

Multiple Intravenous Infusions Phase 1b: Practice and Training Scan

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To fulfill its mandate, HQO conducts systematic reviews of evidence and consults with experts in the health care services community. The resulting evidence-based analyses are reviewed by the Ontario Health Technology Advisory Committee, and published in the *Ontario Health Technology Assessment Series*.

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Abstract

Background

Minimal research has been conducted into the potential patient safety issues related to administering multiple intravenous (IV) infusions to a single patient. Previous research has highlighted that there are a number of related safety risks. In Phase 1a of this study, an analysis of 2 national incident-reporting databases (Institute for Safe Medical Practices Canada and United States Food and Drug Administration MAUDE) found that a high percentage of incidents associated with the administration of multiple IV infusions resulted in patient harm.

Objectives

The primary objectives of Phase 1b of this study were to identify safety issues with the potential to cause patient harm stemming from the administration of multiple IV infusions; and to identify how nurses are being educated on key principles required to safely administer multiple IV infusions.

Data Sources and Review Methods

A field study was conducted at 12 hospital clinical units (sites) across Ontario, and telephone interviews were conducted with program coordinators or instructors from both the Ontario baccalaureate nursing degree programs and the Ontario postgraduate Critical Care Nursing Certificate programs. Data were analyzed using Rasmussen's 1997 Risk Management Framework and a Health Care Failure Modes and Effects Analysis.

Results

Twenty-two primary patient safety issues were identified with the potential to directly cause patient harm. Seventeen of these (critical issues) were categorized into 6 themes. A cause-consequence tree was established to outline all possible contributing factors for each critical issue. Clinical recommendations were identified for immediate distribution to, and implementation by, Ontario hospitals. Future investigation efforts were planned for Phase 2 of the study.

Limitations

This exploratory field study identifies the potential for errors, but does not describe the direct observation of such errors, except in a few cases where errors were observed. Not all issues are known in advance, and the frequency of errors is too low to be observed in the time allotted and with the limited sample of observations.

Conclusions

The administration of multiple IV infusions to a single patient is a complex task with many potential associated patient safety risks. Improvements to infusion and infusion-related technology, education standards, clinical best practice guidelines, hospital policies, and unit work practices are required to reduce the risk potential. This report makes several recommendations to Ontario hospitals so that they can develop an awareness of the issues highlighted in this report and minimize some of the risks. Further investigation of mitigating strategies is required and will be undertaken in Phase 2 of this research.

Plain Language Summary

Patients, particularly in critical care environments, often require multiple intravenous (IV) medications via large volumetric or syringe infusion pumps. The infusion of multiple IV medications is not without risk; unintended errors during these complex procedures have resulted in patient harm. However, the range of associated risks and the factors contributing to these risks are not well understood.

Health Quality Ontario's Ontario Health Technology Advisory Committee commissioned the Health Technology Safety Research Team at the University Health Network to conduct a multi-phase study to identify and mitigate the risks associated with multiple IV infusions. Some of the questions addressed by the team were as follows: What is needed to reduce the risk of errors for individuals who are receiving a lot of medications? What strategies work best?

The initial report, *Multiple Intravenous Infusions Phase 1a: Situation Scan Summary Report*, summarizes the interim findings based on a literature review, an incident database review, and a technology scan.

The Health Technology Safety Research Team worked in close collaboration with the Institute for Safe Medication Practices Canada on an exploratory study to understand the risks associated with multiple IV infusions and the degree to which nurses are educated to help mitigate them. The current report, *Multiple Intravenous Infusions Phase 1b: Practice and Training Scan*, presents the findings of a field study of 12 hospital clinical units across Ontario, as well as 13 interviews with educators from baccalaureate-level nursing degree programs and postgraduate Critical Care Nursing Certificate programs. It makes 9 recommendations that emphasize best practices for the administration of multiple IV infusions and pertain to secondary infusions, line identification, line set-up and removal, and administering IV bolus medications.

The Health Technology Safety Research Team has also produced an associated report for hospitals entitled *Mitigating the Risks Associated With Multiple IV Infusions: Recommendations Based on a Field Study of Twelve Ontario Hospitals*, which highlights the 9 interim recommendations and provides a brief rationale for each one.

Table of Contents

Abstract.....	5
Background.....	5
Objectives	5
Data Sources and Review Methods	5
Results	5
Limitations.....	5
Conclusions	5
Plain Language Summary	6
Table of Contents	7
List of Tables	9
List of Figures.....	11
List of Abbreviations	12
Background	13
Introduction	13
Objectives of Analysis.....	14
Scope of Analysis	14
<i>Inclusions</i>	15
<i>Exclusions</i>	15
<i>Clinical Areas Studied</i>	16
Clinical Environments Under Special Consideration	17
<i>Critical Care Environments</i>	17
<i>Pediatric Care Environments</i>	18
<i>Outpatient Chemotherapy Clinics</i>	19
Principles of Infusion Therapy	20
<i>Principles of Fluid Flow in IV Systems</i>	20
<i>Dead Volume Considerations</i>	21
<i>Secondary Infusions</i>	22
<i>Concurrent Infusions</i>	24
<i>IV Bolus Administration</i>	25
High-Risk Tasks Associated With Managing Multiple IV Infusions	26
<i>Secondary Infusions</i>	26
<i>IV Bolus Administration</i>	26
<i>IV Line Tracing</i>	26
<i>IV Tubing Changes</i>	27
<i>Shift Handovers and Patient Transfers Between Care Areas</i>	27
Exploratory Ethnographic Analysis.....	28
Research Questions.....	28
Research Methods.....	28
<i>Field Study</i>	28
<i>Nursing Education Interviews</i>	29
Application of the Precautionary Principle	30

Summary of Issues Identified During the Field Study.....	31
<i>Definitions</i>	32
<i>Theme 1: Secondary Infusions</i>	33
<i>Theme 2: Line Identification</i>	45
<i>Theme 3: Line Set-Up and Removal</i>	55
<i>Theme 4: Dead Volume Management</i>	64
<i>Theme 5: IV Bolus Administration</i>	71
<i>Theme 6: Pump-Specific Issues</i>	75
Summary of Issues Identified From Interviews With Nursing Educators	75
<i>Baccalaureate Nursing Degrees Programs in Ontario</i>	76
<i>CCNC Programs in Ontario</i>	79
<i>Discussion</i>	83
<i>Further Investigation Required in Phase 2</i>	84
Conclusions	85
Acknowledgements	90
Appendices	91
Appendix 1: Members of the Multiple IV Infusions Expert Panel	91
Appendix 2: Field Study Interview Questions	92
Appendix 3: Field Study Shadowing Guide	97
Appendix 4: Structural Hierarchy of Concerns With the Potential to Cause Patient Harm	100
Appendix 5: Semi-Structured Interview Questions—Baccalaureate-Level Nursing Programs.....	102
Appendix 6: Semi-Structured Interview Questions—Postgraduate Critical Care Nursing Certificate Programs.....	104
Appendix 7: HFMEA Hazard Scoring Matrices and Results	106
Appendix 8: Contributing Factors for Each Issue.....	110
Appendix 9: Pump-Specific Issues Identified During Field Study	120
References	126

List of Tables

Table 1: Types of Clinical Units Included in the Field Study.....	16
Table 2: Geographic Distribution of Clinical Units Included in the Field Study	16
Table 3: Patient Safety Risks Associated With Multiple IV Infusions	32
Table 4: Hazard Score and Patient Safety Risk—Secondary Medication Is Connected to a High-Alert Primary Medication Infusion	34
Table 5: Hazard Score and Patient Safety Risk—Secondary Medication Is a Continuous Infusion of a High-Alert Medication.....	35
Table 6: Hazard Score and Patient Safety Risk—Insufficient Bag Head Height Differential Between Primary and Secondary Infusions	36
Table 7: Hazard Score and Patient Safety Risk—Secondary Tubing Is Connected to the Wrong Port Along the Primary Tubing	37
Table 8: Hazard Score and Patient Safety Risk—Secondary IV Tubing Remains Clamped After the Secondary Infusion Has Started.....	38
Table 9: Hazard Score and Patient Safety Risk—Secondary IV Tubing Is Connected to a Primary Infusion Set With No Back Check Valve.....	39
Table 10: Hazard Score and Patient Safety Risk—Infusion Pump Does Not Support the Administration of a Secondary Infusion on a Primary Line Programmed Using the Drug Library.....	40
Table 11: Hazard Score and Patient Safety Risk—Secondary Infusion Programming Error Occurs.....	41
Table 12: Hazard Score and Patient Safety Risk—Infusion Pump Settings Are Changed on the Incorrect Pump	46
Table 13: Hazard Score and Patient Safety Risks—Intermittent Medication Is Injected Into the Dead Volume of the Incorrect Infusion Line	46
Table 14: Hazard Score and Patient Safety Risk—Line Set-Up Information Related to Critical Medication Is Not Formally Communicated at Shift Handover	47
Table 15: Hazard Score and Patient Safety Risk—Residual Volume in the Connector Is Not Identifiable When a Medication Is Disconnected From a Multi-Port Connector.....	56
Table 16: Hazard Score and Patient Safety Risk—Leaks Can Occur With the Use of Three-Way Stopcocks	57
Table 17: Hazard Score and Patient Safety Risk—IV Bag and Infusion Pump Are Mismatched.....	58
Table 18: Hazard Score and Patient Safety Risk—Changes in the Flow Rate of One Infusion Affects Other Connected Infusions	64
Table 19: Hazard Score and Patient Safety Risk—Suboptimal Positioning of Infusions on a Multi-Port IV Connector May Delay the Onset of Medication Therapy	67
Table 20: Hazard Score and Patient Safety Risks—A Bolus Is Administered by Manipulating the Pump Settings on an Existing Primary Continuous Infusion.....	73
Table 21: Pumps Observed in Use During the Field Study	75
Table 22: Summary of Baccalaureate Nursing Degree Programs in Ontario	76
Table 23: Ontario Institutions Offering a Postgraduate CCNC Program.....	79
Table A1: Members of the Multiple IV Infusions Expert Panel.....	91
Table A2: HFMEA Scoring Matrices	106
Table A3: HFMEA for Multiple IV Infusion Field Study Data.....	107
Table A4: Contributing Factors—Secondary Medication Is Connected to a High-Alert ^a Primary Medication Infusion	110
Table A5: Contributing Factors—Secondary Medication Is a Continuous Infusion of a High-Alert ^a Medication	110
Table A6: Contributing Factors—Insufficient Bag Head Height Differential Between Primary and Secondary Infusions.....	110

Table A7: Contributing Factors—Secondary Tubing Is Connected to the Wrong Port Along the Primary Tubing	111
Table A8: Contributing Factors—Secondary IV Tubing Remains Clamped After the Secondary Infusion Has Started.....	111
Table A9: Contributing Factors—Secondary IV Tubing Is Connected to a Primary Infusion Set With No Back Check Valve.....	111
Table A10: Contributing Factors—Infusion Pump Does Not Support the Administration of a Secondary Infusion on a Primary Line Programmed Using the Drug Library	111
Table A11: Contributing Factors—Secondary Infusion Programming Error Occurs.....	112
Table A12: Contributing Factors—Infusion Pump Settings Are Changed on the Incorrect Pump	113
Table A13: Contributing Factors—Intermittent Medication Is Injected Into the Dead Volume of the Incorrect Infusion Line	115
Table A14: Contributing Factors—Line Set-Up Information Related to Critical Medication Is Not Formally Communicated at Shift Handover	117
Table A15: Contributing Factors—Residual Volume in the Connector Is Not Identifiable When a Medication Is Disconnected From a Multi-Port Connector.....	117
Table A16: Contributing Factors—Leaks Can Occur With the Use of Three-Way Stopcocks.....	117
Table A17: Contributing Factors—IV Bag and Infusion Pump Are Mismatched.....	118
Table A18: Contributing Factors—Changes in the Flow Rate of One Infusion Affects Other Connected Infusions.....	118
Table A19: Contributing Factors—Suboptimal Positioning of Infusions on a Multi-Port IV Connector May Delay the Onset of Medication Therapy.....	119
Table A20: Contributing Factors—A Bolus Is Administered by Manipulating the Pump Settings on an Existing Primary Continuous Infusion.....	119

List of Figures

Figure 1: Primary and Secondary Infusion Set-Ups	22
Figure 2: Concurrent Administration of IV Agents	25
Figure 3: Contributing Factors, Themes, Patient Safety Risks, and Patient Harm	32
Figure 4: Secondary Infusion Arrangement With Buretrol.....	39
Figure 5: Hospira Plum A+ Infusion Pump	43
Figure 6a: First Mechanical Syringe-Infusion Device Designed at Massachusetts General Hospital	44
Figure 6b: Mechanical Syringe Infusion Device Currently Licensed in the United States	44
Figure 7: Medication Tubing Inside a Neonatal Intensive Care Unit Isolette	49
Figure 8: Medication Tubing Connected to Several Manifolds in an Adult Intensive Care Unit.....	49
Figure 9: Schematic of IV Line Set-Up for a Patient Receiving 15 Infusions.....	49
Figure 10: Actual IV Line Set-Up for a Patient Receiving 15 Infusions	50
Figure 11: One Nurse’s Solution to Minimizing Line Tangling.....	50
Figure 12: Confusing Proximity Between IV Bags and Pump Channels	51
Figure 13: Lines Passing Through a Patient Gown.....	52
Figure 14: Lines Passing Through the Isolette.....	52
Figure 15: Recalled Stopcocks Remained Available for Clinical Use, With Attached Warning	59
Figure 16: Congruent Alignment Between IV Bags and Pump Channels	61
Figure 17: Incongruent Alignment Between IV Bag and Pump Channel.....	61
Figure 18: Circular Hook Arrangement	62
Figure 19: IV Pumps Aligned Vertically	62
Figure 20: Horizontal IV Tubing	62
Figure 21: Normal Saline and Norepinephrine Infusing Through Y-Connector	65
Figure 22: Normal Saline Stopped.....	65
Figure 23: Norepinephrine Concentrates in Dead Volume Over 20 Minutes.....	66
Figure 24: Normal Saline Restarted at 50 mL/h and Bolusing Dead Volume	66
Figure 25: Three-Port Bridges at a Patient’s Bedside.....	68
Figure 26: A Chain of Three-Way Stopcocks.....	68
Figure 27: Suboptimal Positioning of Infusion Flow Rates on a Multi-Port Connector.....	68
Figure A1: Structural Hierarchy—Detail.....	100
Figure A2: Structural Hierarchy—Full Version	101

List of Abbreviations

BScN	Bachelor of Science in Nursing
CCNC	Critical Care Nursing Certificate
CT	Computed tomography
CVP	Central venous pressure
DERS	Dose Error Reduction System
FDA	Food and Drug Administration (United States)
FT	Full-time
HFMEA	Health Care Failure Modes and Effects Analysis
HQO	Health Quality Ontario
HTSRT	Health Technology Safety Research Team
ICU	Intensive care unit
ISMP Canada	Institute for Safe Medication Practices Canada
IV	Intravenous
MAR	Medication administration record
NG	Nasogastric
OR	Operating room
PT	Part-time
VTBI	Volume to be infused

Background

The Multiple Intravenous Infusions research project is being conducted in several phases. Each phase applies different methods to build on the knowledge gained from the previous phases; results in a report; and recommends safety-related measures for implementation by Ontario hospitals (if applicable).

The Phase 1a study report, *Multiple Intravenous Infusions Phase 1a: Situation Scan Summary Report*, is available at:

http://www.ehealthinnovation.org/files/Multiple%20IV%20Infusions_Phase1a_SummaryReport.pdf

Subsequent reports for this project are planned and will be available as *Ontario Health Technology Health Assessment Series* reports on the Health Quality Ontario website:

http://www.hqontario.ca/en/mas/mas_ohtas_mn.html

Introduction

Acutely ill patients with life-threatening conditions require constant care, monitoring, and a number of life-sustaining medications. (1-3) Tight control of medication dosing and the need for immediate therapeutic effects make the controlled administration of medication directly into a patient's bloodstream an invaluable tool for patient care. The administration of medication and fluids into a patient's veins is referred to as intravenous (IV) medication administration, and about 90% of hospitalized patients receive medications via this route. (4) Infusion pumps are devices that accurately control the amount of medication patients receive and the rate at which the medication is administered; nevertheless, medication errors associated with infusion therapy are well documented. (5-7)

While large-volume IV infusion pumps present opportunities for use-error with potentially harmful consequences, they possess a number of advantages compared to gravity infusions, in which no pump is used. Infusion pumps offer increased control and accuracy of fluid flow and the ability to detect or prevent other serious errors (e.g., occlusions, air in tubing, free flow). Given the potency of high-alert¹(8) medications and their critical role in maintaining important physiological parameters, the benefits of infusion pumps outweigh the risks of their use; they should continue to be used as the safest form of IV therapy.

While there has been a growing awareness of the factors that lead to errors in programming infusion pumps, minimal research has been conducted into the errors that can result from the complexities of administering multiple IV infusions to a single patient at the same time. (9;10) Previous research has highlighted a number safety risks associated with managing multiple IV infusions. (5;9) For example, secondary (often referred to as *piggyback*) IV medication infusions are commonly used to deliver single or intermittent doses of IV medication over a safe period of time, followed by an automatic return to a separate, continuous infusion when complete. However, previous studies have indicated that there is a high risk of errors related to the set-up and administration of secondary infusions. (11) In addition, a recent study found that each additional IV medication increased the likelihood of an adverse drug event

¹The Institute for Safe Medication Practices defines high-alert medications as "drugs that bear a heightened risk of causing significant patient harm when they are used in error." For more information, visit: <http://www.ismp.org/tools/highalertmedications.pdf>

by 3%. (12) This suggests that the greatest gains in safety may be found in targeting clinical units (e.g., intensive care [ICU] environments) where high volumes of multiple IV infusions to a single patient are administered.

Research is needed to investigate the current breadth of practice and the risks associated with the administration of multiple IV infusions. There is also a need to understand the nature and comprehensiveness of the education and training of nursing staff with respect to the administration of multiple IV infusions. Finally, empirical research is needed to investigate the key issues associated with multiple IV infusion practices and the effectiveness of various interventions in mitigating those issues.

Objectives of Analysis

The overall objective of this study is to minimize the risks associated with the administration of multiple IV infusions to a single patient by identifying and validating recommendations that can be implemented to reduce the potential for errors that result in patient harm.

This study is being conducted in 3 phases, as described in Scope of Analysis, below. The current phase (Phase 1b: Practice and Training Scan) aims to achieve the following:

- to identify multiple IV infusion issues with the potential to cause patient harm, based on
 - observations at 12 clinical units across Ontario
 - interviews with nursing education program coordinators in baccalaureate nursing and postgraduate Critical Care Nursing Certificate (CCNC) programs
- to identify the factors that explain how and why these issues arise, and what increases their likelihood of occurring
- to identify how nurses are being educated on the key principles required to safely administer multiple IV infusions
- to propose recommendations based on mitigations that do not require further investigation in subsequent phases of the study
- to identify topics for further study in Phase 2 that will facilitate additional recommendations.

Scope of Analysis

In early 2010, the Ontario Health Technology Advisory Committee commissioned the Health Technology Safety Research Team (HTSRT) to identify the risks associated with the administration of multiple IV infusions, and to investigate the effectiveness of risk-mitigating strategies that could be employed to reduce IV infusion errors. To this end, HTSRT designed a 3-phase research study:

- Phase 1: Environmental Scan
 - Phase 1a: Situation Scan
 - Phase 1b: Practice and Training Scan
- Phase 2: Laboratory Study
- Phase 3: Knowledge Translation

The Phase 1a interim report was completed in September 2010 and provided the results of a systematic literature review, a multiple database incident report analysis, and a technology scan (interviews with market leaders in infusion therapy). (9) The report confirmed the lack of research in this area, demonstrated that errors resulting in patient harm do occur in the context of multiple IV infusions, and indicated that further investigation was required.

The current report is a summary of the findings of Phase 1b, which is concerned specifically with the *administration* of multiple IV infusions. It does not address the risks associated with other aspects of the

IV medication process, such as prescribing or medication preparation, nor does it attempt to create a specific pump design to address issues identified in this research.

Note: In the Phase 1b field study, nurses in the 12 clinical units were observed administering multiple IV infusions. For the sake of consistency within and among Phase 1b reports, the term nurse is used throughout, but we recognize that other health care professionals, including physicians, respiratory therapists, and dialysis technicians, may also be involved in the administration of multiple IV infusions.

Inclusions

The IV system components under consideration include the following:

- any agents intended to be administered to a patient by the IV route (e.g., hydration, blood and blood products, total parenteral nutrition, IV medications, IV chemotherapy) via IV bags or IV syringes
- large-volume IV infusion devices
 - single- and multiple-channel devices
 - devices with and without a Dose Error Reduction Systems (DERS)
- IV syringe infusion devices
 - single- and multiple-channel devices
 - devices with and without a DERS
- IV accessories (e.g., tubing, clamps, poles, connectors, splitters, single- and multiple-lumen catheters, pressure transducers)

Exclusions

Topics

The following topics and components of the infusion system were not considered in this research:

- pharmaceutical interactions and pharmacokinetics of multiple IV medication therapy (e.g., medication compatibility)
- interaction and/or absorption of IV medications by IV bags, tubing, and connectors
- misconnections between IV tubing and tubing delivering fluids or gases via other routes (e.g., IV/epidural, IV/intrathecal, and IV/nasogastric)

Several of these topics are being investigated elsewhere. (13-15) Although work done in these areas has immediate applicability to improving patient care and is complementary to the findings presented in this report, it will not be discussed further.

Components

The following medication therapy components are not covered by this study:

- insulin, elastomeric, patient-controlled analgesia, and ambulatory pumps
- magnetic resonance imaging (MRI)–compatible IV pumps
- pumps intended for non-IV routes (e.g., nasogastric, intrathecal, epidural)
- arterial lines
- gravity infusions

Clinical Areas Studied

The researchers invited 12 hospital clinical units with a high volume of patients receiving multiple IV infusions to participate in the study. The clinical units comprised 8 critical care (intensive care) units, 2 oncology (chemotherapy) units, an emergency department, and a surgical ward. The oncology units (1 inpatient and 1 outpatient) and the emergency department were included because of their potential for high volumes of multiple IV infusions, and because they encompass a different set of task requirements than critical care units (e.g., a higher number of patients being cared for per nurse, a higher number of double-checks and safe handling procedures). The cardiac postsurgical unit (general ward environment) was included to determine whether there are potential issues unique to environments in which patients are not critically ill. The distribution of unit types included in this field study is shown in Table 1. The geographic distribution of sites is shown in Table 2.

Table 1: Types of Clinical Units Included in the Field Study

Adult		Pediatric	
Unit Type	Number	Unit Type	Number
Medical/surgical ICU	3	Medical/surgical ICU	1
Cardiac ICU	1	Cardiac ICU	1
Medical/surgical/cardiac ICU	1	Neonatal ICU	1
Outpatient oncology	1	Inpatient oncology	1
Emergency department	1		
Surgical ward	1		
Subtotal	8	Subtotal	4

Abbreviation: ICU, intensive care unit.

Table 2: Geographic Distribution of Clinical Units Included in the Field Study

Region	Number
Northern Ontario	1
Eastern Ontario	1
Southwestern Ontario	3
Greater Toronto Area	7
Total	12

The only hospital setting in which patients frequently receive multiple IV infusions that was intentionally excluded from observation was the operating room (OR). This is because medication administration practices in the OR are different from those in other clinical areas. In the OR, IV infusions are administered by anesthesiologists, who are subject to different regulations, policies, and work practices than nurses (who are primarily responsible for medication administration elsewhere in the hospital). In addition, the infusion-related technology used in the OR is different from that used elsewhere in the hospital. Thus, the decision to exclude the OR environment allowed the researchers to focus on clinical areas with a greater likelihood of broad generalizability across hospital settings.

Clinical Environments Under Special Consideration

This study aims to improve the safety of multiple IV infusion administration in as broad a way as possible; however, the following 3 environments included in the scope of this study administer a particularly high rate of multiple infusions to patients and have unique environmental conditions (described below).

Critical Care Environments

Critical care environments, often called ICUs, provide specialized care for patients whose conditions are life-threatening and who require comprehensive care and constant monitoring for a variety of reasons, including premature birth, major trauma, myocardial infarction, sepsis, and postsurgical recovery (brain, heart, lungs, or major blood vessels). ICU patients generally require life-support systems, which typically involve “a panoply of technology—a mechanical ventilator and perhaps a tracheostomy tube if the lungs have failed, an aortic balloon pump if the heart has given out, a dialysis machine if the kidneys don’t work.” (3) Additionally, these patients require a variety of medications that need to be administered intravenously because their bodies are incapable of processing the medications via the gastrointestinal system (either by the oral or nasogastric tube routes), and/or, more importantly, because the action of the medication is needed immediately, along with the ability to tightly control its effect with as little delay as possible. A 2008 study by Moss et al (2) showed that, on average, ICU patients receive 13 medications per day, 7 of which are given intravenously.

In addition to the number of medications administered, the types of medications prescribed make ICU patients vulnerable to medication errors. Patients are often prescribed medications that are highly potent and require frequent titration and dose manipulation. Examples of high-alert medications frequently administered include sedatives, opioids, vasopressors, and anticoagulants. (2)

Critical care nurses are responsible for managing all aspects of care for an ICU patient, including assessing and monitoring; preparing and administering medications; managing the technology at the bedside; and general care (e.g., mouth care, wound care, turning, bathing, documenting and charting, and supporting the patient’s family). They work as part of a team that includes many different types of specialist physicians (both staff and trainees), pharmacists, respiratory therapists, radiologists, physiotherapists, nutritionists, and social workers; nurses are often the primary team coordinators. The nurse-to-patient ratio is typically 1:1 or 1:2, but can be higher during nurses’ break times.

Given the complexity of the ICU environment and the responsibilities of ICU nurses, their workload—both cognitive and physical—is extremely demanding. A 2003 study conducted by human factors engineers in Israel (16) found that over a 24-hour period, an average of 178 activities were required for a single patient, and that a single nurse carried out 84% of these tasks. The study also showed that nurses maintained a high rate of activity throughout their shifts. Further increasing the cognitive workload is the fact that the status of an ICU patient can change quickly and without warning, requiring a constant reprioritization of tasks. For example, a patient who appears stable 1 minute can be in cardiac arrest the next, obliging the nurse to leave his/her current task unfinished to attend to the most imminent need. Interruptions come in many other forms as well. Nurses frequently interrupt each other to request assistance; patients’ families interrupt with questions; other care team members interrupt with requests; overhead pages interrupt with messages such as “code blue” that may require the nurse to leave his or her patient and run to another area of the hospital; and there is a cacophony of alerts and alarms from medical equipment that provides frequent interruptions. A study of interruptions in the ICU environment at the Veterans Affairs Hospital in Salt Lake City, Utah, revealed that nearly 30% of tasks in the ICU were interrupted, and that approximately one-third of those tasks involved direct patient care. (17)

Given the complexity and demanding nature of critical care environments, errors would be expected to occur frequently, but in the Israeli study on human errors in the ICU environment, nurses and doctors were observed to make an error in just 1% of observed actions; nevertheless, that still amounted to an average of 2 errors per day for every patient. (16)

Any consideration of the findings from the current HTSRT field study must be evaluated in the context of the following key messages, based on the literature described above and the observations made:

- Critical care environments are complex work environments that place significant physical and cognitive demands on nurses.
- Due to the nature of the work environment, nurses must frequently reprioritize their tasks, meaning that they may not be able to fully complete a task as per a standard work practice or professional guideline. However, the deviation from accepted practice better serves the patient.
- Frequent interruptions increase the likelihood that tasks will be forgotten, regardless of how routine they may be or how critical they are to patient safety.

Wherever possible, emphasis should be placed on *system-based*—rather than *people-based*—solutions, given that human performance and adherence to specified work practices are inherently variable as a result of the contextual factors described above. Furthermore, where practice changes are recommended in this and subsequent phases of this research, the impact of the recommendation *not* being implemented consistently must also be considered.

Pediatric Care Environments

Some of the challenges associated with administering multiple IV infusions in adult care environments are magnified in pediatric environments, mainly because the risks associated with treating pediatric and neonatal patients with IV therapy is higher, and children and infants differ from adults in “weight, body surface area and organ system maturity, which can affect their ability to metabolize and excrete medications.” (18)

Pediatric patients’ tolerance of additional fluid volume is lower, and inaccuracies in flow rate may be more likely to cause harm. The margin of tolerance for error of even small inaccuracies is also much lower, and the possible consequences of error far worse. For these reasons, pediatric and neonatal care environments tend to use the following:

- higher concentrations of IV medications to reduce the total fluid volume absorbed by the patient
- syringe infusion pumps because of their high accuracy at low flow rates
- different IV components than are used in adult care environments (e.g., microbore IV tubing in neonatal units to reduce dead volume and IV agent waste)
- weight-based dosing to ensure that the IV medication administered is appropriate for the patient (this may require additional calculation tasks, which may be prone to error)

While these strategies are important for managing the lower tolerances of pediatric patients to excess IV fluids and medication, they may also introduce other problems. For example, the use of highly concentrated medications may increase the risks associated with infusion inaccuracy when multiple infusions are joined together to infuse into a single patient access port. In addition, the use of slow infusion (low flow) rates may cause considerable delays before the medication actually reaches the patient’s bloodstream. These issues are discussed in detail in the Exploratory Ethnographic Analysis section Theme 4: Dead Volume Management.

Outpatient Chemotherapy Clinics

Outpatient chemotherapy clinics administer IV chemotherapy medications to patients who do not need continuous hospital care. Clinics can treat a high volume of patients (>100 patients in larger clinics) every day, and each patient has a specific and potentially complex medication regimen. (19;20) Nurses are the primary care providers in this setting and are responsible for the following tasks:

- admitting and discharging patients
- determining whether or not a patient is in an acceptable condition to receive chemotherapy
- administering chemotherapy and related medications (including changing infusions)
- monitoring patients
- tending to patients when they experience symptoms that need immediate assistance (including help getting comfortable)
- educating patients and families about the treatment and its associated side effects
- contacting physicians and pharmacists as the need arises

Chemotherapy patients frequently require multiple IV infusions (both secondary and concurrent). (19) Sometimes medications must be administered in a carefully planned sequence as ordered by the treating physician.

A number of environmental factors increase the challenge of safely administering multiple IV infusions in an outpatient chemotherapy environment.

- There is a high level of patient-related activity. Nurses must work quickly to ensure that all patients are treated, while trying to minimize the wait time for each one. Also, because patients often receive their treatment in a single (large) room, the high level of nurse activity (particularly the use of infusion technology) results in high ambient noise levels. (20)
- Observational data collected in the field study and by the HTSRT in oncology safety research projects revealed that in some chemotherapy clinics, nurses are not assigned to specific patients. A group of nurses on a unit will collectively care for all patients receiving chemotherapy. This practice has the advantages of increasing nurses' flexibility and speed of response to urgent needs, but the disadvantages of increasing the difficulty of prioritizing their tasks, the number of interruptions they must attend to, and the reliance on communication between nurses.
Group practice also makes it more difficult to know which infusion tasks are required for a specific patient, and which special factors, if any, must be considered after the initial infusion has completed, particularly since the nurse hanging subsequent infusions may not be the same nurse who admitted the patient, conducted the initial assessment, or administered the initial infusion.
- Almost all medications administered in the oncology clinic are considered to be intermittent and, depending on organizational practices, can be hung as secondary infusions. This differs from an inpatient setting, where many multiple infusions are administered as continuous infusions. Several issues are associated with secondary infusion set-up tasks (see the Exploratory Ethnographic Analysis section Theme 1: Secondary Infusions), and the frequency of set-up errors may be higher than in other environments.
- When a patient requires multiple IV medications, nurses usually bring all medications to the bedside at 1 time, regardless of the infusion sequence. Nurses sometimes hang all of the medications on the IV hooks in an effort to streamline the administration process and minimize workspace clutter, but this practice may increase the risk of mix-up errors (see Theme 3: Line Set-Up and Removal).

Principles of Infusion Therapy

This section provides an overview of the principles of infusion therapy required to safely manage IV infusions and describes the high-risk tasks that nurses conduct routinely.

