

Multiple Intravenous Infusions Phase 2b: Laboratory Study

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Abstract

Background

Administering multiple intravenous (IV) infusions to a single patient via infusion pump occurs routinely in health care, but there has been little empirical research examining the risks associated with this practice or ways to mitigate those risks.

Objectives

To identify the risks associated with multiple IV infusions and assess the impact of interventions on nurses' ability to safely administer them.

Data Sources and Review Methods

Forty nurses completed infusion-related tasks in a simulated adult intensive care unit, with and without interventions (i.e., repeated-measures design).

Results

Errors were observed in completing common tasks associated with the administration of multiple IV infusions, including the following (all values from baseline, which was current practice):

- setting up and programming multiple primary continuous IV infusions (e.g., 11.7% programming errors)
- identifying IV infusions (e.g., 7.7% line-tracing errors)
- managing dead volume (e.g., 96.0% flush rate errors following IV syringe dose administration)
- setting up a secondary intermittent IV infusion (e.g., 11.3% secondary clamp errors)
- administering an IV pump bolus (e.g., 11.5% programming errors)

Of 10 interventions tested, 6 (1 practice, 3 technology, and 2 educational) significantly decreased or even eliminated errors compared to baseline.

Limitations

The simulation of an adult intensive care unit at 1 hospital limited the ability to generalize results. The study results were representative of nurses who received training in the interventions but had little experience using them. The longitudinal effects of the interventions were not studied.

Conclusions

Administering and managing multiple IV infusions is a complex and risk-prone activity. However, when a patient requires multiple IV infusions, targeted interventions can reduce identified risks. A combination of standardized practice, technology improvements, and targeted education is required.

Plain Language Summary

Very sick patients in hospital often need several different medications at the same time. Many of these medications are given directly into their veins (*intravenously*). Caregivers use tools called *infusion pumps* to control how much medication patients receive, and how quickly. When more than 1 medication is given this way (called *multiple intravenous infusions*), mistakes can happen that make patients worse.

Health Quality Ontario asked HumanEra, a research team at the University Health Network, to explore what mistakes can happen with multiple intravenous infusions, and what can be done to prevent or reduce them.

This report describes what we found when 40 nurses completed common tasks on pretend patients who were receiving multiple intravenous infusions. Nurses completed the tasks the way they usually would. They also completed the same tasks using new tools, work practices, or training to see if those changes helped prevent or reduce mistakes.

Our findings showed that new tools, work practices, and training could reduce and even prevent mistakes in giving multiple intravenous infusions.

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List of Abbreviations

AAMI	Association for the Advancement of Medical Instrumentation
ANOVA	Analysis of variance
CPOE	Computerized prescriber order entry
DERS	Dose error reduction system
FDA	Food and Drug Administration
ICU	Intensive care unit
ISMP (United States)	Institute for Safe Medication Practices (United States)
ISMP Canada	Institute for Safe Medication Practices Canada
IV	Intravenous
KVO	Keep vein open
MAUDE	Manufacturer and User Facility Device Experience
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. Two reports precede this one:

- The Phase 1a study report, *Multiple Intravenous Infusions Phase 1a: Situation Scan Summary Report*, is available at: http://ehealthinnovation.org/wp-content/uploads/Multiple-IV-Infusions_Phase1a_SummaryReport1.pdf
- The Phase 1b study report, *Multiple Intravenous Infusions Phase 1b: Practice and Training Scan*, is available at: http://www.hqontario.ca/en/eds/tech/pdfs/2012/multipleinfusions1b_May.pdf

Recommendations endorsed by the Ontario Health Technology Advisory Committee based on the study findings can be found on the Health Quality Ontario website: <http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations/ohtac-recommendations>.

Introduction

Issue and Research Motivation

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) administration, and about 90% of hospitalized patients receive medications this way. (4) Infusion pumps are devices that accurately control the amount of medication patients receive and the rate at which the medication is administered; still, medication errors associated with infusion therapy are well documented. (5-7)

IV administration via a large-volume infusion pump has a number of advantages compared to a gravity infusion (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). In this way, infusion pumps are the safest way to administer IV therapy. However, infusion pumps have also been associated with a high rate of recalls and adverse events, resulting in patient injuries and deaths. A review of the United States Food and Drug Administration (FDA) records over a 4-year period revealed that there were 87 infusion pump recalls and 56,000 adverse events (including 710 deaths) associated with infusion pump use. (8;9) Since 2010, organizations such as the Association for the Advancement of Medical Instrumentation (AAMI) and the FDA have made improving the safety of infusion pumps a priority.

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 administering multiple IV infusions to a single patient at 1 time. (10;11) Previous research has highlighted a number of safety risks associated with managing multiple IV infusions. (7;10) For example, secondary (often referred to as *piggyback*) IV 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, but previous studies have indicated that there is a high risk of errors related to the setup and

administration of secondary infusions. (7;12) In addition, a recent study found that each additional IV medication increased the likelihood of an adverse drug event by 3%. (13) Further research is needed to systematically and comprehensively identify the risks and contributing factors associated with multiple IV infusions. There is also a need to investigate the effectiveness of various practice-, technology-, and education-related interventions to mitigate or reduce those risks. To address this research gap, the Ontario Health Technology Advisory Committee commissioned HumanEra (formerly the Health Technology Safety Research Team), with support from Health Quality Ontario and in collaboration with the Institute for Safe Medication Practices Canada (ISMP Canada), to generate evidence-based recommendations to reduce the hazards associated with administering multiple IV infusions to a single patient.

Project Phases

A challenge to studying the risks associated with multiple IV infusions is that they are not confined to a single controlled element (e.g., an isolated technology issue); instead, a detailed understanding of many system elements (e.g., clinical tasks and processes, infusion pump technology, hospital policies and procedures, individual practices, nursing training) is required. As such, HumanEra aimed to identify and help mitigate the risks associated with multiple IV infusions while accounting for the complex interactions between system elements. Different but complementary human factors methods and tools were used to achieve this objective, and the following multi-phase project was designed (see Figure 1):

- Phase 1: Environmental Scan
 - Phase 1a: Situation Scan
 - Phase 1b: Practice and Training Scan
- Phase 2: Risk Prevalence and Mitigation
 - Phase 2a: Ontario Survey
 - Phase 2b: Laboratory Study
- Phase 3: Knowledge Translation

In addition, a Multiple IV Infusions Expert Panel (henceforth referred to as the *expert panel*) was established as a project advisory group, consisting of representatives from clinical, professional practice, and/or regulatory groups (see the Acknowledgements for a full list of expert panel members).

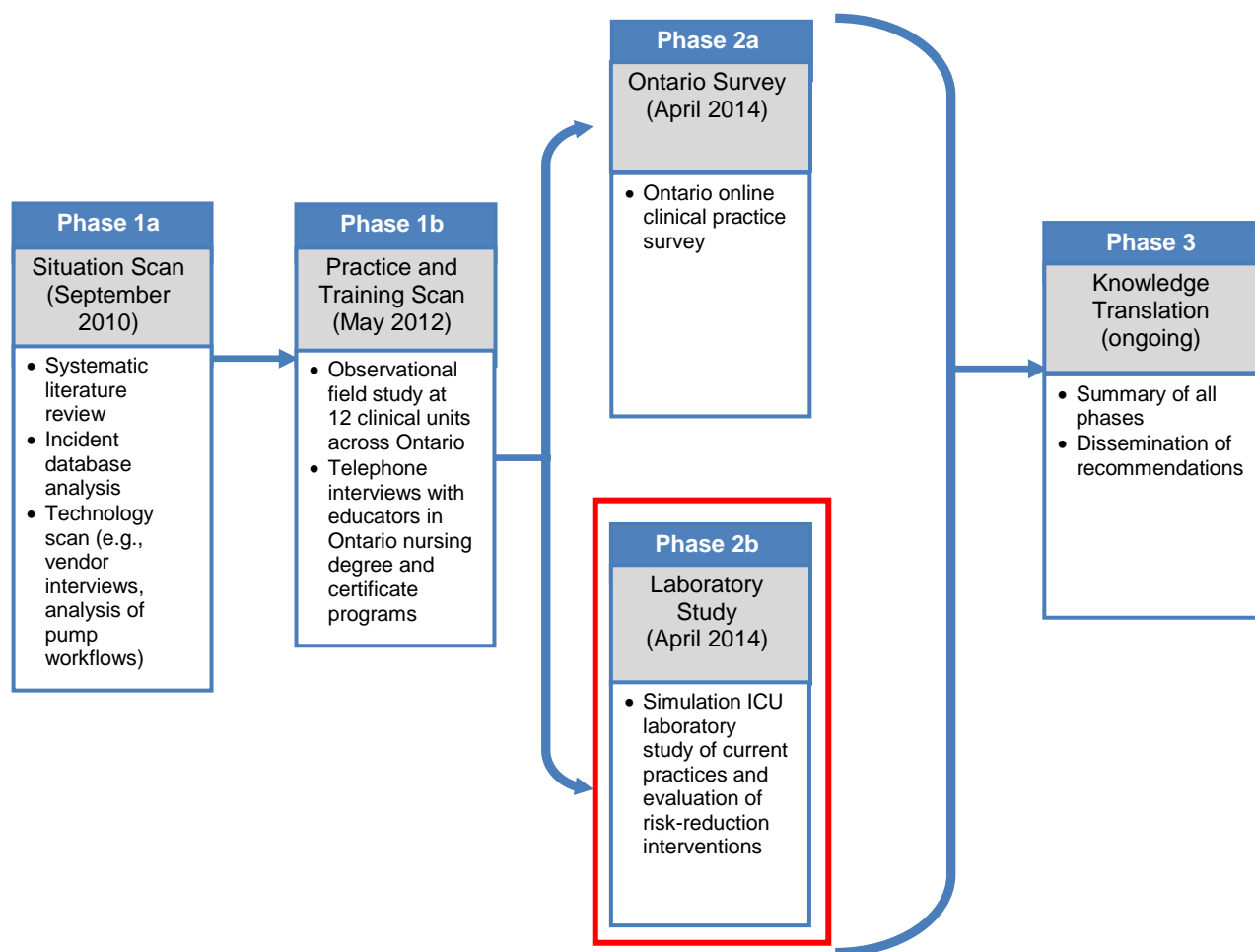


Figure 1: Multiple IV Infusions Project Phases

Abbreviations: IV, intravenous; ICU, intensive care unit.

Phase 1a (10) 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.

Phase 1b (14) identified the breadth of practices (e.g., workflows, tasks), infusion setups, technology (e.g., infusion pumps, IV components), and education associated with administering multiple infusions in different clinical environments (e.g., critical care, pediatric care, outpatient chemotherapy). Analysis identified specific safety issues with the potential to cause direct patient harm, along with related contributing factors. These were categorized using the following themes:

- infusion setup and removal
- infusion identification
- dead volume management
- secondary IV infusion setup
- IV pump bolus administration
- pump-specific issues

Objectives of Analysis

The objectives of this report (Phase 2b: Laboratory Study) were as follows:

- to identify issues with current practices that may contribute to the risk of patient harm
- to test the effectiveness of practice-, technology-, and education-based interventions in mitigating errors
- to gather feedback from registered nurses about the tested interventions
- to propose recommendations that may decrease the risk of patient harm

Scope of Analysis

The current study attempted to embrace and protect the complexity inherent in administering multiple IV infusions. To this end, it was critical to scope the project carefully in terms of the environment, tasks/topics, and IV components to be analyzed.

Note: Throughout the Multiple Intravenous Infusions reports, the study team generally refers to nurses, because they are the primary group responsible for administering IV infusions in the clinical environments that are in the study scope. However, we recognize that other health care professionals may be involved in the administration of multiple IV infusions (e.g., physicians).

Environment

Multiple IV infusions are common in a variety of care areas, including adult critical care, pediatric critical care, and outpatient oncology. (2;14) There are marked differences between these environments, but the laboratory study simulated an adult intensive care unit (ICU) for several reasons:

- Adult ICUs contain critically ill and often unstable patients who require immediate and unplanned interventions by nurses.
- Adult ICUs are prevalent in most acute care hospitals, and there are approximately 2,000 adult critical care beds in Ontario. (15)
- Adult ICUs administer a high number of infusions—in particular, high-alert continuous IV medications. (2;14)
- Adult ICUs commonly experience IV administration errors, (16-19) and these errors are associated with greater severity, length of stay, and cost compared to general care units. (20;21)

Adult ICUs are a prevalent and high-risk care setting in Ontario hospitals. Reducing the risk of error in these environments is likely to have a large impact on the health care system because of the volume of IV infusions they administer and the severity of errors that can occur. This made adult ICUs a favourable setting to evaluate in the laboratory study.

Tasks/Topics

Previous project phases identified numerous potential patient safety issues related to multiple IV infusions (10;14) and grouped them into themes. (14) The laboratory study focused on the following¹:

- setting up and programming multiple primary continuous IV infusions
- identifying IV infusions
- managing dead volume
- setting up secondary intermittent IV infusions
- administering an IV pump bolus

The above themes were extensive; focusing on these tasks/topics necessitated the exclusion of others, including the following:

- pharmaceutical interactions and the pharmacokinetics of multiple IV medications (e.g., medication compatibility)
- interaction with and/or absorption of IV medications by IV containers, tubing, and connectors
- misconnections between IV tubing and tubing that delivers fluids or gases via other routes (e.g., IV/epidural, IV/intrathecal, or IV/nasogastric)
- impact of cables not related to IV medication administration (e.g., power cables for bedside equipment, patient leads for use with a physiological monitor)²
- impact of equipment failure
- infection-control issues (e.g., access site management, swabbing of injection ports)
- inserting IV catheters
- infusions not controlled by large-volume pumps (e.g., gravity IV infusions, syringe-pump infusions, IV patient-controlled analgesia)
- side-by-side comparative evaluation of large-volume infusion pumps
- strategies for IV infusion pump programming beyond pump-controlled primary, secondary, and bolus modes (e.g., IV loading doses, IV multistep therapy in which the flow rate changes automatically based on a preprogrammed schedule)

Some of these topics are being investigated elsewhere. (8;9;22-26) 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 here.

¹Theme names may differ slightly from previous work (14) to emphasize the specific tasks evaluated in the Phase 2b laboratory study simulation.

²Although these components were not explicitly studied, they were included in the simulation setups for scenario realism.

IV Components

IV system components included in the laboratory study were as follows:

- large-volume IV infusion devices
 - single- and multiple-channel pumps
 - traditional and smart infusion pumps (i.e., devices with and without a dose error reduction system [DERS])
- IV accessories (e.g., IV bags, tubing, clamps, poles, connectors, IV tubing content labels)

The following were not explicitly analyzed as part of this study³:

- syringe pumps, insulin pumps, elastomeric pumps, patient-controlled analgesia pumps, ambulatory pumps, magnetic resonance imaging-compatible pumps, and high-pressure infusors (e.g., fluid resuscitation units for use in trauma cases)
- arterial or central venous blood pressure monitoring
- blood and blood products, total parenteral nutrition, and IV chemotherapy
- closed drug-transfer systems (e.g., to prevent exposure to chemotherapy agents upon connecting and disconnecting IV components)
- IV glass bottle containers
- IV container medication labels
- IV tubing labels specifying the date and time to facilitate planned tubing changes

³Although these components were not explicitly studied, some (e.g., IV components related to arterial blood pressure monitoring, IV container labels, enteral pumps) were included in the simulation setups for scenario realism.

IV Infusion Terminology

The following section provides a brief introduction to key terms used in this report (see also the Glossary).

IV Components

In general, an IV pump-controlled infusion consists of the following components (Figure 2):

- IV pole, upon which the IV container hangs and the IV pump attaches (①)
- IV container (e.g., bag, glass bottle; ②)
- primary IV tubing (③), which runs from the IV container through the pump and then attaches directly to a patient's venous catheter, or indirectly via an IV connector or add-on device. Primary IV tubing typically has a secondary infusion port⁴ above the pump (④) to connect secondary infusions and 1 or more lower injection ports below the pump (⑤) for manual IV pushes or to connect with another infusion (i.e., to merge to a common access port)
- infusion pump (⑥)
- IV add-on devices (e.g., extension tubing, connection adaptors, in-line filters, cannula caps) (⑦)
- IV connectors (e.g., 3-way stopcock, multiport connector, multi-lead connector) (⑧)
- peripheral or central venous catheter (⑨), a flexible line inserted into a patient's vein to which IV tubing, an IV connector, or an IV add-on device is attached via an access port (+)

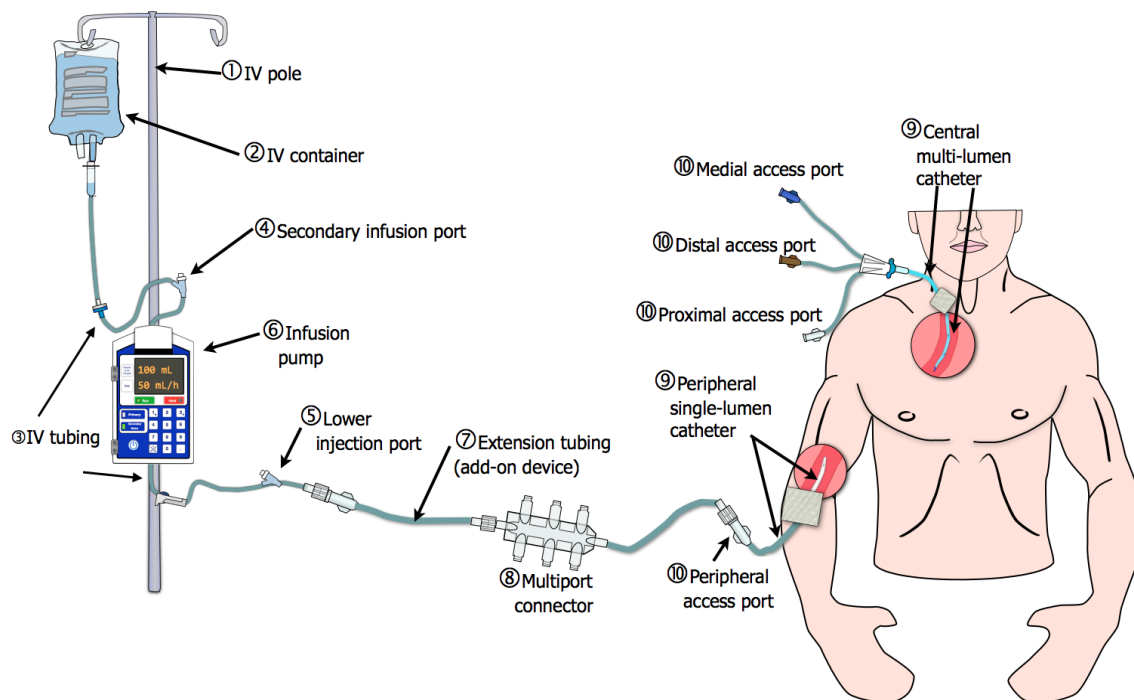


Figure 2: IV Infusion Components

Abbreviation: IV, intravenous.

Note: Components have been enlarged for visibility (i.e., they are not to scale).

⁴Port describes a connection point between 2 IV infusion components. For example, IV tubing is connected to a venous catheter via a port. Ports often facilitate joining via a luer lock connector system, where male and female ends are twisted together to ensure a tight, secure fit.

Catheters

The terminology describing IV catheters in this report revolves around 2 key distinctions: *central venous* versus *peripheral venous* catheters, and *single-lumen* versus *multi-lumen* catheters.

Central venous catheters are inserted into large central veins close to the heart (e.g., inferior or superior vena cava), so that there is a large volume of blood to dilute the contents of the infusion, and the heart rapidly distributes the infusate throughout the body. Common insertion sites (referred to as *access sites*) include the neck (internal jugular vein), the upper chest (subclavian vein), and the groin area (femoral vein).⁵ *Peripheral venous catheters* are inserted into veins in the patient's extremities (e.g., hand or arm). Medications infused through a peripheral vein are not diluted by a large volume of blood; peripheral veins tend to be smaller and are inappropriate for medications that are highly concentrated and damaging (e.g., vesicant medications). Although multiple infusions may be connected to a peripheral catheter, the number of infusions is often low given compatibility issues and the capacity of peripheral veins.

Catheters may have 1 or more internal *lumens* (*single-lumen* or *multi-lumen* catheters); each lumen provides a unique and independent pathway into a patient's bloodstream, using a single catheter and access site. Multi-lumen catheters are important when prescribed medications are incompatible and must be infused separately.

In Figure 2, the patient has a peripheral single-lumen catheter and a central multi-lumen catheter (⊙). The central multi-lumen catheter has 3 lumens, which can be accessed using the distal, medial, and proximal access ports (+). The contents of the distal port leave from the tip of catheter, the contents of the medial port leave the middle portion of the catheter, and the proximal port leave at a point closest to the insertion site. Some nurses may refer to these ports by colour (e.g., in Figure 2, the distal port is the "brown port"), but these colours are not standardized.

Access Port/Access Site

It is important to clarify the difference between the terms *access site* and *access port*. In this report, an *access site* refers to the point at which a catheter enters the patient's body (e.g., a peripheral access site or a central access site; ⊙ in Figure 2). An *access port* refers to a connection point to an IV catheter that provides a unique and independent pathway to the patient's bloodstream (⊕ in Figure 2). Only 1 catheter is inserted into an access site, but that catheter may provide multiple access ports (e.g., "central multi-lumen catheter", ⊙ in Figure 2). Furthermore, 1 or more compatible infusions may be connected to a single access port (e.g., a multiport/lead connector, ⊗ in Figure 2).

⁵ A central venous catheter may be inserted in a peripheral vein and then advanced through the vein until the tip reaches close to the heart.

Laboratory Study: Overview

This section describes the research questions, methods, and limitations for the entire laboratory study (i.e., all themes). Details specific to each theme can be found in the next section (Laboratory Study: Themes).

Research Questions

1. What errors are associated with administering and managing multiple IV infusions—in particular errors regarding the following:
 - setting up and programming multiple primary continuous IV infusions
 - identifying IV infusions
 - managing dead volume
 - setting up secondary intermittent IV infusions
 - administering an IV pump bolus
2. To what extent do practice-, technology-, and education-oriented interventions mitigate these errors?
3. What are nurses' perceptions regarding the safety of practice-, technology-, and education-oriented interventions, and would they use those interventions in their clinical practice?

Research Methods

To answer the above research questions, a literature review and simulation laboratory study were completed.

Literature Review

A systematic literature review was completed in Phase 1b (14), but a second (non-systematic) literature review was performed as part of Phase 2b to provide background and context for the selection and evaluation of interventions. PubMed, Ovid MEDLINE, ScienceDirect, IngentaConnect, the International Network of Agencies for Health Technology Assessment, Ovid Embase, EBSCO Cumulative Index to Nursing & Allied Health Literature, the Cochrane database, ACP Journal Club, the Database of Abstracts of Reviews of Effects, Health Business, and Web of Science were searched using a combination of keywords and reference lists. Google Scholar, pump manufacturer reports, reports published by health care organizations or groups, relevant discussion boards, and accredited websites were also searched for relevant evidence. Preference was given to original studies published in English in peer-reviewed journals that investigated issues related to multiple IV infusions.

Simulation Laboratory Study

Participants

Forty registered nurses were recruited from 3 different ICUs (cardiovascular, coronary, and medical-surgical) at 1 Ontario hospital. Institutional ethics approval was secured from the participating hospital, and participants were compensated for their time. Participant characteristics are shown in Table 1. Participants had no previous experience with the interventions tested.

Table 1: Participant Characteristics

Characteristic		Frequency ^a
Role	Staff nurse	39 (100%)
Sex	Female	37 (95%)
	Male	2 (5%)
Age range	18–29 years	8 (21%)
	30–39 years	14 (36%)
	40–49 years	8 (21%)
	50–64 years	9 (23%)
Years of critical care experience	< 1 year	3 (8%)
	1–3 years	3 (8%)
	4–10 years	18 (46%)
	> 10 years	15 (38%)
Clinical care area	Cardiovascular ICU	12 (31%)
	Coronary ICU	6 (15%)
	Medical-surgical ICU	21 (54%)
Average shift(s) per week	< 1	1 (3%)
	1–2	0 (0%)
	3–4	21 (54%)
	> 4	17 (44%)
Completed postgraduate studies ^b	Critical care nursing core program	36 (92%)
	Full Critical Care Nursing Certificate	17 (44%)
	CNA specialty credential in critical care nursing	11 (28%)
	Additional IV therapy courses at educational institution (not specified)	1 (3%)

Abbreviations: ICU, intensive care unit; IV, intravenous; CNA, Canadian Nurses Association.

^an = 39. One participant's data were not collected due to a technical failure. Percentages may appear inexact due to rounding.

^bParticipants could select more than 1 answer.

Experimental Design

This was an experimental simulation study with a repeated-measures design; all participants completed equivalent infusion tasks for all experimental conditions (baseline and intervention) in a high-fidelity simulated adult ICU.

Simulated patient information and scenarios were created. Patient information consisted of a name and a history, including a diagnosis, a list of infusions being administered, and associated medication orders. Patient scenarios consisted of a sequence of appropriate and realistic tasks for the participant to complete. Four different patient scenarios were created to facilitate evaluation of the different experimental conditions; multiple interventions were evaluated in each scenario, but each intervention targeted different issues and tasks. Each participant completed all 4 scenarios.

Given the experimental design, there was a risk that the order and combination of interventions in any single scenario would influence participant performance. For example, participants could have become primed or biased to tasks or interventions as they progressed through the laboratory study (e.g., learning effects). To correct for this, the following were counterbalanced:

- the order of conditions⁶
- the combination of conditions (i.e., interventions) within a scenario
- task interruptions⁷

Still, a full counterbalancing of all variables was not possible for the following reasons:

- There were not enough participants for all combinations.
- Some interventions could not be tested together in 1 scenario because they may have interacted (i.e., 1 intervention would bias participants' performance on other tasks).
- Some interventions had to be combined for logistical reasons (e.g., infusion pumps could not be changed within a patient scenario).
- Some interventions could not be counterbalanced because of their effect (e.g., education-based interventions had to occur in the last patient scenario, since the effects would be carried over to other conditions; participants could not “unlearn” material).

Location and Apparatus

The experiment was conducted in state-of-the-art simulation laboratories that allowed for high-fidelity simulations of clinical environments and scenarios. The labs were equipped with 9 ceiling-mounted cameras and microphones; audio/video recording and editing equipment; testing rooms with fully configurable walls; and observation rooms with 1-way mirrors to view the testing rooms.

The simulation laboratories were used to create a mock-up of an adult ICU. The simulated environment was informed by field observations at the participating institution and elsewhere. (14) The expert panel, together with nursing and pharmacy specialists from the participating institution's ICU, also helped to ensure that the laboratory study was representative of a real adult ICU.

The simulation included patient beds equipped with appropriate props to support realistic patient care and nursing workflow (Figure 3):

- biomedical equipment (e.g., large-volume infusion pumps, physiological monitor, ventilator, enteral pump)
- IV infusion supplies and equipment (e.g., IV poles, IV bags with realistic labels, IV tubing, IV connectors)
- furniture (e.g., chairs, bedside tables)
- ancillary props (e.g., venous and arterial pressure monitoring components, Foley catheter and collection container, oxygen saturation probe)
- simulated patients (e.g., mannequins, gowns, catheters taped down to appropriate access sites, drainage bags to “absorb” infusions)
- supplies (e.g., sharps containers, gloves, alcohol swabs)
- documentation and reference materials (e.g., patient binder with flow sheets, drug compatibility charts)

⁶Simulated patients were designed to be of equivalent acuity so that the patient history and condition would not be relevant to the counterbalancing design.

⁷Since interruptions are common in clinical practice, task interruptions were included in the patient scenarios. All interruptions were designed to be equivalent but different, and they were counterbalanced to avoid confounding results.

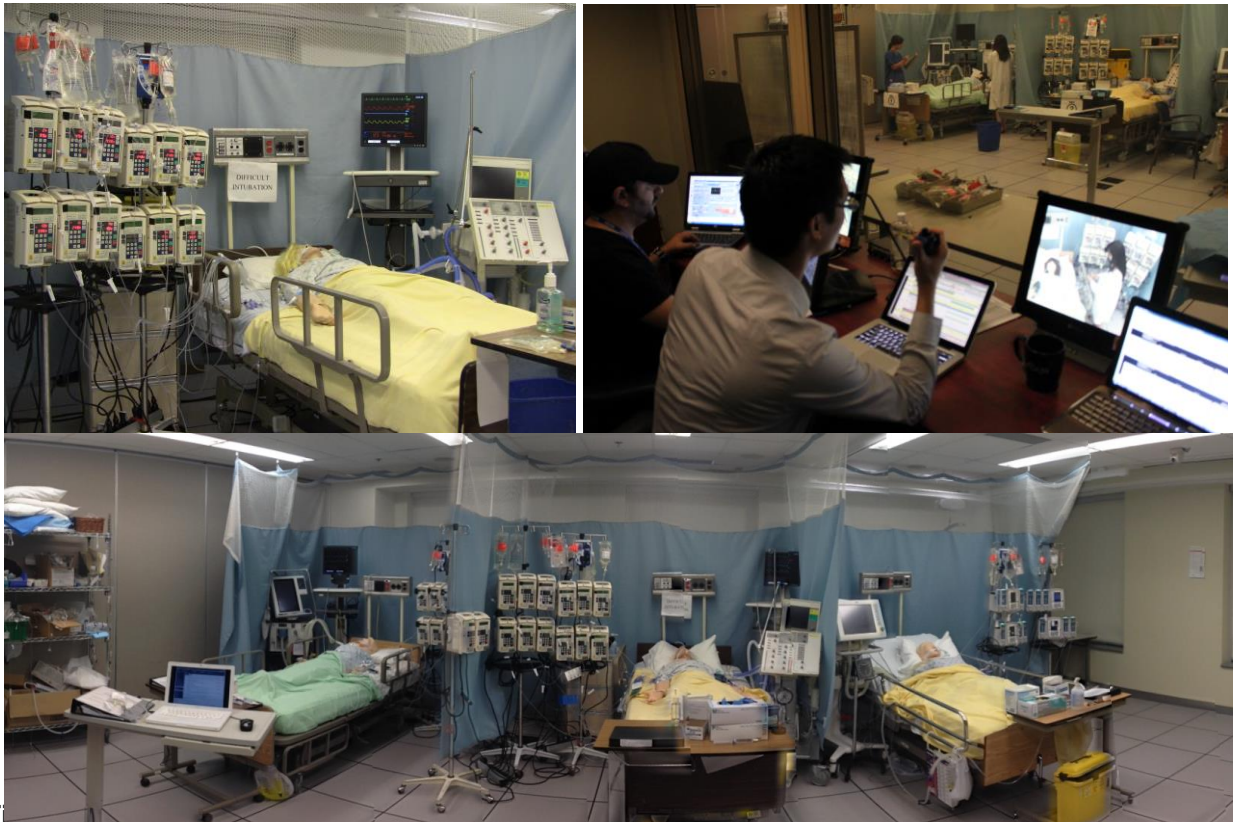


Figure 4

Abbreviation: ICU, intensive care unit.

Top left: Infusion pumps, physiological monitor, and ventilator at the simulated patient's bedside.

Top right: The view from the observation room where the audio/video recording was controlled, and performance metrics (e.g., time-stamps, errors) were recorded.

Bottom: A panoramic view of the simulated ICU environment.

Medication orders were presented to participants using a mock computerized prescriber order entry (CPOE) system to simulate how nurses from the participating institution viewed orders. A recording of critical care ambient noise was played during simulated scenarios.

The physical setup for each simulated patient remained constant (except for the interventions being evaluated). For example, each patient had 2 IV poles, and each pole had 6 infusion pumps/channels. At the start of the scenario, each patient was receiving 11 continuous IV infusions, so there was always 1 unused pump/channel. As shown in Figure 4, each patient was receiving 9 continuous IV infusions (7 infusions of medications and 2 infusions of sodium chloride 0.9%) through a central venous triple-lumen catheter, and 2 infusions (both continuous IV medications) through a peripheral catheter. An emergency medication line (i.e., a plain IV line typically kept available for intermittent or “as-needed” medication administration) was always connected to the distal access port of the triple-lumen catheter (port 2 in Figure 4); a multiport connector was connected to each of the medial and proximal access ports (ports 1 and 3 in Figure 4), through which all other IV infusions were connected. To mimic common practice at the participating institution, inotropic/vasopressor-related medications were grouped on the proximal access port (port 3), and sedative or narcotic medications were grouped on the medial access port (port 1).

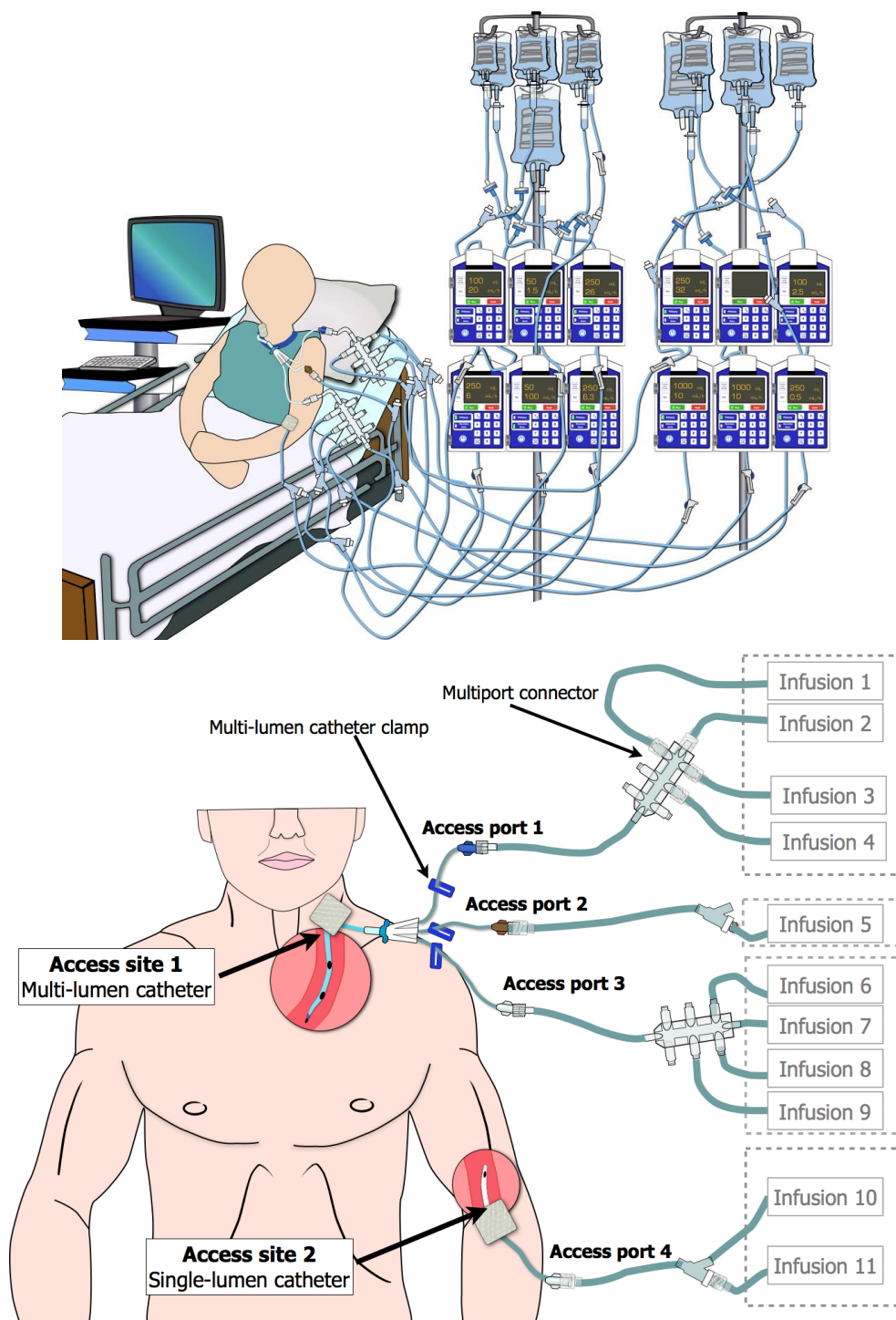


Figure 4: Patient Infusion Setup in All Scenarios

Abbreviation: IV, intravenous.

Top: The 11 continuous IV infusions at bedside (wide view).

Bottom: Distribution of infusions by access site for each patient. Note that there were blue, brown, and white capped leads emerging from the triple-lumen catheter that corresponded to medial, distal, and proximal exit points at the tip of the catheter, respectively.

No real drugs or patients were used. Water was used instead of drugs, but the IV containers were authentic (i.e., IV packaging, bags, and labels were the same as those used in the ICU). Drainage bags were discreetly connected to both the peripheral and central venous catheters and hidden underneath the simulated patient to collect all water infused.

The physiological monitor was connected to patient simulator software, allowing the research team to manipulate patient vital signs in real time. This allowed specific tasks to be triggered in certain cases to facilitate the progression of the laboratory study.

Interventions

HumanEra developed a short list of interventions (by theme) based on several sources:

- technology scan (e.g., innovative technologies commercially available or in development) (10)
- field observations and interviews (e.g., innovative practices or technologies developed and/or used by clinicians) (14)
- gaps in current nursing training and education (14)
- targeted literature and/or market searches

A short list of interventions was presented to the expert panel. The expert panel considered various factors (including intervention approach—practice, technology, or education) and then recommended interventions for inclusion (by theme) to address identified risks. Table 2 provides a description of the different intervention types, the errors they targeted, and potential uses by stakeholders.

Table 2: Intervention Types

Type	Errors Targeted	Examples	Potential Use of Results by Stakeholders			
			Manufacturer	Health Care Organization	Professional/ Standards Association	Educator
Practice (i.e., rule)	Planning errors due to incorrect rules or inadequacy of plan: actions match intentions, but the intention is flawed due to misapplication of a good rule, failure to apply a good rule, or application of a bad rule (<i>rule-based error</i>)	Policy or procedure	—	To inform policies, procedures, and practices	To establish clinical best practices	To inform an education curriculum
Technology (i.e., object, interface)	Execution errors (slips and lapses): actions do not match intentions	Infusion pump feature IV tubing organizer Reference sheet	To inform future product development	To inform capital acquisition decisions and device configuration when technology is commercially available	To inform criteria for evaluating technology To update technology-related standards	—
Education (i.e., knowledge)	Planning errors due to a lack of knowledge: actions match intentions, but the intention is flawed due to a knowledge deficit. Knowledge-based errors often occur in novel or infrequent situations when rules to provide guidance (i.e., practice interventions) do not exist or are unknown	Computer education module	To inform technology implementation training plans	To inform staff education (e.g., new-hire orientation, in-service, annual recertification)	To inform professional education requirements	To inform an education curriculum

Abbreviation: IV, intravenous.

It was also desirable to include a mix of interventions that could be implemented immediately to mitigate risks (i.e., short-term impact) and others that could be used to help inform future capital acquisition decisions, research, and product development (i.e., long-term impact). The interventions included in the laboratory study are outlined in Table 3.

Table 3: Interventions Tested

Theme	Intervention(s) Tested	Intervention Type		
		Practice	Technology	Education
1. Setting up and programming multiple primary continuous IV infusions	One-at-a-time protocol	☐		
2. Identifying IV infusions	Preprinted labels and infusion organizers		☐	
	Smart pump/channel labels		☐	
	Light-linking system		☐	
3. Managing dead volume	Education module on dead volume principles			☐
4. Setting up secondary intermittent IV infusions	Smart pump with clamp detector		☐	
	Separate pump	☐	☐	
	Education module on IV principles			☐
5. Administering an IV pump bolus	Traditional pump with bolus feature		☐	
	Smart pump with bolus feature		☐	

Abbreviation: IV, intravenous.

Tasks

The tasks used to study the interventions in each theme are shown in Table 4 and described in detail later by theme. Tasks were designed with the help of pharmacists and nurses (from the participating institution and the expert panel) to ensure validity and nurse familiarity.

Table 4: Themes and IV Infusion Tasks Studied

Themes	Tasks Studied
1. Setting up and programming multiple primary continuous IV infusions	Conduct a line change involving 4 infusions and a multiport connector
2. Identifying IV infusions	Disconnect an infusion
	Document infusion architecture and infusing medications for a single access port
3. Managing dead volume	Administer a medication by manual IV push
	Double the concentration of a continuous IV medication infusion
4. Setting up secondary intermittent IV infusions	Set up a standard secondary IV infusion
	Set up a non-standard secondary IV infusion (i.e., a large IV container or a high flow rate)
5. Administering an IV pump bolus	Administer an IV pump bolus

Abbreviation: IV, intravenous.

Procedure

Upon arriving at the simulation laboratory, participants completed the following (over approximately 3 hours):

- an introduction to the study
- a background (demographic) survey
- patient scenario 1 (which included training on interventions, if applicable)
- patient scenario 2 (which included training on interventions, if applicable)
- patient scenario 3 (which included training on interventions, if applicable)
- patient scenario 4 (which included training on interventions, if applicable)
- an intervention feedback questionnaire

The introduction involved a brief explanation of the activities involved in the session, assurances that the data collected were to be kept anonymous, and emphasis that it was the interventions being evaluated—not nursing performance. Participants were also given an orientation on the simulation laboratory. They were informed that the study was investigating interventions to minimize the risks associated with administering multiple IV infusions, but not given specifics (e.g., metrics being recorded) to avoid influencing behaviour. It was also stressed that participants should complete tasks as they would in their clinical practice (i.e., no “pretending”). After their questions had been answered, participants were asked to review and sign a consent form to participate in the study. They were then asked to complete a background survey to collect demographic information (Appendix 1).

In each patient scenario, participants were:

- given training on the set of interventions being evaluated (unless no interventions were being tested)
- briefed by a confederate nurse (an actor playing the role of the charge nurse) on the history of the patient they would be covering while the designated nurse was temporarily preoccupied (e.g., on break)
- given time to familiarize themselves with the infusion setup
- given IV infusion orders (e.g., in CPOE) and asked to execute them as per their usual clinical practice

Once participants had completed all tasks in a given scenario, they received training on the next set of interventions and the procedure was repeated until all 4 scenarios had been completed and all conditions and tasks had been evaluated. After participants had completed all 4 scenarios, they filled out a questionnaire to capture their feedback on the perceived effectiveness of each intervention and its desired use, as well as open-ended feedback (Appendix 2). A 4-point scale was used to avoid neutral replies.

The confederate nurse acted as a nursing colleague and ensured that the participant conducted scenario tasks in the required sequence. He/she also discreetly recorded error metrics using a data collection sheet. Together with another actor, the confederate nurse also provided preplanned interruptions and distractions.

Behind a 1-way mirror in the observation room, test facilitators used a structured data collection tool to record errors (number and type), workflow deviations, task time, and any qualitative observations. Test facilitators were able to communicate with the confederate nurse as needed using a wireless radio from the observation room, but there was no direct interaction between test facilitators and participants. If participants did not know how to complete a task or were confused, they were asked to communicate with

the confederate nurse as they would in a real clinical environment, or to do what they would normally do if they encountered a similar situation in their practice.

Metrics and Analysis

The metrics used were specific to each theme (see Laboratory Study: Themes). For the first 31 participants, data collectors (i.e., the confederate nurse and up to 3 test facilitators) came to a consensus on the recorded metrics at the end of the test. For the 32nd participant, test facilitators independently assessed the participant's actions on measures of task time and error rate to establish inter-rater reliability. A Fleiss's kappa value of 0.95 was established between the 3 test facilitators (based on 181 observations/metrics for 1 participant), and this was deemed high enough to require only a single data collector for the remaining 8 participants.

Three expert panel members (2 nurses, 1 pharmacist) helped define the criteria for errors and evaluated the clinical impact of the errors observed (errors were categorized as having clinical impact if they were likely to result in temporary or permanent harm to the patient, including death). The expert panel also helped translate the results into evidence-based recommendations for mitigating observed errors.

