Smart Medication Delivery Systems: Infusion Pumps

Supplementary Report

Evaluation of Effective Smart Pump Design & Education Strategies

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Executive Summary

"Smart" infusion pumps are designed with drug specific safety software to help users detect and correct infusion programming errors. However, despite a cost of three to four times more than traditional pumps, achieving the safety benefits of smart pumps has been difficult[1]. To address this problem, the Ontario Ministry of Health and Long Term Care (MoHLTC) and the Ontario Health Technology Advisory Committee (OHTAC) commissioned the University Health Network's (UHN's) Healthcare Human Factors (HHF) team to:

(a) Collect evidence on the potential safety benefits of smart infusion pumps;
(b) Measure the adoption rate of smart pump systems by Ontario hospitals; and
(c) Develop strategies for Ontario hospitals to improve implementation of smart pump systems.

An initial report was completed in early 2009 (hereafter referred to as the "Primary Report") addressing these three core objectives[1]. It provided guidance to hospitals looking to migrate from traditional infusion pumps to smart infusion systems. The report found that smart pump system implementation must be viewed as a patient safety initiative rather than a stand-alone pump replacement initiative. A broad interdisciplinary approach is required to:

- Develop a smart pump strategy to achieve incremental benefits through system integration (e.g., bar coding capabilities)
- Standardize drug concentrations and dosing units
- Plan for routine drug library updates and log analyses; make every effort to implement a wireless network
- Support users for the cultural shift required to use smart pumps effectively (e.g., use dose rate field)

Without consideration of these factors, it is unlikely that the full benefits of smart pump technology will be achieved.

This supplementary report provides additional findings regarding the third objective: developing strategies for Ontario hospitals to improve implementation of smart pump systems. Through the use of two lab studies, field research and a literature review, this report describes how pump design and training can be optimized to help ensure successful pump implementation and uptake.

Assessment & Recommendations

This report presents three key ideas that lay the foundation for an effective smart pump implementation.

1. Prioritize Design Oriented Medication Safety Strategies

The acquisition of a well-designed smart pump is more likely to promote safe intravenous (IV) infusions than training programs. In general, error prevention strategies that change the system (i.e., design oriented) are more effective than those that rely on human vigilance and memory (e.g., training). Therefore, hospitals should place emphasis on the

smart pump acquisition phase of the recommended migration process to maximize the intended safety benefits of smart pump technology.

2. Acquire Design Features that Encourage Safe Infusion Programming

There is no perfectly designed smart pump commercially available that meets the needs of each organization's medication processes. As such, each organization should evaluate and acquire smart pumps based on their unique needs. However, organizations will benefit from smart pumps that utilize design features that have been shown to augment their effective and safe use. Some of these are summarized in the following recommendations:

1. **Smart pumps must encourage users to use the dose error reduction system (DERS). A workflow that defaults users into the DERS is ideal.** By automatically placing users in the DERS, hospitals maximize use of the drug library and therefore increase both safety and efficiency.

2. **The default programming parameters on the pump (e.g., dose rate, volume to be infused) should match the information provided to the end-user (e.g., drug order, IV bag label) and be presented in the same order.** This will help eliminate error prone unit conversions. Given the wide variation of prescribing practices, this may not be feasible in all circumstances, but is highly recommended when possible. To facilitate this process, manufacturers should consider allowing hospitals to customize the availability and sequence of parameters on data entry screens. Hospitals should select a pump that matches their prescribing requirements and/or seek to change prescribing practices (e.g., implement computerized physician order entry (CPOE)).

3. **Smart pumps should utilize informative and salient warning messages to optimize their effectiveness**. This is particularly important for limit alerts that are triggered when user entered parameters fall outside the safety limits defined in the DERS. Limit alerts should prudently use colour and audio to draw attention to the alert. They should also include clear text explanations of what has happened, the value of the limit that was violated, and intuitive user options.

4. **Smart pumps should ensure secondary infusion mode is easily accessible and the infusion mode (i.e., primary or secondary mode) should be clearly visible.** In addition, smart pumps should ensure that users can intuitively switch between modes as this further reinforces the understanding of which mode is currently being accessed.

3. Create Conditions that Enhance Staff Training

Training is a valuable component of implementation processes. If performed poorly, training sessions may fail to correct improper programming behaviour and provide minimal value in preventing medication error. Key recommendations regarding training include:

1. **Training should not be used as the primary response to error prone systems; it was found to be of limited effectiveness in remediating errors associated with smart medication delivery systems.** Our education-based experiment showed that users performed no better after focused educational training based on observed errors than users who received general training. Error reduction through the use of system changes that include forcing functions is likely to achieve better outcomes.

2. **Training sessions must provide trainees direct hands-on practice with a smart pump during the training session, a learning environment free from distraction, and assess trainees on their programming behaviour.**

3. **Training sessions should provide trainees with materials that are representative of clinical practice.** Sample drug orders should be representative of what users typically receive, drug libraries on the practice pumps should be identical or highly representative of their final version, and hospital policies and procedures regarding smart pump use (e.g., how to properly respond to limit alert messages) should be clearly explained.

All these recommendations highlight the need for further collaboration between pump manufacturers and healthcare providers and end users. Further collaboration will help enhance smart pump system designs and training programs, resulting in more effective and safe implementations.

HHF will continue to research the safety of smart pump systems with an added focus on the administration of multiple concurrent IV infusions. Multiple infusions increase the complexity and risks of administration due to the high number of pumps, channels, IV bags and tubing combinations that must be properly coordinated. Research in this area is particularly relevant for critical or intensive care areas where multiple infusions are common.

Abbreviations

Abbreviation	Definition
ADE	Adverse Drug Event
CCA	Clinical Care Area
CPOE	Computerized Physician Order Entry
CQI	Continuous Quality Improvement
DERS	Dose Error Reduction System
eMAR	electronic Medication Administration Records
HFET	Human Factors and Education Informed Training
HHF	Healthcare Human Factors
ISMP	The Institute for Safe Medication Practices
ISMP Canada	The Institute for Safe Medication Practices Canada
IT	Information Technology
IV	Intravenous
MAS	Medical Advisory Secretariat
MoHLTC	Ministry of Health and Long-Term Care of Ontario
OHTAC	Ontario Health Technology Advisory Committee
PCA	Patient-Controlled Anesthesia
REB	Research Ethics Board
UHN	University Health Network
VBT	Vendor Based Training
VTBI	Volume To Be Infused

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We also acknowledge the involvement of the hospital staff at the University Health Network (UHN) and in particular, Ms. Eliza To for her pharmacy advice and insights. Finally the authors would like to especially thank Dr. Patricia Trbovich for her hard work in executing the overall smart medication delivery system project.

1 Introduction

1.1 Issue and Motivation for Research

"Smart" infusion pumps have the potential to improve the safety of delivering intravenous (IV) medications. However, despite a cost of three to four times more than traditional pumps, achieving the safety benefits of smart pumps has been difficult. To address this problem, the Ontario Ministry of Health and Long Term Care (MoHLTC) and the Ontario Health Technology Advisory Committee (OHTAC) commissioned the University Health Network's (UHN's) Healthcare Human Factors (HHF) team to:

(a) collect evidence on the potential safety benefits of smart infusion pumps;
(b) measure adoption rate of smart pump systems by Ontario hospitals; and
(c) develop strategies for Ontario hospitals to improve implementation of smart pump systems.

HHF completed an initial report (hereafter referred to as the "Primary Report") addressing these three core objectives. This supplementary report aims to provide additional guidance for the third objective: developing strategies for Ontario hospitals to improve implementation of smart pump systems. In particular, it focuses on how pump design and training can be optimized to help ensure successful pump implementation and uptake. Given the complexity of the IV medication administration process, additional work regarding multiple infusions (i.e., secondary infusions, multiple channels, multiple pumps etc.) will be published in future reports.

1.2 Goals and Approach

This supplementary report aims to:

1. Assess the impact of pump design features on nurses' abilities to safely and efficiently administer intravenous (IV) medications and provide guidance on preferable design features.
2. Assess the strategies currently used to train smart pump users and provide guidance on the design and execution of training programs.

The Primary Report outlined a six phase roadmap to a recommended migration process, illustrated in Figure 0.

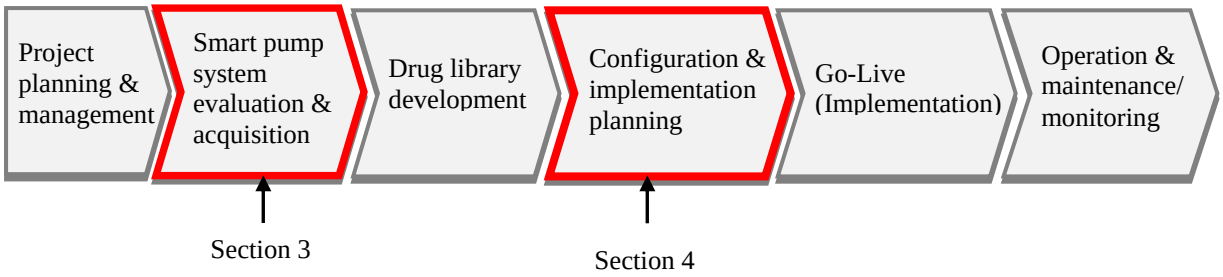

Figure 1 - Roadmap to Recommended Pump Migration Process

The two goals of this report are closely aligned with the two phases of the roadmap depicted. Specifically, section 3 of this report summarizes recommendations regarding preferable pump design features and thus plays an important role in "smart pump system evaluation & acquisition". Section 4 of this report discusses key elements to address in pump training sessions and is best considered in the context of "configuration & implementation planning".

Smart pump design and training were both investigated through experiments in a high fidelity simulated clinical environment with representative pump end-users, which are described in sections 3 and 4, respectively. The discussion of these topics, particularly education, extends beyond experimental results and is supplemented with evidence from the literature as well as through field work. This included interviews with various hospitals, an Ontario-wide hospital survey, observation of vendor training sessions and documentation, and site visits to hospitals. The field work is described in greater detail in section 4.

1.3 Scope

This report focuses on primary infusions delivered with large volume general infusion pumps, and to a lesser degree, secondary infusions on the same pump type. This report does not examine the technology or processes related to:

- patient controlled analgesia (PCA) infusions
- enteral feedings infusions
- ambulatory infusions
- syringe infusions

For further details on what infusion scenarios were examined in the experimental work, please refer to appendices 7.3 and 7.4.

2 Background

2.1 Summary of Smart Pump Technology

Medication errors, and in particular, IV errors are a significant cause of medical injuries[2-4]. While infusion pumps have greatly improved the accuracy and continuity of IV infusions, they are involved in 35-60% of the estimated 770,000 Adverse Drug Events (ADEs) that occur each year [5-8]. Most of these errors are the result of nurses manually inputting incorrect settings or parameters into the pump [5, 8, 9].

In an attempt to reduce infusion errors, manufacturers have developed pumps that have Dose Error Reduction Systems (DERSs), which include hospital-defined drug libraries with dosing limits and other clinical advisories integrated into the system (i.e., smart pumps). Rather than have nurses work with traditional general-purpose infusion pumps that have a wide range of acceptable programming parameters, smart pumps are designed with drug specific safety software to help nurses detect and correct infusion programming errors or prescribing errors.

When the dosage parameters are entered, the software checks to ensure the dosage values are within pre-determined dosage ranges set by the institution. If the parameters entered by the nurse are within the range allowed by the pump's drug library, the pump allows the infusion to begin. If, however, the parameters entered by the nurse exceed the specified limits in the pump's drug library, the pump will alert the nurse. The pump will provide either a "soft" or "hard" limit warning. A soft limit allows the nurse to override the warning and continue infusing the medication. Conversely, a "hard" limit requires the nurse to re-program the pump with parameters that are within the institution's specified limits prior to starting the infusion.

2.1.1 Mapping Smart Pump Workflow

Figure 2 provides a general overview of the workflow for programming a smart pump. The user will program a smart pump by first selecting the Clinical Care Area (CCA) and entering into DERS. The user will then select the drug name and concentration and enter the infusion parameters (e.g., dose rate, volume to be infused) before starting the infusion. The order and design of the programming subtasks can differ between smart pump models, but the overall tasks performed during programming are the same.

The programming subtasks vary slightly depending on whether the user is programming the first infusion on the smart pump or programming additional infusions. To incorporate all programming subtasks, the workflow in Figure 2 is reflective of a user programming the first infusion. Typically, subsequent infusions (e.g., on a second channel for multiple channel pumps or secondary 'piggyback' infusions) only require the user to enter DERS before starting to program the IV order; the user does not need to complete the other preceding steps indicated in Figure 2 (e.g., select new or old patient, select CCA).

It is important to note that the term “DERS” typically encompasses multiple aspects of the pump software such as: pump drug library (i.e. list of all drugs and concentrations), dosing limits, limit alerts, clinical advisories, key press logging etc. However, usage of the DERS system depends on the user’s adherence to entering the pump drug library during pump programming. References to “programming outside the drug library” are associated with the pump’s generic programming mode (i.e., programming without the aid of the DERS system). This is also termed “bypassing the drug library”[10].

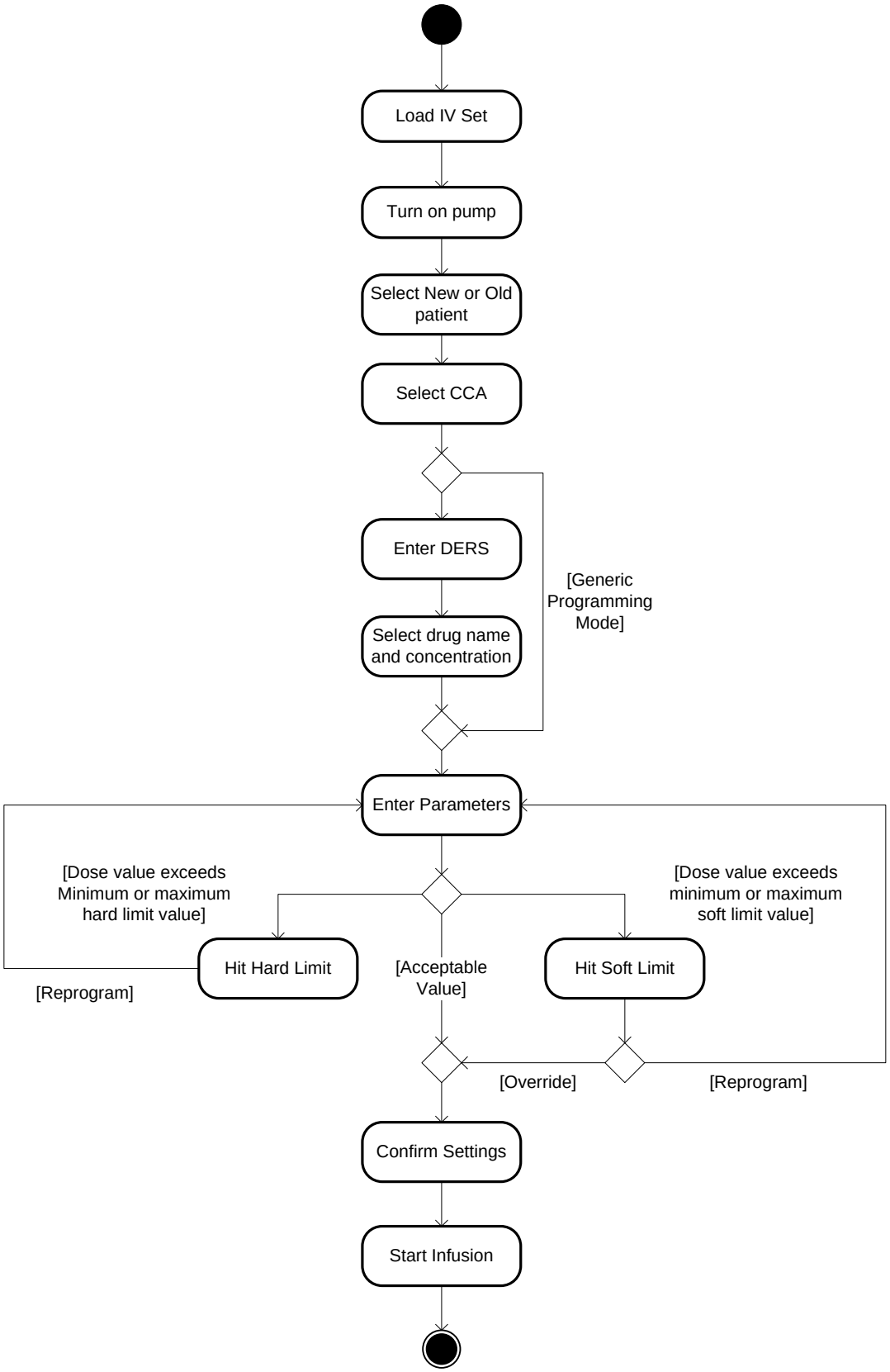

Figure 2 - General Infusion Programming Workflow on Smart Pump: Primary/First Infusion

2.1.2 Limitations of Smart Pump Technology

While smart pumps do help reduce miscalculated doses and/or data entry errors, the value of smart pumps is limited and dependent on implementation. As highlighted by the Primary Report, smart pumps alone do not protect against all errors: they do not help prevent errors related to administering the right drug, to the right patient, by the right route, at the right time. To address these errors, smart pumps must be integrated with other components in the medication process (e.g., bar code medication administration and positive patient identification systems).

The process of programming and administering IV infusions using smart pumps themselves is not without a number of issues. Rothwell's review of the literature identifies several issues in regards to smart pump design and groups them into five major categories[11]:

1. **Failure to program within the pump drug library:** If users program outside of the DERS there are no safety features available and smart pumps are essentially being used as the current error prone traditional pumps. Users may opt out of the DERS due to:
    a. Difficulty navigating menu pathway[12-15]
    b. Drug library composition[15, 16]
    c. Low perception of risk[12, 14, 17, 18]
    d. Easy access to generic programming mode[14, 19, 20]
2. **Data Entry Errors**: The following are known errors relating to smart pump data entry:
    a. Multiple of ten errors[7, 12, 14, 21-26]
    b. Transposition of rate and dose-rate errors[12, 14, 27]
    c. Unit errors[14, 18, 24, 26]
    d. Calculation errors
    e. Keystroke errors[22, 23, 27]
    f. Parameter selection errors
    g. Key Bounce errors[14, 28]
    h. Failure to correctly adjust dosage parameters after an infusion has started[24, 29]
3. **Overriding Limit Alerts:** The Primary Report revealed that when presented with a soft limit warning, users often do not respond in a safe manner, minimizing their impact. This is consistent with other research, which has shown that nurses often override soft limit alerts[21, 30].
4. **Complex Multi-Step Tasks:** Smart pumps, due to their software, increase the number of menus and options that users must navigate. This increases the complexity of initiating and modifying multi-step tasks such as:
    a. Secondary infusions[31, 32].
    b. Boluses[24, 25].
    c. Generic infusions[14, 33, 34].
5. **Multiple Infusions:** The Primary Report revealed that smart pump technology fails to address some of the known risks associated with secondary and multiple infusions (e.g., bag misalignment, tubing mix-ups, and failing to open the secondary clamp). Literature shows that confusion can occur via IV line mix-ups or navigating programming pathways[14, 31, 35-37].