The principles behind infusion therapy are fundamentally related to the movement of fluids; key factors include gravity, hydrostatic pressure, and the displacement of fluids within a tightly controlled space or volume. This section discusses the fundamentals of IV fluid flow and explains their application to the concepts of dead volume, secondary infusions, and concurrent infusions.

Principles of Fluid Flow in IV Systems

IV Systems Are Fixed-Volume Systems

In the context of IV therapy, *fluids* refers to all IV agents relevant to this study (see Scope of Analysis). These agents are contained in several IV components, including, but not limited to:

- IV containers (i.e., IV bags, IV glass bottles, IV syringes)
- IV tubing
- IV connectors (e.g., 3-way stopcocks, bridges, manifolds)
- venous catheters (central and peripheral)

The use of these components together will be referred to as the *IV system*.

The IV system provides a pathway for IV agents to flow from the IV container into the patient's vein. Tubing and connectors have a fixed "priming volume" displayed on the package to indicate how much fluid is required to fill the empty space within the component. Except for small amounts of elasticity in the IV tubing, the IV system provides a fixed volume or space in which the IV agents can move.

Liquids Are Noncompressible

IV agents are liquids, and are therefore considered to be noncompressible. If an IV system is full and the tip of the catheter is blocked, it is not possible to inject additional liquid into the IV system.

Fixed Volumes Require Displacement for Fluid Movement

When the IV system is first assembled, it is filled with air. When nurses prime the system (i.e., fill the tubing with an IV agent), they are expelling the air in the tubing by displacing it with fluid. Under normal conditions, every millilitre of IV agent added to the tubing results in a millilitre of air expelled. Similarly, when an infusion is started, every millilitre of IV agent that leaves the container (e.g., a glass IV bottle) must be replaced with a millilitre of air, or the container (e.g., an IV bag or an IV syringe) must collapse/shrink as the IV agent leaves.

For example, non-vented IV tubing does not allow air into the IV system. If non-vented IV tubing were inserted into a glass IV bottle (i.e., a fixed-volume container), no fluid would leave the bottle, because it would not be possible for air to replace the fluid. Therefore, infusions performed using glass bottles require vented IV tubing that allows air to enter the bottle and replace the fluid leaving the container. Non-vented tubing can be used with IV bags, because bags can shrink as the IV agent leaves.

Fluid Movement Relies on the Manipulation of Pressure

All methods for moving IV agents in the IV system rely on the concept of pressure. In the context of IV infusions, pressure can be defined as "the force that overcomes the natural resistance to flow." (21) Fluids move from areas of higher pressure to areas of lower pressure. Therefore, manipulating the pressure in the IV system also manipulates the fluid flow.

Three common means of generating pressure in the IV system include gravity, infusion pumps, and manual injections/drawback of fluid using a syringe.

Gravity is almost always used to move fluid out of the IV container. By hanging the container higher than the desired output area (e.g., the patient or the IV pump), the weight of the IV agent under gravity will lead to progressively higher levels of pressure than lower down in the IV system. This higher pressure encourages the IV agent to exit the container and flow towards the desired output area.

Infusion pumps use a variety of strategies to generate pressure in the IV system (e.g., peristaltic compression of tubing, filling and compressing pump chambers). The pressure generated by the IV pump allows IV agents to overcome resistance to flow (e.g., vascular backpressure from the patient, filters in the IV tubing). The advantages of infusion pumps are numerous, but the key benefits include the following:

- tightly controlled flow rates
- detection of occlusions (e.g., blockages or other conditions that resist the pressure generated by the infusion pump)
- detection of air in the IV tubing

Finally, manual injections and drawback with syringes employ the principles of displacement to generate positive or negative pressure in the IV system. For example, pulling on a syringe while it is connected to the IV system reduces the pressure in the injection port to which the syringe is connected, so that fluid flows from areas of higher pressure (the IV tubing) to areas of lower pressure (the syringe being pulled).

Dead Volume Considerations

The principles of fluid flow discussed above explain the basic mechanics of how pressure is transmitted through the IV system, and how IV agents flow. However, the manipulation of multiple IV agents in the IV system is not a trivial task, and it is difficult to conceptualize and monitor.

The volume in the IV tubing between the point where multiple IV agents are connected (and share volume in the IV tubing) and the patient's vein has been referred to as *dead volume*. (22) Often, IV agents are colourless liquids that cannot be distinguished from one another, making it difficult to determine the concentration of medications mixed in the dead volume and their impact on IV agent administration. The concentration of each IV agent in the dead volume depends on both the flow rate of connected infusions and the size of the dead volume itself.

The manipulation of flow rates in IV systems that have multiple infusions connected to a single infusion line is common in clinical settings. Typical clinical scenarios include, but are not limited to, the following:

- adjusting the flow rate (i.e., titrations) on any 1 of the connected infusions
- manually injecting medications into the IV system
- bolusing any 1 of the connected infusions
- adding, pausing, or removing infusions
- responding to unexpected alarms (e.g., air-in-line, occlusion, temporary pump reprogramming) that temporarily delay an infusion

Suboptimal arrangements of IV tubing and connectors can result in larger-than-necessary dead volumes, increasing the amount of medication temporarily stored in the IV system before it is administered to the patient. If the flow rate of 1 connected infusion is decreased or increased, the concentration of other connected medications in the dead volume will increase or decrease, respectively. This may result in

temporary delays of medication, or unexpected boluses of dead volume contents. As the number of infusions connected to the same IV line increases, so does the risk that changes to 1 infusion will affect the administration of the others, making it increasingly difficult to predict the behaviour of each.

Disturbances in the concentration and flow rate of connected medications in the dead volume are mainly a concern when the infusion system changes in some way. Once the infusions have established a steady state of administration through the dead volume, delays or boluses of medication are unlikely.

In caring for patients who are highly fluid-restricted, or for whom small volumes must be accounted for exactly (e.g., renal or pediatric patients), the total volume that remains in the IV system once the IV container has emptied must be accounted for (i.e., the sum of the priming volume of all components in addition to the dead volume). It is common for nurses in pediatric environments to “flush” the priming volume and dead volume with another IV agent (usually a compatible maintenance fluid) to ensure that the residual agent in the priming volume is administered to the patient.

Secondary Infusions

Defining a Secondary Infusion

Figure 1 depicts 2 IV infusion set-ups. In the set-up on the left, the contents of IV bag A will be administered to the patient at a controlled rate through a large-volume infusion pump. This arrangement of components is referred to as a *primary infusion*.

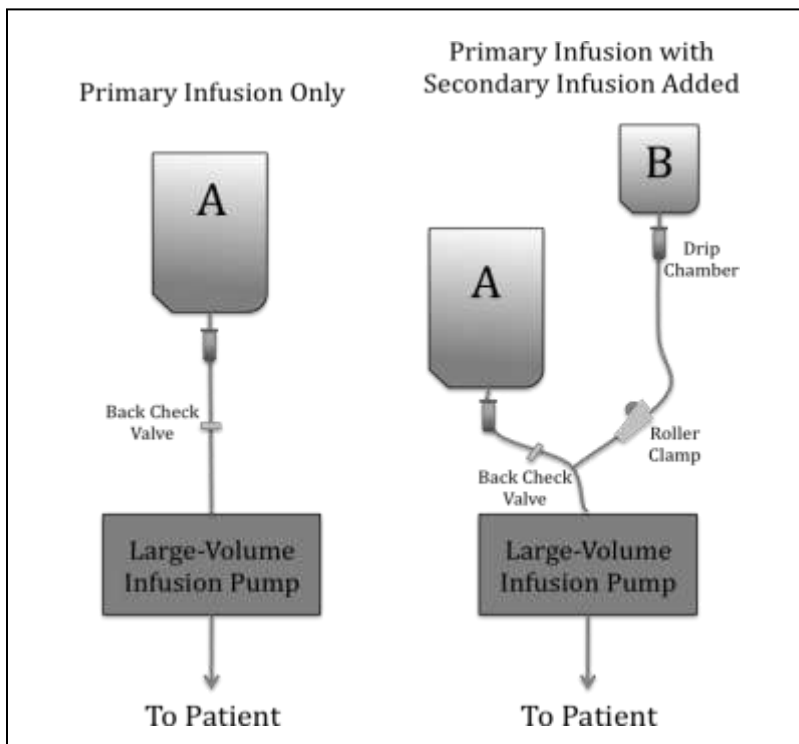


Figure 1: Primary and Secondary Infusion Set-Ups

The IV set-up on the right shows the addition of a *secondary infusion*. A new IV bag (B) is hung higher than bag A and is connected to the primary infusion via a luer-fitted port above the infusion pump with a short piece of IV tubing (i.e., secondary infusion “set” or tubing).

With this arrangement, the contents of bag B are administered first (provided the roller clamp on the secondary IV tubing is open), followed by the contents of bag A, because the effect of gravity will activate the back check valve on the primary infusion tubing, ensuring that only bag B flows and preventing retrograde flow from bag B to bag A.

When no fluid is left in bag B, the lack of pressure will cause the back check valve to open, and gravity will then pull fluid from bag A. As long as the pump continues to run, the primary infusion will be administered automatically. The programming sequence of the pump allows the secondary and primary infusions to be administered at different rates.

Secondary Infusions vs. Piggyback Infusions

Unlike a continuous infusion, which administers a steady amount of IV agent until it is discontinued, an intermittent infusion administers an IV agent as a single dose, usually fairly quickly (between 10 and 60 minutes, but possibly longer for some agents, such as chemotherapy). Intermittent infusions are often used to administer electrolytes and antibiotics, and may be given either only once or repeated at a prescribed frequency. Patients may require several intermittent infusions of different medications. Nurses frequently administer these as sequential, secondary infusions on the same primary infusion, provided that the relevant IV tubing has been flushed to prevent medication incompatibilities. Secondary infusions are well suited to the administration of intermittent infusions, because they use an existing IV access port; if the patient requires hydration, the original maintenance fluid (i.e., the primary infusion) can automatically continue following the intermittent infusion without further intervention from the nurse.

In both the literature and in clinical practice, the terms *secondary* and *piggyback* are used inconsistently and interchangeably. (11;23) Informal online sources such as nurse discussion groups highlight the variety of definitions used and the resulting confusion created. (24;25) When the term *secondary infusion* appears, it typically refers to the set-up shown in Figure 1 and, anecdotally, matches the understanding of many nurses. (11;23) However, the term *piggyback* shows more variation in usage:

- administering intermittent medication(s) as a secondary infusion on a primary one (as shown in Figure 1)
- switching between 2 continuous infusions of the same medication (i.e., to replace an empty IV container with a full one) with minimal disruption (25)
- administering intermittent medications using other methods that do not involve an ongoing primary infusion (e.g., using a saline-locked IV catheter) (25)

Whereas the various methods of administering intermittent infusions may achieve the same therapeutic effect if done correctly, the risks of error with each method are likely to be different.

This report considers both secondary and piggyback infusions to be the administration of a second medication in the style demonstrated in Figure 1, but for consistency, this report will use the term *secondary infusion*.

Key Considerations for Secondary Infusion Set-Up

The administration of secondary infusions requires careful attention to the set-up of the IV system. Three key considerations should be addressed when setting up secondary infusions. A cursory description of each is provided in the following sections, but more detail is provided in the Exploratory Ethnographic Analysis section Theme 1: Secondary Infusions.

Back Check Valve and Back Flow

Failure to achieve a sufficient head height differential between IV bags will prevent the back check valve from activating. This leads to an unpredictable combination of both fluids being drawn through the IV tubing and the potential for the contents of the secondary infusion bag to back flow into the primary

infusion tubing and IV bag. Most infusion pumps in Ontario have no means of protecting against this possibility, no ability to detect that this is occurring, and no way of alerting nurses. Depending on the IV agents being infused, this may harm the patient.

Back flow may also be problematic if an incompatible IV agent is administered as a secondary infusion at a later time on the same primary IV tubing. This can cause a precipitate to form in the IV tubing, or lead to a detrimental interaction of medications. Therefore, a back check valve is essential for ensuring that the secondary fluid is administered as programmed, and does not mix with the primary fluid.

Even in the presence of a back check valve and a sufficient head height differential between bag A and bag B, the flow rate of the infusion pump may be high enough to overcome the protection of the back check valve, causing fluid from bag A to be simultaneously infused at an indeterminate rate. However, if a nurse detects this problem (by observing that the primary infusion drip chamber is active), he or she can mitigate it by increasing the head height differential between the primary and secondary IV bags. Alternatively, the nurse can clamp the primary IV tubing while the secondary infusion is running.

Secondary IV Tubing Clamp

The secondary IV tubing is usually clamped after the nurse has primed it to avoid spilling its contents. Once the secondary IV tubing has been connected to the primary IV tubing and the pump has been appropriately programmed, the secondary IV tubing clamp must be reopened. Failure to open the clamp will result in the administration of bag A at the rate programmed for bag B (assuming all other aspects of the set-up have been done correctly). Most pumps licensed for use in Ontario have no means of detecting this error.

Connection of Primary and Secondary IV Containers Must Occur Above the Pump

It is critical that the secondary IV tubing be connected to the primary IV tubing above the pump so that the pump can control the flow rate of both IV agents. Previous research has found that a number of incorrect configurations are possible. (11) Connections below the pump were observed in previous simulation research. (5)

Concurrent Infusions

The concurrent infusion of multiple IV agents through a single IV port is often required to treat acutely ill patients. Concurrent infusions are the administration of 2 or more infusions simultaneously through the same IV line, each at its own flow rate. Each infusion must be individually controlled so that it has its own flow rate; therefore, each infusion must have its own infusion pump or pump channel (Figure 2 illustrates a simple example of 2 concurrent infusions). It may also be possible for 1 or more of the concurrent infusions to have its own secondary infusion set-up. Concurrent infusions may be advantageous because they minimize the need for additional access sites by joining multiple infusions into 1 port; this may reduce the work demands associated with inserting new IV access devices. The reduction of nonessential lumens or ports for central access sites is also associated with reduced infection risk. (26)

Unlike secondary infusions, which are connected upstream of a single pump/pump channel that infuses each bag sequentially, concurrent infusions connect together downstream of their respective pumps/pump channels. Both concurrent infusions actively infuse through the IV line at the same time (Figure 2).

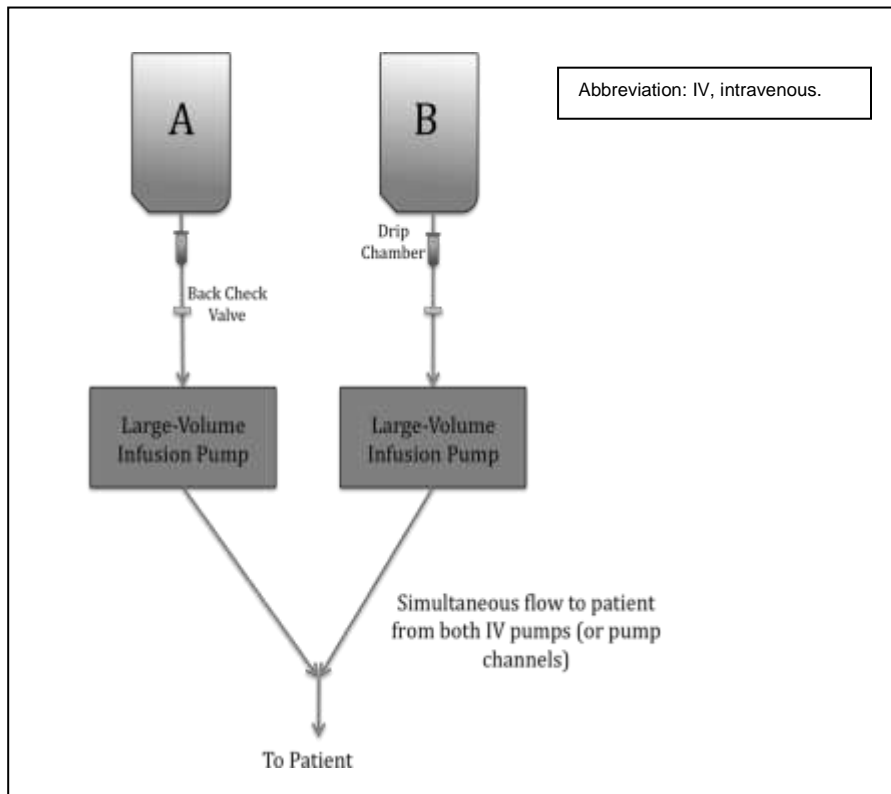


Figure 2: Concurrent Administration of IV Agents

IV Bolus Administration

IV boluses are commonly used to administer IV medications or fluids in order to rapidly produce a desired physiological effect. Depending on the concentration and volume of medication or fluid to be bolused, the duration of administration may range from less than a minute to an hour or more, and may include 1 or more doses. An IV bolus can be a rapid, short additional dose of a continuous medication already being administered to the patient, or a new medication not previously administered.

A variety of methods can be used to administer boluses quickly; these range from temporary increases in pump flow rate to manual injections with an IV syringe (the latter is sometimes called *IV direct*, *direct injection*, or *manual IV push*).

The term *bolus* on its own may be ambiguous without knowing the medication and the dose to be administered; its use may also differ between different clinical units in terms of infusion duration and the method of administration (e.g., manual vs. pump-controlled methods). Terminology such as *administer IV now* or *slow loading dose* may or may not refer to boluses. Therefore, the characteristics of boluses are variable in clinical practice and depend strongly on context. The lack of consistent use of this terminology is a potential source of confusion among nurses, particularly for those who work in differing clinical environments and organizations.

High-Risk Tasks Associated With Managing Multiple IV Infusions

Previous sections have described the considerable cognitive demands and time pressures present in environments where many patients receive multiple IV infusions. During the course of a nurse's shift, some IV infusion tasks may be particularly prone to error, and thus may be high risk, for the following reasons:

- The task places additional cognitive demands on the nurse.
- The task is not well standardized.
- The task has many associated failure modes.
- The failures are not easily detected.

This section presents an overview of several high-risk tasks associated with administering multiple IV infusions. Detailed descriptions of the issues related to each task are included in the Exploratory Ethnographic Analysis.

Secondary Infusions

The administration of secondary infusions requires that both infusion pump programming and physical IV tubing set-up be done properly in order for the infusions to be administered safely. These processes may not be intuitive and may be prone to error. The specific issues leading to harm are discussed in Principles of Infusion Therapy, above, and in the Exploratory Ethnographic Analysis section Theme 1: Secondary Infusions.

IV Bolus Administration

As noted above, a bolus is the administration of an IV fluid/medication, usually at a flow rate higher than that of a continuous infusion of the same fluid/medication, in order to rapidly achieve a specific physiological effect. Errors in the administration of rapid infusions may be more likely to cause harm than errors in the administration of slower infusions. The administration of IV boluses is a high-risk task for the following reasons:

- There are various methods with which it can be accomplished.
- Varying degrees of safety are associated with each administration method.
- Administration errors are difficult to intercept. (27)

The specific issues around IV bolus administration are discussed in greater detail in the Exploratory Ethnographic Analysis section Theme 5: IV Bolus Administration.

IV Line Tracing

Line tracing is a critical task for managing multiple IV infusions. To make appropriate decisions regarding where to connect, disconnect, and change the flow rate of each infusion, the contents, pump origin, and patient access destination of all infusions must be well understood. This information must then be reconciled with additional information, such as the following:

- medication compatibility with other infusions
- flow rates
- the volume to be infused
- the ideal types of access for specific infusions (i.e., central venous vs. peripheral catheters)

Errors made during line tracing may negatively impact all IV infusions—not only the incorrectly traced line. As multiple infusions often share a single IV line, the error may compound rapidly and affect a large proportion of the patient’s IV therapy. For these reasons, IV line tracing is considered to be a high-risk task. It is discussed in more detail in the Exploratory Ethnographic Analysis section Theme 2: Line Identification.

IV Tubing Changes

To reduce the risk of infection, nurses replace IV tubing, IV medication and fluid containers, and IV connectors as frequently as required by hospital policy. Each time this task is done for a patient who is receiving multiple IV infusions, the nurse must once again set up the multiple infusions at 1 time. The risks associated with this task are further discussed in the Exploratory Ethnographic Analysis section Theme 3: Line Set-Up and Removal.

Shift Handovers and Patient Transfers Between Care Areas

The transfer of accountability for patient care between nurses (i.e., shift handover), or between care areas (e.g., OR to ICU) creates opportunities for error if information is not effectively communicated. (28) Patients requiring multiple infusions often have complex conditions, making it difficult for the transfer of all relevant information to occur, even with standardized protocols. Communication between care providers in transfer situations may be interrupted, or there may be a limited window of time for the information exchange to occur. Differences in experience between care providers and in the use of terminology can also impede the accuracy of information transfer. The lack of explicit and effective sharing of information at shift handovers or at patient transfers raises serious concerns about how well incoming nurses are prepared to act in the face of sudden complications in the patient’s condition, particularly before they have completed their independent initial assessment. Multiple IV infusion issues associated with inadequate shift handovers are further discussed in the Exploratory Ethnographic Analysis section Theme 2: Line Identification.

Exploratory Ethnographic Analysis

Research Questions

1. What practices are employed at hospitals across Ontario with respect to administering and managing multiple IV infusions?
 - What risks exist with current practices?
 - What mitigating strategies should be employed to reduce these risks?
 - How effective are the proposed mitigating strategies?
2. What infusion therapy concepts are nurses taught in baccalaureate and postgraduate nursing training programs to assist them in safely administering and managing multiple IV infusions? What concepts need to be added to existing curricula?

Research Methods

Field Study

A field study was conducted at 12 hospital units across Ontario from December 2010 to September 2011. Units were selected with input from the Multiple IV Infusions Expert Panel (Appendix 1) to include a range of adult and pediatric units, as well as critical care and noncritical care units, from across the province. Consideration was also given to the type of pump used at each facility to ensure that a range of infusion devices were observed.

A team of 2 to 3 human factors researchers from the University Health Network's HTSRT in Toronto observed each site. In addition, a nurse collaborator from the Institute for Safe Medical Practices (ISMP) Canada participated in 3 sites of the field study to further support the human factors researchers in understanding the clinical context. The field study was conducted in 2 parts:

- conducting interviews with as many as possible of the following: unit nursing administrators, nurse educators, unit pharmacists, infusion specialists, hospital risk managers, and prescribing physicians
- shadowing nurses while they cared for patients receiving multiple IV infusions

Informed consent was collected from all participants prior to beginning either part of the research activity.

Interviews

Interviews with unit nursing administrators (e.g., nurse managers), nurse educators, unit pharmacists, infusion specialists, hospital risk managers, and prescribing physicians were conducted in a group setting on the first morning at the first 5 sites of the field study. The interviews lasted approximately 2 to 3 hours, and participants left as necessary to fulfill clinical duties. Interviews were conducted as semi-structured discussions, aimed at understanding the medication administration process and associated policies and procedures within the unit being studied.

A high-level analysis of the data gathered during the first 5 sites of the field study was used to develop a detailed set of 91 field study interview questions (Appendix 2), grouped by issue category. The resulting questionnaire was administered in a group setting at the remaining 7 field sites.

Observations

The subsequent 2½ days at each site were spent shadowing registered nurses who cared for patients receiving multiple IV infusions. A shadowing guide (Appendix 3) was developed as a minimum list of items to observe or learn about during shadowing; however, the process of observation was very much enhanced by the opportunities that emerged given patients' status, scheduled and unscheduled activities, and the willingness of participants to show or describe certain aspects of their work. Handwritten notes were taken and later transcribed into electronic documents. Photographs were taken as part of the data collection, along with physical artifacts from the clinical environment, such as tubing, connectors, and paper forms. A list of multiple IV infusion–related concerns was generated for each site and tracked on a master spreadsheet.

Analysis

After the field study was completed, a preliminary analysis of concerns was conducted to identify themes. The following 6 key themes were identified:

- secondary infusions
- line identification
- line set-up and removal
- dead volume management
- IV bolus administration
- pump-specific issues

These 6 key themes were explicitly explored for the remainder of the data collection. Once all of the data had been collected, the finalized list of concerns and contributing factors was analyzed. No new key themes emerged during this analysis. Each concern was compared with those described in Phase 1a of this research, to determine if any Phase 1a concerns had not been observed in Phase 1b (and thus were not investigated as contributing factors). However, the only concerns identified in Phase 1a that were not described in Phase 1b were those deemed to be outside the scope of the current research (e.g., IV bag mix-ups during medication preparation).

Data elements (comprising multiple IV infusion–related concerns and their contributing or enabling factors) were modelled using a cause-consequence structural hierarchy, a tool developed as part of Rasmussen's 1997 Proactive Risk Management Framework. (29) Data elements were represented in boxes and graphically linked with arrows according to the cause-consequence relationships among them, such that every pathway eventually led to an action with the potential to cause patient harm. Over 100 data elements were represented in the model (Appendix 4).

What is particularly useful and unique about this model is that it is intended to show the cause-consequence relationships between factors that may ultimately lead to harm at all levels of the system. Whereas observational field work tends to focus only on the actions and decisions of front-line staff, this model also considers factors at the organizational, regulatory, and government levels. It does this by placing each issue and contributing factor on the structural hierarchy at the level associated with the most responsible individuals and organizations, thereby making the locus of control for each issue more explicit. This approach may prove useful in Phase 2 of this research, during which researchers will develop and test mitigating strategies.

Nursing Education Interviews

Interviews were conducted with program coordinators or instructors from both the Ontario baccalaureate nursing degree programs and the Ontario postgraduate CCNC programs. Participants were invited by email to take part in the interviews; if interested, they were required to confirm that their institution was

currently offering a baccalaureate nursing degree or CCNC program and that they would be available for approximately 1 hour by telephone for the interview.

Baccalaureate Nursing Degree Program Interviews

Eight telephone interviews with baccalaureate program coordinators or instructors were conducted between June and November 2010. Interviews were semi-structured (Appendix 5) and lasted approximately 45 minutes. A human factors researcher and an internship student from the HTSRT conducted the interviews.

Postgraduate CCNC Program Interviews

Five telephone interviews with CCNC program coordinators or instructors were conducted between April and October 2011. Interviews were semi-structured, but included a detailed set of questions about the specific infusion therapy concepts related to issues observed during the preliminary field site visits (Appendix 6). The interviews lasted approximately 60 minutes and were conducted by 2 human factors researchers from the HTSRT.

Application of the Precautionary Principle

The precautionary principle dictates that even if the cause and effect data are not fully established scientifically, precautionary measures should be taken. (30;31) The recommendations in this report are derived from direct observational and interview data. While these methods of field study yield a rich source of data, there are limitations to applying these methods—mainly that the prevalence of a particular issue cannot be established. The rationales for the recommendations in this report were based on the potential for particular types of errors (i.e., the existence of failure modes) rather than the direct observation of errors, for 2 reasons:

- The frequency of errors for each individual failure mode is not high enough for all to be detected in the time allotted.
- The failure modes are not identified a priori to allow for routine inspection.

Nonetheless, some errors were directly observed during the study.

The failure modes identified in this report have the potential to occur during tasks related to administering multiple IV infusions; these tasks are routine elements of patient care across Ontario. Although not all errors necessarily lead to patient harm, in some cases a patient may incur serious harm, and even death. The findings of this field study are consistent with those of other studies that highlight the severity of infusion errors. (7;32)

Furthermore, research highlighting the prevalence of infusion errors (33-35) correlates with the United States Food and Drug Administration (FDA) statistics (36) that between 2005 and 2009, more than 56,000 infusion pump incidents were reported, including 710 deaths. While the failure modes associated with these incidents and those described in the literature may not include all the failure modes identified in the current field study, the precautionary principle dictates that even if the cause and effect data are not fully established scientifically, precautionary measures should be taken.

The analysis and recommendations in this report encourage a cautious and measured approach to improving safety in IV care. While modifications to infusion systems and related work practices are suggested to improve the safety of infusions administered via a large-volume infusion pump, substitution of gravity infusions for pump-controlled, large-volume infusions is not recommended, given the many advantages provided by large-volume infusion pumps. All findings and recommendations should be implemented, with careful appraisal of the risks and benefits of doing so for each specific context.

Summary of Issues Identified During the Field Study

The error pathways on the structural hierarchy were analyzed to identify the failure modes most directly related to patient harm, and these were identified as primary issues. A total of 22 primary issues were identified that covered the key themes. An adapted version of the Healthcare Failure Modes and Effects Analysis (HFMEA) was conducted on the primary issues to determine their relative priority. (37) HFMEA is a proactive risk management tool that ranks failure modes based on the severity of the issue, the likelihood the issue will occur, and the detectability of the issue once it has occurred but before it results in harm. The human factors researchers and the ISMP Canada nurse collaborator collectively developed the HFMEA scoring matrix and applied it to each of the primary issues to determine the hazard scores. Each of the 3 dimensions of the hazard score (i.e., likelihood, detectability, and severity) was assigned a discrete value between 1 and 4. The product of these 3 values was the hazard score.

The HFMEA scoring matrix and the results table are shown in Appendix 7. Hazard scores ranged from 8 to 64. Issues with hazard scores greater than 24 were identified as the most critical and are discussed in this report. Those with hazard scores of 24 or lower did not appear to pose an immediate and significant risk to Ontario hospitals and are not discussed in the main text of this report.

This section of the report is divided into 6 themes, based on the critical issues identified from the field study observation data:

- secondary infusions
- line identification
- line set-up and removal
- dead volume management
- IV bolus administration
- pump-specific issues

For each theme, information is generally presented using the following structure:

1. Background
2. Results
 - a. Issues (including patient safety risks)
 - b. Contributing Factors
3. Discussion
4. Recommendations
5. Further Investigation Required in Phase 2

The relationship between contributing factors, issues, patient safety risks, and patient harm is illustrated in Figure 3. The Definitions section further describes the content of Figure 3.



Figure 3: Contributing Factors, Themes, Patient Safety Risks, and Patient Harm

Definitions

Patient Safety Risks

Patient safety risks are the consequences of an issue that may lead to patient harm. Table 3 lists and describes each patient safety risk identified during the field study.

Table 3: Patient Safety Risks Associated With Multiple IV Infusions

Patient Safety Risks
A: IV medication/fluid running at the incorrect rate <i>A medication controlled by an infusion pump is not being pushed into the patient at the desired rate.</i>
B: Incompatible medications running together <i>Medications known to be incompatible are mistakenly connected into a single line.</i>
C: Vesicant medications administered via a peripheral IV line <i>A medication that is intended to be administered to a patient through a central line (a vesicant) is infused via a peripheral line.</i>
D: Required medications not being administered to the patient <i>A medication is connected to the infusion system but is not being pushed into the patient.</i>
E: Delay/interruption in administering critical medication to the patient <i>A medication takes longer to reach the patient than intended, or is interrupted after the infusion has started.</i>
F: Bolus of incorrect fluid/medication administered <i>A rapid, single infusion not ordered or intended to be administered is mistakenly administered.</i>
G: Administration of a discontinued medication/fluid <i>A medication has been discontinued by a prescriber but continues to be administered to the patient.</i>

Abbreviation: IV, intravenous.

Themes

Themes are groupings of similar issues as they relate to specific aspects of multiple IV infusion administration. In this report, an *issue* is defined as an action or omission that can lead directly to patient harm. The field study data revealed a total of 22 primary issues related to the management of multiple IV infusions. Seventeen of these issues (i.e., critical issues) had a HFMEA hazard score greater than 24 and will be described in the Issues portion of each theme section. All issues, regardless of their hazard score, are presented in Appendix 7.

Contributing Factors

Contributing factors are actions or omissions that may lead to an issue. These can include environmental conditions or decisions made at an earlier point relative to the occurrence of an issue (e.g., training, workflow, equipment purchasing decisions). Contributing factors have been divided into 3 categories:

- first-level contributing factors: those most directly responsible for the issues
- second-level contributing factors: those most directly responsible for first-level contributing factors
- third-level contributing factors: those most directly responsible for second-level contributing factors

A description of the most relevant contributing factors is provided in the Discussion portion of each theme section. Tables that summarize the first-, second-, and third-level contributing factors for each issue can be found in Appendix 8.