Limitations

Tasks Tested

Given the time constraints of the study, results were limited to the tasks and situations tested. The following were not evaluated:

- setup of interventions
- use (and misuse) in other possible scenarios (e.g., tasks)
- operational issues with intervention implementation (e.g., intervention storage and supply)
- ability to detect and remedy errors (some tasks were cut short in the interests of time)

Longitudinal Effects

The longitudinal effects of the interventions were not studied (e.g., long-term knowledge retention, intervention compliance). Participants had no previous experience with the interventions, so results are representative of nurses who received training in the interventions but had little experience using them. In addition, training was provided immediately before participants used the interventions; knowledge gained and participant performance were measured immediately after training.

Generalizability of Findings

The results were limited to the interventions tested. Other similar interventions (e.g., infusion organizers, smart pumps) may offer benefits or risks that were not evaluated. In addition, the small sample size (40 participants) limited statistical power (although significant differences were detected in most themes). A larger sample size might provide greater insight into the diversity of practices (e.g., those used in other hospital settings) and capture new and unexpected errors. Laboratory results were also specific to the adult ICU environment tested and the participating institution's critical care nurses; careful consideration would be required before adopting these findings in other settings where multiple IV infusions are common (e.g., pediatric ICU environments or outpatient chemotherapy environments).

Partial Intervention Counterbalancing

Every effort was made to counterbalance the order and combinations of tested interventions. However, given the sample size and effect of some interventions, only partial counterbalancing was possible. For example, education modules were always presented in the last patient scenario to avoid influencing baseline behaviour. This may have meant that participants were more familiar with the tasks in the education condition compared to previous conditions.

Laboratory Study: Themes

This section provides background, methods, results, and analysis specific to each of the 5 study themes:

1. setting up and programming multiple primary continuous IV infusions
2. identifying IV infusions
3. managing dead volume
4. setting up secondary intermittent IV infusions
5. administering an IV pump bolus

Within each theme, the following are discussed:

- issues
- interventions⁸
- experimental method
- results
- discussion
- limitations

Some issues and findings overlapped multiple themes, but for simplicity, cross-referencing between sections has been minimized.

⁸Potential practice-, technology- or education-related interventions are described, including those tested in the laboratory study (education-based interventions are described only if a gap in nursing education in Ontario was identified in previous phases of this project).

Theme 1: Setting Up and Programming Multiple Primary Continuous IV Infusions

Setting up and programming an infusion refers to the processes of assembling, arranging, and configuring the components required to deliver an IV agent to a patient. This section focuses specifically on setting up and programming multiple concurrent primary continuous IV infusions for a single patient (setting up secondary intermittent IV infusions is discussed in Theme 4: Setting Up Secondary Intermittent IV Infusions). Primary continuous IV infusions administer a steady amount of fluid/medication to a patient until they are discontinued, which may be after days or even weeks.

Note: This section focuses on setting up multiple IV infusions at a patient's bedside. Preparing medication (e.g., IV bag contents and label) and inserting venous catheters were out of scope.

Issues

The tasks involved in setting up and programming a primary continuous IV infusion may vary, but generally include the following (not necessarily in this order):

- spiking the IV container with IV tubing and priming the tubing
- hanging the IV container on the IV pole
- loading the IV tubing into an infusion pump
- programming the infusion pump
- connecting the IV tubing to the appropriate IV connector and IV patient access port
- starting the infusion pump
- labelling IV components (e.g., IV tubing)

Setting up more than 1 primary continuous IV infusion is a common task when caring for acutely ill patients, and may be required in the following situations:

- when multiple new IV infusions are prescribed to be initiated immediately (e.g., a new patient is admitted who requires multiple IV therapies)
- when patients are transferred to a new clinical unit and infusions have to be set up again because of differences in infusion equipment (e.g., pump manufacturer/model, drug libraries), medication concentrations, or decentralized inventory management (requiring that pumps be returned to their home unit) (14;27)
- when all IV containers, tubing, and connectors must be changed as part of a “line change” (a best practice to reduce the risk of infection)

Infusion setup and programming risks may be compounded with multiple IV infusions. (8;10;14) The number of infusions at a patient's bedside may increase both the physical complexity (e.g., more IV containers, pumps, IV tubing, poles) and the cognitive load (e.g., managing multiple drug orders). (14) Medication errors are more common in clinical environments where patients are receiving multiple medications, such as ICUs; (17) when more medications are prepared and administered, the likelihood of an error increases. Kane-Gill et al (13) found that each additional IV drug administration increased the likelihood of adverse drug events by 3%.

When multiple IV infusions must be set up, the onus is on the nurse to safely select and connect the correct IV components and program the pump with the correct parameters. Researchers have observed nurses in the field setting up multiple IV infusions in parallel (i.e., repeating a task for several IV

infusions at the same time, such as hanging the IV container and tubing), an approach that requires switching attention between infusions. (14;28) Programming 2 or more pumps in parallel is more likely to result in omission errors than programming them in series; (29) remembering to perform an associatively cued setup task (e.g., opening the roller clamp) is more likely to be forgotten when attention is distributed over multiple goals.

Incidents have occurred from mix-ups when infusions are set up in parallel, (30-32) including the following (Figure 5):

- IV tubing and pump mix-ups (physical errors): Nurses can mistakenly identify the IV tubing and insert the wrong tubing into a pump (①). (31;33)
- Drug order and pump mix-ups (cognitive load errors): Multiple IV infusions ordered at the same time create a high cognitive load. A heavy reliance on the clinician's memory to set up and program all the infusions correctly can result in confusion. (34) Errors have occurred in duplicating an infusion (i.e., 1 ordered medication is set up twice) (10;35) or mixing up pump programming parameters (e.g., dose/flow rate and volume to be infused [VTBI]); this would result in the same error as an IV tubing and pump mix-up, above). (34)
- Label⁹ mix-ups: If tubing is labelled all at once for multiple IV infusions, a label may be incorrectly placed on an IV component (e.g., placing a label for infusion D on the IV tubing of infusion E and vice versa; ②). (10;14) This can lead to subsequent changes to the wrong infusion. The risk of mix-ups is heightened if labels are applied to infusion pumps and multiport connectors and not removed before changing an infusion. (14;31)

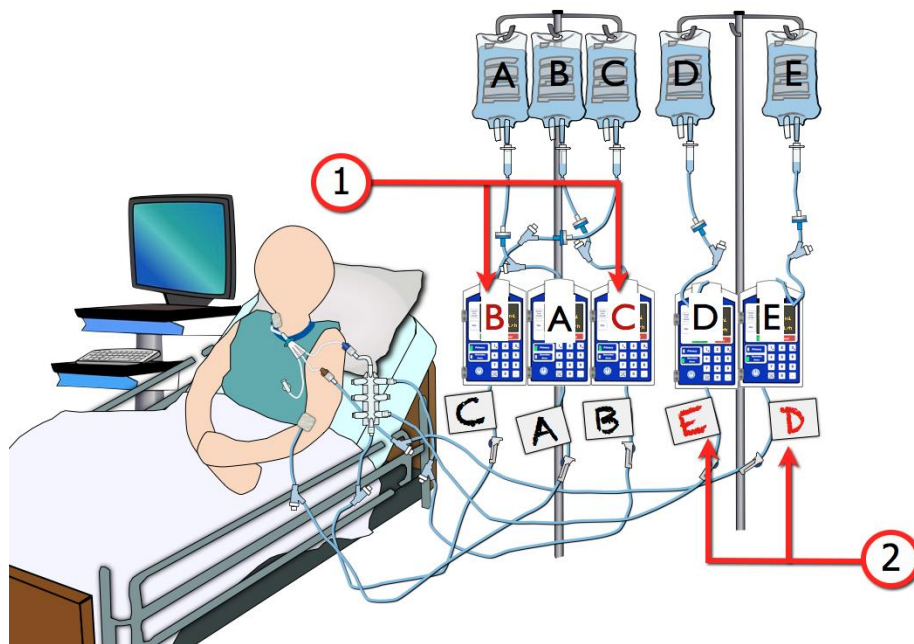


Figure 5: Setting Up and Programming Multiple Primary Continuous IV Infusions: Inter-infusion Mix-up Errors

Abbreviation: IV, intravenous.

⁹Labelling refers to auxiliary labels on IV components (e.g., IV tubing) and *not* the medication label on the IV container. In the laboratory study, all IV containers were pre-labelled; errors in labelling IV containers were not investigated. However, it is important to note that IV container labelling mix-up errors can also occur when preparing multiple IV containers at the same time. Once the medication is prepared with a wrong label, this error is difficult to detect; for this reason, only 1 medication should be prepared (and labelled) at a time.

There are numerous types of inter-infusion mix-ups, but the impact is often the same: the pump is incorrectly programmed for the infusate, leading to medication dosing errors. Reported incidents (e.g., in FDA Manufacturer and User Facility Device Experience [MAUDE] and ISMP Canada databases) include the following:

- The flow rates for insulin and sodium chloride 0.9% were mixed up; the pump was programmed incorrectly to deliver insulin at the sodium chloride 0.9% flow rate of 75 mL/h instead of 3 mL/h, resulting in an overinfusion of insulin (internal document¹⁰).
- The flow rates for sodium chloride 0.9% and diltiazem (Cardizem) were switched; the overdose of diltiazem resulted in a patient death (internal document¹⁰).
- The flow rate of morphine was titrated up instead of the flow rate for norepinephrine because labels were swapped, resulting in an overdose of morphine. (14)

Setting up multiple primary continuous IV infusions may exacerbate the known risks of setting up 1 infusion. Infusion pump programming errors are well documented and can occur for a variety of reasons, including miscalculations, drug-unit errors, button-push mistakes, or multiple-of-10 errors. (6) Programming any IV infusion is a risk-prone activity, but it has been suggested that setting up continuous IV infusions is more error-prone than setting up intermittent IV infusions. (6) The calculation of programming parameters for continuous IV infusions from drug orders is complex and involves many variables. (36) As well, such errors are likely to have greater potential for harm since they are sustained, less likely to be detected, and involve more potent medications than intermittent infusions. (6)

Setting up multiple IV infusions at the same time is a required task in many clinical units (e.g., ICUs), but issues associated with setting up and programming 1 or more continuous IV infusions in a multi-infusion environment have not been empirically studied. Research is required to further understand these issues and effective risk-mitigation strategies.

Interventions

Practice Interventions

Specific clinical practices may decrease risk in setting up and programming multiple primary continuous IV infusions. For example, best practices for the setup of a single IV infusion may also apply to the setup of multiple IV infusions:

- Always trace an infusion from the IV container through the infusion pump to the patient access port before making connections or administering IV infusions. (31;37;38)
- “Mind the drip” (i.e., check drip chamber) to ensure the pump is pulling fluid from the intended IV container. (39;40)
- Independently double-check the setup and programming of high-alert IV medications by having a second nurse validate the order, patient, dose/concentration, route, and pump/channel programming. (31;41)

Nurses typically do not receive specific guidance on how to set up multiple primary continuous IV infusions, so processes vary by nurse. (14) Given the many other demands on their time, nurses may use methods that they perceive to be efficient, but those methods may not be optimal from a safety perspective. (14)

It has been suggested that when multiple IV infusions are being set up at one time, each infusion should be set up as completely as possible before beginning the next, to avoid confusion; (14;31;34;39) this is

¹⁰HumanEra internal document, August 18, 2010.

referred to as a *one-at-a-time protocol*. Figure 6 illustrates the setup of 3 infusions following a one-at-a-time protocol.

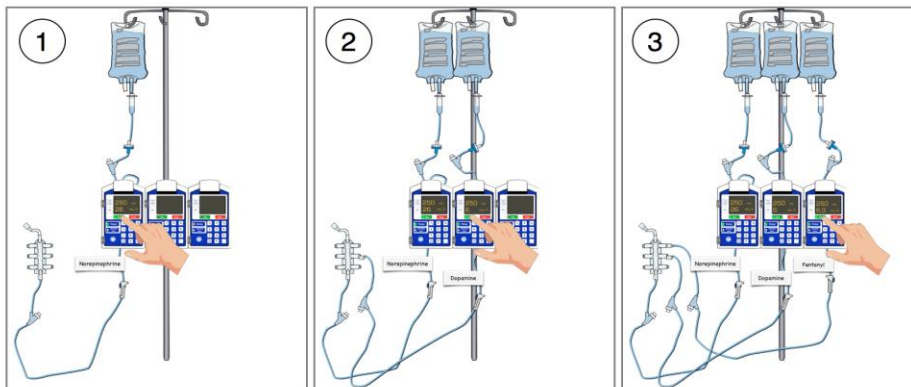


Figure 6: Setting Up and Programming Multiple Primary Continuous IV Infusions: Sequential Setup (One-at-a-Time Protocol)

Abbreviation: IV, intravenous.

This figure illustrates the setup of 3 infusions following a one-at-a-time protocol. The first infusion (●) is set up as completely as possible (i.e., the IV container and tubing are hung; IV tubing is inserted in the pump, attached to the multiport connector and labelled; the pump is programmed) before the second infusion is set up (●). After the second infusion is set up as completely as possible, the third infusion is set up (●).

Figure 7 illustrates the set up of 3 infusions in parallel (also referred to as “batching”), where some or all setup tasks are completed in groups across multiple infusions.

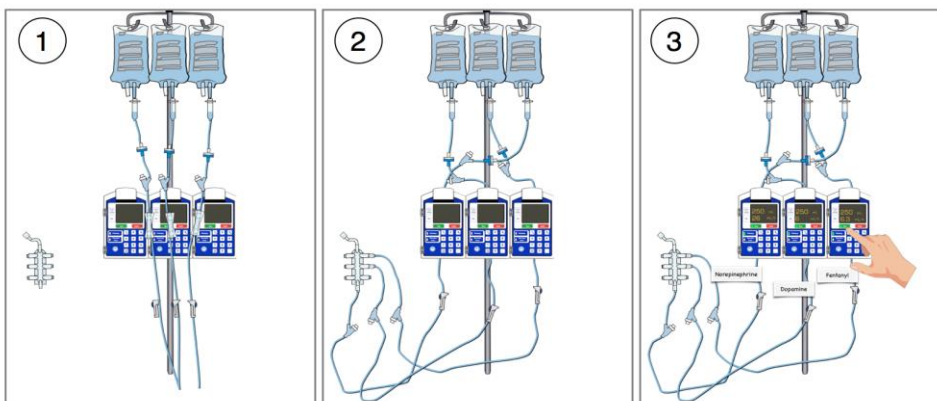


Figure 7: Setting Up and Programming Multiple Primary Continuous IV Infusions: Parallel Setup (Batching)

Abbreviation: IV, intravenous.

This figure illustrates the setup of 3 infusions in parallel; IV bags and tubing are hung for all 3 infusions (○); IV tubing is inserted into the pumps and attached to a multiport connector for all 3 infusions (○); and/or the pumps are concurrently programmed and IV tubing labelled for all 3 infusions (⌘).

Batching creates opportunities for mix-up errors (e.g., loading the wrong IV tubing into a pump, programming a pump with the wrong parameters, or attaching the wrong label to a pump). Although performing tasks in parallel may seem to be more efficient, (29;42) humans are more likely to make errors when they multitask. (43;44)

A study by Back et al (29) found that when people programmed 2 infusion pumps sequentially, they made fewer setup errors than when they programmed in parallel. However, the study focused on how drug order

presentation affected infusion setup and was conducted with nonclinicians in a low-fidelity simulation where users were encouraged to set up 2 IV infusions concurrently. Thus, while the “one-at-a-time” protocol has the potential to reduce infusion setup errors, empirical research is required to evaluate its effect in representative users (i.e., nurses), tasks, and environments, and to determine the resource and time implications of implementing it.

Given this research gap, the one-at-a-time protocol was selected for further investigation in the laboratory study. It was hypothesized that nurses would make more errors—particularly inter-infusion mix-up errors—in the baseline condition (i.e., not following a one-at-a-time protocol) than in the intervention condition (i.e., following a one-at-a-time protocol). It was also hypothesized that the task time would not increase when following the one-at-a-time protocol, since the intervention was intended to simplify the overall task.

Technology Interventions

Technologies such as smart pumps have the potential to improve medication safety. Unlike traditional infusion pumps, which have a wide range of acceptable programming parameters, smart pumps include hospital-defined drug libraries with drug-specific dosing limits to alert users to potential programming/dosing errors. Research has shown that smart pumps reduce pump programming errors compared to traditional pumps; (7;45;46) smart pumps may help reduce errors that result from confusing programming parameters (i.e., drug orders) when setting up multiple IV infusions concurrently. However, the effectiveness of smart pumps at reducing programming errors has been limited because nurses often bypass drug libraries and override soft-limit alerts, even when doing so is clinically inappropriate. (3;7;47;48) In addition, using smart pumps does not address physical inter-infusion mix-up errors; the wrong IV tubing can still be inserted into a smart pump. (8;31)

Some smart infusion pumps are *multichannel* pumps, which allow multiple continuous IV infusions to be administered using 1 pump; infusions are programmed from a central programming unit, but administered via separate pump channels. Multichannel pumps offer numerous advantages, including the ability to detect and alert when 1 ordered infusion is mistakenly duplicated on 2 channels. (35) However, nurses have mixed up IV tubing and/or channels while setting up or programming an infusion on a multichannel pump. (31) Such mix-up errors have also occurred on single-channel pumps, but it has been suggested that the close proximity of the tubing on multichannel pumps may further facilitate mix-up errors. (31;33;49)

Some smart pumps interface with networked bar code administration systems. Design varies by manufacturer, but in general, networked infusion systems allow nurses to scan information at the bedside (e.g., bar codes on staff badges, the patient’s armband, the IV drug container, and the pump), and compare the scanned information to records upstream (e.g., physician orders) to automatically program the pump or verify information that has been manually programmed. (24) This type of fully integrated/networked system could significantly reduce programming errors (7;50) and has been suggested as a way of detecting mismatch errors between the IV container and the pump. (8;49;51) However, it is still possible to insert the wrong IV tubing into a networked pump and scan the correct IV container; this error would not be detected by a bar code system. Bar code technology may also introduce the potential for new mix-up errors, including scanning the wrong bar code when multiple IV containers hang on the same IV pole.

Smart infusion technology has the potential to greatly improve medication safety, but current designs do not explicitly target the risks associated with setting up and programming multiple IV infusions. In addition, at the time of this study, no integrated smart pump and bar code system was available in Canada for testing. Consequently, the use of smart infusion technology to reduce errors in setting up and programming multiple primary continuous IV infusions was not evaluated in the laboratory study.

Experimental Method

Forty ICU nurses each completed 1 task (a line change) under 2 different experimental conditions (baseline and using a one-at-a-time protocol).

Task

A *line change* is a routine clinical task in which all the IV tubing, connectors, and containers are replaced to prevent infection. Nurses were asked to do a line change for the infusions connected to access port 3 in Figure 8, meaning that 4 new primary continuous IV infusions needed to be set up and programmed: 3 vasopressors and 1 sodium chloride 0.9% chaser. To save time, nurses were provided with the IV containers pre-mixed, labelled, and spiked with primed IV tubing, but they were required to complete the following (not necessarily in this order):

- hang the new IV containers and tubing on the IV pole
- load the IV tubing into the infusion pumps
- program the infusion pumps
- label the IV components (e.g., IV tubing) according to usual practice
- connect the IV tubing to a new multiport connector (not yet connected to the patient)
- start the pumps
- exchange the old multiport connector (attached to access port 3) for the new multiport connector

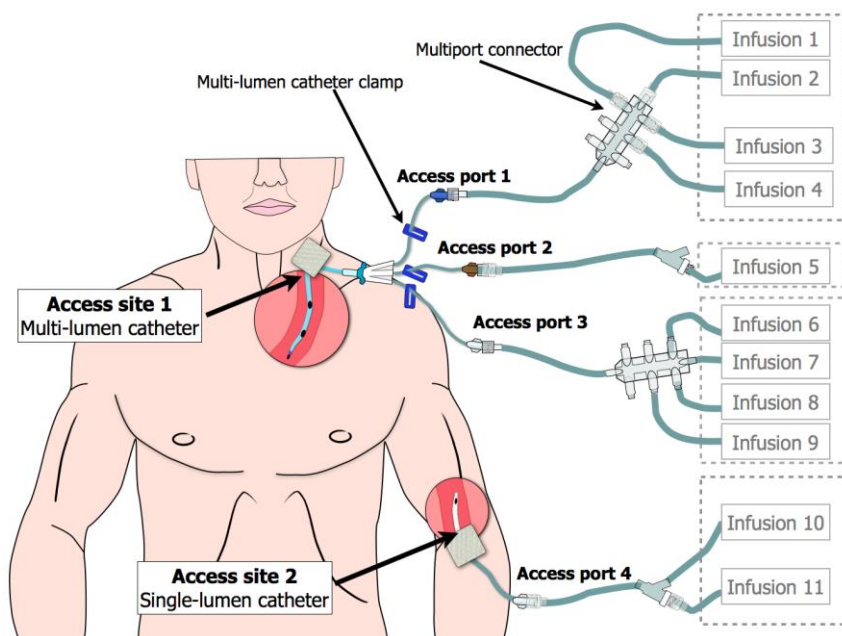


Figure 8: Setup of Patient Infusions in the Simulation Laboratory Study

Nurses were not required to dismantle the 4 old infusions. The task was stopped after the multiport connectors were exchanged and all 4 new infusions were started. Participants were given new pumps to use for the line change.

Since interruptions are common in clinical practice, (7;52-56) the confederate nurse interrupted with a scripted question when a participant had completed about 50% of the line change (i.e., 2 IV infusions had been set up).

Nurses were provided with blank adhesive labels and markers to label IV components (such as the IV tubing and/or the pump). Labelling was not mandated, but if participants labelled components in the baseline condition, they were required to label them in the intervention condition to ensure equivalency. Conversely, if participants did not label IV components in the baseline condition, they were instructed not to label components in the intervention condition.

Experimental Conditions

The 2 experimental conditions are described in Table 5. The intervention condition was always completed last, since training on the one-at-a-time protocol had the potential to affect baseline performance.

Table 5: Setting Up and Programming Multiple Primary Continuous IV Infusions: Experimental Conditions and Training

Experimental Condition	Description	Training Content
Baseline	No intervention (i.e., control)	No training required
One-at-a-time protocol	<p>Each infusion was to be set up sequentially. In particular, participants had to complete the following for 1 infusion before starting to set up the next^a:</p> <ul style="list-style-type: none"> • hang IV container • load IV tubing into the pump • program infusion pump • label IV components (if done in the baseline condition) <p>Participants could complete the above steps in whatever sequence they desired for 1 infusion</p>	<p>Training reviewed the one-at-a-time protocol and compared it to setting up and programming infusions in parallel. The trainer and participant completed a simulated hands-on one-at-a-time line change of 2 infusions attached to a multiport connector to promote protocol understanding. The training also stressed the importance of minimizing infusion down time by allowing the multiport connector to fill with all connected infusions</p> <p>Total training time was about 5 minutes</p>

Abbreviation: IV, intravenous.

^aParticipants were allowed to complete the following (because there was no opportunity for mix-up errors, and this could minimize nuisance alarms and infusion waste):

- attach all infusions to the multiport connector at the same time
- start all infusions at the same time
- switch the old multiport connector for the new multiport connector with as many infusions attached as they chose

Procedure

The procedure was as described in the Research Methods. In the intervention condition, the confederate nurse prompted the participant if needed to ensure he/she followed the one-at-a-time protocol.

Metrics and Analysis

Participant Performance

Participant performance in each task was recorded by the confederate nurse and test facilitators. The metrics for each task were as follows (see Table 6 for definitions and analysis):

- programming errors (out of 3)
- auxiliary labelling errors (out of 4)
- task time (seconds)

Table 6: Setting Up and Programming Multiple Primary Continuous IV Infusions: Performance Metrics and Analysis

Performance Metrics and Analysis	Programming Error	Auxiliary Labelling Error	Task Time
Definition	Programmed rate after the line change was not equivalent to programmed rate before the line change ^a	Label on IV tubing or pump contained incorrect information (e.g., wrong drug, wrong access port)	Time from when the first IV container was hung to when the new multiport connector was attached to the patient and all 4 new infusions started Time to respond to the planned interruption (initiated by the confederate nurse) and any other unplanned non-task time (e.g., if participant asked the confederate nurse a question) was deducted from the total task time ^b
Performance metric (per participant per condition)	Number of programming errors (maximum of 3)	Number of auxiliary labelling errors (maximum of 4)	Total task time (seconds)
Analysis			
Number of participants included in the analysis	20 ^c	6 ^d	20 ^c
Opportunities for error per condition	60 (3 errors per line change; 1 line change per participant per condition)	24 (4 errors per line change; 1 line change per participant per condition)	No errors possible Time recorded for 1 line change per participant per condition
Statistical test (performance metric as a function of experimental condition)	Paired sample (dependent) t-test	NA (statistical analysis not conducted, since no errors were made in either condition)	Paired sample (dependent) t-test

Abbreviations: IV, intravenous; NA, not applicable; VTBI, volume to be infused.

^aAllowances were made to account for minor flow rate differences observed, depending on whether the participant used the pump calculator (which was restricted to 2 decimal points), manually calculated the flow rate using the provided calculator, or used the flow rates in the provided patient documentation. The VTBI programmed by participants was not included as a programming metric, since for a continuous IV infusion, the flow rate determines the dose rate.

^bIf the interruption time was not collected, the average interruption time (24 seconds) was used.

^cTwenty (of 40) participants were excluded from the comparative analysis of programming errors because they either did not complete the line change task in both the baseline and one-at-a-time conditions due to time constraints ($n = 7$) and/or they naturally followed a one-at-a-time protocol in the baseline condition ($n = 15$). Two participants did not complete the task in both conditions *and* naturally followed a one-at-a-time protocol in the baseline condition. Thus, the number of participants included in the comparative analysis was 20 (i.e., $40 - 7 - 15 + 2$).

^dOnly 6 (of 40) participants labelled infusions in the baseline condition; only those 6 were included in the comparative analysis of labelling errors.

Programming errors were recorded for only the 3 vasopressor infusions, since the sodium chloride 0.9% chaser¹¹ is not usually prescribed by a physician (nurses set programming parameters using their clinical judgment). Each coded programming and auxiliary labelling error was analyzed to determine whether inter-infusion mix-up errors may have occurred.

¹¹A *chaser* is an infusion that is used to “push” or “carry” the contents of other infusions connected downstream, minimizing variations in dead volume concentration and ensuring the patency of the IV catheter.

Table 7 provides a summary of the line changes completed and included in the analysis.

Table 7: Setting Up and Programming Multiple Primary Continuous IV Infusions: Line Changes Completed and Included in the Analysis

Experimental Condition	Line Changes Completed ^a	Line Changes Completed in Compliance With the One-at-a-time Protocol	Line Changes Included in the Comparative Analysis of Programming Errors and Task Time	Line Changes Included in the Comparative Analysis of Auxiliary Labelling
Baseline	38 ^b	15	20 ^c	6 ^d
One-at-a-time protocol	33 ^e	33	20 ^c	6 ^d
Total	71	48	40	12

Abbreviation: IV, intravenous.

^aTest facilitators aimed to keep the total experiment time to less than 3 hours; the first task to be eliminated when time was a concern was the line change.

^bTwo (of 40) participants did not complete the line change task in the baseline condition due to time constraints.

^cTwenty (of 40) participants were excluded from the comparative analysis of programming errors because they either did not complete the line change task in both the baseline and one-at-a-time conditions due to time constraints ($n = 7$) and/or they naturally followed a one-at-a-time protocol in the baseline condition ($n = 15$). Two participants did not complete the task in both conditions *and* naturally followed a one-at-a-time protocol in the baseline condition. Thus, the number of participants included in the comparative analysis was 20 (i.e., $40 - 7 - 15 + 2$).

^dOnly 6 (of 40) participants labelled infusions in the baseline condition; only those 6 were included in the comparative analysis of labelling errors.

^eSeven (of 40) participants did not complete the line change task in the one-at-a-time condition due to time constraints (note: 2 of those 7 also did not complete the line change in the baseline condition due to time constraints).

Three expert panel members (2 ICU nurses and 1 pharmacist) independently reviewed programming errors to evaluate whether they would have been likely to result in clinical impact. Final coding was determined by majority rule. The test facilitators also recorded unanticipated errors or hazards.

Participant Feedback

Participants completed a questionnaire (Appendix 2) to capture their perception of each intervention with respect to its effectiveness in reducing errors and the likelihood of its use in clinical practice. Open-ended feedback was solicited about each intervention (as part of the questionnaire), from which summary comment themes were developed.

Results

Participant Performance

Table 8 summarizes performance metrics by experimental condition. A summary of other observed hazards is provided below

Table 8: Setting Up and Programming Multiple Primary Continuous IV Infusions: Performance Metrics by Experimental Condition

Performance Metric	Sample Size, n	Opportunities for Performance Metric Per Experimental Condition	Experimental Condition		Statistics
			Baseline ^a	One-at-a-Time Protocol	
Programming errors, n (%)	20 ^b	60 (3 per participant)	7 (11.7%)	4 (6.7%)	t(19) = 1.14 P = 0.27
Auxiliary labelling errors, n (%)	6 ^c	24 (4 per participant)	0 (0.0%)	0 (0.0%)	NA
Task time, s	20 ^b	20 (1 per participant)	528	469	t(19) = 2.16 P = 0.04

Abbreviations: IV, intravenous; NA, not applicable

^aData from participants who used the one-at-a-time protocol in the baseline condition were excluded.

^bTwenty (of 40) participants were excluded from the comparative analysis of programming errors because they either did not complete the line change task in both the baseline and one-at-a-time conditions due to time constraints (n = 7) and/or they naturally followed a one-at-a-time protocol in the baseline condition (n = 15). Two participants did not complete the task in both conditions *and* naturally followed a one-at-a-time protocol in the baseline condition. Thus, the number of participants included in the comparative analysis was 20 (i.e., 40 – 7 – 15 + 2).

^cOnly 6 (of 40) participants labelled infusions in the baseline condition; only those 6 were included in the comparative analysis of labelling errors.

The rate of programming errors when setting up multiple IV infusions was not significantly different between the baseline and one-at-a-time conditions. The magnitude of programming errors ranged from 20% to 333% of the required flow rate. Three members of the expert panel determined that 64% of the errors (7 of 11) would likely have had a clinical impact.¹² No inter-infusion mix-up programming errors were noted.

Only 30.0% of participants used auxiliary labels in the baseline condition. Of those who used labels, the drug name was written on the label (6 of 6 participants, 100%), and labels were placed on the pump (4 of 6, 66.7%) or the IV tubing (2 of 6, 33.3%).

Participants were able to complete a line change 11.2% (59 seconds) more quickly when following a one-at-a-time protocol.

New Hazards

During the experiment, new issues were uncovered that had not been identified in previous phases of this research or in the literature review.

Lack of Understanding of the One-at-a-Time Protocol

When participants were required to complete a line change using the one-at-time protocol, 10 of 20 (50%) who were new to the protocol started to complete some tasks in parallel and had to be reminded to follow the protocol. The fact that these participants found compliance challenging highlights the difficulties in changing ingrained practices.

Practice Issues in Exchanging Multiport Connectors

During a line change in which multiple IV infusions are connected to 1 access port, any connectors and add-on devices must be changed at the same time as the IV tubing. (57) Issues were observed related to the work practices used to exchange the old multiport connector for the new one, and these resulted in unnecessary interruptions to life-sustaining therapies (Table 9). The one-at-a-time protocol did not provide specific guidance on these issues, so the data in Table 9 combine all findings from both the

¹²Clinical impact was defined as causing temporary or permanent harm (including patient death).

baseline and one-at-a-time conditions (total number of line changes: 71). Almost half of the line changes observed (32 of 71, 45.1%) included 1 or more multiport connector exchange–related error.

Table 9: Setting Up and Programming Multiple Primary Continuous IV Infusions: Practice Issues in Exchanging Multiport Connectors

Hazard	Description	Frequency ^a
Exchanging the old multiport connector for the new one before attaching and starting all new drug infusions	Some participants attached the new multiport connector to the patient access port before attaching and running all the new infusions; this led to an interruption in life-sustaining therapies. In the baseline condition, some participants choose to reuse currently infusing pumps for the new infusions rather than using the spare pumps provided (in the one-at-a-time condition, participants were required to use the spare pumps to comply with the protocol). The reuse of pumps exacerbated interruptions in therapy, since existing infusions had to be stopped and dismantled before setting up new infusions	27 (38.0%)
Connecting the new multiport connector when it was full of sodium chloride 0.9%	Some participants attached the new multiport connector to the patient access port when the connector was primed with only sodium chloride 0.9% and did not contain a mix of the attached medications (i.e., infusions were not started and allowed to fill the connector prior to attaching it to the access port). This led to a temporary interruption in therapies while the sodium chloride 0.9% was pushed through the multiport connector and into the patient (see Theme 3: Managing Dead Volume)	13 (18.3%)
Forgetting to unclamp the patient catheter after attaching the new multiport connector to the patient	Participants typically clamped the access port on the patient catheter when the old multiport connector and infusions were removed to prevent air embolism, venous backflow into the catheter, and infection (Figure 8). However, some participants failed to open the clamp once the new multiport connector was attached to the access port. Consequently, there was likely an interruption in all therapies (rate-dependent). A downstream occlusion alarm would eventually have been triggered on the infusion pumps, which would have helped participants identify and recover from this hazard ^b	5 (7.0%)
Exchanging the wrong old multiport connector (and attached infusions)	One participant disconnected the wrong multiport connector (i.e., the one on access port 1 instead of the one on access port 3, Figure 8). Consequently, the new multiport connector with the new infusions was attached to the wrong access port. As a result, the patient received some infusions twice (i.e., an overdose of infusions 1 to 4 in Figure 8), and others were disconnected (i.e., interrupted therapy of infusions 6 to 9 in Figure 8). This error may or may not have been identified by the participant during the dismantling of the old infusions	1 (1.4%)

Abbreviation: IV, intravenous.

^an = 71. The 71 line changes in the analysis included all line changes completed by participants in both the baseline and one-at-a-time conditions.

^bThe line change task was the last to be completed in the patient scenario. Since infusions were running at a low flow rate, the downstream occlusion alarm was not triggered, and participants' ability to detect and remedy errors was not evaluated.

Variability in VTBI Programming

VTBI was not coded as a programming error, since for a continuous IV infusion, the infusion dose is determined by the programmed flow rate. However, the programmed VTBI determines when a nurse is called back to an infusion, and errors may result in interruptions in therapy.

There was a wide variation in programming the VTBI, ranging from 0.9% of the IV container volume to 359% (i.e., 898 mL for a 250 mL container). Of the 213 primary continuous drug infusions programmed (71 line changes, each with 3 drug infusions), 30 (14.1%) were programmed with a VTBI that was > 10% more or less than the IV container volume:

- Twenty-eight of the 30 (93.3%) were programmed with a VTBI > 10% *less* than the IV container volume. The expert panel suggested that some participants may have intentionally programmed a lower VTBI to trigger a call-back alarm as a reminder to retrieve or prepare the subsequent IV container for the continuous infusion. However, a nurse may be unable to immediately respond to the end-of-infusion alarm, so this may contribute to interruptions in therapy or reduced flow rates (some pumps revert to a keep vein open [KVO] rate instead of stopping).
- Two of 30 (6.7%) infusions were programmed with a VTBI > 10% *more* than the IV container volume. Although an infusion pump alarms when a container runs dry, nurses may not have a replacement IV container immediately available. In addition, nurses may have to clear air in the IV tubing as a result of the infusion running dry, leading to an interruption in a life-sustaining medication. In the tested scenarios, the detectability of this hazard was high, because infusion flow rates were low. The IV container would not deplete prior to a shift change or a scheduled IV container change (i.e., IV containers must be changed every 24 hours for infection prevention or more frequently based on medication protocols), at which time the VTBI could be verified and/or reset. Nevertheless, the observed practice of participants entering a VTBI greater than the IV container volume was identified by the expert panel as a potential concern.

Although these variations in programming the VTBI may not directly affect the dose administered for a continuous infusion and constitute a medication error, they did introduce the risk of causing unnecessary interruptions to therapy, which in some cases could be clinically significant.

Participant Feedback

All 40 participants completed a questionnaire to collect their feedback on the interventions tested. Participant feedback is summarized in Table 10 (see Appendix 2 for details).

Table 10: Setting Up and Programming Multiple Primary Continuous IV Infusions: Participant Feedback

Question		One-at-a-Time Protocol
Effectiveness at reducing medication errors ^a		3.4
Likelihood of using intervention in clinical practice ^b		3.3
Comment themes	<ul style="list-style-type: none">• Already adhere to this protocol in current practice• Good general principle, but protocol cannot always be followed for clinical and operational reasons; for example, pump inventory shortages and space limitations may force nurses to reuse the pumps that are already infusing• Protocol is too restrictive; nurses should be given the flexibility to set up their infusions depending on their mental model or patient needs	

Abbreviation: IV, intravenous.

^aFour-point scale: 1, very ineffective; 2, somewhat ineffective; 3, somewhat effective; 4, very effective.

^bFour-point scale: 1, definitely not use; 2, probably not use; 3, probably use; 4, definitely use.

Participants provided insightful comments to explain their ratings and describe potential implementation issues that were not studied in the laboratory simulation. Some participants indicated that the one-at-a-time protocol was redundant because they already set up new infusions using this protocol in their clinical practice. However, 2 of 6 (33.3%) did not set up their lines according to the one-at-a-time protocol in the baseline condition, indicating a gap in their understanding. During training on the one-at-a-time protocol, some participants expressed confusion about the terms *one-at-a-time* and *batching*; they initially assumed that in the context of a line change involving multiple IV infusions, *one-at-a-time* meant setting up the new infusions with the existing pumps (i.e., reusing pumps), which would require switching the patient over to the new infusions 1 at a time. In contrast, they thought *batching* referred to setting up the new infusions on a separate bank of new pumps all at the same time (i.e., batch setup of the infusions) and then switching the patient over to the newly set up infusions all at once. They did not associate the terms with the order in which the subtasks (e.g., hang IV container, program pump) were completed, as defined in this study.

Discussion

The study findings confirmed that setting up and programming multiple primary continuous IV infusions on 1 patient is an error-prone activity, and risk mitigations are needed. In particular, the results highlighted the need to:

- provide clinicians with best practices to safely set up and program multiple IV infusions (i.e., one-at-a-time protocol)
- improve the design of IV components and infusion pumps to avoid setup and programming errors
- minimize the frequency of setting up and programming multiple IV infusions

Best Practice: One-at-a-Time Protocol

This study investigated the impact of a one-at-a-time protocol on reducing errors when multiple IV infusions were set up and programmed. One key motivation for using the one-at-a-time protocol was to reduce opportunities for inter-infusion mix-up errors. However, mix-up errors were not observed during the study, so the effectiveness of the one-at-a-time protocol at reducing such errors could not be evaluated.

Another key motivation for using the one-at-a-time protocol was to reduce general programming errors, since it has been suggested that the risk of these types of errors may be increased in a multi-infusion environment. (8;10;14) Compared to baseline, participants made 42.8% fewer programming errors when following a one-at-a-time protocol. However, since 39.5% of participants (15 of 38) naturally followed the one-at-a-time protocol in the baseline condition (and thus were excluded from the analysis), statistical power was limited. Still, the fact that many participants already complied with the one-at-a-time protocol was telling; it suggested that nurses had intuitively developed this practice or learned it from mentors as a best practice.

There were 2 other positive indications that the one-at-a-time protocol may improve nurses' ability to safely set up multiple IV infusions. First, following a one-at-a-time protocol decreased task time, suggesting that it would also decrease resource requirements. As well, decreased task time has been associated with a positive effect on performance (i.e., reduction in errors) in other studies. (58-61) Second, the protocol was well-received by participants, who ranked it *effective* to *very effective* in reducing medication errors and indicated that they would follow the protocol in their clinical practice.

Although the one-at-a-time protocol had a positive effect on participant performance and was well accepted, results suggested that it required clarification and further research prior to its effective implementation. In particular, research must be expanded to clarify the following 2 points:

- Label infusions (e.g., IV tubing) as part of infusion setup: Participants often did not place auxiliary labels on IV components (e.g., IV tubing) in the baseline condition as part of the initial setup, which may suggest that participants considered labelling to be nonessential. As such, infusion components may not be labelled, or labelling may be deferred and then batch-processed across multiple IV infusions, resulting in mix-up errors. Other research has identified that infusions are often labelled incorrectly or not at all. (16;27;49) If auxiliary labelling is required by hospital policy, it should be 1 of the steps in the one-at-a-time protocol. Further discussion of auxiliary infusion labels is provided in Theme 2: Identifying IV Infusions.
- Requirements when completing a line change involving a multiport/lead connector: When exchanging the multiport connector during the line change, unnecessary interruptions to life-sustaining medications occurred, likely as a result of a lack of knowledge regarding the risks and best practices associated with this task (e.g., how to flush the multiport/lead connector when following a one-at-a-time protocol). In addition, some participants mistakenly thought the one-at-a-time protocol required that each infusion be started and *attached* to the new multiport connector (attached to the patient access port) prior to setting up the next infusion. Therefore, the one-at-a-time protocol needs to be augmented to provide additional information and avoid interruptions to life-sustaining therapy during a line change involving a multiport connector. Although further research is required to validate best practices, the following additions to a one-at-a-time protocol should be considered:
 - The setup of infusions should be grouped by access port. That is, all infusions connected to 1 access port should be set up and started before initiating the setup of infusions for another access port.
 - For each access port, the following should be completed in sequence:
 1. Each infusion should be set up one at a time (i.e., as completely as possible) on new pumps/channels and attached to the others sharing the access port (e.g., to a new multiport/lead connector or y-injection site, but not yet to the patient access port).
 2. Infusions should be started so they can fill the shared dead volume (e.g., priming volume of the multiport/lead connector, IV tubing below a y-injection site) to allow for the appropriate mix of the attached infusates for the patient access port.¹³
 3. The new infusions should be attached to the patient access port (e.g., access port should be clamped and the old multiport/lead connector and infusions disconnected, and then the new multiport/lead connector attached to the patient access port with the new [but same] infusions).

The study findings also highlighted that implementation of the one-at-a-time protocol requires organizational support. Participants expressed initial confusion over the definition of the protocol, and this confusion was reflected in their compliance (50% had to be reminded to follow the one-at-a-time protocol). Protocol implementation should be accompanied by comprehensive training to clarify motivations, procedures, terminology, and applications in different situations (e.g., IV tubing change with and without a multiport/lead connector, lack of availability of spare pumps). Training should also stress that the one-at-a-time protocol should be used in addition to existing recommended practices to minimize medication errors (e.g., nurses should trace all IV infusions before administering new ones, check the drip chamber, and do an independent double-check of high alert drugs). Health care providers should address

¹³Caution: there is a risk that in urgent situations the IV connector may be attached to the patient before removing all air from the connector; further research is required to minimize this risk.

operational requirements for implementing the one-at-a-time protocol, such as ensuring sufficient pump inventory to set up multiple life-sustaining infusions on new pumps.

IV Component and Pump Design

The study also identified new setup and programming hazards that must be addressed through improved IV component and pump design. However, since the study did not explicitly investigate the impact of IV component and pump design on the reducing the risks associated with setting up and programming multiple IV infusions, further research is required to validate technology-related risk reduction strategies.

The design of patient catheters and clamps likely contributed to unnecessary interruptions in life-sustaining therapy when exchanging the multiport connector during the line change. Errors in failing to open the clamp and exchanging the multiport connector on the wrong patient access port were likely the result of unintentional actions. That is, nurses knew these practices were inappropriate, but they occurred as a result of insufficient user feedback from the setup. It is difficult to determine whether a clamp on a patient catheter is open or closed. It is also difficult to identify which patient access port on a multi-lumen catheter infusions are connected to. While these errors would likely be detected (e.g., downstream occlusion alarm, detection when dismantling old infusions), they could result in a temporary interruption in therapy or overdoses of medications. Infusion connection and clamp errors in general are well-documented in other research (7;12;29) and reported incidents. (62) When setting up multiple connected infusions, 1 clamp or connection error may impact several IV infusions. Therefore, the design of patient catheters and clamps must improve so users can clearly identify infusion pathways and clamp status.