For a number of these issues, the physical and software design of smart pumps have a strong role in mitigating these error types. Manufacturers and hospitals both have a role to play in optimizing aspects of smart pump design. For example, issue 1b suggests that the improper composition of the drug library (e.g., its completeness, relevance and the suitability of limit thresholds) may frustrate users leading them to program in the generic programming mode. Therefore, pump designers need to ensure drug libraries have sufficient capacity to include all infusion fluids and drugs used in large hospitals. Furthermore, hospitals need to continually monitor and refine the drug library content to ensure it matches current clinical best practice.

Given the complexity of IV medication administration, further research is needed to explore the above listed issues. In particular, future work on multiple IV infusions may be able to uncover further details and strategies to prevent errors related to infusions where multiple pumps and channels are involved as well as secondary infusions. HHF plans to study this issue in the future.

2.2 Hierarchy of Effectiveness

One error prevention framework found in the literature is particularly relevant to the topic of smart infusion systems. This framework is referred to as the "Hierarchy of Effectiveness"[38, 39] and was presented in a "Medication Safety Alert!" bulletin published by the Institute of Safe Medication Practices (ISMP)[40].

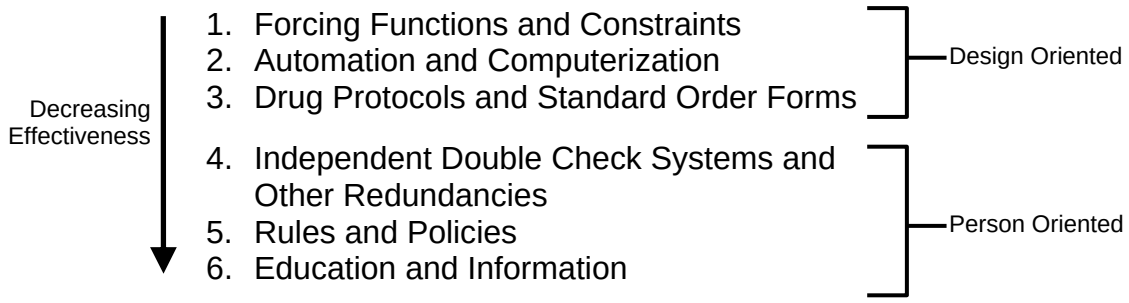

Figure 3 - Illustration of the Hierarchy of Effectiveness

Figure 3 categorizes various error prevention tools hospitals can utilize when attempting to reduce medication errors. Effective error prevention requires the utilization of strategies at all levels of the hierarchy. However, tools that change the system (i.e., design oriented) provide more effective and longer lasting safety benefits than those that rely on the vigilance of people[40], and as such, are placed at the top of the list. Smart pumps themselves utilize various strategies from the hierarchy. For example, the use of limit alerts serve as an automated independent double check (point #4 in the hierarchy) but can also force users to reprogram an infusion (e.g., hard limits act as a forcing function; point #1). While tools such as education and policy are at the bottom of the list, they still represent an important aspect of error prevention and should still receive adequate consideration.

There is little evidence that nurses who have committed errors associated with harm are different from their peers[41]. In addition, superior performance or treatment outcomes are not

clearly linked to nurses' level of experience[42]. This suggests that systematic/design issues affect all nurses regardless of experience and reinforces the concept that system design interventions are preferable.

Based on the hierarchy of effectiveness, it is recommended that hospitals should prioritize their efforts on selecting and configuring a smart pump that is intuitive and safe, which will help minimize reliance on less effective interventions such as training. However, as stated above, effective error prevention requires a well rounded approach, likely drawing from interventions at all levels of the hierarchy. As such, this report helps hospitals select a smart pump with recommended design features (section 3) and also provides recommendations to help design effective training (section 4).

3 Smart Pump Design

As previously described in section 2.2 (hierarchy of effectiveness), design oriented error prevention strategies are more influential in reducing errors than other strategies, such as training. Therefore, health care organizations can help minimize the potential for medication errors by maximising the effective use of safe design features (e.g., forcing functions such as hard limit alerts) when evaluating and acquiring smart pumps.

As such, the findings presented in this section are likely to be most useful for health care organizations evaluating and acquiring smart pump systems. While the acquisition of an effective smart pump system requires health care organizations to consider numerous technical, clinical, financial and human factors issues (see the Primary Report[1]), the information provided in this section contributes specifically to the human factors analysis of smart pumps. The human factors analysis of smart pump drug library and continuous quality improvement (CQI) software is beyond the scope of this work.

To this end, this section will provide human factors analyses of the various design elements that three different manufacturers have employed in their smart pumps. It is important to understand which design features are desirable, and for what reasons (e.g., safety, efficiency), in order to make informed decisions during the pump procurement process. Some design elements exist in numerous smart pumps on the market, and are likely to appear in future pump designs as well. Therefore, this analysis focuses specifically on the effectiveness of design features rather than ranking or recommending a preferred smart pump product. The design features observed in this study are based on three specific smart pumps. Given the complexities of smart pump design, the advantages and disadvantages of these features may change depending on how manufacturers implement them into their products. However, our current recommendations are based on how these features were implemented in the three designs studied. Hospitals should review the analysis and recommendations in this section to determine whether it is applicable to their clinical practices and/or pumps under consideration.

It is important to note that the findings in this section can also be used by current smart pump users to proactively highlight potential design risks with their current smart pumps.

This section of the report is divided into three groups:

1. **Section 3.1** explains the methodology used to conduct an experiment comparing smart pump designs. The evaluation was restricted to the physical and software design of the pumps as they pertained to administering an infusion. Other aspects such as drug library software and wireless functionality were not evaluated.
2. **Sections 3.2 to 3.6** utilize a two-part format. Each subsection will first describe the design features evaluated in the experiment as they apply to the pump programming workflow (**Market Options)**. Following Market Options, a discussion of statistically significant and/or safety related findings from the experimental work is presented (**Results and Recommendations**). Tables detailing all findings (e.g., statistically significant, safety related and efficiency related) can be found in the appendix (appendices 7.1 and 7.2). Note that section 3.2 differs from the other subsections

because it describes general design features that cannot be linked directly to performance measures. Therefore, instead of a "Results and Recommendations" section, a short description of key considerations is presented (**Discussion).**

3. **Section 3.7** briefly discusses mitigation strategies for hospitals who have already acquired a smart pump infusion system.

3.1 Methodology

A within-group study was conducted that compared three different commercially available smart pumps. The results of this study aimed to clarify the impact of various design features on infusion safety and efficiency. A detailed explanation of the experimental methodology is provided in the appendix (section 7.3).

In summary, twenty four nurses recruited from UHN in Toronto delivered seven IV infusions on each of three smart pumps. Thus, the experimental design was a 3 (pump model) x 7 (infusion scenario) repeated measures design. The order of the pump models and infusion scenarios were counterbalanced to avoid carry-over effects.

The infusion scenarios were completed in a high fidelity simulated clinical environment containing patient beds, mannequins, patient identification wristbands, IV poles, bags and tubing, and drug labels. Nurses received infusion drug orders in the same format as their typical practice. That is, physician orders were presented on an integrated computer physician order entry (CPOE) and electronic medication administration (eMAR) system to mirror current nursing practicing at UHN. For some unique drugs, paper orders are still used at the UHN, and in these cases, the standardized form was used instead of CPOE/eMAR to reflect current practice.

3.2 General Design Features

This section describes features of pump design that affect overall pump functionality and usability. In particular, three general design features are discussed:

1. Screen size and colour
2. Programming control schemes
3. Accommodation of multiple channels

Significant findings from the lab study cannot be attributed to any of these general design features because they impact multiple aspects of pump programming. There is interdependence between these general design features (which are predominantly hardware based) and the pump software. For example, small screen sizes can be used effectively if the pump software optimizes its use (i.e., less is more). Conversely, large screen sizes can be misused and consequently, communicate less effectively than a smaller screen. Given that the pump software for each phase of pump programming is discussed in subsections 3.3 to 3.6, this subsection will focus on the typical advantages and disadvantages of these general design features.

3.2.1 Screen size and colour

Market Options

The experimental study examined a spectrum of pump displays:

1. A “large” colour screen measuring approximately 17 cm tall and 13 cm wide (see Figure 4).
2. A “medium” sized colour screen measuring approximately 9.7 cm tall by 7.3 cm wide (see Figure 5).
3. A “small” wide screen with green text on a black background measuring 2 cm tall by 7.3 cm wide (see Figure 6).

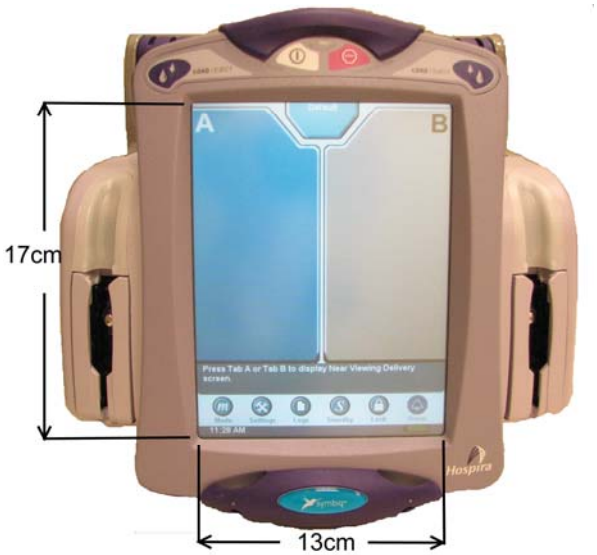

Figure 4 - Large Colour Touch Screen

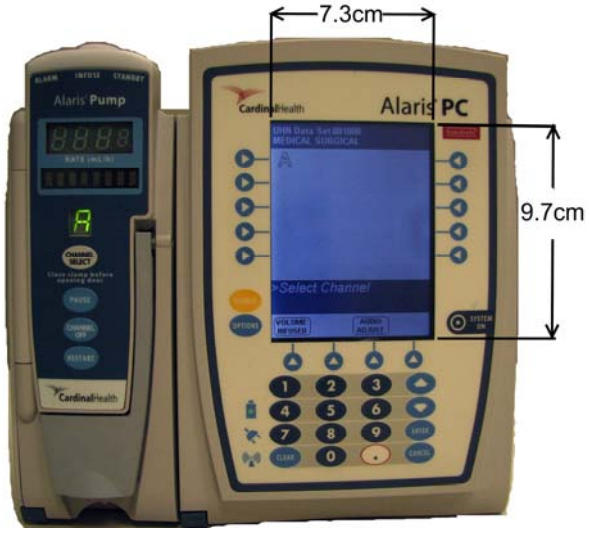

Figure 5 - Medium Colour Screen with Hard and Soft Keys

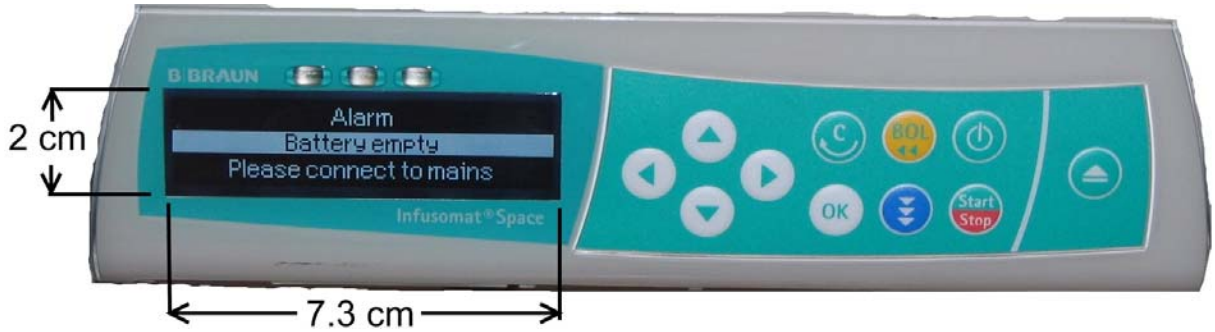

Figure 6 - Small Screen with Hard Key Arrows

Discussion

Screen size is best regarded for its ability to maximize the amount of information available to pump users as well as increasing the font visibility (i.e., font size) on the pump. In general, a large screen size allows pumps to provide more contextual information to users. The benefits of large screen sizes allow for flexibility in the layout and design of the screens in the pump programming sequence. For example, large screen sizes allow the “mode” the

pump is operating in to be displayed more prominently, error messages can be longer and more descriptive, and users may be able to view more entries from the drug library or options menus at one time. In addition, text can be larger, and in the case of colour screens, contrast/salience can be improved.

Screen size also has an impact on the pump's control scheme. For example, touch screens and contextual soft keys require screen space. Therefore, these two control schemes are more easily implemented on larger screens. However, large screen sizes tend to dominate the face of the pump and therefore minimize space for hard keys. The advantages and disadvantages of these control schemes are discussed in section 3.2.2.

The disadvantages of larger screen sizes can include increases in pump size and weight because a larger unit must be used to accommodate the screen. This has implications for intensive care units (ICU) or other clinical units where multiple pumps may be required for a single patient as it may add to mobility and space constraints for the patient.

In addition to screen size, another key screen characteristic is whether it can display colour. Colour provides more options for pump designers and appears to be a factor in effective limit alerts (see section 3.6).

Manufacturers and healthcare organizations should be aware that large displays and colour can be misused or inappropriately relied upon. Manufacturers should be particularly vigilant not to place too much information on the screen, as it can detract from the advantages of large screen sizes; sometimes less is more. Similarly, heavy reliance on colour can be confusing or overpowering and may present issues to those who have difficulty distinguishing colours, particularly as conditions vary throughout the hospital (i.e., fluorescent lighting, sunlight, low-light etc.).

Given these potential risks, the design of pump screens should not specifically focus on size and colour specifications, but rather that the pump software and control scheme complements the screen size. The pump screen should provide clear and unambiguous messages to the user without distracting them with extraneous design elements, regardless of its size and/or use of colour.

Table 1 on page 61 summarizes the issues relevant to screen size and colour. It also provides links to other report sections (i.e., analysis of task-based pump features) that are impacted by this design element.

Summary of Key Findings: Screen Size and Colour

Pump screens should be evaluated based on their ability to effectively communicate with end users, rather than on technical specifications (e.g., size and colour). However, the following are some general considerations:

- Large screen sizes provide more space to potentially:
  - increase text readability;
  - reduce scrolling (e.g., more entries can be displayed at once);
  - have additional contextual soft keys; and
  - have longer error messages and headings.
- Small screen sizes are typically associated with smaller and lighter pumps and increase the ease with which multiple infusions can be run in technology intensive areas such as ICU settings.
- Large screen sizes and colour can be powerful tools to communicate with users, but must be used with prudence to prevent creation of information dense or distracting screen designs.

3.2.2 Programming Control Schemes

Market Options

Three unique methods of pump navigation were observed:

1. **Touch Screen:** One pump utilized a large display that occupied most of the pump face (Figure 4). Users could touch the screen to select the options displayed. Additional hard keys were also present on the pump: "Load/Eject", "On/Off", "Emergency Stop" and "Silence".
2. **Hard and Soft Keys:** One pump used a combination of soft and hard keys (Figure 5). Spread across the left, right and bottom of the screen area arrows that point towards the screen. These are termed "soft keys" because their function changes based on what is displayed on the screen at the time. For example, an arrow might be lined up with an option called "Exit" when selecting the drug name from the drug library, allowing the user to exit the drug library, but on a parameter entry screen it might be lined up with an option "Drug Library" allowing users to return to the drug library. This pump also used a number of hard keys (keys that always provide the same function), including a full numerical key pad on a central unit and hard keys on modular pumping units (e.g., "Channel Select", "Pause", "Channel Off", and "Restart").
3. **Hard Keys Only:** One pump's chief navigation method was the use of four hard key arrows: up, down, left and right (Figure 6). The up and down arrows allowed users to scroll up and down lists, or increase/decrease numerical values (instead of a numeric key pad). The left and right arrows were often used to select a desired entry after the user had scrolled to it, or to shift between decimal places when entering a numerical value.

Discussion

Each of the programming control schemes possesses certain benefits and drawbacks at different phases of the infusion programming workflow. It is difficult to highlight one

scheme as more preferable to others because it relies heavily on its interaction with screen design and pump functionality.

Generally, user input involves menu selections and parameter entry. Common issues that emerge in these two processes involve identifying what to select or press to accomplish the intended action, and making sure the pump registers user input. Touch screens for example, excel in the former, clearly allowing users to point and press the desired options. However, touch screens if not calibrated correctly, can fail to properly register a user's input and this may lead to delays, confusion or even unintentional input. In addition, touch screens are likely to require a large screen size so that buttons or options are large enough to be pressed by a finger and also be spaced apart to prevent unintentional selections. This issue can be exacerbated when multiple pumps are on an IV pole and the viewing angle compromises the user's ability to accurately select button or options on pumps high or low on the pole.

In contrast, hard and soft key approaches require users to interpret what the pump screen is asking for, and then associate the correct key press with each option. Touch screens allow users to bypass this step because accessing the desired option is as simple as touching it. The process of translating user options to key presses can be error prone. For example, pump designs that unintentionally place options close to soft keys can lead users to assume that the soft key will select that option (instead users are required to press a hard key to access option). This error was observed frequently in one pump design

Hard and/or soft keys do have some advantages however. The use of keys minimizes the risks of input issues that are present in the touch screen design. In addition, hard and/or soft keys allow the screen size to be smaller because buttons do not have to be large for finger presses.

Table 2 on page 61 summarizes the various issues relevant to programming control schemes. It also provides links to report subsections where the control scheme may affect programming tasks.

Summary of Key Findings: Programming Control Schemes

- Touch screens can be intuitive to users. However, the screen may have difficulty registering user's screen touches.
- Control schemes that utilize hard keys or soft keys easily register user's key presses. However, they are more likely to place higher demands on users because users must translate user options to key presses, potentially resulting in errors.

3.2.3 Accommodation of Multiple Infusions

Market Options

Various approaches were employed by the evaluated smart pumps to manage multiple infusions. In the experiment, only two channels (i.e., two primary lines) were required. However, given that ICU settings tend to use more than two channels, these descriptions will describe how more channels can be added. The design approaches included:

1. **Modular System with Horizontal Channel Additions:** One pump used an approach where users could attach up to four pumping modules to a central unit. Modules are added onto the central unit on either its left or right size, thus expanding the pump horizontally. The central unit is where the majority of pump navigation and data entry occurs. Each module is accessed by pressing one of the module's hard keys, and then programmed from the central unit.
2. **Dual-channel Pump with Horizontal Channel Additions:** One pump inherently possessed two channels on its left and right side. The main screen is divided into two halves (each half corresponds to a channel). All access to and programming of each channel comes from the central pump screen. Additional channels require additional pumps; these pumps can be attached to each other at the side (so all screens face forward) to form a horizontal pump array.
3. **Single channel pump with Vertical Channel Additions:** One of the pumps evaluated was a small single channel pump. With the use of a pump "station", up to four pumps could be slotted into the station, in a vertical stacked manner, in order to provide multiple "channels". Each pump is programmed independent of the other.

