</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Trace Lines</td>
</tr>
<tr>
<td><strong>Task 1: Susan Chur - Secondary Infusion Task (Practice-based Intervention)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Identify Med Line</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Verify drug label against Paper Order</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Check patient’s armband</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Load pump</td>
<td></td>
<td>Connect RNAD to Med Line (Attach to Distal TLC Line) Downstream of NS pump</td>
</tr>
<tr>
<td>Prime IV Line (Start)</td>
<td></td>
<td>Enter RNAD rate</td>
</tr>
<tr>
<td>Prime IV Line (End)</td>
<td></td>
<td>Enter RNAD VTBI</td>
</tr>
<tr>
<td>Hang “secondary” bag</td>
<td></td>
<td>Participant indicates that Secondary Infusion Rate is too High</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Optional) Stop Flow “Primary” Line (NS)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Optional) Titrate down “Primary” Fluid (NS) (Record Rate)</td>
</tr>
<tr>
<td>Distraction (Start)</td>
<td></td>
<td>Press Run (Time Stamp)</td>
</tr>
<tr>
<td>Distraction (End)</td>
<td></td>
<td>Open Line Clamp on RNAD Line</td>
</tr>
<tr>
<td><strong>Clinical Trial Drug (RNAD)</strong></td>
<td></td>
<td>Manually Trace Amiodarone Line</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Stop Amiodarone Flow on pump/Turn off pump</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Disconnect Amiodarone Line from Bridge of Medial Line (BLUE)</td>
</tr>
<tr>
<td><strong>Distraction - Mrs Chur’s daughter is at the door. Confederate Nurse exchange secondary bag</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Task 2: Susan Chur - Line Identification</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amiodarone</td>
<td></td>
<td>Manually Trace Amiodarone Line</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Stop Amiodarone Flow on pump/Turn off pump</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Disconnect Amiodarone Line from Bridge of Medial Line (BLUE)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Distraction (Start)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Distraction (End)</td>
</tr>
<tr>
<td><strong>End of Clinical Trial Drug (RNAD)</strong></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Manually Trace Morphine Line to Locate Pump</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Option 1) Press Hold and Press Secondary Infusion/Bolus button</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Option 1) Enter Bolus VTBI (4 mL)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Option 2) Press Hold and Reprogram under Primary Mode</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Option 2a: Specify Volume)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Option 2b: Manually Time Bolus )</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Participant Manually Time Duration of Bolus (Start of Bolus)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Participant Manually Start Time Duration of Bolus (End of Bolus)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Distraction (Start)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Distraction (End)</td>
</tr>
<tr>
<td><strong>Task 3: Susan Chur - Bolus Task</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Control Room) Increase Heart Rate and Blood Pressure on Sim Man Monitor</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Manually Trace Morphine Line To Locate Pump</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Option 1) Press Hold and Press Secondary Infusion/Bolus button</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Option 2) Press Hold and Reprogram under Primary Mode</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Option 2a: Specify Volume)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Option 2b: Manually Time Bolus )</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Participant Manually Time Duration of Bolus (Start of Bolus)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Participant Manually Start Time Duration of Bolus (End of Bolus)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Distraction (Start)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Distraction (End)</td>
</tr>
<tr>
<td><strong>Control Room</strong></td>
<td></td>
<td>Return Ms. Chur’s Heart Rate and Blood Pressure to normal on Sim Man Monitor</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Option 2) Reprogram primary infusion to restart continuous morphine infusion after bolus completes</td>
</tr>
</tbody>
</table>
### Task 4: Susan Chur - Line Identification Task

<table>
<thead>
<tr>
<th>Line Identification (Dopamine)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manually Trace Dopamine Line</td>
</tr>
<tr>
<td>Identify that Dopamine is running on Proximal Line of Triple Lumen Catheter (WHITE)</td>
</tr>
<tr>
<td>Identify Vasopressin</td>
</tr>
<tr>
<td>Identify Norepinephrine</td>
</tr>
<tr>
<td>Identify Normal Saline</td>
</tr>
</tbody>
</table>