Another design-related hazard identified in the study was the high frequency of infusion-rate programming errors and large variations in programming the VTBI—errors that are not unique to setting up multiple primary continuous IV infusions. Smart pumps have been shown to reduce some dosing (i.e., rate) errors compared to traditional pumps by alerting users to potential problems. (7;45;46)

Ideally, users should not be required to program a VTBI, because the pump automatically detects and monitors the IV container volume (similar to a syringe pump). However, until such technology exists, an option is for smart pumps to default the VTBI based on the concentration selected during pump programming (note: the defaulted value would need to account for variables such as IV tubing priming volume and IV container overfill, if applicable) to minimize unnecessary interruptions to life-sustaining therapy. Another VTBI hazard is using the VTBI to trigger call-back alarms. As highlighted by AAMI, many current infusion pump designs do not provide users with timely notification for the preparation of follow-up IV containers. (8) As such, nurses programmed the VTBI for less than the IV container volume to trigger call-back alarms, resulting in unnecessary interruptions to therapy. Infusion pump design may benefit from a separate feature that detects when IV containers must be replaced and notifies users in advance. Other pump design recommendations to limit VTBI variability are discussed in Theme 4: Setting Up Secondary Intermittent IV Infusions, since a large variation in programming VTBI was also observed when participants programmed secondary intermittent IV infusions.

Another tactic for reducing errors in setting up and programming multiple primary continuous IV infusions is to decrease the physical complexity of infusions and improve infusion organization and communication; this concept is further discussed in Theme 2: Identifying IV Infusions.

Minimizing the Setup and Programming of Multiple IV Infusions

Although best practices and technology can help reduce setup and programming errors, the actual use of multiple primary continuous IV infusions should be minimized, since it is an error-prone activity. Clinicians need to consider the risks and benefits when deciding to add an IV medication to a patient's therapy, particularly if the patient is already receiving multiple IV therapies (e.g., to keep the overall complexity manageable, it may be possible to discontinue 1 or more existing medications or administer

the IV medication in a less error-prone manner). The more IV infusions administered to a patient, the more likely it is that a medication error will occur; more IV infusions may not always be better.

When a patient requires multiple IV infusions, the task of setting up and programming multiple IV infusions at one time should be minimized. For example, health care organizations should ensure that line changes are not completed more often than recommended; the Centers for Disease Control and Prevention (63) and Infusion Nurses Society (37) recommend that in general, primary and secondary *continuous* IV administration sets (and add-on devices) should be changed no more often than every 96 hours, because more frequent changes do not decrease the risk of infection (note: there are exceptions to this general rule). In addition, greater standardization between transferring units (e.g., infusion setups and delivery devices) could help minimize the need to re-establish infusions already running. (27;64) Centralized fleet management of infusion pumps (allowing pumps to travel with the patient to new care areas) can also reduce the need to recreate infusion setups that are already running. (14) However, centralized fleet management requires careful coordination to ensure pumps are available in a timely fashion.

Limitations

In this study, the order of experimental conditions was not counterbalanced; the baseline condition always occurred before the one-at-a-time condition to avoid influencing baseline behaviour. This may have meant that participants were more familiar with the task in the one-at-a-time condition, possibly contributing to the decrease in task time. In contrast, the line change task using the one-at-a-time protocol was always the last task participants performed in the 3-hour simulation session, so they may have been more fatigued, increasing the probability of error and augmented task time. As a result, it is unlikely that the lack of counterbalancing would account for the significant (11.2%) reduction in task time.

Another limitation was that participants' ability to detect and remedy errors was limited by time; for example, it is probable that some of the errors identified in exchanging the multiport connector would have been detected by participants if they had been given the opportunity to dismantle the old infusions (as they would have done in real practice).

Summary

Setting up and programming multiple primary continuous IV infusions is a risk-prone activity that should be minimized where possible (e.g., through greater standardization between sending/receiving units). When required, setting up and programming infusions using a one-at-a-time protocol may help improve safety, but further research is required, particularly to clarify protocol and organizational requirements when setting up multiple infusions connected to a multiport/lead connector. Design improvements to IV components (e.g., patient catheters and clamps) and infusion pumps may also help reduce risks, but further research is required to validate their effectiveness.

Theme 2: Identifying IV Infusions

Once an IV infusion has been set up, clinicians must be able to quickly and accurately identify its contents (e.g., medication, concentration), status (e.g., infusing, stopped/paused), and pathway (e.g., the access port to which the infusion is connected, other connected infusions). This section provides further information on identifying IV infusions.

Issues

Each infusion should have a visually distinct and discrete pathway, beginning at the IV container and ending at the patient. Instead, IV components—particularly IV tubes in multi-infusion environments—become twisted and easily confused. The resulting visual clutter above and below infusion pumps, commonly referred to as *spaghetti syndrome*, makes it challenging for even experienced nurses to quickly and accurately identify infusions and their components. (10;14;65;66)

Spaghetti syndrome can create frustration and tension between staff (e.g., between transferring units, at shift handovers), as is evident from nursing blogs, (67) but it can also result in patient harm, particularly in critically ill patients, who often require urgent and frequent changes in therapy. (65) Although spaghetti syndrome is a well-known problem, there has been little empirical research to investigate it. Nevertheless, 3 issues related to spaghetti syndrome have been identified in the literature.

First, patient harm may arise because of delays in critical changes to treatment while a nurse sorts through a complex setup. (14;65) Sorting through the setup requires significant nursing resources, and while nurses sort, they are likely to be distracted and less able to focus on monitoring the patient. (14;65)

Second, young children have become entangled in IV tubing, as well as in other medical tubing and cords (e.g., monitor cables), resulting in strangulation and death. (68-71) It has been recommended that health care providers identify patients at risk of IV tubing entanglement and consider minimizing the number of IV infusions they receive; using accessories to reduce the chance of IV tubing wrapping around limbs; and augmenting supervision. (68-71)

Finally, spaghetti syndrome may also make it difficult for nurses to correctly identify infusion components, resulting in patient harm. A root-cause analysis of drug infusion error reports at 1 hospital identified IV tubing confusion as a key contributing factor. (72) Infusion confusion has contributed to the following reported errors:

- Incorrect pump/channel: Nurses must frequently adjust infusion pump parameters (e.g., increase, decrease, pause, or stop the flow rate) and to do this, they must quickly identify the correct infusion pump. However, incidents have been reported in which parameters were adjusted on the wrong pump/channel. (14;27;31;49) The implications of this type of error depend on the setting changed, but generally would result in an action performed on the incorrect pump and/or no action performed on the correct pump. For example:
 - After a patient was transferred to a new unit, the receiving nurse confused an infusion pump administering insulin with one administering sodium chloride 0.9% and unintentionally titrated the insulin pump's flow rate to the desired sodium chloride 0.9% rate (i.e., from 3 mL/h to 75 mL/h), resulting in an overdose of insulin. (10)
 - A nurse intended to titrate up the flow rate of an infusion pump administering norepinephrine, but instead titrated morphine because of a pump labelling error, resulting in an overdose of morphine. (14)
- Incorrect line tracing: To complete various tasks (e.g., disconnect an infusion, administer a manual IV push), nurses must routinely identify and verify an infusion pathway by sliding their

hands along the tubing from the IV container to the patient access port (or vice versa) and around various obstructions (e.g., patient gowns, other tubing, pumps). This is referred to as *line tracing*. Nurses have been known to choose the wrong IV tubing to trace or inadvertently switch to the wrong IV tubing during line tracing. (31;65) Incorrect line tracing can result in a number of errors, including the following:

- Disconnection errors: The nurse may disconnect the wrong infusion from an IV connector or patient access port. (65) The patient would then receive an infusion that was meant to be discontinued and not receive an ordered infusion.
- Documentation errors: The wrong infusion information (e.g., volume infused, dose infused, access port used) may be documented in the chart, including the medication administration record. Infusion documentation errors are common in a multi-infusion environment, and although they do not result directly in patient harm, they may adversely affect clinical decision-making or staff hand-off communication and lead to inappropriate actions or other errors (e.g., dose adjustment, available IV lines). (16)

Each infusion added to a patient setup increases complexity, which may increase the potential for misidentifying IV infusions. (14) Other factors that may compound the challenges associated with identifying correct infusions include the following:

- Visual complexity and poor organization: An IV infusion requires the assembly of many separate components; the resulting pathways are long (e.g., IV tubing can be as long as 250 cm), can easily become entwined, and may not be continuous (e.g., there may be obstructions, such as gowns¹⁴). (14;65) Furthermore, different arrangements of components may put IV containers, tubing, pumps, and patient catheters out of alignment. For example, if a carousel IV pole-top is used, IV containers may not align vertically with a horizontal row of pumps attached to the IV pole below. (10;14;49)
- Lack of information about an infusion along the pathway: Most IV infusion components look similar, and lack clear differentiation. (10;14) In addition, infusion information such as contents (e.g., infusate type and dose), status (e.g., infusing, stopped/paused), and connections (e.g., to other infusions and to which patient access port) is at best only partially communicated along the infusion pathway (e.g., IV container label, infusion pump display, auxiliary labels, if used). In particular, there is a lack of information about infusion contents below the pump at the patient's bedside. (10;14)
- Non-standard setup: Nurses construct infusion systems over time in response to a patient's changing needs. This may result in non-standard setups (e.g., different groupings of pumps per pole, various types of IV connectors), making it challenging to quickly identify an infusion, particularly when nurses are caring for a patient they are unfamiliar with (e.g., shift change, covering a colleague's break). This issue includes "daisy-chaining" infusions, where infusions are joined in a linear fashion using the lower injection port on the IV tubing; the end result is an extended chain of medications progressively funnelled into a single IV tube before entering the access port. (14) This type of setup also influences dead volume (Theme 3: Managing Dead Volume): increasing or decreasing the rate of 1 of the connected infusions may affect the rate of all the others.

Since misidentifying infusion pumps and line-tracing errors have been identified as causes of medication errors, empirical research is required to further understand effective risk-mitigation strategies.

¹⁴Obstructions may necessitate the disconnection of infusions to perform patient care tasks, such as gown changing and bathing, further increasing the risk of mix-ups between infusions.

Interventions

Finding ways to mitigate infusion identification errors is a challenge because these errors involve multiple and variable physical components that may change with a patient's condition (e.g., new medication orders). Numerous practice- and technology-related interventions have been suggested to help correctly identify infusions, but there is little empirical research evaluating these strategies; the literature search identified only 1 controlled study by Porat et al. (72)

Practice Interventions

Current practice recommendations aimed at reducing infusion identification errors are as follows:

- Caregivers should trace infusions from the patient to the point of origin (or vice versa) in the following situations:
 - before making any connections/disconnections (e.g., connecting a secondary IV infusion to a primary IV infusion, administering a manual IV push) or altering IV infusions (e.g., increasing the flow rate) (31;38;57)
 - during staff hand-off processes (e.g., patient's arrival to a new unit, staff shift changes) (38;57)
 - several times a shift when double-checking all IV solutions (31)
- Doses of high-alert medications should be independently double-checked. (30;31;41;64)

While the above practices are important, they are person-focused; for this laboratory study, it was decided to investigate design-oriented interventions.

Technology Interventions

Technology-oriented interventions may help mitigate infusion identification errors in 2 ways.

First, they can minimize the need to make infusion changes, relying less on individual clinicians to correctly identify infusions. Infusion pump algorithms are being developed that automatically adjust pump programming parameters to meet a targeted blood or effect-site effect (e.g., insulin pump parameters adjusted based on blood glucose levels); such infusion systems are referred to as *target-controlled infusions* (TCIs) and minimize the need for clinicians to titrate infusion rates. (73;74) Similarly, patient gowns with snaps or ties minimize the need to disconnect/ reconnect infusions during a gown change. (14) However, while such changes are important, they are limited to specific tasks and/or medications, and as such were not selected for further study.

Second, technology can minimize the potential for infusion identification errors by decreasing bedside physical complexity, augmenting infusion organization, and/or improving and standardizing infusion system communication. The following ideas have been suggested and are discussed below:

- colour-tinted IV tubing
- adhesive auxiliary labels
- infusion organizers
- infusion pump/channel displays
- light-linking systems

Colour-Tinted IV Tubing

Colour-tinted IV tubing has been suggested as a way to help minimize infusion identification errors, (65) and it is commercially marketed (offered for gravity and secondary IV tubing in a variety of colours). Colour-tinted tubing may help clinicians distinguish between infusions and visually trace infusion pathways; it also avoids some known problems with adhesive labels, such as adherence and timely removal.

However, the Institute for Safe Medication Practices (ISMP) (United States) has cautioned that there is a lack of evidence about whether colour-coding can prevent medication identification errors. (75) Furthermore, ISMP (United States) has identified several concerns and risks related to colour-tinted tubing that have led to harmful consequences (this list is not complete): (75-77)

- Colour memory: Humans have poor colour memory, particularly for similar shades, limiting the scope of a colour-coding scheme.
- Colour mix-ups: Colour-tinted tubing may be mixed up with other colours used in health care (e.g., yellow-tinted tubing may be confused with yellow-striped epidural tubing), or the tubing colour may be altered by the infusate colour (e.g., a red drug may give blue tubing a purple tint). Colour-tinted IV lines may not match colour-coded labels, leading to confusion. Clinicians may also select the wrong tinted tubing, either unintentionally (in error) or intentionally (e.g., because there is insufficient inventory of a desired colour).
- Colour misperceptions: Some staff may have colour-blindness. Poor lighting may also contribute to the misperception of colour.
- Lack of colour standardization: There is no established or universal medication colour scheme in health care. Colours used between clinical units, hospitals, or vendors are often different and can have very different meanings.

In addition to the above, coloured IV tubing may lead users to rely on colour to identify an infusion instead of line tracing to confirm infusion contents and connections. (76-78)

Given these and other issues, the Joint Commission (38) cautioned that colour-coding of IV tubing may have unintended consequences. The Infusion Nursing Society (57) and the Royal College of Nursing (37) recommended that nurses not use colour-coding, colour for differentiation, or colour-matching for product or medication identification.

Research is required to investigate whether colour can be used to improve infusion identification; a critical first step is to investigate how colour can be implemented without introducing new risks (e.g., establish an implementation guide). However, such research is beyond the scope of this study; colour-tinted IV tubing was excluded from further investigation.

Adhesive Auxiliary Labels

Labelling infusions is a well-recognized strategy for informing clinicians about infusion setups, placing information where it is needed and reducing memory load. (14;27;72) A variety of infusion-related labels are in use, but in this report the term *label* was used specifically to refer to auxiliary labels added to IV components (i.e., IV tubing, pump) to help identify the infusion; medication labels (added to IV containers) and date/time labels (added to IV tubing) were out of scope.

The literature and professional associations have provided general recommendations about the use of auxiliary labels to avoid misidentification. (27;33;38;79-81) ISMP (United States) (31) and Wetterneck et al (49) have recommended labelling IV tubing with the drug name at the end closest to the patient and near each pump/channel. However, there is no widely accepted standard for auxiliary labelling in terms of what labels should communicate, or about how, where, and when to apply them. (72)

Given such lack of explicit guidance, researchers have observed variation in labelling practices between hospitals, clinical units, and clinicians. (14;72) Furthermore, research studies have found that infusions are frequently labelled incorrectly or not at all. (16;27;49) Labels may:

- be placed on an incorrect IV component (10;14)
- be confusing or illegible (57;66;78)
- not adhere to the desired component (65)
- not be visible at all angles (e.g., wrapped around IV tubing) (14)
- not distinguish the emergency medication line(s) from other infusions (14)
- present cleaning and infection-control challenges
- contain outdated information (e.g., pump labels not removed when a medication is discontinued and then the pump is reused for a new and different infusion) (14;31;66)

IV tubing label errors have been associated with patient incidents; (14;82) for example, a nurse titrated up a morphine infusion instead of norepinephrine because the labels were switched. (14)

Using labels with a preprinted drug name has been suggested as a way of minimizing some labelling risks. (27;31;49;72) Well-stocked and readily available preprinted labels have been found to increase infusion labelling conformity and compliance. (27) Porat et al (72) conducted a controlled simulation study in which colour-coded preprinted labels on IV containers, pumps, and tubing were compared to handwritten labels (i.e., control). Preprinted labels decreased nurses' time to identify, trace, and describe infusing drugs and lines, and to detect labelling errors. Nurses also preferred using the preprinted labels compared to the handwritten labels. Porat et al (72) attributed the success of the preprinted labels to the fact that they provided more standard, visible, and structured communication about infusions at the bedside. However, since this was the first empirical study assessing the use of preprinted labels, the authors suggested that more research would be required.

Based on such encouraging evidence, the use of preprinted IV tubing labels was selected for further study in an attempt to improve the identification of IV tubing below the pump. Similar to those used by Porat et al, (72) the labels used in this study wrapped around IV tubing, and the infusion drug/fluid name was apparent on either side of a flag (Figure 9). Unlike Porat et al, (72) the use of colour was minimized, given that coloured labels can be 4 to 5 times more expensive than non-coloured labels (72) and that issues with colour-coding had already been identified (see Colour-Tinted IV Tubing, above). ISMP (United States) indicated that black-and-white medication labels promote careful reading to differentiate between infusions, reducing error potential. (75;76) Therefore, all infusion labels were white with black text, except the emergency medication line label, which was yellow with black text to facilitate accurate and quick identification. As recommended by ISMP (United States) (31) and Wetterneck (49) labels were placed at 2 standard locations—below pump and near the distal end of the tubing—but with slight modifications:

- One label was placed about 3 inches below the pump to augment communication at the pump (Figure 9A). It was not placed on the pump, given the risks associated with labels not being removed when a medication is discontinued.
- One label was placed directly above the lowest injection port on the IV tubing to augment communication near the patient access port (Figure 9B). Labels were not placed below the lower injection port (i.e., closer to patient), since they could have misrepresented the tubing contents if another infusion was attached to the same injection port. To minimize the risk of the label not being removed when a medication is discontinued, labels were not placed on the multiport connector.

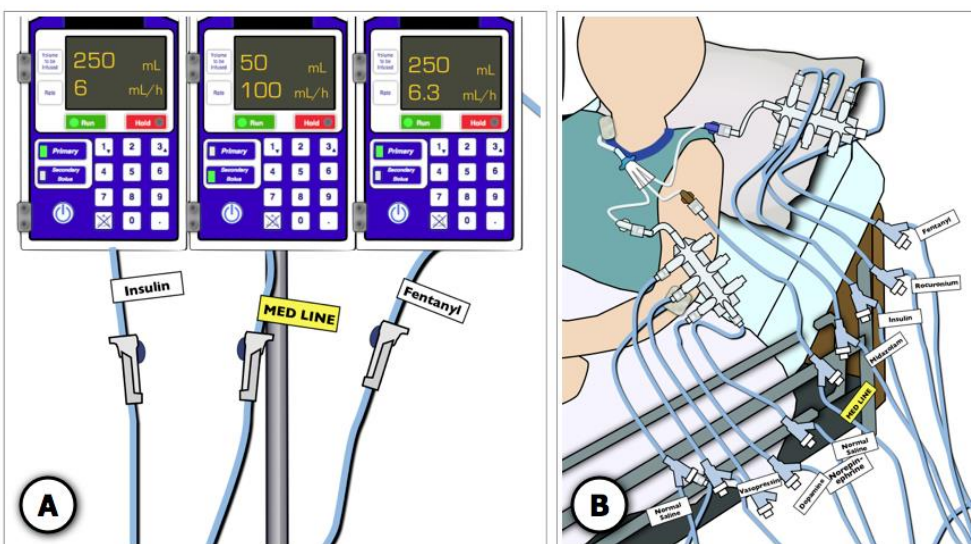


Figure 9: Identifying IV Infusions: Preprinted Labels

Abbreviation: IV, intravenous.

Preprinted labels (A) below the pump and (B) above the lower injection port.

Infusion Organizers

Labels can help augment system communication, but they do not address the problem of physical complexity at the bedside. Infusion organizers—accessories that can be used along the infusion pathway from the IV pole-top to the patient bedside—have been proposed as a complementary approach to labelling. (49) They aim to do the following:

- align infusion components based on the “proximity compatibility principle” (items that are close to each other are related). (83) Setting up IV components in a way that contravenes this principle, may lead to errors; for example, clinicians may falsely assume that IV containers and pumps/channels on the left side of an IV pole are associated, or worse yet, that an IV container and the pump/channel directly below it are associated
- reduce inter-infusion tangles by keeping IV tubes separate from each other using physical guides. (10)

When infusion organizers are used as intended, they can give clinicians a more organized view of infusions and their pathways. However, there is no empirical evidence on the effect of infusion organizers.

Given the lack of evidence, infusion organizers were selected for further study to evaluate their impact on nurses’ ability to correctly identify infusions. The expert panel reviewed market options and selected the following organizers for inclusion:

- IV pole-top organizer: IV poles can be purchased with different tops, which vary in the number, type, and physical layout of hooks (e.g., carousel, star, or rake). A rake pole-top was selected to help align IV containers with the vertical-channel pumps directly below them. The rake pole-top had 2 rows of 4 hooks for hanging IV containers.
- IV tubing organizer: A tubing guide was used to help separate IV tubing and minimize interweaving of tubing below the pump. Each guide held up to 4 IV tubes (which snapped into the guide) and was available in 4 different colours (blue, brown, white, and green) to help group tubing by patient access port. Blue, brown, and white guides were used to group infusions

running into the medial, distal, and proximal access ports on the central line catheter, respectively (i.e., guides were colour-matched the access port). Green guides were used for peripheral lines. The guides were placed in 2 locations to minimize tubing tangles: immediately below the pump (Figure 10A) and below the lowest injection port (Figure 10B). The lower guides were attached to one another to create a central panel for viewing infusions at the bedside.

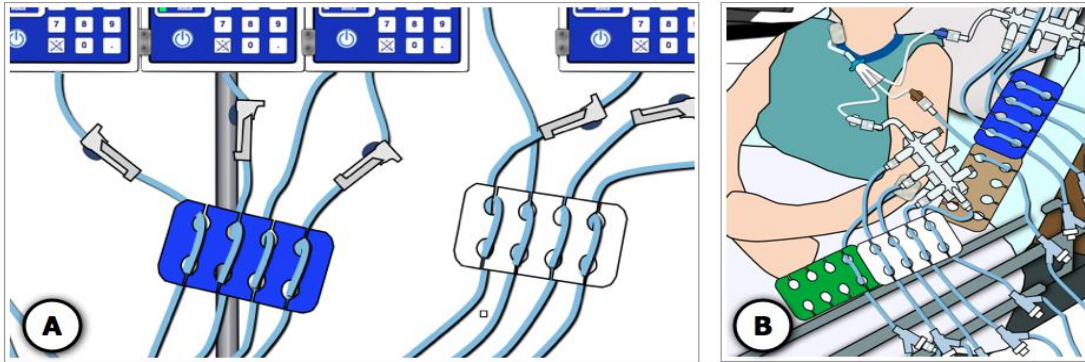


Figure 10: Identifying IV Infusions: IV Tubing Organizer

Abbreviation: IV, intravenous.

IV tubing organizers (A) below the pump and (B) below the lower injection port.

Infusion organizers can be combined with auxiliary adhesive labels to create a system that clearly organizes infusions and communicates information to clinicians. Therefore, preprinted labels and tubing guides were studied together as a complementary system (Figure 11). It was hypothesized that when no labels or organizers were used (i.e., baseline condition), participants would misidentify infusion pumps and perform line-tracing errors (e.g., disconnect the wrong infusion and make documentation errors). However, when infusions were set up with preprinted labels and infusion organizers (i.e., intervention condition), participants would make fewer errors for the following reasons:

- reduced physical complexity above and below the pump by aligning infusion components and separating IV tubing
- augmented IV system communication by having:
 - legible tubing labels
 - colour differentiation of the emergency medication line
 - colour differentiation of infusion groupings by patient access port
 - standardized placement, style, and content of tubing labels

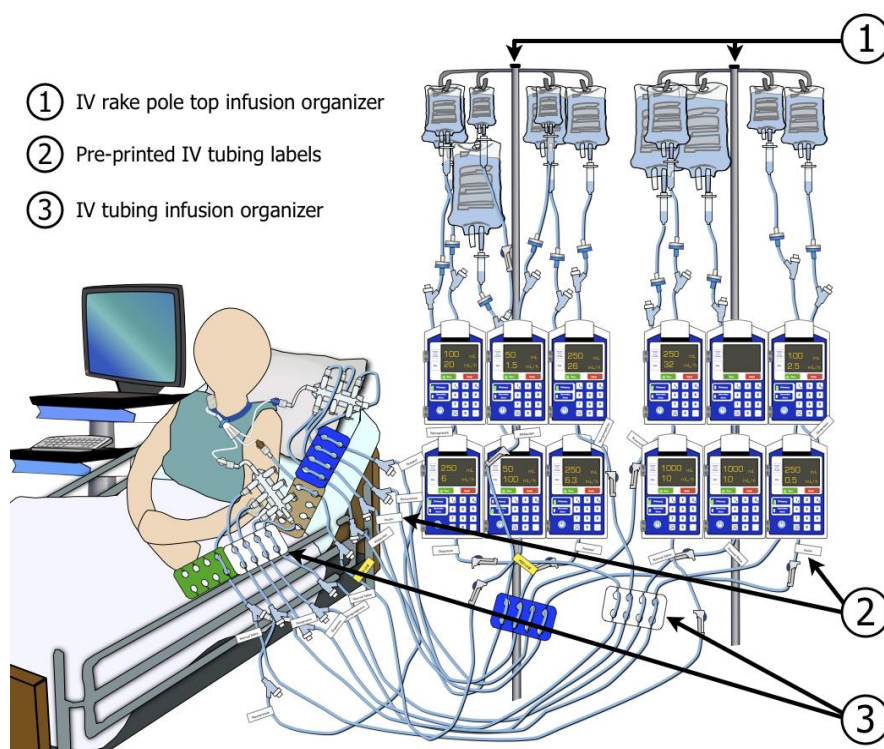


Figure 11: Identifying IV Infusions: Preprinted Labels and Infusion Organizers

Abbreviation: IV, intravenous.

Infusion Pump/Channel Displays

Applying adhesive labels (including preprinted labels) requires time and compliance and can introduce new errors (e.g., labels placed on the wrong infusion, labels not removed when a medication is discontinued and the equipment is reused for a new and different infusion). Electronic labels built into infusion pumps have the potential to mitigate some of these issues, since they can be created, updated, and removed automatically to reflect the current system state based on programmed pump parameters (e.g., drug order, infusion status). (66) Electronic labels also reduce cleaning and infection-control issues, since they are built into the pump. However, no empirical studies could be found evaluating the effectiveness of electronic versus adhesive labels.

One of the critical IV components that requires clear, salient, and informative feedback is the infusion pump itself, since this is where many infusion changes are made (e.g., titrating or stopping an infusion). Suggested information for the pump display includes the following:

- drug name (66;84) and concentration (66)
- flow rate (66;84)
- VTBI or time remaining (66;84)
- pump status (e.g., alert, stopped, pumping, etc.) (66;84)
- medication dose rate (84)
- access port to which infusion is connected (14)

Traditional (i.e., non-smart) pumps often do not display the drug name/concentration, dose rate, or access port. The drug name and dose rate can be added to most traditional infusion pumps/channels with additional navigation and button presses (e.g., pump channel labels, dose-rate programming), but nurses often do not use this option since it can be complex and time-consuming, pump drug lists can be incomplete, or information can be difficult to read (e.g., small text, abbreviated information). Consequently, it is common for nurses—particularly those in critical care—to add handwritten adhesive labels to traditional infusion pumps indicating the drug name and access port, since this information is required to complete numerous tasks (e.g., documenting infusions on a patient care flow sheet). (14)

When programming an infusion in the drug library of a smart pump, users must select a drug and concentration as part of the programming sequence. As such, the drug name, concentration, and dose rate are automatically displayed on the pump/channel. Therefore, smart pumps/channels typically communicate all of the information listed above, except for the access port. Larsen et al (36) described smart pumps as providing better information display and feedback than traditional pumps. However, there is no empirical evidence evaluating the impact of smart pump displays on nurses' ability to correctly identify infusions compared to traditional pumps.

Given this research gap, a smart pump was selected for inclusion in the laboratory study. The design of smart pump/channel labels varies by pump model. The smart pump studied in the laboratory study (similar to the one shown in Figure 12) was a multichannel pump. On its programming unit, the drug name and dose rate alternated with the VTBI for each infusion (see “Smart pump screen” in Figure 12). On each pump channel, the volumetric flow rate was displayed, and beneath it, the drug name and dose rate (see “Scrolling marquee” in Figure 12). The smart pump displayed all of the information listed above, except for the access port.

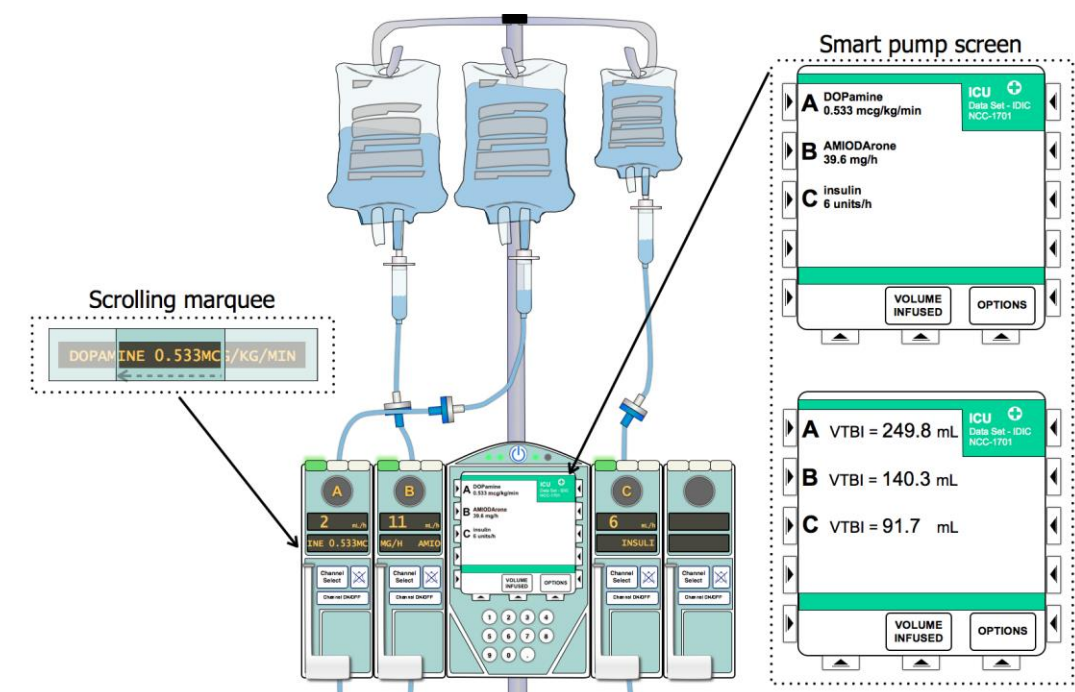


Figure 12: Identifying IV Infusions: Smart Pump/Channel Labels

Abbreviation: IV, intravenous.

It was hypothesized that when smart pump/channel labels were used, participants would make fewer errors in identifying infusion pumps compared to the baseline condition (i.e., traditional pump with no pump/channel labels) by augmenting and standardizing what, how, and where information was displayed. It was also hypothesized that smart pump/channel labels would decrease line-tracing errors (i.e., infusion disconnection and documentation errors) compared to baseline, since having infusion information clearly communicated at the pump would reduce the need to trace IV tubing up to, or down from, the IV container (assuming the pump was programmed correctly and verified at shift change); nurses could rely on the information on the pump, reducing the need to trace infusions between the pump and IV container.

Light-Linking Systems

One challenge with identifying IV infusions is that each infusion consists of many separate components (e.g., IV pole, container, tubing, pump, connectors) that are not integrated or even designed by the same vendor. In an effort to improve system integration, some pump vendors are developing tools to link a pump/channel with its attached components using light (i.e., the pump that is touched emits a light, which illuminates the IV tubing up to the IV container and down to the patient access port) (internal document¹⁵). As of June 2012, no prototype of a light-linking system was available for testing, so there was no evidence in the literature about the effect of such systems, or of any other type of IV component–linking systems. However, interviews with multiple vendors highlighted such linking tools as a key tactic for reducing infusion-identification errors; it was decided to evaluate the effectiveness of an IV component–linking system in the study.

HumanEra designed a simple prototype to help clinicians visually trace an infusion pathway. The initial goal was to design a system that would allow the user to press a button and continuously illuminate an entire infusion pathway, but this was not feasible given timing, resource, and technical constraints. Instead, a prototype was developed that consisted of 3 discrete components per infusion, as shown in Figure 13. Given that this system was only a prototype, it was not practical for health care providers to implement this system. Rather, the goal of this intervention was to acquire data on the effectiveness and challenges of a proof-of-principle light-based IV line-tracing aid to inform infusion identification research and product development.

¹⁵HumanEra internal document, August 18, 2010.

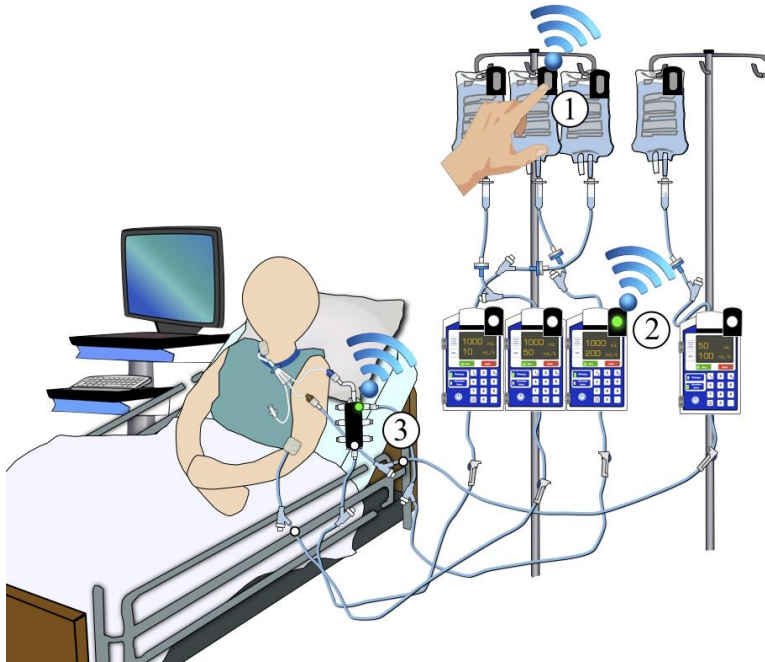


Figure 13: Identifying IV Infusions: Light-Linking System

Abbreviation: IV, intravenous.

HumanEra developed a prototype *light-linking* system to help users trace infusion pathways. It consisted of 3 discrete components per infusion; when a user pushed the button on the IV container (○), a wireless signal was transmitted to receivers on the corresponding pump (○) and the distal end of the IV tubing (○), causing a green light to flash for 7 seconds.

It was hypothesized that using the light-linking system would improve nurses' ability to correctly identify infusion pumps and trace infusion pathways compared to the baseline condition (i.e., no light-linking system). The light-linking system replaced the need to manually trace infusions by illuminating the infusion pathway at discrete points, facilitating accurate line tracing.

Experimental Method

Forty ICU nurses each completed 2 tasks (disconnecting an infusion and documenting running infusions) under 4 different experimental conditions (baseline, preprinted labels and infusion organizers, smart pump/channel labels, and light-linking system).

Tasks

Participants were asked to complete the 2 infusion identification tasks described in Table 11 in each experimental condition.

Table 11: Identifying IV Infusions: Tasks

Task	Notes
Infusion disconnection	Disconnect an infusion: <ul style="list-style-type: none"> • identify and stop the correct pump • trace the correct IV tubing from the pump to the patient • disconnect the IV tubing from the multiport connector
Infusion documentation	Verbally identify: <ul style="list-style-type: none"> • the patient access port to which a particular infusion was connected (i.e., identify the IV container, trace the infusion from the IV container to the multiport connector, and identify the patient access port; or use the labels in the preprinted label/infusion organizer condition) • the 3 other infusions connected to the same patient access port (i.e., trace the 3 other infusions from the multiport connector to their respective IV containers and identify the medications/fluids; or use the labels in the preprinted label/infusion organizer condition)

Abbreviation: IV, intravenous.

Experimental Conditions

The 4 experimental conditions are described in Table 12. Participants were trained on the new interventions as described below.

Table 12: Identifying IV Infusions: Experimental Conditions and Training

Experimental Condition	Description	Training Content
Baseline	No intervention (i.e., control). The IV tubing above and below the pump was interweaved using a standard setup to replicate severe spaghetti syndrome. No adhesive labels were applied to the IV tubing or pumps, but medication labels were applied to the IV containers	No training required
Preprinted labels/infusion organizers	Preprinted labels and infusion organizers were used. IV tubing was not tangled, since the organizers prevented tangles. Medication labels were applied to the IV containers	Hands-on training was provided to review the preprinted labels, the IV pole-top organizer, and the IV tubing organizers (about 5 minutes). Participants were encouraged to try the interventions
Smart pump/channel labels	Smart pump/channel labels were used. IV tubing was set up with the same interweaving as the baseline condition (i.e., severe spaghetti syndrome). No adhesive labels were applied to the IV components, but medication labels were applied to the IV containers	Hands-on training on the smart pump/channel labels was provided as part of training on the basic functionality of the entire smart pump (about 10 minutes), which included reviewing all information on the display and channels. At the end of the training, participants were asked questions about an infusion already running (e.g., drug name, VTBI, dose rate) to verify training comprehension
Light-linking system	The light-linking system was used. IV tubing was set up with the same interweaving as in the baseline condition (i.e., severe spaghetti syndrome). No adhesive labels were applied to the IV components, but medication labels were applied to the IV containers	Hands-on training on the light-linking system was provided (about 5 minutes). As part of the training, participants were asked to use the intervention to identify an infusion pathway

Abbreviations: IV, intravenous; VTBI, volume to be infused.

Procedure

The procedure was as described in Research Methods. The confederate nurse prompted participants if needed to ensure they used the light-linking system at the start of both infusion identification tasks.

In all tested conditions, the patient scenario had the participant covering for another nurse who was on a break, so the infusions were already set up and participants were not familiar with the patient's infusions. Participants were given 1 minute to assess the patient's infusions before the confederate nurse asked them to complete the first task. Since participants were not assuming responsibility for the patient, they were instructed not to reorganize (e.g., untangle or label) the infusions. This helped to ensure setup equivalency in the different experimental conditions.

Metrics and Analysis

Participant Performance

Participant performance in each task was recorded by the confederate nurse and test facilitators. The metrics for each task were as follows (see Table 13 for definitions and analysis):

- pump identification errors (out of 1)
- line-tracing errors
 - infusion disconnection (out of 1)
 - infusion documentation (out of 4)

Table 13: Identifying IV Infusions: Performance Metrics and Analysis

Performance Metrics and Analysis	Pump Identification Error		Line-Tracing Error
	Infusion Disconnection Task ^a	Infusion Disconnection Task ^a	Infusion Documentation Task
Definition	Stop wrong pump	Disconnect wrong IV tubing (of identified pump)	Identify wrong access port Identify wrong infusion (x 3) connected to identified access port
Performance metric (per participant per condition)	Pass or fail	Pass or fail	Number of line-tracing errors (maximum of 4) ^b
Analysis			
Number of participants included in analysis	40	40	39 ^c
Opportunities for error per condition	40 (1 error per disconnection task; 1 disconnection task per participant per condition)	40 (1 error per disconnection task; 1 disconnection tasks per participant per condition)	156 (4 errors per documentation task; 1 documentation task per participant per condition)
Statistical test (performance metric as a function of experimental condition)	Cochran's Q test followed by pairwise comparisons between the different combinations of intervention conditions by use of the McNemar χ^2 test with Bonferroni correction	NA (statistical analysis not conducted, since no errors were made across all conditions)	One-way ANOVA test followed by post hoc paired sample t-test comparisons using Bonferroni correction

Abbreviations: ANOVA, analysis of variance; IV, intravenous; NA, not applicable.

^aIn the infusion disconnection task, there was the potential for 2 errors: identifying/stopping the wrong pump and tracing the infusion to the wrong patient access port/disconnecting the wrong infusion.

^bIn the infusion documentation task, there was the potential for 4 line-tracing errors: identifying the wrong access port and connected infusions (3 times).

^cOne participant (of 40) could not complete the documentation task with the light-linking system because of technical difficulties.

The test facilitators also recorded unanticipated errors or hazards.

Participant Feedback

Participants completed a questionnaire (Appendix 2) to capture their perception of each intervention with respect to its effectiveness in reducing errors and the likelihood of its use in clinical practice. Open-ended feedback was solicited about each intervention (as part of the questionnaire), from which summary comment themes were developed. A one-way repeated measure analysis of variance (ANOVA) test was conducted to assess for statistically significant differences between intervention conditions, and post hoc paired sample t-test comparisons were done using Bonferroni correction.

Although preprinted labels, the IV pole-top organizer, and the IV tubing organizer were tested as a system in the simulated scenarios (i.e., 1 intervention condition), feedback from participants was collected and analyzed separately on these components, since they could be implemented separately.

Results

Participant Performance

Table 14 summarizes performance metrics by experimental condition. A summary of other observed hazards is provided below.

Table 14: Identifying IV Infusions: Performance Metrics by Experimental Condition

Performance Metric	Sample Size, n	Opportunities for Performance Metric Per Experimental Condition	Experimental Condition				Statistics
			Baseline	Preprinted Labels and Infusion Organizers	Smart Pump/Channel Labels	Light-Linking System	
Pump identification errors, n (%)	40	40 (1 per participant)	0 (0.0%)	0 (0.0%)	1 (2.5%)	0 (0.0%)	Cochran Q = 3.00 P = 0.39
Infusion disconnection errors, n (%)	40	40 (1 per participant)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	NA ^a
Infusion documentation errors, n (%)	39 ^b	156 (4 per participant)	12 (7.7%)	0 (0.0%)	10 (6.4%)	5 (3.2%)	F(3, 114) = 4.33 P = 0.006

Abbreviation: NA, not applicable.

^aStatistical analysis not conducted, given that no errors were made.

^bOne participant (of 40) could not complete the documentation task with the light-linking system because of technical difficulties.

There was no statistical difference in pump identification errors between experimental conditions. In the infusion disconnection task, no line-tracing errors were observed in any of the conditions. In the infusion documentation task, line-tracing errors were observed, with statistical differences in errors between experimental conditions. When using preprinted labels and infusion organizers, participants made significantly fewer errors than in the baseline ($P = 0.005$) and smart pump/channel labels conditions ($P = 0.02$). The light-linking system did not significantly affect line-tracing errors compared to the other conditions. Similarly, there was no significant difference in line-tracing errors in the smart pump/channel labels and baseline conditions. Thus, the preprinted labels and infusion organizers reduced line-tracing errors compared to baseline, but the smart pump/channel labels and light-linking system did not.

New Hazards

During the experiment, a new issue was uncovered that had not been identified in previous phases of this research or in the literature review.

Although they were asked to use the light-linking system, some participants used it only partially to complete the infusion documentation tasks. The light-linking system was designed so that it could be used only to trace the infusion pathway down from the IV container to the pump and patient access port (Figure 14A); it could not be used to trace the infusion pathway up from the patient access port to the pump and IV container (Figure 14B). Therefore, although all participants used the light-linking system to identify which patient access port an infusion was connected to, some (9 of 39; 23%) did not use it to identify which infusions were also connected to the same patient access port. Instead, these participants preferred to manually trace the infusion up from the multiport connector to the IV container; this limited the light-linking system's ability to reduce line-tracing errors.