Discussion

The different methods in which pump designs accommodated multiple channels have a number of impacts. This section is predominantly interested in how these designs affect pump users. However, it is important for health care organizations to also consider how these designs can affect equipment management concerns (i.e., module or pump storage, channel inventory usage, pump charging, pump station accessibility, IV pole availability). From the perspective of a pump user, key concerns include channel identification, pump or module size and weight, the number of pumps that can fit on an IV pole, and the ease in which IV tubing can be clearly attributed to specific IV bag and pump channel.

Modular systems allow time savings as more channels can be easily added without the need to repeat pump set-up and CCA selections. In addition, modules are light and small (although the central unit can be heavy and large). However, modular systems can cause confusion because users use one central unit to program multiple infusions. Furthermore, the addition or removal of modules may change the module identifiers, compounding channel confusion.

Dual channel pumps avoid this issue of changing module identifiers because they utilize dedicated pump channels. However, they lose the benefit of light and small module channels. Another drawback is that the use of more than two channels requires nurses to acquire and setup a new pump unit.

The pump design utilizing a small single channel pump stacked vertically offers a compact footprint that is not as prone to creating unbalanced IV poles in the horizontal approaches used by other designs. However, vertically stacking pumps results in fewer pumps being able to fit on one IV pole, forcing users to acquire additional IV poles and possibly a new pump station to hold new pumps.

Table 3 on page 63 summarizes the various issues relevant to accommodating multiple channels. It also provides links to report subsections where the organization of pump channels may affect programming tasks.

Summary of Key Findings: Accommodation of Multiple Infusions

- Modular systems allow time savings as more channels can be easily added without the need to repeat pump set-up. However, the addition or removal of modules can present challenges when channel identifiers change.
- Dual channel pumps can easily allow users to identify which channel is being programmed, but the addition of additional channels requires users to acquire a new pump which may have size and weight implications.
- Single channel pumps that are stacked vertically offer a more balanced and compact footprint on an IV pole than horizontal approaches, but are unlikely to fit as many pumps on the same IV pole.

3.3 Initiating an Infusion

Initiating an infusion consists of the following two major tasks:

1. Loading the IV set
2. Starting-up the pump and entering DERS

The following subsections summarize how the pump designs evaluated vary with respect to these two features. In addition, significant and/or safety-related findings from the lab study and recommendations regarding the initiation of an infusion are presented.

3.3.1 Loading IV Set

Market Options

There were a number of differences in loading strategies employed by the smart pumps in the experiment:

1. **Loading Mechanism:** Some pumps utilized a loading compartment that was powered by the pump and opened by key press. These powered compartments closed either on key press, automatically after a set period of time, or when the user physically pushed the compartment back into place. Other pumps used a manual approach where a latch would open and close the loading compartment.
2. **IV Set Complexity:** The complexity of the pump specific IV tubing/cassette differed greatly between pumps. Specifically, the IV tubings/cassettes varied in the number of fittings (i.e., clamps, clips, cassettes) and allowable insertion orientations that users must manually fit into the pump's loading compartment.
3. **IV Set Orientation:** The IV tubing can be inserted either vertically (as it hangs off the IV pole) or horizontally into the loading mechanism.
4. **Door Clearance:** The design of the loading compartments varied in how much clearance they provided between the IV tubing and the door/carriage, and therefore how precisely nurses had to fit the tubing into its proper location to prevent occlusions.

5. **Error Messages:** When pump powered loading compartments did not close properly, one pump design provided clear and specific feedback regarding the need to check the cassette/door while the other pump provided ambiguous feedback (e.g., "Invalid Line. Please Check Line"). The third pump design was not pump powered and only checked if the pump was loaded when the infusion was started; errors were reported with a scrolling message "Check IV Line".
6. **Forced Loading:** One pump did not allow users to initiate pump programming unless an IV set was loaded into the channel. Other pumps did not alert users that an IV set was missing until the infusion was started, allowing users to insert the IV set at any stage during pump programming.

Results and Recommendations

The experiment found that the loading process with the fewest steps was most effective. Statistically significant differences were observed between pump designs in terms of how quickly nurses could load the pump ($p<0.001$) and the percentage of nurses deviating from the ideal loading process ($p<0.05$)[11]. Therefore the design of the pump loading process has implications for efficiency as well as user frustration. Comments from nurses often mentioned frustration with or appreciation for the loading process depending on its design. Table 5 on page 65 summarizes all the key issues associated with loading the IV set.

Based on the statistically significant differences described above[11], it is recommended that the loading process utilize powered loading compartments that are opened and closed by the pump because users often had difficulty locking or closing the pump door on manual designs. However, powered loading compartments must be designed to open and close efficiently and minimize maintenance (e.g., from routine constant use) to prevent user frustration. It is also recommended that an IV set is comprised of a simple one piece cassette that easily slides into place in the loading compartment because this was the most intuitive to nurses and was quickest to complete. The cassette should be designed so that it fits into the loading compartment in only one way. Determining the correct cassette orientation is accelerated when unacceptable orientations clearly do not fit the loading compartment.

Loading the IV set poses a number of safety risks in terms of tubing occlusions or medication free flow. As such, it is recommended that loading compartments minimize the available slack in IV tubing to prevent the tubing from being occluded when the compartment is closed. Furthermore, it is important that accurate error messages are provided to users in the event of any mis-load situations. Literature provides an account of an unintended free flow incident which is due in part to an inaccurate error message[43]. These two recommendations may increase the detection rate of occlusions (alarms may not trigger until the nurse has left the pump) and increase the likelihood of the loading process being completed correctly.

Summary of Significant or Safety-related Findings: Loading IV Set

- ❑ Loading compartments that open and close automatically are preferred because they minimize user frustration associated with manual locking/closing mechanisms.
- ❑ The IV tubing should require minimal insertion points into the loading compartment. A one piece cassette that can slide into the loading compartment is preferred.
- ❑ The design of the loading compartment should minimize the risk of occluding IV tubing when closed. Similarly, any hard components on the IV tubing should not prevent the loading compartment from closing without triggering an error message.
- ❑ Loading error messages should clearly describe what error exists and appropriate actions should be suggested (e.g., Door not closed properly. Press "Load" to open door and try again).

3.3.2 Pump Start-up and Entering DERS

Market Options

It is important to note that the DERS encompasses multiple aspects of the pump software such as: pump drug library (i.e. list of all drugs and concentrations), dosing limits, limit alerts, clinical advisories, key press logging etc. However, usage of the DERS system depends on the user's adherence to entering the pump drug library during pump programming. Therefore, from the perspective of the end-user, accessing the drug library is equivalent to entering the DERS.

The pump start-up phase of programming contains relatively standard choices across smart pumps. Pumps must be turned on, the user must specify whether previous settings are to be reused (i.e., same patient information, same CCA etc.), and if not, the user must enter the necessary information so that the appropriate drug library is loaded. However, differences were observed in the execution of these steps, such as:

1. **Selection Order:** Pumps differed in the order that options were presented to users (e.g., choosing to use a drug library and then selecting a CCA, or selecting a CCA and then choosing a drug library).
2. **DERS Entry Style:** Three entry methods were observed (see Figure 7):
    a. **Default:** One pump defaulted users into the DERS by making selections from the drug library the only way to initiate the programming of a primary infusion.
    b. **Select:** One pump gave a few options that the user could select: drug library, fluids library or generic programming.
    c. **Opt-in or out:** One pump asked users if they would like to use the drug library or not (if no, nurses were placed in generic programming mode).
3. **Option Descriptions:** Pumps varied in how options were described:
    a. **New Patient:** In two of the pump designs, the user was asked whether the pump was being prepared for a "New Patient?" whereas the third design asked users whether they wanted to "Use last therapy?"
    b. **Drug Library:** In one pump design, access to the drug library came from affirmatively answering a question stated as "Enter drug library?" while another design required users to press a button labelled "Select Infusion".

In another design, users selected a “Guardrails Drug Library” or “Guardrails Fluid Library”, where the term “Guardrails” reflects the DERS system as implemented by that particular manufacturer. This was also the only pump design that separated IV fluids and IV drugs into two separate library options.

The infusion scenarios used in the experiment focused on new patients only, so the workflow in Figure 7 depicts that particular path of the pump’s workflow. Figure 7 provides some examples of the variations in the order of start-up steps between pumps as well as how entry into the DERS is accomplished.

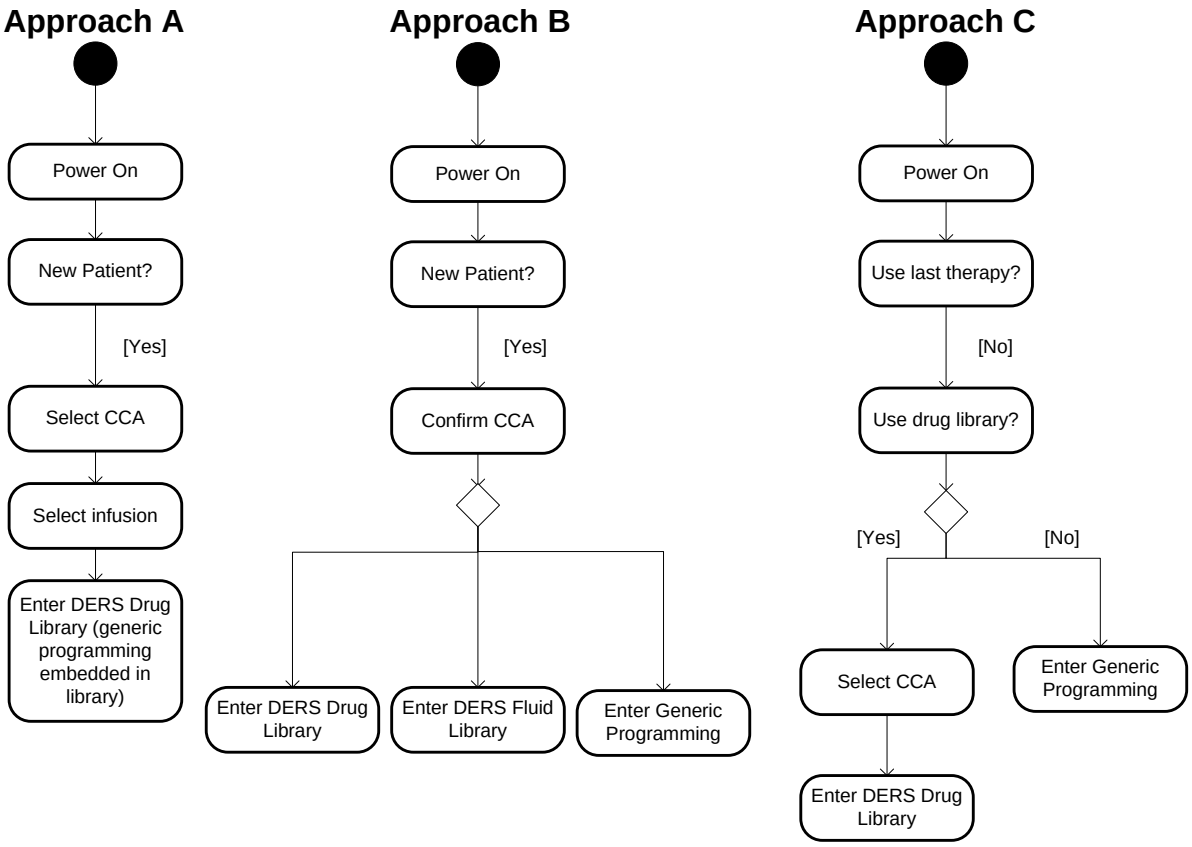

Figure 7 - Three Examples of Pump Start-up and DERS Entry Workflow

Results and Recommendations

No significant differences were observed between pump designs in terms of the safety and efficiency of starting-up the pump and entering the DERS. Table 6 on page 68 summarizes all the key issues uncovered with starting up the pump and entering the DERS, most of which can be traced to issues with the control scheme (see section 3.2.2). In addition, many of the design choices in this phase of programming affected the ability of nurses to access generic programming (see section 3.4.2).

During the experiment, DERS use on all three designs was superior (approximately 1-4% of infusions were programmed outside the DERS) to rates published in literature (25% to 85%

Therefore, it is recommended that pump designs encourage, or even force users, into the drug library (e.g., default users into the DERS). This recommendation increases safety because it increases the likelihood of drug library use.

Despite the lack of statistical differences between pump designs, some potentially troubling trends were observed with regard to drug library compliance for maintenance fluids. For example, the pump design that separated IV drugs from fluids had an increased number of maintenance infusions (i.e., normal saline) delivered in generic programming. Normal saline is usually acknowledged as an IV fluid, yet during the experiment, nurses occasionally chose to utilize generic programming, despite being informed in training to reserve that functionality for emergencies or for infusions that could not be completed from within the pump's library. Another example involves nurses being uncertain as to whether heparin or insulin would be found in the drug library or fluids library, sometimes causing them to search both, leading to delays. Serious safety risks exist when users begin to choose generic programming over the drug library voluntarily.

Therefore, it is recommended that if multiple drug libraries exist, clarity must exist in regards to the purpose and content of each library (i.e., additional descriptors may be required for each option if this approach is taken) otherwise delays and frustration may occur as nurses search through both libraries.

Summary of Significant or Safety-related Findings: Pump Start-Up and Entering DERS

- ❑ The designs evaluated did not affect nurses' ability to enter the DERS or select the CCA.
- ❑ A DERS system that navigates users into the DERS by default is preferred.
- ❑ If users are required to select between multiple drug libraries, the purpose and content of each library should be clear.

3.4 DERS Pump Programming: Primary Infusion

After pump start-up and entrance into the DERS, the process of programming a primary infusion consists of:

1. Selecting a drug and concentration. If the drug is not in the drug library, users will have to access the generic programming mode.
2. Entering parameters (i.e., patient weight, rate, VTBI etc.).

The following subsections summarize how the pump designs evaluated varied with respect to these phases of infusion programming. Discussions of significant and/or safety-related findings are presented and recommendations are provided at the end of each subsection.

3.4.1 Drug and Concentration Selection

Market Options

Each of the three pumps evaluated in the experiment utilized unique design features to facilitate drug and concentration selection. Three key differences were observed between pump designs:

1. **Navigation:** Pumps varied in how nurses could navigate through the list of drug entries in the pump library. Designs included variable speed scrolling where nurses' could scroll up and down the list at increasing speed (from one drug entry per key press up to four) as well as the use of alphabetical shortcuts where nurses' would be brought closer to the desired drug name.
2. **Selection:** Some pump designs elected to select drug and concentration at the same time (they are paired together for each entry in the drug library) versus selecting the drug first, and then selecting concentration on a separate menu.
3. **Confirmation:** One pump utilized a confirmation screen asking nurses to confirm whether the drug and concentration selected were correct while the other pumps did not. Note that one pump utilized a confirmation screen later in the programming sequence to confirm all data entry (e.g., drug, concentration, volume to be infused, dose rate, etc.) (see section 3.4.3).

The navigation workflows studied are shown in Figure 8.

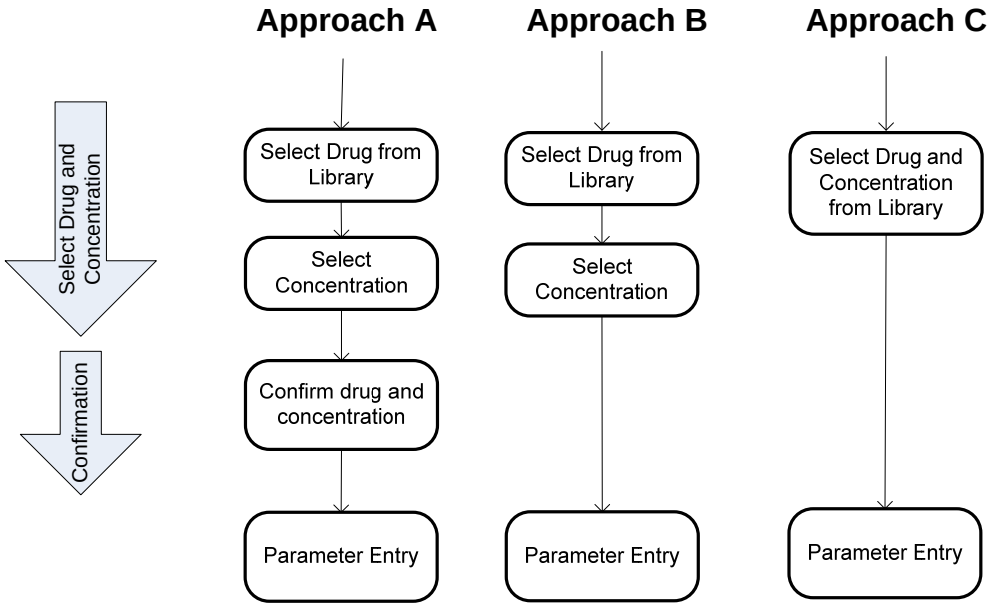

Figure 8 - Illustration of Three Drug and Concentration Selection Workflows

Results and Recommendations

There were no significant differences in measures of task time and error rates across the smart pump models[11]. Nurses rarely selected the wrong drug or concentration, but those who did quickly realized their error and corrected it. However, in one pump design (Approach C), error correction was more difficult and in three cases, nurses failed to correctly complete the infusion due to confusion with the control scheme[*]. Table 7 on page 70 summarizes the key issues associated with drug and concentration selection.

Despite the lack of statistical significance, some general good design principles were deduced to potentially improve safety. Overall, it is recommended that navigation through this programming section should emphasize the selection of a drug name first, followed by selection of concentration on a second menu. The separation of these two characteristics reduces the amount of scrolling that nurses must perform to find the correct drug entry. This also has the benefit of lowering the perceived effort of using the pump's drug library, increasing compliance. Finally, this reduces the likelihood of selecting the wrong entry on similar items (i.e., Vancomycin 6mg/100mL versus Vancomycin 8mg/100mL), which could result in inappropriate infusion dosing limits.

For health care organizations where a pump has already been selected, it may be possible to adjust the terminology used in the drug library to minimize the need for scrolling. This is highly dependent on the customizability and flexibility of the pump's drug library software. Health care organizations may be able to creatively manipulate terminology and existing menu options in the drug library in order to facilitate the development of new workflows. However, it is important that new workflows are adequately tested for intuitiveness and explained to staff. Given the resource intensive nature of this strategy, health care organizations should consider the cost benefit ratio carefully. Alternatively, health care organizations can utilize training to ensure nurses understand the pump's scrolling functionality and any shortcut features.

Summary of Significant or Safety-related Findings: Drug and Concentration Selection

- ❑ Selection of drug and concentration should occur on separate menus.

3.4.2 Accessing Generic Programming

Nurses may have to program an infusion using generic programming in some unique cases (e.g., drug is not in the drug library or emergency situations). Generic programming takes place outside of the DERS, and therefore there are no safety limits similar to current traditional infusion pumps. No drug or concentration selections are required, so the programming process is faster. For this reason, users may be tempted to utilize generic programming if compliance with the drug library is considered time consuming, tedious or not valuable. This process is known as "bypassing"[10] because the safety features of the pump are being bypassed, and is typically discouraged in order to maximize the safety features of the pump.

[*] Refer to Table 2 on page 61, disadvantages of "Hard Key Arrows", for discussion of this control scheme issue.

This section is discussed here because it typically occurs after users do not find a drug entry that matches their needs and must "exit" out of the drug library to access generic programming.