Theme 1: Secondary Infusions

Background

Secondary infusion is a convenient method of administering an intermittent infusion or a 1-time IV medication dose, because it enables a primary continuous infusion (e.g., a maintenance fluid) to automatically resume and/or flush the secondary medication in the primary tubing after the secondary infusion completes. The automatic transition from the secondary infusion to the primary infusion reduces the nurse's workload, which is especially helpful if the nurse is caring for multiple patients.

Secondary infusions are prone to use errors, however, because even though the infusion rate is automatically controlled by the infusion technology, the initiation of the secondary infusion, and the order in which it flows relative to the primary infusion, remains completely dependent on the natural laws of fluid dynamics, and this must be manually managed by nurses. (10;38) The following factors all increase the likelihood of human error related to secondary infusions:

- a complex work environment
- a high cognitive load
- a high frequency of interruptions
- a lack of standardized training and education about the principles relating to secondary infusions

Results

Eight issues associated with the administration of secondary infusions were identified from the field study data. A wide range of contributing factors are responsible for these issues, including the following:

- high-alert medications associated with secondary infusions
- poor technology design
- inadequate technology selection and implementation
- nurse training and education

Issues

During the field study, the following 8 secondary infusion issues were identified with the potential to lead directly to patient harm:

- The secondary medication is connected to a high-alert primary medication infusion.
- The secondary medication is a continuous infusion of a high-alert medication.
- There is insufficient bag head height differential between primary and secondary infusions.
- The secondary tubing is connected to the wrong port along the primary tubing.
- The secondary IV tubing remains clamped after the secondary infusion has started.
- The secondary IV tubing is connected to a primary infusion set with no back check valve.
- The infusion pump does not support the administration of a secondary infusion on a primary line programmed using the drug library.
- A secondary infusion programming error occurs.

Secondary Medication Is Connected to a High-Alert Primary Medication Infusion

The impact of this issue is described in Table 4.

Table 4: Hazard Score and Patient Safety Risk—Secondary Medication Is Connected to a High-Alert Primary Medication Infusion

HFMEA Hazard Score	Patient Safety Risk
48	F: Bolus of incorrect fluid/medication administered

Abbreviation: HFMEA, Healthcare Failure Modes and Effects Analysis.

A high-alert IV medication could harm a patient if it were inadvertently discontinued or administered as a bolus. There is no standardized list of high-alert medications; however, ISMP Canada has defined a list of high-alert medications, which are “drugs that bear a heightened risk of causing significant patient harm when they are used in error.” (8)

If a secondary medication is connected to a high-alert primary medication infusion, the primary medication in the dead volume of the tubing (i.e., the dead volume in the primary tubing downstream of the secondary port) 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 medication could cause patient harm.

No instances of a secondary medication connected to a high-alert primary medication were observed during the field study; however, an incident of this nature has been reported to ISMP Canada. (38)

This issue has the potential to affect all hospitals in Ontario.

Secondary Medication Is a Continuous Infusion of a High-Alert Medication

The impact of this issue is described in Table 5.

Table 5: Hazard Score and Patient Safety Risk—Secondary Medication Is a Continuous Infusion of a High-Alert Medication

HFMEA Hazard Score	Patient Safety Risk
48	A: IV medication/fluid running at the incorrect rate E: Delay/interruption in administering critical medication to the patient

Abbreviation: HFMEA, Healthcare Failure Modes and Effects Analysis; IV, intravenous.

The secondary infusion mode on an IV infusion pump administers a fixed volume of an IV agent at the programmed secondary rate before it automatically switches to infusing continuously at the programmed primary rate. For this reason, the secondary feature is intended to administer either single-dose or repeated-dose (i.e., intermittent) infusions. If a continuous medication were to be administered using the secondary mode, 2 consequences with the potential to cause patient harm could occur.

The first consequence associated with administering a continuous medication using the secondary feature relates to programming errors. If a programming error is made on the secondary infusion (particularly if the volume is not entered correctly), the infusion may run at the incorrect rate because the pump will switch to the primary rate either too soon or too late (see Case Study 1).

Case Study 1: Continuous Secondary Infusion Error

An experienced nurse worked on a general ward that rarely ran secondary infusions. She was not trained specifically on this feature of the infusion pump, but was able to figure out how to use it. Her patient was receiving D5W mixed with half-normal saline via an infusion pump at 40 mL/h. She had orders to administer morphine prepared in a 100 mL bag. She administered it as a secondary infusion on the D5W–half-saline primary line at a rate of 2 mL/h. The nurse was caring for several other patients and wanted to receive an alert after 5 hours to check on the morphine infusion before the end of her shift, so she (deliberately) set the volume to be infused (VTBI) to 10 mL instead of the 100 mL bag volume, expecting the pump to stop and sound a volume-complete alarm, as it does in the primary mode. However, the secondary mode is not designed this way on all pumps. After 5 hours, the pump automatically switched from the secondary to the primary mode, resulting in the remaining 90 mL of morphine in the secondary bag being infused at 40 mL/h. The nurse went home at the end of her shift not having noticed the error, and several hours later the patient was found dead in bed.

While there were no observations during the field study of continuous medications programmed as secondary infusions, there is empirical evidence of this practice (as in Case Study 1). It is foreseeable that less experienced nurses who manage multiple IV infusions outside of critical care environments (where fewer infusion pumps are available) may be more prone to making this error.

The second consequence is that once the secondary volume has infused, the pump will automatically interrupt the continuous secondary infusion with the primary continuous infusion. Even if a call-back alarm is set to alert the nurse that the pump is switching over, if the nurse is not in the immediate vicinity of the pump at the time the alarm sounds, he or she will not be aware that the secondary IV bag is empty. If the continuous secondary infusion is a high-alert medication, patient harm could result from the infusion interruption (i.e., the therapy would be delayed until the secondary infusion medication has been replaced).

Insufficient Bag Head Height Differential Between Primary and Secondary Infusions

The impact of this issue is described in Table 6.

Table 6: Hazard Score and Patient Safety Risk—Insufficient Bag Head Height Differential Between Primary and Secondary Infusions

HFMEA Hazard Score	Patient Safety Risk
48	E: Delay/interruption in administering critical medication to the patient F: Bolus of incorrect fluid/medication administered

Abbreviation: HFMEA, Healthcare Failure Modes and Effects Analysis.

When running a secondary infusion, the secondary IV bag must be hung higher than the primary IV bag to ensure that the secondary bag has greater fluid pressure (due to gravity) than the primary IV bag. After the infusion pump has been started, IV fluids will flow from the secondary IV bag first. Once the secondary IV bag has been emptied, IV fluid will automatically begin to flow from the primary IV bag. The automatic switch from the secondary to the primary fluid is strictly the result of changes to hydrostatic pressure (see Principles of Infusion Therapy). At no point can the infusion pump sense which bag it is pulling from.

In cases in which an insufficient bag head height differential exists between the primary and secondary IV bags, the hydrostatic pressure of the secondary IV bag may not be great enough to prevent the flow of the primary IV infusion, and fluid will flow from both IV bags at unpredictable rates. Even if the infusion pump has been correctly programmed for a secondary infusion, this issue can have 2 unintended consequences.

The first consequence is that a mixture of primary and secondary fluids/medications will infuse, each at an indeterminate flow rate.

The second consequence is that once the pump has infused the programmed secondary volume, it will revert to the primary rate but continue to infuse both the primary and remaining secondary infusions at the primary rate. Because primary infusions tend to run at slower rates, the remainder of the secondary infusion will be infused more slowly than ordered unless the nurse resets the secondary infusion. Even if he or she does reset the secondary infusion, additional primary fluid would then be administered together with the secondary infusion at the higher secondary rate. It is difficult to determine the remaining volume in the IV bag by visual inspection in order to reset the secondary volume.

Depending on the medication and other variables, these errors could cause patient harm. For example, a critical medication such as an electrolyte may only be partially infused over the intended time period, leaving the patient vulnerable to side effects. Furthermore, this error can lead to the unintended consequence of having to administer additional fluids at the higher, secondary rate (i.e., the nurse would need to reprogram and restart the secondary infusion pump); this could potentially harm some patients who may not be able to tolerate the additional fluid volume.

The risks associated with incorrect flow rates are exacerbated if either the primary or secondary medication is a high-alert medication. Given the complexity of the work environment and the overall cognitive and physical demands on nurses, bag head height differential errors may go undetected, because no pump alarms will be triggered. Incidents related to insufficient bag head height differential between primary and secondary IV bags have been reported to ISMP Canada. (9)

During field study observations, no instances of insufficient bag head height differentials between a primary and secondary IV bag were observed. However, 1 nurse commented that the secondary hangers that come with the secondary IV tubing sets are not long enough to facilitate proper primary-secondary flow when larger-volume secondary IV bags are used. As a result, when hanging larger IV bags, nurses must remember to use 2 secondary hangers joined together to create enough head height differential between the primary and secondary IV bags. When nurses were asked about the required distance between a primary and secondary IV bag, none of them was aware of a specific quantitative measurement, but said that the head height differential created by the secondary hanger provided with their tubing was enough. One nurse in an outpatient oncology setting acknowledged that the head height differential created by a secondary hanger is sometimes not enough to prevent the primary fluid from infusing before the secondary infusion completes, in part because of the fast flow rates required to administer some chemotherapy agents. The nurse said that when she notices that the primary infusion is flowing before the secondary is complete, she further lowers the primary IV bag to create an even greater head height differential.

This issue affects all Ontario hospitals except pediatric environments that exclusively use buretrols or syringe pumps (syringe tubing has no port into which to attach secondary infusions).

Secondary Tubing Is Connected to the Wrong Port Along the Primary Tubing

The impact of this issue is described in Table 7.

Table 7: Hazard Score and Patient Safety Risk—Secondary Tubing Is Connected to the Wrong Port Along the Primary Tubing

HFMEA Hazard Score	Patient Safety Risk
32	E: Delay/interruption in administering critical medication to the patient F: Bolus of incorrect fluid/medication administered

Abbreviation: HFMEA, Healthcare Failure Modes and Effects Analysis.

In order for a secondary infusion to be controlled by the infusion pump, it must be connected to a port along the primary IV tubing that is upstream of the infusion pump. If the secondary IV tubing is connected to a port that is downstream of the pump, the pump cannot control the secondary infusion and the infusion will be controlled only by gravity. At the extremes, the secondary infusion will either free-flow into the patient very quickly or will not infuse at all, whereas the primary infusion will infuse at the secondary infusion rate (because the force of gravity acting on the secondary infusion cannot overcome the line pressure created by a fast-flowing primary infusion).

This issue was observed during a simulation study on smart infusion pumps, and was also observed in 1 site of the field study. (5) The incident observed during the field study was detected quickly and did not result in patient harm. Because the primary infusion was running quickly (at the secondary rate), the secondary infusion (an antiemetic medication) was not able to overcome the line pressure and did not infuse. Before the nurse left the patient’s bedside, she noticed that the drip chamber on the secondary infusion was not filling from the IV bag, and she quickly corrected the problem. If this issue is not detected quickly and a high-alert medication is on the primary line, patient harm could result.

Patient harm could also result if the secondary medication is inadvertently connected to a downstream port and the patient’s IV catheter becomes blocked; the primary medication could back up into the secondary IV tubing and no overpressure alarm would sound until the back pressure from the secondary IV tubing was sufficient to trigger it. This could deprive the patient of any medication therapy and also result in an indeterminate mix of medication in the secondary IV tubing/bag.

In general, if a high-alert secondary medication is connected to the wrong port along the primary tubing and the programmed secondary rate is slower than the primary rate, the secondary infusion could free-flow into the patient, causing harm.

This issue affects all Ontario hospitals except pediatric environments that exclusively use syringe pumps or buretrols (i.e., they do not administer secondary IV infusions).

Secondary IV Tubing Remains Clamped After the Secondary Infusion Has Started

The impact of this issue is described in Table 8.

Table 8: Hazard Score and Patient Safety Risk—Secondary IV Tubing Remains Clamped After the Secondary Infusion Has Started

HFMEA Hazard Score	Patient Safety Risk
32	A: IV medication/fluid running at the incorrect rate E: Delay/interruption in administering critical medication to the patient

Abbreviation: HFMEA, Healthcare Failure Modes and Effects Analysis; IV, intravenous.

If the secondary IV tubing is occluded for any reason, fluid will be drawn from the primary IV bag and infused at the secondary infusion rate. Most secondary occlusions are the result of a nurse forgetting to unclamp the secondary IV tubing, although occlusions can also result for other reasons. When connecting a secondary infusion, the nurse clamps the secondary IV tubing to prevent medication from spilling out of the tubing until it is safely connected to the primary IV tubing and the pump is programmed appropriately. When the secondary infusion is ready to be administered, the nurse must remember to unclamp the secondary IV tubing prior to starting the pump, so that the infusion pump can draw fluid from the secondary IV bag.

Errors of omission in which the secondary clamp has not been opened after the infusion pump has started in secondary mode have been reported in the literature; these errors are highly predictable because the correct procedure is solely dependent on the nurse’s memory. (38;39) In addition, the pump cannot detect and alert the nurse to the error when it occurs. If the secondary IV tubing remains clamped, the infusion pump will draw fluid from the primary IV bag at the secondary rate, resulting in a delay in the administration of the secondary infusion and the primary infusion being administered at an incorrect rate (usually too fast, since secondary infusions tend to be faster than primary infusions). Both of these consequences have the potential to cause patient harm, particularly if a high-alert medication is involved.

Although this issue was not observed during the field study, during shadowing some nurses acknowledged that forgetting to unclamp the secondary IV tubing is an easy error to make, and that they have either experienced or witnessed it.

This issue affects all Ontario hospitals except pediatric environments that exclusively use syringe pumps or buretrols (i.e., they do not administer secondary IV infusions) (see next section, Secondary IV Tubing Is Connected to a Primary Infusion Set With No Back Check Valve, for an explanation).

Secondary IV Tubing Is Connected to a Primary Infusion Set With No Back Check Valve

The impact of this issue is described in Table 9.

Table 9: Hazard Score and Patient Safety Risk—Secondary IV Tubing Is Connected to a Primary Infusion Set With No Back Check Valve

HFMEA Hazard Score	Patient Safety Risk
32	A: IV medication/fluid running at the incorrect rate E: Delay/interruption in administering critical medication to the patient

Abbreviation: HFMEA, Healthcare Failure Modes and Effects Analysis; IV, intravenous.

A back check valve is a pressure-sensitive device that prevents the flow of fluid from a higher-pressure line to a lower-pressure line. Primary IV tubing sets that do not have a back check valve are prone to back-flow from the secondary IV line, which can result in the 2 fluids mixing into the primary IV bag. The infusion system is particularly vulnerable to this problem if the pump is running at a high flow rate or if the primary infusion bag contains a small volume of fluid. The result of back-flow is that the actual rate of administration for each of the fluids is indeterminate.

However, even with a back check valve, primary infusions can leak into the secondary infusion. High secondary flow rates can overcome the static pressure of the back check valve, resulting in fluid being drawn from both the primary and secondary infusions. Nurses need to identify this situation when it arises and create a greater head height differential between the primary and secondary infusions in order to restrict primary infusion flow. A straightforward method for identifying whether the primary fluid is flowing with the secondary infusion is to check the status of the drip chambers to make sure that the one on the secondary infusion is running and that the one on the primary infusion is static.

During the field study, 1 nurse noted that the primary IV infusion sets on her unit did not have back check valves. However, she was working on a pediatric unit that administered secondary infusions through a buretrol, which has a minimal risk of back-flow into the primary bag, so the absence of a back check valve in that instance was appropriate. Figure 4 illustrates how the buretrol acts as an intermediate reservoir so that nurses can define the contents and volume of the IV medication they intend to infuse. Since the buretrol is rarely filled to its maximum volume, there is minimal risk of back-flow entering either infusion bag.

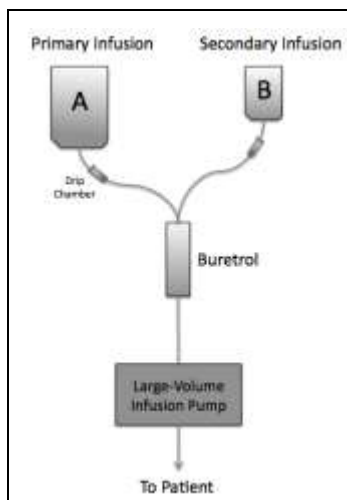


Figure 4: Secondary Infusion Arrangement With Buretrol

The absence of a back check valve on the primary IV tubing was not identified as a problem on any other unit during the field study.

This issue affects Ontario hospitals that

- purchase primary infusion pump tubing sets without a back check valve
- administer secondary infusions from a secondary IV bag to primary infusion sets upstream of the pump chamber

Exceptions include pediatric environments that exclusively use syringe pumps or buretrols (i.e., they do not administer secondary IV infusions).

Infusion Pump Does Not Support the Administration of a Secondary Infusion on a Primary Line Programmed Using the Drug Library

The impact of this issue is described in Table 10.

Table 10: Hazard Score and Patient Safety Risk—Infusion Pump Does Not Support the Administration of a Secondary Infusion on a Primary Line Programmed Using the Drug Library

HFMEA Hazard Score	Patient Safety Risk
32	A: IV medication/fluid running at the incorrect rate

Abbreviation: HFMEA, Healthcare Failure Modes and Effects Analysis; IV, intravenous.

A drug-dose calculator is a tool within an infusion pump that automatically calculates the infusion rate according to the standard dose units for that drug as identified by the hospital, based on the appropriate input values (units, concentrations, dose, volume). Smart pumps have more sophisticated drug-dose calculators with additional safety features called DERS. DERS include a drug library with fixed medication-concentration pairs that calculate the infusion rate in the required units and verify that the rate is within predetermined programming limits; this facilitates the automatic detection of programming errors. (40)

At least 3 infusion pumps sold in Ontario (1 smart infusion pump manufactured by Baxter [the Colleague model] and 2 traditional infusion pumps with drug-dose calculators manufactured by Graseby and Alaris [Graseby 3000 and Alaris IVAC, respectively]), limit the use of the drug-dose calculator and drug library when programming secondary IV infusions (see Appendix 9 for further details about these pump designs). A secondary IV infusion cannot be programmed into any of these pumps if the primary IV infusion is programmed using the drug library or drug-dose calculator. The rationale for these design decisions is to prevent secondary infusions from interrupting potentially high-alert, continuous medications. This is consistent with ISMP Canada’s recommendation “do not piggyback a secondary infusion into a high-alert (e.g., insulin) primary drug infusion.” (38) Initiating a secondary IV infusion in such situations could also have harmful effects if the dead volume of the primary infusion medication were bolused by the secondary infusion.

The consequences of not allowing secondary infusions to be programmed if the primary infusion is programmed using the drug-dose calculator or drug library are mainly positive; however, there are certain circumstances, such as trying to administer a controlled IV bolus when no bolus feature is available in the pump, that may lead a nurse to choose to program the primary infusion without using the drug library in order to access to the feature for the secondary infusion. This increases the risk of an undetected primary infusion programming error. During the field study, nurses were observed to bypass the drug library or

not use the drug-dose calculator for primary infusions when they anticipated needing to use the secondary mode to administer a bolus of the primary infusion (see the Exploratory Ethnographic Analysis section Theme 5: IV Bolus Administration).

Other risks associated with connecting a secondary medication to a primary infusion of a high-alert medication can also manifest themselves in this scenario (see Secondary Medication Connected Is to a High-Alert Primary Medication Infusion, above).

This issue has the potential to affect Ontario hospitals that use the Baxter Colleague pump, the Graseby 3000 pump, the Alaris IVAC pump, or any other pump that does not support programming secondary infusions on primary infusion lines that have been programmed using a drug library or drug-dose calculator.

Secondary Infusion Programming Error Occurs

The impact of this issue is described in Table 11.

Table 11: Hazard Score and Patient Safety Risk—Secondary Infusion Programming Error Occurs

HFMEA Hazard Score	Patient Safety Risk
32	A: IV medication/fluid running at the incorrect rate

Abbreviation: HFMEA, Healthcare Failure Modes and Effects Analysis; IV, intravenous.

Secondary programming errors can result in gross over- or underinfusions of either the primary or secondary infusion. (38;39) Errors in specifying the VTBI can result in the primary infusion running at the secondary rate or vice versa, which may cause serious patient harm if the infusion rates of the primary and secondary infusions differ greatly. Smart-infusion technology can facilitate the detection of secondary infusion programming errors; however, not all smart infusion pumps allow secondary infusions to be programmed through the drug library.

This issue affects all Ontario hospitals, particularly those not using smart infusions pumps, those that do not strongly comply with the use of the DERS (drug library), or those not using the DERS for secondary infusions.

Contributing Factors

The most relevant contributing factors responsible for the 8 secondary infusion issues are described below.

High-Alert Medications Associated With Secondary Infusions

Although connecting a secondary medication to a high-alert primary infusion was not observed during the field study, an incident report to ISMP Canada confirms that this practice does occur and can lead to patient harm. (38) In addition, secondary medications can be high-alert medications themselves, meaning that the secondary set-up issues described earlier in this section are more likely to result in patient harm. Limited guidance exists on which medications are appropriate to administer as a secondary infusions in order to minimize patient safety risks.

Poor Technology Design

With the exception of programming-related errors (some of which are detectable by smart pump technology), other secondary infusion issues discussed in this report are not detectable by current infusion technology and thus rely on human vigilance. The only exception to this is the Hospira Plum A+ infusion pump, which has separate inlet ports on the pump cassette portion of the primary IV tubing for the

primary and secondary IV tubing; each rate is controlled separately. This design facilitates both the sequential (i.e., secondary) and concurrent infusion of 2 medications on a single channel, and has the following additional benefits for secondary infusions:

- No bag head height differential between the primary and secondary IV bags is required.
- Occlusions on the secondary IV line can be detected.
- The secondary infusion cannot back up into the primary infusion tubing.

Secondary programming issues were observed to stem from 3 types of design flaws:

- Secondary medications are not included in the drug library based on the manufacturer's software design; therefore, no upper or lower limits are available to help identify programming errors.
- In modular pumps, a single pump interface is used to program and control the primary and secondary infusions, enabling value transposition errors.
- The unique user interface design of each pump has the potential to influence programming use errors. The theme Pump Design Issues provides some specific examples of poor user interface design, and are described in Appendix 9.

The bag hangers packaged with secondary infusion tubing sets are sufficient for separating the heights of the primary and secondary infusions to facilitate proper infusion flow in most circumstances. However, they may not be long enough for all circumstances, such as when larger secondary IV bags are used, or when secondary flow rates are very high.

Inadequate Technology Selection and Implementation

Procurement and implementation decisions related to clinical tools and technology are critical for promoting safety. If user requirements and the use environment are not well understood and considered when making a purchasing or implementation decision, not only will the benefits of the technology not be realized but also the risk of patient harm may be increased. (41) Specific procurement and implementation decisions that may increase risks to patients receiving multiple IV infusions include the following:

- purchasing primary IV infusion tubing with no back check valve
- purchasing tubing with an IV port that is downstream of the pump but high enough for the secondary IV tubing to reach it. This facilitates a misconnection that results in the secondary infusion not being controlled by the infusion pump and the primary infusion infusing at the secondary rate. This type of error was observed during the field study and in previous simulation studies on smart infusion systems. (42) The rationale for having an IV port downstream but close to the bottom of the infusion pump is to support air removal from the line. The relevant risks and benefits of these ports should be considered carefully by each health care organization
- purchasing pumps that do not include secondary infusion medications in the drug library
- purchasing pumps that do not allow secondary infusions to be programmed on primary infusions when primary infusions are programmed in the drug library or drug-dose calculator

Nurse Training and Education

Nurses are taught specific rules about how to set up and manage secondary IV infusions; however, they are not consistently taught the underlying foundational principles from which the rules derive. For example, nurses know that a head height differential is required between the primary and secondary IV bags, and that this is because of the effect of gravity. However, training and education on managing secondary infusions does not always focus on patient safety issues based on known areas of difficulty and empirical evidence. Specifically, nurses are not consistently taught the basics of hydrostatics, how to determine the minimum head height differential required between a primary and secondary infusion, or how to troubleshoot a secondary infusion that is not infusing as expected.

Discussion

Secondary infusion errors are difficult to detect and have the potential to cause patient harm. To reduce the impact of secondary infusion errors, ISMP Canada has recommended “do not piggyback a secondary infusion into a high-alert (e.g., insulin) primary drug infusion.” (38)

In general, clinical units treating adult patients are likely to benefit the most from improvements to secondary infusion practice. Pediatric environments were observed to be far less prone to secondary infusion issues because of the increased use of syringe pumps and buretrols, which restrict and/or minimize many of the secondary infusion risks.

The research team is aware of 3 promising technology-based mitigating approaches to secondary infusion issues that are either under development or currently on the market.

First, the Hospira Plum A+ infusion pump (Figure 5) has several important features:

- The pump allows the primary and secondary infusions to be independently controlled by a single pump channel, so that bag head height differential between the primary and secondary IV bags is not required. This eliminates the associated failure mode.
- The pump can sense upstream occlusions on the secondary line, thus eliminating infusion delays from secondary IV tubing clamp errors.
- The pump has a single port dedicated to the secondary IV tubing, which minimizes wrong-port connection errors.
- The pump pulls IV fluid from the primary and secondary IV bags separately. Therefore, secondary programming errors on the VTBI will cause less severe harm to patients, because there is no risk that the infusion will be pulled at a rate intended for the other infusion.



Figure 5: Hospira Plum A+ Infusion Pump

While these features are all useful for mitigating secondary infusion issues, the Hospira Plum A+ does not have a bolus feature to support the safe administration of IV boluses using the primary infusion line. The overall safety of the Hospira Plum A+ pump design must be evaluated by each institution in every context of use to determine its overall effectiveness and safety potential.

Second, another infusion pump vendor has developed a new technological innovation that allows upstream occlusions (line clamps) to be detected at the start of a secondary infusion. However, this technology has not yet been integrated into a licensed product in Ontario.

Third, a mechanical syringe IV infusion pump without an electronic programmable interface, designed specifically for controlled administration of non-rate-critical, small-volume, and intermittent IV medications, is available and used in the United States. This product eliminates the potential for secondary bag height issues, secondary clamp issues, and secondary programming errors; however, not all medications administered as secondary infusions are eligible for this administration method.

Massachusetts General Hospital (MGH) in Boston has used a mechanical syringe pump to administer many of its secondary infusions since 1987 (Figure 6a), and currently administers approximately 250,000 doses of secondary medications annually using this type of infusion device. The most current version of the mechanical syringe driver, the Baxa Infuse T10 (Figure 6b), had not been submitted for approval to Health Canada at the time of writing.



Figure 6a: First Mechanical Syringe-Infusion Device Designed at Massachusetts General Hospital



Figure 6b: Mechanical Syringe Infusion Device Currently Licensed in the United States

The relative merits of these technological solutions—in conjunction with limiting the use of high-alert medications associated with secondary infusions—need to be evaluated further.

Since most hospital organizations will continue to use the infusion technology already purchased and implemented in their organizations, at least in the short term, mitigating strategies that are low-cost and oriented to policy, work practice, and/or training and education should also be considered in order to quickly reduce the error potential for secondary infusion issues. Three short-term recommendations are provided in the next section. Other mitigating approaches will be identified and evaluated in Phase 2 of this research.

Recommendations

Based on the data collected in Phases 1a and 1b of this study, as well as on a detailed discussion with members of the Multiple IV Infusions Expert Panel, the following mitigating strategies for secondary infusion issues are recommended:

1. When initiating a secondary medication infusion (often referred to as a *piggyback* infusion), nurses should verify that the secondary infusion is active—and that the primary infusion is not active—by viewing the activity in both drip chambers. Full drip chambers should be partially emptied to restore visibility.
2. *Continuous* high-alert (9) medications should be administered as primary infusions. *Continuous* high-alert medications should not be administered as secondary infusions. No secondary medications should be connected to high-alert primary continuous infusions. (38)
3. Secondary infusions should be attached to primary infusion sets that have a back check valve. If infusion sets without back check valves are also available, multiple strategies should be employed to ensure that the types of tubing available are easily differentiated, and that the likelihood of a mix-up is minimized.

Further Investigation Required in Phase 2

In addition to the recommendations described above, further mitigating strategies are required to minimize the risks associated with administering secondary infusions. The next phase of research will include a comparative study of various technologies in terms of their potential to minimize secondary infusion set-up risks. Efforts will be made to include tools or technologies that can be implemented by Ontario hospitals in the short term, as well as design changes that should be included in the next generation of infusion technology.

Theme 2: Line Identification

Background

Patients often require the administration of several different IV infusions at the same time. As the health care system becomes more able to manage patients with increasingly more complex conditions due to improvements in medications and medical device technology, the number of infusions administered to a single patient is also increasing. When managing multiple IV infusions, nurses must be able to quickly identify the contents, location, and infusion pump parameters for each IV line. Misidentifying an infusion—or not identifying a line quickly—can lead to actions performed on the incorrect infusion, no action performed on the correct infusion, or a delay in administering a life-sustaining medication. Any of these errors may lead to patient harm.

Results

Three issues associated with line identification were identified from the field study data. Factors contributing to these issues included physical complexity, suboptimal drug tubing, labelling practices, line tracing methods, lack of standardization, and lack of guidance on shift handovers.

Issues

During the field study, the following 3 line identification issues were identified with the potential to lead directly to patient harm:

- Infusion pump settings are changed on the incorrect pump.
- Intermittent medication is injected into the dead volume of the incorrect infusion line (this practice is more common in pediatric units).
- Line set-up information related to critical medication is not formally communicated at shift handover.

Infusion Pump Settings Are Changed on the Incorrect Pump

The impact of this issue is described in Table 12.

Table 12: Hazard Score and Patient Safety Risk—Infusion Pump Settings Are Changed on the Incorrect Pump

HFMEA Hazard Score	Patient Safety Risk
32	A: IV medication/fluid running at the incorrect rate D: Required medications not being administered to the patient E: Delay/interruption in administering critical medication to the patient F: Bolus of incorrect fluid/medication administered G: Administration of a discontinued medication/fluid

Abbreviation: HFMEA, Healthcare Failure Modes and Effects Analysis; IV, intravenous.

Once a pump has been programmed, there are many potential reasons for changing the programming parameters, including the following:

- titrating the dose
- adding a secondary infusion
- pausing the infusion
- administering a bolus
- discontinuing the infusion

If a nurse identifies the incorrect line when noting that the pump requires a setting change, the wrong infusion pump/pump channel could be manipulated, resulting in several patient safety risks (see Table 12). This situation could be particularly harmful to the patient if an error is made while titrating an infusion, since there may be an immediate need for a change in the medication dose; the error prevents the dose change of the required medication from reaching the patient and the administration rate of another medication is unintentionally altered. No instances of infusion pump settings being changed on the wrong pump/pump channel because of a line identification error were observed during the field study. However, researchers recognized the potential for a line identification error to lead to this type of consequence. The fact that the FDA recently issued an alert on this subject suggests that incidents of this nature have likely occurred. (43) All Ontario hospitals are affected by this issue, regardless of the type of pump used.

Intermittent Medication Is Injected Into the Dead Volume of the Incorrect Infusion Line

The impact of this issue is described in Table 13.

Table 13: Hazard Score and Patient Safety Risks—Intermittent Medication Is Injected Into the Dead Volume of the Incorrect Infusion Line

HFMEA Hazard Score	Patient Safety Risk
32	A: IV medication/fluid running at the incorrect rate B: Incompatible medications running together E: Delay/interruption in administering critical medication to the patient F: Bolus of incorrect fluid/medication administered

Abbreviation: HFMEA, Healthcare Failure Modes and Effects Analysis; IV, intravenous.

In some pediatric settings, particularly neonatal settings, intermittent medications are administered 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. The dose is so small that it can reside in this space without reaching the patient until it is pushed through with a primary infusion, either manually using an IV syringe or by infusion pump.

If an infusion pump is used to push the intermittent medication residing in the dead volume, as researchers observed during the field study, the pump is either stopped or turned off prior to injecting the secondary medication into the lower portion of the tubing. The secondary mode of the pump is programmed for the appropriate intermittent infusion parameters (even though no secondary IV bag is connected); when the pump is started, it will push the primary IV fluid at the secondary rate, consequently pushing the intermittent medication at the same (desired) rate.

