

# MITIGATING RISKS ASSOCIATED WITH SECONDARY INTRAVENOUS (IV) INFUSIONS: AN EMPIRICAL EVALUATION OF A TECHNOLOGY-BASED, A PRACTICE-BASED, AND A TRAINING-BASED INTERVENTION

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## ABSTRACT

Multiple intravenous (IV) infusions are commonly used in the clinical setting to administer numerous fluids and medications to patients. *Secondary infusion*, also known as *piggyback infusion*, is a specific multiple IV infusion setup to deliver intermittent medications. Errors related to the setup and administration of secondary infusions have led to patient safety concerns[1, 2]. However, there is currently no study that specifically aims to empirically test the effects of interventions on the safety of secondary infusions in the clinical setting.

The objective of this experimental study was to empirically evaluate interventions that may reduce errors during the administration of secondary infusions. Three mitigating strategies (a technology-based, a practice-based, and a training-based intervention) were tested. Forty critical care nurse participants performed secondary infusion tasks in a high-fidelity simulated clinical environment, with and without interventions. The types and frequency of errors were collected. The effects of the interventions on workflow and the reduction of secondary infusion errors were investigated.

## BACKGROUND

*Secondary infusion* (or *piggyback infusion*) is a common method to administer medications intermittently to patients. During secondary infusion, a "piggyback" IV solution is connected to the primary infusion line and the two infusions are administered sequentially to the patient through a single IV access (Figure 1). In order to deliver the "right medication" during secondary infusion at the "right time" and "right

dose", all steps in the setup of the secondary infusion must be conducted correctly.

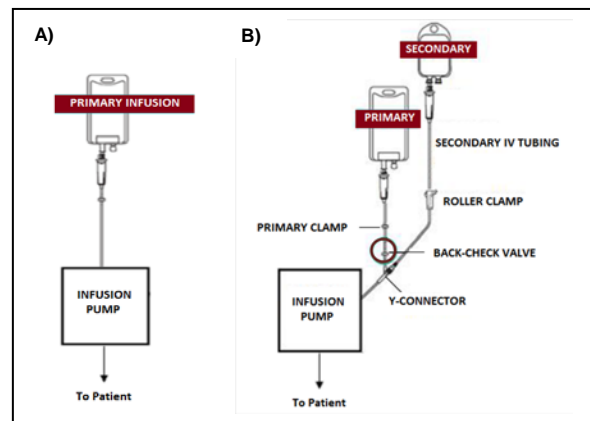


Figure 1: (A) Primary IV Infusion Setup. (B) Secondary Infusion Setup.

Figure 1 shows the setup of primary infusion and a secondary infusion. During secondary infusion, the secondary line is connected to the primary line above the infusion pump. The secondary infusion bag is hung above the primary infusion bag. This height differential is essential in establishing a higher hydrostatic pressure in the secondary infusion line than the primary line. This difference in hydrostatic pressure closes the back-check valve on the primary line and prevents the contents in the primary bag from infusing during secondary infusion. When the secondary infusion finishes, the primary infusion automatically resumes flowing.

## Patient Safety Concerns

A high frequency of secondary infusion errors has been reported. In 2008, 211 Multiple IV Infusion incidents were reported in the Manufacturer and User Facility Device Experience database (MAUDE) by the Food and Drugs Administration (FDA). Thirty-nine

percent of incidences were related to secondary infusion errors, of which 45% led to moderate and severe patient harm [3]. Nunnally and Bitan (2006) conducted a simulation study to investigate secondary infusion errors. They reported that clinicians were unable to complete secondary infusions correctly in 53% of cases in a simulated clinical environment [2]. Similarly, Trbovich et al. (2010) reported that the error rates of administering secondary infusion were as high as 44% in a simulation study[4].

### Secondary Infusion Errors

Table 1 shows the common secondary infusion errors types and risks reported by Trbovich et al. (2010) [4].