### Task 5: Susan Chur - Secondary Infusion Task (Practice-based Intervention)

| Verify drug label against computer order |
| Identify Med Line                     |
| Check patient’s armband               |

#### Flushing

- Flush Primary IV line with 50 cc Normal Saline bag (Start)
- Flush Rate (Record)
- Flush Volume (Record)
- Flush Primary IV line with 50 cc Normal Saline bag (End)

#### Priming

- **(Option 1)** Use same IV set: Prime tubing (Start)
  - Use same IV set: Prime tubing (End)
- **(Option 2)** Use different IV set: Prime line (Start)
  - Use different IV set: Prime line (End)

#### Spike IV Bag

- **(Option 2)** Use different IV set: Load pump

#### Hang Piptazo bag

- **(Option 2)** Use different IV set: Load pump

#### Connect Piptazo to Med Line (Attach to Distal TLC Line) Downstream of Normal Saline pump

- Enter Piptazo rate
- Enter Piptazo VTBI
  - (Optional) Stop flow “Primary” Line (NS)
  - (Optional) Titrate down “Primary” Fluid (NS)

#### Distraction (Start)

#### Distraction (End)

#### Press Start (Time Stamp)

#### Open Secondary Line Clamp on Piptazo Line
## PATIENT 3

### Task 1: Thomas Sim - Secondary Task (under no intervention/baseline)

<table>
<thead>
<tr>
<th>Task</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Identify Med Line</strong></td>
<td>Verifies drug label</td>
</tr>
<tr>
<td><strong>Check patient's armband</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Spike IV Bag</strong></td>
<td>Prime (Start)</td>
</tr>
<tr>
<td><strong>Prime (End)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Hang secondary bag</strong></td>
<td>Lower primary bag (Normal Saline on Med Line)</td>
</tr>
<tr>
<td><strong>Connect Ceftriaxone to primary above pump</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Enter Vancomycin rate</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Enter Vancomycin VTBI</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Distraction (Start)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Distraction (End)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Press Run</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Open clamp</strong></td>
<td>Clamp Primary Line (Normal Saline)</td>
</tr>
</tbody>
</table>

### Task 2: Thomas Sim Line Identification

<table>
<thead>
<tr>
<th>Task</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Use Nursebuddy and Labels to Trace Humulin R Line to Locate Pump</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Stop Insulin Flow on pump</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Disconnect Insulin Line from Bridge of Medial Line</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Distraction - “Can you check to see if there’s a message for Mr. Sim?” (Confederate Nurse exchanges secondary bag)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>End of Vancomycin Infusion</strong></td>
<td>(Optional) UNC* “Primary” Line (NS)</td>
</tr>
</tbody>
</table>

### Task 3: Thomas Sim - Secondary Task (under no intervention/baseline)

<table>
<thead>
<tr>
<th>Task</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Identify Med Line</strong></td>
<td>Verify drug label against paper order</td>
</tr>
<tr>
<td><strong>Check patient's armband</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Spike IV Bag</strong></td>
<td>Prime (Start)</td>
</tr>
<tr>
<td><strong>Prime (End)</strong></td>
<td>(Option 1) Use same IV set: Prime Line (Start)</td>
</tr>
<tr>
<td><strong>Use different IV set: Priming (End)</strong></td>
<td>(Option 2) Use different IV set: Prime Line (Start)</td>
</tr>
<tr>
<td><strong>Hang Secondary Bag</strong></td>
<td>(Option 2) Use different IV set: Load pump</td>
</tr>
<tr>
<td><strong>Primary Bag was lowered</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Connect to primary above pump</strong></td>
<td>Enter Rate</td>
</tr>
<tr>
<td><strong>Enter VTBI</strong></td>
<td>(Optional) Stop flow “Primary” Line (NS)</td>
</tr>
<tr>
<td><strong>(Optional) Titrator down “Primary” Fluid (NS)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Distraction (Start)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Distraction (End)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Press Run</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Open clamp Primary Line (Normal Saline)</strong></td>
<td></td>
</tr>
</tbody>
</table>