Market Options

Accessing generic programming is highly dependent on how the user enters the DERS as it is typically at this point where they are offered the option not to use the DERS. Based on the pumps evaluated in the experiment, there are two different processes to enter generic programming:

1. **Bypassing the DERS:** Users may opt to program an infusion in generic mode at the outset of programming an infusion, without first verifying whether the drug and concentration are in the drug library. The three design options evaluated to enter generic programming upon initial infusion programming are:
    a. **Negation:** On one pump, users gained access to generic programming by choosing not to enter the DERS. For example, the pump prompted the user to "Enter drug library?" and the user responded "no" to enter generic programming.
    b. **Selection:** One pump presented three options to users: 1) Drug Library, 2) Fluids Library and 3) Generic Programming. In this case users needed to select option 3) to enter generic programming.
    c. **Defaulting:** One pump required users to select a drug entry from within the drug library (e.g., "Other Drug" or "Generic") to access generic programming. That is, users were placed in the DERS by default, but entered generic programming by exiting the DERS from within the drug library.
2. **Exiting Drug Library:** In some cases, users may realize the drug library does not contain the desired drug or concentration and must exit the DERS in order to access generic programming. There were three different methods used by the pumps studied:
    a. **Contextual Soft Key:** One design offered an "exit" soft key in the drug library, which returns users to the main screen where the infusion can be initiated anew (users can then choose to bypass the DERS as described above).
    b. **Hard Key**: One design required users to press a "correction" or "undo" hard key (in the drug library), which allowed users to navigate backwards through the programming sequence, as necessary, to bypass the DERS.
    c. Drug Selection: One pump design placed users into the DERS by default (i.e., 1c), but users could select a drug entry that represented generic programming (e.g., "Other Drug" or "Generic" drug names).

Results and Recommendations

There were statistically significant differences between two of the pump designs evaluated in terms of users' success rate in accessing generic programming ($p<0.001$)[11], but not users' completion time. Table 8 on page 72 summarizes the findings related to this high performing design.

In general, it is recommended that the option for generic programming is embedded in the drug library (i.e., option 1c in Market Options) as it simplifies pump workflow and is demonstrably superior to the other approaches evaluated. Furthermore, embedding this option within the drug library allows the pump to default users into the DERS, making bypassing the library more difficult. In the experiment, the pump design that embedded generic programming in the drug library required users to select "Other Drug" from the drug library (note: the drug list was ordered alphabetically). However, it is possible to configure the library so that "Other Drug" is at the top of the drug list. This increases the accessibility of generic programming and consequently, increases the inappropriate use of generic programming. While, it is important that generic programming is accessible when required, it should not be easier than accessing and using the drug library. but no easier than the intended safe use of the drug library. This will help ensure that generic programming is used appropriately and responsibly.

Health care organizations may be tempted to add a new drug with no safety limits in their drug libraries to simulate these recommendations, but should note that the programming process may not be the same as the pump's genuine generic programming mode (e.g., users may have to enter a concentration). Differences between "simulated" generic programming and actual generic programming may result in confusion between nurses, and safety issues, particularly if generic programming is also used in emergency situations.

Summary of Significant or Safety-related Findings: Accessing Generic Programming

- ❑ It is preferable that an option for generic programming is placed inside the drug library, but it should not be immediately accessible.
- ❑ The process of exiting the drug library should be simple and intuitive. One successful approach is a soft key labelled "Exit" within the drug library.

3.4.3 Parameter Entry and Infusion Start

Market Options

The design of how users enter infusion parameters (e.g., volume to be infused, dose, rate, patient weight, etc.) is critical to correct pump programming, yet a number of key characteristics separate the pump designs evaluated (see Figure 9):

1. **Patient Weight Field:** One pump placed patient weight on the parameter entry screen at all times and simply "greyed" it out when it was not applicable. The other two designs used a dedicated patient weight screen. This screen did not appear for non weight-based drugs in one design, but in another design it always appeared because it served two functions: data entry of patient weight (only selectable for weight-based drugs) and confirmation of other infusion information (e.g., total drug amount, diluent volume, concentration), including dose per weight (i.e., mg/kg) based on the patient weight entered, if applicable.
2. **Infusion Specific Fields**: Two pump designs utilized a general parameter entry screen that applied to all infusion types, and allowed users to program any parameters of their choice. The remaining pump design limited programming to specific parameter entry fields depending on whether a continuous or intermittent

infusion was being administered; some fields were not present (e.g., duration for a continuous infusion). Of the fields that were displayed, some were not programmable unless the user took steps to enable them. The fields that were not immediately programmable were still displayed, allowing users to see their value (automatically calculated after the user had entered other parameters). Fields requiring data entry were outlined with a rounded rectangle.

3. **Order of Fields:** Pumps displayed parameters in a different order on the screen (e.g., volumetric rate as the first option instead of dose-rate).
4. **Calculated Fields**: Pumps typically auto-calculate the remaining parameters on the screen after the user has entered the requisite information. However pumps varied in whether VTBI was recalculated or remained static as the user had programmed.
5. **Viewing Fields**: One pump design required nurses to scroll downward in order to see all available parameters to program while other designs showed all parameters on the screen without scrolling.
6. **Field Terminology:** All pumps used the term *dose* to refer to dose-rate rather than total dose.
7. **Format of Duration Field**: When programming duration, two pumps separated the fields for hours and minutes. The remaining pump used a single field and labelled the data entry format (e.g., hh:mm).
8. **Confirmation screen:** One pump provided a final confirmation screen after data entry, summarizing all information entered by the user up to that point.

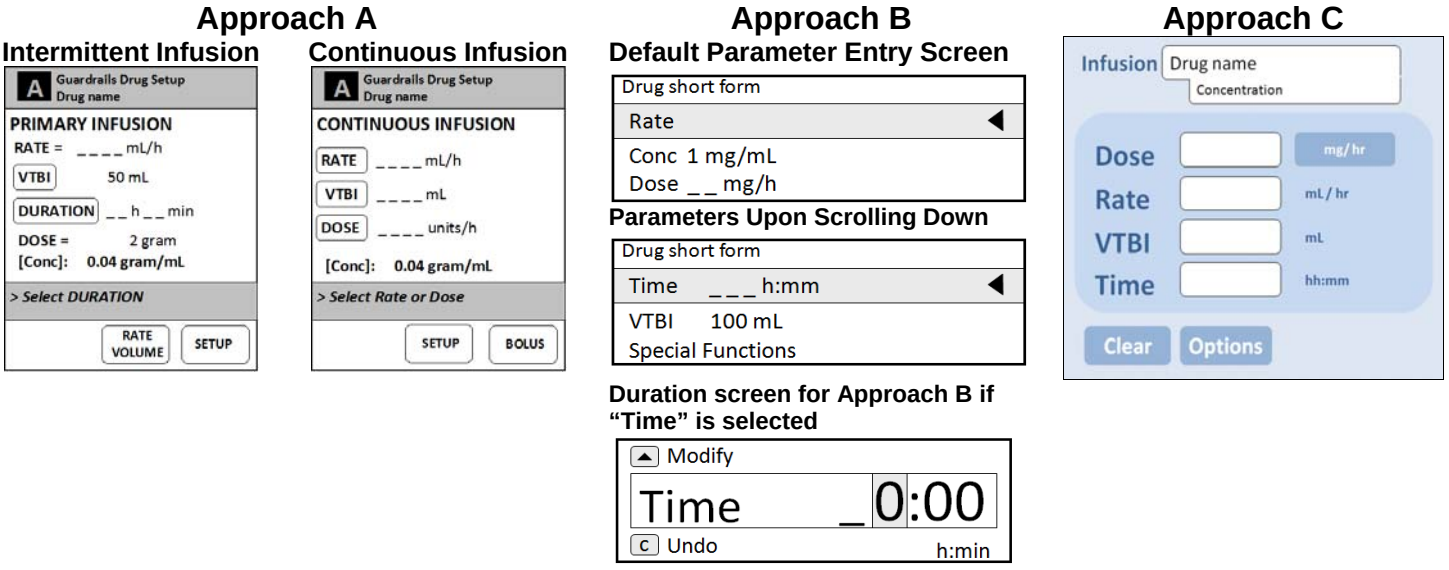

Figure 9 - Illustration of Three Different Parameter Entry Screens

Results and Recommendations

The success of users in entering infusion parameters is highly correlated to overall infusion success. As a result it is important to consider the issues in this section carefully. Table 9 on page 74 summarizes all the key issues associated with parameter entry.

Experimental results found no significant differences in parameter entry success between pumps for continuous infusions (nurses achieved an 80-90% success rate using any pump). However, significant differences in parameter entry success did exist for intermittent (p=0.05) and approached significance for secondary infusions (p<0.06)[11]. For example, differences of up to approximately 30% in task success rate were observed between the intermittent parameter entry screen of Approach A compared to Approach C (Approach C performed more poorly). This is likely because:

(a) The intermittent infusion screen used in Approach A limited programmable fields to VTBI and duration by default (which was specifically provided in the drug orders used in the experiment), whereas all programming fields were available in Approach C. In addition, other fields (e.g., rate) were not programmable without further enabling steps. This resulted in a screen that encouraged direct transcription of parameters from available information (e.g., drug order) instead of parameters prone to calculation error.

(b) Users were more likely to mistakenly enter total dose (e.g., mg) instead of dose-rate (e.g., mg/h) in Approach C. This is because the field is labelled dose, but users are required to enter dose-rate (e.g., mg/h).

(c) Users often noticed errors (such as the one described in (b) above) in the auto-calculated duration field in Approach C. Attempts to correct duration by users resulted in the pump re-calculating VTBI instead of volumetric rate or dose-rate. Users would then attempt to correct the VTBI and become trapped in a programming loop because this would restore the incorrect value to the duration field.

Conversely for continuous infusions, both Approaches A and C allowed dose-rate and volumetric rate fields to be programmable, and no differences in task success rate were found.

For all infusion scenarios, it was possible for nurse participants to transcribe the necessary parameters from the drug order to the pump, but nurses often preferred to calculate additional parameters (e.g., rate) themselves. Calculation errors across all pumps occurred approximately 6-9.5% of the time, with less than half being caught by the nurse or smart pump. However, the nature of many of the calculation errors were that of an under dose and within the soft limits, which may explain the low rate of detection. In addition, when nurses transcribed parameters from the drug order to the pump, nurses transcribed the value incorrectly in 4-5% of infusions. This indicates that errors are likely to occur regardless, even if the task involves transcription only. Nevertheless, transcription is preferred as it is less error-prone than calculation. This view is supported by the statistically significant findings described above.

In summary, the following is recommended based on the statistically significant findings and/or observed potential safety issues:

- **Infusion Specific Fields:** The default available programming fields should match the parameters provided to nurses (e.g., drug orders, drug bag labels, IV manual) for each infusion type (i.e., continuous and intermittent infusions). This is because the use of transcription as described above minimized the risk of incorrect parameters being entered into the pump. The value of transcription instead of calculation is also

thoroughly discussed in the Primary Report[1]. However, health care organizations should be aware that this recommendation may not be feasible in some cases (e.g., complex therapies that require titration, last minute changes, and/or verbal orders). However, as much as possible, this recommendation should be applied to the majority of standard orders.

- **Order of Fields:** The order of fields on parameter entry screens should match the order of parameters provided in the drug order and IV bag label. This finding is intended to improve both safety and efficiency because it will assist nurses' ability to directly transcribe drug order information to the pump. Direct transcription prevents calculation errors and reduces the likelihood of parameters being entered in the wrong field (e.g., entering dose rate in the volumetric rate field, and vice versa, which was an observed issue).
- **Calculated Fields:** Auto-calculation of parameters should not change VTBI. Pumps that recalculate VTBI may result in confusing programming loops as described above. There is a risk that infusions could be started with incorrect parameters[45]. In addition, this has impacts on programming efficiency.
- **Viewing Fields:** All programmable parameters should be visible on the screen without the need for scrolling. It is important that users be able to see all parameters on the screen at the same time without scrolling because it allows them to see what parameters are available and observe changes resulting from pump auto-calculations. This has potential impacts on safety and efficiency because users will not have to repeatedly scroll to view parameters. In addition, users may be more likely to select the parameter that allows order transcription, preventing calculation errors.
- **Field Terminology:** Terminology describing each parameter should be clear to users to prevent data entry errors (e.g., dose and dose-rate confusion as described above). This issue presents safety concerns because infusions may be started with incorrect parameters, or at best, result in delays if users realize the error and/or encounter a limit alert.
- **Format of Duration Field:** The duration field should clearly distinguish data entry for hours and minutes (e.g., having separate fields for hours and minutes). Clarity of what units are being entered reduces the likelihood of errors (e.g., some nurses entered 60 hours instead of 60 minutes on one pump design) and thus impacts safety.
- **Confirmation Screen:** There is no conclusive evidence that the use of a confirmation screen increased safety during parameter entry.

Summary of Significant or Safety-related Findings: Parameter Entry and Infusion Start

- ❑ The default programmable parameters on the pump should match those provided on the drug order and IV bag label, and be presented in the same order. However, all parameters should be visible and accessible with additional action.
- ❑ The "volume to be infused" parameter should not be recalculated by the pump when other parameters are changed.
- ❑ All programmable parameters should be visible on the screen without the need for scrolling.
- ❑ Terminology describing each programmable parameter should be clear to users (e.g., clarify dose-rate from total dose).
- ❑ Time/duration data entry should clearly distinguish between hours and minutes.

3.5 DERS Pump Programming: Secondary Infusion

Overall, programming a secondary infusion is similar to that of a primary infusion. However, the following are two key differences:

1. Access: Secondary infusions can only be programmed once a primary infusion has been initiated. Consequently, accessing secondary infusion programming differs from initiating a primary infusion.
2. Parameter Entry: Secondary infusions sometimes have different parameter entry screens and data requirements from primary infusion to help distinguish the infusions from each other.

The following section summarizes how the evaluated pump designs vary with respect to these two differences. In addition, significant and/or safety-related findings and recommendations on preferred design features are presented.

3.5.1 Accessing Secondary Infusion Programming

Market Options

Pump designs for initiating a second infusion varied in several dimensions:

1. **Primary infusion status:** The secondary infusion mode on some pumps was only available when the primary infusion had been stopped, while other pumps allowed access regardless of infusion status.
2. **Navigation:** On some pumps, the secondary infusion mode was placed inside a submenu that was accessible from the primary infusion screen. Other pump designs placed the secondary infusion mode option directly on the primary screen (i.e., not in a submenu).

Results and Recommendations

Statistically significant differences were observed between two of the pump designs in terms of successfully accessing the secondary infusion mode ($p<0.001$)[11]. Table 10 on page 79 summarizes the key findings.

It is recommended that the secondary infusion mode option is directly accessible from the primary infusion screen, and is available whether the pump is running or stopped. The ability to access the secondary infusion mode regardless of the primary infusion status had safety and efficiency implications. This is because the pump design where the primary infusion had to be stopped resulted in the lowest success rate of all three pumps. Over 40% of nurses were unable to access the secondary infusion mode on that design, in part due to that feature. Additional compounding issues were the lack of descriptive error messages and the need to access a submenu to find the secondary option, further prolonging user confusion and delivery delays. In contrast, nurses using pumps abiding by these recommendations demonstrated a statistically significant higher success rate.

Summary of Significant or Safety-related Findings: Accessing Secondary Infusion Programming

- ❑ Secondary infusion mode should be accessible whether the primary infusion has been stopped or is still running.
- ❑ Secondary infusion mode should be easily accessible from the primary infusion screen (i.e., not buried in pump submenus)

3.5.2 Secondary Infusion Parameter Entry

Market Options

Overall, parameter entry for secondary infusions is similar to primary infusions. However, key differences between pumps were observed in regards to CCA selection and the type of feedback they provided to users to communicate infusion mode (i.e., primary or secondary mode). These differences are described in more detail below:

1. **CCA Selection:** In one pump design, users were required to select the CCA of the drug library for the secondary infusion, but in other pumps the CCA defaulted to that of the primary infusion.
2. **Infusion Mode Feedback:** Pumps used various tools to distinguish programming a primary infusion from a secondary infusion, including the following (note: one pump did not provide any feedback during parameter entry):
    a. **Screen Headings:** Some pumps displayed a text heading describing whether a primary or secondary infusion is being programmed during parameter entry. Pumps used varying terminology to refer to the primary infusion, including the following terms: continuous, primary, basic.
    b. **Graphics:** Some pumps also included a small graphic during infusion setup showing a single IV bag or two IV bags to distinguish a primary and secondary infusion, respectively.
    c. **Tabs:** One pump also utilized various tabs for each infusion mode (i.e., primary infusion, bolus, secondary, etc.) and used contours to connect the tabs with the parameters being displayed.

Results and Recommendations

Significant differences were observed between two pump designs in terms of successfully completing parameter entry of a secondary infusion. The main reasons for these significant

The difference in CCA selection requirements between pumps during secondary infusion programming highlights a larger issue relating to patient handoffs between CCAs. Health care organizations must consider how they plan to manage these handoffs in regards to pump settings. Policies that demand nurses update the pump's CCA settings as soon as the pump is transferred may result in user frustration because some pump designs require nurses to restart the pump in order to change CCAs. This also forces nurses to reprogram any infusions that were running before the transfer, and introduces additional programming issues (e.g., estimating remaining VTBI, addressing limit alerts from new CCA dose limits). The implications of incorrect CCA settings or poor handover procedures may result in unnecessary reprogramming and delays, as well as introduce the potential for incorrect CCAs to be used, compromising the benefits of the pump's DERS.

In addition, it is recommended that infusion modes are clearly communicated to users; for example by tabs that remain on the screen or with headings. Also, the option to switch between programming modes should be intuitive to users (e.g., while entering a secondary infusion, an option labelled "primary" might enable users to switch to the primary screen and vice versa). This will make it clear that different modes exist and help distinguish which mode the user is currently viewing. A failure to adhere to these design principles has severe safety impacts, as observed during the lab study. In one case, the participant inadvertently replaced the primary infusion with secondary infusion parameters. It is suspected that the lack of clear feedback regarding the programming mode was a strong contributing factor.

Summary of Significant or Safety-related Findings: Secondary Infusion Parameter Entry

- ❑ The process of reprogramming the pump to reflect patient & pump handoffs between CCAs must be clear to users.
- ❑ The programming mode (i.e., primary or secondary) should be clearly communicated to users.
- ❑ The ability to access primary and secondary infusion modes should be intuitive during programming (e.g., tabbed headings while programming or headings describing current infusion mode with an option to switch to a different mode).

3.6 Limit Alert Messages

Two different types of limit alert messages are discussed in this section:

1. Soft limit alerts; and
2. Hard limit alerts.

The following two sections describe the differences in limit alert design between the pumps evaluated. In addition, significant and/or safety-related findings are presented as well as recommendations regarding preferred features. Mitigation strategies for those who have already purchased a pump are also discussed.