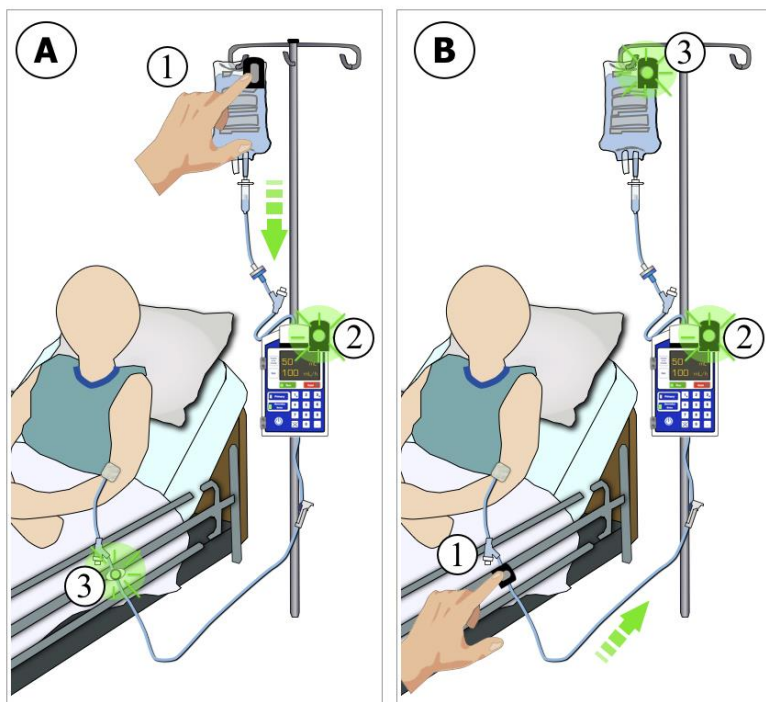


Figure 14: Identifying IV Infusions: Light-Linking System Limitation

Abbreviation: IV, intravenous.

Ⓐ The tested prototype allowed users to trace down from the IV container to the pump and access port; Ⓑ The tested prototype did *not* allow users to trace from the access port up to the pump and IV container.

Participant Feedback

All 40 participants completed a questionnaire to collect their feedback on the interventions tested. Participant feedback is summarized in Table 15 (see Appendix 2 for details).

Table 15: Identifying IV Infusions: Participant Feedback

Question	Preprinted Labels and Infusion Organizers			Smart Pump/Channel Labels	Light-Linking System	Statistics
	Preprinted Labels	Pole-Top Organizer	Tubing Organizers			
Effectiveness at reducing medication errors ^a	3.9	3.5	3.3	3.4	3.1	F(4, 195) = 8.22 P < 0.001
Likelihood of using intervention in clinical practice ^b	3.8	3.8	3.1	3.5	2.9	F(4,195) = 10.88 P < 0.001
Comment themes	<ul style="list-style-type: none"> •Improved efficiency to generate, apply, and identify labels by standardizing label content, legibility, and location •Must still verify the labels by manually tracing the lines •Concern with storage of labels in patient rooms, given infection-control concerns (could have pharmacy send labels with IV containers for pharmacy-supplied infusions and store in the medication room for floor-admixed medications) 	<ul style="list-style-type: none"> •Easy to implement •Effectiveness compromised by user vigilance (i.e., must be used as intended) •Effective only for vertical-channel pumps •Difficult to access the IV containers on the back hooks, so may not be used 	<ul style="list-style-type: none"> •Information should be static (i.e., not scrolling or flashing); larger type (e.g., must be viewed from door to isolation rooms); and better organized and formatted •Missing access port information (important in critical care) •Would add adhesive labels to compensate for above deficiencies 	<ul style="list-style-type: none"> •Liked ability to group IV tubing by access port and prevent tangles •Effectiveness compromised by user vigilance (i.e., must be used as intended) •Not practical at the bedside for certain patients (e.g., ambulating patients) or during clinical procedures and patient transport when space on bed is limited 	<ul style="list-style-type: none"> •Liked having a tracing aid using light, particularly during an emergency •Tracing aids must be bidirectional (i.e., initiated at patient access port and IV container), not affect photo-sensitive drugs, link entire infusion system (i.e., not discrete points as tested), limit inter-infusion confusion •Tracing aid not needed if physical setup, organization and communication at the bedside are improved 	

Abbreviation: IV, intravenous.

^aFour-point scale: 1, very ineffective; 2, somewhat ineffective; 3, somewhat effective; 4, very effective.

^bFour-point scale: 1, definitely not use; 2, probably not use; 3, probably use; 4, definitely use.

Participant ratings of the perceived effectiveness of the interventions at reducing medication errors was statistically different between interventions. The preprinted labels were rated significantly higher than any other intervention (pole-top organizer, $P = 0.03$; tubing organizers, $P < 0.001$; smart pump labels, $P = 0.03$; light-linking system, $P < 0.001$). There was no statistical difference between the other conditions.

Participants generally indicated that they would use all of the studied interventions in their clinical practice. They rated their expected use of the preprinted labels and pole-top organizer significantly higher than the tubing organizers ($P < 0.001$ and $P = 0.004$, respectively) and light-linking system ($P < 0.001$ for both). There was no significant difference between the other interventions.

Participants provided insightful comments to explain their ratings and describe potential implementation issues that were not studied in the laboratory simulation. They indicated that even with the interventions tested, current best practices—such as routinely tracing infusions to verify infusion pathways—are

essential. Participants also indicated that they would still want to label and organize their infusions when using a smart pump or light-linking system.

Discussion

The study findings were consistent with other research in that they confirmed that infusion identification errors occur in a multi-infusion environment.(10;14;72) In particular, pump identification and line-tracing errors were observed, and risk mitigations are needed.

Preprinted Labels and Infusion Organizers

When infusions were set up correctly with preprinted labels and infusion organizers (i.e., IV rake pole-top above the pump and IV tubing organizers below the pump), line-tracing errors were eliminated. The success of the preprinted labels and infusion organizers could be attributed to the fact that the system of interventions helped mitigate many of the factors that contributed to infusion identification errors; it decreased physical complexity, augmented organization, and improved and standardized visual communication about an infusion across multiple IV components and from IV container to patient access port. Table 16 summarizes the underlying design principles that likely contributed to the intervention's success. While the results are specific to the tested designs and situations (and did not evaluate setup or longitudinal effects), the principles can be used by manufacturers and health care providers to develop more integrated infusion systems for both traditional and smart pumps.

Table 16: Identifying IV Infusions: Summary of Design Principles Associated With Reduced Errors

Design Principles	Examples (Designs Tested in Laboratory Study)
Decrease Visual Complexity and Augment Organization	
Map IV container with the corresponding IV pump/channel	IV rake pole-top organizer
Separate infusions and minimize tangles	IV tubing organizers below the pump and at the patient bedside (bedside organizers were attached to create 1 central panel)
Improve and Standardize Visual Communication Along the Infusion Pathway	
Clearly and accurately communicate the name of the infusing drug/fluid on the IV tubing (regardless of tubing orientation) ^a	Preprinted wraparound flag labels with the name of the drug/fluid on either side of flag (white labels with black type)
Visually distinguish the emergency medication line	Colour-differentiated preprinted labels (yellow instead of white)
Communicate infusion contents near/at pump and lower injection port (i.e., at the patient bedside)	2 labels per infusion: 1 immediately below the pump ^b (not on the pump ^c) and 1 above the lower injection port (not below the port ^d). Note: The IV tubing organizer immediately below the lower injection port created a central panel for viewing labels
Communicate which patient access port an infusion is connected to	IV tubing organizer that groups infusions by patient access port (organizer colours matched access port colours for the central triple-lumen catheter)

Abbreviation: IV, intravenous.

^aMay not be required for all infusions (further research is required).

^bMay not be required when infusions are programmed in the drug library of a smart pump that clearly communicates infusion details on its display.

^cAdhesive labels placed on a pump may not be removed when a medication is discontinued and the pump is reused for a new and different infusion.

^dAdhesive labels placed below an injection port may not accurately reflect the IV tubing contents, because the tubing may contain more than 1 medication.

In contrast to the preprinted labels and infusion organizers, interventions that targeted only a single infusion component (i.e., infusion pump) and/or a single contributing factor (i.e., visual communication of infusion pathway) did not significantly reduce line-tracing errors.

Smart Pump/Channel Labels

The smart pump intervention attempted to minimize infusion identification errors by improving user feedback at the pump. However, the smart pump tested did not improve participants' ability to correctly identify the infusion pump or trace infusions in a multi-infusion environment. Participants indicated design qualities of the tested smart pump/channel labels that may have limited the effectiveness of this intervention:

- information should be static (i.e., not scrolling or flashing)
- text should be large (e.g., must be able to view it from the door of isolation rooms)
- information should be clearly formatted and organized
- pump should include the potential to add information about the patient access port (e.g., important in critical care)

Salient and clear information at the pump is essential, but the use of smart pump/channel labels to reduce all infusion identification errors may be inherently limited, since it can improve user feedback at only 1 point in the infusion pathway. A more comprehensive approach that incorporates the principles from Table 16 into the system design may be required to effectively reduce infusion identification errors. In the meantime, the results suggested that similar to traditional pumps, smart pumps need add-on accessories (e.g., preprinted labels) to reduce infusion-identification errors.

Light-Linking System

The light-linking system attempted to minimize infusion identification errors by augmenting user feedback about an infusion pathway and eliminating the need to manually trace infusions, but it did not improve participants' ability to correctly identify infusions. Participants' performance and feedback suggested that this may have been because of significant design limitations with the tested prototype:

- it required users to search and visually identify IV components, since it did not continuously light the entire infusion pathway
- it could not be initiated at the patient access port to aid line-tracing from the patient bedside up to the IV container

One of the purposes of studying the light-linking system was to help inform future product development. Addressing the limitations identified with the light-linking system—particularly the second point listed above—may prove challenging given the design of current IV tubing and connectors (e.g., it may be difficult to add electronic components at the distal end of tubing or on a multiport connector).

Participants' feedback also indicated that tracing aids in general are limited in their effectiveness; to be useful, they would also have to address physical complexity, organization, and user feedback challenges at the bedside. Therefore, instead of focusing on tracing aids, it may be more beneficial to research and develop systems that improve IV component integration and minimize—or even eliminate—the need to trace infusions. For example, IV containers are currently hung above the IV pump on the IV pole; integrating the IV container (both primary and secondary) and pump, similar to syringe pumps, would eliminate the need to trace IV tubing between components.

Limitations

Although a number of infusion-identification errors were observed, only 1 pump-identification error was observed, so our results may underestimate this risk. Participants were allowed to assess the patient's infusions after an introduction from the confederate nurse, as per standard practice, but this may have reduced the probability of an infusion-identification error. In some urgent situations (e.g., patient transfer), nurses do not have the opportunity to assess infusions prior to completing a task. In addition, participants noticed the severe infusion tangling during the initial assessment, and may have alerted exercised extra vigilance when identifying IV infusions.

As previously discussed, the setup and longitudinal effects of the interventions (e.g., misuse, compliance, and potential for other errors) were not tested. This may have particularly affected the results of the preprinted labels and infusion organizers, given the following:

- The preprinted labels were placed on the correct infusions, but incidents have occurred as a result of labels being placed on the wrong infusion; still, Porat et al (72) found that preprinted labels helped clinicians detect labelling errors better than handwritten labels.
- IV tubing was not tangled (prevented by the IV organizers), and IV containers were hung directly above the corresponding infusion pump. Participant feedback highlighted the fact that correct use of the infusion organizers depends on user vigilance, and past research has identified issues with compliance (e.g., IV containers not hung on IV pole-tops to align with the associated pump/channel below). (14) It is also unknown how infusion organizers would be applied in situations where multiple IV medications are being initiated at 1 time.

The preprinted labels and infusion organizers were evaluated together; the individual effect of each component (i.e., preprinted labels, IV pole-top organizer, and IV tubing organizer) could not be isolated.

Operational issues with intervention implementation were not studied (e.g., intervention storage and supply). However, during the debrief with participants, potential issues and solutions were identified. For example, some participants expressed concern about the storage of preprinted labels, since there is a trend toward minimizing the storage of technology and supplies in patient rooms to prevent infection. However, 1 participant suggested that preprinted labels could be stored in the medication room (for floor-admixed medications) or sent up with the IV container from the pharmacy (for pharmacy-supplied infusions).

Summary

To effectively decrease infusion-identification errors, a shift in perspective is needed to see an infusion as an integrated, holistic system rather than as a collection of individual components. This shift is needed on the part of regulators when they evaluate infusion-system licencing applications, and on the part of vendors, to incorporate the principles identified in this study into technology road maps and improved infusion design. In the meantime, system-wide best practices must be developed for the use of accessories such as preprinted labels and infusion organizers to create standardized infusion setups shown to augment safety. Accessories do not eliminate the potential for errors, however; current recommended practices, such as always tracing infusion pathways before making a change and during staff hand-off process, must still be promoted.

Theme 3: Managing Dead Volume

The term *dead volume* has been used in different ways in the literature, (85;86) but in this report it refers to the common volume shared by 2 or more infusates; dead volume includes all the shared volume from the point infusions are connected to the patient's bloodstream. This is also referred to as *dead space* or *line dead space*.

Issues

Critically ill patients routinely require more infusions than there are available patient access ports, requiring that multiple IV infusions be connected to a single port. (87;88) This results in dead volume, since 2 or more infusates are connected. Dead volume may be of concern in many setups and situations, some of which are shown Figure 15.

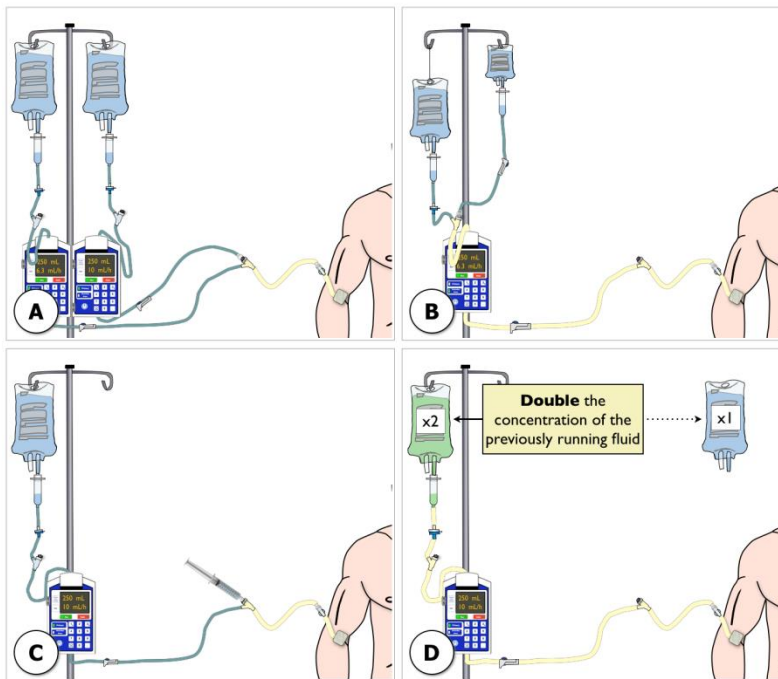


Figure 15: Managing Dead Volume: Sample Setups (Dead Volume in Yellow)

Abbreviation: IV, intravenous.

- (A): Primary IV infusions connected below the pump using a lower injection port.
- (B): Primary and secondary IV infusions connected above the pump.
- (C): IV syringe push connected to a primary IV infusion below the pump (at a lower injection port).
- (D): Double-strength IV container attached to primary IV tubing containing a single-strength concentration of the same medication.

When a patient receives a single infusion, changes to the infusion (e.g., start, stop, change of flow rate) are instantly reflected at the patient's bloodstream. (88;89) In contrast, when multiple IV infusions are connected to a single access port, there is a time lag to clear the dead volume before the desired change is reflected at the patient's bloodstream. (88-90)

Dead volume can result in unrecognized and potentially dangerous reservoirs of medications, potentially leading to uncontrolled and unplanned changes in drug delivery. (89-91) For example, a large increase in the flow rate of 1 connected infusion will instantly increase the flow rate of the dead volume and deliver a

greater amount of all medications in the reservoir until a new steady state is achieved (i.e., when the concentration of medications in the reservoir will no longer change and the patient is receiving the medication dose rates programmed in the infusion pumps that control them).

Most dead volume research to date has focused on using laboratory and mathematical models to understand the complex drug delivery dynamics emerging from dead volume when a change is made to connected infusions. (87-96) Without proper consideration, changes to dead volume may result in unintended patient harm (89) and a variety of medication errors, such as accidental bolusing, (86;87;90;93;96) delays in therapy, (97) and drug incompatibilities. (97) Dead volume management is of particular concern when infusing concentrated and potent drugs (e.g., vasoactive drugs, inotropics, antiarrhythmics, sedatives, opioids, and paralytics) at low flows, which requires greater consistency and accuracy in administration (88;89;94) for critically ill and/or pediatric patients. (85;91;93)

It is difficult to visually identify dead volume, so dead volume–related errors are not easy to detect. Failure to consider dead volume may result in a discrepancy between expected and observed patient effects when an infusion change is made. If clinicians make premature adjustments to medications (e.g., titrating an infusion flow rate) before the dead volume has cleared, the result may be patient harm and/or further instability. (90)

Evidence from the literature shows that some nurses do not consider dead volume in their practice. In an observational study of 47 nurses in an Australian public hospital, the majority of nurses did not acknowledge the presence of dead volume. (86) Similarly, the results of a questionnaire from emergency departments in the U.K. showed that the majority of respondents (85% of 143 departments) had poor dead volume–related practices. (98) Apart from these studies, research and discussion of dead volume impact on nursing tasks is largely absent, (86) even though dead volume issues have been identified with common nursing tasks. Two tasks that have been associated with dead volume errors are administering a manual IV push dose (Figure 15©) and doubling the concentration of a medication in an IV container (Figure 15ⓓ). These 2 tasks are described further below to demonstrate how simple but different infusion setups and tasks can lead to significant dead volume issues.

Administering a Medication by Manual IV Push

A common task in critical care is to deliver a single drug dose using an IV syringe and manually pushing it into the IV tubing of a pre-existing infusion (henceforth referred to as a *manual IV push*). There are dead volume considerations at the start and end of this task, as described in the following example.

Consider the situation where a manual IV push of Drug A (in a 5 mL syringe) is ordered to be delivered over 1 minute (i.e., at a rate of 5 mL/min, 300 mL/h; Figure 16). An emergency medication line infusing sodium chloride 0.9% at 10 mL/h can be used for the manual IV push. The following is a detailed description of the dead volume implications associated with the execution of this task:

- Before Drug A reaches the patient’s bloodstream, the dead volume from the injection port to the patient’s vein (i.e., 3.5 mL) must be cleared (◆ in Figure 16). Therefore, for the first 3.5 mL of Drug A pushed, the patient will actually receive a 3.5 mL bolus of sodium chloride 0.9%; as well, the administration speed of the syringe contents for the first 3.5 mL is likely unimportant, since Drug A has not yet reached the patient.
- When the medication syringe contents have been emptied, the patient will have received only 1.5 mL of Drug A; the remaining 3.5 mL from the syringe is still in the dead volume (◆ in Figure 16) and if dead volume is not taken into account, would flow to the patient with the sodium chloride 0.9% continuous IV infusion at 10 mL/h, which in this example would take about 21 minutes.

- To ensure the patient receives Drug A as ordered, the dead volume must be cleared by flushing it (e.g., by flush syringe) with at least 3.5 mL of fluid (e.g., sodium chloride 0.9%) at a rate of 5 mL/min (300 mL/h) (● in Figure 16).

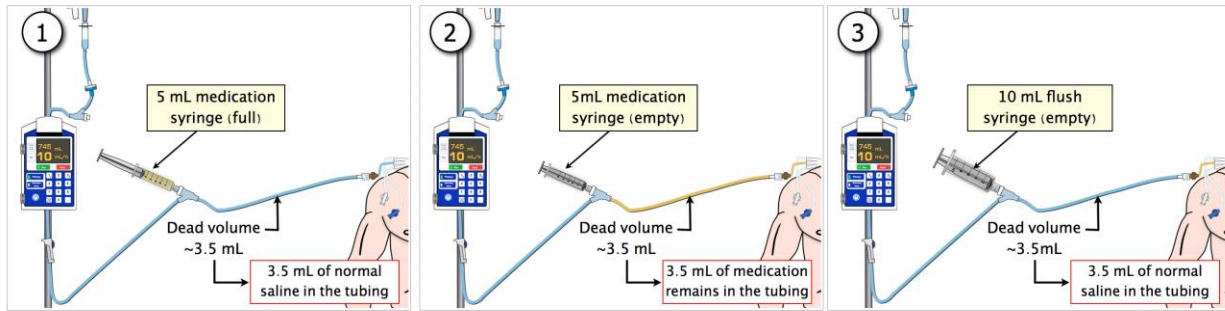


Figure 16: Managing Dead Volume: Sample Manual IV Push

Abbreviation: IV, intravenous.

Thus, there are 2 dead volume–related risks associated with administering a manual IV push. First, all or some of the medication (depending on the size of the dead volume and syringe) may remain in the dead volume if the IV tubing is not flushed. Second, if the IV tubing is flushed, it may be flushed at the wrong flow rate. Researchers (86) have observed that the majority of nurses failed to account for the dead volume in the IV tubing when administering a manual IV push. Seventy-five percent of nurses who flushed by syringe did it at a speed greater than recommended, resulting in an unintended medication bolus that could have had serious effects, depending on the drug and patient (e.g., neonate). (86)

Doubling the Concentration of a Continuous IV Medication Infusion

Another common nursing task with dead volume considerations is doubling the concentration of a continuous IV medication but maintaining the same dose rate. This task is required when patients require less fluid volume than they are receiving or when transferring to units that use different standard drug concentrations. Failure to manage the dead volume safely during this task may result in patient harm, as described in the following incident.

ISMP Canada (64) received an incident report in which a critical care patient was receiving multiple IV infusions. Due to the large volume of fluid being infused, it was decided to double the strength of the norepinephrine (Levophed). The clinician attached a norepinephrine IV container with double the concentration (● in Figure 17) to the previously used IV tubing (● in Figure 17); this meant that the infusion contained 2 different norepinephrine concentrations: the IV container contained the double-strength concentration, and the IV tubing and connectors contained the single-strength concentration. The clinician decreased the pump programming to account for the new double-strength concentration, so that the single-strength concentration in the dead volume infused at half the intended dose (● in Figure 17). The patient's systolic blood pressure fell to 40 mm Hg, and aggressive interventions were required to rectify the situation. ISMP Canada indicated that this risk could have been avoided if new IV tubing primed with the double-strength concentration had been used.

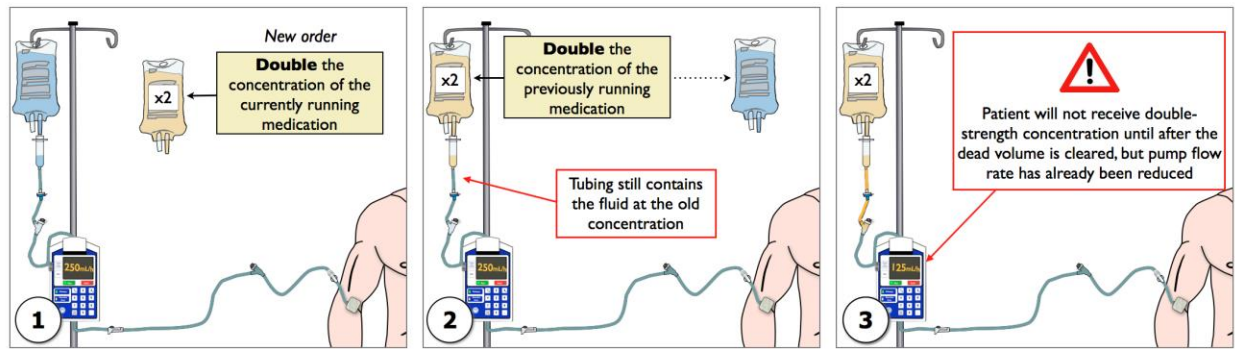


Figure 17: Managing Dead Volume: Doubling of a Continuous IV Medication Concentration

Abbreviation: IV, intravenous.

Issues: Overview

Dead volume creates unrecognized and potentially dangerous reservoirs of medications that can result in uncontrolled and unplanned changes in drug delivery. (89-91) While dead volume is acknowledged as a hazard, empirical research is needed to examine how nurses consider and account for it in common nursing tasks, specifically tasks such as delivering a manual IV push and changing an IV container, where dead volume issues are known to be a problem. In addition, research is needed to understand how to minimize the risks associated with dead volume.

Interventions

Although the literature includes some suggestions and recommendations for managing dead volume, controlled studies investigating the effectiveness of these recommendations on nursing performance were largely absent, except for studies focusing on IV tubing and connector design (see below).

Practice Interventions

Policies and procedures to reduce dead volume have been recommended in the literature. When multiple IV infusions are required, increasing the number of patient access ports (e.g., multi-lumen catheters) can minimize the need to connect infusions, since they can be attached directly to the patient, thereby eliminating dead volume. (93) However, increasing the number of patient access ports may not be possible and may increase other risks (e.g., infection). (63)

When infusions must be combined and dead volume created, procedural recommendations to reduce the risk of potential issues include the following:

- Minimize the size of the dead volume in the assembly and configuration of IV components: (93;94)
 - connect infusions as close to the patient as possible (88;93) (e.g., for multiport manifolds, place critical medications on the port closest to the patient)
 - dedicate a medication infusion line to emergent needs (such as drugs delivered by manual IV push) to avoid unintended drug boluses (93)
 - block or remove side ports on IV tubing (which are not close to the patient) to minimize manual IV pushes at these sites (94)

- Clearly communicate the architecture of infusion setups during transitions of care between providers, so clinicians are aware of which infusions share dead volume. (94)
- Minimize the amount of drug accumulated in the dead volume by diluting infusions and increasing flow rates (i.e., to administer same dose). It should be noted, however, that since this practice increases total fluid delivery, it may not be practical for critically ill (particularly pediatric) or fluid-restricted patients. (93)

The recommendations above were published in anesthesia-related journals; dead volume best practices were largely absent from nursing publications, indicating a need for greater awareness of dead volume issues. Prior to the adoption of new practices, nurses must have a fundamental understanding of dead volume (e.g., basic principles and risks). For this reason, it was decided to investigate an education-related intervention rather than a practice-related intervention in the laboratory study.

Technology Interventions

Technology interventions have also been proposed to minimize the impact of dead volume and improve drug delivery accuracy:

- IV tubing and multiport/lead connectors that minimize priming volumes (e.g., micro bore tubing) and/or prevent infusions from mixing (e.g., multi-lumen connector), thereby reducing dead volume (51;88;89;94;95;99;100)
- IV components with decreased material elasticity to minimize drug accumulation in the dead volume (e.g., during an occlusion) (96)
- infusion pump algorithms that account for dead volume by automatically adjusting infusion rates to minimize the effect of dead volume (90) or by giving users guidance (e.g., warnings and/or lag time prediction curves) (101)
- clear identification of the priming volume on the packaging of all IV tubing and add-on devices to inform infusion setup architecture and dead volume management (86)

While the above interventions are important, they were not selected for further investigation in the laboratory study because they have supporting evidence from theoretical models and are being studied by other researchers (IV component design); unavailable for testing (new pump algorithms); or based on reasonable good practices (identification of dead volume on packaging).

Education Interventions

Increasing clinicians' knowledge of dead volume principles and risks has been suggested as a way to improve patient safety. (51;86;89;93;94) Research has shown that some nurses do not consider dead volume in their practice, (86;98) and in Ontario, nurses generally receive little to no training on how to manage dead volume. (14) There is no evidence to support the effectiveness of dead volume education on improving safety, so educating nurses on dead volume principles and risks was selected for further study (prior to testing any of the aforementioned recommended dead volume-related practices or technologies), since such fundamental knowledge is critical before the adoption of practice- or technology-based interventions.

HumanEra developed a computer-based education module about dead volume (Figure 18). A computer-based module was chosen, since it would be scalable to many learners and allowed for the use of multimedia to augment learning. Fundamental to the module design was “making the invisible visible”—that is, showing nurses what they cannot see in the dead volume when they make a change to connected infusions. The module was iteratively reviewed by nursing experts (including a critical care nurse

educator). It was about 16 minutes long and included the following:

- defining dead volume and showing examples of dead volume in common infusion setups
- explaining infusion principles important to understanding dead volume (i.e., flow rate versus dose rate changes in the dead volume)
- showing a detailed example of the dead volume issues associated with administering a single dose by manual IV push

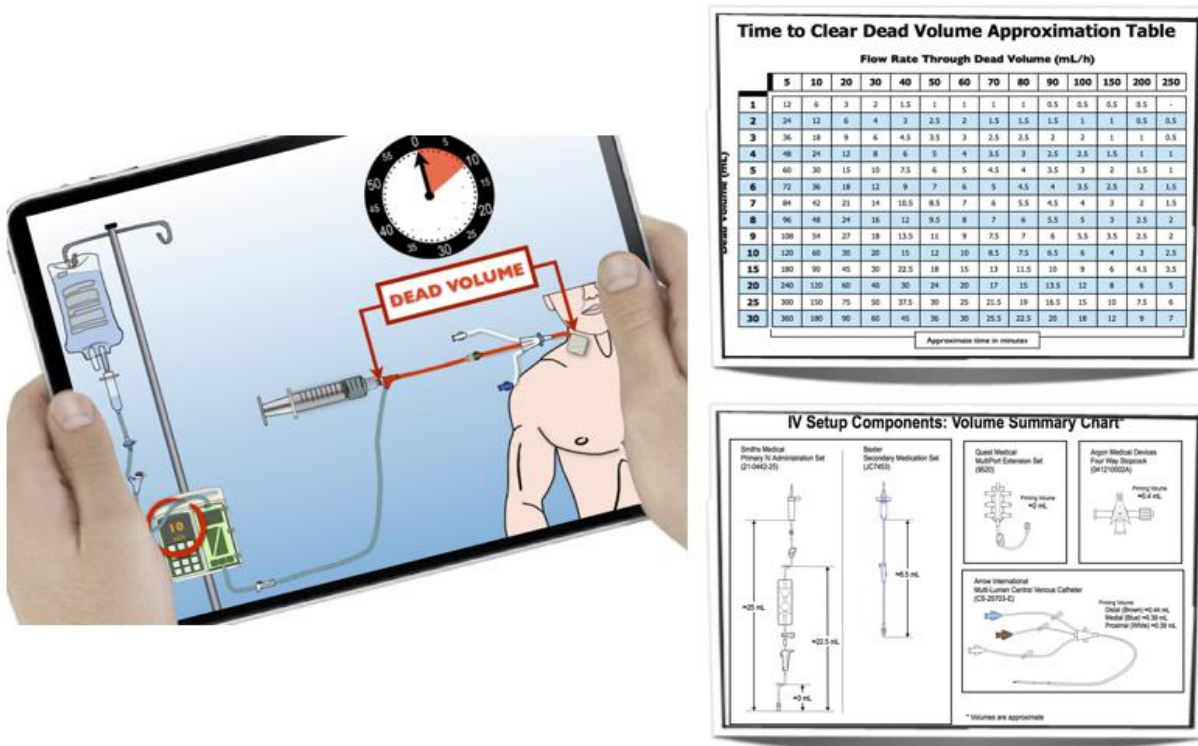


Figure 18: Managing Dead Volume: Education Module and Reference Sheet

This education tool, developed by HumanEra, dynamically demonstrated the key principles and rationales behind dead volume management.

A double-sided reference sheet accompanied the module (Figure 18). The purpose of the reference sheet was to support nurses in applying dead volume concepts to situations in which dead volume may be an issue in their clinical practice. One side of the sheet listed manufacturer-stated priming volumes of common IV tubing and connectors used at the participating institution to allow nurses to estimate the dead volume for different infusion setups. The other side included a lookup table to help nurses estimate the time required to clear the dead volume.

It was hypothesized that prior to viewing the education module and obtaining the reference sheet, nurses would make dead volume–related errors in common nursing tasks. After completing the module, nurses would make fewer dead volume–related errors because they were more aware of its existence and had knowledge and tools to support improved decision-making.

Experimental Method

Forty ICU nurses each completed 2 tasks (manual IV push and double IV container concentration) under 2 different experimental conditions (baseline and after dead volume education).

Tasks

Participants were asked to complete the 2 dead volume–related tasks described in Table 17 in each experimental condition. These 2 tasks were selected because they are common nursing tasks that have been associated with dead volume management errors. In particular, the details of the tasks tested in the laboratory study replicated the specific scenarios described in Issues, above.

Table 17: Managing Dead Volume: Tasks

Task	Notes
Administering a medication by manual IV push	<p>Participants were asked to administer furosemide (Lasix) as a 50 mg IV push (provided in a 5 mL parenteral syringe) over at least 1 minute.^a To successfully complete this task, participants had to:</p> <ul style="list-style-type: none">attach the 5 mL parenteral syringe to the lower injection port of the emergency medication line (which was administering a continuous sodium chloride 0.9% IV infusion at 10 mL/h through an infusion pump); andpush the dose into the IV tubing at the ordered rate (i.e., at rate slower than or equal to 5 mL/min or 300 mL/h) <p>Participants could make a dead volume error if they did not correctly manage the furosemide remaining in the dead volume. The dead volume from the lower injection port to the patient's vein was about 3.5 mL. Therefore, participants had to consider the following:</p> <ul style="list-style-type: none">whether they needed to flush the IV tubing to deliver the remaining 3.5 mL of furosemide in the IV tubing (a 10 mL prefilled syringe of 0.9% sodium chloride was available to participants on an over-bed table at the foot of the patient's bed^b); andthe rate at which to deliver the flush, which determined the delivery rate for the furosemide remaining in the dead volume
Doubling the concentration of a continuous IV medication infusion	<p>Participants were asked to double the concentration of a norepinephrine infusion (already infusing) but maintain the same dose rate (the IV container of the double strength norepinephrine IV infusion was provided). When hanging the new IV container, participants could choose to:</p> <ul style="list-style-type: none">ask for new IV tubing (which was provided when asked); orreuse the existing tubing; if the dead volume (i.e., old concentration) was not accounted for and the pump was reprogrammed to account for the new concentration, the patient's physiological parameters were changed by the test facilitators (i.e., blood pressure and SpO₂ decreased and heart rate increased), since the patient was now receiving half the ordered norepinephrine dose <p>Participants were asked to explain the rationale for their actions (e.g., why they asked for new IV tubing or why patient's condition had changed)</p>

Abbreviations: IV, intravenous; SpO₂, saturation of peripheral oxygen.

^aWhen furosemide is pushed too quickly, there is a risk of ototoxicity (the nursing IV drug list used at the participating institution indicates that furosemide should be pushed at a rate of less than 40 mg/min).

^bParticipants were oriented to the room and all supplies, including the sodium chloride 0.9% in 10 mL prefilled parenteral syringes, at the start of the study.

Experimental Conditions

The 2 experimental conditions are described in Table 18. The intervention condition was always completed last, since training on dead volume management had the potential to affect baseline performance.

Table 18: Managing Dead Volume: Experimental Conditions and Training

Experimental Condition	Description	Training Content
Baseline	No intervention (i.e., control)	No training required
Education module	<p>The education module focused on reviewing fundamental concepts to inform proper dead volume management (i.e., must clear dead volume prior to medication entirely reaching patient's bloodstream) and included an example of dead volume considerations when administering a manual IV push. However, the module did not review all tasks and setups in which dead volume may be a concern (e.g., it did not reference the dead volume implications of doubling of the concentration for a continuous IV medication infusion)</p> <p>A copy of the dead volume reference sheet was provided to participants during training and posted in the simulation room</p>	<p>Participants viewed the 10-minute module once (they were not allowed to repeat the module)</p> <p>The module was shown together with the secondary IV infusion module (Theme 4: Setting Up Secondary Intermittent IV Infusions); 20 participants saw the dead volume module first, and 20 participants saw the secondary IV infusion module first</p>

Abbreviations: IV, intravenous.

Procedure

The procedure was as described in Research Methods.

Metrics and Analysis

Participant Knowledge

Participants completed 2 written tests to measure their dead volume knowledge: 1 before viewing the education module and 1 after (Appendix 3). Two different but equivalent tests were created to minimize testing effects (i.e., improvement on the second test that could be attributed to familiarity with the questions). An independent sample t-test was performed to evaluate the equivalence of the 2 tests, and there was no significant difference between them ($t[38] = -1.49$, $P = 0.15$). The order of the tests was counterbalanced to minimize any order effect: 20 participants completed Test A before the module and Test B after; 20 participants completed Test B before the module and Test A after.

The test included 9 multiple-choice questions, of which 4 were related to dead volume management (the other 5 questions were related to Theme 4: Setting Up Secondary Intermittent IV Infusions). Test questions were reviewed for content validity by engineers and nurse specialists (e.g., nurse educators/professional development nurse leaders). Participants were given 10 minutes to complete each test (questions were designed to take about 1 minute each to answer).

The 4 test questions about dead volume targeted an understanding of the following:

- identification of dead volume in an infusion setup
- changes to a connected continuous IV infusion flow rate in a multiple IV infusion setup instantaneously changes the dead volume infusion mixture (where the IVs mix together in the tubing) and the flow rate of all connected IV infusions
- changes to a connected continuous IV infusion flow rate does not instantaneously result in the desired dose at the patient's bloodstream (i.e., there is a time lag during which the dead volume must be cleared and a new steady state established prior to achieving the desired change)
- the rate of the syringe flush (sodium chloride 0.9%) given after a medication IV push determines the rate at which the remaining medication in the IV tubing or dead volume is delivered

Mean test scores (%; out of 5 questions) were tabulated per participant before and after watching the education module. A paired sample (dependent) t-test was used to determine any significant differences in mean scores (%) before and after completing the module.

Participant Performance

Participant performance in each task was recorded by the confederate nurse and test facilitators. The metrics for each task were as follows (see Table 19 for definitions and analysis):

- manual IV push:
 - IV tubing not flushed (out of 1)
 - flush rate error (out of 1)
- double medication concentration:
 - IV tubing error (out of 1)
 - dead volume awareness error (out of 1)

If a participant chose not to flush the line, it was not possible to identify the following:

- whether the participant had not considered clearing the dead volume
- whether the participant had considered the need to clear the dead volume, but determined it was unnecessary (i.e., the medication line would clear the 3.5 mL dead volume at 10 mL/h, which would take about 20 minutes; although slow, this would still be in compliance with the order, which specified that the dose should be delivered not faster than 5 mL/min or 300 mL/h; furthermore, if it had been delivered in a minibag as a secondary IV infusion, this would be within the expected time frame limits)

Therefore, although this metric was recorded and analyzed, it was not considered an error not to flush.

Table 19: Managing Dead Volume: Performance Metrics and Analysis

Performance Metrics and Analysis	Manual IV Push		Doubling Medication Concentration	
	IV Tubing Not Flushed	Flush Rate Error	IV Tubing Error	Dead Volume Awareness Error
Definition	Residual IV push medication remained in dead volume (i.e., IV tubing not flushed)	Residual IV medication in dead volume not administered at ordered flow rate (i.e., faster than 5 mL/min or 300 mL/h)	IV containers switched without asking for new tubing and pump programmed to half the flow rate (as required for the concentration of the new IV container)	Did not explain that single-strength concentration remained in dead volume (27.4 mL)
Performance metric (per participant per condition)	Pass or fail	Pass or fail	Pass or fail	Pass or fail
Analysis				
Number of participants included in analysis	40	25 ^a	40	40
Opportunities for error per condition	40 (1 error per manual IV push task; 1 manual IV push task per participant)	25 (1 error per IV manual push task; 1 manual IV push task per participant)	40 (1 error per double medication concentration task; 1 double medication concentration task per participant)	40 (1 error per double medication concentration task; 1 double medication concentration task per participant)
Statistical test (performance metric as a function of experimental condition)	McNemar non-parametric test	McNemar non-parametric test	McNemar non-parametric test	McNemar non-parametric test

Abbreviation: IV, intravenous.

^aTwenty-five (of 40) participants (62.5%) were included in the comparative analysis of flush rate errors, because participants who did not flush in both conditions were excluded from the comparative analysis (the purpose was to compare the difference in flush rate before and after watching the education module).

The test facilitators also recorded unanticipated errors or hazards.

Participant Feedback

Participants completed a questionnaire (Appendix 2) to capture their perception of each intervention with respect to its effectiveness in reducing medication errors and the likelihood of use in clinical practice. Open-ended feedback was solicited about each intervention (as part of the questionnaire), from which summary comment themes were developed.

Results

Participant Knowledge

There was no significant improvement in the overall knowledge-based test scores after watching the education module (Table 20).

Participants scored well on 3 of the 4 questions in the baseline condition (questions 1, 2, and 4 had average scores $\geq 80\%$), leaving little opportunity for improvement with the education module. However, they scored poorly on question 3, which focused on the implications of dead volume changes to dose delivered (i.e., while dead volume is being cleared, the infusion rates of other infusions co-administered will not match ordered rates until the mixture of all infusions reaches a new steady state). After watching the education module, the average score for this question increased from 28% to 53%. Thus, participants had a good basic understanding of dead volume prior to watching the module, but the module helped augment knowledge in understanding the dose implications of dead volume changes.

Table 20: Managing Dead Volume: Knowledge Test Scores

Concepts	Average Test Score ^a		Test Score Difference	Statistics
	Baseline	After Education Module		
1. Identification of dead volume in an infusion setup	98%	95%	-3%	—
2. Changes to a connected continuous IV infusion flow rate in a multiple IV infusion setup instantaneously changes the dead volume infusion mixture (where the IVs mix together in the tubing) and the flow rate of all connected IV infusions	88%	83%	-5%	—
3. Changes to a connected continuous IV infusion flow rate does not instantaneously result in the desired dose at the patient's bloodstream (i.e., there is a time lag during which the dead volume must be cleared and a new steady state established prior to achieving the desired change)	28%	53%	+25%	—
4. The rate of the syringe flush (sodium chloride 0.9%) given after the medication IV push determines the rate at which the remaining medication in the IV tubing or dead volume is delivered	80%	88%	+8%	—
Average for All Dead Volume Management Questions	73%	79%	+6%	t(39) = 1.53 P = 0.13

Abbreviation: IV, intravenous.

^an = 40.

Participant Performance

Table 21 summarizes performance metrics by experimental condition. A summary of other observed hazards is provided below.

Table 21: Managing Dead Volume: Performance Metrics by Experimental Condition

Performance Metric	Sample Size, n	Opportunities for Performance Metric Per Experimental Condition	Experimental Condition		Statistics
			Baseline	Education Module	
Manual IV Push					
IV tubing not flushed	40	40 (1 per participant)	13 (32.5%)	5 (12.5%)	<i>P</i> = 0.02
Flush rate error	25 ^a	25 (1 per participant)	24 (96.0%)	22 (88.0%)	<i>P</i> = 0.63
Doubling Medication Concentration					
IV tubing error	40	40 (1 per participant)	10 (25.0%)	10 (25.0%)	<i>P</i> > 0.999
Dead volume awareness error	40	40 (1 per participant)	11 (27.5%)	4 (10.0%)	<i>P</i> = 0.04

Abbreviation: IV, intravenous.

^aTwenty-five (of 40) participants (62.5%) were included in the comparative analysis of flush rate errors, because participants who did not flush in both conditions were excluded from the comparative analysis (the purpose was to compare the difference in flush rate before and after watching the education module).

After watching the education module, significantly more participants flushed the residual medication in the dead volume compared to baseline. This suggests that after watching the education module, participants were more aware of the need to clear the dead volume to ensure the patient received the entire dose in a timely manner.