### Task 4: Mr. Thomas Sim - Line Identification Task

<table>
<thead>
<tr>
<th>Task</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Use Nursebuddy and Labels to Trace Norepinephrine Line to Locate Pump</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Identify that Norepinephrine running on White Proximal Line of Triple Lumen Catheter</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Identify Vasopressin</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Identify Dopamine</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Identify Normal Saline</strong></td>
<td></td>
</tr>
<tr>
<td>Task 5: Mr. Thomas Sim - Dead Volume Task</td>
<td></td>
</tr>
<tr>
<td>----------------------------------------</td>
<td></td>
</tr>
<tr>
<td><strong>Outcome 1:</strong> “Can I get a new IV line (or can I get a new pump)?”</td>
<td></td>
</tr>
<tr>
<td>Participant Response: Indicate Dead Volume Issue</td>
<td></td>
</tr>
<tr>
<td><strong>Outcome 2:</strong> “Keep the original flow rate (26mL/h) or Lower flow rate (above 13mL/h)”</td>
<td></td>
</tr>
<tr>
<td>- Keep the original flow rate (Range: 1.69 - 29.5 mL/h) (26mL/h)</td>
<td></td>
</tr>
<tr>
<td>- Lower flow rate (Range: 1.69 - 29.5 mL/h) (above 13mL/h)</td>
<td></td>
</tr>
<tr>
<td>[Nurse Actor] Are you all done, it looks like the rate is the same (it looks like the rate is a little lower than before)?</td>
<td></td>
</tr>
<tr>
<td>Participant Response: Indicate Dead Volume Issue (PASS)</td>
<td></td>
</tr>
<tr>
<td>Participant Response: Titrate epinephrine down to 13mL/h after ___ min has passed (PASS)</td>
<td></td>
</tr>
<tr>
<td><strong>Outcome 3:</strong> Decrease the original flow rate in half (13mL/h)</td>
<td></td>
</tr>
<tr>
<td>- Enter Norepinephrine VTBI (250 mL)</td>
<td></td>
</tr>
<tr>
<td>- Enter Norepinephrine VTBI (13mL/h)</td>
<td></td>
</tr>
<tr>
<td>Press Run</td>
<td></td>
</tr>
<tr>
<td>[Control Room] Increase Heart Rate and Blood Pressure on Sim Man Monitor</td>
<td></td>
</tr>
<tr>
<td>[Nurse] “It looks like the blood pressure is decreasing. Why do you think that's the case?” [Record Response]</td>
<td></td>
</tr>
<tr>
<td>Participant Explains Dead Volume Issue</td>
<td></td>
</tr>
<tr>
<td>[Nurse] “Should we do something about the drop in pressure?...” (Ask participant for reason behind his/her action)</td>
<td></td>
</tr>
<tr>
<td>Participant tried to fix issue by delivering more medication</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Task 6: Line Change Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>Label lines/pumps</td>
</tr>
<tr>
<td>Flush Bridge with Normal Saline right before connecting to patient (FAIL)</td>
</tr>
</tbody>
</table>
### PATIENT 4

#### Patient 4: Mr. Calvin Madee

<table>
<thead>
<tr>
<th>Task</th>
<th>Timestamp</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>INTRO</strong></td>
<td>Introduction to Mr. Calvin Madee</td>
<td>Trace Lines</td>
</tr>
<tr>
<td><strong>Task 1: Mr. Calvin Madee - Line Identification Task</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ketamine Line (Bridge of Medial Line (Blue) on TLC)</td>
<td>Use Light Linking System to trace lines</td>
<td>Manually Trace Ketamine Line</td>
</tr>
<tr>
<td><strong>Task 2: Calvin Madee - Secondary Infusion Task (after training intervention)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Piptazo</td>
<td>Identify Med Line</td>
<td>Go to computer</td>
</tr>
<tr>
<td><strong>Task 3: Mr. Calvin Madee - Line Identification Task</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Line Identification (Vasopressin)</td>
<td>Use Light Linking System to Trace Vasopressin Line</td>
<td>Manually Trace Vasopressin Line</td>
</tr>
<tr>
<td><strong>Task 4: Mr. Calvin Madee - Bolus Task</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Midazolam</td>
<td>[Control Room] Increase Heart Rate and Blood Pressure on Sim Man Monitor</td>
<td>Manually Trace Midazolam Line to Locate Pump</td>
</tr>
<tr>
<td></td>
<td>(Option 2) Press Hold and Reprogram under Primary Mode</td>
<td>Enter Bolus Rate (Record Rate)</td>
</tr>
</tbody>
</table>
### Calvin Madee - End of Secondary Infusion