3.6.1 Soft Limits

Market Options

The design of soft limit alerts is a critical aspect of pump design because it is one of the key features underlying the expected benefits of smart pumps (i.e., alerting users to potential errors). The designs evaluated in the experiment varied across a number of dimensions (see Figure 10):

1. **Alert Language:** The limit alerts on two pumps clearly stated in text that a parameter exceeded a limit. In contrast, the limit alerts on one pump provided user feedback through incomplete sentences.
2. **Alert Limit Information:**
    a. **Programmed Parameter:** The soft limit alerts of two of the pumps evaluated displayed the value of the parameter that the nurse programmed (i.e., value that is outside of the limit); the third design (i.e., Approach C) did not provide this information.
    b. **Limit(s) Violated:** There was variation between limit alerts in terms of what alert values were presented to the user:
        i. Approach A: Only the limit violated (e.g., the upper soft limit if the parameter is too high);
        ii. Approach B: Upper and lower soft and hard limits for the parameter violated; or
        iii. Approach C: Upper and lower soft limits for the parameter violated.
    c. **Limit Field (units):** Some pumps displayed the same parameter that was programmed in the limit alert while other pumps presented a different parameter. For example, a nurse may have programmed a duration that was inappropriately low (therefore the infusion would take place at an inappropriately high volumetric rate). However, the limit alert on one pump stated that a limit had been exceeded in terms of volumetric rate, while the other stated that a limit had been exceeded in terms of duration. In the former case, feedback is provided in a parameter that the user did not program.
3. **Alert Formatting:** The limit alert may use the following to enhance user feedback:
    a. **Graphics:** One pump's limit alerts used a scale to depict the data entered in relation to the limits in the drug library.
    b. **Colour:** Pumps with a colour screen used different colours to increase the salience of the limit alert.
    c. **Audio:** Two pump designs utilized a short alarm tone to signify an alert had been triggered, while one pump did not provide auditory feedback.
4. **Alert Timing:** In one pump design the limit message appeared after all parameters were entered and the user had attempted to start the infusion whereas the other two pump designs displayed the alert immediately after a parameter exceeding a limit was entered.
5. **Alert User Options:** Pumps provided various means to describe a user's options once a soft limit was hit. These included labelling user options (e.g., override or edit), asking a question which users responded to with a yes or no (e.g., proceed?), or simply displaying the parameter in question with a question mark and asking the user to respond yes/no.

6. **Reprogramming Post Alert:** If the user decided not to override the limit and return to the parameter entry screen, the parameters the user programmed may have been erased or may be displayed for the user to review.

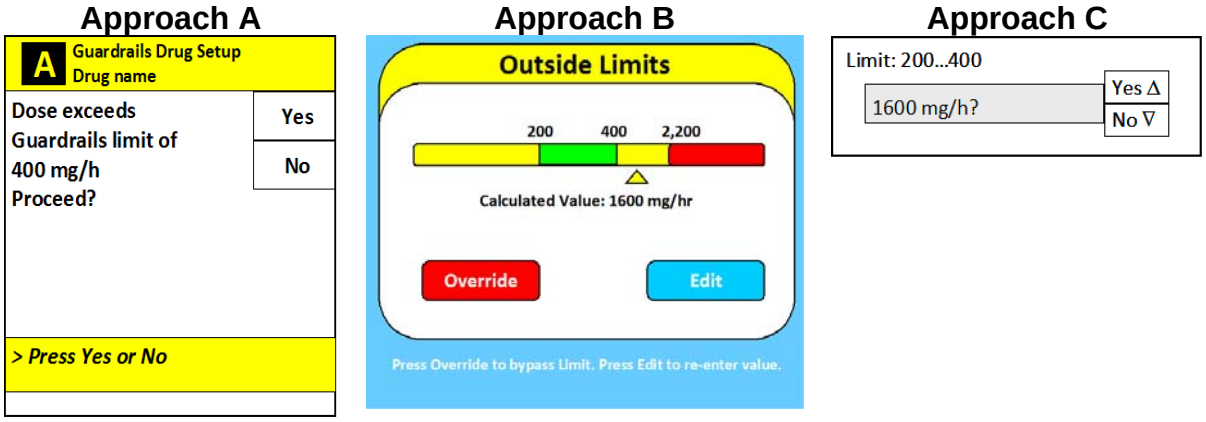

Figure 10 - Examples of Various Soft Limit Alerts

Results and Recommendations

The experiment found that the design of the soft limit screen had a large impact on whether nurses responded to the limit correctly. The experimental infusion scenarios were such that it was not clinically appropriate to ever override a limit alert. Significant differences existed between the pump designs with regard to nurses' ability to correctly respond to soft limit alerts ($p<0.001$)[11]. In particular, approach C was significantly worse than the other two approaches with a success rate of only approximately 50%. This suggests that limit alert design has strong implications for nurses' ability to recognize limit alerts and respond appropriately. Given the number of factors involved in effective soft limits, as described above in Market Options, it is likely that a combination of factors is responsible the significant difference between pump designs. Table 12 on page 82 summarizes the key issues related to effective soft limit design.

Overall, it is recommended that pump limit alerts should clearly state:

- what has occurred when a limit is exceeded;
- what parameter and value was violated; and
- what will happen when the nurse selects the options provided.

The first two points above are concerned with the clarity of the limit message. A clear textual explanation should be provided to users stating that a limit has been exceeded. This clearly indicates that the parameters of the infusion may be inappropriate. To increase the specificity of this statement, the second point above recommends that users benefit from knowing which parameter (i.e., dose-rate, volumetric rate, duration) is in error, and what the value of the exceeded limit is. While the pump may have auto-calculated all three parameters, it should provide the parameter that the user programmed last.

The last point above warrants further discussion. The clarity of a user's responses is a function of how clearly the limit alert poses options to the user. The response options "Yes" and "No" are not descriptive by themselves and therefore require a clear and direct question to be understood. In contrast, options such as "Override" or "Reprogram" are more descriptive. An added safety measure may be that affirmative answers lead users back to parameter entry (e.g., "Would you like to reprogram?" as opposed to "Would you like to Override?").

There may also be the danger that limit alerts superficially resemble a confirmation screen. Generally speaking, smart pumps require users to make three types of inputs: selections from a menu, data entry, or data confirmation. As users gain proficiency with smart pumps, they will navigate through the programming sequence more quickly, and there may be a risk of users rapidly "confirming" the parameters on the limit screen if it is not thoroughly examined. This is particularly likely if the same keys are used for each screen (e.g., "Confirm" or "Okay" is always the same soft key). However, this concern requires further research.

In addition, pump limit alerts should use colour and a distinctive alarm tone to increase attention and salience to this important communication. All of these alert characteristics play a critical role in increasing user recognition that a limit alert has been hit and should not be confirmed idly. One pump design (Approach C) failed to meet these design criteria (with the exception that it provided the parameter and value violated) and demonstrated a statistically significant higher risk of inappropriately overriding the soft limit alert when compared to the other pump designs evaluated. It is suspected that clarity of the limit alert message may also decrease comprehension time and increase efficiency.

Health care organizations should continuously monitor the occurrence of limit alerts for each drug and CCA to determine if changes are needed to match clinical best practice. Failure to do so may result in frequent limit alerts, which in turn, may lead to alert fatigue[30].

Summary of Significant or Safety-related Findings: Soft Limits

- ❑ Limit alerts should clearly state that a limit has been exceeded.
- ❑ Limit alerts should be communicated using the parameter entered by the user (e.g., if the user entered volumetric rate, the limit for volumetric rate should be provided, rather than the corresponding dose-rate).
- ❑ Limit alerts should be displayed with a different colour scheme from the rest of the programming sequence and be accompanied with a short audible tone. However, the use of colour and audio feedback should be used with prudence.
- ❑ Users should clearly understand the implications of their actions in response to a limit alert. In addition, the pump should guide users to reprogram the infusion instead of overriding the alert.

3.6.2 Hard Limits

Market Options

Hard limits maintain most of the same characteristics as soft limits, so it is recommended that readers consult section 3.6.1 when considering hard limits. However, one feature that differed between pumps that was unique to hard limit alerts was regarding alert confirmation. One pump displayed a hard limit alert that disappeared after a few seconds without being confirmed by the user. Other pump designs required user input before returning to the parameter entry screen to reprogram the infusion. See Figure 11 below

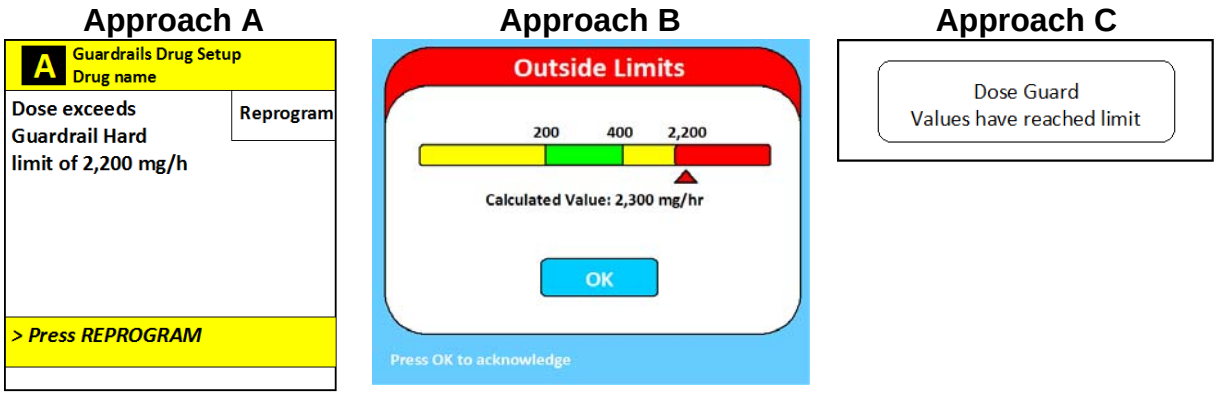

Figure 11 - Examples of Various Hard Limit Alerts

Results and Recommendations

No significant differences were observed between pumps regarding the effectiveness of the hard limit alert. This is attributed to the fact that all hard limit alerts evaluated in the experiment forced users to return to the previous screen and consequently, achieved the intended function of a hard limit alert. This suggests that whether nurses understood the hard limit alert or not, hard limit alerts are effective if it halts the programming sequence. However, poor comprehension of the hard limit may contribute to frustration with the pump's response, and consequently lead to unsafe behaviour (e.g., entering generic mode to deliver the medication). Therefore, while all hard limit alerts studied were "successful" by definition, further research may be required to determine how well nurses comprehend hard limit messages.

Table 13 on page 85 summarizes the key recommendation for hard limits. Overall, the recommendations for soft limit design (see section 3.6.1) should be applied to hard limit alerts as well.

Summary of Significant or Safety-related Findings: Hard Limits

- ❑ While no significant or safety-related findings specific to hard limits were found, all recommendations for soft limits (section 3.6.1) also apply to hard limit alerts.

3.7 Mitigation Strategies

For health care organizations that have already acquired a smart pump, it is worthwhile to briefly summarize what options are available to increase the safety and efficiency of the pump programming process. Generally, health care organizations have two options:

(a) Design oriented: Customize pump settings and design using the associated pump software (i.e., drug library software or biomedical engineering software).
(b) Person oriented: Develop pump related policies and procedures and train users. Another potential strategy is to use specific protocols (e.g., double checks) to reduce the likelihood of error.

As discussed in section 2.2 (hierarchy of effectiveness), the customization of smart pump design is the preferred mitigation strategy. Changes to the pump design are likely to prevent programming errors by constraining users to safer programming choices (e.g., defaulting parameter entry to fields that do not require calculation). However, the scope of pump functionality that can be customized through the pump software tends to be limited to the construction of the drug library and pump settings (e.g., occlusion pressure, alarm volume etc.). For example, the addition of new menu levels (e.g., separating drug and concentration selection into two separate menu lists) or alteration of parameter entry screens (e.g., default data entry fields and order of fields) are not currently within the scope of pump software to customize. While there are inherent risks to providing too much flexibility (e.g., confusing and potentially dangerous programming workflow and screen design could be created), the benefits of proper customization offer organizations the ability to meet their specific needs, and may outweigh the risks with proper support.

Person oriented strategies (e.g., policies, procedures and training), as a second mitigation strategy, are unlikely to compensate for the safety issues posed by poor pump design. Furthermore, as a remedial strategy, training must overcome existing habits and cultural patterns in regards to the infusion process. Often, poor programming habits gain acceptance because of their convenience and efficiency. These habits can be difficult to undo, and without changes in design, there is no hard barrier to stop those behaviours from continuing.

Manufacturers have a large role to play in addressing the issues presented in section 3. Additional work must be done to create effective smart pump designs using a user centred design approach. This section relays how some specific design features can contribute to and mitigate error and confusion while programming smart pumps. Manufacturers are encouraged to review this information in the context of designing the next generation of smart pumps or when providing updates or upgrades to existing pumps.

Health care organizations that are in the process of migrating to smart pumps are strongly advised to follow the recommendations reported in this section. The acquisition of a well-designed pump at the start of the implementation process is likely to minimize numerous downstream issues (e.g., pump customization and training later on).

4 Smart Pump Training

As previously discussed in section 2.2 (hierarchy of effectiveness), health care organizations should prioritize design oriented error prevention strategies over person oriented strategies. However, despite training and policy being categorized as less effective interventions in preventing medication errors (i.e., person oriented), organizations should not underestimate the necessity for training. Smart pump training is a critical component of effective smart pump implementation and error prevention for the following reasons:

- There is no perfectly designed smart pump currently commercially available that meets the needs of each organization's medication processes
- Smart pumps are complex technology that change workflows
- Smart pumps still require human vigilance and adherence to policy

Health care organizations should be prepared to invest considerable resources to this end and utilize informed strategies when providing staff training. This section draws conclusions from an experiment conducted on the efficacy of two different smart pump training curricula. It also presents a discussion based on field research and published literature on key elements health care organizations should consider in their overall smart pump training strategy as well as specific components to address in end-user training sessions.

This section is divided into three subsections:

1. **Section 4.1** discusses the methodology of the field study and lab study comparing two different training curricula. It also presents the key findings from the lab study.
2. **Section 4.2** provides an overview of general training factors health care organizations should consider regarding associated smart pump systems (i.e., drug library software and CQI software) and technical support of smart pumps and associated networks.
3. **Section 4.3** focuses on the training of smart pumps themselves and presents the current state of smart pump training in Ontario from the field study and provides recommendations on how to optimize training sessions.

4.1 Methodology and Results

The findings in section 4 are drawn from two streams of research: a field study and a lab experiment. Both are discussed in more detail in the following subsections.

4.1.1 Field Study

In late 2008 and early 2009, phone interviews were conducted and questionnaires were distributed to Ontario hospitals that were currently using smart infusion pumps. Research Ethics Board (REB) approval was obtained. Thirteen Ontario hospitals were smart pump users at the time of the field study. Findings related to their pump training processes are highlighted in section 4.3. Additional details regarding the field study data can be found in the Primary Report[1].

4.1.2 Lab Study

No published studies could be found that empirically tested the effects of a training program that specifically targeted the human factors issues of a particular technology. Therefore, an experimental study was conducted in which the type of training was manipulated (i.e., traditional vendor based training vs. human factors and education informed training). Participants in both groups completed the same infusion scenarios to investigate the impact of the training they received on their ability to safely and efficiently deliver IV medications. The results of this research were intended to provide greater insight into how training, given its pervasive status as a response to error, might be effective in improving technology use. A detailed description of the experimental methodology can be found in the appendix (section 7.4) and is summarized below.

A mixed factors design was used. Forty-seven nurse participants were recruited from UHN. The first twenty four nurses received a shortened form of traditional vendor based training (VBT) while the remaining twenty three nurses received training designed with modern education principles and human factors analysis of the smart pump. This second training protocol was called human factors and education informed training (HFET). Participants in each group were asked to complete the same set of seven IV infusion scenarios. Therefore the between group variable is the training protocol, and the within subject variable is the infusion scenario.

Analysis of Safety

The reasons for failed infusions were summarized in four categories between the two training methods. No significant differences were found between training methods overall, or in any failure category (see Figure 12).

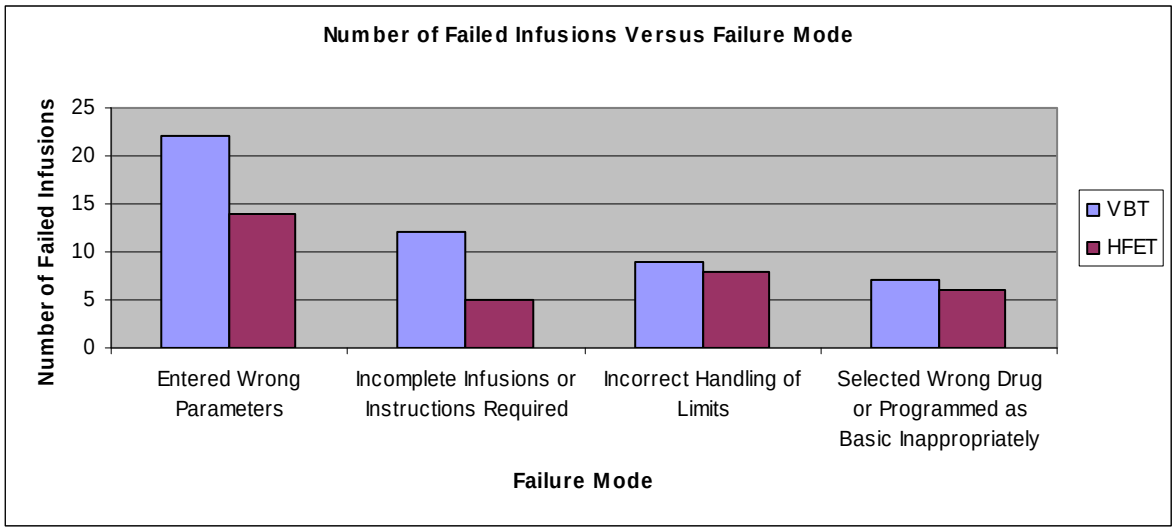

Figure 12 - Number of Failed Infusions as a Function of Failure Mode

These results indicate that the HFET protocol was not significantly effective in reducing the errors observed in the VBT protocol. The most frequent error for either training protocol was that users failed to enter correct programming parameters. This supports literature

Analysis of Efficiency and Nurse Behavior

There was no significant difference in the total task completion time between the VBT and HFET method. However, efficiency results suggest that the HFET method provided improvements in some aspects of the pump programming process, particularly for key issues such as accessing secondary infusions and recognizing what to do when the drug cannot be found in the drug library (both of which were specifically targeted for improvement in the HFET curriculum). While these results are positive, they are overshadowed by the fact that the efficiency improvements were not correlated to improvements in ability to avoid errors.

Attempts were also made to change nurse programming behaviour (e.g., loading the IV set prior to programming the infusion and programming dose-rate instead of volumetric rate.). While participants trained with HFET showed some changes in behaviour, these initial improvements disappeared over the course of the experiment. As discussed previously, the hierarchy of effectiveness promotes changes in design in order to generate effective safety systems. This concept is reinforced by the rapid deterioration of trained behaviours in the experiment.

Limitations and Future Work

The experimental design was not optimal for the evaluation of some training interventions. For example, one of the continuous infusions where nurses had the opportunity to program dose-rate instead of volumetric rate (one of the changes encouraged by the HFET curriculum) was biased because the drug order used at the UHN provides the values for both dose-rate and volumetric rate. In order to test for a reduction in calculation errors, it would have been preferable if nurses were provided strictly with dose-rate in the drug order. This would be more likely to provide insight into whether they would simply transcribe dose-rate rather than calculate volumetric rate.