One potential risk identified (although neither observed nor reported) during the field study is injecting the intermittent medication into the incorrect primary IV drug tubing. This error is unlikely to be detected, because most medications are colourless; once they are injected, there is no way of tracing which piece of tubing received the injection.

This type of error may carry the following patient safety risks:

- A temporary delay occurs in the administration of the primary medication/fluid in the line into which the intermittent medication was injected.
- The intermittent medication runs at an incorrect rate.
- The primary medication of the line intended to host the intermittent infusion temporarily runs at an incorrect rate (likely too fast).
- The intermittent medication could be incompatible with the primary infusion into which it was injected.

Pediatric patients are highly vulnerable to receiving medications at the incorrect rate, particularly patients who are severely fluid-restricted.

This issue impacts pediatric units that administer intermittent medications by injecting them into the lower medication port. The number of pediatric hospitals that administer intermittent infusions using this method is unknown.

Line Set-Up Information Related to Critical Medication Is Not Formally Communicated at Shift Handover

The impact of this issue is described in Table 14.

Table 14: Hazard Score and Patient Safety Risk—Line Set-Up Information Related to Critical Medication Is Not Formally Communicated at Shift Handover

HFMEA Hazard Score	Patient Safety Risk
48	E: Delay/interruption in administering critical medication to the patient

Abbreviation: HFMEA, Healthcare Failure Modes and Effects Analysis.

Shift handover is defined as “the exchange between health professionals of information about a patient accompanying either a transfer of control over, or the responsibility for, the patient.” (28) Handover communication is important for ensuring that patients receive consistent, appropriate, and timely care. The risks of poorly executed shift handovers are well documented in the literature, as is the variability in approaches to and content included in a shift handover. (28;44-47) According to a 2006 study by

Alvarado et al (44) on handovers in the Canadian context, many Canadian hospitals have no policy or standards for shift handover. The field study observations confirmed these findings in the 12 sites, particularly with respect to the communication of multiple IV infusion information.

During shift handover, researchers observed nurses consistently exchanging information about patient medications, but inconsistently discussing IV line set-up information, such as:

- which IV line was assigned as an emergency medication line
- which pumps and associated IV access locations were associated with life-sustaining medications
- whether or not any medications routinely bolused should not be bolused because of the line set-up

These 3 pieces of information are particularly important for managing multiple IV infusions in a safe and timely way. Some nurses used their flow sheet to guide their presentation of information at shift handover, whereas other nurses kept notes throughout their shift on a blank piece of paper that they referenced. Still others relied entirely on their memory. At 1 field site, nurses used a paper tool to facilitate shift handover, but no information related to multiple IV management was included on the tool. At another site, nurses relied entirely on electronic notes for shift handover information; no face-to-face information was exchanged.

At the start of each shift, nurses were required to and often (but not always) observed to consistently trace each IV line from the IV bag to the IV catheter and ensure the line set-up was appropriate and consistent with the ordered medications. Line tracing gives nurses a first-hand understanding of important IV line set-up information. During field observations, nurses indicated that they relied on the information gained from their independent line tracing more than on the information exchanged during shift handover, which could explain why infusion set-up information is not commonly included in the shift handover communication. However, if an emergency situation arises before the nurse has completed the line-tracing assessment, the administration of critical medications may be delayed while the nurse identifies an appropriate line to infuse medications. Given the stressful nature of the situation, errors in determining the appropriate IV line may be more likely.

Contributing Factors

The most relevant contributing factors responsible for the 3 line identification issues are described below.

Physical Complexity

Understanding how the system of infusions is connected, the status of each infusion, and how to best interact with the infusion system to meet a patient's highly dynamic medication needs, is challenging for even the most experienced nurses. Figures 7 and 8 illustrate the physical complexity of line set-ups in the pediatric and adult environments, respectively. The degree of difficulty increases with the number of infusions running. During the field study, the greatest number of IV infusions observed on a single patient at 1 time was 15. This was achieved using 11 individual large-volume infusion pump channels (2 different types of large-volume infusion pumps were used) and 2 syringe pumps, with 1 secondary infusion and 2 medications running together using the concurrent mode of a single channel of the Hospira Plum A+ pump (see Figures 9 and 10).



Figure 7: Medication Tubing Inside a Neonatal Intensive Care Unit Isolette



Figure 8: Medication Tubing Connected to Several Manifolds in an Adult Intensive Care Unit

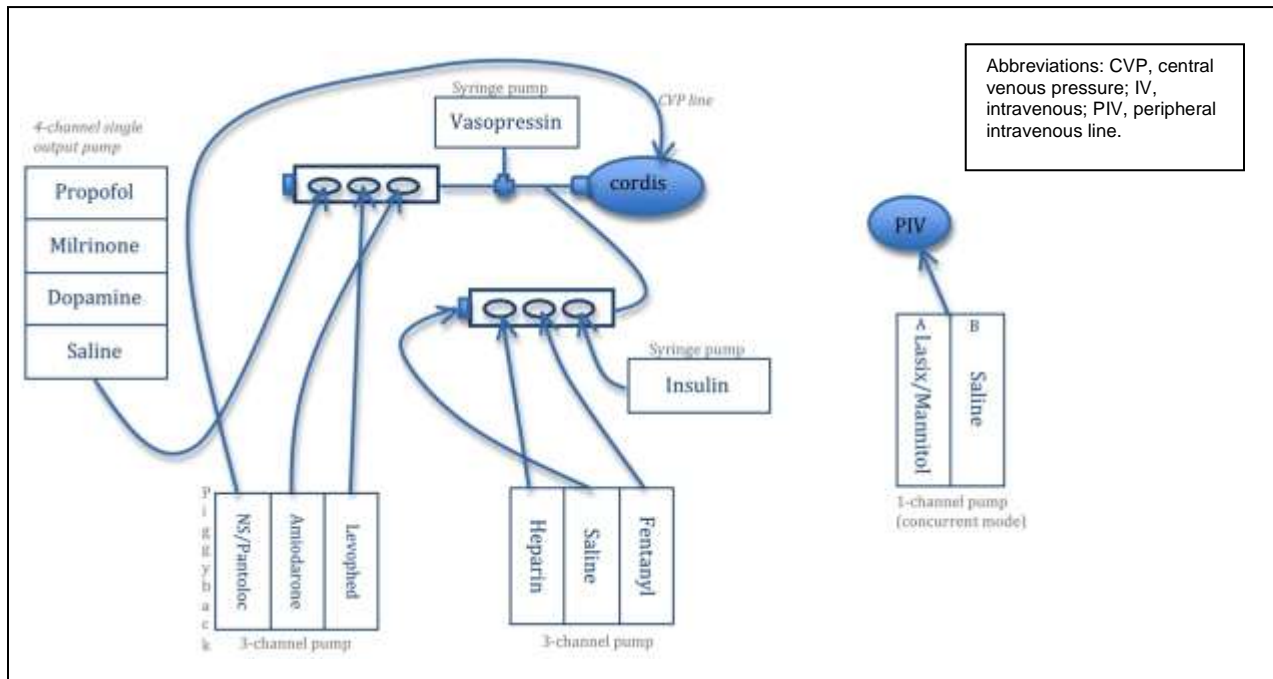


Figure 9: Schematic of IV Line Set-Up for a Patient Receiving 15 Infusions



Figure 10: Actual IV Line Set-Up for a Patient Receiving 15 Infusions

Abbreviation: IV, intravenous.

In addition to the number of infusions running, the following factors were observed to increase the challenges of monitoring and managing multiple IV infusions:

- IV tubing looks similar (i.e., they all contain a colourless or white fluid).
- IV tubing gets very tangled (see Figure 11 for 1 nurse's solution to managing IV lines).
- IV lines do not line up with their associated pump for 1 of 2 reasons:
 - The pumps are aligned either vertically or horizontally, but some hospital units use circular IV hooks at the top of the IV pole.
 - Nurses do not consciously hang IV bags in an order that corresponds with the pump channels.
- To improve the visibility of each IV bag label, some nurses attempt to separate IV bags more widely than the IV hooks allow by using the secondary IV hanger or by spreading the IV bags out across multiple IV poles. This further confuses the proximity relationship between each IV bag and its associated pump (Figure 12).



Figure 11: One Nurse's Solution to Minimizing Line Tangling



Figure 12: Confusing Proximity Between IV Bags and Pump Channels

Abbreviation: IV, intravenous.

Use of Suboptimal Drug Tubing and Pump Labels

During the field study, the researchers observed nurses labelling emergency medication lines, individual pieces of IV drug tubing, line connectors, and IV pumps to make it easier to identify each system component. In principle, labelling can be a helpful way to reduce cognitive workload by putting information in the environment where it is needed. However, researchers noticed several problems associated with the labelling practices at the field sites:

- Only 1 unit had standard work practices related to how and when infusion pump labels should be used. No organizations had standard work practices related to labelling IV drug tubing, and no organization had a formal policy about any type of label other than those to identify the date the tubing was hung or needed to be changed. As a result, labelling practices were inconsistent within a unit and between hospital organizations.
- Labels were not designed for the purpose for which they were used (e.g., patient ID stickers were used to label IV drug tubing), nor were they the appropriate size and shape for displaying information.
- Labels fell off the tubing when placed lengthwise.
- Labels could not be read when they were wrapped around the tubing, since only part of a word was visible from any angle.
- The writing on labels was illegible.
- Inconsistent use of colour coding led to confusion.
- Pump labels generated by the drug library had small fonts and did not include patient access information; since some nurses like to have this information on their pumps, they had to create additional labels.
- Labels were not removed from infusion pumps when a medication was discontinued; this increased the likelihood of a programming error when setting up a new infusion on a pump.

Methods for Line Tracing Are Error-Prone

As a result of the physical complexity of IV line set-ups, each time a nurse needs to interact with the IV system to identify any aspect of the line set-up, to add or remove an infusion, or to change a programming parameter, he or she must manually trace the relevant lines. Line tracing is the process of holding onto a single piece of IV drug tubing and, starting at 1 end, sliding one's hand along the tubing to the other end to confirm

- the IV bag contents
- the associated pump
- the infusion parameters that correspond to the patient's IV access ports

This process was observed repeatedly during the field study; the opportunity to make a line-tracing error was apparent on several occasions. Line-tracing errors can occur when the line-tracing hand accidentally moves from 1 line to another when

- moving a tangled piece of tubing out of the way
- tracing a line through a patient's gown sleeves (Figure 13)
- tracing a line through an incubator (Figure 14) or crib sides in the pediatric environment (Case Study 2)



Figure 13: Lines Passing Through a Patient Gown



Figure 14: Lines Passing Through the Isolette

Case Study 2: Line Tracing

A nurse was observed tracing a line that passed through the small opening on the side of an incubator. She was asked about the potential risk of landing on the wrong line when she moved her hand from the outside to the inside of the incubator. The nurse indicated there was no chance of this happening because she conducts this task slowly and holds the tubing on either side of the incubator, pulling on the outside to ensure the corresponding piece of tubing is tugged on the other. However, the likelihood that this level of vigilance can be maintained each time a line is traced, particularly in an emergency situation, is not realistic, making this task error-prone.

Lack of Standardization

Before efforts are made to improve line identification tools and processes, efforts to simplify the complexity of IV lines should be considered as a more effective strategy for IV line management. Standardization can be an effective strategy, but in the case of multiple IV infusions, standardization is challenging because nurses must construct the IV system over time in response to the patient's changing needs. No standard approach to connecting IV lines was used by nurses in the field study (see Case Study 3).

Case Study 3: Nurses Use Inconsistent Approaches to Line Set-Up

During a field study in 1 of the participating hospitals, a nurse was caring for a very sick patient who was receiving 15 different concurrent infusions (see Figures 9 and 10). The patient had limited IV access relative to the number of infusions, so the nurse needed to carefully construct the system of IV lines to support the best possible flow of medications. One of the researchers documented the IV line set-up and then reviewed the set-up with another nurse who was caring for the patient in the next bed. The second nurse said it was “not possible” to connect the lines in the way they had been connected (i.e., that the physical components would not allow them to be connected that way). The researcher returned to the first nurse and reviewed the line set-up again, looking for a mistake in the documentation. No mistake had been made—the IV lines had been connected exactly as documented. In response to the question about why the second nurse did not understand the line set-up, the first nurse said that there were many ways to connect the system of lines together; as long as they allowed proper flow—and as long as they were understandable by the person caring for the patient—the connection system was entirely valid. Inconsistent approaches to line set-up present a risk to patient safety during the time someone else is covering a patient during a break, or at shift handover.

Each time 1 or more IV infusions are administered, individual nurses apply their own prioritization scheme that considers factors such as the following:

- determining the compatibility between IV medications
- determining whether the medication is vesicant or nonvesicant
- ensuring that life-sustaining medications infuse via a central line
- ensuring that only intermittent infusions infuse via the central venous pressure line
- ensuring that peripheral IVs or IV locks are kept patent for future use
- ensuring that 1 or more lumens on a central line are reserved for future use
- ensuring that a line for the administration of intermittent and stat medications is established and preserved

In addition, researchers observed some nurses simplifying their line set-ups with 1 or more of the following strategies:

- Always identify an emergency medication line with a unique label on both the pump and the drug tubing (near the IV push port).
- Always reserve the IV pump channel on the furthest left of a modular pump for the emergency medication line.
- Place similar types of medications on the same IV access port (if compatible) and label the infusion pumps with the associated lumen colour on the access port (appropriate for multi-lumen catheters that colour-code each lumen).
- Physically group IV pumps running similar types of medications so that they are close together (e.g., all on 1 pole, all in a single line if modular).

Standardization of line set-ups was observed more frequently in units that treat a relatively homogeneous patient population (e.g., cardiac postsurgical ICUs, outpatient adult oncology). On these units, the medication protocols throughout the length of stay are common for most patients. Despite the tendency towards standardization in units with homogeneous patient populations, researchers observed that 2 different nurses caring for patients receiving the same medications via the same IV access, and with access to the same physical connectors, would sometimes set up their lines differently. Set-up approaches in units with heterogeneous patient populations were even more varied in terms of the approach to connecting lines and the connectors used.

Lack of Guidance on Shift Handovers

At a provincial level, no guidance exists from either a professional practice organization or a regulatory agency on best practices for conducting a shift handover, in terms of either process or content. This is reflected in the variation of handover practices and policy standards within each individual health care organization.

Discussion

Line identification issues are challenging to mitigate, because they result from the arrangement of complex physical IV components required to care for critically ill patients.

Line tracing is the best practice available for identifying the contents of each piece of IV tubing and determining the infusion parameters and IV access; however, current methods are error-prone. One approach to improving line tracing is to remove physical obstacles that interfere with the tracing path. Gowns without snaps at the shoulders make it difficult to follow IV lines to the access location; this encourages nurses not to put gowns on their patients but rather to simply drape them over the patient. Additionally, when performing a gown change, gowns without snaps require the nurse to stop each pump, take the IV bag out of the pump, and feed it through the gown, causing a temporary interruption of medication, which could be harmful to the patient if uninterrupted delivery of the medication is critical. Thus, hospitals should consider purchasing patient gowns with shoulder snaps, ties, or Velcro that allow for a barrier-free line tracing path for patients. Metal fasteners (e.g., metal snaps) should be avoided to prevent patient burns if a gown with metal fasteners goes into the magnet room of an MRI suite. (48)

Line labelling is also a useful approach for identifying the contents and location of elements in the IV infusion system. However, approaches to line labelling vary in terms of content, type of sticker, and location of the label. Ontario hospitals do not receive guidance on optimal line labelling practices, and may or may not choose to define their own labelling practices. In most cases, nurses develop their own individual approaches to labelling, or an informal labelling strategy may develop on the unit to address clinical needs.

Another approach to minimizing the complexity of line identification tasks is to introduce elements of standardization to line set-ups. However, no consistent approach to standardizing line set-ups was observed during the field study. Nurses described a fairly common set of factors that they consider each time they administer a new medication, suggesting that some degree of standardization may be possible.

Recommendations

Based on the data collected in Phases 1a and 1b of this study, as well as on a detailed discussion with members of the Multiple IV Infusions Expert Panel, the following mitigating strategies for line identification issues are recommended:

1. Hospitals should work towards the use of gowns that have snaps, ties, or Velcro on the shoulders and sleeves to facilitate line tracing and gown changes. Metal fasteners (e.g., metal snaps) should be avoided to prevent patient burns if a gown with metal fasteners goes into the magnet room of an MRI suite.
2. If an “emergency medication line” controlled by an infusion pump is set up, it is strongly suggested that the associated primary IV tubing be labelled as the emergency medication line at the injection port closest to the patient. The label should be prominent and visually distinct from all other labels in the environment.

Further Investigation Required in Phase 2

In addition to the recommendations described above, further mitigating strategies are required to minimize the risks associated with line identification. The next phase of research will include a comparative study of various technologies in terms of their potential to minimize line identification risks. Efforts will be made to identify best practices related to drug tubing and component labelling, standardization of practices for line set-ups, and shift handover practices.

Theme 3: Line Set-Up and Removal

Background

Line set-up and removal refers to the processes of arranging all components of the IV system, and removing infusions when required. This involves connecting or disconnecting any of the elements of the IV system to facilitate the infusion or discontinuation of an IV agent. The system components consist of the IV agent in a container (i.e., IV bag, IV syringe, glass bottle), IV tubing appropriate for use with an infusion pump, an infusion pump to control the infusion flow rate, and IV connectors (if multiple IV tubing needs to be joined to fit into the patient’s available access sites). The types of components used, the order in which they are connected, and the process for performing these tasks are all associated with the issues identified during the field study.

The set-up and removal of IV lines occurs frequently in environments with acutely ill patients and in outpatient chemotherapy environments, because a high number of infusions are prescribed and discontinued. In addition, regular IV tubing changes (to reduce the risk of line infection) require nurses to assemble a new IV system of IV agent containers, tubing and connectors, adding to the frequency of set-up and removal tasks. Patient transfers between care areas (e.g., such as between the OR and ICU, or between facilities) may also necessitate a change of infusion pumps, tubing and infusions, due to differences in infusion equipment, drug libraries, medication concentrations, and hospital practices related to ownership of the pumps in each unit.

Results

Three issues associated with the set-up and removal of IV lines were identified from the field study data. Factors contributing to these issues include hospital procurement processes, product recalls, multiple concurrent IV infusions, batching tasks, failure to line up IV containers with pumps or pump channels, and lack of standard processes for residual volume of disconnected/removed infusions.

Issues

During the field study, the following 3 line set-up and removal issues were identified with the potential to lead directly to patient harm:

- The residual volume in the connector is not identifiable when a medication is disconnected from a multi-port connector.
- Leaks can occur with the use of 3-way stopcocks.
- The IV bag and its infusion pump are mismatched.

Residual Volume in the Connector Is Not Identifiable When a Medication Is Disconnected From a Multi-Port Connector

The impact of this issue is described in Table 15.

Table 15: Hazard Score and Patient Safety Risk—Residual Volume in the Connector Is Not Identifiable When a Medication Is Disconnected From a Multi-Port Connector

HFMEA Hazard Score	Patient Safety Risk
64	B: Incompatible medications running together
	E: Delay/interruption in administering critical medication to the patient
	F: Bolus of incorrect fluid/medication administered
	G: Administration of discontinued medication/fluid

Abbreviation: HFMEA, Healthcare Failure Modes and Effects Analysis.

IV medications are sometimes disconnected from the IV system (e.g., they are no longer needed, or the patient has had a negative response to the medication). In cases where multiple IV infusions are joined together to infuse through a single IV access site, an IV connector may be used (e.g., bridge, manifold, stopcock, Y-connector). The IV connector typically features a luer lock connection where the IV infusions are securely attached. This portion of the connector has a small priming volume that the IV medication must pass through before it reaches the shared portion of the IV connector where all medications mix (i.e., dead volume). When IV medications are disconnected from the IV system, the priming volume contains a residual amount of the disconnected medication, which cannot be identified once the IV tubing has been disconnected.

While being observed in 1 pediatric environment, a nurse expressed concern about the residual dead volume in the IV connector after the IV tubing was removed. The nurse labelled the IV connector containing the dead volume with the name of the medication being disconnected to ensure that the nurse on the next shift was aware of the medication in the dead volume. The nurse educator and the nurse working on the next shift both felt that the label should have been placed on the IV tubing rather than on the connector, so that when the tubing was disconnected the line could easily be identified, as long as it had not been removed from the pump. This was the labelling approach most frequently observed during the field study. Researchers did not observe nurses systematically identifying the contents of the dead volume of an IV connector.

When asked about this issue, some nurses suggested covering the connector port with tape to prevent future use of that port. In 1 pediatric institution, a nurse stated that she would manage the dead volume in the IV connector by drawing out the medication in the dead volume with a syringe, filling the dead volume with saline or heparin, and clamping it (i.e., creating a saline or heparin “lock”). The locked priming volume could then be drawn out with a syringe before the new medication was about to be infused. It was not clear how the nurse would indicate the fluid contents in the lock; if not clearly

indicated, the patient safety risks associated with unidentified dead volume in IV connectors would remain.

This issue existed at all field study institutions, as researchers were not made aware of any established practices for identifying residual volume in IV connector ports when IV tubing is disconnected, either through observations or interviews. However, this issue was not identified until the later stages of the field study, so information related to this topic was not actively recruited in the earlier stages of the field study.

Leaks Can Occur With the Use of Three-Way Stopcocks

The impact of this issue is described in Table 16.

Table 16: Hazard Score and Patient Safety Risk—Leaks Can Occur With the Use of Three-Way Stopcocks

HFMEA Hazard Score	Patient Safety Risk
32	E: Delay/interruption in administering critical medication to the patient

Abbreviation: HFMEA, Healthcare Failure Modes and Effects Analysis.

The use of stopcocks to connect multiple IV infusions into a single infusion line was observed in 5 sites of the field study. In 1 site, it was the sole means of joining multiple infusions. The use of 3-way stopcocks is associated with a higher likelihood of leaks, which may result in a delay or interruption of the administration of IV medications to the patient. Leaks are difficult to detect, because they may not be visible (e.g., they may be obscured by bedding and other equipment), and changes in the patient’s condition may mistakenly be attributed to other factors.

Although no leaks were observed directly in the field study, several nurses reported that leaks are more common if 3 or more stopcocks are connected in series. In these instances, 1 or more stopcocks may “pop off” or become disconnected due to pressure in the IV line and/or torque on the line from several rigid connectors being pulled at 1 end when a patient moves. Failure to connect the stopcocks tightly was described as another factor leading to disconnections, as was overtightening, which causes cracks in the stopcocks themselves. Nurses noted that the detection of leaks is often delayed because the stopcocks are covered by bed linens and the leaks may be absorbed by the bedding. Eventually the nurse will notice soaked bedding or an inability to positively affect the patient’s condition with changes to the infusion flow rates, and realize that a leak has occurred.

The field study observations also identified the use of a recalled stopcock to connect multiple IV infusions together. The stopcock was recalled because the stopcock handle was prone to over-rotation, causing the connector to leak. The product was recalled in both Canada and the United States (recall #59149 by Health Canada (49) and a class 2 recall by the FDA (50)). It was not clear from the field study data how many sites were using this particular product, nor whether staff at the sites were aware of the recall. However, unit managers and staff at 1 site did indicate that they were aware of this issue and the associated recall.

The risk of leaks when using stopcocks is highest in clinical units where stopcocks are the only component available to join multiple IV infusions into a single line. The use of stopcocks to join multiple IV infusions was observed in roughly half of the clinical units visited. Few units (typically pediatric environments) restricted the use of stopcocks, suggesting that many Ontario hospitals may be affected by this issue.

IV Bag and Infusion Pump Are Mismatched

The impact of this issue is described in Table 17.

Table 17: Hazard Score and Patient Safety Risk—IV Bag and Infusion Pump Are Mismatched

HFMEA Hazard Score	Patient Safety Risk
32	A: IV medication/fluid running at the incorrect rate B: Incompatible medications running together C: Vesicant medications administered via a peripheral IV line E: Delay/interruption in administering critical medication to the patient

Abbreviation: HFMEA, Healthcare Failure Modes and Effects Analysis; IV, intravenous.

When setting up multiple, concurrent infusions, the potential exists to connect an IV bag to the incorrect pump or pump channel. This error can occur via 1 of 2 pathways, depending on whether the IV container or infusion pump is addressed first:

- The IV container is connected to an infusion pump first, and the pump is then programmed with settings inappropriate for the connected IV agent.
- The infusion pump is programmed for a specific IV agent, and an IV agent that the pump was not programmed for is then connected to the pump.

In either case, an IV agent is infusing at the wrong flow rate and/or is programmed for the wrong VTBI.

No mismatch errors were observed during the field study, but the potential for this error was noted in several sites because of the process nurses followed to set up their infusions. The process of setting up IV lines is a strong potential contributing factor (see Contributing Factors, below). There was no evidence from either the interviews or the shadowing data that nurses receive guidance on how to set up multiple IV infusions; this suggests that IV set-up processes likely vary widely at an individual level, and that the observed error-prone practices may be occurring in many institutions. The time-sensitive demands associated with caring for patients receiving multiple concurrent IV infusions may lead to infusion set-up methods that nurses feel are most efficient, but that may not be optimal from a safety perspective.

Contributing Factors

The most relevant contributing factors responsible for the 3 line set-up and removal issues are described below. Some overlap exists between the factors.

Some Hospital Procurement Processes Do Not Ensure That Clinical Needs Are Met

In 1 of the clinical units visited, 3-way stopcocks used to join multiple IV infusions were the only connecting components purchased by the unit. However, other connecting components designed specifically to join multiple IV infusions are available for purchase and are widely used in many Ontario hospitals.

Product Recalls Are Not Managed Safely and Efficiently by Hospitals

The continued use of recalled products is also a less-than-ideal practice. In at least 1 field site, a stopcock used on the unit had been recalled and prohibited from being used with IV lines (Figure 15) due to the risk of leaks when the stopcock handle was over-rotated. (49;50) The stopcocks remained available for other purposes, but could potentially be used for IV purposes, regardless of a warning posted in the supply room. In this particular example, a new stopcock product that met the demands of the clinical unit could have been purchased to replace the recalled product, thereby reducing known risks.



Figure 15: Recalled Stopcocks Remained Available for Clinical Use, With Attached Warning

Multiple IV Infusions Need to Be Set Up at the Same Time

The risk of IV line set-up errors is highest when multiple IV infusions are being set up or modified at 1 time. The study team observed a variety of conditions that influenced the need for multiple infusions to be set up at the same time. These factors are primarily associated with patient transfers between different clinical areas, where the equipment or processes are handled differently.

During the field study, patient transfers between clinical areas often resulted in changes to the IV set-up due to the following factors:

- Different infusion pumps may be used on different units, requiring a completely new line set-up with the appropriate tubing on the pumps used in the receiving unit.
- Infusion pumps may need to be returned to the home unit.
 - As a means of inventory control, some clinical units may keep their allotment of infusion pumps; this forces the receiving unit to set up a new bank of infusion pumps, IV tubing, and medications so that the patient can be seamlessly switched over and the home unit can retain its infusion pumps.
 - If the infusion pump has a specific list of medications for a limited set of care areas (e.g., only the neonatal intensive care unit) in the drug library or drug dose calculator, infusion pumps may need to be returned to the home unit. In some cases the pumps can stay with the patient in the receiving unit and be transitioned to the appropriate drug library, but this transition may require a shut-down of the pump and reprogramming of the infusion, depending on the pump's design.
- Medication concentrations may differ between the home and receiving units, requiring a new set of IV medication bags to be prepared in the receiving unit and their associated tubing primed. This results in multiple IV infusions being set up at the receiving unit.

- IV tubing and connectors may differ between patient care areas or organizations (e.g., patients transported from an ambulance will be connected to different components than are available at the hospitals). This requires the receiving unit to assemble IV medications, tubing, and connectors that are compatible with their existing systems, to replace what is already infusing into the patient.

In addition, regular IV tubing changes (replacement of IV tubing and IV containers to prevent infection risk) also require the set-up of multiple infusions at the same time to facilitate a smooth changeover from the old tubing to the new tubing. Unlike the various patient transfer scenarios described above, regular IV tubing changes are more controlled and less urgent. It is likely these will occur when the patient is stable, and after the nurse has had time to plan the necessary steps and obtain the required equipment. However, some patients are critically dependent on a continuous flow of certain medications, and the downtime associated with line changes needs to be carefully managed, leading to less-than-ideal line set-up practices.

Nurses Choose to Batch-Process Their IV Infusion Set-Up Tasks

The process of setting up an infusion generally consists of several tasks:

- hanging the IV container
- spiking the IV container with IV tubing and priming the tubing
- loading the IV tubing into an infusion pump
- programming the infusion pump
- connecting the tubing to the appropriate IV connector or IV access port/device
- labelling the appropriate components

While various hybrid approaches are possible, nurses may opt to take 1 of 2 pathways when setting up multiple infusions. They may perform each of the tasks described above for all of the medications being set up, or they may perform all of the tasks for a single IV infusion before moving on to the next medication. The former approach, called “batching,” may lead to a greater risk of mismatch errors. For example, if all IV medications with their associated IV tubing are hung on an IV pole prior to being connected to their respective pumps, the risk of selecting the wrong IV tubing when loading an infusion pump is higher than if only 1 IV bag had been hung and connected at a time. The same risk exists for labelling. If IV tubing or IV pump labelling is done after the pumps have been set up, the wrong label could be placed on an IV system component (see Case Study 4).

Case Study 4: Infusion Rate Changed on Wrong Pump

This incident occurred during the week prior to our observations at 1 of the clinical units. A critical-care patient was admitted to the ICU and had several new orders for continuous medications. A nurse set up each infusion on its own infusion pump, grouping together (batching) similar tasks. After hanging all the IV bags, connecting them to the pumps, programming the pumps, connecting the drug tubing to the patient, and then starting the pumps, she applied labels to each pump to make it easier to identify each pump when charting and changing pump values.

When applying the labels, she accidentally switched the morphine and norepinephrine (Levophed) labels. Morphine is a potent narcotic that can decrease respiratory drive at certain dose levels. It can also cause vasodilation, which can decrease blood pressure, particularly in patients with reduced fluid volume. Norepinephrine is a vasopressor used to vasoconstrict blood vessels to increase blood pressure. Later in the shift, the patient’s blood pressure began to drop. The nurse intended to titrate the norepinephrine to a higher dose, but because of the labelling error, she increased the morphine. After several minutes, when no improvement in the patient’s blood pressure was observed, she again increased the dose of morphine (intended to be norepinephrine). She made several titrations to the morphine. Since the patient had

already been ventilated, the effects of morphine on the patient’s respiratory drive were not harmful; however, the error went undetected until shift handover, when the incoming nurse identified the error while tracing the lines.

The risks associated with batch-processing IV set-up tasks can be reduced if a nurse sets up each IV medication completely and connects it to the patient before introducing the next one (a one-at-a-time set-up process). When changing multiple lines as part of a routine line change, a one-at-a-time process is also advised for setting up each medication line from the IV bag to the lowest connector above the venous access catheter. If a multi-port or multi-lead connector is being used, all medications should be attached to a new connector following a one-at-a-time approach before exchanging the new connector with the old connector in the manner least disruptive to medication flow, particularly if the medications are maintaining hemodynamic stability.

IV Containers Do Not Line Up With the Associated Pump or Pump Channel

There is a general tendency to assume that items that are close to each other are related. This is known as the “proximity compatibility principle.” (51) For example, IV containers that are hanging on the left side of the IV pole are likely to be associated with pumps on the left side of the IV pole. Because IV bags and IV pumps are not always arranged this way, the intuitive application of this principle can be misleading and may lead to error.

For example, 1 modular pump observed during the field study has modules that proceed outward from the central programming interface, such that there are 4 vertical channels where IV tubing would enter from the top and emerge from the bottom. Therefore, the ideal orientation of the IV container hangers on the IV pole would also be horizontal, so that the leftmost IV container would run towards the leftmost pump channel (Figure 16). Note that despite the alignment of pole hooks to pump channels, the IV container could still be hung so that it does not align with its associated pump channel (Figure 17).



Figure 16: Congruent Alignment Between IV Bags and Pump Channels

Abbreviation: IV, intravenous.



Figure 17: Incongruent Alignment Between IV Bag and Pump Channel

Abbreviation: IV, intravenous.