<table>
<thead>
<tr>
<th>Task 5: Manual IV Push Task</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Optional</strong> Unclamp &quot;Primary&quot; Line (NS)</td>
</tr>
<tr>
<td><strong>Syringe Flush</strong></td>
</tr>
<tr>
<td>Start Flush</td>
</tr>
<tr>
<td>End Flush</td>
</tr>
<tr>
<td><strong>Pump Flush</strong></td>
</tr>
<tr>
<td>Enter Rate (Record Rate)</td>
</tr>
<tr>
<td>Enter VTBI (Record Volume)</td>
</tr>
<tr>
<td>Start Flush (Press Run)</td>
</tr>
<tr>
<td>End Flush</td>
</tr>
<tr>
<td>Pull Tab on Pressure Transducer</td>
</tr>
</tbody>
</table>

### Task 6: Mr. Calvin Madee - Dead Volume Task

<table>
<thead>
<tr>
<th>Outcome 1: “Can I get a new IV line (or can I get a new pump)?”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participant Response: Indicate Dead Volume Issue</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Outcome 2: “Keep the original flow rate (30mL/h) or Lower flow rate (above 15mL/h)”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enter Epinephrine VTBI (250 mL)</td>
</tr>
<tr>
<td>Keep the original flow rate: Rate: 1.69 - 20.5 mL/h (30mL/h)</td>
</tr>
<tr>
<td>Lower flow rate: Rate: 1.69 - 20.5 mL/h (above 15mL/h)</td>
</tr>
<tr>
<td><strong>Nurse Actor</strong> Are you all done, it looks like the rate is the same (it looks like the rate is a little lower than before)?</td>
</tr>
<tr>
<td>Participant Response: Indicate Dead Volume Issue (PASS)</td>
</tr>
<tr>
<td>Participant Response: Titrate epinephrine down to 15mL/h after ___ min has passed (PASS)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Outcome 3: Decrease the original flow rate in half (15mL/h)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enter Epinephrine VTBI (15mL/h)</td>
</tr>
</tbody>
</table>

### Control Room

<table>
<thead>
<tr>
<th>Outcome 4: Increase Heart Rate and Blood Pressure on Sim Man Monitor</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nurse</strong> It looks like the blood pressure is decreasing. Why do you think that's the case? (Record Response)</td>
</tr>
<tr>
<td>Participant Explains: Dead Volume Issue</td>
</tr>
<tr>
<td><strong>Nurse</strong> Should we do something about the drop in pressure?....? (Ask participant for reason behind his/her action)</td>
</tr>
</tbody>
</table>