Both before and after watching the education module, there was a high rate of flush rate errors (i.e., flow rate was greater than 5 mL/min or 300 mL/h). However, in analyzing the mean flush rates using a paired sample dependent t-test, participants flushed the IV tubing (and consequently the furosemide in the dead volume) significantly more quickly in the baseline condition (mean, *M* = 3,401 mL/h) than after watching the education module (*M* = 1,383 mL/h; *t*[24] = 2.4, *P* = 0.03). Thus, while the education module did not affect the overall error rate, it did reduce the magnitude of the error by 59%. This suggests that participants were more conscious that the flush rate impacted the delivery of the furosemide in the dead volume after watching the education module.

In both experimental conditions, 25% of participants reused the IV tubing that contained single-strength concentration to administer the double-strength infusion. These participants changed the pump programming parameters to match the new double-strength concentration and did not account for the need to clear the dead volume of the old single-strength concentration in the IV tubing. Participants were not able to immediately translate the presented dead volume principle from the education module into new practices when switching the continuous IV infusion to a new strength.

Participants' ability to explain the dead volume-related issues associated with the task statistically improved after watching the education module compared to the baseline condition. The change in dead volume awareness occurred with those participants who did not ask for new tubing (i.e., dead volume management error). In the baseline condition, of the 10 participants who did not ask for new tubing, none (0%) was able to accurately explain the dead volume-related contributing factors to the change in the

patient's vital signs. Participants' explanation for the change in patient's physiological parameters was that the patient was very unstable and/or could not tolerate the temporary interruption in flow that occurred from switching IV containers. All 10 indicated that they would have either given the patient a small bolus or titrated up the flow rate to counteract the patient's response. After watching the education module, 6 of the 10 (60%) were able to explain the dead volume–related factors. The education module did not change performance, but it did help participants identify dead volume–related errors after they had occurred.

Among participants who asked for new IV tubing, almost all were able to accurately explain the dead volume rationale behind their actions (29 of 30 in the baseline condition and 30 of 30 in the education module condition). That is, there was no change in dead volume awareness with participants who managed the dead volume correctly at baseline because they were already aware of the dead volume risk. Participants who proactively identified the dead volume issue managed it correctly.

Although participants were trained on the dead volume reference sheet, only 1 participant used it.

New Hazards

During the experiment, new issues were uncovered that had not been addressed by the education module; the following sections combine data for both baseline and education module conditions.

IV Push Medications Given Too Quickly

The manual IV push task required that participants administer the ordered medication over at least 1 minute (i.e., at rate of less than 50 mg/min or 5 mL/min or 300 mL/h). In 50 of 80 manual IV pushes (40 in the baseline condition and 40 in the education module condition) or 62.5% of time, the IV push medication was administered too quickly.

Variety of Flush Practices Used

Of the 62 flushes observed in both conditions (27 in the baseline condition and 35 in the education module condition), a variety of practices were used to ensure residual medication did not remain in the dead volume (Table 22).

Table 22: Managing Dead Volume: Flush Techniques Following Manual IV Push

Flush Technique	Frequency, n (%) ^a
Syringe Flush	
Administered entire contents of the 10 mL prefilled syringe of sodium chloride 0.9% provided	49 (79.0%)
Administered only some of the 10 mL prefilled syringe of sodium chloride 0.9% provided, but sufficient to clear dead volume (i.e., more than 3.5 mL)	7 (11.3%)
Infusion Pump Flush^b	
Administered an IV pump bolus of sodium chloride 0.9% (from the emergency/plain line) after emptying the contents of the medication syringe ^c	4 (6.5%)
Administered an IV pump bolus of sodium chloride 0.9% (from the emergency/plain line) concurrently with the manual IV push ^c	2 (3.2%)
Total Flushes	62 (100%)

Abbreviation: IV, intravenous; VTBI, volume to be infused.

^an = 62.

^bAdministering a flush by titrating up the flow rate of the "plain line" may result in an uncontrolled fluid bolus if a VTBI is not programmed (Theme 5: Administering an IV Pump Bolus).

^cIV pump boluses were administered at 90 mL/h, 100 mL/h, 500 mL/h, or 999 mL/h. The pump was titrated back down to 10 mL/h after a period of time (all participants waited long enough to clear the dead volume).

^dIV pump boluses were administered at 100 mL/h or 555 mL/h and titrated back down to 10 mL/h after administering the IV syringe contents.

Failure to Account for Syringe Volume

The ordered furosemide was prepared in a 5 mL IV syringe, whereas the sodium chloride 0.9% 10 mL was provided as a prefilled syringe, the standard flush syringe volume used at the participating institution. To push the residual furosemide in the dead volume at the ordered dose/flow rate, the 10 mL syringe, which had twice the volume of the 5 mL furosemide syringe, had to be pushed over twice the time (i.e., 2 minutes rather than 1 minute). When flushes were given by administering the entire contents of the 10 mL sodium chloride 0.9% prefilled IV flush syringes, they were all (49 of 49; 100%) pushed in 67 seconds or less. Thus, participants in both conditions failed to account for the increased flush syringe flush volume; they focused on ensuring the syringe contents were delivered over the same time period rather than ensuring a similar rate per mL between the medication and flush syringe pushes.

Participant Feedback

All 40 participants completed a questionnaire to collect their feedback on the interventions tested. Participant feedback is summarized in Table 23 (see Appendix 2 for details).

Table 23: Managing Dead Volume: Participant Feedback

Question		Education Module
Effectiveness at reducing medication errors ^a		3.7
Likelihood of using intervention in clinical practice ^b		3.6
Comment themes	<ul style="list-style-type: none">• Increased my understanding of dead volume• Would still not consider dead volume in my clinical practice, given its complexity and other clinical demands and priorities• Would be useful for new hires and should be added to the hospital's annual recertification program• The dead volume reference sheet is a good resource, but it would not be used in routine practice given other clinical demands and priorities	

^aFour-point scale: 1, very ineffective; 2, somewhat ineffective; 3, somewhat effective; 4, very effective.

^bFour-point scale: 1, definitely not use; 2, probably not use; 3, probably use; 4, definitely use.

Overall, participants thought the education module would be effective at reducing medication errors and that they would want to view it as part of their professional training.

Discussion

The study results confirmed previous research and reported incidents that dead volume–related errors are common when delivering a manual IV push medication/flush, and when changing a medication concentration. (64;86) Given the likelihood of these errors, effective interventions to minimize dead volume–related errors are required. To our knowledge, this was the first study to empirically evaluate the effectiveness of an intervention to improve dead volume management by nurses.

Education Module

Prior to the adoption of any new tool and/or practice to mitigate dead volume issues, clinicians must have a fundamental understanding of dead volume principles and risks. Previous research has shown that Ontario nurses receive little to no training on how to manage dead volume from their formal nursing education or hospital orientation, (14) but in this study participants scored well in 3 of 4 areas on a written test about dead volume. Participants may have gained dead volume knowledge by caring for critically ill patients on IV medications, receiving real-time feedback on changes in the rate of certain medications

(via physiological monitors). After watching the education module, participants scored better on 2 test questions (e.g., changes to connected infusions do not instantaneously result in the desired dose at the patient's bloodstream), but the ability to achieve statistically significant results was limited, since participants generally had high test scores even in the baseline condition.

Despite participants' basic dead volume knowledge, however, they had difficulty translating and applying their knowledge to clinical practice and made errors in managing dead volume. It is challenging for nurses to learn independently about this topic and develop best practices, because patients may respond differently to dead volume changes (e.g., adults versus children, where concentrations are often different because of IV fluid maintenance volume requirements); dead volume is difficult to see; and dead volume is a concern in many different setups and situations.

Providing an education module that focused on dead volume fundamental principles significantly improved dead volume management practices, but only when the module explicitly targeted specific tasks and provided users with detailed recommended practices (i.e., flush IV tubing after a manual IV push); participants were unable to translate the knowledge gained to untaught tasks (i.e., doubling of the concentration for a continuous IV medication infusion task).

Manual IV Push

In the baseline condition, participants often failed to flush the tubing after administering a manual IV push, or they flushed too quickly; this was consistent with previous research. (86) The education module demonstrated the importance of flushing the dead volume after a manual IV push, and 29.6% more participants flushed after watching it. In addition, participants flushed 59% more slowly (i.e., performance improvement) after watching the module, although they still administered the flush too quickly (i.e., high rate of flush rate errors); this was likely related to 2 issues not addressed by the module.

First, participants often administered all manual IV push medications and flushes too quickly, consistent with other research and reported incidents. (86;102-104) This error was likely not due to a knowledge gap, as reflected by the written test scores (i.e., most were aware that the syringe flush rate determined the rate that the medication in the dead volume is administered). Instead, it may have been related to challenges in perceiving and dedicating time to complete the task, particularly in high workload environments where clinicians may be distracted with their next task. Other research has shown that clocks showing elapsed time can improve correct syringe administration. (104) ISMP (United States) has also suggested that manufacturers design a syringe that supports the slow administration of drugs. (103) Technologies should be developed, validated, and used to support the administration of manual IV push medications and flushes over the correct duration.

Second, participants failed to account for the different volumes of the flush syringe (10 mL) and the drug syringe (5 mL). When drug and flush syringes are different volumes (which may be required given other considerations; for example, flushing the dead volume with twice the volume to prevent drug incompatibilities as recommended by the Infusion Nurses Society), (57) clinicians must adjust the flush administration time to a "per mL" rate to ensure correct administration. This risk may be associated with a clinician knowledge gap; clinicians who administer medications should be taught about this risk.

Doubling the Concentration for a Continuous IV Medication Infusion

In contrast to the manual IV push task, the education module made no explicit reference to the dead volume implications of doubling of the concentration of a continuous IV medication. Instead, the education module simply provided learners with the underlying dead volume principles related to this task (e.g., the need to clear residual volume when infusion changes are made). Participants were required to recognize the dead volume-related issue associated with this task and develop a new clinical practice if their current practice was simply to reuse the original tubing and readjust the infusion to the new dose rate

(i.e., wrong practice). Participant performance was not affected after watching the module, implying that the indirect reference to this issue was too much to ask of learners; participants continued to reuse IV tubing, resulting in a temporary underdose. However, after watching the module, participants were able to more accurately identify and explain the contributing factors to the patient's response to a dead volume-related error. This suggests that the education module increased their ability to identify dead volume issues with patient experience (i.e., bedside learning), but not develop new clinical practice.

Education Module: Overview

The study results underscore the complexity of dead volume issues and the need for dead volume education to go beyond fundamental principles. Dead volume education must help clinicians improve their awareness of the issues and their clinical decision-making skills, so that they can apply their knowledge to untaught situations. Providing learners with numerous interactive applied examples of dead volume setups with accompanying best practices (such as those previously discussed) can help develop not only situation-specific skills but also generic skills to help avoid risky setups, identify when dead volume may be a concern, and minimize unintended patient harm. An interactive, simulation-based education tool may help support such iterative and applied learning (105) and can facilitate a shift away from learning about dead volume at the patient bedside.

Other Interventions

While dead volume education can augment clinician knowledge about dead volume-related task requirements, other complementary interventions are needed to effectively minimize dead volume risks. As noted above, technology interventions (e.g., visual timers to help administer syringes) and practice interventions (e.g., accounting for flush syringe volume when determining post-medication flush flow rate) may help improve dead volume management and medication safety. However, other technology- and practice-based interventions not evaluated in this study may help to minimize dead volume risks.

First, and perhaps most importantly, dead volume can be avoided entirely by not connecting infusions. However, this may not always be practical given the number of lines available on central catheters and the potential increased risk of infection with an increased number of access ports. (63) Research has shown that dead volume issues can be minimized by improving the design of IV components (e.g., microbore tubing that connects close to the patient's bloodstream). (88-90;94;95;99) Manufacturers need to minimize unnecessary priming/dead volume in the design of IV components; health care organizations need to include consideration of priming/dead volume when determining which IV components to purchase and stock; and health care practitioners need to consider dead volume when setting up multiple IV infusions to be administered into 1 access port.

Although dead volume can be reduced via improved component design and use, it is currently impossible to completely eliminate dead volume when multiple IV infusions share 1 access port. Thus, clinicians must be equipped to manage dead volume effectively when caring for a patient who requires precise drug administration. To this end, key tactics include educating clinicians, as previously discussed, but also improving the visual feedback to clinicians about the presence of dead volume and disseminating dead volume-related best practices.

When dead volume exists, clinicians need to be able to easily identify its presence. Infusion systems should have a way of informing clinicians when dead volume may be a concern to support decision-making (90) (e.g., identification of when infusions are running together, infusion pump algorithms that account for dead volume). (101) However, given the current absence of such "smart" communication, the onus is on clinicians to be aware of the priming volume of connected components and to calculate and manage dead volume. For this to occur, the priming volume of IV components must be clearly labelled (e.g., embossed on IV components and packaging). (86) Health care providers can use this information directly from packaging or create reference tools (e.g., posters or online reference sheets). Although not

ideal, they can then use this information to calculate dead volume by summing the shared priming volumes of connected IV components for an infusion setup. In turn, this information can be used to estimate the time to clear the dead volume based on flow rate (time [minutes] = dead volume [mL] ÷ dead volume flow rate [mL/minute]). Although only 1 participant used the dead volume reference sheet in this study, most indicated that they would find it useful when caring for complex or unstable patients. In addition, the use of a reference sheet may increase with clinician dead volume awareness and experience.

There is a lack of explicit professional guidance on dead volume best practices for adoption by health care providers. Practice recommendations to minimize dead volume issues have been published in peer-reviewed literature, but have not been widely adopted by professional associations, taught to clinicians, or incorporated into clinical practice by health care organizations. (14) For example, when multiple IV infusions must be connected together, standardization of infusion setups should be established that minimize dead volume and its impact based on the following principles:

- connecting IV infusions as close as possible to the patient access port (e.g., use add-on devices such as extension sets judiciously, but when required, select and assemble components with minimal priming volume) (88;93)
- use multiport/lumen connectors (i.e., do not join infusions using the lower injection port on IV tubing)
- group medications (if compatible) by therapeutic class (e.g., group sedatives on 1 patient access port and vasopressors on another)

There is also a lack of task-specific, evidence-based best practices to minimize the impact of dead volume. For example, guidance on how to deliver a flush is lacking and where it is available, it is conflicting. (86) Flushing technique is often surprisingly ill-defined and tends to focus on flushing to check/maintain patency of the IV cannula and address drug incompatibilities. (86) A variety of flush practices (i.e., syringe IV flush and infusion pump flush) that contributed to errors were observed in the laboratory study after administration of the medication IV push. Manual IV push best practices and procedures should be updated to stress the importance of flushing to clear residual medication in IV tubing and ensure residual intermittent IV medication in primary IV tubing is administered at the recommended rate. (86) Similarly, practice guidelines must explicitly inform practitioners that when the medication concentration of an infusion is changed, new IV tubing should be used to limit impact of the dead volume.

Limitations

The order of experimental conditions was not counterbalanced; the baseline condition always occurred before the education module, which may have meant participants had more practice with the task in the education module condition and were more fatigued. Nevertheless, this was necessary since watching the education module prior to completing the baseline condition would have influenced baseline behaviour.

Participants' knowledge and performance were measured immediately after watching the education module; the longitudinal effects of the intervention were not studied.

Use of the dead volume reference sheet was not enforced, so its impact on errors could not be evaluated.

Summary

Dead volume may be a concern in numerous infusion setups and can result in unrecognized and potentially dangerous reservoirs of medications. The results of this study underscore the importance of augmenting clinician dead volume knowledge and skills through interactive and iterative simulation-

based education. However, effective dead volume risk mitigation will also require new or improved tools to minimize (or eliminate) dead volume and support safe management. In addition, best practices must be created or updated to incorporate dead volume considerations.

Theme 4: Setting Up Secondary Intermittent IV Infusions

In a primary continuous IV infusion, a steady amount of fluid/medication is delivered continuously until the drug order is stopped, which may be after days, or even weeks (Theme 1: Setting Up and Programming Multiple Primary Continuous IV Infusions). However, IV infusions can also be used to administer *intermittent* medications (i.e., single doses) via *secondary IV infusions*.

Secondary IV infusions allow nurses to administer a single dose of medication over a finite duration (several minutes to several hours) using a large-volume infusion pump (they are also referred to as *piggyback infusions*, because they “piggyback” onto an existing primary continuous IV infusion of a replacement or maintenance fluid, using the same pump and patient IV access). Medications administered in this manner may be ordered as 1-time infusions, such as a stat medication (e.g., epinephrine 0.1 mg IV over 1 hour); on an as-needed basis based on blood work or other parameters (e.g., potassium chloride 20 mmol in 100 mL SW over 1 hour every 6 hours as needed for potassium less than 3.7 mmol/L); or as a scheduled medication repeated at specific intervals (e.g., cefazolin 1 g IV every 8 hours). A secondary IV infusion is a common and convenient way of administering an intermittent medication, particularly when it must be diluted or administered over a duration that would make it unreasonable or unsafe to use a manual IV push.

Issues

The terms *secondary infusion* and *piggyback infusion* are used inconsistently and interchangeably in both literature and clinical practice. (14) In this report, both terms refer to administering an intermittent infusion on a primary continuous IV infusion, as shown in Figure 19. During the secondary IV infusion, the primary infusion temporarily pauses; when the secondary IV infusion is complete, the pump reverts to the primary infusion flow rate and the primary infusion resumes. For most large-volume infusion pumps, the 2 infusions are administered sequentially (not concurrently).

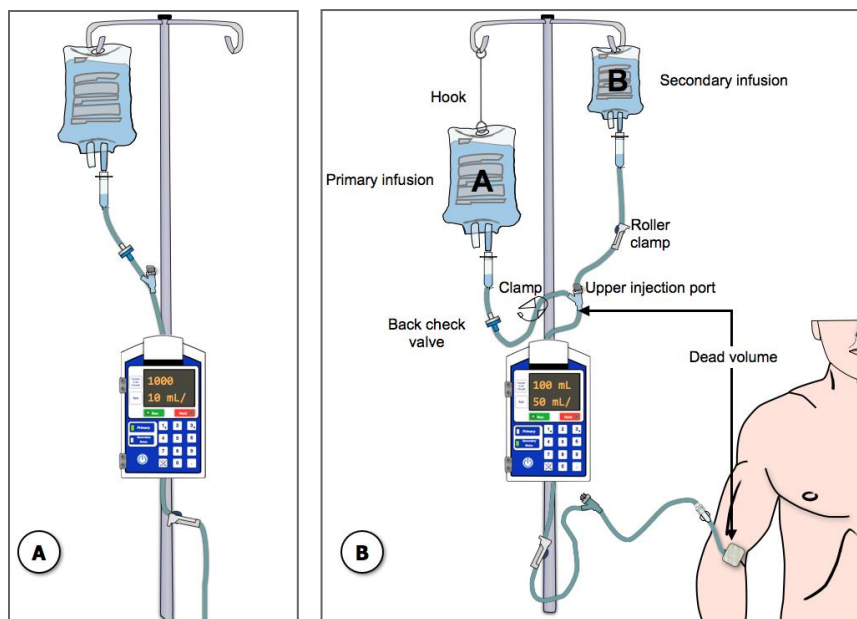


Figure 19: Setting Up Secondary Intermittent IV Infusions: Setup and Components

Abbreviation: IV, intravenous.

Ⓐ Primary continuous IV infusion.

Ⓑ Secondary intermittent IV infusion.

Proper secondary IV infusion administration depends on its physical setup, but setup errors occur frequently. (7;12;106) Nunnally and Bitan (12) reported that clinicians were unable to complete a secondary IV infusion task successfully in 53% of cases. Similarly, Trbovich et al (7) found that the error rates on secondary IV infusions were high (44.4%) and did not vary by pump type (traditional pump, smart pump, or smart pump with bar coding). Although programming errors were common in these 2 simulation studies, the most common error was a failure to create the correct physical setup.

Secondary IV infusion setup errors were also reflected in systematic searches of incident databases (i.e., the ISMP Canada Medication Incident Report database, the US FDA MAUDE database, the ECRI Institute patient safety organization database, and the Iowa Health–Des Moines database). (10;12;107;108) Although incident databases are often limited in detail, researchers were able to determine that incorrect physical setup of secondary IV infusions was likely the contributor to many reported incidents.

Secondary IV infusions are prone to physical setup errors because they make high user demands and are receiving expanded clinical application.

High User Demands

Most infusion pumps (traditional or smart) cannot detect physical setup errors and notify users if tasks such as lowering the primary infusion bag or opening the roller clamp on secondary IV tubing have been omitted or completed incorrectly¹⁶; the onus is on the clinician to set the infusion up so that the pump draws fluid from the correct IV container. Common setup errors are summarized in Table 24. Nunnally and Bitan (12) found that 38% of secondary IV infusions set up by nurses in a simulation study had pressure-differential and connection errors. Similarly, Trbovich et al (7) found that 37% of secondary IV infusions had pressure-differential errors, 9% had secondary clamp errors, and 6% had connection errors. Thornburg et al (108) found that secondary clamp errors were the most common reported medication- or device-related event at 3 U.S. midwestern hospitals. Failure to complete setup requirements can lead to the primary and secondary IV infusions being administered at incorrect, and often indeterminate, flow rates.

¹⁶One commercially available pump independently controls the administration of the primary and secondary infusions and thus eliminates the need for primary IV tubing to have a back check valve and sufficient pressure differential between the primary and secondary infusions (by lowering Bag A in Figure 19[®]). It can also detect when the secondary IV tubing is clamped.

Table 24: Setting Up Secondary Intermittent IV Infusions: Errors and Consequences

Error	Requirement	Consequence
Pressure-differential error	The pressure in the secondary infusion must be higher than the pressure in the primary infusion to ensure that the pump draws fluid from the secondary IV container (and not the primary IV container). To create this pressure differential, clinicians must position the primary IV container lower than the secondary IV container (usually using a hook provided with the secondary IV tubing)	If the secondary IV container is not hung high enough above the primary IV container to create sufficient pressure differential between infusions, the pump will draw from both containers at the secondary rate. If the primary solution flows and mixes with the secondary solution, the medication will not be delivered within the intended time frame If the pressure in the primary IV container is higher than the pressure in the secondary IV container (e.g., primary IV container is higher than the secondary IV container), then a large volume of fluid from the primary IV container may be added into the secondary IV container
	The secondary IV tubing must be attached to primary IV tubing that has a pressure-sensitive back check valve to prevent reverse flow	If secondary IV tubing is attached to primary IV tubing that does not have a back check valve, the secondary solution will flow into the primary IV container, resulting in an unknown amount of the secondary medication in the primary IV container
Secondary IV tubing clamp error	When clinicians initiate the secondary IV infusion, they must open the roller clamp on the secondary IV tubing so that fluid from the secondary IV container can flow (the roller clamp is typically closed when new secondary IV tubing is initiated after priming; depending on individual practice, the roller clamp may also be closed at other times, such as between secondary IV medications)	Secondary infusions cannot run if the roller clamp is closed. Clinicians must ensure that the clamp on the secondary tubing is open. If the roller clamp remains closed, the pump will draw the primary infusion at the rate intended for the secondary infusion. If this goes unnoticed, the patient will not receive the intended secondary medication or may receive it much later than intended
Connection error	Clinicians must connect the secondary IV tubing to the correct primary infusion (e.g., a compatible primary infusion, a primary infusion that is not a continuous IV medication—particularly a high-alert medication) (14;106)	If a secondary infusion is not connected to a primary infusion, it will not be administered, and the primary infusion will be administered at the secondary infusion rate If a secondary infusion is connected to an incompatible primary infusion, a drug interaction can result, leading to a wide variety of possible physical and chemical reactions (e.g., precipitation can change the effect of the medication, block the line, and/or lead to other issues because the precipitate is infused into the bloodstream) If a secondary infusion is connected to a primary infusion that is a continuous IV medication, the primary medication in the tubing below the secondary connection (i.e., dead volume) will be administered at the secondary IV rate (Theme 3: Managing Dead Volume). This is particularly problematic if the primary infusion is a high-alert medication; the wrong rate is more likely to lead to an error causing harm
	Clinicians must connect the secondary IV tubing to an injection port above the pump to ensure administration is controlled by the pump	Connecting the secondary infusion to an injection port below the pump will lead to the secondary infusion flowing at an uncontrolled rate. The primary infusion will also be administered at the secondary rate, concurrently with the free-flowing secondary infusion

Abbreviation: IV, intravenous.

Expanded Clinical Application

The expanded clinical use of secondary IV infusions has led to the need for additional setup requirements to ensure they are safely administered. Historically, secondary IV infusions were designed to administer small volumes of medications (e.g., 50–100 mL) at slow flow rates (i.e., < 300 mL/h). More recently, secondary IV infusions have been used to infuse more medications, requiring larger volumes (e.g., 1,000 mL) and/or faster flow rates (e.g., > 500 mL/h). Larger secondary IV containers and/or higher secondary flow rates affect system fluid dynamics as follows:

- As a large secondary IV container empties, the fluid level may reach a height similar to that of the primary IV container (most likely if the primary IV container is lowered by only 1 hook, and particularly if the primary IV container is full). When this occurs, the pressure differential between infusions is no longer sufficient to keep the back check valve closed, and the secondary solution will flow into the primary IV container. Furthermore, without sufficient pressure differential between infusions, the pump will draw an indeterminate mix of fluid from both containers at the secondary rate.
- A high secondary flow rate reduces the pressure in the IV line and creates a suction effect that may cause the back check valve to open, allowing concurrent flow of both primary and secondary solutions.

In both situations (henceforth referred to as *non-standard secondary IV infusions*), clinicians must take additional precautions to ensure that the primary and secondary infusions do not mix and flow concurrently. Specifically, they must:

- increase the pressure differential between the primary and secondary IV containers (e.g., use a second hook to further lower the primary container); and/or
- clamp the primary IV tubing above the secondary injection port until the secondary IV infusion is complete

Issues: Overview

Proper administration of secondary IV infusions requires clinicians to complete numerous routine mechanistic tasks that, when omitted or done incorrectly, are not detected by infusion technology. While the risks associated with secondary IV infusion setup errors are well documented, empirical research is needed to understand how to minimize such errors.

Interventions

The literature search revealed no studies that empirically evaluated how to effectively reduce the risks associated with setting up a secondary IV infusion. However, various practice, technology, and education-related recommendations to improve the safety of secondary IV infusion administration have been proposed.

Practice Interventions

Practice-based recommendations have focused on clarifying and verifying secondary IV infusion setup requirements:

- attaching secondary infusions to primary IV tubing that has a back check valve and to a port above the pump (10;14)
- viewing the activity in both drip chambers to verify that the secondary infusion is infusing (and the primary infusion is not infusing) (14;75)
- avoiding the administration of secondary infusions on continuous IV medications, particularly high-alert medications (14;106)

These best practices are critical to administering secondary IV infusions safely, and no further evidence is required to support their dissemination and uptake. They were not investigated in the laboratory study.

Technology Interventions

The following 2 technology-related interventions have been suggested to decrease secondary IV infusion setup errors: built-in reminders or alarms, which can alert clinicians to errors; and independent control of primary and secondary infusions, which eliminates some of the error-prone setup requirements.

Reminders and Alarms

In 2005, ISMP Canada advocated for improvements to infusion pump design to prevent secondary IV infusion errors. In particular, it recommended that infusion pumps notify nurses when a secondary infusion is not flowing. (106)

A market scan identified that some infusion pumps are starting to incorporate reminders into secondary infusion programming sequences to prompt users to lower the primary IV container and unclamp the secondary IV tubing prior to infusion initiation. However, even when a reminder is well-designed (e.g., with conspicuous, timely, clear, and sufficient content), it does not guarantee that all intended and required setup requirements will be completed. (109) In addition, the effectiveness of reminders may degrade with time due to “alert fatigue”; (110;111) for example, clinicians may bypass the reminder out of habit, without reading its contents, since the alert is presented every time they set up a secondary IV infusion, even when setup tasks have been successfully completed.

Although it has not yet been licensed for sale in Canada, 1 smart pump has been developed that alarms if the user has not opened the secondary roller clamp at the start of a secondary infusion (a “clamp detector”; Figure 20). The clamp detector alarms only when this omission error has occurred, making it more specific than a general reminder and potentially less susceptible to alert fatigue.

Although the clamp detector has the potential to reduce the risk of failing to open the secondary IV tubing clamp, there is no empirical evidence about its effectiveness. For this reason, a prototype of the clamp detector was included in the laboratory study. It was hypothesized that nurses would make secondary IV infusion physical setup errors (i.e., pressure-differential, secondary clamp, and connection errors) when using the secondary infusion feature on a pump. Using a smart pump with a clamp detector would reduce clamp omission errors compared to baseline (i.e., no detector) by alerting users to this error and facilitating error identification and recovery.

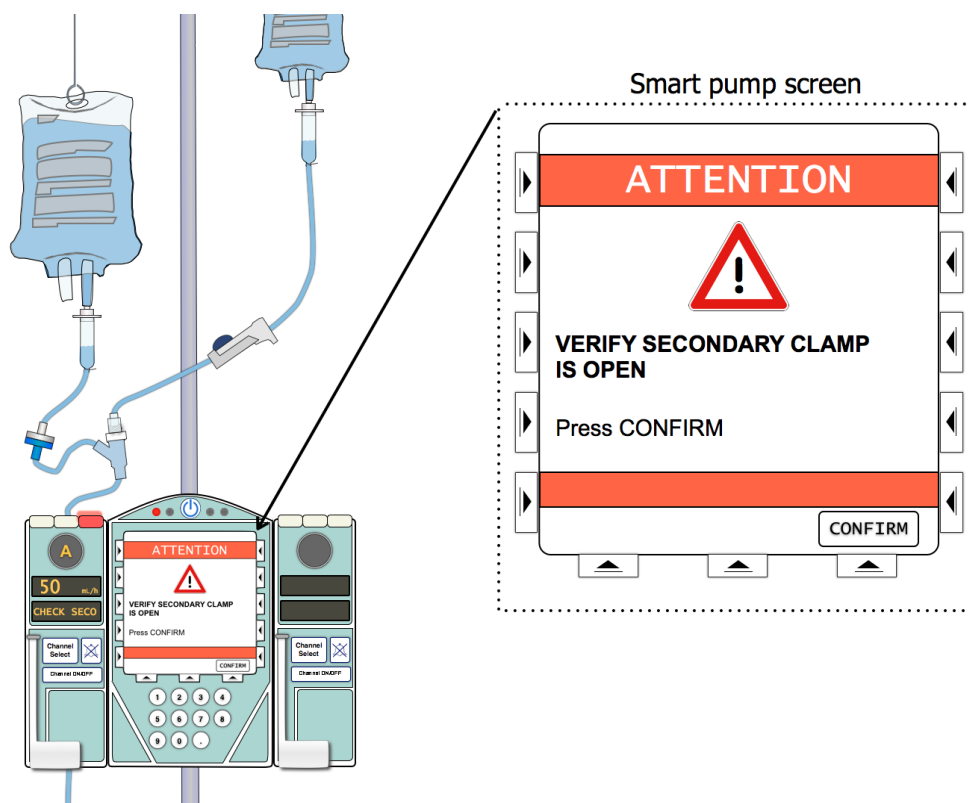


Figure 20: Setting Up Secondary Intermittent IV Infusions: Smart Pump With a Clamp Detector

Abbreviation: IV, intravenous.

Independent Infusion Control

It has been suggested in the literature that independently controlling primary and secondary infusions could eliminate the potential for many secondary IV infusion setup errors. (12;112) Infusion pumps that infuse IV fluid separately from the primary and secondary IV containers have the following advantages:

- They do not require a pressure differential between the primary and secondary IV containers; neither a back check valve on the primary IV tubing nor a height differential between the primary and secondary IV containers is needed.
- They can detect occlusions (or no flow) above the pump and alert users to upstream clamp or connection errors.

The following 2 methods of independently controlling primary and secondary IV infusions have been proposed:

- **Pump design:** One commercially available large-volume pump has separate primary and secondary inlet ports on the pump cassette portion of the primary IV tubing, so that it can administer primary and secondary infusions independently (i.e., secondary infusion administration does not depend on correct physical setup).
- **Separate pump:** Administering intermittent infusions on a separate pump as a primary infusion has been suggested in the literature as a solution, because it decreases setup complexity (Figure 21®). (12) Anecdotal evidence indicates that some hospitals in Quebec, Massachusetts, Brazil, and Europe have minimized the use of secondary IV infusions by administering intermittent

infusions on a separate pump (referred to as *primary intermittent infusions*).¹⁷ When separate pumps are used to administer continuous (Bag A in Figure 21Ⓐ) and intermittent (Bag B in Figure 21Ⓑ) infusions, they must be connected below the pump if they are to share a single IV access port. A variation of this intervention is to use a syringe pump to administer the primary intermittent infusion, instead of another large-volume infusion pump. A mechanical syringe pump designed specifically for controlled administration of non-rate-critical, small-volume, intermittent IV medications is available and used in the United States, but is not licensed for sale in Canada.

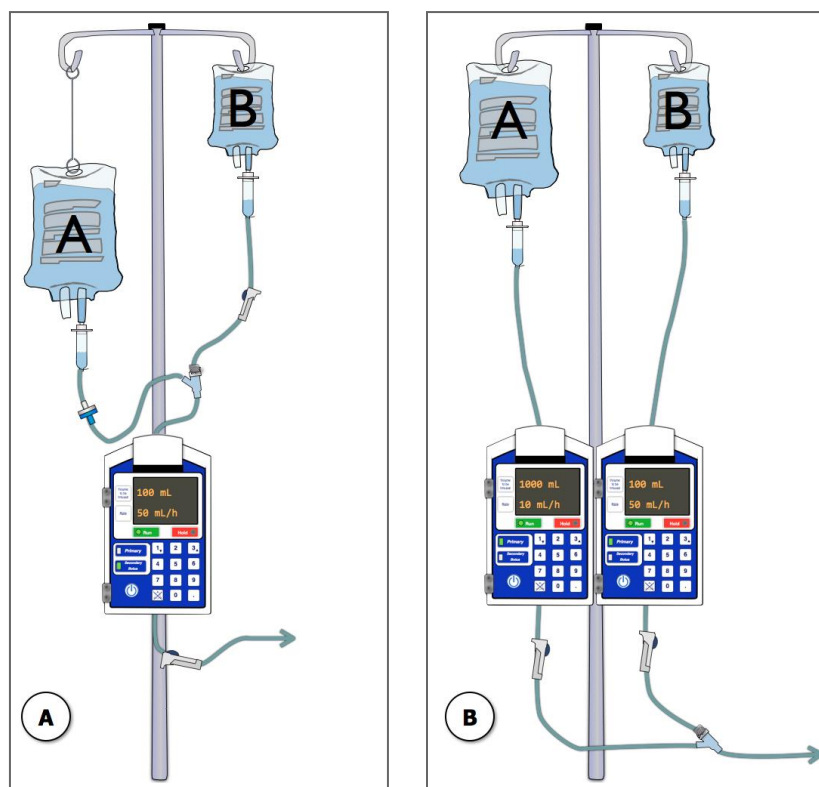


Figure 21: Setting Up Secondary Intermittent IV Infusions: Primary Intermittent IV Infusion (Separate Pump)

Abbreviation: IV, intravenous.

Ⓐ Setup to administer an intermittent infusion as a secondary IV infusion (connected to a primary continuous IV infusion).

Ⓑ Setup to administer an intermittent infusion as a primary IV infusion (using a separate pump).

Administering an intermittent infusion independently of a primary continuous infusion may eliminate many secondary infusion setup errors, but there is no empirical evidence for the effectiveness of this strategy. This intervention (using a separate large-volume pump) was selected for further study, since most hospital organizations will continue to use the infusion devices they already have available (at least in the short term). It was hypothesized that secondary IV infusion physical setup errors (i.e., pressure-differential, secondary clamp, and connection errors) would be eliminated when a separate large-volume pump was used to administer the primary intermittent infusion; each infusion would be independently controlled, so secondary setup requirements would no longer be required.

¹⁷In such cases, a syringe pump was used most often.

Education Interventions

Clinicians' lack of knowledge and experience with medications and infusion devices has been identified as a key contributing factor to 79% of IV administration errors. (102;113) Furthermore, a recent Queen's University study examined third-year undergraduate nursing student confidence and performance in programming infusion pumps using a virtual IV pump education module; almost a third (32.5%) reported that they were not confident programming a secondary medication infusion in the laboratory or clinical area. (113) Educating nurses about secondary IV infusion risks and best practices have been recommended as a way of reducing secondary IV infusion setup errors. (12;106)

Nursing training and education in Ontario does not focus on secondary IV infusion setup risks. Nurses are trained on how to set up secondary IV infusions, but they are not taught the underlying principles from which the rules are derived. (14) This lack of knowledge may compromise nurses' ability to correctly complete setup requirements.

Given this knowledge gap, educating nurses on the underlying principles and known failure modes of secondary IV infusion administration was selected for further study. To address this need, HumanEra developed a 10-minute, computer-based education module to review the following:

- fluid pressure principles associated with secondary IV infusion administration (e.g., rationale behind the height differential requirement, function of the back check valve)
- common secondary IV infusion errors (e.g., omitting to open the secondary IV tubing clamp)

The education module (Figure 22) was iteratively reviewed by nursing experts (including critical care nurse educators). It was hypothesized that after watching the module, nurses' knowledge about secondary IV infusion principles and risks would increase, translating to fewer errors in secondary IV infusion physical setup (i.e., pressure-differential, secondary clamp, and connection errors) compared to baseline (i.e., before watching the module).

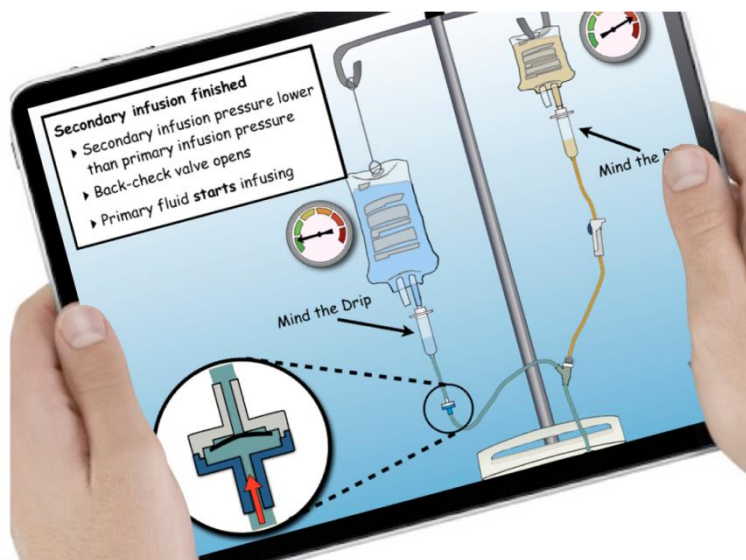


Figure 22: Setting Up Secondary Intermittent IV Infusions: Education Module

Abbreviation: IV, intravenous.

This education tool, developed by HumanEra, dynamically demonstrated the key principles and rationales behind secondary IV infusion setup.

Experimental Method

Forty ICU nurses each completed 2 tasks (a standard secondary IV infusion and a non-standard secondary IV infusion) under 4 different experimental conditions (baseline/no intervention, smart pump with clamp detector, separate pumps, and education module).

Tasks

Participants were asked to complete the 2 secondary IV infusion tasks described in Table 25 in each experimental condition. Since interruptions are common in clinical practice, (7;52-55) the confederate nurse interrupted the participant with a question during each secondary IV infusion setup; the interruptions were scripted and counterbalanced to ensure equivalence across conditions.

Table 25: Setting Up Secondary Intermittent IV Infusions: Tasks

Task	Notes
Standard secondary IV infusion	A common secondary IV infusion of a medication routinely used in critical care (e.g., vancomycin, Piptazo, or ceftriaxone) and was prepared in a minibag (e.g., 250 mL)
Non-standard secondary IV infusion ^a	A less common secondary IV infusion (e.g., a clinical trial drug) that required a high flow rate (e.g., 750 mL/h) or was prepared in a large IV container (e.g., 1,000 mL)

Abbreviation: IV, intravenous.

^aA secondary IV infusion requiring additional precautions, such as hanging the primary IV container using 2 hooks or clamping the primary IV tubing above the pump.

In all scenarios, the patient was receiving multiple continuous IV infusions, including 2 separate sodium chloride 0.9% IV infusions. One of the sodium chloride infusions was attached to a multiport connector and used as a “chaser” to help carry other continuous IV infusions attached to the same connector (infusion 7 in Figure 4). The other sodium chloride infusion was attached directly to the patient as an emergency medication line; infusion 5 in Figure 4). As part of setting up the secondary IV infusion, participants had to identify which primary IV infusion they should use to connect the secondary infusion (i.e., the emergency medication line).

In the interests of time, the following modifications were made to the tasks:

- In the first task, participants were provided with a premixed secondary IV container attached to primed secondary IV tubing.
- In the first task, after setting up and starting the secondary IV infusion, participants were distracted (e.g., the arrival of an inquisitive family member), and the confederate nurse artificially accelerated time to avoid waiting until the secondary IV infusion completed (changed the IV container to an identical but empty IV container and reduced the VTBI so the secondary infusion would finish in a few minutes).
- In the second task, participants were provided with a premixed secondary IV container, but participants could choose to reuse the secondary IV tubing from the first task or ask for new secondary IV tubing.

Experimental Conditions

The 4 experimental conditions are described in Table 26. The order of the conditions was partially counterbalanced; the education module intervention condition was always completed last, since training on secondary infusions had the potential to affect performance in the other conditions. Participants were trained on the new interventions as described below and were asked throughout the training whether they had questions.

Table 26: Setting Up Secondary Intermittent IV Infusions: Experimental Conditions and Training

Experimental Condition	Description	Training Content
Baseline	No intervention (i.e., control)	No training required
Smart pump with clamp detector	Participants were asked to set up 2 secondary intermittent IV infusions on a smart pump with a clamp detector (Figure 20)	Hands-on training on the clamp detector was provided as part of training on the basic functionality of the smart pump (about 10 minutes), including how to set up a secondary IV infusion. Participants had to respond to a clamp detector alarm as part of the training
Separate pump	Participants were asked to set up 2 intermittent infusions as primary infusions on a separate large-volume pump (empty pump provided) and connect them to the emergency medication line at the lowest injection port below the pump (Figure 21®)	Hands-on training on this intervention (about 5 minutes) stressed the following 3 new considerations when an intermittent infusion is administered on a separate pump: <ul style="list-style-type: none">• the infusion in the emergency medication line should be manually titrated down or paused (it is not automatically paused)• the residual intermittent medication in the primary IV tubing must be flushed after infusion completion to ensure the complete dose is administered• an alarm will sound upon completion of the primary intermittent infusion
Education module	Participants were asked to complete the 2 secondary infusion tasks after watching an education module	Participants viewed the 10-minute module once (they were not allowed to repeat the module). The module was shown together with the dead volume module (Theme 3: Managing Dead Volume); 20 participants saw the secondary IV infusion education module first, and 20 participants saw it after the dead volume module

Abbreviation: IV, intravenous.

Procedure

The procedure was as described in Research Methods.

Metrics and Analysis

Participant Knowledge

Participants completed 2 written tests to measure their knowledge of secondary IV infusion setup requirements: 1 before viewing the education module and 1 after (Appendix 3). Two different but equivalent tests were created to minimize testing effects (i.e., improvement on the second test that could be attributed to familiarity with the questions). An independent sample t-test was performed to evaluate the equivalence of the 2 tests, and there was no significant difference between them ($t[38] = -1.49$, $P = 0.15$). The order of the tests was counterbalanced to minimize any order effect: 20 participants completed Test A before the module and Test B after; 20 participants completed Test B before the module and Test A after.

The test included 9 multiple-choice questions, of which 5 were related to setting up a secondary IV infusions (the other 4 questions were related to Theme 3: Managing Dead Volume). Test questions were reviewed for content validity by engineers and nurse specialists (e.g., nurse educators/professional development nurse leaders). Participants were given 10 minutes to complete each test (questions were designed to take about 1 minute each to answer).