Researchers observed several suboptimal configurations, including the use of IV poles with the hooks arranged circularly (Figure 18), and infusion pumps that did not connect horizontally, leading to multiple pumps stacked vertically on the same pole (Figure 19). In addition, some pumps had IV tubing loaded horizontally, such that all upstream IV tubing entered the pump from the left and exited from the right (Figure 20).



Figure 18: Circular Hook Arrangement



Figure 19: IV Pumps Aligned Vertically

Abbreviation: IV, intravenous.



Figure 20: Horizontal IV Tubing

Abbreviation: IV, intravenous.

Lack of Standard Processes for Residual Volume of Disconnected and Removed Infusions

The field study did not identify any standard protocols or guidance available to nurses for managing the residual volume of medication left in IV connectors when an infusion was disconnected. As described above, nurses developed their own strategies for managing residual volumes, but this appeared to be driven largely by personal preference and experience.

Discussion

The risks of line set-up and removal issues depend strongly on decisions made at an organizational level (e.g., IV component procurement decisions, infusion pump inventory strategies), as well as on individual nurse practices (e.g., placement of IV bags, batching infusion set-up tasks). As a result, mitigating strategies that target multiple contributing factors at various levels of the health care system are required. Based on the field study and existing literature, several promising areas should be pursued.

In general, a greater degree of standardization across a hospital organization in terms of medication concentrations, infusion pumps, IV tubing and connectors, and pump inventory management can reduce the number of unnecessary line set-ups and decrease the risks associated with patient transfers.

In addition, the development of standard work practices related to line set-ups would help reduce the frequency of misconnections and unintended boluses. These standards should specify the optimal order of carrying out tasks related to setting up multiple IV infusions and the optimal management of residual medications in multi-port connectors.

The line set-up and removal issues identified during the field study have the potential to affect all Ontario hospitals.

Recommendations

Based on the data collected during the field study, as well as on discussions with the members of the Multiple IV Infusions Expert Panel, the following mitigating strategies for line set-up and removal issues are recommended:

1. When setting up multiple IV infusions at the same time (e.g., a new patient requires many ordered infusions immediately, routine line changes), infusions should be set up 1 at a time, as completely as possible, before setting up the next infusion. Set-up tasks required for each infusion vary and may include:
 - labelling (e.g., IV tubing, pump)
 - spiking and hanging the IV bag
 - connecting the IV tubing to the pump
 - programming the IV pump
 - connecting the IV tubing to the appropriate location (e.g., patient access, manifold)
 - starting the pump (unless a secondary infusion must be set up prior to starting the pump, or other infusions need to be connected to a multi-port connector before flushing)

Minor modifications to this recommendation are required for routine line changes (see *Nurses Choose to Batch-Process Their IV Infusion Set-Up Tasks*, above).

2. Multiple 3-way stopcocks joined together in series to connect multiple IV infusions into a single line are prone to leaks, which may often be undetectable. Hospitals should provide multi-port or multi-lead connectors, and nurses should use these connectors to join multiple IV infusions into a single line, as required.

Further Investigation Required in Phase 2

In addition to the recommendations described above, further research is required to understand the following:

- ideal strategies to for managing IV infusions during patient transfers (e.g., impact of standardized IV medication concentrations, impact of various pump inventory strategies)
- ideal strategies for identifying residual IV medication content in IV connectors after IV tubing has been disconnected.

Theme 4: Dead Volume Management

Background

In situations in which the number of infusions required for the patient exceeds the available IV access ports, multiple infusions must be joined together to share the same IV line. The shared volume that multiple IV agents must flow through is known as the *dead volume* (see Principles of Infusion Therapy).

In acute care environments, the administration of multiple continuous infusions through a single IV line is a common occurrence, and the medications being infused require high degrees of accuracy (i.e., unchanging flow rate and concentration). However, when continuous infusions are titrated, added, paused, or removed, they affect the other infusions sharing the same dead volume. This can interfere with the accuracy of IV therapy, and may be difficult to detect unless a change to a patient’s physiological status is observed and the effects of perturbations in the dead volume of the tubing are suspected (e.g., patient’s blood pressure changes quickly and noticeably if a vasopressor infusion is affected by changes to the dead volume).

Results

Two issues associated with the proper management of dead volume that impact infusion accuracy were identified from the field study data. In addition to the inherent complexity of managing dead volume and the lack of detectability of a dead volume issue due to a lack of direct visual feedback, the 2 factors contributing to these issues are inadequate training of nurses about the management of dead volume, and IV tubing and connector design.

Issues

During the field study, 2 dead volume management issues were identified with the potential to lead directly to patient harm.

Changes in the flow rate of 1 infusion affects other connected infusions.

- Suboptimal positioning of infusions on a multi-port IV connector may delay the onset of medication therapy.

Changes in the Flow Rate of One Infusion Affects Other Connected Infusions

The impact of this issue is described in Table 18.

Table 18: Hazard Score and Patient Safety Risk—Changes in the Flow Rate of One Infusion Affects Other Connected Infusions

HFMEA Hazard Score	Patient Safety Risk
64	E: Delay/interruption in administering critical medication to the patient F: Bolus of incorrect fluid/medication administered

Abbreviation: HFMEA, Healthcare Failure Modes and Effects Analysis.

In scenarios in which multiple IV infusions are connected together before entering the patient, titrating, pausing, adding, or removing any one of those infusions may change the following:

- the total flow rate emerging from the dead volume to the patient
- the concentration of each IV agent in the dead volume

Therefore, modifications to an IV system in which multiple medications are being infused into the same IV line can have unpredictable effects on a patient, particularly when multiple changes are made and the concentrations of each IV agent in the dead volume have not stabilized. As more infusions are connected, the complexity and unpredictability of changes also increases.

A detailed visual example of the mechanics of the dead volume issue is provided in Figures 21 to 24. Suppose a medication (norepinephrine) and a hydration fluid (normal saline) are both being infused. While they are each individually controlled by an infusion pump and have their own tubing, they are connected to the same IV catheter via a Y-connector, and thus share the space in the bottom of the Y-connector and the catheter. Assume that the volume of shared tubing, including the access catheter or port, is approximately 2 mL before reaching the patient's bloodstream. The combined flow rate of the norepinephrine and normal saline is 56 mL/h (Figure 21).

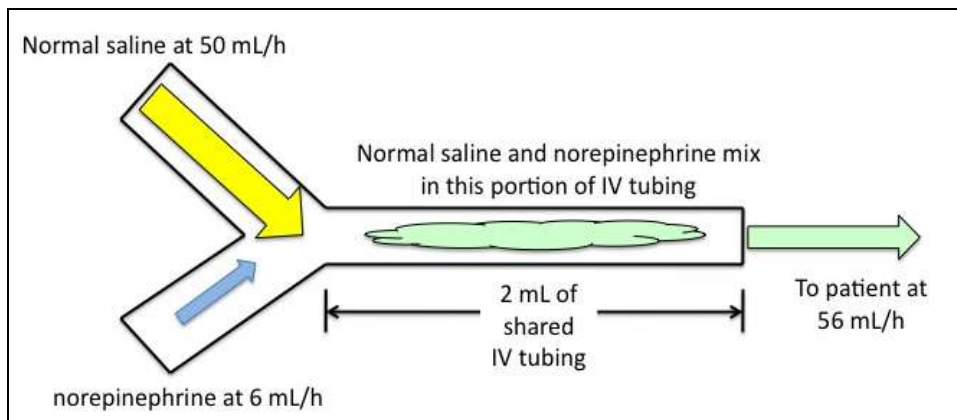


Figure 21: Normal Saline and Norepinephrine Infusing Through Y-Connector

Abbreviation: IV, intravenous.

If the normal saline is suddenly stopped, the flow rate of a residual mix of both agents is reduced to only 6 mL/h (Figure 22).

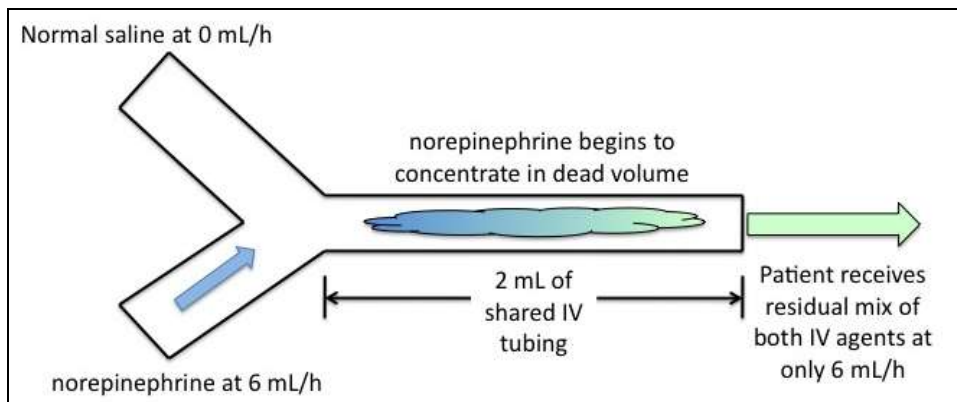


Figure 22: Normal Saline Stopped

Abbreviation: IV, intravenous.

Given the higher flow rate of the normal saline, the majority of fluid in the shared 2 mL space consists of normal saline. With norepinephrine continuing to infuse at 6 mL/h, it would take approximately 20 minutes for the norepinephrine pump to push the remaining fluid in the shared space before the desired flow rate of norepinephrine is consistently reaching the patient again (Figure 23).

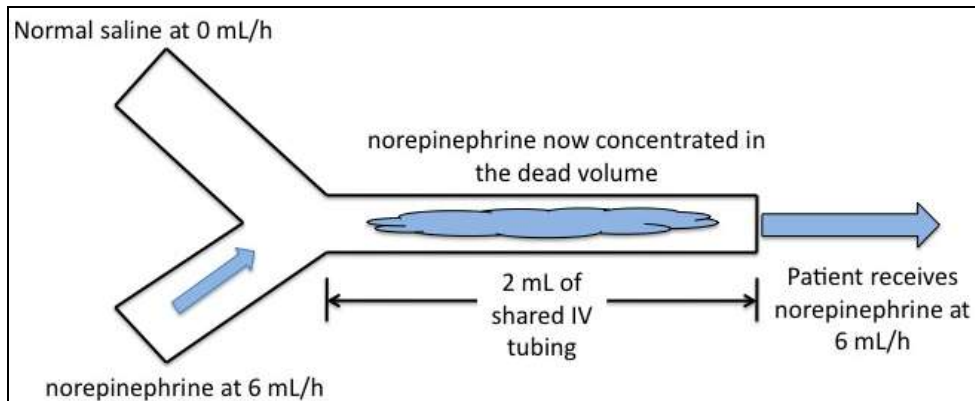


Figure 23: Norepinephrine Concentrates in Dead Volume Over 20 Minutes

Abbreviation: IV, intravenous.

Conversely, suppose that after the system has stabilized, the normal saline is restarted at 50 mL/h (Figure 24). In this case, the opposite effect will occur, with approximately 2 mL of norepinephrine that filled the shared tubing space quickly being administered in only 2.14 minutes as opposed to the intended 20 minutes. While the volume of this unintended bolus is small, the flow rate is nearly 10 times faster because of this change. After this amount of time, the system should return to steady state (Figure 21).

If the dead volume were increased (e.g., norepinephrine connected to an upper port, or extension tubing used below the Y-site), the bolus could be larger if sufficient time had elapsed for the dead volume to concentrate with norepinephrine while the normal saline was paused.

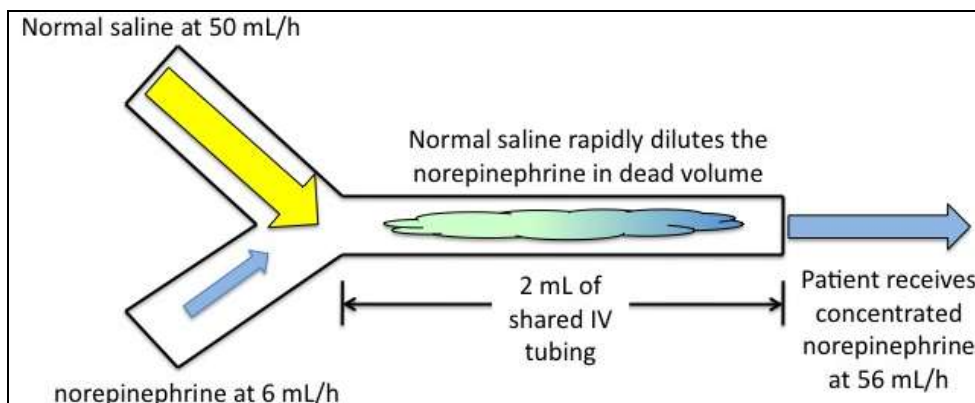


Figure 24: Normal Saline Restarted at 50 mL/h and Bolusing Dead Volume

Abbreviation: IV, intravenous.

As this example demonstrates, significant changes in flow rate can either delay or interrupt an infusion or administer an unintended bolus of a medication sharing the IV line.

While this example is simple (1 medication, 1 hydration fluid and a simple Y-connector), and nurses may be able to anticipate and mitigate issues associated with this set-up, many patients require more complex

set-ups, making it more difficult to predict the dead volume dynamics that will occur as changes are made to the system.

During the field study, there were no observations of unintended medication delays or boluses due to changes of flow rate affecting the contents of the dead volume; however, these types of issues are difficult to detect by observation. Observations of nurses’ unique individual strategies for managing dead volume are what uncovered this issue.

For example, various strategies to accomplish a tubing change (a regularly scheduled occurrence to prevent infection risk, usually every 72 hours in most institutions) were observed. When patients were hemodynamically unstable, nurses sometimes chose to set up, about an hour before conducting a line change, a separate set of infusion pumps with all of the patient’s current medications running. This practice helped to ensure that the concentration of the medications joined together in the new IV tubing was similar to that in the tubing they were intended to replace. Not all nurses in all field study sites used this strategy, and no formal guidance for managing dead volume during the tubing changes was identified in any of the sites. Another observed strategy for managing dead volume during line changes was priming the new tubing with the most critical medications last, to ensure that, after the new tubing was connected, the patient would immediately receive the most critical medication. The consequence of this strategy is that the other medications will be slightly delayed because they are staged further back in the tubing.

A second example of the need to manage perturbations in the dead volume of the system arose from the observation that different units had different levels of concern for minimizing dead volume. In a cardiac surgery ICU, a 4-channel infusion pump with a single tube output was used, which created a very large dead space, where all medications were mixing together as soon as they left the pump. Titrations of any infusion controlled by the pump would affect the administration of all medications in the line for an extended time until steady state administration was re-established. Conversely, in a pediatric ICU, IV connectors that split the IV tubing as close to the IV access port as possible were used, thereby minimizing dead volume.

The potential for this issue exists in all Ontario hospitals.

Suboptimal Positioning of Infusions on a Multi-Port IV Connector May Delay the Onset of Medication Therapy

The impact of this issue is described in Table 19.

Table 19: Hazard Score and Patient Safety Risk—Suboptimal Positioning of Infusions on a Multi-Port IV Connector May Delay the Onset of Medication Therapy

HFMEA Hazard Score	Patient Safety Risk
48	E: Delay/interruption in administering critical medications to the patient F: Bolus of incorrect fluid/medication administered

Abbreviation: HFMEA, Healthcare Failure Modes and Effects Analysis.

When multiple IV infusions are connected together, infusions at slower flow rates will take longer to pass through the dead volume than infusions at faster flow rates. Therefore, it is best to position medications with a short half-life or those requiring immediate administration as close to the patient as possible to minimize delays in IV therapy.

One common IV connector relevant to the positioning of the infusions is a bridge (or manifold). Bridges/manifolds are rigid IV connectors that accept multiple infusions (Figure 25). Three-way stopcocks were also used to serially join multiple infusions (Figure 26).



Figure 25: Three-Port Bridges at a Patient's Bedside



Figure 26: A Chain of Three-Way Stopcocks

The issue of suboptimal positioning can occur with these types of IV components. Figure 27 shows 3 infusions connected together with a multi-port connector. Infusion 1 must flow past a portion of the dead volume at its own slow rate before it mixes with the faster flow rate of infusion 2 and is then “carried” the rest of the way. Infusion 3 has the benefit of being downstream of infusion 2, and therefore is immediately pushed into the patient with less delay.

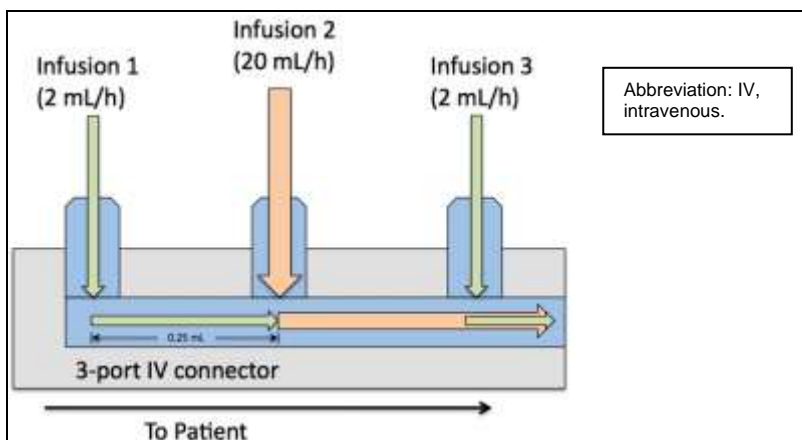


Figure 27: Suboptimal Positioning of Infusion Flow Rates on a Multi-Port Connector

During the field study, researchers identified this issue by noticing that most units set up an IV “chaser” infusion (also described as a “driver” or “carrier”); this was a maintenance fluid connected last in a series

of infusions so that it infused at a faster flow rate than the other connected infusions. Nurses offered the following reasons why chasers are beneficial:

- Chasers provide fluid volume, useful if the patient requires hydration.
- Chasers ensure IV line patency if the total IV output through the catheter is insufficient to maintain patency with the existing medications.
- Chasers help to “push” medications in the line through the dead volume.

Some nurses noted that the chaser should not be titrated or adjusted because of its impact on the dead volume (i.e., it could lead to delays or boluses of IV therapy); this suggests that some nurses are keenly aware of this issue. Secondary infusions should not be initiated on a chaser infusion for the same reason.

However, in some institutions, the chaser was stopped or disconnected if:

- the total fluid flow of the medications being infused was sufficient to ensure IV line patency
- the patient required a restriction of IV fluids

In situations where no fast-flowing chaser infusion is used to push slower medications into the patient, modifications to the connected infusions will take longer to manifest, because the dead volume of the IV connector must be cleared before steady state is re-established. For example, suppose the dead volume between infusion 1 and infusion 2 is 0.25 mL (see Figure 26). At its current flow rate of 2 mL/h, infusion 1 will require roughly 7.5 minutes (450 seconds) before it reaches infusion 2 and is carried the rest of the way at the higher rate of 20 mL/h. In contrast, if the locations of infusion 1 and infusion 2 were switched, it would take infusion 2 only about 45 seconds to progress through the same dead volume, reducing the onset of its administration by a factor of 10.

The potential for this issue was identified in all field study units with the exception of a general ward, where continuous multiple IV infusions connected together into 1 access port or device were uncommon.

Contributing Factors

The most relevant contributing factors responsible for the 2 dead volume issues are described in this section.

Inadequate Training on Dead Volume Management

In most clinical units treating adult patients, nurses had received little to no training on how to manage dead volume from either their formal nursing education or their hospital unit orientation. Nurses explained that dead volume was a concept they became more familiar through direct experience, or through observing more experienced nurses. In the majority of cases, nurses were not concerned about this issue because most adult patients can tolerate temporary IV medication fluctuations. One exception to this is patients who are critically dependent on a tightly controlled rate of blood pressure— and heart rate—altering medications, which generally require close monitoring and precise adjustments. Nurses were often initiated to the concept and importance of managing dead volume when managing these types of patients, in large part due to the real-time feedback offered by patient monitoring systems in response to changes made to the infusions.

However, in pediatric units, nurses tended to demonstrate a greater awareness of dead volume due to the tight control of fluid required for pediatric patient care. For example, 1 common practice in pediatric environments is to administer “secondary” medications by manually injecting medication from a syringe into the dead volume of the primary IV tubing and then programming a secondary infusion so that the pump will push the injected medication at the required rate and then return to the primary rate once it has infused. This minimizes the dead volume that needs to be cleared before the medication reaches the patient (i.e., the injected medication must pass only through the dead volume below the lower tubing port

site where it is injected, rather than through the additional dead volume between the highest and lowest tubing ports). In 1 pediatric unit, several nurses used this strategy based on their own discovery of its usefulness. In a neonatal environment, nurses administered secondary infusions in this way because it was the unit's standard practice. Nurses in the neonatal unit were explicitly supported in following this approach by being provided with a standard volume of secondary medication in a syringe intended for manual injection into the dead volume, and by being given standard infusion durations for infusion pump programming to ensure the entire dose was administered with a short flush.

This standard protocol does not address variations in tubing set-up, so it may not be optimal if additional tubing connectors or splitters are used. One nurse remarked that he or she would not alter the administration protocol if additional connectors were used. Therefore, while practices and policies are helpful, it is important that the principles underlying dead volume issues are well understood so that they can be applied to unanticipated situations and/or variations in IV tubing set-ups.

IV Tubing and Connector Design

Dead volume is a concern when multiple IV agents share the same tubing. Therefore, IV components with a greater-than-necessary dead volume exacerbate the issues described in this section. Components with smaller priming volumes (e.g., microbore tubing) reduce the dead volume that needs to be overcome when new infusions are started, and minimize the amount of IV agent that can be unintentionally administered to a patient at too high a rate.

Discussion

Dead volume management issues garnered a high hazard score because delays and unintended boluses of IV medication resulting from dead volume are hard to detect. Even when the infusion pumps are programmed correctly and all medications are connected to the correct IV components, unexpected boluses and delays of infusion therapy can still occur undetected. Dead volume issues often depend on the timing and sequence of infusion modifications, the type of medications infusing (e.g., onset of action and half-life), and the set-up of IV infusion tubing (which may vary between nurses and which affects the size of the dead volume itself). In addition, nurses often care for patients whose infusions have been previously set up by another nurse, and they are less likely to consider dead volume issues associated with the line set-up because so many other tasks are required at the start of a new shift. Since the dead volume considerations for every patient are unique, knowledge of the principles related to dead volume and a detailed understanding of any recent infusion changes are required for such issues to be identified and appropriately mitigated.

Dead volume issues present higher risks to pediatric patients, because their IV therapy tends to use slower infusion rates and sometimes high concentrations (due to fluid restrictions). As a result, delays can be extended and unintended boluses are more dangerous. Neonatal units mitigate extended delays to some degree by using microbore tubing.

Dead volume issues are prevalent in all Ontario hospitals. Therefore, experimental laboratory testing is the best strategy for identifying how changes in the IV system alter the concentrations in the IV line. The literature contains a number of experimental studies on the characteristics of dead volume, including the impact of the following:

- dead volume size (22;52-57)
- antireflux valves in IV systems (53;54)
- changes in carrier flow rate (i.e., chaser flow rate) (22)
- elasticity/compliance of IV tubing (58)
- manifold design and whether critical medications should be placed on the port closest to the patient in multi-port manifolds (57)

Given the reliance on infusion pumps to detect back pressure in IV lines and the importance of antireflux (back check) valves in IV connectors as demonstrated in the literature, it would be valuable if IV pump, tubing, and connector manufacturers continued to develop and design solutions for these issues. It remains critically important that IV infusion pumps also administer infusions at the continuous and constant rate for which they are programmed; otherwise, there will be an extended delay in creating a steady state output from the dead volume. The use of IV tubing and connectors with low elasticity and compliance is also likely to enhance the infusion pump's ability to detect high back pressure that could signify either pressure imbalances in the IV connector or downstream occlusions.

Recommendations

Based on a discussion of these findings with the members of the Multiple IV Infusions Expert Panel, no recommendations are proposed for implementation at this time. Further investigation of potential mitigation strategies will occur in Phase 2 of the research study.

Further Investigation Required in Phase 2

Phase 2 research will investigate which dead volume concepts should be included in formal nurse education programs and/or hospital orientation programs, based on the safety risks identified in this section. This is likely to occur within the Phase 2 work proposed in Summary of Issues Identified From Interviews With Nurse Educators, below.

Theme 5: IV Bolus Administration

Background

An IV bolus is a single dose of medication administered to rapidly produce a desired physiological effect. When a bolus of an IV medication already running as a primary continuous infusion is required to quickly increase the level of that medication in a patient's system, nurses have several administration options that may vary in terms of degree of safety; however, the researchers found no references comparing the relative safety merits of the various IV bolus methods.

Two particularly safe IV bolus administration options are the following:

- preparing an IV syringe with the bolus dose and administering the bolus as a manual IV push
- preparing an IV bag with the bolus and administering the bolus as a secondary infusion on an appropriate primary infusion line (i.e., a line running a maintenance fluid or other compatible, non-high-alert medication that can be temporarily stopped) (see Secondary Medication Is Connected to a High-Alert Primary Medication Infusion)

The contents of the primary infusion tubing (dead volume) will be flushed as the bolus is administered; therefore, the second method can only be safely applied to primary infusions that are not administering high-alert medications. However, both the IV push and secondary infusion bolus administration methods may require the nurse to leave the bedside to retrieve and prepare the medication, which may not be feasible if the patient's condition is unstable. Additionally, not all medications administered as a bolus can be prepared in syringes or IV bags (i.e., there is no dilution specified for bolus doses given in this manner), and in the case of drug shortages, it may be advantageous to bolus using the primary IV medication rather than preparing a separate IV container. In these situations, if the medication being bolused is already running as a primary continuous infusion, administering a bolus dose directly from the primary continuous medication IV bag may be the preferred option.

Three options for administering a bolus directly from the primary continuous medication IV bag are described below.

1. If the infusion pump provides a bolus feature, that feature can be used to define the bolus parameters and administer the infusion from the continuous IV medication bag. Smart infusion pumps with a bolus feature can be set up so that there are limits on the bolus dose. The risks associated with this bolus administration approach have not been studied, but may include
 - calculation errors if the infusion rate units in the bolus feature are inconsistent with the prescribed bolus rate units
 - programming errors due to suboptimal user interface design
 - primary infusion programmed outside the drug library to support administering a bolus using the pump (e.g., manually increasing the primary rate or programming the bolus as a secondary infusion) if the time to program the bolus using the dedicated bolus feature in the drug library is longer than nurses are willing to spend, given the workflow for that task
2. If the infusion pump does not provide a bolus feature and the pump allows a secondary infusion to be programmed on the primary infusion, the bolus parameters (infusion rate and total volume to be infused) can be programmed using the secondary mode (but without hanging a secondary IV bag). When the secondary infusion is started, the bolus dose will be administered from the primary bag. When the secondary infusion ends, the pump will revert back to the primary continuous infusion rate. The risks associated with this method of IV bolus administration have not been studied, but may include
 - calculation errors if the prescribed bolus units are inconsistent with the pump's infusion rate units for secondary infusions
 - programming errors due to suboptimal user interface design
 - incorrect volume remaining value for the primary infusion, since the bolus volume is not automatically accounted for by the primary infusion

Researchers observed this method of IV bolus administration being used by several nurses during the field study, but no formal guidance encouraging nurses to use this method was identified. As a result, some nurses who used this practice felt uncomfortable admitting that they chose this approach for fear of reprimand (see Case Study 5).

Case Study 5: Administering a Bolus Using the Secondary Mode

During a shadowing session, a nurse was asked if she had ever used the secondary mode to administer a bolus of a continuous primary medication. She indicated that she never had, and that the triple-channel pumps on her unit would not allow a secondary infusion to be programmed if the primary infusion was programmed using the drug library. The researcher pointed out that the single-channel pumps (also found in the unit) would allow a secondary infusion to be programmed even if the primary infusion were programmed using the drug library, thus enabling the use of the secondary feature to administer a bolus. The nurse responded by whispering, "You didn't hear that from me," indicating that she did do this sometimes but felt that it was an unsupported method of administering a bolus. Nurses at other organizations were very forthcoming about this practice and felt it was a safe approach.

3. A third way to administer an IV bolus from the primary continuous medication IV bag is to temporarily increase the rate of the primary infusion (e.g., to 999 mL/hr—the maximum rate for most infusion pumps without a hard limit), wait for a short period of time, and then lower the rate back to the original setting. The risks associated with this method of IV bolus administration have not been studied, but may include
 - the inability to precisely control the bolus dose
 - distractions or interruptions that can result in overdosing the patient (see Case Study 6)

Case Study 6: Administering a Bolus by Increasing the Primary Infusion Rate

During a shadowing session, a nurse described a past incident during which she was administering a bolus by programming the primary infusion to run at the fastest possible rate. She intended to specify a VTBI to limit the bolus; however, she became distracted by a patient across the hall who was self-extubating. She pressed the start button without changing the VTBI from the previously programmed value (entire bag volume); while she was assisting the patient across the hall, the first patient received a very large dose of morphine. The patient was not seriously harmed, but the nurse was so upset that she no longer administers bolus infusions by changing the primary infusion rate.

It is possible to limit the risks associated with this method of IV bolus administration by resetting the VTBI to the desired bolus volume; however, unlike using a bolus feature or the secondary mode, this step can be inadvertently omitted. In addition, the original nurse may not be the one to respond to the infusion pump alarm when the volume infused completes; another nurse may respond to clear and reset the VTBI (i.e., leaving the infusion rate at the bolus rate), resulting in the remainder of the continuous infusion infusing at the bolus rate. Depending on the type of medication infusing, and the patient's sensitivity to fluid overload, this type of overdose may be fatal.

During the field study, many nurses described this approach to administering a bolus as being too risky, and instead chose 1 of the alternative methods described above. In addition, when faced with infusion rate limitations in what is perceived to be an urgent or emergent situation, nurses may remove the IV tubing from the pump and bolus the medication by free flow, or in the case of a syringe infusion, remove the syringe from the pump and manually inject the syringe into the patient. In either case, overadministration of the total dose can easily occur.

Although programming errors are well documented in the literature, the researchers could not identify any studies that explicitly highlight the IV bolus administration issues described above. (5;7;59)

Results

Issues

During the field study, 1 IV bolus administration issue was identified with the potential to lead directly to patient harm: a bolus is administered by manipulating the pump settings on an existing primary continuous infusion.

A Bolus Is Administered by Manipulating the Pump Settings on an Existing Primary Continuous Infusion

The impact of this issue is described in Table 20.

Table 20: Hazard Score and Patient Safety Risks—A Bolus Is Administered by Manipulating the Pump Settings on an Existing Primary Continuous Infusion

HFMEA Hazard Score	Patient Safety Risk
48	A: IV medication/fluid running at the incorrect rate

Abbreviation: HFMEA, Healthcare Failure Modes and Effects Analysis; IV, intravenous.

During the field study, bolus administrations were observed using all 3 of the infusion pump manipulation methods described above. Nurses at sites with pumps that had a bolus feature used it; however, bolus features were not always enabled for every medication that nurses needed to bolus. At 1 site, the nurses perceived that administering a bolus using the secondary mode was unsafe, although they practiced this way because it saved time and was somewhat controlled. However, since they could not gain access to the secondary mode by programming the primary infusion using the drug library, the nurses chose to program

the primary infusion outside of the drug library (i.e., bypassing it) so that they could use the secondary mode to administer a bolus. This is considered risky, particularly for high-alert medications, because the primary infusion parameters are no longer verified against the safety limits identified by the hospital to minimize programming errors.

Contributing Factors

The following factors contribute to this issue:

- Not all infusion pumps (whether traditional or smart infusion pumps) have a bolus feature dedicated to supporting the administration of a bolus of a primary continuous infusion.
- The bolus feature on a smart pump is not enabled for every relevant medication, either because of the effort required to get consensus for the bolus administration limits or because of a lack of awareness that the bolus feature is needed for a particular medication, or both. These may be a lack of awareness of the practice implications that can emerge due to the lack of availability of this feature.
- Lack of familiarity with (or in some cases, complexity of) programming the bolus mode may lead to excessive amounts of time required to execute the programming sequence. This time requirement may exceed what nurses feel is reasonable.