Both training methods were significantly shorter than what is provided in the field. Vendor training sessions observed in the field were about 2 to 3 hours, but training in the study was reduced to approximately 15-20 minutes to focus on the tasks required in the scenarios (e.g., training on priming the IV set was not provided since users were not asked to complete this task). This may have benefited nurses by minimizing demands on their attention, or hindered nurses by failing to provide peripheral material that may have been useful.

Furthermore, there was a difference in training length between the two training methods. The VBT method required just under 15 minutes, while the HFET method required an average of approximately 20 minutes, and was therefore longer than the VBT method. However, even with this additional time, the HFET method did not significantly improve the user's ability to avoid errors.

Summary of Key Findings: Training Lab Study

- ☐ A training program utilizing modern educational techniques targeting usability and safety issues specific to a smart pump (i.e., HFET method) had no significant effect in reducing the occurrence of incorrect infusions when compared to a vendor based training program (i.e., VBT method).
- ☐ The HFET method was able to generate improvements in efficiency for some aspects of pump programming, but overall task completion time was not significantly improved.
- ☐ The HFET method generated some significant changes in nurse behaviour at the start of the experiment, but those differences were not observed in the latter half of the experiment, suggesting that training induced effects can rapidly diminish. This reinforces the framework set forth by the hierarchy of effectiveness in that training is of limited effect in compensating for poor pump design.

4.2 Drug Library, Technical Support and CQI Training

In comparison to traditional infusion pumps, smart pumps require a training program that addresses a broader group of users and needs. Health care organizations should seek training for:

- Typical pump users (e.g., nurses, anaesthesiologists, and any other users)
- Pump trainers (e.g., clinical educators, advanced/super users)
- Drug library specialists (e.g., pharmacists)
- CQI analysts (e.g., risk management, pharmacists, nurses)
- Maintenance and repair specialists (e.g., biomedical engineering and information technology specialists)

Smart pump end user training is the primary focus of most hospital pump training programs and is discussed in detail in section 4.3. However, health care organizations must also ensure that appropriate staff receive training on the drug library software, CQI software, and technical support of smart pumps and associated networks. Key issues to consider include who will receive the training and when. It is general good practice to ensure at least two people receive the same training as backup.

Health care organizations need to clearly identify roles and responsibilities associated with developing and continually maintaining the drug library. Once defined, it is preferable that drug library specialists receive training immediately following product selection to prevent delays in building the drug library. Drug library creation is a critical and time-consuming process. In some cases, vendors provide staff to assist drug library specialists not only to learn the drug library software, but to construct and update the drug library itself[47]. One of the benefits of a drug library completed in advance is that it can be used in smart pump training sessions, increasing users' familiarity with the pump programming process as it will actually appear when implemented. End user feedback can also be used to refine its content prior to go-live.

While most organizations are aware of the need for training on the drug library software, many organizations do not plan for, or receive, CQI software training. The field study revealed that 75% of surveyed Ontario hospitals never received CQI software training and

13% received it longer than one year post go-live. The timely use of the CQI software to monitor drug library use and track issues by specific drug and CCA is necessary to maximize the effectiveness of smart pump technology[1]. A failure to review this data may encourage users to develop workarounds that compromise the intended benefits of smart pumps (e.g., programming in generic programming mode or selecting an incorrect concentration entry because the correct concentration is not available in the drug library). Health care organizations should clearly identify staff roles that are responsible for CQI data and develop mechanisms for CQI feedback to update hospital policies, procedures, training and drug library. It is preferable if an individual from each CCA is selected to represent, and be accountable for, their clinical area. All staff involved in reviewing and analyzing CQI data should receive training.

Similarly, training for maintenance and repair specialists should not be neglected. Training for maintenance and repair specialists should be equivalent to factory-level training and cover all preventive maintenance requirements, schematics and in-depth troubleshooting. This training should be completed prior to inventory arrival so that staff may assist in acceptance testing.

Summary of Key Findings: Drug Library, Support and CQI Training

- ☐ Drug library specialists, CQI analysts and technical support staff should have clearly defined roles and receive appropriate and timely training to prevent delays and help ensure optimal smart pump use.

4.3 Smart Pump End-User Training

Smart pump end-users, usually nurses, are likely the largest staff population that must receive training. End-user training plays a significant role in ensuring the correct and safe use of the pumps in clinical practice, and as such, health care organizations should be aware of the many factors that contribute to this process. This section discusses user training from three perspectives:

1. **Planning:** This subsection discusses organizational strategies that facilitate training sessions (e.g., budgeting, staff roles, attendance policies etc.).
2. **Curriculum:** This subsection discusses the key components of the training session format and content.
3. **Delivery:** This subsection discusses issues related to executing the training sessions and managing the training environments.

Each of these subsections will first describe current training practices as described by the literature[12, 44, 47-49] as well as by field research conducted by HHF (**Current State)**. The prevalence of some Current State characteristics are provided as percentages in brackets based on interviews with and a survey of Ontario hospitals. A discussion of the current state of pump user training follows, highlighting effective strategies or areas requiring additional attention (**Recommendations)**.

4.3.1 Training Planning

Current State

The development of an effective training campaign requires specific resources and policies that facilitate nurse attendance and ensure supportive training conditions. Hospitals have used some of the following strategies when planning smart pump training:

1. **Staff Attendance:** The majority of hospitals interviewed tracked nursing attendance at training sessions. Hospitals were typically capable of achieving an 80% attendance rate of their nursing population. One small Ontario hospital (32 beds) interviewed was able to achieve 100% nursing attendance.
2. **Staff Recruitment:** The survey of Ontario hospitals found that almost all hospitals (90%) stipulated mandatory pump training for all end users. Some hospitals (40%) backfill staff that attend training sessions, while others (10%) conduct training sessions in parallel with regular staff shifts. In the latter case, training sessions typically occur on or near clinical units so that nurses can drop in to training sessions as their availability allows.
3. **Staff Roles:** The survey found that super users were used at the majority of organizations (73-91%). One vendor suggested that super users comprise approximately 10% of the end-user population to facilitate pump implementation and support other users in the long term.
4. **Policies:** The field study revealed that many hospitals (33%) have not prepared comprehensive policies (e.g., how to respond to soft or hard limit alerts) in time for end-user training sessions. In one observed training session, the vendor stated that the proper response to limit alerts are strictly within the jurisdiction of hospital staff and simply advised users to defer to hospital policy when such situations arise. It was not clear whether hospital policies were already prepared, but vendor staff was unwilling to make recommendations on what to do as it could place them in a position of liability, resulting in no guidance being provided to end users.
5. **Pilot Testing:** One account in the literature describes a pump implementation that was first piloted on a few clinical units to identify any major issues and fine-tune the training curriculum[44]. However, based on the hospitals interviewed, the majority of pump implementations in Ontario have been hospital-wide.
6. **Number of Training Sessions per User:** The interviews with Ontario hospitals, as well as the literature, suggests that users usually receive one training session that covers pump functionality and use. However, one account from the literature states that the vendor intended to return to provide more training on advanced pump functionality[47].

Recommendations

The main training objectives from an organizational planning perspective are to maximize training attendance and impact. New initiatives, such as the implementation of smart pumps, are an opportunity to develop and reinforce an organizational culture committed to medication safety. The resources committed to training and its priority on the agendas of leaders, particularly nursing managers, play large roles in demonstrating the importance of medication safety to users.

Although the literature on pre-training conditions is sparse[50], one article from the literature suggests that making attendance mandatory may influence trainee motivation by demonstrating it is of high organizational priority, [51]. It is also recommended that efforts be made to provide trainees an environment free of distractions so that learning can be a priority. This assists in communicating that training is a priority to the institution, and the lack of distraction may also encourage stable training attendance because trainees are not distracted by multiple objectives (e.g., tending to clinical demands and training sessions at the same time). Finally, it is important that monitoring mechanisms are in place to measure training penetration of each clinical unit (see section 4.3.3). This information can be used by nursing management to track progress against attendance goals, encourage staff (e.g., provide incentives, if possible) and make arrangements for outstanding staff to attend training.

The Primary Report suggests that health care organizations consider the formation of a smart pump training team dedicated to educating staff and raising awareness of the incoming pumps. This team may have a powerful impact on attendance at training sessions by describing the rationale for migration to the new pumps and the potential benefits of the transition. Clear examples of how DERS can reduce programming errors (e.g., video from usability testing, case studies from actual incidents or realistic examples) may decrease resistance to, and promote excitement for, the new technology.

In order to help boost training effectiveness, health care organizations should utilize super users. Super users have been used by most organizations as a component of their training strategy because they provide a number of benefits. As sources of in-depth knowledge regarding pump use, they provide a distributed network of localized “experts” for end-users to draw on prior to and during pump go-live, as well as ongoing training after pump implementation. Super users can also assist with promoting adherence to organizational policy.

Along these lines, users should be informed of their health care organization’s new smart pump policies (e.g., mandatory use of drug libraries for all infusions, how to respond to limit alerts, what to do if drug is not in library) during training. Therefore, organizations should aim to complete all policies and procedures prior to the start of end-user training. Failure to accomplish this may result in high rates of policy violation which may severely limit the intended safety benefits of smart pump features.

Depending on the institution, the use of alternative training methods may help optimise training delivery (see section 4.3.3). For example, the use of additional training sessions to cover advanced pump functions, or the use of pilot testing pump implementations to refine the training curriculum, may be effective additions to an overall training strategy. Evidence from the experiment on education suggests that knowledge gains from targeted pump training may quickly dissipate if not a part of nurses’ typical clinical practice. Kneebone suggests that practice should be broken into smaller units[52], but this may be difficult to achieve from a staff scheduling perspective. Few accounts in the literature exist that utilized multiple sessions to train users, but it may be a worthwhile strategy to consider if feasible.

Summary of Key Findings: Training Planning

- ❑ Attendance at training sessions should be made mandatory.
- ❑ Attendance should be monitored and a goal set.
- ❑ Training sessions should take place in an environment that allows staff to concentrate and attend training sessions without interruption.
- ❑ The formation of a smart pump training team that raises awareness regarding incoming pumps and educates staff about the potential benefits of the technology should be used.
- ❑ A "train the trainer" approach should be used in which clinical educators and a portion of pump users receive advanced training before the standard training sessions begin. This allows them to become "super users" who can assist in immediate and ongoing education efforts.
- ❑ Pump use policies should be finalized prior to training sessions so that they can be disseminated during staff training. Important policies include guidance on how users should respond to limit alert messages and utilize the drug library.
- ❑ Alternative training methods should be considered to optimize training delivery and retention (e.g., multiple short training sessions instead of a single extended training session, piloting pump implementations to refine training delivery).

4.3.2 Training Curriculum

Current State

There are many variables to consider regarding the training format and content, including the following:

1. **Representative conditions (e.g., drug libraries, orders, policy):** Some hospitals ensure that the training environment will be similar to nurses' practice (e.g., sample drug orders and IV labels match current practice, drug library is up to date, policies on pump use have been prepared). However, it appears that training is often based primarily on the vendor's pre-established curriculum, which may not venture into the specifics of nursing practice because of liability concerns (see "Policies" in Current State of section 4.3.1), and may not be modified to reflect institution specific workflows (e.g., sample drug orders and IV bag labels). In addition, sample drug libraries are often used during training sessions, possibly because hospitals have not yet completed their drug library or are concerned about contaminating CQI logs with training data.
2. **Hands-on Training:** Based on the survey of Ontario hospitals, the majority (89%) of training sessions appear to involve hands-on training where nurses have access to their own pump. However, accounts of nurses watching pump programming demonstrations in a large classroom have also been noted (11%).

3. **Class Content:** A mix of lecture material and demonstrations were always (100%) provided by hospitals interviewed. A walkthrough of the pump's functions and typical infusion tasks are usually performed with learners following along on their own pump. Given the new features of smart pumps, there is often an emphasis on:
    a. The concept and purpose of the DERS with vendor specific pump terminology (e.g., Guardrails, Pharmguard, DoseGuard)
    b. How to check whether existing infusions are programmed in the drug library
    c. The new programming parameters other than rate (e.g., dose and duration)
    d. Identifying a limit alert and users options
4. **Trainee Assessment:** There is little published on smart pump trainee assessment and how it is typically conducted, if at all. Observations from one institution's training sessions showed that users were only required to submit a signed checklist indicating that they learned the skills listed on the form; no formal behavioural evaluation was made.
5. **Class Duration:** Based on the field study, training sessions vary from 30 minutes to 4 hours long. However, typically (60%) they are between 45min and 60min. However, in some cases, duration is difficult to measure because nurses are allowed to drop-in to the sessions and leave as desired.
6. **Instructors:** The survey revealed that vendors always (100%) provide training, but they may be assisted by super users (73%) and/or clinical educators (55%).

Recommendations

An effective training curriculum should reliably produce the intended pump programming behaviour in trainees as they demonstrate learned competencies on the job. The key elements to achieve this can be summarized into two categories:

1. Representative training conditions; and
2. Trainee assessment.

The objective of representative training conditions is to ensure that the scenarios and tasks that trainees perform during training mimics their work on clinical units. As discussed above, health care organizations may fail to achieve this in many regards. For example, some hospitals may provide "practice" drug libraries that are not representative of the actual hospital drug library or drug orders different from what users normally encounter in clinical use (usually simplified for training purposes). In some cases, training sessions may fail to provide clear policies on how to respond to limit alert messages in the training sessions. In order to effectively transfer competencies from training to on the job conditions, these factors should be effectively mimicked during training sessions as they have implications for the cognitive demands of the infusion workflow[53]. By extension, nurses should also have their own pump to practice on in the training sessions because active participation results in higher knowledge and skill retention compared to passive observation[54]. The combination of these attributes in training sessions should help minimize differences in cognitive demands between training sessions and clinical practice.

There is minimal evidence that thorough assessments of trainees occurs in the field. Therefore it is worthwhile to discuss how assessment can be conducted. One popular framework for analyzing training outcomes is Kirkpatrick's typology[50]. The framework

draws distinctions between different types of evaluation criteria, specifically reaction, learning, behavioural and results criteria. For example, it is possible for trainees to learn new information (success using a learning criteria), but fail to engage in the behaviour that the knowledge suggests they utilize (failure to meet behavioural criteria)[55]. Conversely, simply performing pump tasks may contribute to experience, but not learning[52].

Salas states that training evaluation is often "labor intensive, costly, political, and many times is the bearer of bad news", which may explain the lack of thorough assessments observed in the literature for smart pump training. For example, Wetterneck et al. attributes positive drug library compliance to effective training efforts, but does not describe any formalized approach to assessing the impact of training on nurses' behaviour[49]. Crimlisk et al. discusses the use of workshops, focusing on evidence based practice and critical thinking skills for intravenous continuous infusions, but focuses on observed error rates rather than any individualized nurse assessments post training[46]. Fields and Peterman state that "ability to demonstrate competency with the pump was mandatory", but do not discuss it in further detail[48].

It is critical that health care organizations employ some form of behavioural assessment of pump users to monitor the ability of the training curriculum to reliably produce safe and intended pump programming; self-reported feedback or knowledge based tests do not appear to be effective in this regard. Without this form of assessment, there is a lack of evidence that training was effective and trainees do not receive corrective feedback on improper programming behaviour. Trainees are also not able to distinguish between superb and poor role models when learning from peers[54]. As a result, improper programming behaviours or workarounds may propagate into clinical practice with implications for safety.

There is a growing amount of literature that discusses the use of simulation in healthcare for training and assessment, which may provide useful lessons in this context. Based on this literature, it is suggested that in order to effectively evaluate behavioural criteria, users should be required to perform specific pump tasks designed to assess specific competencies[42, 52, 53, 56-58]. In addition, a continuous relationship between an expert user and trainee is beneficial because it encourages trainees to remain focused on learning key competencies through timely and diagnostic feedback[53]. To this end, it is suggested that each clinical unit provide assessment sessions where users work one-on-one with an expert (e.g., clinical educator, vendor or super-user) to complete scenarios addressing competencies that are specific to that unit. These scenarios should be determined ahead of time by vendor educators and senior user staff. Super users are likely to play a critical role in any such detailed tutoring/assessment sessions. These interactions may only represent a portion of the training session time given it is resource intensive.

There is no clear evidence regarding the optimal duration of training sessions and the effect of who teaches training sessions; health care organizations should consider what works best for their needs. One book author suggests that the longest lecture length students can attend to is approximately 20-30 minutes and is subject to learners arousal levels and the variability of stimulation[59]. It is likely that longer durations are required for smart pump training sessions to cover the necessary material. Fortunately, smart pump training sessions feature

high levels of pump interaction, high relevance to learners' daily tasks, and builds on learners existing knowledge, all of which are likely to increase the amount of time that learners can focus. While Kneebone suggests multiple shorter training sessions may be advisable, the optimal length of each session is difficult to determine.

In addition, it is not clear whether there is a benefit to having hospital staff train pump users versus vendors. Vendors may not be able to provide unit specific examples as clearly as hospital staff, and may be reluctant to provide information that suggests their pump requires specific strategies to prevent error. Vendors may also be reluctant to disseminate hospital policy for fear of liability in medication errors. Nevertheless, vendors are likely to possess greater understanding of pump functionality and more experience in delivering pump training. As such, it is recommended that health care organizations employ a mix of vendor and hospital staff as instructors in each training session so that the benefits of both can be provided to users.

Summary of Key Findings: Training Curriculum

- ❑ Training must provide each user their own pump to practice on during training sessions.
- ❑ Training must be reflective of organizations' unique clinical practice, including the following:
  - a copy of the final drug library (or a practice drug library that is highly representative of the final version) loaded into practice pumps
  - finalized pump related policies and procedures incorporated into the training curiculum
  - representative drug orders and IV bag labels when asking trainees to complete infusion scenarios
- ❑ Training must include an assessment of nurse programming behaviour to monitor training effectiveness, provide corrective feedback to each user, and maximize the likelihood of competencies being utilized as intended on the job.
- ❑ Training should include both hospital staff and vendor staff in each training session to capitalize on their respective strengths as instructors.

4.3.3 Training Delivery

Current State

The results from the survey revealed that hospitals have used the following strategies in the execution and delivery of end-user training sessions:

1. **Class Location:** Training sessions have been conducted directly inside clinical units (44%), in a room near the clinical units (33%), and in some cases a room separated from clinical areas (44%). Sessions are not usually conducted off-site.
2. **Ratio of Instructors to Learners:** Typically classes are done in small groups (78%), but at some interviewed hospitals they were done individually (11%) or in large groups (11%) with two to three instructors for 25 learners. As such, the ratio of instructors to learners may be as high as one to one to or as low as one to eight.
3. **Attendance:** Attendance may be recorded by trainees signing their name on a pre-made roster, by assessment, or by backfill payments.

4. **Supplementary Training:** In addition to formal training, hospitals may offer additional self directed training through computer based training modules (18%), practice pumps (18%) and training documentation such as tip sheets (27%), or may occur on the job via super users (91%). Videos and manuals were not used by any interviewed hospital.
5. **Timing:** Hospitals typically provide training one week before go live (71%) but some hospitals provide it two to three weeks (14%) or even one month (14%) prior to go live.