The 5 test questions about secondary IV infusion setup targeted an understanding of the following:

- pressure-differential requirements (3 questions):
 - impact of pressure differential (i.e., bag height) on fluid flow
 - function of the back check valve
 - setup requirements for secondary IV infusions with a large IV container (e.g., 1,000 mL) and/or fast flow rates (e.g., 850 mL/h)
- the role of the secondary clamp (1 question)
- the impact of connecting a secondary IV infusion to the IV injection port below the pump (1 question)

Mean test scores (%; out of 5 questions) were tabulated per participant before and after watching the education module. A paired sample (dependent) t-test was used to determine any significant differences in mean scores (%) before and after completing the module.

Participant Performance

Participant performance in each task was recorded by the confederate nurse and test facilitators. The metrics for each task were as follows (see Table 27 for definitions and analysis):

- pressure-differential error
 - standard secondary IV infusion (out of 1)
 - non-standard secondary IV infusion (out of 1)
- secondary IV tubing clamp error (out of 2)
- connection error (out of 2)

Table 27: Setting Up Secondary Intermittent IV Infusions: Performance Metrics and Analysis

Performance Metrics and Analysis	Pressure-Differential Errors		Secondary IV Tubing Clamp Errors (All Tasks)	Connection Errors (All Tasks)
	Standard Secondary IV Infusion	Non-Standard Secondary IV Infusion		
Definition	Primary IV container was not lowered below the secondary IV container using the hook provided in the package, and the clamp on the primary IV tubing above the pump was open	Primary IV container was not hung below the secondary IV container by joining 2 hooks, and the clamp on the primary IV tubing above pump was open	Secondary IV tubing clamp was left closed upon infusion initiation	Secondary IV tubing was connected to the wrong primary IV tubing or to the wrong port on the primary IV line (i.e., port below infusion pump)
Performance metric (per participant per condition)	Pass or fail	Pass or fail	Number of secondary clamp errors (maximum 2)	Number of connection errors (maximum 2)
Analysis				
Number of participants included in analysis	40	40	40	40
Opportunities for error per condition	40 (1 error per standard secondary IV infusion task; 1 standard secondary IV infusion task per participant)	40 (1 error per non-standard secondary IV infusion task; 1 non-standard secondary IV infusion task per participant)	80 (1 error per secondary IV infusion task; 2 secondary IV infusion tasks per participant)	80 (1 error per secondary IV infusion task; 2 secondary IV infusion tasks per participant)
Statistical test (performance metric as a function of experimental condition)	Cochran's Q test followed by pairwise comparisons between the different combinations of experimental conditions using the McNemar χ^2 test with Bonferroni correction	Cochran's Q test followed by pairwise comparisons between the different combinations of experimental conditions using the McNemar χ^2 test with Bonferroni correction	One-way ANOVA test followed by post hoc paired sample t-test comparisons using Bonferroni correction	One-way ANOVA test followed by post hoc paired sample t-test comparisons using Bonferroni correction

Abbreviations: ANOVA, analysis of variance; IV, intravenous.

The requirements for correctly setting up the secondary IV infusion pressure differential varied by task, so pressure-differential errors were analyzed separately (standard and non-standard secondary IV infusions). Secondary clamp and connection requirements were not affected by task, so data per participant were combined into 1 metric (i.e., score out of 2 per participant per condition for each).

The test facilitators also recorded unanticipated errors or hazards.

Participant Feedback

Participants completed a questionnaire (Appendix 2) to capture their perception of each intervention with respect to its effectiveness in reducing medication errors and the likelihood of its use in clinical practice. Open-ended feedback was solicited about each intervention (as part of the questionnaire), from which summary comment themes were developed. A one-way repeated measure ANOVA test was conducted to assess for statistically significant differences between intervention conditions, and post hoc paired sample t-test comparisons were done using Bonferroni correction.

Results

Participant Knowledge

The mean test score after watching the education module was significantly higher than the mean baseline score (Table 28). The education module improved participants' score on all but question 4 (role of secondary clamp), because the average score was 100% in both conditions.

Table 28: Setting Up Secondary Intermittent IV Infusions: Knowledge Test Scores

Concepts	Average Test Score ^a		Test Score Difference	Statistics
	Baseline	After Education Module		
Pressure Differential				
1. Impact of pressure differential (i.e., bag height) on fluid flow	30%	78%	+48%	—
2. Function of the back check valve	23%	73%	+50%	—
3. Setup requirements for secondary IV infusions with a large IV container (e.g., 1,000 mL) and/or fast flow rates (e.g., 850 mL/h)	13%	40%	+27%	—
Average for pressure-differential questions	22%	64%	+42%	—
Secondary IV Tubing Clamp				
4. The role of the secondary clamp	100%	100%	0%	—
Secondary to Primary Infusion Connection				
5. The impact of connecting a secondary IV infusion to the IV injection port below the pump	63%	85%	+22%	—
Average for All Secondary IV Infusion Questions	46%	76%	+30%	t(39) = -8.11 P < 0.001

Abbreviation: IV, intravenous.

^an = 40.

Participant Performance

Table 29 summarizes performance metrics by experimental condition. A summary of other observed hazards is provided below.

Table 29: Setting Up Secondary Intermittent IV Infusions: Performance Metrics by Experimental Condition

Performance Metric	Sample Size, n	Opportunities for Performance Metric per Experimental Condition	Experimental Condition				Statistics
			Baseline	Smart Pump With Clamp Detector	Separate Pump ^a	Education Module	
Pressure-differential errors, standard secondary IV infusions	40	40 (1 per participant)	14 (35.0%)	17 (42.5%)	0 (0.0%)	7 (17.5%)	Cochran Q = 30.52 <i>P</i> < 0.001
Pressure-differential errors, non-standard secondary IV infusions	40	40 (1 per participant)	35 (87.5%)	40 (100.0%)	0 (0.0%)	20 (50.0%)	Cochran Q = 83.63 <i>P</i> < 0.001
Secondary IV tubing clamp errors	40	80 (2 per participant)	9 (11.3%)	0 (0.0%)	0 (0.0%)	12 (15.0%)	F(3,117) = 7.52 <i>P</i> = 0.001
Connection errors	40	80 (2 per participant)	4 (5.0%)	5 (6.3%)	4 (5.0%)	2 (2.5%)	F(3,117) = 0.34 <i>P</i> = 0.80

Abbreviation: IV, intravenous.

^aAlso referred to earlier as a *primary intermittent IV* infusion since technically they are infused using primary IV tubing and one a separate infusion pumps.

In the baseline condition, almost half (19 of 40; 47.5%) of standard secondary IV infusions were set up with at least 1 error.

Pressure-Differential Errors

There was a statistical difference in pressure-differential errors between experimental conditions for both standard and non-standard secondary IV infusions.

Setting up standard secondary IV infusions on a separate pump eliminated pressure-differential errors; this was significantly different from the other conditions, since the intervention abolished the potential for this type of error ($P < 0.001$ for all comparisons). Participants also made significantly fewer pressure-differential errors after viewing the education module than when using the smart pump with a clamp detector ($P = 0.04$). There was no statistical difference between the other conditions.

Setting up non-standard secondary IV infusions on a separate pump also eliminated pressure-differential errors ($P < 0.001$ for all comparisons). Participants made significantly fewer pressure-differential errors after viewing the education module than compared to baseline ($P = 0.006$) and smart pump ($P < 0.001$) conditions. There was no statistical difference between the other conditions.

In both the baseline and smart pump with clamp detector conditions, there was a particularly high rate of pressure-differential errors when setting up a non-standard secondary IV infusion. No participant lowered the primary IV container by 2 hooks in either condition. In the baseline condition, some participants (5 of 40; 12.5%) used the clamp on the primary IV tubing above the secondary infusion injection port (not the clamp on the secondary IV tubing) to prevent concurrent flow (this was not possible with the primary IV tubing on the smart pump, which did not have a clamp above the secondary infusion injection port). After watching the education module, many participants (17 of 40; 42.5%) used 2 hooks to lower the primary IV container.

Secondary IV Tubing Clamp Errors

The separate pump and smart pump with clamp detector conditions eliminated secondary IV tubing clamp errors compared to the baseline and education module conditions. The reduction in errors for the separate pump and smart pump with clamp detector conditions was statistically significant compared to the education module condition ($P = 0.01$ for both), and it approached statistical significance compared to the baseline condition ($P = 0.06$ for both). There was no statistical difference between the other conditions.

By design, the separate pump condition removed the potential for secondary IV tubing clamp errors, since the IV infusion was administered using primary IV tubing. The smart pump with clamp detector condition notified users of this error but did not prevent the error from occurring. Participants failed to open the secondary clamp in 20 of 80 (25%) secondary IV infusions initiated in the smart pump condition, but the smart pump clamp detector alarmed and all participants (20 of 20; 100%) opened the secondary clamp in response; the error was successfully intercepted and rectified.

Connection Errors

There was no significant difference in connection errors across the interventions. However, if a connection error occurred in setting up the first secondary IV infusion, it persisted in the subsequent secondary IV infusion task in each condition in all cases except 1, since IV tubing was often reused (New Hazards).

The following 2 connection errors were made across experimental conditions (40 participants completing 2 secondary IV infusions in each of 4 experimental conditions, or 320 observations):

- Wrong primary infusion used: 9 of 320 (2.8%) secondary IV infusions were attached to the wrong primary IV infusion (i.e., not the emergency medication line).
 - In 7 of 9 (77.8%), the secondary IV infusion was attached to the wrong sodium chloride 0.9% IV infusion (i.e., to the sodium chloride 0.9% IV infusion that was being used as a chaser on a multiport connector and thus was connected to other medications, such as dopamine, vasopressin, or norepinephrine). This error would have resulted in drug incompatibilities and dead volume issues (e.g., an unintentional bolus) (Theme 3: Managing Dead Volume).
 - In 2 of 9 (22.2%), the secondary IV infusion was attached to the peripheral access port instead of the distal port on the central catheter. Both errors were made by the same participant in the separate pump condition. In the first task, the participant attached the secondary IV infusion to a continuous heparin drip, which was attached to a continuous insulin drip connected to the peripheral access port (infusions were connected to each other using the lower injection port on the primary IV tubing). This would have resulted in drug incompatibilities and dead volume issues (e.g., a bolus of insulin and heparin). In the second task, the participant detached the continuous heparin drip from the insulin drip and attached the primary intermittent infusion directly to the insulin drip, so that the heparin dripped on the floor. This connection error led to an interruption in therapy and would have also resulted in dead volume issues (e.g., bolus of the IV insulin).

- Wrong injection port used on right primary infusion: 6 of 320 (1.9%) secondary IV infusions were attached below the pump instead of above the pump, so that the secondary IV infusion was free-flowing (i.e., uncontrolled) to the patient. All 6 errors were made by 1 participant in the baseline, smart pump with clamp detector and education module conditions (2 errors per condition). This participant did not make this error in the separate pump condition, because the infusion was meant to be connected below the pump. During the debrief, this participant indicated that (s)he thought the pump could control the secondary IV infusion flow rate even if it was connected to an injection port below the pump.

While the separate pump intervention eliminated the potential to connect the secondary IV infusion to an injection port below the pump, it did not eliminate the potential for other connection errors (i.e., connecting to wrong primary IV infusion). Overall, none of the interventions was effective at reducing connection errors.

New Hazards

During the experiment, new issues were uncovered that had not been identified in previous phases of this research or in the literature review.

Reuse of IV Tubing

Participants were required to set up 2 secondary IV infusions in each experimental condition, 1 after another. When setting up the second infusion, participants frequently chose to reuse the secondary IV tubing across all experimental conditions (124 of 160; 77.5%). In half of the infusion setups, the 2 secondary IV infusions administered consecutively were incompatible; participants reused the secondary IV tubing without flushing in 26 of 80 (32.5%) secondary IV infusions, resulting in the mixing of incompatible solutions.

Variability in VTBI Programming

Although pump programming errors were not the focus of this study, there was a wide variation in VTBI programming for the secondary IV infusions across all experimental conditions using the traditional pump (i.e., baseline, separate pump, and education module). Thirty-one of 240 (12.9%) secondary IV infusions were programmed with a VTBI that was more than 10% greater or less than the IV container volume: 25 (80.6%) were greater than the secondary IV container volume, and 6 (19.4%) were less than the secondary IV container volume. VTBIs ranged from 8% to 400% of the secondary IV container volume.

The programmed VTBI of a secondary IV infusion (baseline and education module conditions) determines when the pump switches back to the primary flow rate from the secondary flow rate. A VTBI greater than the secondary IV container would lead to the primary infusion being administered at the secondary flow rate after the secondary IV container emptied. Conversely, a VTBI smaller than the secondary IV container would cause the remaining volume in the secondary IV container to be administered at the primary flow rate. Such differences in flow rate would be clinically significant if the primary rate was different from the secondary rate (e.g., a primary KVO rate could cause the secondary infusion not to be completed in the time frame required).

In the smart pump used for the clamp detector condition, all programmed VTBIs (80 of 80; 100%) matched the IV container size. The tested smart pump autopopulated the VTBI with the volume of the IV container selected from the drug library.¹⁸

The laboratory study results associated with VTBI programmed for a continuous IV medication infusion were discussed in Theme 1: Setting Up and Programming Multiple Primary Continuous IV Infusions.

¹⁸Although the smart pump autopopulated the VTBI with the IV container volume, users could edit the VTBI if desired.

Separate Pump Condition Issues

Setting up a secondary IV infusion using a separate pump (i.e., as a primary intermittent infusion) introduced new hazards. These hazards are described in Table 30 by identifying some of the setup requirements to administer an intermittent infusion using a separate pump.

Table 30: Setting Up Secondary Intermittent IV Infusions: New Hazards in Separate Pump Condition

Secondary IV Infusion Characteristic	Separate Pump			
	Requirement	Hazard	Frequency ^a	Consequence
The priming volume of the secondary IV tubing is about 6.5 mL (depends on tubing used); some of the residual medication in the tubing after the secondary infusion is completed is pumped concurrently with the primary infusion	The residual volume in the primary tubing should be delivered to the patient at the prescribed rate	The priming volume of primary IV tubing is much greater than that of secondary IV tubing (e.g., 25 mL vs. 5 mL). For most intermittent infusions, the container size (e.g., minibag) means that there will be a significant amount of medication left in the tubing if it is not flushed. Participants were required to flush the IV tubing (e.g., by hanging a new plain minibag solution) using the same rate as the intermittent medication	31 (77.5%)	Tubing not flushed could lead to underdose of medication (e.g., if IV tubing was changed post-administration) or delayed/split dosing of a medication not intended to be administered in this manner (this could have far-reaching complications, depending on the clinical condition and IV medication affected) Flushing the tubing requires using a new minibag container, increasing the probability of contamination errors Additional fluid volume from required flushes may be an issue for fluid-restricted patients
During administration of a secondary IV infusion, the primary continuous IV infusion temporarily halts	The primary continuous IV infusion should be manually paused or titrated down	There is a risk that during administration of the primary intermittent infusion, the primary continuous infusion will not be stopped or titrated down to the participating institution's KVO rate (i.e., 10 mL/h or less)	29 (72.5%)	Unnecessary IV fluid volume would be administered, which may be an issue for fluid-restricted patients

Abbreviations: IV, intravenous; KVO, keep vein open.

^an = 40.

Participant Feedback

All 40 participants completed a questionnaire to collect their feedback on the interventions tested. Participant feedback is summarized in Table 31 (see Appendix 2 for details).

Table 31: Setting Up Secondary Intermittent IV Infusions: Participant Feedback

Question	Smart Pump With Clamp Detector	Separate Pump	Education Module	Statistics
Effectiveness at reducing medication errors ^a	3.7	2.7	3.6	F (3,117) = 22.59 P < 0.001
Likelihood of using intervention in clinical practice ^b	3.8	2.0	3.6	F (3,117) = 38.90 P < 0.001
Comment themes	<ul style="list-style-type: none"> • Important feature to improve patient safety • More time to set up (e.g., prime primary IV tubing), which would be particularly problematic in emergency situations • Increased workload upon infusion completion, since nurse would be called back to the bedside to answer an end-of-infusion alarm and flush the residual medication in the IV tubing; this may be a more of an issue in general wards where the staffing ratio is lower • Requires at least 1 more pump at the bedside where space is already limited; pump shortages are common; contributes to infusion identification confusion • Financial and environmental costs of using more primary IV tubing and flush IV minibags • Does not increase safety 			<ul style="list-style-type: none"> • Increased my understanding of IV principles • Would be useful for new hires and should be added to the hospital's annual recertification program • Module was too long to be viewed while at work

Abbreviation: IV, intravenous.

^aFour-point scale: 1, very ineffective; 2, somewhat ineffective; 3, somewhat effective; 4, very effective.

^bFour-point scale: 1, definitely not use; 2, probably not use; 3, probably use; 4, definitely use.

Participant ratings of the perceived effectiveness of the interventions at reducing medication errors was statistically different between interventions. Specifically, participants rated the separate pump intervention lower than the smart pump with clamp detector ($P < 0.001$) and education module interventions ($P < 0.001$); there was no statistical difference between the other conditions.

Similarly, participants' ratings of the likelihood of use of the interventions were statistically different between conditions. Participants rated the likelihood of using the separate pump intervention statistically lower than the smart pump with clamp detector ($P < 0.001$) and education module ($P < 0.001$). In fact, the separate pump intervention was rated the lowest of all tested interventions across all themes. There was no statistical difference between the other conditions.

Participants provided insightful comments to explain their ratings and potential implementation issues not studied in the laboratory simulation (Table 31; see Appendix 2 for detailed information).















Discussion

The results of this study were consistent with previous research and emphasized that the physical setup of secondary IV infusions is error-prone. (7;12;108) Mitigations to secondary IV infusion setup errors are discussed in the following sections by considering whether the errors were ones of *omission* or *commission*.

Omission Errors

Omission errors occurred as a result of an action not taken. Failure to set up appropriate pressure differential and failure to open the secondary IV tubing clamp were the 2 most common secondary IV infusion setup errors seen in this study, and both were omission errors. Research has identified properties that increase the likelihood of task omission, (109) and many of them are applicable to these 2 setup errors (Table 32).

Table 32: Setting Up Secondary Intermittent IV infusions: Contributing Factors to Pressure-Differential and Secondary IV Tubing Clamp Omission Errors

General Factors That Increase the Likelihood of Omission Errors ^a	Secondary Intermittent IV Infusions		
	Factor Applicable to Pressure-Differential Omission Error?	Factor Applicable to Secondary Clamp Omission Error?	Comments
High information load during step completion			Setting up a secondary IV infusion is a task with a high memory load (must complete numerous steps and remember drug order parameters)
Step is functionally isolated (i.e., no cues from previous step)			There is no cue from preceding actions to set up the pressure differential between the primary and secondary infusions or open the clamp
Recursive or repeated action (i.e., second of 2 similar steps may be neglected)			Setting up the pressure differential or opening the secondary IV tubing clamp is completed only once per infusion
Step is near the end of a task			Opening the clamp is usually 1 of the last actions completed; clinicians may be preoccupied with their next unrelated task
Lack of conspicuous feedback to perform the step			Most infusion pumps do not remind users to set up the appropriate pressure differential or open the clamp on the secondary IV tubing. It is also difficult to detect if these steps have been omitted (e.g., whether the pump is infusing fluid from the primary or secondary IV container except via the drip chamber; the clamp position)
Step follows interruption	 ^b	 ^b	Interruptions are common in clinical practice
Step requires departure from standard procedure	 ^b		Setting up a non-standard secondary IV infusion (i.e., large IV container or high flow rate) requires additional precautions (e.g., double-hook primary IV container)

Abbreviation: IV, intravenous.

^aBased on Reason, 2002 (109).

^bContributing factor in some situations.

Improvements to the design of infusion systems can eliminate some of the secondary IV infusion setup requirements and eliminate omission errors. One option, implemented by some hospitals (particularly outside of North America, based on anecdotal reports), is to abolish the use of secondary IV infusions and require all intermittent infusions to be administered as a primary infusion on a separate pump. However, results of the current study showed that while this intervention eliminated some omission errors (failing to lower the primary IV container and failing to open the secondary clamp), it introduced new hazards. For example, when an intermittent infusion is administered as a primary IV infusion, a much greater amount of residual medication remains in the IV tubing, and this must be flushed once the infusion container is empty. Although the need for flushing was highlighted to participants in the training before they were asked to set up the infusions using a separate pump, only a small proportion (9 of 40; 22.5%) fully flushed the IV tubing upon completion of the tasks. Flushing the IV tubing may also introduce infection risks (from changing the IV container) and air embolism risks (air may be introduced into the IV tubing upon IV container depletion and inadvertently administered to the patient during flushing). Improvements to infusion pump design are needed to eliminate setup requirements but preserve the benefits of secondary IV infusions (e.g., convenient infusion administration that minimizes residual fluid left in the IV tubing and does not need an additional pump or access port). (106) One option would be to have 1 infusion pump/channel independently recognize and control primary and secondary IV infusions.

While eliminating the potential for secondary setup errors is preferred, the current study also found that identifying and alerting users to omission errors can improve the safe administration of secondary IV infusions. The smart pump with the clamp detector alerted users who failed to open the clamp on the secondary IV tubing at infusion initiation, eliminating this type of error. The intervention alarmed only when a clamp error occurred; this is preferable to routine reminders, which can promote alert fatigue.

The design of IV tubing may also have affected the rate of omission errors. Some participants (10% in the baseline condition) closed the clamp on the primary IV tubing above the pump to stop flow from the primary infusion, eliminating the need to lower the primary IV container (for both standard and non-standard secondary IV infusions). However, the primary IV tubing for the smart pump used in the laboratory study did not have a clamp on the primary tubing above the pump (although this issue is not specific to smart pumps). The manufacturer decided to not provide a clamp since it introduced other, unintentional consequences with their infusion system, such as pulling air into the primary IV tubing upon secondary infusion completion. However, in the current study, participants who were accustomed to using the clamp to prevent concurrent flow failed to lower the primary IV container when the clamp was unavailable. Health care providers need to confirm recommended setup requirements with the manufacturer. Also, since having a clamp on the primary tubing above the pump is not standard on all infusion systems, clinicians should be alerted to this issue, particularly when migrating from a system with a clamp to one without, or when using multiple infusion systems.

Some omission errors were partly attributable to a lack of knowledge about infusion principles. This gap compromised participants' ability to correctly set up the required pressure differential between the secondary and primary IV infusions; this was especially true for non-standard secondary IV infusions, because participants had to identify and adjust setup requirements to ensure appropriate drug administration. Until infusion technology design eliminates the potential for secondary IV infusion setup errors, educating clinicians about the underlying infusion principles, setup risks, and best practices associated with secondary IV infusions can help support decision-making and problem-solving.

Lack of task experience may also increase the risk of a knowledge-based omission error. Not all participants routinely administered non-standard secondary IV infusions in their clinical practice; the critical care units at the participating institution rarely administered secondary IV infusions that required a large IV container or were administered at high flow rates. The high rate of omission setup errors for non-

standard secondary infusions observed in this study may be lower in other clinical units (e.g., oncology) where non-standard secondary infusions may be more common.

Although it was not tested in the current study, another omission error that may benefit from targeted education was that of reusing secondary IV tubing without flushing or back-priming when the new drug is incompatible with the previous one.¹⁹ ISMP Canada reported an incident in which 2 incompatible secondary IV infusions were initiated using the same IV tubing, resulting in precipitate in the IV tubing. (114)

Still, education is not effective at addressing all secondary IV infusion setup omission errors, because not all omission errors are related to knowledge gaps. Secondary clamp errors were not significantly reduced after watching the education module, for example; participants knew the clamp should be open (as evident in the written test results), but many failed to complete this step, likely because of a lapse in attention. As well, education may be limited in its longitudinal effects.

Commission Errors

In contrast to omission errors, which occur as the result of actions not taken, commission errors occur as a result of incorrect actions taken. This study identified 2 commission-related issues: connection errors and VTBI pump programming variability.









Connection Errors

Participants made 2 connection-related commission errors: connecting secondary IV tubing to the wrong primary infusion (i.e., not the emergency medication line); and connecting secondary IV tubing to the wrong injection port on the correct primary infusion (i.e., below the pump instead of above). Although such connections errors were infrequent, they may be particularly problematic; participants frequently chose to reuse the secondary IV tubing from the first infusion to administer subsequent secondary infusions (i.e., kept the secondary IV tubing connected to the primary infusion and exchanged the IV container), causing connection errors to persist.

Although none of the tested interventions significantly reduced the frequency of such connection errors, a combination of poor technology design and gaps in knowledge likely contributed to both error types. Potential mitigations are suggested in Table 33, but further research is required to validate these tactics.

¹⁹While education may help increase clinicians' awareness of this risk, it is not practical for clinicians to remember all possible drug interactions. Technology can reduce reliance on memory by alerting users to incompatibility risks when reusing secondary IV tubing for sequential secondary IV infusions—for example, drug interaction information may be contained in smart pump drug libraries or CPOE systems—but evidence suggests that improvements are required to minimize alert fatigue. (114) Another proposed option is self-flushing infusion bags (<http://www.aquettant.fr/uploads/publication/revue-de-presse/2011/article-aquettant-poche-06-2011.pdf>). These technologies need further research to validate their effectiveness and ensure that they do not introduce new hazards.

Table 33: Setting Up Secondary Intermittent IV Infusions: Potential Tactics for Reducing Connection Commission Errors

Potential Error Mitigation Tactic (Not Validated)	Wrong Primary Infusion	Wrong Port on Primary Infusion	Rationale
Design			
Conspicuous emergency medication line			A clearly and distinctively labelled emergency medication line differentiates it from other infusions at the patient bedside (Theme 2: Identifying IV Infusions); this may reduce the risk of connecting a secondary IV infusion to the wrong primary infusion
Unique connector used to connect secondary IV tubing to primary IV tubing			A unique connector (not a luer connector) to fasten secondary IV tubing to primary IV tubing above the pump would prevent secondary IV tubing from being connected to primary IV tubing below the pump
Knowledge			
Augment clinician knowledge regarding dead volume ^a risks			A lack of dead volume knowledge may have contributed to errors in connecting the secondary IV tubing to the wrong primary IV infusion (e.g., a sodium chloride 0.9% IV infusion connected to other medications; Theme 3: Managing Dead Volume); education targeted at addressing this knowledge gap may reduce these errors
Augment clinician knowledge regarding pump control of fluid			A lack of knowledge about how an infusion pump controls the flow rate of an IV infusion may have contributed to wrong port connection errors (participant thought the pump could control the secondary IV infusion flow rate even when connected to an injection port below the pump). Although the education module reviewed the risks associated with connecting the secondary IV tubing below the pump instead of above the pump, it did not change participant behaviour, which suggests an opportunity to improve the education module to explicitly address this misunderstanding of pump control

Abbreviation: IV, intravenous.

^aThe dead volume in a secondary IV infusion is the volume between the upper injection port on the primary IV tubing (i.e., entry point of secondary infusion) and the point at which the infusion enters the patient's bloodstream. (51)

VTBI Variability

Pump programming was not a focus of this study, since much research has been and is being conducted in this area (e.g., smart pump research). Still, although it was not coded as an error, variation in programming the pump VTBI for secondary infusions (for volumes both greater and less than the IV container) was noted in our study.²⁰ The programmed VTBI for a secondary infusion determines when the pump reverts to the primary infusion parameters. There is a need to eliminate VTBI programming variability, and to ensure that the secondary IV infusion dose is administered before the pump reverts to the primary infusion parameters.

²⁰In Theme 1: Setting Up and Programming Multiple Primary Continuous IV Infusions, a large variation in VTBI programming was also noted.

Eliminate VTBI Variability

Variation in VTBI can partly be attributed to the fact that the traditional pump used in the current study defaulted to the VTBI of the last infusion; it did not reset between infusions. Some participants did not enter a new VTBI after setting up the new infusion, resulting in a discrepancy between the new IV container volume and the pump VTBI. In contrast, the smart pump used in the current study auto-populated the VTBI based on the IV container volume selected during programming (part of selecting the drug concentration in the drug library), so that VTBI programmed using the smart pump matched the stated IV container volume (i.e., variability was eliminated).

These results suggest that the secondary infusion VTBI should be autopopulated only when the IV container volume is identified during pump programming (i.e., programmed within the drug library of a smart pump);²¹ otherwise (i.e., programming a traditional pump or in generic mode in a smart pump), infusion pumps should clear the previous infusion VTBI (rather than defaulting to a previous VTBI value) and require users to enter a new VTBI value when the pump is turned on and a new infusion is started. However, this begs the question: what volume should be autopopulated/programmed to ensure the complete secondary IV infusion dose is administered at the correct rate? Further research is needed to answer this question.

Ensure Secondary IV Infusion Is Administered at Intended Rate

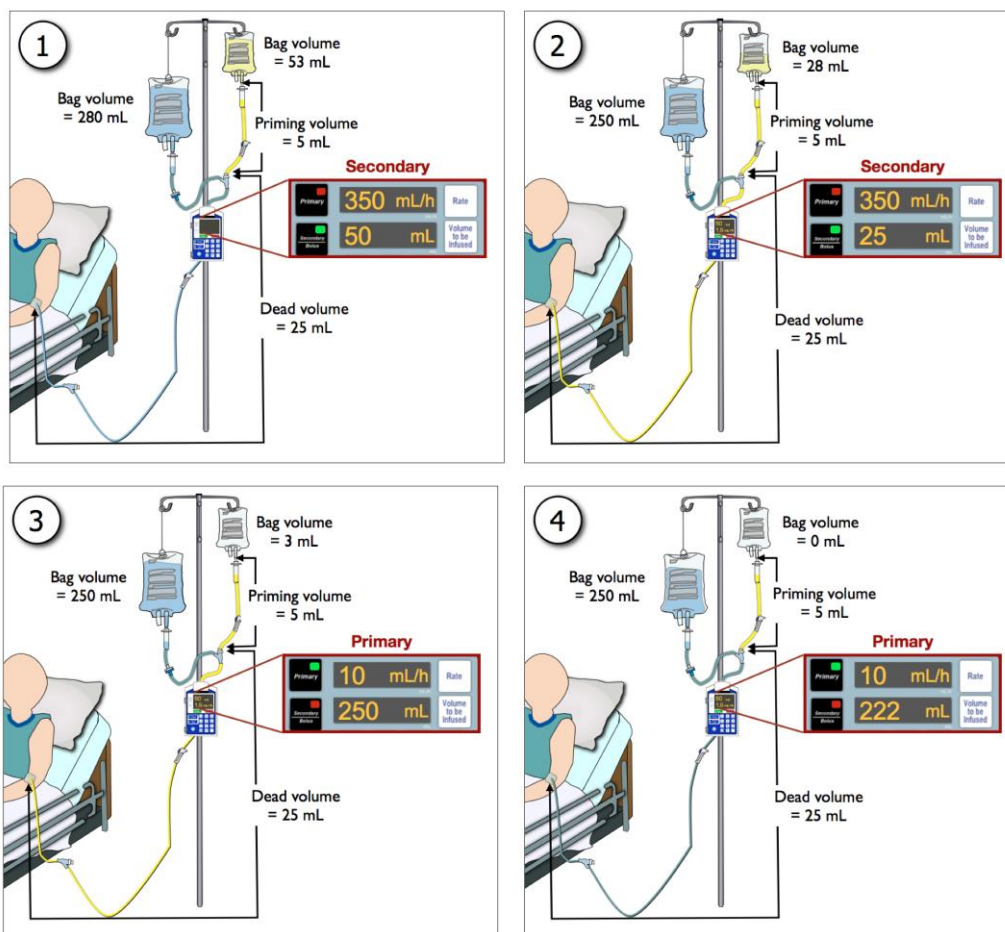
The programmed VTBI for a secondary infusion determines when the pump reverts to the primary infusion parameters. If the VTBI on the secondary infusion is too small, the pump will revert to the primary infusion parameters before administering the complete intermittent dose, and some of the secondary IV infusion will be administered at the primary infusion flow rate. Conversely, if the secondary infusion VTBI is too large, some of the primary infusion will be administered at the secondary infusion flow rate.

Ideally, users should not have to program a VTBI because the pump automatically detects and monitors the IV container volume (e.g., similar to a syringe pump) or senses whether the pump is infusing the secondary or primary solution. However, until such technology is widely available, most infusion systems must rely on the VTBI programmed by clinicians. Determining the appropriate VTBI for a secondary IV infusion is complicated by 2 issues:

- There may be more volume in the IV container than stated. Some manufacturers overfill their IV containers—one by up to 132% of the stated volume, depending on the size (e.g., a 25 mL IV bag may be filled with 30 mL \pm 3 mL). (115) Medication added to the IV container may further increase the overfill.
- Dead volume in the primary IV tubing (i.e., volume between the entry point of secondary IV infusion to the point the infusion enters the patient's bloodstream, (51) which varies with IV tubing, but may be about 25 mL) must be cleared before the patient receives the secondary IV medication. Conversely, when the pump reverts to the primary flow rate (i.e., secondary infusion VTBI has counted down to 0 mL), the dead volume in the primary IV tubing contains secondary IV medication, which will be administered to the patient at the primary flow rate.

These 2 issues may result in a considerable proportion of primary and secondary infusions being administered at unintended rates. Figure 23 shows an example comparing the intended secondary infusion with the actual infusion administered. Only 43% (25 mL) of the secondary infusate would be administered at the programmed secondary flow rate; the remaining 57% (33 mL) would be administered at the primary flow rate (or slower). In addition, 9% (25 mL) of the primary infusate would be administered at the secondary flow rate.

²¹Users should still be able to edit the VTBI, if desired.



	Programmed Parameters	Patient Received			
		①	②	③	④
Primary Infusion					
Volume, mL	250	—	25	—	—
Flow rate, mL/h	10	—	350	—	—
Secondary Infusion					
Volume, mL	50	—	—	25	28 (+ 5)
Flow rate, mL/h	350	—	—	350	10 (+ indeterminate)

Figure 23: Setting Up Secondary Intermittent IV Infusions: Programmed Secondary Infusion Parameters Versus Actual Infusion Received by the Patient

Abbreviations: IV, intravenous; VTBI, volume to be infused.

① The secondary IV infusion bag has a stated volume of 50 mL, but actually contains 58 mL because of overfill; 5 mL are used to prime the secondary IV tubing, leaving 53 mL in the container when it is hung on the IV pole. The dead volume from the secondary injection port to the patient is 25 mL, which contains primary infusate. The pump is programmed to administer the secondary infusion at 350 mL/h with a VTBI of 50 mL, and the primary infusion will resume at 10 mL/h with a VTBI of 250 mL.

② When the secondary infusion begins, the pump will immediately start infusing fluid at the secondary flow rate. Consequently, for the first 25 mL of the programmed secondary infusion, the patient will receive the primary infusate at the secondary flow rate.

③ When the dead volume is cleared of primary infusate, the patient will start to receive the secondary medication/fluid at the secondary flow rate. The pump will revert to the primary infusion parameters when the secondary VTBI counts down to 0 mL. However, at this point, the patient has only received 25 mL of the secondary infusate at the secondary flow rate.

④ The remaining secondary infusate will infuse at the primary infusion rate, except for the last few mL (e.g., about 5 mL remaining in the secondary IV tubing), which will flow concurrently with the primary infusion because there is no pressure differential (i.e., height difference) between the primary and secondary infusions. The rate of administration of the residual fluid in the secondary IV tubing will be indeterminate, but since it is infusing concurrently with the primary infusion, it would be less than the programmed primary infusion rate.

There is currently no guidance for clinicians about how to program the VTBI appropriately for secondary infusions to account for overfill (if present) and dead volume. In the short term, health care organizations should identify overfill in their IV containers (which may vary by factors such as source of IV container, admixing practices) and dead volume in their primary IV tubing (and connectors, if applicable), to provide guidance on how to account for these factors and ensure the dose is administered as intended. In the long term, standardization of practices (e.g., IV container overfill) and improved design of infusion systems should eliminate this burden.

Limitations

The order of experimental conditions was not fully counterbalanced; the education module condition always occurred last, so participants may have been more familiar with the task in the education module condition (i.e., practice effects) and more fatigued. Nonetheless, this was necessary since watching the education module prior to completing the other experimental conditions would have influenced behaviour (i.e., participants cannot “unlearn” material).

Study participants were not accustomed to routinely administering non-standard secondary IV infusions, so the error rate may have been higher compared to what it would have been with clinicians who administer non-standard secondary IV infusions more frequently (e.g., nurses in oncology units). Nevertheless, all clinicians administering secondary infusions should know the fundamental principles associated with such infusions and be able to identify and adjust setup requirements to administer them.

Finally, participants’ knowledge and performance was measured immediately after watching the education module, so the longitudinal effect of the intervention was not studied. Similarly, participants’ longitudinal response to the smart pump clamp detector was not studied. Interventions were not tested in every possible use scenario, so other unintended consequences with the tested interventions may not have been identified.

Summary

The accurate setup of secondary IV infusions requires clinicians to identify, remember, and complete numerous tasks. The study findings highlight that these routine mechanistic tasks are often not completed, or completed incorrectly. In the short term, educating clinicians about the underlying principles, setup risks, and best practices associated with secondary IV infusions can help clinicians identify setup requirements. However, to achieve higher accuracy and reliability in the administration of secondary IV infusions, greater automation (or elimination) of the routine setup requirements is needed—or at a minimum, infusion systems must be able to detect and communicate setup errors to facilitate interception and correction.

Theme 5: Administering an IV Pump Bolus

An IV bolus refers to a 1-time or intermittent dose of IV medication that is administered intravenously to achieve a desired physiological effect. This section provides further information regarding the administration of an IV bolus using an infusion pump.²²

Issues

Clinicians often administer an IV bolus dose of medication, but giving a patient an IV bolus is an error-prone activity. Nuckols (35) found that 40% of preventable injuries from IV medication errors involved bolus infusions. Similarly, Fahimi et al (17) found that fast bolus injection was the most common (43.4%) IV medication error. Taxis and Barber (102;116) conducted an ethnographic study and determined that 73% of observed IV boluses contained an error, and the majority were clinically significant. The most common bolus error (95%) was administering it too quickly, (102;116) which can result in patient harm (including patient death) for some medications. (117)

An IV bolus may be administered in different ways, but all methods have been associated with medication errors; no comparative evidence could be found to identify the safest method. One method involves using a parenteral syringe that is manually injected as an IV push. Another is to prepare a separate IV container and deliver it as a primary or secondary IV infusion. Some issues associated with these practices have already been discussed (Theme 3: Managing Dead Volume and Theme 4: Setting Up a Secondary Intermittent IV Infusion). When a patient is already being given a continuous IV infusion of the medication to be bolused, another option is to temporarily increase the infusion pump's flow rate to administer a more rapid intermittent "top-up" dose (e.g., using a dedicate pump bolus feature or directly changing the rate of the primary continuous IV infusion); this is referred to as an *IV pump bolus*, and is the focus of the rest of this section.

An IV pump bolus may be more common in certain clinical areas, such as critical care, where a patient is more likely to require an urgent supplemental dose of a medication that is already being infused continuously. An IV pump bolus may also be more likely when a nurse cannot leave the bedside (i.e., to retrieve additional IV medication and other supplies) or the IV medication is not available for preparation (e.g., not available as floor stock or hospital policies impede preparation in clinical areas for urgent "as-needed" doses). (14)

Administering an IV pump bolus requires the pump to switch temporarily from the primary continuous IV infusion parameters to the bolus infusion parameters and then revert to the primary infusion parameters when the bolus is completed. There are different ways to program an infusion pump to administer an IV pump bolus. While methods vary by pump manufacturer, they can be categorized as outlined in Table 34 (pumps may allow some or all of these methods).

²²Programming loading doses and multistep protocols were out of scope. Administering a bolus by removing a primary continuous IV infusion from an infusion pump and running it by gravity was also out of scope, but this practice may have unintended consequences and should be monitored.

Table 34: Administering an IV Pump Bolus: Methods

Method	Description	Comments
Increasing the flow rate of the primary continuous IV infusion	Clinician manually increases the flow rate of the primary continuous IV infusion to the bolus flow rate (note: the clinician may or may not set a VTBI to limit the bolus dose). Upon bolus completion, the clinician decreases the flow rate to the original primary flow rate	<ul style="list-style-type: none"> Incidents have occurred because bolus administration was extended (i.e., no bolus dose/VTBI programmed) (14;47) and/or the primary continuous IV infusion was reprogrammed with the wrong flow rate upon bolus completion Although many hospitals have policies limiting this practice, it occurs more frequently than anticipated (47) Nurses frequently override soft-limit warnings on smart pumps to provide IV pump boluses in this manner (47;118) There are anecdotal reports that nurses sometimes do not limit bolus doses of sedatives (i.e., set a VTBI) because they do not know how much medication is required to achieve the desired therapeutic effect (e.g., to stop a patient from pulling on tube or trying to get out of bed). This practice has resulted in the administration of deep anesthetic doses instead of sedative doses
Using the secondary IV infusion feature	Clinician programs a secondary IV infusion with the bolus parameters (i.e., VTBI/dose and flow rate/duration), but does not hang a secondary IV container. The pump infuses fluid from the primary IV container at the programmed IV secondary flow rate. The pump automatically reverts to the initial primary IV flow rate once the secondary VTBI (i.e., bolus dose) has been administered	<ul style="list-style-type: none"> Minimizes the potential for an overdose (i.e., an uncontrolled bolus), since it forces clinicians to program a bolus VTBI and flow rate/duration Does not alter primary continuous IV infusion parameters (i.e., the primary continuous IV infusion is automatically resumed after administration of a secondary/bolus infusion) Uses an infusion pump feature in an unintended manner The volume history in the infusion pump will not be accurate. The bolus volume administered from the primary IV container will be recorded in the pump as being delivered as a secondary IV infusion and will not be subtracted from the VTBI of the primary infusion. The programmed VTBI of the primary infusion may be unintentionally greater than the volume remaining in the primary IV container, and this may lead to issues such as air in the line (Theme 1: Setting up and Programming Multiple Primary Continuous IV infusions) Some pumps do not allow secondary infusions to be programmed when the primary continuous IV infusion is programmed using a drug calculator (i.e., traditional pump) or a drug library (i.e., smart pump)
Using a dedicated pump bolus feature	Clinician programs the IV bolus parameters (i.e., VTBI/dose and flow rate/duration) using a dedicated pump bolus feature, which temporarily pauses the continuous primary infusion rate to deliver the bolus and then reverts to the primary flow rate after the bolus dose/VTBI has been administered	<ul style="list-style-type: none"> Minimizes the potential for an overdose (i.e., uncontrolled bolus), since it forces clinicians to program a bolus VTBI/dose and flow rate/duration Does not alter primary continuous IV infusion parameters (i.e., the primary continuous IV infusion is automatically resumed after administration of a secondary/bolus infusion) Not all infusion pumps have a bolus feature Some hospitals have bolus features on their infusion pumps, but have not enabled them Usability of the design for a bolus feature can vary by pump model (e.g., between pump manufacturers) and pump type (e.g., smart pump versus traditional pump)

Abbreviations: IV, intravenous; VTBI, volume to be infused.

No empirical studies were identified that focused specifically on the risks associated with administering IV pump boluses. However, many of the general programming errors previously discussed (Theme 1: Setting Up and Programming Multiple Primary Continuous IV Infusions) also apply to programming an

IV pump bolus. It may be programmed with the wrong parameters (bolus VTBI/dose and/or flow rate/duration) and/or the wrong primary continuous IV infusion parameters (VTBI and flow rate) upon bolus completion. Users may enter incorrect data into the pump due to suboptimal user interface design and/or calculation errors if the prescribed bolus units are inconsistent with the pump's programming parameters. (8;14) The risk for these data-entry errors may be increased when programming an IV pump bolus, given that boluses are often required in emergency situations. Under stressful situations, human performance can degrade because of a decrease in attentional resources. (119) Furthermore, the implications of bolus programming errors can be grave, since they often involve high-risk medications and physiologically unstable patients.