Discussion

Of the 3 potential approaches to administering a bolus using an infusion pump, it is clear that increasing the primary rate or free-flowing the medication has the highest degree of risk compared to the other methods, and therefore should be avoided where possible. The implementation of smart pumps will help eliminate this practice, as typical bolus rates fall outside the primary infusion safety limits defined in the drug library. However, medications without hard upper limits are still susceptible to this issue. The relative safety merits of programming a bolus infusion using a dedicated bolus function appear to be greater than programming a bolus infusion using the secondary mode, but a detailed comparative analysis of the failure modes of each approach is required, taking into consideration the various design approaches of the bolus feature used by each manufacturer across all products; such an analysis is beyond of the scope of this analysis.

Recommendations

Based on the data collected in Phases 1a and 1b of this study, and on a detailed discussion with members of the Multiple IV Infusions Expert Panel, the following mitigating strategies for IV bolus administration issues are recommended for implementation:

1. Hospitals should develop a policy to limit the practice of manually increasing the infusion rate to administer a medication bolus of a primary continuous infusion. If a separate medication bolus cannot be prepared, and the bolus is administered using the primary continuous infusion pump/pump channel, then the nurse should program the bolus dose parameters (i.e., total amount of medication to be given over a defined duration) into the pump without changing any of the primary infusion parameters. Some examples of how to specify the bolus dose parameters include the following:
 - programming a bolus using a dedicated bolus feature in the pump (preferred, if available)
 - programming a bolus using the pump's secondary feature but without connecting a secondary IV bag (pump will draw the bolus from the primary IV bag)
2. Hospitals should ensure that their smart pump drug libraries include hard upper limits for as many high-alert medications as are appropriate for each clinical area, in order to prevent the administration of a bolus by manually increasing the primary flow rate.

Further Investigation Required in Phase 2

In addition to the recommendations described above, further guidance on IV bolus administration is required to help standardize the associated administration practices. The next phase of research will include a comparative study of various approaches to IV bolus administration to identify the safest technologies and processes for IV bolus administration. Efforts will be made to include tools or technologies that can be implemented by Ontario hospitals in the short-term, as well as design changes that should be included in the next generation of infusion technology.

Theme 6: Pump-Specific Issues

During the field study at all 12 sites, 4 different large-volume IV pumps, 2 different electronic syringe pumps, and 2 pumps that administer both large-volume and syringe infusions were observed to be in use (Table 21). A mix of traditional and smart infusion pumps were included. However, not all infusion pumps licensed and used in Ontario were observed in use at the field sites. In particular, use of the Hospira Symbiq smart pump, which has a growing market share in Ontario, was not observed; 2 of the field sites identified as Symbiq users had purchased them but had not yet implemented them.

Table 21: Pumps Observed in Use During the Field Study

Large-Volume Infusion Pumps	Syringe Infusion Pumps	Combined Syringe and Large-Volume Infusion Pumps
Smart Pumps		
Baxter Colleague Hospira Plum A+	—	Alaris System
Traditional Pumps		
Alaris IVAC/SE Gold Pump Graseby 3000	Baxter AS50 Syringe Pump Smith's Medical Medfusion 4000	Hospira Omni-Flow 4000

Pump design issues as they relate to the administration of multiple IV infusions were observed during the field study, and were reported to the research team by nurses. These issues are described in greater detail in Appendix 9.

Summary of Issues Identified From Interviews With Nursing Educators

The issues identified from the field study demonstrate that a high level of understanding is required to safely and accurately administer multiple IV infusions. In particular, nurses must be made aware of the known risks and how to manage them in patients with complex care needs. Interviews were conducted with nursing program coordinators from 8 Ontario baccalaureate nursing programs and 5 Ontario postgraduate CCNC programs, in order to address the following themes:

- Curricular concepts: What infusion therapy concepts are currently included in the curriculum?
- Curriculum development: What guides curriculum development with respect to infusion therapy?
- Curriculum delivery: What teaching tools or approaches are used to convey the principles of infusion therapy to nursing students?

The remainder of this section will present a summary of the findings of the interviews with baccalaureate educators and CCNC program educators.

Baccalaureate Nursing Degrees Programs in Ontario

Background

In 2005, the prerequisite for practice registration as a registered nurse (RN) in Ontario was changed to a baccalaureate degree in nursing, as opposed to the previous minimum requirement of a college diploma. (60;61) To support this change and enhance program accessibility to nursing students, partnerships called “collaborative baccalaureate nursing programs” were created between colleges, universities, and practice settings. (61;62) In other words, baccalaureate nursing programs are now offered at both college and university sites.

To qualify as an RN in Ontario, a student must complete a 4-year degree Bachelor of Science in Nursing (BScN) degree program, and then pass the licensing exam set by the College of Nurses of Ontario. (63)

Interview Sites

A total of 14 universities in Ontario are accredited to provide baccalaureate nursing education. (64) However, 22 colleges collaborate with those universities, for a total number of 36 Ontario institutions providing baccalaureate-level nursing training. The relationships between the colleges and universities is summarized in Table 22.

Table 22: Summary of Baccalaureate Nursing Degree Programs in Ontario

Ontario University	Ontario College(s) Collaborating With University
Brock University	Loyalist College
Lakehead University	Confederation College
Laurentian University	Cambrian College, Collège Boréal, Northern College, Sault College, St. Lawrence College of Arts and Technology
McMaster University	Conestoga College, Mohawk College
Nipissing University	Canadore College
Queen’s University	—
Ryerson University	Centennial College, George Brown College
Trent University	Fleming College
University of Ontario Institute of Technology	Durham College
University of Ottawa	Algonquin College, La Cité Collégiale
University of Toronto	—
University of Western Ontario	Fanshawe College
University of Windsor	Lambton College, St. Clair College
York University	Georgian College, Seneca College
University of New Brunswick ^a	Humber College

^aUniversity is not based in Ontario, but offers a collaborative nursing program with Humber College and therefore grants baccalaureate degrees to students in Ontario.

At least 1 institution from each collaborative group (i.e., each row of Table 22) was invited to participate in the interviews. Eight program representatives responded with interest during the allotted time frame for the interviews. Semi-structured interviews were conducted with program instructors from the following 8 colleges and universities:

- Algonquin College
- Centennial College
- Lakehead University
- Nipissing University
- Queen’s University
- Ryerson University
- Trent University
- University of Western Ontario

Curricular Concepts

According to our interviewees, the BScN program is intended to train students as “generalists” who could potentially work in any care environment. However, the opportunity exists for students to explore their areas of interest, such as long-term or acute care, when they choose their clinical placements. For example, students wishing to further specialize in critical care nursing would do so after graduating by receiving training through their employer or by taking additional courses or certification.

The theory and practice of IV medication administration is usually introduced during the second year of the BScN program, through a nursing fundamentals textbook, lectures, or both. One of the most commonly used texts in the BScN program in Ontario is Potter and Perry’s *Fundamentals of Nursing*. (65) Only 6 pages of the book are dedicated to the technical set-up and maintenance of all IV infusions. The section gives basic instructions for setting up simple IVs, including “piggyback” infusions and “tandem” infusions (i.e., concurrent, gravity infusions with 1 IV bag connected to lower Y-site port of an accompanying infusion). There is minimal discussion of IV bolus administration, except by manual IV syringe push; no discussion of dead volume management or related issues; no explanation of hydrostatics or how this concept can inform line set-ups; and no explicit discussion of infusion errors or how to prevent them.

At the BScN level, teaching the technical aspects of setting up and monitoring IV infusions generally includes the following:

- setting up IV infusion sets
- hanging a primary line
- monitoring infusions
- secondary infusions/piggybacking
- setting up tandem infusions
- being aware of compatibility of IV medications

None of the interviewees stated that there was any explicit safety training around preventing specific errors with multiple infusions, other than reminding students to “check” their work. Students may learn personal tips and tricks from specific instructors in their clinical placements, but there is no formal error-prevention training curriculum. Hydrostatics is not explicitly taught in any of the 8 programs. For example, students receive a basic explanation that the higher bag in a secondary infusion set-up infuses first because of gravity, but further explanation is usually not provided.

Furthermore, no BScN curricular content specifically addresses the topic of multiple IV infusions. None of the interviewees explicitly teach safety strategies for managing multiple IV infusions and preventing misconnections, other than a passing mention to “be careful not to misconnect.”

Curriculum Development

Findings from the interviews suggested that the BScN programs view the administration of multiple IV infusions as beyond their scope. One rationale provided was that patients requiring complex IV therapy are more likely found in critical care environments, and nurses working in such environments generally receive further training via formal programs (i.e., critical care nursing programs), orientation to the clinical unit, and work experience. The interviewees could not provide standards or guidelines with specific relevance to the administration of multiple IV infusions that impact BScN curricula.

In terms of general requirements, BScN programs must meet the standards of the Canadian Association of Schools of Nursing and the Postsecondary Education Quality Assessment Board in order to be approved by the College of Nurses of Ontario. (61;63;64) However, these standards appear to be more concerned with whether the structure of the program (e.g., governance, human resources, presence of qualified staff) is capable of maintaining high-quality educational standards, rather than with specifying the precise curricular concepts.

In addition, for the purposes of developing curricula, educators may refer to the list of competencies for the Canadian Registered Nurse Exam that all nurse graduates must complete to practice in Ontario. However, while universities and colleges may address some of the required theoretical content to pass the examination, no applied or practice skills are observed or assessed. A brief scan of the list of competencies determined that only 1 required competency explicitly makes reference to IV therapy, and is unlikely to be assessed in detail. (66)

Therefore, although BScN programs are provided guidance based on Canadian Association of Schools of Nursing and Postsecondary Education Quality Assurance Board standards, no readily available resources with a particular focus on the development of curricular content about multiple IV infusions appear to be available to educators.

Curriculum Delivery

In BScN programs in Ontario, learning takes place in classroom, self-directed, laboratory, and clinical settings, but the combination varies depending on the program. More classroom learning tends to occur in the early years, with more hands-on and clinical exposure during the later years. However, some programs have little or no in-class teaching or laboratory work. Clinical experience involves rotating through different clinical areas under the supervision of a college- or university-employed supervisor. Students learn primarily via observation and discussion. “Preceptorship” takes place in year 4: students are assigned one-on-one with a preceptor (a registered nurse) and have the opportunity to play a role in patient care.

There is significant variation in how the technical aspects of IV infusions are taught. At 1 extreme, students may go straight from self-directed learning to a clinical placement without demonstrations, lectures, a chance to practice in a laboratory environment, or any structured evaluation of skills. At the other extreme, students may receive lectures, demonstrations, and extensive hands-on training with high-fidelity simulated patient scenarios and a subsequent technical evaluation before they enter their clinical placement. The instructor for a program with the latter structure said that many students fail the evaluation the first time because the skills are so challenging to learn.

Other programs fall between these 2 extremes. Some programs include hands-on training on infusion pumps, whereas others do not teach this explicitly because of the variation in makes and models of pumps

found in the various facilities and health regions. This means that students in some programs have their first exposure to pump programming in the clinical setting.

Some interviewees described general differences between programs in colleges and universities, but researchers did not find these differences to be generalizable. For example, a few interviewees said that colleges tend to be more “technical” and universities more “theoretical” in their focus, but that some university programs have very strong technical components and some colleges have very strong theoretical components.

In terms of approaches to student evaluation, the programs interviewed vary widely; there is no standard approach to student evaluation, either in the classroom or in clinical placement settings. While BScN students are under clinical supervision, they are monitored informally and may not be tested explicitly. Instructors observe students and try to focus on identifying areas for improvement. The postgraduation Canadian Registered Nurse Exam is the only universal test of knowledge of IV theory and practice in Canada. However, because it is a written multiple-choice test, testing technical competency is impossible. According to the interviewees, the exam does not tend to have questions about preventing errors related to the administration of multiple IV infusions.

CCNC Programs in Ontario

Background

An initial scan of the postgraduate CCNC programs in Ontario revealed that 9 institutions were currently offering programs at the time of writing. The majority of CCNC programs are offered as part-time (PT) programs. Only 3 programs offered full-time (FT) enrolment, and 2 programs delivered all theoretical course requirements online. A summary of the program structure and delivery for the 9 CCNC programs is shown in Table 23. The data in this table were reported by the colleges during the interviews or gathered online for colleges that did not participate in the interview process.

Table 23: Ontario Institutions Offering a Postgraduate CCNC Program

Institution Name	Full-Time	Part-Time	Online Courses	Average Time to Complete	Total Clinical Practicum Hours
Algonquin College		✓	✓	1 year	120
Centennial College		✓	✓	2.5 years	240
Conestoga College		✓	✓	Information not provided	120
Durham College			✓	1 year	120
George Brown College	✓		✓	14 weeks	240
Georgian College		✓		8 months	100
Humber College	✓	✓		Full-time: 11 weeks Part-time: 2.5 years	Full-time: 188 Part-time: 96
Mohawk College			✓	2 years	84
Seneca College	✓			12 weeks	180

Abbreviation: CCNC, Critical Care Nursing Certificate.

Based on the program information available online, the programs appear to have similar structures, consisting of both theoretical modules and a clinical practicum component. Also, most programs have access to a simulation laboratory. However, from the initial scan, it is not clear whether practice in a simulation laboratory is compulsory or optional.

Interview Sites

All 9 active CCNC programs in Ontario were invited to participate in the interviews. Five colleges elected to participate, and semi-structured interviews were conducted with program instructors from each of the following:

- Centennial College
- Durham College
- George Brown College
- Georgian College
- Humber College

Curricular Concepts

The interviews highlighted the fact that many principles of multiple IV infusion therapy are not formally and explicitly taught in CCNC programs. However, content on IV medication administration and the administration of multiple IV infusions is integrated into classroom discussions (e.g., critical thinking and problem-based class discussions) within the context of how to treat patient conditions specific to critical care. Generally speaking, content focuses primarily on medications used for infusion therapies, medication calculations, and medication compatibility.

An important assumption that was conveyed by the interviewees is that students should already have received training on how to set up IV infusions from their baccalaureate training and/or their clinical practice in the field. Infusion set-ups are considered to be nursing fundamentals and are not specific to critical care training.

Interviews with the CCNC programs centred around specific topics related to the administration of multiple IV infusions that are not covered in the baccalaureate program. A summary of how each topic is taught within the CCNC program curriculum is discussed below.

Secondary Infusions (Large-Volume IV Bag Infusions)

The interviews revealed that program instruction on secondary infusions is not taught formally, because it is perceived to be either a skill taught in the BScN programs or material that each hospital should teach during unit orientation, or both. It is, however, discussed with the students during critical thinking scenarios. Instructors focus on medication calculations rather than on the set-up and programming of the pump. The rationale for this is that different hospitals use different pumps. The clinical practicum and/or simulation laboratory more commonly cover pump programming and management (e.g. priming the pump, titration, which port to use, primary vs. secondary), but this varies depending on the training program.

Managing Dead Volume

Based on the interview data, responses were mixed. Critical thinking exercises are used to review titration principles, delays in medication onset, hemodynamics, and their resulting impacts on the patient. These exercises may be presented as scenarios or case presentations. Program instructors may provide additional instruction regarding dead volume if a question arises. Some educators instruct nurses to “remember the space in the tubing,” and that when the nurse changes the rate, it will bolus the remaining medication in the line. Also, most program instructors encourage nurses not to infuse a medication through a port on the central venous pressure (CVP) line, if possible, to avoid unintentional bolusing of the dead volume when zeroing the line. Therefore, it appears that instruction about dead volume management occurs during critical thinking exercises or if a question arises in class. It is not clear from the interviews if the concept is reviewed during practice in the clinical practicum component or whether all of the characteristic scenarios that require an awareness of dead volume are taught.

Administering an IV Bolus

Based on the interview data, it appears that programs do not engage in formal discussions of either bolus administration methods or the relative safety risks associated with each method (e.g., increasing the rate on a primary infusion, using the secondary mode on the pump to administer a bolus from the primary IV bag, hanging a separate IV bag as secondary infusion for bolus purposes, giving a manual IV push). A few program instructors mentioned that they do not use pumps to administer a bolus and were not aware of the bolus feature on some pumps. Therefore, students are most likely to learn bolus administration methods if the topic emerges during class discussions, during a simulation scenario (i.e., a student raises a question about bolusing), or during a clinical practicum. As a result, it is unlikely that the various bolus administration options and relative safety merits of each are taught in detail.

Line Management and Labelling

Line Set-Up

Most interviewees indicated that, although line set-up procedures and concepts could be introduced in the classroom, it is much easier to demonstrate them in context. Thus, practicing line set-up skills is encouraged in the clinical practicum component, although the specific opportunities are highly variable and dependent on protocols across hospital sites. In classroom discussions, the teaching focuses on the principles and concepts of medication management (e.g., medication compatibility, medications that must go centrally, the size of the port) rather than on line set-up approaches. In 1 program, the educator stated that they always teach IV line set-up as a task that needs to be completed 1 infusion at a time, but this was not described by other interviewees and is not likely a standard curricular concept.

Line Tracing

All program instructors encouraged individual nurse accountability for medication management, and stressed that it is the nurse's duty to perform double-checking, including line tracing, at the bedside. A general description of the need to trace lines from the bag label to the patient is reviewed. However, the potential failures associated with line tracing are not addressed. Instruction on line tracing is primarily done at the bedside during the clinical practicum and/or simulation (where available).

Line Changes

Approaches to minimizing down time when conducting line changes are not formally taught; however, strategies to minimize the interruption of critical continuous infusions during line changes are often shared. Safety considerations, such as the order in which line set-up tasks should be completed to minimize line mix-ups, are not taught. Most programs teach nurses to set up new lines well in advance of a line change (complete with labelling) to help with the process of changing them all at once.

Connectors and Components

Most program instructors use hands-on demonstrations to review the differences between, for example, manifolds, stopcocks, triple lumen catheters, and 3-way stopcocks. However, instructors did note that this is difficult to teach in a generalized manner since the equipment varies across hospital sites.

Labelling

Instruction on information requirements for labels occurs in the classroom and is reinforced at the bedside during the clinical practicum. Most program instructors review the need for nurses to label the tubing with the medication name; however, individual labelling procedures are established by each hospital site and therefore vary. Instructors stress the need for nurses to follow hospital labelling protocols and therefore do not indicate best practices for how to label the tubing, teach how to adhere the label to the tubing, or indicate which safety considerations must be taken into account. Labelling may also be discussed during critical-thinking exercises (e.g., the need to cope with many lines or incidents that can occur) and is often covered during a clinical practicum, a simulation, or both.

Shift Handover (Transfer of Accountability)

With regards to shift handover, specific information requirements provided in the handover report are usually reviewed at the bedside during the clinical practicum component. In 1 program, the additional simulation component also assesses handover report competencies. However, the need to include specific types of information to support the administration of multiple IV infusions is not routinely stressed.

Curriculum Development

All CCNC programs use the *Standards for Critical Care Nursing in Ontario*, published by the Ontario Critical Care Secretariat, (67;68) to inform the curriculum development of CCNC programs. The *Standards* document describes critical care nursing competencies based on the *Standards of Nursing Practice* of the College of Nurses of Ontario and the Canadian Association of Critical Care Nurses. (68) These standards comprise 5 categories, each with associated competencies, criteria, or performance behaviours. A few interviewees stated that the *Standards* document contains only broad criteria related to infusion therapies. Based on this feedback, the researchers performed a brief scan of the competencies and criteria, and found the following reference relating to infusion therapies:

Category 5: Clinical Skills, Knowledge, Integration, and Critical Thinking

- Criterion 14.9 states “The critical care nurse intervenes to correct alterations in cardiac output by
 - (14.9.1) manipulating preload/afterload (e.g., fluids, pharmacologic agents);
 - (14.9.4) troubleshooting invasive hemodynamic parameters;
 - (14.9.7) initiating and managing fluid therapy.” (68)

Researchers also scanned the document for safety concepts relating to infusion therapies and found the following statement:

Category 3: Client and Nurse Safety/Risk Prevention

- Criterion 4.1 states “the critical care nurse incorporates safety measurements for the patient, family, and members of the health care team when developing the plan of care.” (68)

Therefore, the findings suggest that while *Standards for Critical Care Nursing in Ontario* is an essential resource to guide curriculum development, more specific criteria related to infusion therapy concepts, particularly safety strategies for managing multiple IV infusions, are required. (68)

Curriculum Delivery

Theoretical Modules

Most programs are flexible in terms of how the theoretical part of the curriculum is delivered. Courses may be offered in the classroom or laboratory, entirely online, or in a hybrid format that combines classroom tutorials with online sessions. One program offered an e-learning online program for all theoretical modules. Variation exists in the total number of theoretical modules/courses required and the total number of hours required per module/course. A scan of the course outlines reveals that modules focused on body systems and course titles were not standardized across all programs. A scan of the textbook listings also revealed variation.

In general, minimal detail was included in the curricula about the risks associated with the administration of multiple IV infusions. For example, a brief scan of the *Critical Care Nursing: Diagnosis and Management, 6th Edition* textbook (69) revealed 1 reference to an infusion pump safety issue; it appeared on page 402 in a patient safety alert box with a short description of an IV incident. It describes a case involving the free flow of IV solution and discusses its implications, along with a list of safety organization websites available for further information.

Simulation Laboratory

Based on the interview data, the majority of CCNC programs have access to a simulation laboratory. However, it is not clear whether simulation laboratory practice is optional or required in some of the programs. Only 1 program lists a simulation course in its course listing.

Clinical Practicum

A clinical practicum is a compulsory requirement for all of the programs. The assignment of students to a hospital critical care unit is coordinated by the college, and can reflect a student's (or employer's) request, when possible. Generally speaking, the assignment of students to clinical placements is easier for FT programs due to their direct affiliation with participating hospitals, many of which sponsor and/or refer students to the college. PT programs do not usually have a direct hospital affiliation, and graduates go on to work at 1 or more of many different hospitals spread over a wide geographical area. One main advantage of the FT programs, then, is the higher number of hours included in the clinical practicum compared with PT programs. A few programs attempt to integrate the weekly content taught in the theoretical module into the practice hours in the accompanying clinical practicum, as a means of reinforcing theoretical concepts. One FT program includes conference sessions during the clinical practicum (i.e., educator-guided discussions with nursing students about specific cases and observations occurring on the unit).

Both PT and FT programs offer clinical placements. However, FT programs tend to offer these more frequently with the sponsoring critical care units, giving students the opportunity to reinforce their classroom learning with clinical experience. This approach is available in the FT programs because of the close partnership between the college and the critical care units that have hired the nurses (and paid for their training). A liaison between the college and the hospital strives to ensure that nurse-trainees are exposed to the most appropriate patients to support their recent classroom learning. PT programs are not partnered with a particular hospital unit and tend to have only 1 clinical placement that occurs at the end of the program. This placement is not well integrated into the overall program. In both the FT and PT clinical placements, students are evaluated in terms of the required nurse competencies set out by the *Standards for Critical Care Nursing in Ontario*, as interpreted by the educating college. (68)

Discussion

Educational instruction on the technical aspects of administering and managing multiple IV infusions begins in the undergraduate BScN programs, when students are taught to be “generalists” who could potentially work in any care environment. Based on the content of the texts used to support classroom learning, the administration and management of multiple IV infusions is not covered in detail. Key theoretical concepts that may help students understand patient safety risks (e.g., hydrostatics, approaches to IV bolus administration) are likely not covered at all.

Postgraduate CCNC programs also do not formally teach the key principles for administration and management of multiple IV infusions, based on the assumption that fundamental infusion skills are taught in the BScN program; CCNC educators may not be reviewing infusion fundamentals in the context of complex IV therapy for this reason. However, BScN programs are more likely to focus on single infusion set-up fundamentals rather than practices for multiple infusions, which they consider to be beyond their programs' scope. The mistaken belief that skills applicable to single infusion set-ups easily transfer to complex, multiple infusion set-ups may leave nurses unprepared to handle multiple IV infusion set-ups. For example, concepts such as line set-up and labelling (which may be covered in BScN education or learned while working in noncritical care areas) are relatively straightforward in single infusion set-up scenarios, but are considerably more complex when multiple infusions are required. The increase in number of pumps, visual clutter, medication compatibility concerns, diverse venous access devices, and presence of high-alert medications present challenges that basic infusion skills cannot address.

Moreover, our interview data revealed that, in the instances where content about the administration and management of multiple IV infusions is provided, it is usually part of a classroom discussion because a student has asked a specific question based on his or her clinical experience or because the instructor has initiated a “case-based discussion” to prompt a critical-thinking session. Most of the IV infusion content in CCNC programs focuses on high-alert IV medication administration (particularly inotropes and vasoactive medications), dosage calculations, and medication compatibility. It also includes discussions about “treatments” for different conditions seen in a critical care areas, rather than about concerns related to the administration and management of multiple IV infusions. Students are not made aware of known patient safety risks associated with the administration of multiple IV infusions, nor are they systematically taught formal error-prevention strategies to use when administering multiple IV infusions.

Interview findings revealed variations in program delivery, modes of instruction, course offerings, and number of hours devoted to theoretical and clinical components. These differences tend to relate to whether the course is offered FT or PT. The advantages of FT programs include the reinforcement of concepts with embedded clinical practicums, allowing students immediate opportunities to apply concepts most recently taught in the classroom and discuss concerns when they return to the classroom. In addition, the FT program is structured in such a way that clinical practicum leaders are aware of the concepts recently taught in the classroom and can provide relevant learning opportunities. Conversely, in the PT and online programs, clinical experience tends to be concentrated towards the end of the program, giving nurses exposure to many important concepts and types of patients all once.

The evidence suggests, therefore, that the potential exists to improve current education in both the baccalaureate and postgraduate settings with respect to multiple IV infusion administration and management concepts, particularly those associated with known patient safety risks.

Further Investigation Required in Phase 2

Researchers identified several areas for improvement stemming from the nursing education interviews. During Phase 2, efforts will be made to advance nursing education to better prepare nurses for administering multiple IV infusions. Specifically, the following activities will be conducted:

- identify key stakeholders responsible for creating, implementing, and enforcing nursing education standards in Ontario
- propose a committee made up of key stakeholders from governmental, professional, and regulatory agencies to:
 - identify key concepts that should be provided to nursing students at the baccalaureate and postgraduate levels and during in-hospital orientation programs
 - identify and update relevant standards with new IV therapy content
 - raise awareness of new curricular concepts
 - seek support from accreditation agencies to reinforce the need for delivery of new concepts
 - assess students during simulated and/or clinical practice

Conclusions

The administration of multiple IV infusions to a single patient is a complex task with many potential associated patient safety risks. The observation and interview data collected in Phase 1b of this study has highlighted varying degrees of awareness of these risks by nurses, hospital administrators, educators, regulators, and technology vendors; few systematic efforts have been implemented to reduce the risks.

Improvements to infusion and infusion-related technology, education standards, clinical best practice guidelines, hospital policies, and unit work practices are required to reduce the risk potential.

This report has made several recommendations to Ontario hospitals so that they can develop an awareness of the issues highlighted in this report and minimize some of the risks. However, further investigation of mitigating strategies is required and will be conducted in Phase 2 of this research. Accompanying the completion of Phase 2 will be a final report summarizing all relevant recommendations based on the current data and additional knowledge gained during Phase 2.

Glossary

Bolus	A 1-time or intermittent dose of IV fluid or medication given to rapidly achieve a physiologic effect (see Principles of Infusion Therapy, IV Bolus Administration).
Bridge	Alternative terminology for a Manifold .
Buretrol	A type of infusion container that holds limited quantities of IV fluids or medications to minimize the impact of free-flow or rate-related errors. IV fluids are attached above the buretrol and refilled manually as the volume decreases. Buretrols are used primarily in pediatric settings, because the impact of free-flow and rate-related errors can be more severe than in adult patients.
Call-back alarm	A feature common to large-volume infusion pumps that alerts nurses to the completion of a secondary infusion.
Central venous catheter	A short tube inserted into a large vein in the patient, which allows IV fluids/medication to be infused directly into the patient's bloodstream. Central venous catheters are placed close to the superior or inferior vena cava, or to the right atrium of the heart, where a large volume of blood can dilute the contents of the infusion(s). Fluids/medications are rapidly distributed throughout the body because of their immediate uptake by the heart.
Central venous pressure line	An IV line connected to a central venous catheter that facilitates the use of a pressure-monitoring transducer.
Concurrent infusions	The administration of 2 or more infusions simultaneously, each at its own flow rate, through the same IV line. Each infusion must be individually controlled by its own infusion pump or pump channel.
Continuous infusion	An infusion administered on an ongoing (continuous) basis. Some patients require a constant intake of fluids for hydration, and therefore have a continuous, maintenance infusion started (see Maintenance line).
Chaser	See Maintenance line .
Dead volume	The total volume of the catheter and all associated IV tubing and connecting components from the point where 2 or more IV fluids/medications meet up until they reach the patient's bloodstream.
Dose Error Reduction System (DERS)	A software feature found in "smart" infusion pumps that contains a library of medications and concentrations for nurses to select from when administering IV infusions. Each medication and concentration is associated with dosing limits, so that nurses are warned or prevented from starting the infusion if the dose exceeds the limits. The drug library and its associated dosing limits can be tailored to different clinical care areas and their unique requirements.

Drug-dose calculator	A feature common to large-volume infusion pumps, in which nurses enter parameters such as the concentration, intended dose, and volume to be infused such that the infusion pump calculates the correct flow rate for the infusion.
Head height differential	The distance between the fluid height of 2 IV containers. This term is commonly used to refer to the distance between the fluid level in a secondary infusion container and the fluid level of the primary infusion container.
High-alert medications	Medications that bear a heightened risk of causing significant patient harm when they are used in error.
Intermittent infusion	An infusion administered on a periodic basis. For example, an intermittent infusion of antibiotics may require a short IV dose to be administered every 8 hours. Typically, each dose is contained in its own IV bag.
Intravenous (IV)	Means “within vein.” Any equipment prefaced with the term <i>IV</i> refers to its intended use for administering fluids or medications intravenously (e.g., IV infusion pump).
IV agent	Any fluid or solution intended to be administered to a patient via the IV route; may include hydration fluids, blood and blood products, total parenteral nutrition, IV medications, IV chemotherapy, or others.
IV tubing	A tubular pathway for IV agents to travel from 1 location to another.
Large-volume infusion pump	A programmable device that controls the rate and volume of an infusion. Large-volume infusion pumps can control the flow of IV agents from containers of various sizes, provided the containers are hung above the pump such that gravity encourages them to flow towards the pump.
Line/IV line	A pathway for IV agents to enter a peripheral or central venous catheter. In some cases, catheters may consist of multiple lumens (see Triple-lumen catheter) so that several IV agents can infuse through the same catheter without mixing until they reach the bloodstream; each of these lumens is considered a separate IV “line.”
Luer lock	A “push and twist” connector system that allows IV components to securely connect together (e.g., IV tubing, catheters, syringes). Screw-like threads and the precise tapering of the male/female ends facilitate a tight fit between the components.
Lumen	The tubular space inside IV tubing or catheters in which IV agents can flow and be contained. Some IV catheters have multiple lumens (e.g., see Triple lumen-catheter).
Manifold	A rigid IV component with multiple ports that facilitates the joining of multiple IV components together. Manifolds usually possess only 1 lumen, so all connected infusions mix together.