Recommendations

As discussed earlier (see section 4.3.1), the delivery of training should be designed to maximize training transfer and staff attendance. As such, it is recommended that training sessions take place in a location distanced from clinical units because it will minimize the likelihood of users being distracted by activities on their unit.

There is no clear evidence regarding the optimal ratio of instructors to trainees for training transfer. If the use of individualized nurse assessment is part of the training strategy (as recommended in section 4.3.2), it is preferable that a higher number of instructors is available per trainee to accommodate that aspect of training.

It is also recommended that attendance be measured by users meeting assessment criteria, ensuring that a nurse's attendance at training is based on their competency with the pump, rather than simply showing up for a portion of the class.

Health care organizations should also consider supplementary training in addition to the formal training provided by the vendor. Practice pumps on the unit may be preferable to computer based training because it allows users the ability to familiarize themselves with the behavioural attributes required to demonstrate competency with the pump, rather than only a knowledge based approach that computer based training may provide. However, to ensure practice is relevant and correct, it is recommended that specific infusion scenarios and tasks accompany the pumps (e.g.. a competency workbook with solutions). This is because "deliberate practice" targeting specific competencies is more likely to generate consistently superior performance[42]. This form of additional training may also result in over-learning which supports training retention[52]. Ideally, these infusion scenarios will cover the same competencies that users must demonstrate in assessment. The presence of tip-sheets on the unit may also be a valuable source of immediate reference[1].

Training should be completed as close as possible to the go-live date to maximize training retention[60]. In-house experts (e.g., clinical educators, super users) should receive training before typical pump user training so that they can assist in the education effort. However, the timeframe over which training sessions take place are likely to be a function of the size of the user population to be trained, and the availability of both hospital and vendor staff. Within these constraints, a shorter timeframe is preferred because users trained in the early sessions will exhibit better retention the less time they must wait before go-live. Traditional training timeframes may be extended with the use of assessment, and health care

organizations should be cognizant of underestimating the magnitude of an effective training program.

Summary of Key Findings: Training Delivery

- ❑ Training should be conducted at a location distanced from clinical units and trainees should be provided dedicated time to attend training sessions. This will help ensure trainees are not distracted by clinical duties.
- ❑ Training attendance should be based on the number of users meeting assessment criteria rather than attendance.
- ❑ Supplementary training should include practice pumps on the clinical units with workbooks of infusion tasks designed to train specific competencies that are measured in the assessment criteria. Tip sheets on the unit may also be beneficial.
- ❑ Training should be completed as close to go-live as possible to maximize training retention.

5 Conclusion

In summary, the key finding of this report is that the acquisition of a well-designed smart pump is more likely to promote safe IV infusions than training programs. This is reinforced by the hierarchy of effectiveness and lab studies[11, 61].

Overall, there is no perfectly designed smart pump commercially available that meets the needs of each organization's medication processes. However, fundamental smart pump design features have been found to augment the effective and safe use of smart pumps. The design recommendations discussed in this report have implications for both manufacturers and health care organizations. Manufacturers should prioritize the development of pump designs that address the issues presented in this report through user-centered design. They should also provide means for health care organizations to customize certain aspects of the pump design to meet their unique needs (e.g., expand the functionality of pump software). Health care organizations should prioritize the evaluation and acquisition of a smart pump that contains design features that have been shown to increase the likelihood of safe pump programming behaviour.

While design oriented error prevention strategies should be prioritised over person oriented strategies (e.g., training, policies), manufacturers and health care organizations should continue to treat training as an important component of the smart pump implementation process. While field research revealed a large variation in smart pump training practices between Ontario hospitals, some key factors contributing to effective training were recommended that are applicable to both pump vendors and health care organizations.

The top recommendations of the report are summarized below:

1. **Smart pumps must default users into its dose error reduction system (DERS).** By automatically placing users in the DERS, hospitals maximize use of the drug library and therefore increase both safety and efficiency.

2. **The default programming parameters on the pump (e.g., dose rate, volume to be infused) should match the information provided to the end-user (e.g., drug order, IV bag label) and be presented in the same order.** This will help eliminate error prone unit conversions. Given the wide variation of prescribing practices, this may not be feasible in all circumstances, but is highly recommended when possible. To facilitate this process, manufacturers should consider allowing hospitals to customize the availability and sequence of parameters on data entry screens. Hospitals should select a pump that matches their prescribing requirements and/or seek to change prescribing practices (e.g., implement computerized physician order entry (CPOE)).

3. **Smart pumps should utilize informative and salient warning messages to optimize their effectiveness**. This is particularly important for limit alerts that are triggered when user entered parameters fall outside the safety limits defined in the DERS. Limit alerts should prudently use colour and audio to draw attention to the

alert. They should also include clear text explanations of what has happened, the value of the limit that was violated, and intuitive user options.

4. **Smart pumps should ensure secondary infusion mode is easily accessible and the infusion mode (i.e., primary or secondary mode) should be clearly visible.** In addition, smart pumps should ensure that users can intuitively switch between modes as this further reinforces the understanding of which mode is currently being accessed.

5. **Training sessions must provide trainees direct hands-on practice with a smart pump during the training session, a learning environment free from distraction, and assess trainees on their programming behaviour.**

6. **Training sessions should provide trainees with materials that are representative of clinical practice.** Sample drug orders should be representative of what users typically receive, drug libraries on the practice pumps should be identical or highly representative of their final version, and hospital policies and procedures regarding smart pump use (e.g., how to properly respond to limit alert messages) should be clearly explained.

7. **Training has been found to be of limited effectiveness in remediating errors associated with smart medication delivery systems.** Our education-based experiment showed that users performed no better after focused educational training based on observed errors than users who received general training. Error reduction through the use of system changes that include forcing functions is likely to achieve better outcomes.

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7 Appendix

7.1 Summary of Findings for General Design Features

This section contains the tables summarizing the advantages and disadvantages of the three general design features discussed in section 3.2:

1. Screen Size and Colour (Table 1)
2. Programming Control Schemes (Table 2)
3. Accommodation of Multiple Channels (Table 3)

Table 1 – Analysis of Screen Size and Colour

Design Feature	Category		See section
Large Screen Size	Advantages	Increases number of visible entries when users are selecting drug and concentration.	3.4.1
		Provides space for relevant headings (i.e. distinguishing primary and secondary infusions when programming) to be used.	3.5.2
		Provides space for contextual soft keys to be used.	3.4.1 3.5.1
		Potentially prevents the need for scrolling when viewing parameter entry.	3.4.3
		Increases available space for longer error messages, clinical advisories or warning prompts.	3.3.1 3.6
		Allows larger font sizes, increasing readability.	
		Nurses responded positively to the screen size and colour on both the medium and large screen colour pumps.	
	Disadvantages	Potentially increases the size and weight of pump, reducing ability to run multiple infusions in technology intensive areas, such as ICU settings.	
		Nurses indicated that they liked the size of smallest pump (which also had the smallest screen size). Pumps with large screens cannot maintain a small form factor, therefore the benefits of a compact form factor is typically sacrificed in order to achieve large screen sizes.	
		Large screen sizes can be packed with too much information, potentially distracting users from the pump's main messages.	
Colour Screen	Advantages	Increases salience of limit messages.	3.6
		Allows fields to be more visibly "greyed" out, demonstrating their inapplicability to the current context.	3.4.3
	Disadvantages	Colour can be used improperly, or overused, and this may lead to user confusion. Colour may present some issues to those who have difficulty distinguishing between different colours.	

Table 2 – Analysis of Programming Control Scheme

Design Feature	Category	Description	See section
Touch Screen	Advantages	Maximizes intuitiveness because users simply touch the options they desire; no control translation is required.	

Design Feature	Category	Description	See section
		Nurses in the experiment liked the touch screen feature.	
	Disadvantages	Large screen size is required so that buttons can be made large enough for users to touch without accidentally touching another button. As discussed in Table 1, this has implications for pump size/weight.	
		The touch screen observed in the experiment often failed to register touches, leading to confusion and delays while users tried again (i.e., users may briefly think that the option is not selectable). Dirty screens (e.g., from frequent use) can compound this issue. Despite liking the touch screen feature, nurses expressed that the failure of the screen to register touches was something they disliked.	
		When multiple pumps are used (e.g., ICU), it is difficult to register touches on the pumps at the top or bottom of the IV pole; viewing angles compromises the ability to accurately touch screen options.	
Hard Key Arrows	**Advantages**	The pump evaluated in the experiment that used hard keys had only a few hard keys, minimizing the amount of space required on the front of the pump.	
		Start-up tasks are generally handled quickly because users do not have to look for where to press, all actions take place on the same keys (i.e., arrow keys in the design evaluated).	3.3.2
	Disadvantages	Requires numerous key presses for parameter entry because each decimal place of a parameter must be scrolled to and incremented individually.	3.4.3
		It appears that the left arrow key caused confusion for nurses on the drug and concentration selection screen. It is believed users attempting to "go back" or exit the drug library using the left arrow key; this resulted in unintentional drug selection. It appears that directional control schemes may interfere with other mental models (i.e., associating moving backwards or forwards in the programming sequence with left and right).	
		Nurses in the experiment disliked the use of hard key arrows to navigate the pump.	
Hard and Soft Keys & Modular System	**Advantages**	Accessing pump modules by pressing the module's hard key may make nurses aware of the physical channel they are programming, potentially reducing channel mix-up errors.	
		Soft keys provide useful contextual options for users.	
	Disadvantages	The distribution of hard keys between a central pump unit and pump modules can cause confusion. In the pump evaluated, one task required users to press a hard key on the pump module, but users were more inclined to focus on the central unit, leading to delays before the correct key was pressed. An additional issue that contributed to this problem is discussed below.	
		Screen design must accommodate the soft keys. In one pump design, the main screen displayed the status for each pump channel, but aligned them directly with the soft keys on the left side of the pump. . As a result, users thought the left soft keys would allow them to gain access to the channel, but they did not, leading to delays and confusion (instead, users had to use the hard key on the pump channel).	

Table 3 – Analysis of Multiple Channel Accommodation

Design Feature	Category	Description	See section
Modular System with Horizontal Additions	**Advantages**	Pump modules are more likely to be light and small.	
		Horizontal module additions allow multiple rows of pump modules to fit on one IV pole.	
		Short pump set-up time when new modules are added (no need to turn pump on, repeat CCA selection etc.)	
	Disadvantages	Central programming unit may be heavy.	
		Horizontal channel additions can contribute to wide and unstable pump arrangements.	
		Module identifiers may change with the addition of new modules. For example, the current pump evaluated always identifies the left-most module as "A". If a new module is added to on the left side, it now becomes the new "A" and the original module becomes "B". This may become confusing to users.	
		Modules no longer required (e.g., infusion complete) may become trapped between the central unit and modules in use. Consequently, they cannot be easily removed, resulting in inventory waste.	
		A modular system may contribute to confusion in the control scheme (see Table 2).	3.4.1
Dual Channel Pump with Horizontal Additions	**Advantages**	Horizontal pump additions allow multiple rows of pumps to fit on one IV pole.	
		Channel access may be simplified on a pump when it can be explicitly designed for two channels.	
	Disadvantages	Side by side pump stacking may result in wide and unstable pump arrangements.	
		Pump inventory may not be deployed effectively since single infusions must be infused using a dual channel pump, resulting in an unused channel.	
Single channel pump with Vertical Additions	**Advantages**	Vertical stacking presents a small footprint, leaving more room for other equipment around the IV pole.	
		Pump channels can be easily removed and added, resulting in effective inventory deployment.	
	Disadvantages	Vertical stacking may minimize the number of pumps that can fit on one IV pole, requiring a higher number of IV poles to deliver the same amount of infusions compared to a horizontal approach.	

7.2 Summary of Findings for DERS Design

As described at the start of section 3, the following section presents a series of tables summarizing the findings for each section of the pump programming process. Each table utilizes a standard format as demonstrated in Table 4.

Table 4 - Example of Table Header

Design Feature	Findings*		Impact			Mitigation Strategy		
		Reference	Safety	Efficiency	Notes	Acquisition Consideration	Post Acquisition Consideration	
							Reconfigure with pump software	Training

Note the four main categories depicted above:

- **Design Feature:** Design elements are categorized in Market Options for subsections 3.3 to 3.6; these categories are listed in this column.
- **Findings:** This column discusses conclusions made in regards to the design features observed in the Market Options section. Note that each finding is assigned a letter in the sub-column "Reference" which describes the justification for the finding. As shown, a footnote accompanies the first page of each table to remind readers what each letter represents.
- **Impact:** This column utilizes three sub-columns. The first two sub-columns identify whether the finding has safety or efficiency (time-saving) implications. The "Notes" column describes the impact of the finding in more detail, usually drawing on the justification assigned to it from the "Reference" column.
- **Mitigation Strategy:** This column discusses the preferred strategy for resolving issues related to the design feature. Preferable interventions are organized left to right. For example, purchasing a pump that is designed in accordance with the findings addresses the issue immediately and is therefore the most preferred and least time consuming course of action health care organizations can undertake (refer to 2.2 for more detail). Post acquisition, the two options listed are to either alter the pump's design within the capabilities of the associated pump software, or to train users in the intended use of the pump. Given that training depends heavily on users voluntarily using the system properly rather than being limited to proper options (as reconfiguring the pump design might achieve) it is placed farthest to the right.

* Findings are referenced according to this legend:
A = Finding is supported by statistically significant data in the experiment.
B = Finding is supported by human factors principles and/or strong inferences from the experiment.
C = Finding is supported by additional literature
D = Finding is supported by feedback from nurse participants in the experiment.

Table 5 - Loading IV Set Findings

Design Feature	Finding*		Impact			Mitigation Strategy		
		Reference	Safety	Efficiency	Notes	Acquisition Consideration	Post Acquisition Consideration	
							Reconfigure with pump software	Training
Loading Mechanism	Loading compartments that open and close automatically are preferred because they minimize issues with manual locking/closing mechanisms.	A D		✓	In one pump design, nurses had to push the loading compartment until the pump motor could "catch" the door and complete the locking process, but users often pushed too hard or not hard enough, resulting in a door that was locked, but not properly closed. In another pump design, users had to use a latch to secure the loading door to the pump, however users sometimes did not push the door hard enough for the latch to properly hook into the pump and properly secure the door. In both of these pump designs, more nurses deviated during the loading process and nurses required more time to load the pump. Therefore, it is recommended that a powered loading compartment that is controlled by the pump be used to prevent frustration and delays.	✓		✓
IV Set Complexity	The IV tubing should require minimal insertion points into the loading compartment. A one piece cassette that can slide into the loading compartment is	A B D		✓	It was observed that the higher the number of fittings the IV set requires nurses to insert into the loading compartment of the pump, the greater the task time and frustration nurses experienced. The pump design that demonstrated statistically significant superior performance compared to other designs utilized a simple one piece cassette that simply slid into place. This recommendation should minimize confusion and maximize loading efficiency.	✓		✓

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C = Finding is supported by additional literature
D = Finding is supported by feedback from nurse participants in the experiment.

Design Feature	Finding*		Impact			Mitigation Strategy		
		Reference	Safety	Efficiency	Notes	Acquisition Consideration	Post Acquisition Consideration	
							Reconfigure with pump software	Training
	preferred.							
IV Set Orientation	A vertical IV set orientation is preferred.	B		✓	The pump design with the highest task time and highest number of nurses deviating featured a horizontal IV set orientation. It was observed in some cases that nurses had difficulty inserting components of the IV set when the rest of the tubing was hanging and dragging the IV set down. Given that the natural orientation of IV tubing is to hang vertically from the IV pole, it is recommended that the IV set be oriented vertically when loading the pump to minimize complexity and increase efficiency. Note that other issues exist regarding IV set orientation (see section 3.2.3)	✓		✓
Door Clearance	The design of the loading compartment should minimize the risk of occluding IV tubing when closed. Similarly, any hard components on the IV tubing should not prevent the loading compartment from closing.	B C	✓	✓	The design of the loading compartment can affect the likelihood of IV tubing accidentally being occluded by closing the loading door/carriage. Occlusion of IV tubing may not be detected quickly for slow drip rates, leading to unsafe delays in patient therapy. In addition, occlusion of the loading compartment has been reported in the literature to cause a free flow incident despite extensive training and a thorough FMEA process[43]. Therefore it is recommended that the placement of IV tubing into the pump should minimize the likelihood of tubing occlusion, or even door occlusion by hard components of the tubing.	✓		✓
Error Messages	Loading error messages should clearly describe what error exists and appropriate	B C	✓	✓	The pump design with the lowest levels of performance had no indications that the pump door was closed improperly. It is essential that users receive feedback to troubleshoot issues. For example, Schroeder et al. describes a situation where an error message reported an issue of tubing occlusion when in fact a free flow	✓		✓

Design Feature	Finding*		Impact			Mitigation Strategy		
		Reference	Safety	Efficiency	Notes	Acquisition Consideration	Post Acquisition Consideration	
							Reconfigure with pump software	Training
	actions should be suggested (e.g., Door not closed properly. Press "Load" to open door and try again).				incident was occurring[43]. In order to accurately diagnose loading errors, it is essential that accurate and clear error messages are provided to users with guidance on how to proceed. This will improve loading safety and efficiency because users will understand what is required of the situation instead of ascertaining it on their own.			
Forced Loading	It is unclear whether being forced to load the IV set before programming an infusion is beneficial.	B		✓	In other work, it was observed that some nurses prefer to load the IV set while programming (or have a colleague prepare the IV tubing and load the set while they program). As a result, forcing users to load the IV set before initiating the pump programming has the potential to frustrate users and could possibly lead to harmful workarounds. However, in some cases nurses did not remember to load the IV set until later in the programming sequence, leading to an interruption of their cognitive processes and occasionally delays due to the pump timing out of the programming sequence. Further research is required on this design feature.			

Table 6 - Pump Start-up and DERS Entry Findings

Design Feature	Findings*		Impact			Mitigation Strategy		
		Reference	Safety	Efficiency	Notes	Acquisition Consideration	Post Acquisition Consideration	
							Reconfigure with pump software	Training
Selection Order	The order in which nurses selected drug libraries or CCAs were not found to affect performance.	B			The potential for error remained the same regardless what order the questions were asked.	✓		
DERS entry style	A DERS entry style that defaults users into the drug library is preferred.	B	✓	✓	All three pump designs featured high levels of drug library compliance over all infusions. However, our field study results revealed that pumps that default users into generic mode (i.e., a fourth design not evaluated in our study) resulted in a significantly lower rate of compliance with the drug library than observed in our lab study.	✓		
Option Clarity	If users are required to select between multiple drug libraries, the purpose and content of each should be clear.	B	✓	✓	In one pump design, users were sometimes confused about what the difference between a drug library and a fluids library was. This design was also associated with a higher number of maintenance infusions delivered in generic programming, which was specifically advised against in training (note: the difference was not statistically significant). A lack of clarity regarding what each library contains may decrease efficiency as users may have to search through two libraries, and it may also encourage users to opt for generic programming. It is unclear why users were more likely to program in generic mode on this design, but the presence of three options	✓		

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D = Finding is supported by feedback from nurse participants in the experiment.