**Table 1. Common Secondary Errors & Risks**

Error Types	Error Description	Risks
<b>Secondary Clamp Errors</b>	Failure to open roller clamp on secondary line	Secondary infusion cannot infuse. Unintended delivery of the primary infusion at the secondary infusion rate.
<b>Concurrent Flow Errors:</b> - Bag Height Errors  - High secondary flow rate above pump limit	- The secondary IV bag is erroneously positioned below or at the same level as the primary bag. Or, insufficient height differential when IV bag is large.  - The secondary rate is set too high (500mL/h or higher)	- When there is insufficient head height difference between the primary and secondary bags, the back-check valve on the primary line will fail to close. The contents in the primary bag will continue to flow into the pump, mixing with the fluid from the secondary bag.  - The back-check valve cannot prevent flow from the primary infusion bag. The primary and secondary bags are infused simultaneously at an indeterminate rate.
<b>Connection Errors</b>	The secondary line is connected to the primary line below the infusion pump via a wrong port.	The pump cannot control the flow rate of the secondary IV fluid. Secondary infusion is delivered by gravity at an indeterminate rate.

Currently, clinicians must rely on memory (e.g., remember to open secondary clamp) and individual vigilance to make sure secondary

infusions are set up correctly. In spite of numerous secondary infusion errors, there has been no empirical study that focused specifically on testing the effects of interventions on the safety of secondary infusion delivery in the clinical setting

### Proposed Interventions

Secondary infusion failure modes were identified through task analysis, a market scan, interviews, observation of users performing tasks, and incident analysis [1]. Three interventions were then identified in consultation with an expert panel comprised of nurse practitioners, nurse educators, physicians, and pharmacists.

#### 1) Technology-based Intervention

A smart pump with a secondary clamp detector. It alarms users when a roller clamp is closed at the start of a secondary infusion.

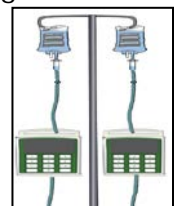
#### 2) Training-based Intervention

A new education module was created to address the lack of information on basic principles and known failure modes in previous secondary infusion training materials [1]. The education tool provides a 10 minute video training that dynamically demonstrates the key principles and rationales behind secondary infusion, including: 1) The basics of hydrostatic principles during secondary infusions, 2) rationale behind the height differential requirement, 3) concurrent flow issues due to high flow rate or large IV bags, and 4) the effects of the back-check valve.

#### 3) Practice-based Intervention

In this intervention, the primary and secondary infusions must be administered by two separate pumps. The advantages of this configuration are:

- No height differential is required between the primary and secondary bags
- There is no secondary roller clamp
- The secondary infusion cannot back flow into the primary infusion tubing



**Figure 2. Separate Pumps Intervention**

It was hypothesized that, in comparison to no intervention, the technology-based, the

training-based, practice-based interventions would each lead to reductions in secondary infusion errors. Furthermore, it was hypothesized that the practice-based intervention would be most effective at reducing secondary infusion errors because it eliminates the need for users to remember to open secondary clamps and adjust the height of the IV bags.

## METHODS

The effects of the proposed interventions were evaluated in a within-subject study, under a high-fidelity simulated clinical environment at the Human Factors laboratory at the Centre for Global eHealth Innovation, at the University Health Network (UHN) in Toronto, Ontario.

Forty critical care nurse participants were asked to perform equivalent secondary infusion tasks under 4 different intervention conditions:

- 1) With Technology-based Intervention
- 2) With Training-based Intervention
- 3) With Practice-based Intervention
- 4) No Intervention (Baseline)

To offset order effects due to the order that the interventions were presented, the order of intervention conditions was partially counterbalanced across participants. The nurse participants were separated into 6 different groups. Each group was asked to complete infusion tasks in different possible orders, designed to balance out the order effects. Two test facilitators recorded the types and frequency of errors, workflow deviations, and other qualitative observations behind the one-way observation mirror. Inter-rater reliability was assessed between test facilitators.

For the training-based intervention, participants received a pre-training and post-training questionnaire. The pre-training questionnaire was used to assess the participant's baseline knowledge of secondary infusion principles. The post-training questionnaire assessed their knowledge post-training. Participants also received a final questionnaire and an interview at the end of the study, where they were asked to comment on their preferences and concerns related to the interventions being evaluated.

## RESULTS AND DISCUSSION

The error types and trends observed in the study are summarized in Table 2.