Maintenance line	A line reserved for maintaining hydrating or line patency, often used to “push” or “carry” the contents of other infusions connected downstream, thereby minimizing variations in dead volume concentration and ensuring the patency of the IV catheter. This line is sometimes also referred to as a Chaser .
Med line	A maintenance line reserved for the coadministration of medication.
Peripheral IV (PIV) line	An IV line connected to a peripheral venous catheter.
Peripheral venous catheter	A short tube placed into a patient’s vein somewhere other than his/her chest, abdomen or femoral vein. Veins in these areas tend to be smaller and farther from the heart than central venous catheters, and they carry smaller volumes of blood.
Piggyback infusion	See Secondary infusion .
Primary infusion	An infusion connected directly to an infusion pump via primary IV tubing (i.e., not connected via a medication port).
Primary IV tubing	IV tubing intended for use with a primary infusion. Primary infusion tubing (primary infusion “sets”) designed for large-volume infusion pumps typically features a Y-site upstream of the connection to the pump where secondary IV tubing can be connected. Primary IV tubing intended for syringe pumps typically does not feature Y-sites.
Secondary infusion (commonly referred to as piggyback infusion)	An infusion designed to temporarily interrupt the primary infusion so that a second IV fluid/medication can be attached and flow through the primary IV tubing. This process requires a separate programming sequence on the infusion pump to control the secondary infusion. When the secondary fluid/medication has infused, the primary infusion resumes at the appropriate flow rate (see Principles of Infusion Therapy, Secondary Infusions).
Secondary IV tubing	IV tubing intended for use with a secondary/piggyback infusion. This tubing tends to be shorter than primary IV tubing.
Smart infusion pump	An electronic infusion pump equipped with a DERS . A central element of all smart pumps and their DERS software is the ability to provide nurses with an alert when specific dosing limits are exceeded during the infusion programming process. Smart pumps may offer the ability to display clinical advisories (depending on the infusion programmed), communicate wirelessly with a pump server, and record timestamp logs of programming keystrokes. Smart pumps may also employ barcode and/or radio frequency identification technology to reconcile medication, patient, nurse, and prescriber order information.
Syringe pump	An electronic or mechanical device that administers the contents of a syringe at a controlled flow rate.

Three (3)-way stopcock	An IV connector that joins 3 IV tubes together (usually 2 infusions joining into 1). It is functionally similar to a Y-site, with the added functionality of being able to stop the flow of 1 of its connections with a handle.
Triple-lumen catheter	A catheter that has 3 lumens, or tubes, inside the catheter. This allows 3 different pathways for IV agents to infuse without interacting until they reach the patient's bloodstream. The lumens exit the catheter at different points inside the patient's vein, minimizing immediate mixing once they leave the catheter.
Vesicant	An IV agent that can cause severe chemical burns and tissue necrosis.
Volume to be infused	The volume of fluid or medication that is intended to be administered to the patient.
Y-site	A luer lock entry point into IV tubing. Due to the fact that it protrudes from the IV tubing at an angle, the combination of 2 IV tubes into 1 resembles the letter Y.

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Appendices

Appendix 1: Members of the Multiple IV Infusions Expert Panel

Table A1: Members of the Multiple IV Infusions Expert Panel

Name (alphabetical)	Expert Panel Role	Organization Represented
Lisa Burry	Pharmacy and Hospital Representative	Canadian Society of Hospital Pharmacists
Pam Cybulski	Nursing Representative	Canadian Association of Critical Care Nurses
Brenda Dusek	Nursing Representative	Registered Nurses Association of Ontario
Tony Easty	Expert Panel Chair	Health Technology Safety Research Team
Patrick Fandja	Regulatory Representative	Health Canada
Kim Greenwood	Hospital Representative	Council of Academic Hospitals of Ontario
Dr. Chris Hayes	Safety and Hospital Representative	Canadian Patient Safety Institute
Christine Koczmar	Safety and Nursing Representative	Institute for Safe Medication Practices Canada
Dr. Bob Lester	Hospital Representative	Ontario Hospital Association
Bronwen McCurdy	Liaison to Health Quality Ontario	Health Quality Ontario
Mitra Nadjmi	Risk Management Representative	Health Insurance Reciprocal of Canada
Kim Newcombe	Nursing Representative	Canadian Vascular Access Association
Kim Streitenberger	Pediatric Nursing Representative	The Hospital for Sick Children
Jeannette Van Norden	Oncology Nursing Representative	Juravinski Cancer Centre
Past Members		
Ilhemme Djelouah	Regulatory Representative	Health Canada
Dr. Jennifer Sarjeant	Hospital Representative	Ontario Hospital Association
Dr. Bill Shragge	Expert Panel Co-Chair	Ontario Health Technology Assessment Committee
Fannie St-Gelais	Regulatory Representative	Health Canada

Abbreviation: IV, intravenous.

Appendix 2: Field Study Interview Questions

General Unit

1. How many beds are on your unit?
2. What type of administrators manage the unit (e.g., registered nurse [RN] manager, resource nurse, continuous quality improvement manager, infusion specialist, physician lead, RN educator)?
3. What are the 24-hour staffing levels (nursing and pharmacy staff, physicians)?
4. Do you use agency staff?
5. What patient population is served by the unit?
6. What kind of intravenous (IV) access do most patients have?

Medication Administration Process

Prescribing

7. Who prescribes the medications?
8. Can you think of any medications that are routinely given by IV on your unit that could be safely and effectively administered using another route? If so, why are they traditionally administered via IV?

Ordering

9. What are all the ways in which medication orders are placed (e.g., electronic, paper, preprinted orders, verbal)?
10. Do orders specify titration ranges, or do nurses titrate freely (how is the range specified on the order; does it need to be specified by a physician)?

Mixing

11. Which medications do nurses mix on the unit?
12. Where are medications stored?
13. Which medications come from the pharmacy?
14. Do you have a single, standardized concentration for all high-alert medications, such as narcotics, sedatives, anesthetics, adrenergic agonists, vasoactive medications, heparin, insulin ... see Institute for Safe Medication Practices Canada list)?
15. Do you have a single, standardized concentration between the operating room (OR), intensive care unit (ICU), and general wards for all high-alert medications?
16. If standardized concentrations between the OR and ICU are not used, what do nurses do when a patient transfers and is receiving an infusion at a different concentration than the unit standard?

Verifying

17. Are any double-checks required from a second nurse when doing tasks related to medication administration (e.g., mixing medications, pump programming)?

Documenting

18. Who generates the medication administration record (MAR)?
19. How/when is the MAR updated?

Training/Education

20. What training are nurses given at your institution when they are hired to work in the ICU?
21. When are nurses taught to use the specific features of your IV infusion pumps (e.g., during hospital orientation, unit orientation)?

22. How are nurses initially trained on the specific features of your IV infusion pumps (person-person, one-on-one, group, on-unit, off-unit, hands-on, hands-off)? How is competency assessed?
23. How and how often are nurses given refresher training on the specific features of your IV infusion pumps?
24. When are nurses taught how to hang secondary infusions (e.g., during hospital orientation, unit orientation)?
25. How are nurses taught to hang secondary infusions (e.g., informally by preceptors, during IV pump training)?
26. What are nurses taught in terms of the required height differential between a primary and a secondary bag?
27. Do nurses receive any training on medication transit time delays (e.g., dead volume delay when IV bag concentration is doubled, variable chaser flow rate, flush volume after secondary infusion completes)?

Secondary Infusions

28. What does the term *secondary infusion* mean to you? What does the term *piggyback infusion* mean to you?
29. Do nurses ever run primary infusions as secondary infusions due to lack of pump availability? For other reasons?
30. What IV medications/fluids are given as secondary infusions? How often?
31. Do you allow medications to be piggybacked onto a primary infusion of a high-alert medication (e.g., could potassium be piggybacked onto insulin)?
32. Can medications requiring titration be hung as secondary infusions on your unit?
33. Do you have any written policies surrounding the set-up and administration of secondary infusions?
34. Do you have any tools in routine use that help nurses determine if a secondary bag is hanging at the correct height relative to the primary bag?
35. Do nurses use hangers when setting up secondary infusions? Are there any policies regarding the use of hangers to ensure a proper bag height differential?
36. Based on your experience, what are some of the dangers associated with the set-up and administration of secondary infusions? In your opinion, have smart infusion pumps helped address the safety issues associated with secondary infusion administration?
37. If no secondary feature were available on your pump, how would you administer medications currently given as secondary infusions? What would be the benefits/drawbacks of administering fluids in this way vs. via a secondary infusion?
38. Does your institution require that new secondary tubing be used every time a new secondary medication is hung?
39. Are you aware of any incidents related to forgetting to unclamp the secondary line?
40. Are you aware of any incidents related to secondary bags being hung at the incorrect height relative to the primary bag?
41. Are you aware of any incidents related to secondary IV medications being administered too rapidly (either by gravity or with the use of pumps)?
42. Are you aware of any incidents related to the primary infusion being run at the rate intended for the secondary, or vice versa?
43. Are you aware of any incidents related to administration of a secondary solution that was incompatible with the primary solution?
44. Do all of your primary IV infusion sets have back check valves to prevent fluid from the secondary line from backing up into the primary line? Or are nurses required to clamp the primary tubing to prevent back flow and return to unclamp it when the secondary bag has completed?

45. Are you aware of any incidents in which a secondary infusion line was accidentally connected to the wrong primary tubing set (i.e., a secondary infusion was run via a pump other than the one programmed to run the secondary)?
46. Do your pumps allow nurses to set the device to sound a call back alarm to signal that the secondary infusion is complete and that it needs to be switched to the primary (as opposed to automatically switching from secondary to primary when piggyback completes)?
47. Are nurses permitted to use the secondary mode feature to administer a bolus of the primary medication? Are there any restrictions, guidelines, policies, or general work practices related to this action?
48. Do errors related to secondary set-up/administration usually get documented? If yes, how so?

Line Diagnosis

49. Is there a standard protocol for how information is exchanged at the transfer of accountability (i.e., at shift handover)?
50. How is this protocol communicated to nurses?
51. Is covering another nurse during his or her break considered a transfer of accountability?
52. Is there a standard protocol for how information is exchanged when a nurse is going on break and another is covering?
53. Are there any commonly used strategies for organizing the set-up to make it quicker and easier to identify the contents of each line, which bag/pump it is connected to, and which patient access site it is connected to (e.g., pump label, type of pump, lumen colour, patient access, bank of pumps)?
54. Can you think of anything that would help make this task quicker or easier?
55. Do you know of any issues related to the misidentification of lines (e.g., disconnecting the wrong tubing, accidentally connecting incompatible tubing)?

Pumps

56. Which pumps are used to administer IV therapy on the unit?
57. How many channels does each type of pump have?
58. Are there any restrictions in terms of what medications are administered by each type of pump (e.g., medications requiring titration not on syringe pump)?
59. How do pumps travel between the OR and the ICU environment?
60. What issues do you have with your pumps currently in use?

Tubing Labels

61. When would you expect nurses to label IV tubing?
62. Do you think nurses on this unit label IV tubing accordingly?
63. Do you know of any incidents related to incorrect, misinterpreted, or absent tubing labels?
64. Where along the tubing are labels usually applied, and why (i.e., closest to connection port, above pump)?
65. What information do you think should be on the tubing label (e.g., medication name, concentration, access)?
 - a) Is this mandated?
 - b) For any specific medications?
 - c) How is it mandated?
66. What process do you expect nurses to follow to ensure that the tubing is labelled correctly (e.g., line tracing, reading pump label, memory)?
67. What tools (i.e., stickers) do people use to label med lines?
 - a) Are they used exclusively/consistently?

68. What tools are used to label all other drug tubing?
a) Are they used exclusively/consistently?

Pump Labels

69. How are pumps labelled (tape, pump screen via drug library)?
70. Why are pumps labelled externally?
71. Are there any standard practices for which information should be included on a pump label?
72. Have you observed any inconsistency between nurses in terms of how pumps are labelled?
73. Is there a standard notation used to describe the information on the label?
a) If yes, how are nurses oriented to this notation?
74. If pump labels need to be altered, are nurses required to create a new pump label, or can they amend the existing label (e.g., during imaging)?
a) Do you feel there are risks associated with this approach?
75. Is there a policy or standard work practice describing who is responsible for removing pump labels and when this should be done?

IV Tubing

76. What is the protocol for how often the following need to be changed?
- primary tubing
 - secondary/piggyback tubing
 - central line catheters
 - peripheral IV catheters
 - connectors to the central line (e.g., Y-connector at cordis)

Set-Up of Multiple Lines

77. How does a nurse determine whether additional IV access is required?
78. Are there any barriers or obstacles to getting additional patient IV access as required?
79. If more patient IV access is required but is not available, what do nurses do?
80. What physical components are used to connect multiple IV lines going into a single patient access (e.g., stopcocks, 3-port manifold, 6-port bridge)?
81. How do nurses determine which physical components to select when connecting a series of lines (assuming they have several connector options)?
82. How do nurses know/decide where to connect a medication line(s)
a) to an already complex line set-up?
b) when multiple new lines are being set up for a new patient?
83. What risks do nurses have to manage when deciding where to add another line?
84. Are nurses encouraged to physically separate classes of medications by lumen or by access to make it easier to keep track, or for other clinical reasons (e.g., medication compatibility, line organization)?
85. Is there anything you have to be concerned about when running a medication at a slow rate? What medications are usually affected?
86. Is there a standard volume rate for plain IV lines used to maintain a steady flow of other medications into the patient?
87. Is it common practice to use a gravity infusion to maintain a steady flow of other medications into the patient?
88. Do you ever experience unintended breaks/disconnections and/or leaks with IV tubing or junction components?
a) How common is this?

89. Do nurses often work together during the set-up of new IV lines? If so, do they divide IV tasks between staff? How (e.g., 1 primes, the other programs the pump)?
90. Have there been situations where IV tubing was either too long or too short?
91. When a nurse must administer 2 or more IV medications, what would you expect him or her to do in terms of the order of steps (e.g., hang all medications first, then connect each to pump, program and label the line and pump)?

Appendix 3: Field Study Shadowing Guide

General

- How do nurses organize their lines to keep them “tidy”?
- What things make it easier or harder to keep track of all the infusions that are running?

Ordering

- Is every intravenous (IV) medication prescribed for the patient absolutely required by IV?
- Is there an alternative safe and effective route of administration?
- Why is IV preferred?

Setting Up/Programming Any New Primary Infusion

- What medications are programmed in volume rate vs. dose rate?
- When is the drug library *not* used (e.g., when hanging a secondary, when medication is perceived to be low-risk, when volume rate programming required)?
- How did the nurse determine where to connect the line in relationship to the other lines running?
- What connectors are used to join multiple IV lines (i.e., stopcocks, manifolds)?
- Are there any rules about when to use/not to use a certain type of connector?
- Does the pump programming sequence have any inappropriate default values?
- Are any programming guides used?

Setting Up/Programming a Secondary Infusion

- How do nurses determine the appropriate head height differential (do they use any tools or do they “eyeball” it)?
- What medication is being administered as the secondary infusion?
- Is the secondary medication a medication that may need to be titrated?
- Is the secondary infusion a bolus of the primary fluid?
- What risk factors would contribute to attaching the secondary tubing to the wrong primary line?
- Does the pump programming sequence have any inappropriate default values?
- Are the primary and secondary infusions running in the same units? Were the units specified in the drug library?

Setting Up Multiple Concurrent Primary Infusions

- Are the tasks of spiking, priming, hanging, programming, attaching, labelling, unclamping, and starting across all required medications done in sequence? One medication at a time? Done in batch by task?

Labelling

- Are there any issues with physically adhering the lines?
- Are there any issues with the visibility of labels?
- Are there any issues with the legibility of labels?

Pumps

- Are the pumps labelled? If so, with what?
- If the pumps are not always labelled, what prompts the nurses to label them?
- At what point in the set-up sequence are pumps labelled (i.e., immediately after hanging each medication, or at the very end as a batch task)?
- What information is on the pump label? Is this consistent across nurses?
- When are pump labels removed? By whom?
- Did you observe old labels still adhered to a pump being set up for a new infusion?
- Is there anything about the interface that increases the likelihood of programming errors?
- Are there any issues with the display of information about multiple infusions on 1 screen?

Med Line

- Are the med lines labelled? If so, with what?
- If the med lines are not always labelled, what prompts the nurses to label them?
- At what point in the set-up sequence are the lines labelled?
- What information is included on the med line label?

Drug Tubing

- Is the drug tubing labelled? If so, with what?
- If the drug tubing is not always labelled, what prompts the nurses to label the tubing?
- What information is included on the drug tubing label?

Getting Additional Patient Access

- What prompted the nurse to request (for central lines) or insert (for peripheral IV lines) additional patient access?
- Was it possible to connect using existing access?

Central Access Lines (e.g., Cordis, Triple Lumen)

- What colours are associated with each lumen (e.g., brown, white, blue)?

Line Tracing

- When do nurses trace the line from bag to patient access?
- Why are they tracing the line?
- How do nurses trace the lines?

Line Changes

- How all new lines are set up (i.e., task analysis)?

Patient Transfers (from Operating Room or Other Unit)

- Were pump switches required?
- Were new medication bags required? Why (e.g., different concentration of medication on new unit)?

Transporting Patients to Imaging

- Any IV line–related concerns (e.g., must free up/obtain PIV access)?

Handoffs

- What information about IV lines is communicated at break coverage?
- What information about IV lines is communicated at shift handover?

Appendix 4: Structural Hierarchy of Concerns With the Potential to Cause Patient Harm

The structural hierarchy is a diagram composed of 6 rows that signify the various decision-making authorities, actors, and components of the health care system, namely:

- government
- professional practice and technology regulators
- organization
- management
- staff and patient activities
- equipment and surroundings

Concerns and outcomes are represented as boxes in the diagram. For example, the central element of the diagram is “Patient Harm,” and is found at the “Staff and Patient Activities” level of the system. All other concerns or characteristics of the health care system represented in the structural hierarchy contribute to this outcome. A detail of the hierarchy is shown in Figure A1.

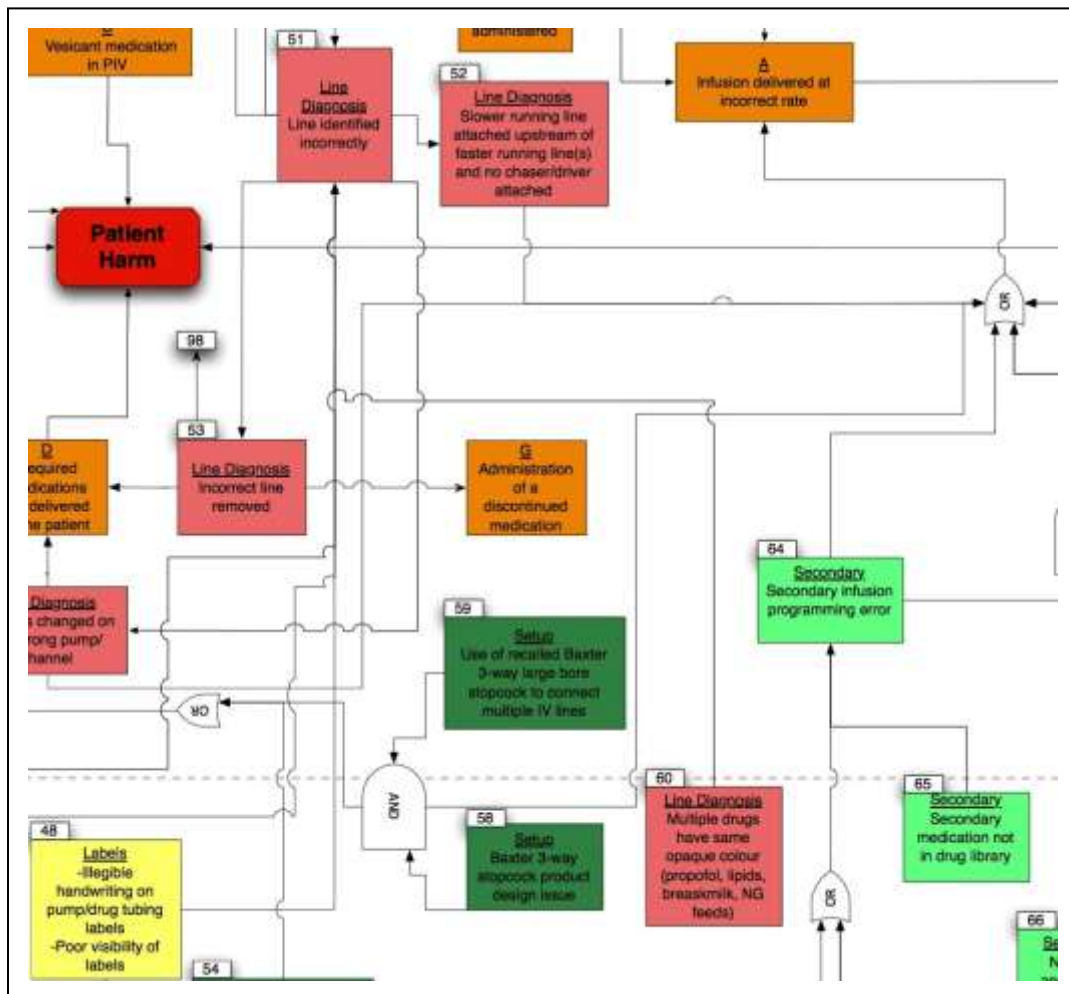


Figure A1: Structural Hierarchy—Detail

Abbreviations: IV, intravenous; NG, nasogastric; PIV, peripheral intravenous

To demonstrate the use of the structural hierarchy, an example can be provided based on the pathways shown in Figure A1, above. On the lower right, a green box represents the issue “Secondary medication not in drug library.” An arrow emerges from box #65 and connects it to box #64, “Secondary infusion programming error” (see Theme 1: Secondary Infusions, Secondary Infusion Programming Error Occurs). Box #64 then connects through an operating room connector before reaching Box A, the patient safety risk “Infusion delivered at incorrect rate.” Box A then connects to “Patient Harm” (not visible in Figure A1).

The structural hierarchy was used to identify and analyze the cause-consequence relationships between various issues observed during the field study. By visually relating the different concerns, a more thorough analysis of the relationships between components of the health care system became possible. The full hierarchy is shown in Figure A2.

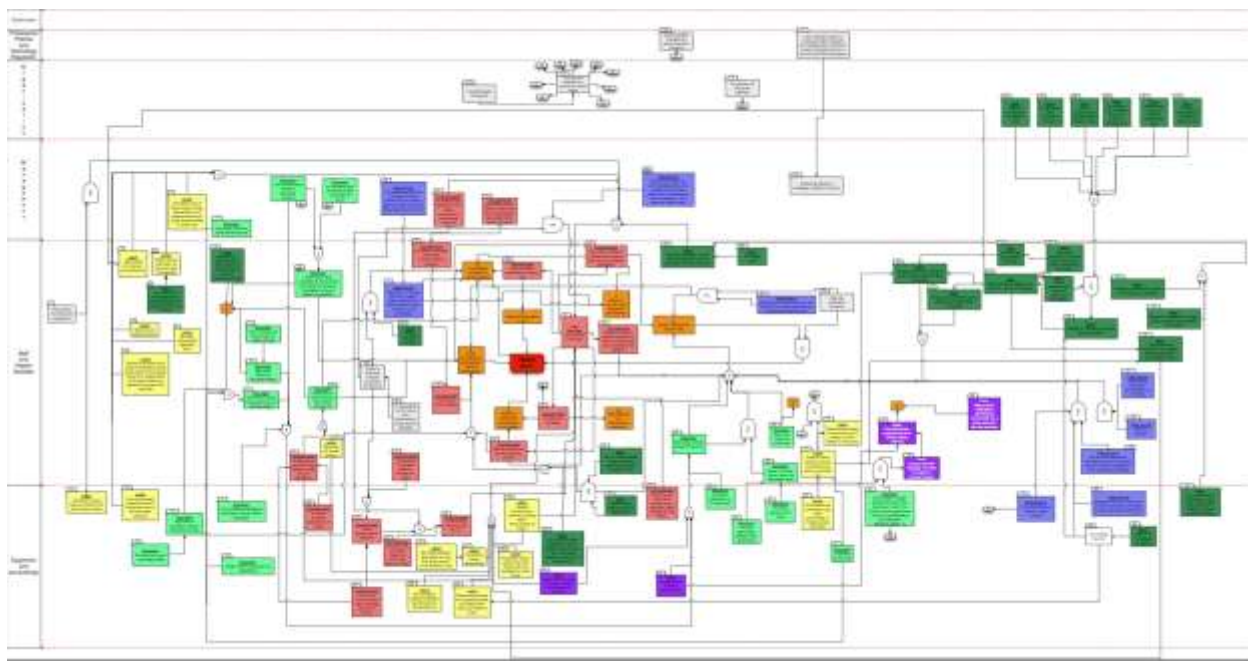


Figure A2: Structural Hierarchy—Full Version

Appendix 5: Semi-Structured Interview Questions— Baccalaureate-Level Nursing Programs

General Questions About the Nursing Program

- Are technical aspects of intravenous (IV) infusion administration taught in the classes of your nursing program?
- Is your nursing program more theory- or practice-based?

Nursing Curriculum Regarding IV Infusions

- Please provide an overview of curriculum related to IV infusions.
- Is there a difference between infusion-related curricula for different programs (e.g., registered nurse [RN] vs. registered practical nurse [RPN])?
- How is competency evaluated regarding infusions within the RN and RPN programs?

Secondary (Piggyback) Infusions

- Are secondary infusions covered? If so, how are they taught?
- How is infusion pump training incorporated into this?
- What mitigation strategies are taught in your curriculum to prevent secondary infusion errors?

Multiple Infusions

- Are multiple infusions covered? If so, how are they taught?
- How is infusion pump training incorporated into this?
- What mitigation strategies are taught in your curriculum to prevent multiple infusion errors?

Detailed Questions (if time available)

Secondary/Piggyback Infusions

- Is the secondary clamp/port discussed?
- Is the correct height of the secondary infusion discussed?
- Are hydrostatics taught?

Infusion by Other Routes of Administration

- What other routes of administration are taught?
- Are methods of teaching similar to teaching IV medication infusions?
- Are students ever expected to work with patients with 2 or more infusions via multiple routes?
- What safeguards are in place for students to prevent mix-ups?

Physical IV Infusion Set-Up

- Is back-priming the standard way to flush between secondary IV meds when administering secondary infusions?
- What types of infusion sets are used and discussed (e.g., buretrols, back check valves, vented sets, noninjection tubing, blood tubing)?
- Is the appropriate volume of the IV bag discussed (e.g., for primary maintenance infusions, for secondary infusions)?
- Is labelling of lines/pumps/other components discussed?

Multiple Infusions

- Is there any discussion on:
 - where to place the pumps?
 - how to manage multiple pump modules?
 - how to manage IV set-ups using additional connectors?
- Are various connectors used and their differentiation taught (e.g., luer locks, sizes, colours, 3-way stopcocks, double/triple Y-connectors, adaptors)?
- Are there strategies in place to prevent misconnections between infusion lines and other components?
- Is a plain line always set up, regardless of whether it is needed to infuse immediately?
- Are students taught how to initiate a new infusion with existing infusions and a single access port?
- Are students taught mitigation strategies to manage/avoid mix-ups between lines?
- Is there a way to manage/avoid tubing spaghetti?
- Given the immense variability in the field, is there any approach nurses are taught or can be taught in school?
- Do you teach any technologies in your curriculum to prevent line misconnections and mixing up infusion lines?

Infusion Workflow

- What troubleshooting is taught regarding IV and other infusions (e.g., looking at the drip rate, checking the clamps, dealing with occlusion alarms, bag volume, patient symptoms)?
- Are gown changes taught? How?
- Are complete changes of infusions taught?
- Are tubing and infusion bag changes a required skill?
- How do nurses work together as a team to set up or maintain multiple infusions? Is this practised in school?
- Are double-checking procedures for shift change taught? For other times?
- Are there any specific risks or challenges that you prepare your students for when infusing secondaries, a maintenance IV, or other infusions?
- Does the introduction of smart pumps change your infusion training curriculum in any way?
- Is an infusion or vascular access specialty program or certificate available at your school?
- Are there any other advanced certificates in IV therapy?
- Does this certification include any content regarding the administration of multiple infusions?

Appendix 6: Semi-Structured Interview Questions— Postgraduate Critical Care Nursing Certificate Programs

Information About the Program

1. What is the name of the program?
2. How long has the program been offered? In its current form? What changed?
3. Part-time/full-time?
4. Program structure (e.g., courses offered, simulation, preceptorship)
5. How often is the course offered?
6. How many students per session?
7. Where does your funding come from?
8. Cost for each student?
9. With which hospitals are most of your students affiliated?
10. Which guidelines inform your program development?

Course Materials

11. What texts/course wares are used?
12. Could we have a copy of the course outline?
13. What courses deal with IV therapy management?

Infusion Management Concepts

Secondary Infusions (Large Volume Bag Infusions)

14. Required height differential between primary and secondary bags:
 - a) How much space is required between bags?
 - b) Why this is necessary?
 - c) How is this information conveyed to students?
 - d) Where do nurses demonstrate their understanding of this?
15. The importance of the tubing being taut between the bag and the pump:
 - a) Why is this necessary?
 - b) How is this information conveyed to students?
 - c) Where do nurses demonstrate their understanding of this?

Bolus Doses (All Pump Types)

16. Is any instruction given on how to safely administer a bolus dose:
 - a) via IV syringe push?
 - b) via an infusion pump?

Labels

17. Drug tubing labels:
 - a) When should labels be applied?
 - b) Where should labels be applied?
 - c) What can registered nurses do to ensure labels are visible?
 - d) What information should be included on a drug tubing label?
 - e) How is this information conveyed to students?

- f) Where do nurses demonstrate their understanding of this?

Line Set-Up and Managing Dead Volume

18. When multiple concurrent infusions are infusing into the same line, what happens when the rate of one:
- Increases?
 - Decreases?
 - How is this information conveyed to students?
 - Where do nurses demonstrate their understanding of this?
19. When connecting multiple compatible medications to the same line in series, what factors should be considered when determining the order in which they are arranged (e.g., compatibility, medications that must go centrally, the need to reserve a push port for emergency meds, the need to keep all lines patent)?
- How is this information conveyed to students?
 - Where do nurses demonstrate their understanding of this?
20. Infusing medications via a transduced central venous pressure line:
- What medications are safe/unsafe?
 - What concerns should the students be aware of?
 - How is this information conveyed to students?
 - Where do nurses demonstrate their understanding of this?
21. If a potent medication (e.g., inotrope) is connected to a Y-connector and then removed, how should the Y-connector line be handled afterwards?
- How is this information conveyed to students?
 - Where do nurses demonstrate their understanding of this?
22. When connecting multiple new IV lines at 1 time, are registered nurses instructed to connect each one separately or to combine similar tasks?
- How is this information conveyed to students?
 - Where do nurses demonstrate their understanding of this?

Line Tracing

23. What information should a nurse obtain when tracing a line from patient to bag?
24. When should a nurse trace his or her lines?
25. What procedure should be followed when tracing a line?
26. How is the information in questions 23–25 conveyed to students?
27. Where do nurses demonstrate their understanding of questions 23–25?

Line Changes

28. What process should be followed when completing a line change for all the lines running?
29. What strategies can be used to minimize the interruption of life-sustaining/critical continuous infusions during line changes?

Connectors/Components

30. What is the difference between a 1-way and a 3-way stopcock?
31. When is it appropriate to use each type of stopcock?

Appendix 7: HFMEA Hazard Scoring Matrices and Results

Table A2: HFMEA Scoring Matrices

Rating	Likelihood
1	Remote = the error may happen within the next 5 years
2	Uncommon = the error is likely to happen within the next 2–5 years
3	Occasional = the error is likely to happen within the next 1–2 years
4	Frequent = the error is likely to happen within the next year
Detectability	
1	No checking process is required to help detect the error
2	A checking process is required to help detect the error, but this process is not well defined and relies on human vigilance
3	The error is not detectable based on current standards for knowledge/experience
4	The error cannot be detected by any reasonable human process
Severity	
1	Minor = the error results in no harm, or the potential harm is unknown
2	Moderate = the patient is temporarily harmed by the error
3	Severe = patient is permanently harmed by the error
4	Critical = the error causes the patient's death

Abbreviation: HFMEA, Healthcare Failure Modes and Effects Analysis.