Although there is a risk of programming errors in all 3 IV pump bolus methods listed in Table 34, it has been suggested that administering an IV pump bolus using the first method (increasing the flow rate of the primary infusion) may be particularly risk-prone, (14;40;47) because it has the potential for errors in both bolus programming and resumption of the primary continuous infusion.

Programming Error: Unchanged VTBI

A clinician may administer an IV pump bolus by increasing the flow rate of a primary continuous IV infusion but fail to change the infusion VTBI to limit the IV bolus dose. If a new VTBI is not programmed specifically for the bolus, the clinician must remain at the patient bedside to monitor the volume infused by the pump. Once the IV bolus dose (volume) has infused, the flow rate must be reprogrammed back to the original primary flow rate; there is a risk of extended bolus administration (overinfusion) if the clinician does not reduce the flow rate immediately following bolus delivery. (47;120) A review of pump bolus incidents showed that distracting nurses during IV pump bolus administration may result in significant overinfusion. In an incident reported by a U.S. hospital, an ICU nurse programmed an IV pump bolus of fentanyl by increasing the flow rate to 999 mL/h. and then walked away from the patient bedside due to an interruption. A family member noticed the continually running bolus infusion and brought it to the attention of the nurse after the patient had received an estimated 1,100 mcg overdose. (121) Similarly, a nurse disclosed the following incident to researchers (14):

I was administering a bolus by programming the primary infusion to run at the fastest possible rate. I intended to specify a VTBI to limit the bolus; however, I became distracted by a patient across the hall who was self-extubating. I pressed the start button without changing the VTBI from the previously programmed value (entire bag volume); while I was assisting the patient across the hall, the first patient received a very large dose of IV morphine.

Programming Error: Incorrect Resumption of Primary Continuous IV Infusion

When an IV pump bolus is administered by directly increasing the flow rate of a primary continuous IV infusion, the clinician must reprogram the primary continuous IV infusion with the right parameters when the bolus has been completed. Clinicians may input incorrect data when reprogramming the flow rate, resulting in either an over- or underinfusion. In addition, if a VTBI is set, the infusion will either stop or revert to a KVO rate when the bolus is completed, potentially causing the interruption of a life-sustaining continuous IV infusion. When an IV pump bolus is administered using either the secondary or bolus features on a pump, the primary continuous IV infusion parameters are not directly altered and do not need to be reprogrammed.

Issues: Overview

Administering an IV pump bolus may be necessary, but it is a risk-prone activity. There is the potential for programming errors when entering the bolus infusion parameters and with resuming the continuous IV infusion after the bolus. Since the administration of an IV pump bolus has been associated with incidents, research is needed to further understand risk-mitigation strategies.

Interventions

The literature review revealed no empirical studies that explicitly evaluated interventions to reduce the risks associated with administering an IV pump bolus, but practice and technology recommendations were proposed.

Practice Interventions

Practice-based recommendations specific to IV pump boluses were identified. Bates et al (120) recommended that hospitals establish policies to limit the administration of bolus doses (particularly of sedatives and narcotics) by directly increasing the flow rate of a continuous primary infusion and not programming a dose/volume. Similarly, ISMP Canada recommended that when administering an IV pump bolus, clinicians should “never increase the rate without setting a limit on the pump”; (40) a VTBI should always be programmed to limit the bolus dose administered.

ISMP (United States) has recommended practices to reduce patient harm from the rapid injection of IV bolus medications (i.e., not just IV pump boluses but all IV boluses, including those administered by manual IV push): (103;117)

- Provide clinicians with easy access to information about the maximum flow rate of rate-sensitive medications (e.g., unit posters, online reference documents, and alerts on pharmacy-applied labels and information systems, such as computer medication administration records and automated dispensing cabinets).
- Dilute rate-sensitive medications (e.g., use a 1 mg/mL strength of midazolam, not a 5 mg/mL) so staff can titrate the dose slowly during administration.
- Administer rate-sensitive medications via an infusion pump (e.g., secondary IV infusion), and use a syringe pump for small-volume boluses.
- Use descriptive terms such as “IV over 5 minutes,” instead of terms such as “IV push” or “bolus” for medications that require administration over 1 minute or longer.

These recommended practices were not selected for further study. Since improving pump design to better manage IV pump boluses has been suggested by Rothschild et al, (3;8;47) AAMI, (3;8;47) and Vanderveen, (47) technology interventions were selected for investigation instead.

Technology Interventions

It has been proposed that the safest way of administering an IV pump bolus is by using a dedicated pump bolus feature. (14;40;122) ISMP Canada recommended that clinicians “use only the bolus mode feature if it is available on your pump.” (40) Administering an IV pump bolus using a dedicated bolus feature has the following advantages:

- It requires that a bolus VTBI/dose and flow rate/duration be programmed, limiting the bolus administration.
- It does not alter the primary continuous IV infusion parameters.
- It automatically resumes the primary continuous IV infusion after bolus administration, so that there is no delay in continuous IV therapy.
- It ensures proper volume documentation in the pump.

Although there is a solid rationale for using a dedicated bolus feature to administer an IV pump bolus, no studies compare the usability and safety of using a bolus feature to not using a bolus feature (i.e., directly increasing the flow rate of the primary continuous IV infusion or using the secondary infusion feature). Furthermore, the usability of a bolus feature varies significantly according to pump model and pump type

(i.e., smart pump versus traditional pump) (internal document²³). (10) There is a need to better understand which design elements of a dedicated bolus feature are associated with the safe delivery of an IV pump bolus. There is also a need to understand whether programming a bolus with a dedicated bolus feature increases programming time, since added task time may limit its adoption and use. To fill this research gap, 2 dedicated bolus features were selected for inclusion in this study: 1 on a traditional pump and 1 on a smart pump.

Traditional Pump Bolus Feature

The design of a bolus feature varies by pump model. Figure 24 shows a traditional pump bolus feature similar to the one used in the laboratory study. For the pump tested, the bolus feature is optional; health care organizations can choose to enable or disable it.

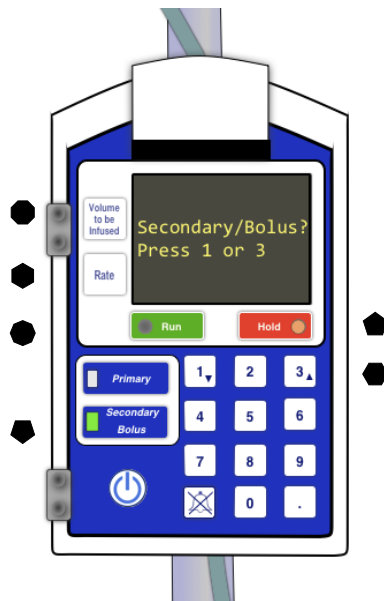


Figure 24: Administering an IV Pump Bolus: Traditional Pump Bolus Feature

Abbreviation: IV, intravenous.

The workflow to program a bolus for this traditional pump using the bolus feature was as follows:

- ① Press *Hold* to pause the primary infusion.
- ② Press *Secondary/Bolus*.
- ③ Press 3 in response to the prompt "Secondary/Bolus? Press 1 or 3."
- ④ Press *Rate* and enter the bolus rate using the numeric keypad.
- ⑤ Press *Volume to be Infused* and enter the volume using the numeric keypad.
- ⑥ Press *Run*.

The workflow is identical to that of programming a secondary infusion, except that when the bolus feature is enabled, step 3 is activated in the programming sequence above.

It was hypothesized that when the bolus feature was disabled (i.e., baseline condition), participants would make programming errors in administering the IV pump bolus (i.e., bolus VTBI and flow rate) and in resuming the primary continuous IV infusion flow rate. When the bolus feature was enabled, participants would make fewer errors.

²³HumanEra internal document, August 18, 2010.

Smart Pump Bolus Feature

Smart infusion pumps have been shown to reduce pump programming errors compared to traditional pumps. (7;45;46) However, their effectiveness has been limited, partly because soft-limit alerts may be overridden by nurses for a variety of reasons, (3;7;47;48) such as administering an IV pump bolus by increasing the flow rate of a primary continuous IV infusion. (47) Hard limits cannot be overridden, and researchers have advised hospitals using smart pumps to review and implement hard upper flow limits for high-alert medications to prevent the administration of an IV pump bolus by increasing the primary flow rate. (14;47;102)

Some smart pumps have a dedicated bolus feature, but not all. The bolus feature on a smart pump has the same potential advantages as that of a traditional pump, as well as some or all of the following features:

- selectively enabling the bolus feature for only appropriate medications and clinical units (as defined in the hospital-specific drug library) (123)
- alerting clinicians to potential bolus programming/dosing errors by providing bolus-specific soft and hard dosing limits (as defined in the hospital-specific drug library)
- minimizing error-prone unit conversion calculations by providing bolus programming fields that match orders (traditional pumps require nurses to calculate VTBI and flow rate based on the infusion concentration and ordered dose or use dose/duration-rate calculators buried in submenus; see Figure 25). Programming errors are decreased when fields are designed so they align with prescriber orders and nurses do not have to derive input parameters (7;46)

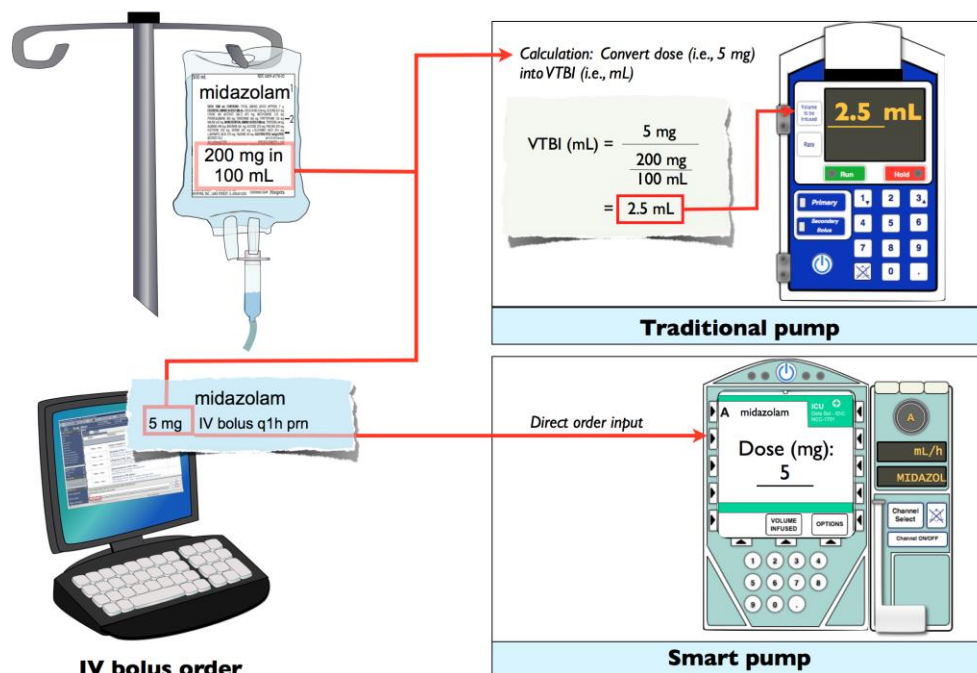


Figure 25: Administering an IV Pump Bolus: Programming a VTBI on a Traditional Pump (With or Without a Bolus Feature) and a Dose on a Smart Pump (With a Bolus Feature)

Abbreviations: IV, intravenous; VTBI, volume to be infused.

Given the potential advantages of smart pump bolus features (and the risks associated with IV bolus administration), Bates et al (120) recommended that IV pump boluses of a continuous IV infusions may be appropriate only when administered using a smart pump that can limit total bolus dose and infusion time.

No empirical evidence was found related to design features that were associated with safe IV pump bolus administration. However, the ECRI Institute has established the following criteria to evaluate the design of smart pump bolus features, focused specifically on the bolus dosing limits in the pump drug library: (24)

The system should permit facilities to set minimum and/or maximum values for the size (dose or volume) and time of a bolus for a particular drug entity in a particular care area. These limits should be set in the same dosing units as the drug entity, but it is advantageous to also allow limits in dosing units other than the programmed dosing units (e.g., a total dose limit for a weight-based drug). The pump should check all relevant limits when a user programs a bolus, and display the appropriate limit warning (i.e., hard or soft) if a limit is violated. The pump should clearly indicate which limit has been violated, as it may not be the limit associated with the parameter the user is programming.

Due to design limitations, not all commercially available smart pump bolus features meet these criteria. Some smart pump drug libraries do not allow users to specify bolus dosing limits. Others allow bolus limits but restrict them to the same units used for continuous IV infusions (e.g., mcg/kg/min), which may not be appropriate for some drugs or align with prescriber orders (e.g., an order for a dose in mcg). (24)

The smart pump bolus feature investigated in the laboratory study was similar to the one shown in Figure 26 and met the ECRI Institute's criteria. (24) In addition, the smart pump provided users with bolus programming fields that matched bolus orders (i.e., no error-prone unit conversions required). The smart pump also had a *rapid bolus* feature, which gave users the option of autopopulating the bolus duration field with the fastest time allowable in the hospital-defined drug library.

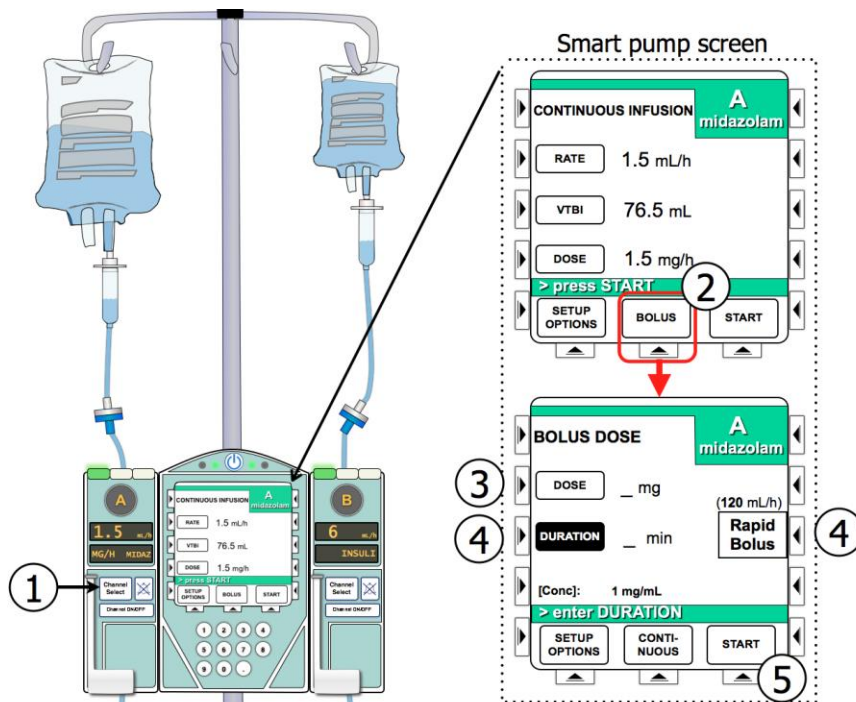


Figure 26: Administering an IV Pump Bolus: Smart Pump Dedicated Bolus Feature

Abbreviation: IV, intravenous.

The workflow to program a bolus for this smart pump was as follows:

- 1 Press *Channel Select* on the desired infusing channel.
- 2 Press *Bolus* on the main programming unit.
- 3 Enter the bolus dose (i.e., drug amount) using the numeric key pad.
- 4 Press *Duration* and enter the time using the numeric key pad, or press *Rapid Bolus*, which delivers the dose at the fastest rate allowable, as defined by the hospital's drug library.
- 5 Press *Start*.

It was hypothesized that when using a smart pump bolus feature, participants would make fewer IV bolus programming errors compared to baseline (traditional pump with no bolus feature).

Experimental Method

Forty ICU nurses each completed 1 task (an IV pump bolus) under 3 different experimental conditions (baseline, traditional pump bolus feature, and smart pump bolus feature).

Task

The IV pump bolus tasks in all 3 experimental conditions were equivalent (i.e., similar level of difficulty), but they were not identical. However, all tasks were designed to be similar to a reported IV pump bolus incident. (14) That is, in all 3 conditions, the confederate nurse asked the participant to deliver an IV pump bolus (e.g., the key to the syringe cabinet was missing so the bolus could no be given by manual IV push) in an urgent critical situation (e.g., ventilated patient who was agitated), and the participant was the only clinician at the patient bedside. Immediately after the participant programmed the bolus, a distraction was planted (scripted and counterbalanced) in an attempt to pull the participant away from the patient bedside (e.g., another nurse calling for help with a patient who was trying to self-extubate).

The ordered IV pump boluses were for either morphine (4 mg) or midazolam (5 mg), which were already being administered via continuous IV infusion. The IV bags of morphine and midazolam were in concentrations of 1 mg/mL to simplify conversion of the bolus dose to the VTBI needed for the traditional pump (with and without the bolus feature).

Experimental Conditions

The 3 experimental conditions are described in Table 35. Participants were trained on the new interventions as described below.

Table 35: Administering an IV Pump Bolus: Experimental Conditions and Training

Experimental Condition	Description	Training Content
Baseline	No intervention (i.e., control; a traditional pump with bolus feature disabled). Participants were allowed to deliver an IV pump bolus using the method of their choice (i.e., manually increasing the primary infusion flow rate or programming a secondary IV infusion without hanging a secondary container)	No training required
Traditional pump with bolus feature	The traditional pump used in the baseline condition was used, but with the bolus feature enabled	Hands-on training on the bolus feature was provided (about 5 minutes). The benefits of using a dedicated bolus feature were reviewed. To verify comprehension, participants were asked to program an IV pump bolus using the bolus feature as part of the training
Smart pump with bolus feature	A smart pump with a bolus feature was used	Hands-on training on the bolus feature was provided as part of training on the basic functionality of the entire smart pump (about 10 minutes). The benefits of using a dedicated smart pump bolus feature were reviewed. To verify comprehension, participants were asked to program an IV pump bolus using the bolus feature as part of the training

Abbreviation: IV, intravenous.

Procedure

The procedure was as described in Research Methods.

Metrics and Analysis

Participant Performance

Participant performance in each task was recorded by the confederate nurse and test facilitators. The metrics for each task were as follows (see Table 36 for definitions and analysis):

- programming errors (out of 2)
- task time

Table 36: Administering an IV Pump Bolus: Performance Metrics and Analysis

Performance Metrics and Analysis	Programming Error	Task Time
Definition	Wrong bolus programming (i.e., bolus dose/VTBI did not match order or were delivered over a period of 10 minutes or longer) ^a Wrong resumption of primary continuous IV infusion (i.e., flow rate did not equal flow rate prior to bolus delivery)	Time from when the participant initiated pump programming to when the bolus infusion commenced. Unplanned non-task time (e.g., questions for the confederate nurse) was deducted from the total task time
Performance metric (per participant per condition)	Number of programming errors (maximum of 2) ^b	Total task time (seconds)
Analysis		
Number of participants included in analysis	39 ^c	38 ^c
Opportunities for error per condition	78 (2 errors per IV pump bolus task; 1 IV pump bolus task per participant)	No errors possible; 38 IV pump bolus tasks were included in the task time analysis
Statistical test (performance metric as a function of experimental condition)	One-way ANOVA test followed by post hoc paired sample t-test comparisons using Bonferroni correction	One-way ANOVA test followed by post hoc paired sample t-test comparisons using Bonferroni correction

Abbreviations: ANOVA, analysis of variance; IV, intravenous; VTBI, volume to be infused.

^aBolus orders at the participating institution specified only the bolus dose (i.e., drug amount) in the laboratory study scenario (morphine or midazolam). Nurses had to convert a bolus dose to the required programming parameters (traditional pump, VTBI and flow rate; smart pump, dose and duration). Since a duration/flow rate was not specified, the expert panel determined that for the situations tested, the bolus dose should be given in less than 10 minutes, equivalent to > 24 mL/h (24 mg/h) or 30 mL/h (30 mg/h) for the bolus dose ordered and concentrations of the primary IV infusion; errors were coded only if the bolus was programmed to be too slow.

^bAlthough each participant set up only 1 IV pump bolus per condition, there were 2 opportunities for error in each task: programming the bolus parameters and/or in resuming the primary continuous IV infusion after administering the bolus dose.

^cOne participant (of 40) refused to give an IV pump bolus in the baseline condition because of concerns about bolusing other infusions running into the same access port (i.e., dead volume, see Theme 3: Managing Dead Volume); this participant's data were excluded from the comparative analysis of programming errors and task time, reducing the sample size from 40 to 39. Because of issues during data collection, another participant's data were excluded from the comparison of task time, further reducing the sample size to 38.

Three expert panel members (2 ICU nurses and 1 pharmacist) independently reviewed programming errors to evaluate whether they would have likely resulted in clinical impact. Final coding was determined using majority rule. The test facilitators also recorded unanticipated errors or hazards.

Participant Feedback

Participants completed a questionnaire (Appendix 2) to capture their perception of each intervention with respect to its effectiveness in reducing medication errors and the likelihood of its use in clinical practice. Open-ended feedback was solicited about each intervention (as part of the questionnaire), from which summary comment themes were developed. A paired sample t-test was done to assess for statistically significant differences between intervention conditions.

Results

Participant Performance

Table 37 summarizes performance metrics by experimental condition. A summary of other hazards is provided below.

Table 37: Administering an IV Pump Bolus: Performance Metrics by Experimental Condition

Performance Metric	Sample Size, n	Opportunities for Performance Metric Per Experimental Condition	Experimental Condition			Statistics
			Baseline (Traditional Pump)	Traditional Pump With Bolus Feature	Smart Pump With Bolus Feature	
Programming errors, n (%)	39 ^a	78 (2 per participant)	9 (11.5%)	8 (10.3%)	1 (1.3%)	F (2, 76) = 3.167 P = 0.048
Task time, s	38 ^a	38 (1 per participant)	30	37	38	F (2, 74) = 0.849 P = 0.43

Abbreviation: IV, intravenous.

^aOne participant (of 40) refused to give an IV pump bolus in the baseline condition because of concerns about bolusing other infusions running into the same access port (i.e., dead volume, see Theme 3: Managing Dead Volume); this participant's data were excluded from the comparative analysis of programming errors and task time, reducing the sample size from 40 to 39. Because of issues during data collection, another participant's data were excluded from the comparison of task time, reducing the sample size to 38.

Programming Errors

IV pump bolus programming errors were noted in all conditions. The size of the bolus dose (i.e., bolus VTBI) programming errors ranged from 0% (i.e., no bolus given) to 250% of the ordered dose. For bolus administration speed, only boluses administered too slowly were coded as an error; these ranged from 30 minutes (10 mL/h) to 90 minutes (4 mL/h). Three expert panel members determined that 11 of 18 errors (55.6%) would likely have had clinical impact.²⁴

There was a statistical difference in programming errors between experimental conditions. When participants programmed the IV pump bolus using the smart pump dedicated bolus feature, they made significantly fewer errors compared to the baseline condition. There was no statistical difference between the other conditions. Nurses' ability to safely program an IV pump bolus using a dedicated bolus feature may depend on pump design.

Table 38 provides a breakdown of the types of programming errors made in each experimental condition. When participants used the smart pump, there were no bolus VTBI/dose errors or errors in resuming the primary continuous IV infusion flow rate. However, 1 error occurred in entering the bolus duration; a participant entered the bolus flow rate into the duration field without converting the units of measure (i.e., mL/h to time in minutes), so that the bolus was administered over 90 minutes instead of at 90 mL/h (about 3 minutes). When participants used the traditional pump with or without the bolus feature enabled, all error types occurred.

²⁴Clinical impact was defined as causing temporary or permanent harm (including patient death).

Table 38: Administering an IV Pump Bolus: Type of Programming Error by Experimental Condition

Type of Programming Error	Sample Size, n	Traditional Pump			Smart Pump	
		Baseline (No Bolus Feature)	Bolus Feature	Notes	Bolus Feature	Notes
Bolus parameter programming ^a	39 ^b	7 (17.9%)	6 (15.4%)	—	1 (2.6%)	—
Bolus VTBI/dose error	39 ^b	6 (15.4%)	4 (10.3%)	—	0 (0.0%)	—
Bolus flow rate/duration error	39 ^b	2 (5.1%)	4 (10.3%)	The ordered bolus dose was input in both the VTBI and flow rate fields (5 of 6 errors, 83%)	1 (2.6%)	The desired flow rate (i.e., 90 mL/h) was entered into the bolus duration field (i.e., 90 minutes) without converting the units of measure (i.e., field unit confusion) ^c
Resumption of primary continuous IV infusion flow rate error	39 ^b	2 (5.1%)	2 (5.1%)	In the baseline condition, participants entered the wrong primary flow rate upon bolus completion When using the bolus feature, participants altered the primary continuous IV infusion parameters, thinking that they were programming the bolus infusion (i.e., infusion mode confusion)	0 (0.0%)	—
Programming errors (out of 2)	39^{b,d}	9 (11.5%)	8 (10.3%)	—	1 (1.3%)	—

Abbreviation: VTBI, volume to be infused.

^aA single bolus parameter programming error may have included more than 1 data entry error (i.e., a bolus VTBI/dose error and a bolus flow rate/duration error).

^bOne participant (of 40) refused to give an IV pump bolus in the baseline condition because of concerns about bolusing other infusions running into the same access port (i.e., dead volume, see Theme 3: Managing Dead Volume); this participant's data were excluded from the comparative analysis of programming errors and task time, reducing the sample size from 40 to 39.

^cThe duration field on the smart pump was new to participants who were accustomed to programming bolus flow rate instead of duration on their current traditional pump.

^dThere were 2 opportunities for error per participant, so percentages are calculated based on a sample of 78.

The traditional pump bolus feature did not reduce programming errors compared to baseline. Although the smart pump bolus feature improved overall safety in administering an IV pump bolus, it introduced a new error, since participants had to program the bolus duration instead of the flow rate.

Task Time

The task time to deliver an IV pump bolus was not significantly different between experimental conditions, even though nurses had less experience with the bolus features on both the traditional and smart pumps.

New Hazards

Having No Bolus Feature

In the baseline condition, participants were asked to administer an IV pump bolus using a traditional pump without a bolus feature. Participants could deliver the IV pump bolus by using the secondary infusion mode (but not hanging a secondary IV container) or by directly increasing the primary infusion flow rate.

In the baseline condition, 34 of 39 (87.2%) IV pump boluses were administered using the secondary infusion mode. Since participants were using a pump feature in an unintended manner, this could have resulted in hazards; for example, the volume history in the infusion pump would not be accurate since the bolus volume would not be subtracted from the VTBI of the primary continuous IV infusion.

The remaining 5 of 39 (12.8%) participants programmed the IV pump bolus by directly increasing the primary continuous IV infusion flow rate. Directly increasing the primary infusion flow rate has been associated with extended bolus administration (i.e., overinfusion) when clinicians do not program a VTBI to limit the bolus dose. Although all participants who used this method (5 of 5; 100%) did program a VTBI to limit the bolus dose, this practice is hazardous; users are not required to set a bolus dose/VTBI and may forget to do so (e.g., nurses may be distracted before they program a VTBI).

Variation in Bolus Administration Speed (Flow Rate Versus Duration)

Bolus administration speed is not typically included in the bolus order; it is determined by a nurse, considering factors such as patient condition, medication, and hospital policy. There was a significant difference in average programmed bolus flow rate/duration across the 3 experimental conditions ($F[2, 76] = 69.9, P < 0.001$). As shown in Figure 27, IV pump boluses were programmed significantly more slowly when participants used the smart pump bolus feature than when they used the traditional pump (with or without a bolus feature) ($P < 0.001$). In fact, using a smart pump dedicated bolus feature resulted in a 5-fold reduction in bolus flow rate compared to the baseline condition.

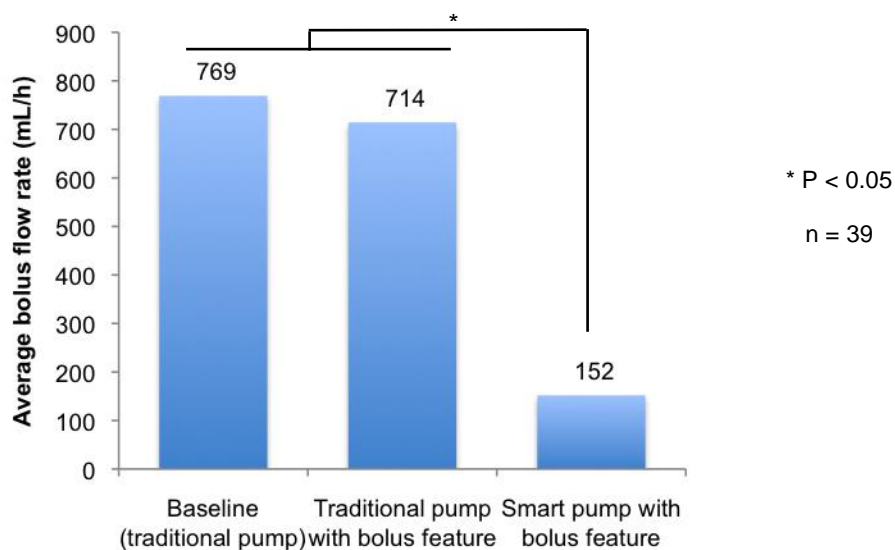


Figure 27: Administering an IV Pump Bolus: Average Bolus Flow Rate by Experimental Condition

Abbreviation: IV, intravenous.

When programming an IV pump bolus on the traditional pump (with and without a bolus feature), participants had to enter a bolus flow rate (i.e., mL/h). Participants frequently programmed a bolus flow rate of 999 mL/h when using the traditional pump, with the bolus feature (22 of 39, 56%) and without the bolus feature (25 of 39, 64%).

When using the smart pump with a bolus feature, instead of programming the bolus flow rate, participants had to enter the bolus duration in minutes or use the “rapid bolus” feature, which automatically populated the duration as 2 minutes (i.e., 150 mL/h for the medication concentration used in the study).²⁵ Sixteen of 39 (41%) bolus infusions were programmed by entering the bolus duration; 23 of 39 (59%) were programmed using the “rapid bolus” feature.

All IV pump boluses (39 of 39; 100%) were programmed to be administered over 1 minute or longer (equivalent to 300 mL/h or slower) for the drug concentrations used in the study. Thus, when participants programmed an IV pump bolus duration or used the rapid bolus feature, it resulted in slower bolus administration than when participants had to program the flow rate.

Dead Volume Hazard

In all tested conditions, the medication for the ordered IV pump bolus was already being administered via a continuous IV infusion attached to other infusions using a multiport connector, so that multiple infusions shared 1 patient access port. For this reason, dead volume existed (Theme 3: Managing Dead Volume). One participant refused to administer the ordered IV pump bolus because of concerns about bolusing other IV infusions that were running into the same access port. When an IV pump bolus is administered to a patient and the bolus medication is connected to other IV infusions, a dead volume hazard may exist.

²⁵In the smart pump with bolus feature condition, participants always administered a 5 mg IV pump bolus of midazolam (1 mg/mL).

Participant Feedback

All 40 participants completed a questionnaire to collect their feedback on the interventions tested. Participant feedback is summarized in Table 39 (see Appendix 2 for details).

Table 39: Administering an IV Pump Bolus: Participant Feedback

Question	Traditional Pump With Bolus Feature	Smart Pump With Bolus Feature	Statistics
Effectiveness at reducing medication errors ^a	3.0	3.6	$t(38) = 28.51$ $P < 0.001$
Likelihood of using intervention in clinical practice ^b	3.0	3.4	$t(38) = 6.44$ $P = 0.02$
Comment themes	<p>Results in correct volume documentation in pump; some participants thought this would improve clinical documentation accuracy, but others thought it might introduce new errors, since participants are used to bolus volumes being documented in the pump as secondary volume (if secondary feature was used)</p> <p>Easy to confuse programming a secondary infusion with an IV pump bolus, given the lack of feedback regarding programming mode</p> <p>Cannot use bolus feature in some situations (e.g., primary infusion programmed using drug calculator)</p> <p>Extra time to program IV pump boluses (and secondary infusions, since enabling the bolus feature adds a step to programming a secondary infusion) not worth it; using secondary feature preferred</p>	<p>Eliminates need for error-prone unit-of-measure conversions</p> <p>Drug library limits help reduce programming/dosing errors</p> <p>Too long to program (and confusing workflow), particularly in emergency situation</p>	

Abbreviation: IV, intravenous.

^aFour point scale: 1. very ineffective; 2. somewhat ineffective; 3. somewhat effective; 4. very effective.

^bFour point scale: 1. definitely not use; 2. probably not use; 3. probably use; 4. definitely use.

On average, all participants ($n = 40$) indicated that both the traditional and smart pump bolus features would be of value in improving medication safety, and that they would use them in their clinical practice, if available. However, as shown in Table 39, the smart pump bolus feature was ranked statistically higher than the traditional pump bolus feature in terms of effectiveness at reducing errors. Similarly, the smart pump bolus feature was rated statistically higher than the traditional pump bolus feature in terms of probability of clinical use.

Participants provided insightful comments to explain their ratings and potential implementation issues not studied in the laboratory simulation (Table 39; see Appendix 2 for detailed information).

Some participants had concerns about the notion of a dedicated pump bolus feature (on a traditional or smart pump), since it did not support their perceived best practice; they were concerned that it would encourage IV pump boluses. These participants indicated that IV bolus doses should be delivered by a separate vial (e.g., manual IV push), when possible, to minimize potential dead volume issues with connected infusions.

Discussion

To our knowledge, this was the first study to empirically evaluate the risks and potential mitigations of administering a bolus of a continuous IV drug infusion. The study findings were consistent with other research (including data presented in Theme 3: Managing Dead Volume), showing that delivering an IV bolus dose is error-prone, (102) but they add to the literature by showing how errors may occur and what mitigations are required. The study findings presented insight into 2 effective risk-reduction strategies for IV pump bolus administration.

Avoid Directly Increasing the Rate of a Primary Continuous IV Infusion to Administer an IV Pump Bolus

When no pump bolus feature was available (i.e., baseline condition), 12.8% of participants programmed the bolus by directly increasing the primary continuous IV infusion rate. Although all of these participants limited the bolus dose by programming a VTBI, this practice should be avoided, since directly manipulating the rate of a primary continuous IV infusion can result in extended bolus administration and has been associated with patient incidents. (14;121) In addition, when participants directly increased the primary rate to administer the bolus, there were errors in both programming the bolus (i.e., VTBI/dose and flow rate) and resuming the primary infusion rate after the bolus was complete. Clinicians should administer IV pump boluses using methods that limit the bolus dose administered and do not alter the programmed parameters of the primary infusion (e.g., smart pump bolus feature).

Use a Well-Designed and -Configured Smart Pump Bolus Feature to Administer an IV Pump Bolus

A dedicated pump bolus feature allows users to program a bolus without altering the primary continuous IV infusion parameters. In our study, using the bolus feature on a traditional pump did not significantly reduce IV pump bolus errors compared to the baseline condition. However, programming a bolus using a dedicated bolus feature on a smart pump significantly reduced errors without increasing programming time compared to using the traditional pump (with and without the bolus feature enabled). These study results suggest that not all IV pump bolus features significantly reduce errors. In comparing the design of the 2 tested bolus features, an infusion pump bolus feature should have several characteristics, as described below.

Require Users to Program Dose Instead of VTBI for Drug Boluses²⁶ (to Minimize Unit-of-Measure Conversions)

On the traditional pump (with and without the bolus feature), drug boluses are typically ordered in a dose (e.g., mg) that participants have to convert to a VTBI based on the infusion concentration (e.g., mg/mL). Such unit-of-measure conversion is known to be error-prone and likely contributed to VTBI programming errors even when the concentrations were 1 mg/mL. (7;46) In addition, the high cognitive load of performing the unit-of-measure conversion when using the traditional pump may have contributed to the observed errors entering the bolus dose in both the VTBI and flow rate fields; keying in the VTBI as the flow rate is a known programming error associated with patient incidents. (32) As previously discussed (Smart Pump Bolus Feature and Figure 25), the smart pump allowed users to directly copy the ordered drug dose during pump programming, eliminating bolus dose/VTBI programming errors (i.e., no unit-of-measure conversion required).

Although not tested in this study, another potential pump design feature that may minimize bolus dose/VTBI programming errors is to give users the option of administering fixed bolus doses/volumes defined by the hospital-specific drug library built into the pump (e.g., option to autopopulate the bolus

²⁶Administering IV pump boluses of fluid- and weight-based drugs (e.g., vasopressors) was not included in this study, but bolus programming fields and units of measure that optimize their safe administration should also be carefully considered by health care providers and pump designers.

dose/volume during bolus programming; a “bolus” button that administers a bolus as long as the button is held down, up to a maximum dose defined in the drug library, with the infused bolus dose displayed). However, further research is required to evaluate the safety of such features.

Require Users to Program the Bolus Duration Rather Than the Rate; Use, if Available, the Option to Autopopulate Bolus Administration Speed From the Drug Library (i.e., Eliminate the Need for Users to Program the Bolus Duration)

When an IV bolus dose is ordered, the bolus administration speed is not typically included in the order; clinicians are required to determine the speed based on institutional medication guidelines. When participants programmed the IV pump bolus using the smart pump bolus feature (i.e., in minutes or using the rapid bolus feature), it resulted in a 5-fold reduction in the bolus administration speed compared to the traditional pump (users had to program flow rate, mL/h).

This finding suggests that boluses may be administered more quickly than intended when programmed using flow rate, since it is likely more difficult to convert flow rate (e.g., mL/h) to a dose delivered over time (e.g., mg/min) than enter a duration (e.g., minutes). In addition, the findings suggest that clinical decision support should be built into infusion pumps to allow clinicians to automatically populate the IV pump bolus administration speed without having to reference medication protocols. A majority of participants in the current study (60%) programmed the IV pump bolus at the maximum flow rate (999 mL/h) when using a traditional pump (with and without the bolus feature enabled) as an unofficial IV bolus infusion rule; this is consistent with other research, which identified that 95% of all IV boluses (not just IV pump boluses) were given too quickly and in violation of guidelines, due to a lack of perceived risk and poor role models. (102;116) When participants were provided with a “rapid bolus” feature on the smart pump, a majority of participants (59%) used it, resulting in greater compliance with institutional medication guidelines.

It is important to highlight that programming bolus dose and duration requires a mental shift for clinicians who are accustomed to thinking of and programming bolus VTBI and rate. Programming bolus dose and duration is preferred to programming bolus VTBI and rate, but it can introduce new transitional errors (e.g., in our study, 1 participant entered the flow rate into the duration field when using the smart pump). Training is required to prepare clinicians for a shift toward direct-order input and to think in terms of bolus dose and duration rather than VTBI and flow rate.

Provide Clear Bolus Mode User Feedback

The smart pump bolus feature had a unique and distinct user interface with clear feedback showing that users were programming and administering a bolus infusion. The traditional pump bolus feature lacked such feedback, and some participants (5%) inadvertently altered the primary continuous IV infusion parameters, thinking they were programming the bolus parameters; participants noted this confusion in their feedback. This problem resulted in no bolus administration and/or errors with resuming the continuous primary IV infusion upon bolus completion. Mode errors have been reported in other studies when multiple programming modes were available from 1 pump interface that had poor user feedback. (124)

Limit Bolus Programming Parameters

The smart pump bolus feature had the ability to alert users to potential programming errors based on institutionally defined soft and hard limits (in the pump drug library). The effectiveness of this attribute was not comprehensively evaluated in our laboratory study, since only 1 participant made a programming error when using the smart pump, and the error was within the safety limits of the drug library (i.e., it did not trigger an alert). However, the error serves as an important reminder that the effectiveness of a smart pump’s drug library depends on its configuration (e.g., soft and hard limits are well defined, appropriate

and updated; bolus feature is enabled for medications that are administered as a bolus; bolus feature is disabled for clinical units that do not, or should not, administer IV pump boluses). (7;47;123)

Limitations

The results of this study provided information about the potential for pump technology to enhance the administration of IV pump boluses when infusion tasks are comparable to those in the experiment. Participants were required to use the pump bolus features immediately after receiving training; longitudinal effects, such as training retention, compliance with feature use, and workarounds (e.g., using the secondary feature on a smart pump to administer an IV pump bolus instead of using the bolus feature, removing the continuous IV infusion from the pump to administer the bolus by gravity) were not studied. In addition, the study findings were based on the evaluation of 2 specific dedicated pump bolus features; other designs were not evaluated and may present improvements or limitations that were not included in this study. For example, Wetterneck et al (49) identified that for the smart pump implemented at 1 hospital, nurses were not programming bolus infusions in the drug library, which may have been related to specific design and/or configuration issues with the bolus feature used at that hospital.

Fluid- and weight-based drug (e.g., vasopressor) boluses, loading doses, and multistep protocols were not included in this study. Infusion pump programming requirements (e.g., fields, units of measure) to administer these intermittent infusions should be carefully considered by health care providers and pump designers.

Summary

Health care providers must be discouraged from programming an IV pump bolus by altering a primary continuous IV infusion's programmed parameters. Instead, IV pump boluses should be administered using a dedicated smart pump bolus feature that allows users to program the drug bolus dose (i.e., facilitates direct order input to minimize unit-of-measure conversions) and duration; that provides bedside clinical decision support (e.g., option to autopopulate bolus duration from drug library, drug library limits); and that provides users with clear feedback that they are programming a bolus infusion.

Conclusions

Errors occur during common tasks associated with administering and managing multiple IV infusions. However, improvements to best practices, infusion system technologies, and education can help reduce many of these risks by addressing a gradual misalignment of practices, technology, and education. In the short term, supporting clinicians via targeted education, standard best practices, and bedside clinical decision support can improve the identification and completion of some task requirements. In the longer term, innovation is needed to minimize the routine and person-dependent tasks that are currently required to administer multiple IV infusions. Still, given the complexity of this practice, even with improved technology the safe administration of multiple IV infusions will likely always require user vigilance. (51)

Addressing the issues and implementing the recommendations identified in this report will require the sustained commitment and alignment of all stakeholders. However, with collective action based on evidence, improvements to the administration and management of multiple IV infusions—and thus patient safety—are obtainable and must be a priority.

Glossary

Access port	A port that allows IV components to connect directly to a patient's venous catheter. An intravenous catheter with multiple lumens (multi-lumen catheter, central venous catheter) would provide multiple access ports with unique and independent pathways into the patient's bloodstream.
Access site	The location where an intravenous catheter is inserted into the patient's body. Access sites may be central or peripheral (central venous catheter and peripheral venous catheter), and can also be identified by anatomical location (left antecubital vein or right internal jugular).
Auxiliary label	Any label applied to IV tubing or IV infusion pumps to assist with the identification of an infusion. Labels on IV bags are not auxiliary labels. Labels that identify the IV tubing replacement date and time were outside of the study scope.
Back check valve	A one-way valve on primary IV tubing that allows fluid to flow only <i>away</i> from the primary IV container . If fluid pressure encourages flow toward the primary IV container, the valve closes, preventing backflow.
Bridge	See multiport connector .
Bolus	A one-time or intermittent dose of IV fluid or medication given to rapidly achieve a physiological effect. This excludes intermittent infusions, loading doses , "as needed" doses injected all at once (without a continuous IV infusion of the same medication running), or IV patient-controlled analgesia.
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 central vein that 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 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.
Continuous IV 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 plain IV 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 connect 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.
Emergency medication line	Refers to an IV line continuously infusing a fluid that is compatible with most IV medications, and is not joined with other infusions. It is often kept available in the event that IV drugs are required immediately, and in some institutions, may also be used to deliver intermittent medications (see plain IV line).
Flush	A term used to describe the administration of a compatible IV fluid (typically a plain solution) into an IV line so that the existing contents of the line are administered into the patient’s bloodstream. This is a method of ensuring residual IV fluid or medications in the dead volume have been administered to the patient or cleared from the IV line. Methods of delivery can be manual (e.g., IV push) or by infusion pump (e.g., infusion of plain solution).
High-alert medication	Medications that bear a heightened risk of causing significant patient harm when they are used in error.
Infusate	Any fluid or solution intended to be administered to a patient intravenously; may include hydration fluids, blood and blood products, total parenteral nutrition, IV medications, IV chemotherapy, or others. Medications mixed at different concentrations are considered to be different infusates.
Injection port	A luer lock entry point into IV tubing . Because it protrudes from the IV tubing at an angle, the combination of 2 IV tubes into 1 resembles the letter Y and may also be referred to as a Y-site . Injection ports are often used to administer a manual IV push, and may be found on primary IV tubing close to the patient end.
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.
IV agent	See infusate .
IV container	A generic term to refer to the reservoir of fluid intended to be administered intravenously. May refer to an IV bag, IV glass bottle, or IV syringe.