**Table 2. Trends in Error Rates with Interventions**

Error Types	Error Rates - Trends (In Comparison to No Intervention)		
	Technology-based Intervention Smart Pump/ Secondary Clamp Detector	Training-based Intervention Education Module	Practice-based Intervention Separate Pumps Only
Secondary Clamp Error <sup>1</sup>	Significant Decrease *	No Significant Change	Significant Decrease *
Concurrent Flow Error <sup>1</sup>	No Significant Change	Significant Decrease *	Significant Decrease *
Bag Height Error <sup>2</sup>	No Significant Change	No Significant Change	Significant Decrease *
Connection Error <sup>2</sup>	No Significant Change	No Significant Change	No Significant Change

Note: \* P<0.01 was considered to be statistically significant

1) One-way repeated measures anova and paired sample t-test

2) Nonparametric Test (Cochran Q's and McNemar Test)

### Technology-based Intervention

Preliminary analyses show that the clamp detector led to a significant decrease in the frequency of secondary clamp errors in comparison to the baseline, where there was no intervention. It was effective in alerting participants to correct clamp errors when they forgot to open the roller clamp. In the post-experiment interview, participants rated this technology-based intervention to have a high level of effectiveness. However, contrary to its perceived effectiveness, the smart pump did not significantly reduce bag height errors or connection errors.

A noteworthy observation is that there was a high number of incidences of participants relying on the detector's reminder to open the roller clamp. This observation highlighted a possible increase in the frequency of errors when a new infusion technology or workflow is introduced.

### Training-Based Intervention

Participants were given pre- and post-training questionnaires to assess their knowledge gained from the education module. There was a significant increase in written performance scores after the training intervention. However, the education module

did not lead to significant reductions in secondary clamp errors, bag placement errors or connection errors when the participants performed secondary infusion tasks in the simulated critical care environment.

However, the training intervention led to a significant decrease in concurrent flow errors that are related to high secondary flow rates and height differential requirements for large IV bags. These two issues are failure modes that are not currently covered in standard nurse training materials [1]. These two issues also require nurses to understand the basic principles of hydrostatics behind secondary infusion. This demonstrates the need to design secondary infusion training materials that educate users on the principles of hydrostatics and possible failure modes, instead of prescribing just step-by-step instructions. In the post-experiment interview, many participants commented that this education module was effective and should be included in routine nurse training.

### **Practice-based Intervention**

This intervention requires the secondary infusion to be set up as an independent infusion, just like a primary infusion. This intervention removes the need for a secondary roller clamp and the need to adjust the heights of the IV bags. Therefore, it was found that this intervention significantly reduced secondary clamp errors and concurrent flow errors. It was also the only intervention in this study that led to a significant reduction of risks related to bag height errors.

However, it was observed that the use of a separate pump introduced new risks to the delivery of the "secondary" medication. After a "secondary" infusion finishes, residual fluid from the secondary bag remains in the IV tubing. The length of the infusion set in this "separate pumps" setup is 4 to 5 times longer than the typical secondary tubing. Firstly, if the user does not flush out the residual fluid and reuses the same tubing for the next "secondary medication", the residual fluid from the first "secondary" medication will be unintentionally delivered to the patient at the rate of new medication. Secondly, if a user disposes of the old IV tubing without flushing and delivering

the residual medication to the patient, there is a risk of under-dosing the patient. Both instances of accidental under-dosing and over-dosing of the "secondary infusion" were observed during the study. Further analysis is needed to determine the clinical impact of these unforeseen issues.

Preliminary assessment of the results from this empirical study provided some insights into the effects of the three proposed interventions. The practice-based intervention was the only intervention that significantly reduced both secondary clamp errors and concurrent flow errors. However, unforeseen issues related to residual volumes were found. Furthermore, out of the three interventions, the perceived effectiveness and the probability of use of practice-based intervention were found to be the lowest in comparison to the other interventions. Further assessment of the clinical impact and trends of the errors observed is needed to investigate the full impact of these interventions on the mitigation of secondary infusion risks.

### **ACKNOWLEDGEMENTS**

The authors would like to thank the support from Health Quality Ontario, the Institute for Safe Medication Practices Canada. This study is part of the Multiple Intravenous Infusions Study for the Ontario Health Technology Advisory Committee and Ontario Ministry of Health and Long-Term Care.

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