Table A3: HFMEA for Multiple IV Infusion Field Study Data

Issue #	Failure Mode	Effects	Ratings			
			Like-lihood	Detect-ability	Severity	Hazard Score
1	Changes in the flow rate of 1 infusion affects other connected infusions	E: Delay/interruption in administering critical medication to the patient F: Bolus of incorrect fluid/ medication administered	4	4	4	64
2	Residual volume in the connector is not identifiable when a medication is disconnected from a multi-port connector	B: Incompatible medications running together E: Delay/interruption in administering critical medication to the patient F: Bolus of incorrect fluid/ medication administered G: Administration of a discontinued medication/fluid	4	4	4	64
3	Secondary medication is connected to a high-alert primary medication infusion	F: Bolus of incorrect fluid/ medication administered	3	4	4	48
4	Secondary medication is a continuous infusion of a high-alert medication	A: IV medication/fluid running at the incorrect rate E: Delay/interruption in administering critical medication to the patient	3	4	4	48
5	Suboptimal positioning of infusions on a multi-port IV connector may delay the onset of medication therapy	E: Delay/interruption in administering critical medication to the patient F: Bolus of incorrect fluid/ medication administered	4	3	4	48
6	Insufficient bag head height differential between primary and secondary infusions	E: Delay/interruption in administering critical medication to the patient F: Bolus of incorrect fluid/ medication administered	4	3	4	48
7	Line set-up information related to critical medication is not formally communicated at shift handover	E: Delay/interruption in administering critical medication to the patient	4	3	4	48
8	A bolus is administered by manipulating the pump settings on an existing primary continuous infusion	A: IV medication/fluid running at the incorrect rate	4	3	4	48
9	IV bag and infusion pump are mismatched	A: IV medication/fluid running at the incorrect rate B: Incompatible medications running together C: Vesicant medications administered via a peripheral IV line E: Delay/interruption in administering critical medication to the patient	4	2	4	32

Issue #	Failure Mode	Effects	Ratings			
			Like-lihood	Detect-ability	Severity	Hazard Score
10	Infusion pump settings changed on the incorrect pump	A: IV medication/fluid running at the incorrect rate D: Required medications not being administered to the patient E: Delay/interruption in administering critical medication to the patient F: Bolus of incorrect fluid/ medication administered G: Administration of a discontinued medication/fluid	4	2	4	32
11	Intermittent medication is injected into the dead volume of the incorrect infusion line	A: IV medication/fluid running at the incorrect rate B: Incompatible medications running together E: Delay/interruption in administering critical medication to the patient F: Bolus of incorrect fluid/ medication administered	2	4	4	32
12	Secondary infusion programming error occurs	A: IV medication/fluid running at the incorrect rate	4	2	4	32
13	Secondary tubing is connected to the wrong port along the primary tubing	E: Delay/interruption in administering critical medication to the patient F: Bolus of incorrect fluid/ medication administered	4	2	4	32
14	Secondary IV tubing remains clamped after the secondary infusion has started	A: IV medication/fluid running at the incorrect rate E: Delay/interruption in administering critical medication to the patient	4	2	4	32
15	Secondary IV tubing is connected to a primary infusion set with no back check valve	A: IV medication/fluid running at the incorrect rate E: Delay/interruption in administering critical medication to the patient	4	4	2	32
16	Infusion pump does not support the administration of a secondary infusion on a primary line programmed using the drug library	A: IV medication/fluid running at the incorrect rate	4	2	4	32
17	Leaks can occur with the use of 3-way stopcocks	E: Delay/interruption in administering critical medication to the patient	4	2	4	32
18	Incorrect IV fluid/medication tubing removed	E: Delay/interruption in administering critical medication to the patient G: Administration of a discontinued medication/fluid	3	2	4	24

Issue #	Failure Mode	Effects	Ratings			
			Like-likelihood	Detect-ability	Severity	Hazard Score
19	Two lines with a very large pressure differential between them that are controlled by 2 separate pumps connected via a Y- connector	E: Delay/interruption in administering critical medication to the patient	2	3	4	24
20	Secondary IV bag is connected to an incorrect primary line	A: IV medication/fluid running at the incorrect rate B: Incompatible medications running together C: Vesicant medications administered via a peripheral IV line E: Delay/interruption in administering critical medication to the patient	3	2	4	24
21	A new medication is connected to the incorrect line	B: Incompatible medications running together C: Vesicant medications administered via a peripheral IV line F: Bolus of incorrect fluid/ medication administered	3	2	3	18
22	Poor flow rate accuracy when using a multi-input single-output pump is problematic when running concurrent critical meds	A: IV medication/fluid running at the incorrect rate	1	3	2	6

Abbreviations: HFMEA, Healthcare Failure Modes and Effects Analysis; IV, intravenous.

Appendix 8: Contributing Factors for Each Issue

Contributing Factors for Secondary Infusion Issues

Table A4: Contributing Factors—Secondary Medication Is Connected to a High-Alert^a Primary Medication Infusion

Contributing Factors		
First Level	Second Level	Third Level
Inadequate training and education on managing multiple IV lines	Lack of guidance from professional bodies on multiple line management concepts or risks in RN training programs	—
Too few pumps available on the unit	Procurement selection process results in a product that does not meet clinical needs	Budget constraints for medical device procurement

Abbreviations: IV, intravenous; RN, registered nurse.

^aThe Institute for Safe Medication Practices defines high-alert medications as “drugs that bear a heightened risk of causing significant patient harm when they are used in error.” (8)

Table A5: Contributing Factors—Secondary Medication Is a Continuous Infusion of a High-Alert^a Medication

Contributing Factors		
First Level	Second Level	Third Level
Inadequate training and education on managing multiple IV lines	Lack of guidance from professional bodies on multiple line management concepts or risks in RN training programs	—
Too few pumps available on the unit	Procurement selection process results in a product that does not meet clinical needs	Budget constraints for medical device procurement

Abbreviations: IV, intravenous; RN, registered nurse.

^aThe Institute for Safe Medication Practices defines high-alert medications as “drugs that bear a heightened risk of causing significant patient harm when they are used in error.” (8)

Table A6: Contributing Factors—Insufficient Bag Head Height Differential Between Primary and Secondary Infusions

Contributing Factors		
First Level	Second Level	Third Level
Some secondary IV hangers are not long enough for long IV bags	—	—
Inadequate training and education on managing multiple IV lines	Lack of guidance from professional bodies on multiple line management concepts or risks in RN training programs	—

Abbreviations: IV, intravenous; RN, registered nurse.

Table A7: Contributing Factors—Secondary Tubing Is Connected to the Wrong Port Along the Primary Tubing

Contributing Factors		
First Level	Second Level	Third Level
Unnecessary port on primary tubing just below the pump	Procurement selection process results in a product that does not meet clinical needs	—
Lack of experience setting up secondary infusions	—	—

Abbreviation: IV, intravenous.

Table A8: Contributing Factors—Secondary IV Tubing Remains Clamped After the Secondary Infusion Has Started

Contributing Factors		
First Level	Second Level	Third Level
Over-reliance on human memory	—	—

Abbreviation: IV, intravenous.

Table A9: Contributing Factors—Secondary IV Tubing Is Connected to a Primary Infusion Set With No Back Check Valve

Contributing Factors		
First Level	Second Level	Third Level
Procurement selection process results in a product that does not meet clinical needs	—	—
Inadequate storage of infusion sets with and without back check valves to prevent mix-ups	—	—

Abbreviation: IV, intravenous.

Table A10: Contributing Factors—Infusion Pump Does Not Support the Administration of a Secondary Infusion on a Primary Line Programmed Using the Drug Library

Contributing Factors		
First Level	Second Level	Third Level
Software/user interface design issues	Procurement selection process results in a product that does not meet clinical needs	Budget constraints for medical device procurement
	Lack of human factors standards in the Health Canada licensing process	—
Drug library/dose calculator is not used to program a primary infusion	Pump design prevents the use of the secondary mode when the drug library/dose calculator is used to program the primary line	Bolus of the primary infusion given via the secondary mode

Table A11: Contributing Factors—Secondary Infusion Programming Error Occurs

Contributing Factors		
First Level	Second Level	Third Level
Software/user interface design issues	Procurement selection process results in a product that does not meet clinical needs	Budget constraints for medical device procurement
	Lack of human factors standards in the Health Canada licensing process	—
Drug library/dose calculator is not used to program a primary infusion	Pump design prevents the use of the secondary mode when the drug library/dose calculator is used to program the primary line	Bolus of the primary infusion given via the secondary mode

Contributing Factors for Line Identification Issues

Table A12: Contributing Factors—Infusion Pump Settings Are Changed on the Incorrect Pump

Contributing Factors		
First Level	Second Level	Third Level
Secondary IV bag hangers used to lower the primary bag even when no secondary bag is connected	Nurse's height	—
	Tubing too short between the IV bag and the pump (single-channel pumps)	Procurement selection process results in a product that does not meet clinical needs
	RN attempts to make each bag more visible	—
Line tracing is prone to error or is lengthy	Pump hardware design issues: memory in tubing requires continuous raising of the IV bag	—
	Tubing intertwined like spaghetti	Only single-channel pumps used, requiring stacking of pumps on IV poles
		Transporting/ambulating patients tangles the lines
		Patient is receiving multiple concurrent infusions
	No standardized approach to line set-ups (e.g., arrangement, components used)	—
IV bags do not line up with the associated pump/pump channel	Incubator and crib sides impede the continuous tracing of lines	—
	IVs need to be rearranged prior to bringing patients for tests (e.g., CT) to free up a PIV line	—
	Only single-channel pumps used, required stacking of pumps on IV poles	—
IV hooks arranged circularly at the top of the IV pole		Procurement selection process results in a product that does not meet clinical needs
Inconsistent use of terminology for medication abbreviations and access locations on labels (between RNs on the same unit) and External pump labels are applied to pumps to provide medication name and access information	Traditional infusion pumps do not have drug libraries	—
	Drug libraries do not display medication name prominently or indicate access information	—
Patient access information on the pump is inaccurate	IVs need to be rearranged prior to bringing patients for tests (e.g., CT) to free up a PIV line	—

Labels placed on incorrect drug tubing or Preprinted colour-coded medication name stickers are available for only some medications	Batch process of infusion set-up tasks Procurement selection process results in a product that does not meet clinical needs	— —
Pump label–bag mismatch or Colour-code scheme for drug tubing labels uses similar colours for different medications	Batch process of infusion set-up tasks Procurement selection process results in a product that does not meet clinical needs	— —
Labels do not adhere well and fall off	Labels not designed for use on tubing/pumps	—
No standardized approach to line set-ups (e.g., arrangement, components)	—	—
Inconsistent use of colour to identify central venous catheter lumens between vendors and RNs work at more than 1 organization	—	—
Illegible handwriting on labels	—	—
Single pump interface used to program multiple pump channels	—	—
Syringe labels applied lengthwise are obscured by the syringe clip	—	—
Med lines not labelled	—	—
Multiple medications have same opaque white colour (e.g., propofol, lipids, breast milk, NG feeding solutions)	—	—
Generic and brand medication names are used inconsistently across the pump, bag, and drug tubing labels for a single patient	—	—
No drug tubing labels applied to lines	—	—
Drug tubing labels are wrapped around IV tubing, leaving part of the medication name obscured from any angle	—	—

Abbreviations: CT, computed tomography; IV, intravenous; NG, nasogastric; PIV, peripheral intravenous line; RN, registered nurse.

Table A13: Contributing Factors—Intermittent Medication Is Injected Into the Dead Volume of the Incorrect Infusion Line

Contributing Factors		
First Level	Second Level	Third Level
Secondary IV bag hangers used to lower the primary bag even when no secondary bag is connected	Nurse's height	—
	Tubing too short between the IV bag and the pump (single-channel pumps)	Procurement selection process results in a product that does not meet clinical needs
	RN attempts to make each bag more visible	—
Line tracing is prone to error/lengthy	Pump hardware design issues: memory in tubing requires continuous raising of the IV bag	—
	Tubing intertwined like spaghetti	Only single-channel pumps used, requiring stacking of pumps on IV poles
		Transporting/ambulating patients tangles the lines
		Patient is receiving multiple concurrent infusions
IV bags do not line up with the associated pump/pump channel	No standardized approach to line set-ups (e.g., arrangement, components used)	—
	Incubator and crib sides impede the continuous tracing of lines	—
	Only single channel pumps used, required stacking of pumps on IV poles	—
IV bags do not line up with the associated pump/pump channel	IV hooks arranged circularly at the top of the IV pole	Procurement selection process results in a product that does not meet clinical needs
Inconsistent use of terminology for medication abbreviations and access locations on labels (between RNs on the same unit) and External pump labels are applied to pumps to provide medication name and access information	Traditional infusion pumps do not have drug libraries	—
	Drug libraries do not display medication name prominently or indicate access information	—
Patient access information on the pump is inaccurate	IVs need to be rearranged prior to bringing patients for tests (e.g., CT) to free up a PIV line	—

Labels placed on incorrect drug tubing or Preprinted colour-coded medication name stickers are available for only some medications	Batch process of infusion set-up tasks Procurement selection process results in a product that does not meet clinical needs	— —
Pump label–bag mismatch or Colour-code scheme for drug tubing labels uses similar colours for different medications	Batch process of infusion set-up tasks Procurement selection process results in a product that does not meet clinical needs	— —
Labels do not adhere well and fall off	Labels not designed for use on tubing/pumps	—
No standardized approach to line set-ups (e.g., arrangement, components)	—	—
Inconsistent use of colour to identify central venous catheter lumens between vendors and RNs work at more than 1 organization	—	—
Illegible handwriting on labels	—	—
Single pump interface used to program multiple pump channels	—	—
Syringe labels applied lengthwise are obscured by the syringe clip	—	—
Med lines not labelled	—	—
Multiple medications have same opaque white colour (e.g., propofol, lipids, breast milk, NG feeding solutions)	—	—
Generic and brand medication names are used inconsistently across the pump, bag, and drug tubing labels for a single patient	—	—
No drug tubing labels applied to lines	—	—
Drug tubing labels are wrapped around IV tubing leaving part of the medication name obscured from any angle	—	—

Abbreviations: CT, computed tomography; IV, intravenous; NG, nasogastric; PIV, peripheral intravenous line; RN, registered nurse.

Table A14: Contributing Factors—Line Set-Up Information Related to Critical Medication Is Not Formally Communicated at Shift Handover

Contributing Factors		
First Level	Second Level	Third Level
Inadequate training on management on multiple IV infusions	Lack of guidance from regulatory bodies on multiple IV infusion concepts required in nursing training programs	—

Abbreviation: IV, intravenous.

Contributing Factors for Line Set-Up and Removal Issues

Table A15: Contributing Factors—Residual Volume in the Connector Is Not Identifiable When a Medication Is Disconnected From a Multi-Port Connector

Contributing Factors		
First Level	Second Level	Third Level
Lack of a standardized process for managing the residual volume in IV connectors	—	—

Abbreviation: IV, intravenous.

Table A16: Contributing Factors—Leaks Can Occur With the Use of Three-Way Stopcocks

Contributing Factors		
First Level	Second Level	Third Level
Procurement selection process results in a product that does not meet clinical needs	—	—

Table A17: Contributing Factors—IV Bag and Infusion Pump Are Mismatched

Contributing Factors		
First Level	Second Level	Third Level
Multiple IV lines need to be administered at the same time	Different pumps used on different units	—
	Pumps need to be returned to their home unit	—
	Lack of standard medication concentrations between units	—
	Drug library not configured for the unit the patient is transferring to	—
	Concentration of medications is different between the units	—
	IV tubing/connectors are not compatible with new unit	—
	Line changes are required	Date of last IV change
Nurses choose to batch-process their infusion administration tasks	—	—
IV bags do not line up with the associated channel	Single-channel infusion pumps used, requiring stacking of pumps on IV poles	—
	IV hooks arranged circularly at the top of the IV pole	—

Abbreviation: IV, intravenous.

Contributing Factors for Dead Volume Management Issues

Table A18: Contributing Factors—Changes in the Flow Rate of One Infusion Affects Other Connected Infusions

Contributing Factors		
First Level	Second Level	Third Level
Incorrect line removed	Line identified incorrectly ^a	—
Inadequate training and education on managing multiple IV lines	Lack of guidance from professional bodies on multiple line management concepts or risks in RN training programs	—

Abbreviations: IV, intravenous; RN, registered nurse.

^aSee Table A13 for contributing factors of line identification issues.

Table A19: Contributing Factors—Suboptimal Positioning of Infusions on a Multi-Port IV Connector May Delay the Onset of Medication Therapy

Contributing Factors		
First Level	Second Level	Third Level
High-alert ^a medication administered	—	—
Limited IV access	—	—
Inadequate training and education on managing multiple IV lines	Lack of guidance from professional bodies on multiple line management concepts or risks in RN training programs	—

Abbreviations: IV, intravenous; RN, registered nurse.

^aThe Institute for Safe Medication Practices defines high-alert medications as “drugs that bear a heightened risk of causing significant patient harm when they are used in error.” (8)

Contributing Factors for IV Bolus Administration Issues

Table A20: Contributing Factors—A Bolus Is Administered by Manipulating the Pump Settings on an Existing Primary Continuous Infusion

Contributing Factors		
First Level	Second Level	Third Level
Inadequate training and education on managing multiple IV lines	Lack of guidance from professional bodies on multiple line management concepts or risks in RN training programs	—
Infusion pump has no bolus feature	—	—

Abbreviations: IV, intravenous; RN, registered nurse.

Appendix 9: Pump-Specific Issues Identified During Field Study

Caveat Related to Pump Issue Descriptions

This section describes pump design issues that increase the likelihood of an error when administering multiple IV infusions, as identified during the field study. These issues do not represent a comprehensive analysis of each pump's capabilities, since the issues observed were based only on the pump-related tasks conducted at the time of the observations and on each organization's particular implementation of the device. No comparative review of products was performed, and safety risks not identified in this report may nevertheless exist.

Baxter Colleague

The use of both single-channel and triple-channel Baxter Colleague infusion pumps was observed during 1 field study. The triple-channel model uses a single control interface for all 3 channels, which presents a risk of accidentally programming the wrong channel.

The Baxter Colleague uses non-set-specific intravenous (IV) tubing that is inserted into the pump to facilitate fluid pumping. Nurses at the field site described problems with flow rate accuracy, and explained that the compression and release of the tubing (i.e., the mechanism used by the infusion pump) modifies the elasticity and shape memory of the tubing. The inability of the tubing to return to its normal size and shape alters the flow rate accuracy of the infusion pump and also triggers air-in-line alarms, because the air-in-line sensor is not calibrated for the altered shape of the IV tubing. The manufacturer has issued warnings related to false air-in-line alarms resulting from the IV tubing being pulled or tugged between the pump channel and the patient, which may occur for a variety of reasons during clinical care. (70) For example, upon determining that a portion of IV tubing in the infusion pump was no longer holding its shape, the nurses at this clinical site would then remove the tubing from the pump and insert a segment of tubing downstream of the last-used portion. This action removes the slack of the IV tubing downstream of the pump, which is likely to increase the risk of pulling or tugging on the IV tubing and/or increase the risk of air-in-line alarms.

Furthermore, additional time spent loading IV tubing into the infusion pump is also likely to increase the risk of loading errors, which have also been implicated in underinfusions. (70)

The Baxter Colleague infusion pump is equipped with a Dose Error Reduction System (DERS) system. On the triple-channel pumps, using the DERS to program a primary infusion automatically disabled the secondary infusion mode for the same pump channel. However, the single-channel pump models used on the unit did not have this restriction, and a secondary infusion could be programmed even if a primary infusion was programmed within the drug library.

The restriction of the secondary infusion mode has an impact on how nurses administer IV boluses. Since the pump does not provide a bolus mode/feature for the primary infusion, some nurses who needed to administer a bolus of a continuous, primary medication that was already running would program the bolus as a secondary infusion on the existing primary infusion, without hanging a secondary IV bag. If the secondary infusion mode is used when only 1 IV bag is connected to the pump, the secondary infusion mode draws fluid from the primary IV bag, providing a functional equivalent to a bolus feature. Because the secondary infusion mode is inactivated by the use of the DERS on the primary infusion, some nurses programmed the primary infusion outside of the DERS if the need to administer a bolus was anticipated, to ensure that this option was available to them when needed. Programming outside of the DERS increases programming risk, because the programming safety features of the pump are not active.

In addition, no DERS was available to assist with programming a secondary infusion. The secondary infusion could be labelled on the pump by selecting a medication name from the medication list in the pump, but no safety benefits were offered in this mode.

Several other issues associated with the Baxter Colleague pump were identified during the field study:

- The pump software allows the secondary infusion to run at the primary rate without warning the user. After programming the primary and secondary parameters, the pump must be on the secondary programming screen at the time the Start key is pressed—otherwise the pump will infuse at the primary infusion rate. The physical set-up of the primary and secondary IV bags will result in fluid being pulled from the secondary bag, regardless of which mode it is in and at what rate the pump is running, which could cause patient harm.
- The drug library in the DERS was set up in alphabetical order; the user manual does not suggest that nonalphabetical organization of the drug library is possible. Commonly used medications required additional scrolling; this may have discouraged the nurses from using the DERS, thus reducing the likelihood of detecting errors. In addition, multiple listings of the same medication (with potentially different concentrations) could be separated by page breaks, leading nurses to choose an incorrect entry in the drug library.
- The pump does not offer an easy method to promote a basic (non-DERS) infusion into the drug library. To do this, users must stop and reprogram the infusion, further reducing the likelihood that the DERS will be used if it has not been initially programmed in this way.
- The association between soft keys and their intended functions can be obscured, because they are not well aligned with the options on the pump screen when viewed at an angle (e.g., when the pump is hung low on the pole). Therefore, there is a risk of misattributing which option is associated with which soft key.
- The pump stores default unit selections, which may not be desirable for every circumstance. The risks associated with inadvertently accepting incorrect default values are discussed in some of the ensuing pump descriptions, some of which include the following:
 - Patient weight units default to either pounds or kilograms, but could be entered in the opposite units, leading to a potential weight parameter entry error and associated medication errors.
 - Some medications could be entered in either units/hour (dose rate) or mL/hour (flow rate).
- The battery status was unclear. Nurses described frequent, sudden power outages, particularly during patient transport, resulting in the institution needing to purchase large batteries from a local hardware store to support the pumps while they were being moved.
- The Baxter Colleague was the only infusion pump observed that featured a horizontal pumping mechanism, such that all tubing heading towards the patient emerged from the right side of the pump, and all tubing connected to the IV bags entered the left side of the pump. This configuration has the potential to increase the risk of errors when visually tracing lines from the pump to either the IV bags or the patient access ports.

CareFusion Alaris Signature Gold/IVAC Signature Edition Pump

The IVAC Signature Edition pump and the Alaris Signature Editing Gold pump (similar pump models) were observed in 1 field study, and were used as either a single-channel or double-channel pump. Nurses noted that programming options between the pumps were sometimes different. It is possible the institution did not have the same software version installed in both pumps.

In numerous cases, nuisance air-in-line alarms occurred, delaying the administration of a blood product called albumin. The alarm was declared a nuisance alarm because no significant air was in the line; only what nurses refer to as “champagne bubbles” were present, and they do not pose a safety risk in the adult population. Nurses explained that it was also common to routinely experience nuisance air-in-line alarms for other medications. When these alarms occurred, some nurses attempted to confirm the alarm multiple times in the hopes that the movement of fluid or tiny bubbles in the IV tubing would shift and the infusion would restart. Some nurses also rotated the pump by 90 degrees so that it would be infusing while lying on its side, thus causing the small bubbles to rise; this would increase the likelihood that the bubbles would bypass the air-in-line sensor without triggering the alarm.

These pumps do not feature any interlocking connectors that allow multiple pumps to connect side by side. Each pump requires its own space on an IV pole, resulting in many vertically aligned pumps on a single pole. This meant that the tubing had to run either in front of or behind the other pumps to reach the lower pumps (Figure 19). This configuration had the effects of

- increasing the number of IV poles required, making it more difficult to visually inspect which IV bag was connected to which pump
- making patient transport more difficult because more poles had to be moved
- increasing the risk of IV line tangles
- increasing the time required for line tracing

CareFusion Alaris System

The CareFusion Alaris System is a modular infusion pump that accepts both large-volume and syringe pump modules. This pump was used at 6 different field sites.

Up to 4 modules can be controlled by a single control interface (the point of care unit, or “brain” of the system). There is an element of risk in this design because the control interface is physically separate from the pump module. However, users are required to first press “Channel Select” on the module they intend to program, which may reduce this risk. The central point of care unit also gives the appearance of providing a unified “patient profile” to all attached modules. However, it was observed that the point of care unit accepted different values for the patient’s weight when programming separate pump modules, which is clinically appropriate, but inconsistent with user expectation. Nurses described that when they changed the weight on 1 pump module, they expected the point of care unit to automatically adjust the weight across all the modules. This expectation is influenced by the fact that when weight-based medications are programmed, the weight field defaults to the weight entered for that patient on the other modules. When the weight value on 1 pump module is changed, there is no message indicating that the weight change will affect only that module.

The Alaris System also uses a DERS in which nurses select the IV medication or fluid from a drug library when they are programming an infusion. The drug library is specific to different clinical care areas in the hospital. It was noted that infusions had to be stopped and reprogrammed in order to change the drug library profile (e.g., when transferring a patient from a ward unit to an ICU). In addition, some nurses were unaware of what drug library profile their pumps were currently set for, or how to determine this. This increases the likelihood that the pump could be used with the incorrect clinical care area profile. Risks of error could occur with this practice if the dosage limits programmed into the DERS correspond to a clinical area other than the one in which the pump is actually being used.

In some units, the bolus feature was not enabled for all of the medications that nurses had to administer as a bolus. In cases where these medications had to be bolused, nurses explained that they would program the pump as if it were infusing a maintenance solution (i.e., as a volume-rate infusion), meaning there would be no safety limits restricting their infusion settings.

Nurses explained that there would be a delay in starting an infusion if the syringe was not loaded and “preprimed” properly. For example, the syringe plunger may not be flush with the syringe driver. At slow flow rates, the driving mechanism will compress the syringe plunger very gradually, but any slack and initial friction may delay the actual administration of the medication. Nurses indicated the infusion delay from an improperly loaded syringe was about 20 to 30 minutes. The pump does not alert users to this delay.

In 2 field sites, the study team also observed a “System Error,” which triggers an alarm. During this error alarm, a red indicator arrow pointing towards the “System On” button begins to flash. Pressing the “System On” button at this stage will turn off the pump and its associated modules. Nurses were unclear as to what triggered this alarm.

Hospira Omni-Flow 4000 Plus

The Hospira Omni-Flow 4000 Plus was observed in 1 field site. This is an infusion pump that supports the concurrent infusion of up to 4 different medications (each infusing at a different flow rate) into a single primary IV tube. The pump is used mainly in the operating room (OR) by anesthesiologists, but is also used in critical care units when patients transfer from the OR to the ICU while attached to the pump. This pump will be phased out of the market within the next couple of years.

The Omni-Flow pump does not provide a true continuous flow rate of each medication, because the pumping mechanism is active for only 1 medication at a time. Observed over a large period of time, the pump administers each medication at the programmed flow rate, but because it must administer multiple medications, each medication is actually pumped in sporadic bursts. The higher the flow rate, the larger the “burst” in each cycle. The result is a punctuated administration of each medication, which is exacerbated by large differences in flow rates. Large differences in flow rates means that some medications will have longer bursts than others and cause larger gaps in the administration of other medications. Because of the punctuated flow rates, ICU infusions—particularly medications with a short half-life and those requiring titration—are transferred to the unit’s primary large volume infusion pump as soon as it is safe and reasonable to do so.

In addition, the Omni-Flow accepts infusion rates only as a volume rate (mL/h) or a weight-based dose rate ($\mu\text{g}/\text{kg}/\text{min}$). This requires the nurse to convert a dose-rate infusion based on any other units in order to use this pump. For example, an infusion in mg/h would need to be multiplied by 1000 then divided by 60, and the patient’s weight must be entered as 1 kilogram to eliminate its influence in the rate calculation. If the patient’s weight is not changed to 1 kilogram (i.e., if the patient’s actual weight is entered), the dose rate will be too high (by the factor of the patient’s weight), leading to an overdose. If any other channel is programmed using the weight-based dose rate units, the patient’s weight will automatically be entered for all the channels. The risks of programming errors are therefore high due to possible calculation errors and the vigilance required to remember to override the default weight and change the patient’s weight to 1 kilogram to convert the infusion rate correctly.

Hospira Plum A+

The Hospira Plum A+ infusion pump is a single- or triple-channel pump with 1 control interface and 1 screen for each pump channel. This pump was observed in use in 3 field study sites.

The Plum A+ pump is unique in that it is able to infuse a secondary infusion concurrently with a primary infusion. This is referred to as the concurrent infusion mode. No other pumps licensed for sale in Ontario (other than the Hospira Omni-Flow 4000 Plus) possess this capability. Therefore, the capabilities of this

infusion pump may not be well understood by many nurses (see Principles of Infusion Therapy for more details on this infusion mode).

The Plum A+ allows both secondary (piggyback) and concurrent infusion modes, but it defaults the second input on the cassette to “piggyback.” If a concurrent infusion is given, the nurse needs to remember to change the mode default to “concurrent.” Once the mode option has been accepted, the pump no longer displays the selection, decreasing the likelihood that a mode selection error will be detected prior to starting the infusion (see Case Study 7).

Case Study 7: Concurrent-Secondary Infusion Mode Mix-Up

A critical care patient was admitted to the ICU and was prescribed furosemide/mannitol and normal saline. Furosemide/mannitol acts as a diuretic to relieve excess fluid retention. The day nurse set up both IV bags on the same infusion pump channel with the intention of programming a *concurrent* infusion of both IV fluids. Roughly 12 hours after the infusion had started, the night nurse noticed that the patient was still fluid overloaded, and that the furosemide/mannitol was not infusing. This outcome would be consistent with the pump accidentally being set up to infuse as a *secondary* infusion (the default setting). The normal saline had been set up on channel “B,” making it the secondary infusion (i.e., the infusion that would infuse first). Infusing at 10 mL/hr, it would have taken 25 hours for the normal saline to complete and the furosemide/mannitol infusion to begin. This error was caught after a significant delay of approximately 12 hours, and may have negatively affected the patient. The patient was placed on dialysis the next day; it is unclear to what degree this incident contributed to the need for dialysis.

Due to its design, the Plum A+ pump does not require a head height differential between the primary and secondary IV bags; this minimizes the risk of back flow, as both IV bags are connected directly into the Plum A+'s pumping mechanism (dual input cassette format). However, this presents a risk of physical set-up confusion between the secondary infusion mode and the concurrent infusion mode. When programming a secondary infusion, the primary infusion must be a maintenance line such that it flushes the secondary medication after the secondary infusion completes. However, in concurrent mode, there is no requirement for a “driver” or “flushing” fluid after the intermittent administration of a medication. Given that there is no requirement for the infusions to be connected to the pump in a certain order when they are infused concurrently, and that the physical connections of the IV bags resembles a secondary infusion, there is a risk of confusion. Some nurses may still prefer to think of 1 of the pump channels as the “primary” infusion, even when this is not the case (i.e., the pump has been programmed to administer concurrently).

Hospira Symbiq Infusion Pump

Researchers attempted to visit clinical units using the Hospira Symbiq, but due to issues of timing and the activities of the targeted units, they were unable to observe the pump in use. One unit was experiencing technical issues and was temporarily using another pump on the dates the study team was able to visit, while the other clinical unit was still a few months away from implementing the Symbiq.

Smiths Medical Graseby 3000 Modular Infusion Pump

The Graseby 3000 infusion pump is a single-channel, large-volume pump that was observed in 1 field site. The pump is equipped with side mounting units that allow the pumps to be connected side by side. The pump is not equipped with a DERS.

The Graseby 3000 pump features a dose-rate calculator that was difficult and confusing for the observed nurses to use. The majority of observed nurses preferred to manually calculate infusion rates from the prescriber's orders rather than use the dose-rate calculator, either because the calculator was difficult to use or because they were unaware that the dose-rate calculator existed. In addition, the use of the dose-

rate calculator prevented users from activating the secondary infusion mode. Therefore, it is likely that nurses foreseeing the potential need to use the secondary infusion mode would prefer not to use the dose-rate calculator. This would lead to the manual calculation of flow rates, which may increase the probability of calculation errors. In addition, the inability to use the secondary infusion mode when the drug-dose calculator is used may negatively impact the ability to administer an IV bolus using the secondary feature of the pump (see the discussion at the beginning of this appendix about the impact of restricting the use of the secondary feature with the Baxter Colleague pump.)

The Graseby 3000 also maintains the most recently programmed values of rate (mL/h) and volume to be infused (mL) when turned off or not in use. These values could be used accidentally for a different patient or medication. There are no prompts by the infusion pump to ask the nurse about whether an infusion is being programmed for a new patient or a new medication.

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