| Participant tried to fix issue by delivering more medication |

### Task 7: Mr. Calvin Madee - Secondary Infusion Task (after training intervention)

<table>
<thead>
<tr>
<th>Sodium Bicarbonate</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hang Secondary Bag</strong></td>
</tr>
<tr>
<td>Connect to primary above pump</td>
</tr>
<tr>
<td>Lower primary bag on (Normal Saline on Med Line) with 2 Hooks</td>
</tr>
<tr>
<td>Enter Sodium Bicarbonate Rate</td>
</tr>
<tr>
<td>Enter Sodium Bicarbonate VTBI (Option)</td>
</tr>
<tr>
<td>(Optional) Stips Flow &quot;Primary&quot; Line (NS)</td>
</tr>
<tr>
<td>(Optional) Titrate down &quot;Primary&quot; Fluid (NS)</td>
</tr>
<tr>
<td><strong>Distraction (Start)</strong></td>
</tr>
<tr>
<td><strong>Distraction (End)</strong></td>
</tr>
<tr>
<td>Press Run</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Task 8: Mr. Calvin Madee - Line Change Task</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Label lines/pumps</strong></td>
</tr>
<tr>
<td>Push Bridge with Normal Saline right before connecting to patient (FAIL)</td>
</tr>
<tr>
<td>Use One-at-a-TIME Method</td>
</tr>
</tbody>
</table>
Appendix J Pre-training and Post-training Tests

There were two different but equivalent tests, Test A and Test B (see Appendix J). The test was field tested with 7 nursing experts to ensure appropriateness of wording and difficulty. Twenty nurses completed Test A prior to the educational module and Test B after the module; 20 nurses completed Test B prior to the module and Test A after the module.

An independent sample t-test was conducted and indicated that there was no significant difference between Test A and B, t(78)= -1.029, p=0.307. This suggests that there was no significant difference in the level of difficulty between Test A and Test B.
Test A

Figure 1

Q1. What most likely describes the scenario in Figure 1?
   a) Pump will alarm - No flow above pump
   b) Pump will alarm – Distal Occlusion
   c) Drug A infusing at 100mL/h
   d) Drug B infusing at 100mL/h
   e) Mix of Drugs A & B infusing at 100mL/h

Q2. In Figure 1, will the back-check valve stop flow from Bag A?
   a) Yes because IV Bag A is lower than Bag B
   b) Yes because IV bag A exerts equal or greater pressure compared to Bag B
   c) No because IV Bag A is lower than Bag B
   d) No because IV bag A exerts equal or greater pressure compared to Bag B
   e) None of the above

Q3. If the secondary IV tubing clamp is closed in Figure 1, what will the patient receive?
   a) No flow will occur
   b) Drug A infusing at 100mL/h
   c) Drug B infusing at 100mL/h
   d) Mix of Drugs A & B infusing at 100mL/h
Q4. If the infusion pumps in Figure 2 are programmed correctly, which set-ups will infuse the contents of Bag B at the programmed rate? Please select all that apply.

a) Setup 1  
b) Setup 2  
c) Setup 3  
d) Setup 4  
e) None of the above

Q5. If IV Bag B in Figure 2 - Setup 1, is connected to the primary IV tubing below the pump, which of the following could be true?

a) Drug A infuses at 850mL/h AND Drug B free flows at an indeterminate rate  
b) Drug A infuses at 425mL/h AND Drug B infuses at 425mL/h  
c) Drug A backflows into Drug B’s IV tubing  
d) No flow of Drug A
Test B

Figure 1

Q1. What most likely describes the scenario in Figure 1?
   a) Drug A infusing at 100mL/h
   b) Drug B infusing at 100mL/h
   c) Mix of Drugs A & B infusing at 100mL/h
   d) Pump will alarm – No flow above pump
   e) Pump will alarm – Distal occlusion

Q2. Will the back-check valve allow flow from Bag A based on Figure 1?
   a) Yes because IV Bag A is bigger than Bag B
   b) Yes because IV bag A exerts equal or greater pressure compared to Bag B
   c) No because IV Bag A is bigger than Bag B
   d) No because IV bag A exerts equal or greater pressure compared to Bag B
   e) None of the above

Q3. If the secondary IV tubing clamp is closed in Figure 1, what will the patient receive?
   a) Drug A infusing at 100mL/h
   b) Drug B infusing at 100mL/h
   c) Mix of Drugs A & B infusing at 100mL/h
   d) No flow will occur
Q4. If the infusion pumps in Figure 2 are programmed correctly, which set-up(s) will infuse the contents of Bag B at the programmed rate? Please select all that apply.