IV pump bolus	A bolus administered using an IV infusion pump. Pump-controlled boluses refer to an additional dose of the medication being administered as a primary continuous IV infusion (e.g., a patient receiving a continuous morphine infusion requires an additional dose for pain management support prior to an invasive procedure).
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 so that gravity encourages them to flow toward the pump.
Loading dose	Refers to a temporarily increased flow rate when starting an infusion. Once this period is complete, the infusion flow rate is lowered for ongoing therapy.
Line	A term that may vary in meaning depending on the context of use. It may refer to either a single IV infusion (e.g., a morphine line), or all IV infusions infusing through a single IV port (e.g., a distal line on the triple lumen central catheter).
Line change	A routine clinical task in which all IV tubing , connectors, and containers connected into a single line are periodically replaced to prevent the risk of infection.
Lower injection port	The port found near the patient end of primary IV tubing . This port is always below the portion of the IV tubing that is inserted into the IV infusion pump. Primary IV tubing may have no lower injection ports, 1, or many.
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 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 multi-lumen catheter).
Manifold	See multiport connector .
Manual IV push	See syringe push .
Multichannel pump	An IV infusion pump that contains a programming interface that allows users to control multiple infusions at once. Each infusion is controlled by a “channel,” which is a section of the pump where IV tubing can be inserted. All channels are connected to the infusion pump, so that the pump resembles 1 larger unit.

Multi-lumen catheter	A catheter that has more than 1 lumen , inside it. This allows 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.
Multiport (or multi-lead) connector	An IV component with multiple ports that facilitates the joining of multiple IV components. Multiport connectors combine all attached medications into only 1 lumen , so all connected infusions mix. Manifolds and bridges are rigid 1-piece connectors where a single lumen runs length of the connector; it has 2 or more ports available for additional IV infusions to be attached. In contrast, multi-lead connectors possess a tree shape, where 2 or more branches join together into a single lumen.
Multistep protocol	An infusion protocol in which the flow rate of the infusion increases or decreases at preset times as programmed by the user. This facilitates appropriate changes to the infusion flow rate during the infusion, without repeated user intervention.
Piggyback infusion	See secondary infusion .
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.
Plain IV line	See emergency medication line . Note that an emergency medication line is usually a plain IV line, but not necessarily vice versa. There may be multiple plain IV lines, but typically only 1 intended for use as the emergency medication line.
Port	A luer lock entry point into IV tubing through which other IV infusions or syringes may be attached (see injection port , secondary injection port , and multiport connector).
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 pump connection where secondary IV tubing can be connected (see secondary IV port). Primary IV tubing may also have 1 or more lower injection ports . Primary IV tubing intended for syringe pumps typically does not feature Y-sites.
Secondary 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 rate.

Secondary IV tubing	IV tubing intended for use with a secondary infusion . This tubing is usually shorter than primary IV tubing and has no Y-sites .
Secondary injection port	An injection port on the primary IV tubing that is typically reserved for secondary IV infusion administration. On primary IV tubing intended for use with IV infusion pumps, the secondary port would be located above the infusion pump after the tubing is loaded into the pump. Injection ports close to the patient end of the IV tubing are <i>not</i> considered secondary ports in this report (they may be referred to as lower injection ports or <i>distal ports</i>). However, lower injection ports are not mandatory; hospitals may elect to use primary IV tubing with no injection ports whatsoever (e.g., similar to syringe pump tubing).
Smart infusion pump	An electronic infusion pump equipped with a dose error reduction system (DERS) . A central element of all smart pumps and their DERS software is the ability to alert nurses when specific dosing limits have been exceeded during infusion programming. Smart pumps may offer the ability to display clinical advisories (depending on the infusion programmed), communicate wirelessly with a pump server, and record time-stamp logs of programming keystrokes. Smart pumps may also employ bar code and/or radio frequency identification technology to reconcile medication, patient, nurse, and prescriber order information.
Syringe push	Refers to manually administering the contents of a syringe by hand. While syringes are used to administer fluids by various oral/parenteral routes, this report typically refers to administration of the syringe contents intravenously (i.e., manual IV push).
Syringe pump	An electronic or mechanical device that administers the contents of a syringe at a controlled flow rate.
Traditional pump	Large-volume infusion pumps that are not equipped with a dose error reduction system (DERS) .
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 ability to stop the flow of 1 connection with a handle.
Volume to be infused (VTBI)	The volume of fluid or medication that is intended to be administered to the patient.
Y-site	See port .

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Editorial Staff

Jeanne McKane, CPE, ELS(D)

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Members of the Multiple IV Infusions Expert Panel

Name (Alphabetical)	Expert Panel Role	Organization(s) Represented
Lisa Burry	Pharmacy and Hospital Representative	Mount Sinai Hospital Canadian Society of Hospital Pharmacists
Vania Costa	Liaison to Health Quality Ontario	Health Quality Ontario
Pam Cybulski	Nursing and Hospital Representative	William Osler Health Centre Canadian Association of Critical Care Nurses
Brenda Dusek	Nursing Representative	Registered Nurses Association of Ontario
Tony Easty	Expert Panel Chair	HumanEra
Patrick Fandja	Regulatory Representative	Health Canada
Kim Greenwood	Clinical Engineering and Hospital Representative	Children's Hospital of Eastern Ontario Council of Academic Hospitals of Ontario
Dr Chris Hayes	Medical, Safety and Hospital Representative	St. Michael's Hospital Canadian Patient Safety Institute
Geeta Juta	Safety and Nursing Representative	Institute for Safe Medication Practices Canada
Christine Koczmara	Safety and Nursing Representative	Institute for Safe Medication Practices Canada
Dr. Bob Lester	Hospital Representative	Ontario Hospital Association
Mitra Nadjmi	Risk Management Representative	Health Insurance Reciprocal of Canada
Kim Newcombe	Nursing Representative	Canadian Vascular Access Association
Kim Streitenberger	Nursing and Hospital Representative	The Hospital for Sick Children
Jeannette Van Norden	Nursing and Hospital Representative	Juravinski Cancer Centre
Past Members		
Ilhemme Djelouah	Regulatory Representative	Health Canada
Bronwen McCurdy	Liaison to Health Quality Ontario	Health Quality Ontario
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

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- Brenda Kisic
- Gary Wong

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- Rachel White
- Stacey Howchin
- Rossini Yue

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Appendices

Appendix 1: Participant Demographic Survey

1. What best describes your role in the hospital?

<input type="checkbox"/> Staff nurse	<input type="checkbox"/> Advanced practice nurse
<input type="checkbox"/> Nurse manager	<input type="checkbox"/> Other:
<input type="checkbox"/> Clinical trials nurse	
2. What age range are you in:

<input type="checkbox"/> 18–29 years old	<input type="checkbox"/> 50–64 years old
<input type="checkbox"/> 30–39 years old	<input type="checkbox"/> 65 years old and over
<input type="checkbox"/> 40–49 years old	
3. Are you:

<input type="checkbox"/> Male	<input type="checkbox"/> Female
-------------------------------	---------------------------------
4. How long have you worked as a registered nurse on a critical care unit?

<input type="checkbox"/> Less than a year	<input type="checkbox"/> 4–10 years
<input type="checkbox"/> 1–3 years	<input type="checkbox"/> Greater than 10 years
5. Have you completed the following postgraduate programs? Please check all that apply.

<input type="checkbox"/> Completed a college-based critical care nursing program (e.g., core fundamentals orientation program)
<input type="checkbox"/> Obtained the full Critical Care Nursing Certificate from a college-based program (includes Coronary Care Level II & Neuro courses)
<input type="checkbox"/> Obtained the additional specialty certification credential in critical care nursing offered by the Canadian Nurses Association
<input type="checkbox"/> Completed additional courses offered by an educational institution that focused exclusively on IV therapy principles (e.g., IV therapy course) and is separate from the critical care nursing program curriculum. Please specify in “other” category box below
6. How often do you work in the critical care units, on average?

<input type="checkbox"/> Less than once a week	<input type="checkbox"/> 3–4 times a week
<input type="checkbox"/> 1–2 times a week	<input type="checkbox"/> More than 4 times a week
7. Which critical care unit (ICU) do you predominantly work at? Please check all that apply.

<input type="checkbox"/> Medical-surgical ICU (MSICU)	<input type="checkbox"/> Coronary ICU (CICU)
<input type="checkbox"/> Cardiovascular ICU (CVICU)	<input type="checkbox"/> Other (please specify)




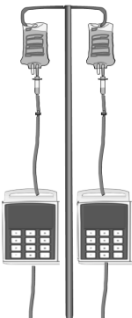

Appendix 2: Participant Feedback

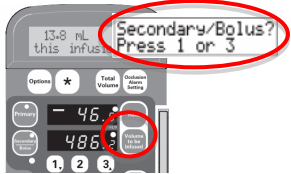
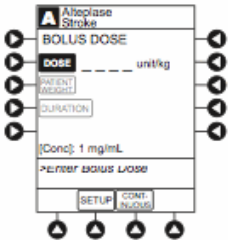
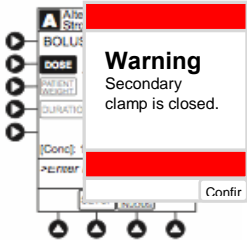

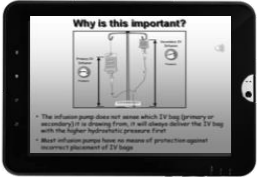
Post-Study Questionnaire

Interventions	1. Please rate the intervention's effectiveness in reducing medication errors?				2. If the intervention was implemented in your clinical unit, please rate your estimated use of the intervention?				Please explain your ratings in the comment box
	Very ineffective	Somewhat ineffective	Somewhat effective	Very effective	Definitely not use	Probably not use	Probably use	Definitely use	
a) Horizontal Rake Pole Top	1	2	3	4	1	2	3	4	
b) Infusion Organizer	1	2	3	4	1	2	3	4	
c) Pre-printed labels below pump & at injection port closest to the patient (above the port)	1	2	3	4	1	2	3	4	
d) Light Line Identifier	1	2	3	4	1	2	3	4	
e) Smart pump channel labels	1	2	3	4	1	2	3	4	
f) One-at-a-time setup	1	2	3	4	1	2	3	4	
g) Bolus Feature on the Traditional Pump	1	2	3	4	1	2	3	4	
h) Bolus Feature on the Smart Pump	1	2	3	4	1	2	3	4	
i) Automated Secondary Line Clamp Detector (on smart pump)	1	2	3	4	1	2	3	4	
j) Deliver Secondary Infusion using a Separate Pump	1	2	3	4	1	2	3	4	
k) Dose Error Reducing Software (DERS) on Smart Pump	1	2	3	4	1	2	3	4	
l) Training Module on Key Principles for Secondary Infusions	1	2	3	4	1	2	3	4	
m) Training Module on Key Infusion Principles on Dead Volume	1	2	3	4	1	2	3	4	

Figure A1: Questionnaire

Table A1: Intervention Description Aid

Intervention	Picture	Description	Goal
a) Horizontal rake pole-top		This pole-top can be mounted on most poles and is like a horizontal rake. Its design attempts to align IV bags with the IV pumps directly below it	To minimize IV bag to pump confusion
b) Infusion organizer		The infusion organizer physically separates IV tubing to help minimize tangles below the pump. It comes in 4 different colours to help group tubing (e.g., white, brown/beige, and blue to match the triple-lumen catheter colours and green for the peripheral IV). It can be placed anywhere along the tubing (e.g., near access port, under pump)	To improve the identification of IV tubing below the pump
c) Preprinted labels below pump and at injection port closest to the patient (above the port)		The preprinted labels attempt to consistently label the fluid/medication and distinguish the medication line. The labels are flag-like stickers with specific drug names already printed on the front and back. These preprinted labels are placed at 2 specific spots on the IV tubing: 1 is placed directly above the lowest injection port on the primary IV tubing; the other is placed about 6 inches below the pump. There are 2 different colours of labels. The med line labels are yellow, and all other drug IV line labels are white	To improve the identification of IV tubing below the pump
d) Light line identifier		The line identifier uses lights to assist with line tracing by connecting the IV bag, the infusion pump and the tip of the IV tubing. The full implementation of this design involves the IV tubing itself being continuously illuminated from top to bottom, similar to a light stick	To improve the identification of IV tubing above and below the pump
e) Smart pump channel labels		The smart pump automatically displays the programmed drug name and drug amount on the pump main screen and channel	To improve the identification of IV fluids/medications at the pump
f) One-at-a-time setup	—	For the one-at-a-time setup, nurses must set up each fluid/medication as completely as possible (e.g., hang IV bag, prime line, load and program pump, attach to patient access) using new pumps prior to setting up the next medication	To minimize confusion errors from setting up more than 1 infusion at the same time

Intervention	Picture	Description	Goal
g) Bolus feature on the traditional pump		The traditional pump has an optional feature to allow users to program a bolus infusion from the primary line. To access this feature, users must press the “Secondary/Bolus” hard key and then select “3” to program a bolus (instead of “1” to program a secondary infusion)	To improve the safety of delivering a bolus using an infusion pump (e.g., minimize dosing and documentation errors)
h) Bolus feature on the smart pump		The smart pump has the option for users to deliver a bolus infusion from within a hospital-defined drug library, thereby setting soft and hard bolus limits. Users must program the dose and duration to select the “rapid bolus” feature for deliver the bolus at the maximum safe rate	To improve the safety of delivering a bolus using an infusion pump (e.g., minimize dosing and documentation errors)
i) Automated secondary line clamp detector (on smart pump)		The secondary line clamp detector senses and alerts users when the secondary line clamp is closed. Users must acknowledge the alarm and restart the infusion	To minimize the risk of forgetting to open the secondary line clamp when running a secondary infusion
j) Deliver secondary infusion using a separate pump		<p>Secondary infusions are set up using a separate infusion pump. That is, secondary infusions must be delivered using primary tubing on a new pump and can only be connected to another infusion using a lower injection port (i.e., below the pump). The motivation for this type of policy is that it removes the risk of:</p> <ul style="list-style-type: none"> • forgetting to open the secondary clamp and lower the primary bag • connecting the secondary infusion downstream of the pump • lack of (or faulty) back check valve on the primary tubing • programming confusion between primary and secondary infusions running on the same pump 	To minimize the risks associated with running a secondary infusion
l) Training module on key principles for secondary infusions		The purpose of the training module is to augment clinicians' knowledge about the fundamental principles regarding secondary infusions and dead volume. In particular, the module aims to provide clinicians with a better understanding of the known failure modes related to these issues, and how to manage them safely when administering multiple IV infusion to patients with complex care needs	To improve safety in delivering secondary infusions
m) Training module on key infusion principles on dead volume			To improve safety in managing infusion dead volume

Abbreviation: IV, intravenous.

Questionnaire Results: Open-Ended Feedback on Interventions

Table A2: Setting up and Programming Multiple Primary Continuous IV Infusions: Participant Feedback

Participant Feedback	Participants, n ^a
One-at-a-Time Protocol	
✓ <input type="checkbox"/> Reflective of my current practice	5
✓ <input type="checkbox"/> Good general safe principle (e.g., teach this way), but can't always be executed (see limitations below)	2
X <input type="checkbox"/> Not practical, since can't always have new pumps and/or space for new bank of pumps	6
X <input type="checkbox"/> Not valuable policy, since must give RN flexibility to set up lines given his/her mental model and/or patient needs	3
X <input type="checkbox"/> Depending on the initial pump setup, it may create problems to remove dead pumps	1
X <input type="checkbox"/> Errors with setting up multiple IV infusions not an issue (e.g., triple-check)	1
X <input type="checkbox"/> Takes more time	1

Abbreviations: RN, registered nurse; IV, intravenous.

^an = 40.

Table A3: Identifying IV Infusions: Participant Feedback

Participant Feedback		Participants, n ^a
Preprinted Labels		
✓ <input type="checkbox"/> Improved efficiency	To identify infusions (once labels verified)	4
	To make and apply labels	2
✓ <input type="checkbox"/> Great tool (especially if used with other tools, like smart pump/channel labels)		2
✓ <input type="checkbox"/> Location	Like by bridge	1
✓ <input type="checkbox"/> Standardized	Location	1
	Legibility	1
X <input type="checkbox"/> Still need to manually trace to verify		7
X <input type="checkbox"/> Location	Want to put on pump (e.g., over pump tubing slot). Perhaps instead of below the pump?	6
	Want to put on bridge	3
X <input type="checkbox"/> Consider different colours for different classes of drugs		2
X <input type="checkbox"/> Implementation	Consider using only for high priority (e.g., med line and vasopressors)	2
	Storage space for all required labels	1
	Need blank labels	1
	Infection-control issues (cannot store in room, so perhaps send up with bag from pharmacy or keep in med room)	1
Pole-Top Organizer		
✓ <input type="checkbox"/> IV tubing more organized		6
✓ <input type="checkbox"/> Hooks easy to use		2
X <input type="checkbox"/> Difficult to access back hooks (especially if small bag)		4
X <input type="checkbox"/> Effective if set up properly but with time, not likely to stay organized		4
X <input type="checkbox"/> Bag-to-pump mismatch is not a significant source of errors		2
X <input type="checkbox"/> Still need to manually trace bag to pump to verify		2
X <input type="checkbox"/> Prefers a “K” top		1
X <input type="checkbox"/> Limited use in transport since can have only 3 pumps per pole		1
Tubing Organizers		
✓ <input type="checkbox"/> Location	Like under pump	3
✓ <input type="checkbox"/> Design	Good colour grouping by port	2
X <input type="checkbox"/> Location	Not useful at bedside (ambulation, space, particularly during procedures)	6
	Not useful under pump	1
X <input type="checkbox"/> Design	Needs labels at bedside line separator	5
	Tubing slips out too easily	3
	Should be smaller and less bulky	3
	Needs more slots (6 insufficient)	1
	Difficult to use during transport	1
	Need different colours for different peripheral IV lines	1
	Infection-control concerns (e.g., sterilize or very wasteful)	2
X <input type="checkbox"/> Still need to manually trace to verify		4
X <input type="checkbox"/> Need further practice to properly evaluate real-world use		3
X <input type="checkbox"/> Can't always remember to set up when adding new line		1
X <input type="checkbox"/> Increase time to change lines		1
Smart Pump/Channel Labels		

Participant Feedback		Participants, n ^a
✓ <input type="checkbox"/> Good double-check (still need bag and tubing labels)		1
✓ <input type="checkbox"/> Visibility (note: must see information from doorway for isolation patients and night shifts)	Information should be static (e.g., not scrolling information on channel, not flashing information on brain); time-consuming to wait	11
	Too much info on screen and font too small	3
	Generally difficult to see	2
	Angle of screen (e.g., tall person)	1
	Need better use of colour	1
X <input type="checkbox"/> Would still add pump labels (since information is not static)		3
X <input type="checkbox"/> Would still manually trace (don't trust, want to verify no errors)		2
X <input type="checkbox"/> Want port information labelled on pump/channel		2
X <input type="checkbox"/> Potential for documentation errors, since channel reference letter may change when a module is added/removed		1
X <input type="checkbox"/> Information layout is not intuitive		1
Light-Linking System		
✓ <input type="checkbox"/> Good for quick identification of line (e.g., emergency)		4
✓ <input type="checkbox"/> Good idea for full implementation		4
X <input type="checkbox"/> Duplication	Still want to label (must see continuously)	6
	Still must manually trace (don't trust, not needed if have labels)	5
	Still must organize/separate lines	1
X <input type="checkbox"/> Design	Awkward and confusing to press button and then visually identify pump and end of tubing (error-prone)	6
	Cannot trace upwards	3
	Have to wait to timeout if want to check more than 1 line	1
	Need button on pump	1
	Need different light colours	1
	Not good for photosensitive drugs	1
	Lights must illuminate for longer	1
X <input type="checkbox"/> Increased time to identify lines		3
X <input type="checkbox"/> Need further practice to properly evaluate real-world use (e.g., battery life, patient reaction)		2
X <input type="checkbox"/> Low value		2
X <input type="checkbox"/> Easy to malfunction		1

Abbreviation: IV, intravenous.

^an = 40.

Table A4: Managing Dead Volume: Participant Feedback

Participant Feedback	Participants, n ^a
Education Module	
<input type="checkbox"/> Good refresher and good for new hires/grads	9
<input type="checkbox"/> Should be added to annual recertification	3
<input type="checkbox"/> Increased my understanding of dead volume	2
<input type="checkbox"/> Cheat sheet is a good reference. It should be posted as a resource (but not needed routinely—see below)	2
<input type="checkbox"/> Very clear and good length	1
<input type="checkbox"/> Currently there is too much focus on complex patient conditions at the cost of not teaching/reviewing core underlying principles	1
<input type="checkbox"/> Cheat sheet is overkill for routine practice	2
<input type="checkbox"/> Still won't consider dead volume, because too complicated (e.g., just use a push line instead or just watch patient condition)	2
<input type="checkbox"/> Too long and boring	2
<input type="checkbox"/> Needs more explicit clinical guidance	1
<input type="checkbox"/> Too fast	1

^an = 40.

Table A5: Setting Up Secondary Intermittent IV Infusions: Participant Feedback

Participant Feedback	Participants, n ^a
Smart Pump With Clamp Detector	
<input type="checkbox"/> Clamp detector is a great feature	3
<input type="checkbox"/> Not new feature; my current pump has this already	2
Separate Pump	
<input type="checkbox"/> Would require only 1 more pump at bedside	1
<input type="checkbox"/> More time and steps (prime and flush primary line; get new pump, insert cassette, program as primary; have to go into room to turn off pump)	12
<input type="checkbox"/> Requires more pumps; inventory and space are already limited	11
<input type="checkbox"/> Not providing increase in safety. Not focused on biggest source of errors, which is programming. Introduces new errors (e.g., residual volume, flush rate not same as drug rate)	7
<input type="checkbox"/> Not cost-effective and wasteful (e.g., use more primary lines, minibag)	6
<input type="checkbox"/> Another line and pump at bedside (e.g., increased confusion)	5
<input type="checkbox"/> Patient fluid overload (i.e., minibag flush)	3
<input type="checkbox"/> Should always just clamp primary line instead (in ICU; may not be practical in ward)	2
<input type="checkbox"/> Worse for wards than ICU given nurse-to-bed ratio (not able to babysit infusions)	2
<input type="checkbox"/> To accommodate residual volume, bags could be overfilled so not have to flush	1
<input type="checkbox"/> Big change in workflow (old habit hard to break)	1
<input type="checkbox"/> Priming a primary line is not feasible in an emergency	1
Education Module	
<input type="checkbox"/> Good refresher and good for new hires/grads	8
<input type="checkbox"/> Should be added to annual recertification	3
<input type="checkbox"/> Increased my understanding of secondary infusions	2
<input type="checkbox"/> Very thorough explanations	1
<input type="checkbox"/> Currently there is too much focus on complex patient conditions at the cost of not teaching/reviewing core underlying principles	1
<input type="checkbox"/> Very auditory. Needs to accommodate more learning styles (i.e., more reading)	1
<input type="checkbox"/> Too long (not time to view at work)	5
<input type="checkbox"/> Too fast	1

Abbreviations: ICU, intensive care unit; IV, intravenous.

^an = 40.

Table A6: Administering an IV Pump Bolus: Participant Feedback

Participant Feedback	Participants, n ^a
Traditional Pump With Bolus Feature	
<input type="checkbox"/> Support correct volume documentation and monitoring (not really for medication errors)	4
<input type="checkbox"/> Convenient and clear function	2
<input type="checkbox"/> Like feature (if allowed to do this practice—see below regarding best practice)	2
<input type="checkbox"/> Does not support best practice, which is to discourage pump-based boluses (because of dead volume issues)	7
<input type="checkbox"/> No value. Not source of error, since currently use secondary mode. Not worth extra programming time	6
<input type="checkbox"/> Confusing workflow (e.g., awareness if programming secondary or bolus) and sometimes give bolus from secondary bag (how to program that?)	5
<input type="checkbox"/> Add more opportunity for error (e.g., adding another step into the workflow, documentation confusion since currently use secondary volumes)	3
<input type="checkbox"/> Difficulty identifying bolus volume from primary volume since now combined	1
<input type="checkbox"/> Not use in an emergency since too many steps (use syringe)	1
<input type="checkbox"/> Cannot bolus infusion programmed using the drug calculator (pump does not allow secondary infusions, and consequently boluses, when the primary has been programmed in the drug calculator)	1
Smart Pump With Bolus Feature	
<input type="checkbox"/> Program dose eliminates need for unit conversion	7
<input type="checkbox"/> Great safety tool: drug library limits (and lock out) very useful	3
<input type="checkbox"/> Good visual design	2
<input type="checkbox"/> Quick to program	1
<input type="checkbox"/> Can see drug name (i.e., verify right drug)	1
<input type="checkbox"/> Rapid bolus feature very helpful (e.g., time and safety)	1
<input type="checkbox"/> Too time-consuming to program (e.g., too many steps), particularly in emergency	6
<input type="checkbox"/> Difficult to use/not intuitive	3
<input type="checkbox"/> Does not support best practice; would not use and would still do manual pushes instead	1

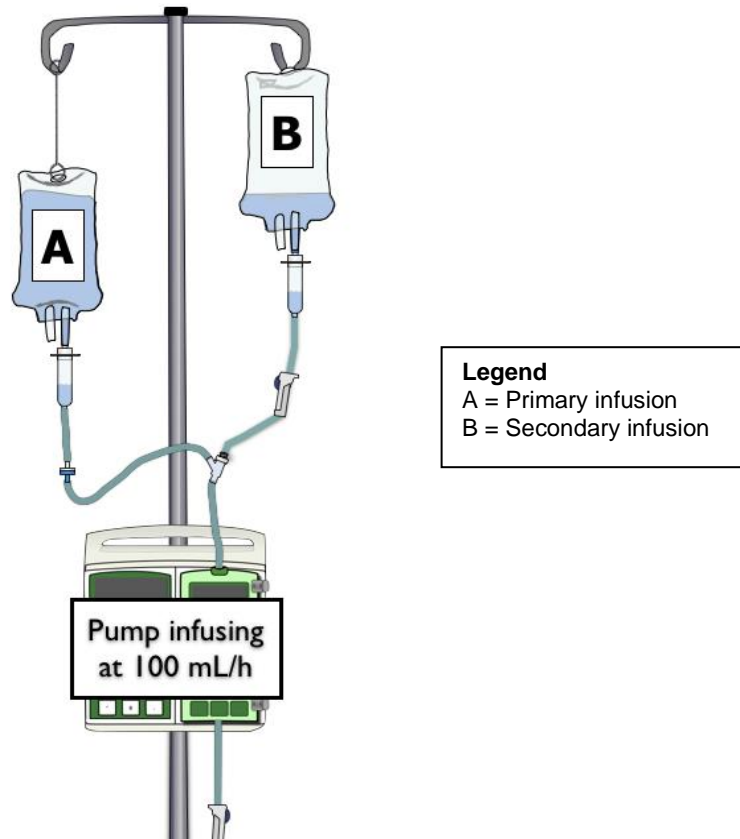
Abbreviation: IV, intravenous.

^an = 40.

Appendix 3: Education Module Tests

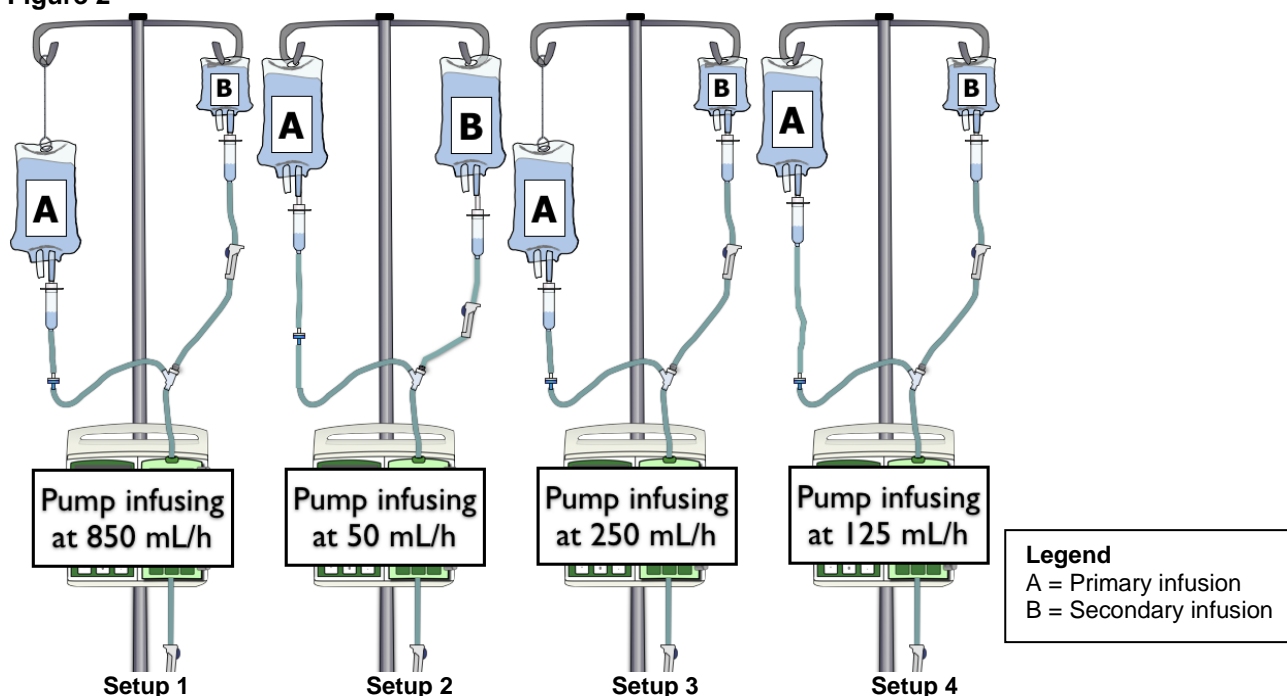
Test A

Figure 1



- Q1. What most likely describes the scenario in Figure 1?
- a) Pump will alarm—no flow above pump
 - b) Pump will alarm—distal occlusion
 - c) Drug A infusing at 100 mL/h
 - d) Drug B infusing at 100 mL/h
 - e) Mix of Drugs A and B infusing at 100 mL/h
- Q2. In Figure 1, will the back check valve stop flow from Bag A?
- a) Yes, because IV Bag A is lower than Bag B
 - b) Yes, because IV Bag A exerts equal or greater pressure compared to Bag B
 - c) No, because IV Bag A is lower than Bag B
 - d) No, because IV Bag A exerts equal or greater pressure compared to Bag B
 - e) None of the above
- Q3. If the secondary IV tubing clamp is closed in Figure 1, what will the patient receive?
- a) No flow will occur
 - b) Drug A infusing at 100 mL/h
 - c) Drug B infusing at 100 mL/h
 - d) Mix of Drugs A and B infusing at 100 mL/h

Figure 2



Q4. If the infusion pumps in Figure 2 are programmed correctly, which setups will infuse the contents of Bag B at the programmed rate? Please select all that apply.

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

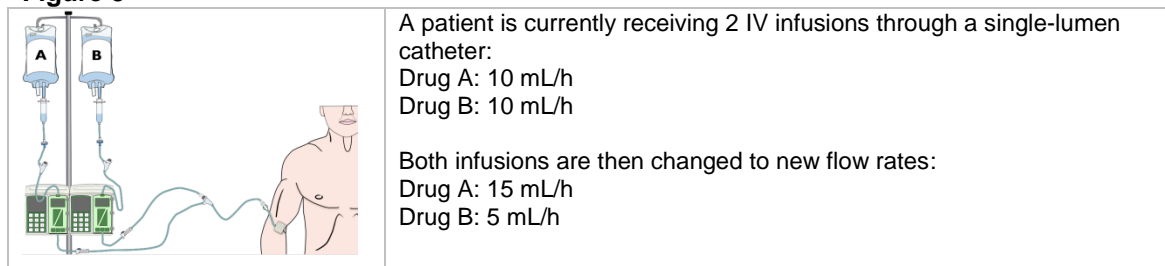
Q5. If IV Bag B in Figure 2 Setup 1 is connected to the primary IV tubing *below* the pump, which of the following could be true?

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

Q6. True or false: When initiating a secondary infusion (i.e., just pressed run and opened the secondary clamp), the secondary drug does not immediately reach the patient.

- a) True, because the primary IV tubing is not filled with the secondary fluid
- b) True, because the primary IV tubing is filled with the secondary fluid
- c) False, because the primary IV tubing is not filled with the secondary fluid
- d) False, because the primary IV tubing is filled with the secondary fluid

Figure 3



Q7. In the scenario in Figure 3 above, how will the total flow rate to the patient change?

- a) The flow rate to the patient will immediately increase
- b) The flow rate to the patient will immediately decrease
- c) The flow rate to the patient will briefly increase and then decrease
- d) The flow rate to the patient will briefly decrease and then increase
- e) The flow rate to the patient is unchanged

Q8. In the scenario in Figure 3 above, which of the following best describes the exact delivery of Drug B after this change?

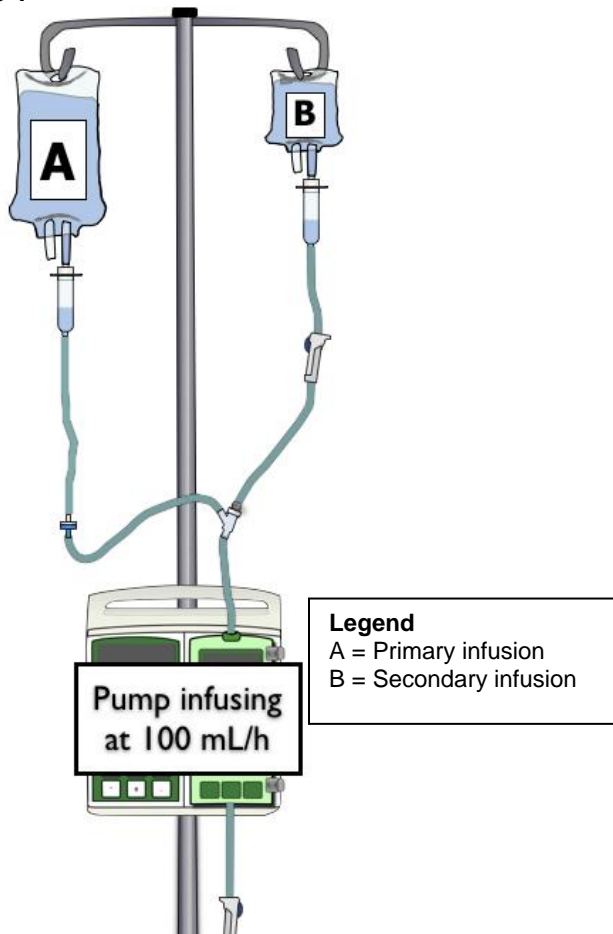
- a) Dose rate of Drug B reaching the patient briefly increases and then steadily decreases to the new dose rate
- b) Dose rate of Drug B reaching the patient steadily decreases from the original dose rate to the new dose rate
- c) Dose rate of Drug B reaching the patient remains the same momentarily, before dropping to the new dose rate
- d) Dose rate of Drug B reaching the patient is unaffected by the change

Q9. An IV syringe push of 5 mg of drug in 5 mL is ordered to be administered over 3 minutes to avoid side effects (i.e., speed shock). The nurse administers the syringe dose into an IV tube that is currently infusing sodium chloride 0.9% at a slow KVO rate. The priming volume from the injection port to the patient's vein is 8 mL. The nurse administers the IV push slowly over 3 minutes and then quickly administers a 10 mL syringe of sodium chloride 0.9% to flush the line. What statement best describes what has just occurred?

- a) The patient received the medication as ordered
- b) The patient received the medication too slowly
- c) The patient received the medication too quickly
- d) The patient did not receive all the medication

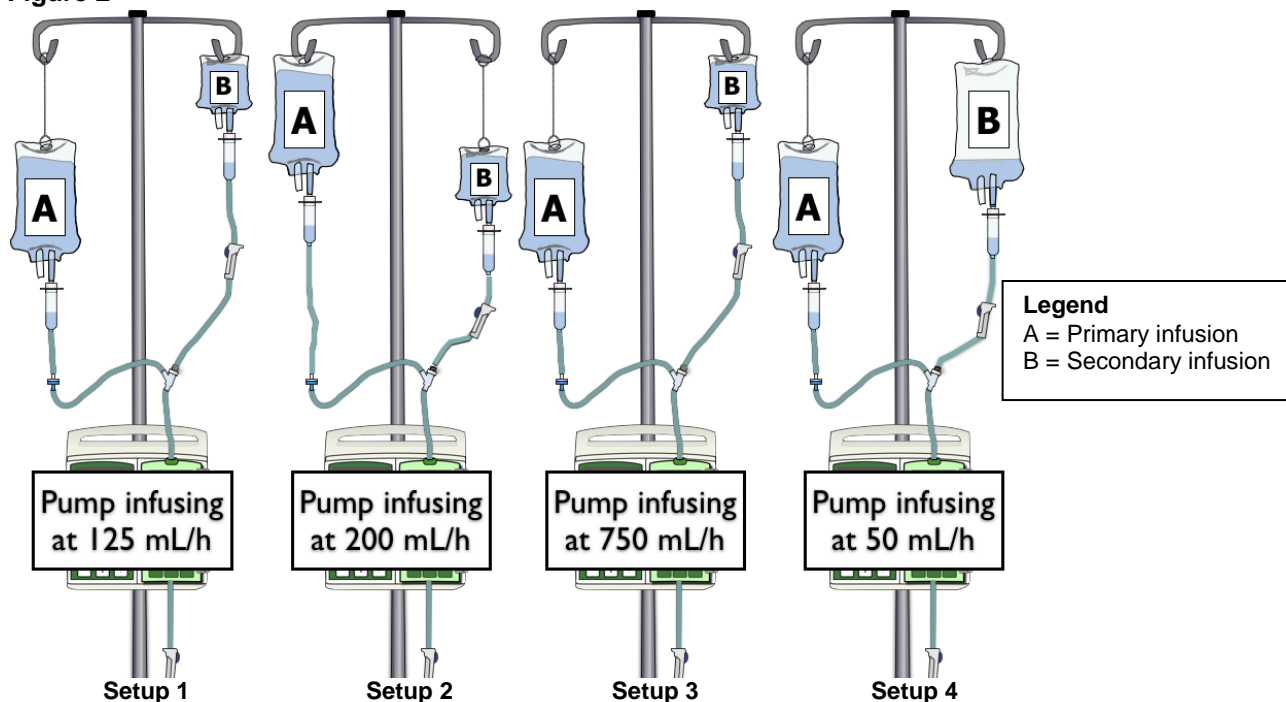
Test B

Figure 1



- Q1. What most likely describes the scenario in Figure 1?
- a) Drug A infusing at 100 mL/h
 - b) Drug B infusing at 100 mL/h
 - c) Mix of Drugs A and B infusing at 100 mL/h
 - d) Pump will alarm—no flow above pump
 - e) Pump will alarm—distal occlusion
- Q2. Will the back check valve allow flow from Bag A based on Figure 1?
- a) Yes, because IV Bag A is bigger than Bag B
 - b) Yes, because IV Bag A exerts equal or greater pressure compared to Bag B
 - c) No, because IV Bag A is bigger than Bag B
 - d) No, because IV Bag A exerts equal or greater pressure compared to Bag B
 - e) None of the above
- Q3. If the secondary IV tubing clamp is closed in Figure 1, what will the patient receive?
- a) Drug A infusing at 100 mL/h
 - b) Drug B infusing at 100 mL/h
 - c) Mix of Drugs A and B infusing at 100 mL/h
 - d) No flow will occur

Figure 2



Q4. If the infusion pumps in Figure 2 are programmed correctly, which setup(s) will infuse the contents of Bag B at the programmed rate? Please select all that apply.

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

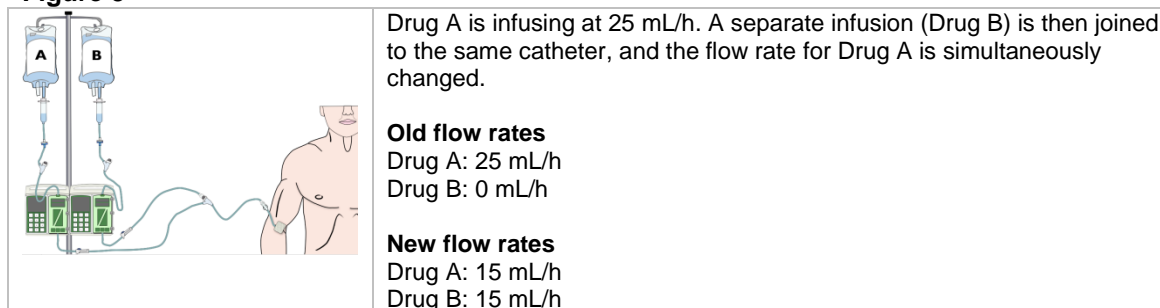
Q5. If IV Bag B in Figure 2 Setup 3 is connected to the primary IV tubing *below* the pump, which of the following could be true?

- a) Drug A infuses at 750 mL/h and Drug B free flows at an indeterminate rate
- b) Drug A infuses at 375 mL/h and Drug B infuses at 375 mL/h
- c) Drug A backflows into Drug B's IV tubing
- d) No flow of Drug A

Q6. True or false: When adding a new infusion to a bridge of existing infusions, the new medication immediately reaches the patient.

- a) True, because the catheter and bridge are not filled with the new medication
- b) True, because the catheter and bridge are filled with the new medication
- c) False, because the catheter and bridge are not filled with the new medication
- d) False, because the catheter and bridge are filled with the new medication

Figure 3



Q7. In the scenario in Figure 3 above, when the infusion rates are changed, what happens to the total flow rate the patient receives?

- a) The total flow rate to the patient increases
- b) The total flow rate to the patient decreases
- c) The total flow rate to the patient will briefly increase and then decrease
- d) The total flow rate to the patient will briefly decrease and then increase
- e) The total flow rate to the patient is unchanged

Q8. In the scenario in Figure 3 above, which of the following best describes what the patient receives when the flow rates are changed?

- a) Dose rate of Drug A reaching the patient is briefly increased followed by the intended dose rate of both drugs
- b) Dose rate of Drug A reaching the patient is briefly decreased followed by the intended dose rate of both drugs
- c) Dose rate of Drug A and Drug B reaching the patient immediately matches the intended dose rate of both drugs
- d) Dose rate of Drug A reaching the patient is unaffected by the change

Q9. An IV syringe push of 3 mg of drug in 3 mL is ordered to be administered over 5 minutes to avoid side effects (i.e., speed shock). The nurse administers the dose into an IV tube that is currently infusing sodium chloride 0.9% at a slow KVO rate. The priming volume from the injection port to the patient's vein is 5 mL. The nurse administers the IV push slowly over 5 minutes and then titrates the infusion pump to 999 mL/h for 1 minute (17 mL) to flush the line. What statement best describes what has just occurred?

- a) The patient received the medication as ordered
- b) The patient did not receive all the medication
- c) The patient received the medication too slowly
- d) The patient received the medication too quickly

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