a) Setup 1  
b) Setup 2  
c) Setup 3  
d) Setup 4  
e) None of the above

Q5. If IV Bag B in Figure 2 - Setup 3, is connected to the primary IV tubing below the pump, which of the following could be true?

a) Drug A infuses at 750mL/h AND Drug B free flows at an indeterminate rate  
b) Drug A infuses at 375mL/h AND Drug B infuses at 375mL/h  
c) Drug A backflows into Drug B’s IV tubing  
d) No flow of Drug A
# Appendix K  Post-experiment Questionnaire

<table>
<thead>
<tr>
<th>Interventions</th>
<th>1. Please rate the intervention’s effectiveness in reducing medication errors?</th>
<th>2. If the intervention was implemented in your clinical unit, please rate your estimated use of the intervention?</th>
<th>Please explain your ratings in the comment box</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Very ineffective</td>
<td>Somewhat ineffective</td>
<td>Somewhat effective</td>
</tr>
<tr>
<td>Automated Secondary Line Clamp Detector (on smart pump)</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Dose Error Reducing Software (DER'S) on Smart Pump</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Educational module on Key Principles for Secondary Infusions</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Deliver Secondary Infusion using a Separate Pump</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>
## Appendix L  Connection Errors

<p>| Type of Connection Errors           | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Discussion of Consequences                                                                                                                                                                                                                                                                                                                                 |
|------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Connection to wrong port           | In 6 instances, a participant connected the secondary line to the port below the pump instead of above the pump.                                                                                                                                                                                                                                                                                                                                                                                                                                           | This error was observed in one participant under the technology-based intervention, the training-based intervention, as well as in baseline (no intervention). The only intervention that prevented the error was the practice-based intervention where the participant was asked to set up the secondary medication using a separate pump. In the secondary infusion setup, when the secondary medication is connected below the infusion pump, the pump can no longer directly control the infusion rate of the secondary medication. The secondary medication will flow into the patient by gravity and the infusion pump will deliver the primary infusion at the rate of the programmed secondary rate until the secondary VTBI is delivered. |
| Connection to wrong primary line   | In 7 instances, participants incorrectly connected the secondary medication to the Normal Saline &quot;chaser&quot; on a multi-port connector instead of the medication line that is reserved for the co-administration of medication (see Figure 26).                                                                                                                                                                                                                                                                                                           | Cassano-Piché et al. (2012) indicated that secondary medication should not be initiated on a IV chaser line. The connection of an IV “chaser” line to a multi-port connector is usually used to provide fluid volume, to ensure IV line patency, or to “push” other medications that are connected downstream on the port to the patient. This &quot;chaser&quot; is typically a maintenance fluid that is connected last in a series of infusions on a multi-port connector (see Figure 26). The IV chaser also described as a “driver” or “carrier”. The connection of a secondary medication to the IV chaser line can abruptly increase the total flow rate in the multi-port connector and may lead to boluses of downstream volume of IV medications to the patient. The term dead space volume is commonly used to refer to this volume in the IV tubing between the point where multiple IV agents are connected and the patient’s vein. Furthermore, if the secondary medication is incompatible with the various medications entering the connector, it can result in the formation of precipitate in the IV line. |</p>
<table>
<thead>
<tr>
<th>Type of Connection Errors</th>
<th>Description</th>
<th>Discussion of Consequence</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Connection to wrong primary line (Cont'd)</td>
<td>In 2 instances, participants connected the secondary medication to the peripheral IV line (PIV). The PIV line was delivering heparin and humulin R (see Figure 27).</td>
<td>The connection of the secondary medication can abruptly increase the total flow rate in the peripheral line and may lead to a bolus of the heparin and humulin R in the dead volume of the IV line to the patient. In one instance, even though the participant disconnected the heparin from the PIV line, the flow from the secondary medication line may still deliver a bolus of the heparin in the dead volume of the line. Inaccurate control of the delivery of heparin and humulin R may affect therapeutic end-points and lead to harmful fluctuations in the patient’s clinical condition.</td>
</tr>
</tbody>
</table>
Appendix M  Frequency of Errors

Baseline
(Without Intervention)

<table>
<thead>
<tr>
<th>Participant #</th>
<th>Baseline (Without Intervention)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Connection Error</td>
</tr>
<tr>
<td></td>
<td>Secondary Clamp Error</td>
</tr>
<tr>
<td></td>
<td>Pressure Differential Error (Typical)</td>
</tr>
<tr>
<td></td>
<td>Pressure Differential Error (Complex)</td>
</tr>
</tbody>
</table>

Clamp Detector/ Smart Pump
(Technology-based Intervention)

<table>
<thead>
<tr>
<th>Participant #</th>
<th>Clamp Detector/ Smart Pump (Technology-based Intervention)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Connection Error</td>
</tr>
<tr>
<td></td>
<td>Secondary Clamp Error</td>
</tr>
<tr>
<td></td>
<td>Pressure Differential Error (Typical)</td>
</tr>
<tr>
<td></td>
<td>Pressure Differential Error (Complex)</td>
</tr>
</tbody>
</table>

Training Intervention

<table>
<thead>
<tr>
<th>Participant #</th>
<th>Training Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Connection Error</td>
</tr>
<tr>
<td></td>
<td>Secondary Clamp Error</td>
</tr>
<tr>
<td></td>
<td>Pressure Differential Error (Typical)</td>
</tr>
<tr>
<td></td>
<td>Pressure Differential Error (Complex)</td>
</tr>
</tbody>
</table>

Use of Separate Pump
(Practice-based Intervention)

<table>
<thead>
<tr>
<th>Participant #</th>
<th>Use of Separate Pump (Practice-based Intervention)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Connection Error</td>
</tr>
<tr>
<td></td>
<td>Secondary Clamp Error</td>
</tr>
<tr>
<td></td>
<td>Pressure Differential Error (Typical)</td>
</tr>
<tr>
<td></td>
<td>Pressure Differential Error (Complex)</td>
</tr>
</tbody>
</table>
Appendix N  Licensed Smart Pump Devices in Canada

The table below provides a list of the licensed smart pump devices in Canada.

Currently, none of the 8 devices has the secondary clamp detector feature.

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Product Name</th>
<th>Date device licensed in Canada</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardinal Health</td>
<td>ALARIS SE SINGLE/DUAL CHANNEL VOLUMETRIC INFUSION PUMP WITH GUARD RAILS</td>
<td>September 22, 1999</td>
</tr>
<tr>
<td>Cardinal Health</td>
<td>ALARIS PATIENT CARE SYSTEM</td>
<td>September 22, 1999</td>
</tr>
<tr>
<td>Baxter Healthcare Corporation</td>
<td>COLLEAGUE CXE 3-CHANNEL OR 1-CHANNEL VOLUMETRIC INFUSION PUMP</td>
<td>June 12, 2007</td>
</tr>
<tr>
<td>Hospira Inc.</td>
<td>PLUM A+ 3-CHANNEL OR 1-CHANNEL VOLUMETRIC INFUSION PUMP</td>
<td>November 25, 2002</td>
</tr>
<tr>
<td>Hospira Inc.</td>
<td>SYMBIQ INFUSION SYSTEM, 1-CHANNEL OR 2-CHANNEL</td>
<td>March 20, 2007</td>
</tr>
<tr>
<td>BBraun</td>
<td>SPACE INFUSION SYSTEM - INFUSOMAT SPACE VOLUMETRIC INFUSION PUMP</td>
<td>November 23, 2006</td>
</tr>
<tr>
<td>BBraun</td>
<td>OUTLOOK SAFETY INFUSION SYSTEM</td>
<td>February 14, 2002</td>
</tr>
<tr>
<td>Sigma International</td>
<td>SPECTRUM INFUSION PUMP WITH MASTER DRUG LIBRARY</td>
<td>October 21, 2008</td>
</tr>
<tr>
<td>Total number of smart pump products licensed by Health Canada</td>
<td>8</td>
<td>N/A</td>
</tr>
</tbody>
</table>