Design Feature	Findings*		Impact			Mitigation Strategy		
		Reference	Safety	Efficiency	Notes	Acquisition Consideration	Post Acquisition Consideration	
							Reconfigure with pump software	Training
					(drug library, fluid library, and generic programming) is hypothesized to play a role because it is one of the distinctive characteristics of that pump design.			

Table 7 - Drug and Concentration Selection Findings

Design Feature	Findings*		Impact			Mitigation Strategy		
		Reference	Safety	Efficiency	Notes	Acquisition Consideration	Post Acquisition Consideration	
							Reconfigure with pump software	Training
Navigation	Hierarchical alphabetical short cuts are preferred for navigating drug lists	B D		✓	Hierarchical shortcuts are a means of drilling down to the correct section of the drug library. Users might select a subsection of the drug library (e.g., letters M-P) with a contextual soft key at which point the drug library displays drugs starting with the letter M. The user can then select the letters "N", "O", or "P" to further specify which section of the drug library to search. Upon being presented with drugs starting with selected letter, the user can then scroll as normal, having significantly narrowed the number of entries. This decreases scrolling and therefore increases efficiency.	✓		✓
	Users should be able to easily recover from an unintended drug or concentration selection	B		✓	It was observed that upon selecting the wrong drug/concentration entry on one pump, users were unable to backtrack to the drug library without entering the VTBI. This resulted in confusion and delays as users were resistant to program VTBI for a drug they did not intend to deliver. This issue resulted in frustration and delays because nurses were aware of their mistake but were unable to easily rectify it. Therefore, correctly addressing this finding will prevent inefficiencies.	✓		✓
Selection	Selection of drug and concentration should occur on separate menus	B	✓	✓	The combination of drug name and concentration for each entry in the drug library decreases nurses' ability to distinguish between lookalike entries. This is a high risk task because incorrect selections result in inappropriate safety limits. Separation of drug selection from concentration selection also minimizes the size of the	✓	✓	

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C = Finding is supported by additional literature
D = Finding is supported by feedback from nurse participants in the experiment.

Design Feature	Findings*		Impact			Mitigation Strategy		
		Reference	Safety	Efficiency	Notes	Acquisition Consideration	Post Acquisition Consideration	
							Reconfigure with pump software	Training
					drug list, increasing ease of use and possibly compliance with the drug library.			
Confirmat-ion	Presence of a confirmation screen immediately after drug and concentration selection was not associated with increased safety.	B			Only one pump evaluated utilized a confirmation screen directly after the drug and concentration were selected. This screen simply presented the drug and concentration selected and asked nurses to confirm it was correct. However, no differences were observed between pumps that had this confirmation screen and those that did not. This may be because parameter entry screens typically also display drug name and concentration, duplicating the information that would be in a confirmation screen. Further research is needed to investigate this finding.			

Table 8 - Accessing Generic Programming Findings

Design Feature	Findings*		Impact			Mitigation Strategy		
		Reference	Safety	Efficiency	Notes	Acquisition Consideration	Post Acquisition Consideration	
							Reconfigure with pump software	Training
Bypassing the Drug Library	It is preferable that an option for generic programming is placed inside the drug library.	A	✓	✓	The lab study found that the pump which defaulted users into the DERS had the highest success rate when users were required to access generic programming. The pump that exhibited this finding used an entry labelled "Other Drug" which nurses could select if they wanted to use generic programming mode. This allows users to easily scroll to a different entry when they realize the drug is not in the library and avoids all issues related to exiting the drug library and selecting a different programming mode. Therefore this design has the advantage of increasing drug library compliance as well as increasing the accessibility of generic programming. It is not clear how effective other approaches (i.e., access via a soft key instead of a drug entry) are when selecting from within the drug library.	✓		✓
Exiting Drug Library	The process of exiting the drug library should be simple and intuitive. One successful approach was a soft key labelled "Exit"	A B	✓	✓	For some pumps, nurses have to exit the drug library to gain access to generic programming. On one pump, due to an issue with the control scheme, nurses often accidentally selected a drug when attempting to exit the drug library, triggering a secondary issue (see Navigation findings in Table 7). Only 20% of nurses recovered from this error leading to lengthy and unsafe delays in patient therapy. Therefore, a soft key labelled "Exit" is easy to understand and use, preventing confusion and unsafe delays.	✓		✓

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C = Finding is supported by additional literature
D = Finding is supported by feedback from nurse participants in the experiment.

Design Feature	Findings*		Impact			Mitigation Strategy		
		Reference	Safety	Efficiency	Notes	Acquisition Consideration	Post Acquisition Consideration	
							Reconfigure with pump software	Training
	within the drug library.							

Table 9 - Parameter Entry Findings

	Findings*		Impact			Mitigation Strategy		
Design Feature		Reference	Safety	Efficiency	Notes	Acquisition Consideration	Post Acquisition Considerations	
							Reconfigure with pump software	Training
Patient Weight Field	Patient weight should be paired with other programmable parameters and "greyed out" when not needed, or placed on its own dedicated screen which only appears if programming a weight based drug.	B		✓	On one pump, patient weight is entered on a screen that displays non programmable parameters such as a drug amount (i.e, mg), diluent volume (i.e. mL), concentration (drug amount divided by diluent volume), and dose per weight unit which is calculated based on what the patient weight is (i.e., mg/kg). The user would then press a "confirm" soft key when finished. However, when patient weight was not applicable, this screen remained, and the patient weight field was not shown. Given that this pump already featured a confirmation screen for drug and concentration, users often misunderstood this screen to contain programmable parameters and attempted to enter parameters. Nurses were confused regarding the purpose of the screen and the resulting deviations increased task time. This finding suggests that when patient weight is not required, all design elements related to patient weight should not appear or be made visibly non programmable to prevent confusion and increase efficiency.	✓		✓
Infusion Specific Fields	The default programming parameters should match the information provided to the end-user.	A B	✓		In the case of intermittent infusions, one pump pre-populated VTBI based on the selected concentration (which includes the IV bag volume) and made duration the default programmable parameter. Rate was not programmable without an enabling step. Given that duration was provided in the drug order for intermittent infusions in the lab study, nurses were able to easily transcribe this value directly into the only field that was immediately programmable. This	✓		✓

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C = Finding is supported by additional literature
D = Finding is supported by feedback from nurse participants in the experiment.

	Findings*		Impact			Mitigation Strategy		
Design Feature		Reference	Safety	Efficiency	Notes	Acquisition Consideration	Post Acquisition Considerations	
							Reconfigure with pump software	Training
					approach lea to a significantly higher success rate than approaches where all fields were available for any infusion because fewer calculation errors were made. Therefore it is strongly recommended that parameter entry screens limit programming to the fields nurses are provided with by default. Furthermore, if fields that are not programmable are still displayed, users can check that they fall within the expected range when the pump auto-calculates them. This allows users to double-check the parameters they may be more familiar with, without risking an error-prone calculation. Similarly, for generic infusions, all parameters should be available to users for programming flexibility. Although no statistical significance was found between generic programming parameter entry, pumps that provided all parameters for programming showed a trend of having a higher success rate for that infusion task.			
Order of Fields	The order of the default programming parameters should match the information provided to the end user (e.g. drug order).	B	✓	✓	Most pump designs placed rate as the first programmable parameter on the parameter entry screen. However, in one pump design, dose-rate was placed first instead, but the field was labelled as “dose”. Nurses using this pump often mistakenly entered total dose in the IV bag rather than dose-rate. This tended to occur with intermittent infusions, and not continuous infusions. The primary difference between these two types of infusions is the format of the drug order, therefore a mismatch between the parameter entry screen and the drug order is suspected of causing the issue. For example, nurses are provided with dose-rate for continuous infusions and duration for intermittent infusions in the lab study. When cued to enter “dose” in the case of a continuous infusions, nurses are able to refer to the dose-rate provided in the drug order. However, when programming an intermittent infusion, the cue for dose leads nurses to look for the only parameter on the drug order resembling dose, which is total	✓		✓

	Findings*		Impact			Mitigation Strategy		
Design Feature		Reference	Safety	Efficiency	Notes	Acquisition Consideration	Post Acquisition Considerations	
							Reconfigure with pump software	Training
					dose. It is recommended that parameter entry screens match the drug order used at the institution where pumps are used because it facilitates transcription of parameters in the correct order, avoiding parameter mix-ups and calculation errors.			
Calculated Fields	The volume to be infused parameter should not be recalculated by the pump when other parameters are changed.	A B C	✓	✓	Typically, once users have selected a concentration and entered a VTBI, the pump requires only one more parameter, which can be rate, dose-rate or duration to determine how quickly the infusion will run. As a result, any one of these three parameters allows the other two to be calculated because they are all related by the speed of the infusion. However, in one pump design, users often entered total dose rather than dose-rate. Upon entering VTBI, the pump auto-calculated rate and duration and because total dose was usually inappropriately high, this resulted in a duration that was too short. Nurses would then attempt to lower duration, but instead of decreasing both rate and dose-rate to match, the pump increased VTBI so that the infusion would now last longer. However, the infusion was intended to last for the volume of the bag, so nurses would then correct volume, and the pump would alter duration again, frustrating nurses. Given that VTBI is typically set to the size of the bag, it is recommended that auto-calculation remain limited to rate, dose-rate and duration based on a static VTBI. It is expected that this finding will minimize confusion, prevent delays and potential mis-programming.	✓	✓ One paper suggests the use of default durations to bypass this issue, and that nurses recheck their settings on the confirmation screen prior to starting an infusion[45].	✓
Viewing Fields	All parameters available for programming should be visible on the screen without scrolling.	B	✓	✓	One pump required users to scroll down to see the duration field. As noted in "Available Fields", users benefit from having the flexibility to use any field when programming generic infusions. Therefore it is recommended that all parameters are visible to users without having to look for other options. This may prevent calculation errors and increase efficiency because it allows nurses to directly transcribe from the drug order to the pump.	✓		✓

	Findings*		Impact			Mitigation Strategy		
Design Feature		Reference	Safety	Efficiency	Notes	Acquisition Consideration	Post Acquisition Considerations	
							Reconfigure with pump software	Training
Field Terminol-ogy	The pump should clearly describe the parameters nurses are programming. For example, nurses should clearly understand whether the pump is asking for total dose (i.e., mcg, mg, g) or dose-rate (i.e., mcg/h, mg/h, g/h)	B	✓	✓	In one pump design, nurses frequently entered the total amount of drug in the IV bag (i.e., mg) rather than the dose-rate (i.e., mg/h). Further discussion takes place in the finding "Order of Fields" (see row below). Pump designs that ensure users understand dose-rate rather than total dose is recommended because it will reduce the incidence of incorrect dose-rate's being entered into the pump.	✓		✓
Format of Duration Field	Time/duration data entry should clearly distinguish hours and minutes. For example: _ _ hh _ _ min.	B	✓		It was noted that in designs where parameter entry was not aided with the time units embedded into the data field that nurses entered the duration value in the wrong column. For example, in Approach B, entering "60" to the left of the colon results in a duration of 60 hours instead of 60 minutes. This type of error did not occur in approach A. Therefore, it is recommended that abbreviations for hours and minutes are embedded in the data field to reduce confusion and minimize the risk of infusions being started with incorrect duration values.	✓	✓ ISMP suggests that one strategy to counteract this issue is to enter default duration for drugs that are commonly ordered at a standard duration[45]. However, this issue is best	✓

	Findings*		Impact			Mitigation Strategy		
Design Feature		Reference	Safety	Efficiency	Notes	Acquisition Consideration	Post Acquisition Considerations	
							Reconfigure with pump software	Training
							addressed by acquiring a pump design that does not possess this concern.	
Confirmation screen	Confirmation screens after parameter entry were not associated with any additional safety benefit.	B			One pump design utilized a confirmation screen after nurses completed parameter entry, but no improvements in success rate were observed.			

Table 10 - Accessing Secondary Infusion Findings

Design Feature	Findings*		Impact			Mitigation Strategy		
		Reference	Safety	Efficiency	Notes	Acquisition Consideration	Post Acquisition Consideration	
							Reconfigure with pump software	Training
Primary Infusion Status	Secondary infusion mode should be accessible whether the primary infusion has been stopped or is still running.	A B	✓	✓	In one pump design, users were unable to access the secondary infusion mode unless the pump was stopped. In addition, when users attempted to access the submenu where the secondary infusion mode option was placed, the pump did not provide a descriptive error message describing why it was not available. In this particular design, over 40% of nurses were unable to successfully access the secondary infusion mode, resulting in safety concerns. Therefore, it is recommended that the secondary infusion mode should be accessible whether the primary infusion has been stopped or not. In pump designs where it is necessary that the pump should be stopped, descriptive error messages should exist to inform the user that the pump must be stopped to enable access. It is expected that these recommendations will reduce unsafe delays to patient therapy.	✓		✓
Navigation	Secondary infusions should be accessible from the primary infusion screen (i.e., not buried in pump submenus).	B	✓	✓	It was found that nurses demonstrated improved performance on pumps that placed the secondary infusion mode option directly on the primary infusion screen. This finding decreases the memory load on nurses and is likely to increase efficiency.	✓		✓

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C = Finding is supported by additional literature
D = Finding is supported by feedback from nurse participants in the experiment.

Table 11 - Secondary Infusion Parameter Entry Analysis

Design Feature	Findings*		Impact			Mitigation Strategy		
		Reference	Safety	Efficiency	Notes	Acquisition Consideration	Post Acquisition Consideration	
							Reconfigure with pump software	Training
CCA selection	The process of reprogramming the pump to reflect patient & pump handoffs between clinical care areas must be clear to users.	B	✓	✓	In one pump design, it was possible for the CCA of the secondary infusion to be different from the primary infusion. While this feature may facilitate some flexibility in pump programming during patient transfers between CCAs, it also contains a number of risks. Mismatching primary and secondary infusions may be inherently confusing, particularly for staff who may not be aware that a mismatch exists. Improper CCA settings affect the validity of the drug library, and therefore pose safety risks.	✓		✓
Infusion Mode Feedback	The programming mode (i.e., primary or secondary) should be clearly communicated to users.	B	✓	✓	It is important that the pump distinguish between primary and secondary infusion programming modes to prevent accidental programming of the wrong mode from occurring. If not, the pump will not be programmed correctly and may result in either confusion or a primary infusion that does not engage once the secondary is complete. Users that are able to detect these mistakes suffer efficiency losses when making corrective action.	✓		✓
	Access to both primary and secondary infusion modes should be visible while programming (e.g., tabbed headings	B	✓	✓	Some pump designs used tabs (i.e., a primary infusion mode tab, a secondary infusion tab etc.) or text headings to display which mode had been activated and was being programmed. These pumps did not result in the same incidence of error as the remaining pump design, suggesting they offer superior infusion mode feedback.	✓		✓

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C = Finding is supported by additional literature
D = Finding is supported by feedback from nurse participants in the experiment.

Design Feature	Findings*		Impact			Mitigation Strategy		
		Reference	Safety	Efficiency	Notes	Acquisition Consideration	Post Acquisition Consideration	
							Reconfigure with pump software	Training
	while programming or headings describing current infusion mode with option to switch to different mode) .							

Table 12 - Soft Limit Alert Findings

Design Feature	Findings*		Impact			Mitigation Strategy		
		Reference	Safety	Efficiency	Notes	Acquisition Consideration	Post Acquisition Consideration	
							Reconfigure with pump software	Training
Alert Language	Limit alerts should clearly state that a limit has been exceeded using words.	A B	✓		The one pump design that did not explicitly state that a limit had been hit had the lowest success rate of all designs. It is likely nurses did not recognize that a soft limit alert had been reached, and were simply confirming the value selected, inadvertently overriding the limit. Therefore, to avoid unsafe medication delivery, it is important that a clear statement of limit violation in text is presented to the nurse so that the soft limit can be properly identified.	✓		✓
Alert Limit Information	Limit alerts should clearly define the value of the limit for the parameter that was violated (i.e., the parameter nurses programmed last (rate, dose-rate or duration)).	B	✓	✓	Limit alerts that display the value of the limit violated allow nurses to interpret the alert without having to refer to a field that they did not program. For example, a pump that returns a limit alert stating that a limit of 40mL/h has been exceeded when the nurse programmed the infusion duration for 2 hours is not providing feedback in the same form as the nurse entered, requiring nurses to exert additional cognitive effort to understand the message. Failure to understand the implications of the limit message may result in safety risks (as users may be more inclined to override the limit if it presents no understandable warning) and inefficiency as nurses must spend more time reviewing what might be wrong. Of the two high performing pump designs, one abided by this recommendation and one did not. Therefore, this finding is not statistically supported, but preferred from a human factors perspective. In addition, no significant difference was found between pumps that	✓		✓

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C = Finding is supported by additional literature
D = Finding is supported by feedback from nurse participants in the experiment.

Design Feature	Findings*		Impact			Mitigation Strategy		
		Reference	Safety	Efficiency	Notes	Acquisition Consideration	Post Acquisition Consideration	
							Reconfigure with pump software	Training
					provided only the value of the limit exceeded versus all limits set for that drug. Therefore, at the minimum, the specific value exceeded by the programmed parameters is preferred. In summary, this recommendation is critical to delivering appropriate and relevant feedback to nurses so that the limit alert can be recognized and addressed safely. Intuitive interpretation of the alert also reduces the likelihood of confusion, and therefore delays.			
Alert Formatting	Limit alerts should be displayed with a different colour scheme from the rest of the programming sequence and be accompanied with a short audible tone. Further research is required to determine if graphic scales and depicting the range of acceptable values is helpful.	A B	✓		The pump design that showed a low success rate in this task did not use colour, while those designs that were significantly higher performers from a statistical perspective did utilize colour. This data suggests that the use of colour may play a role in increasing nurse recognition to the limit alert. Therefore it is recommended that colour be used because it may increase the success rate of correct responses to soft limit messages.	✓		✓
Alert Timing	No conclusions can be drawn regarding the timing of the alert.	B		✓	Current experiment data suggests that whether the limit alert appears immediately after nurses enter a parameter or after all parameters have been entered and the infusion is started, does not have an impact on the correct response to the soft limit. One high performing pump design used the former alert timing, while the second high performing design used the latter timing approach. Further research is required on this issue.			

Design Feature	Findings*		Impact			Mitigation Strategy		
		Reference	Safety	Efficiency	Notes	Acquisition Consideration	Post Acquisition Consideration	
							Reconfigure with pump software	Training
Alert User Options	Users should clearly understand what "yes" or "no" means in the context of the limit alert. Alternatively, options can be labelled more descriptively (i.e., "override" or "reprogram").	A B	✓		This finding is directly related to "Alert Language" because the meaning of a user's options depends on how clearly the limit describes what has happened and solicits a response. It was found that nurses using a pump design that provided the options "yes" or "no" after being presented with clear alert language and asking a question "Proceed?" had significantly higher success rates than the pump design that did not. A second high performing pump design simply stated "Outside Limits" and offered two descriptive options "Override" or "Edit". It is hypothesized that clear options on how to proceed enhances nurses' ability to recognize that a limit has been reached and make appropriate decisions. This should result in increased safety benefits.	✓		✓
Reprogramming post alert	If users decide to return to the parameter entry screen, the value of the parameter that exceeded the soft limit should be highlighted.	B		✓	In one pump design, the "Alert Timing" was such that only when the nurse attempted to start an infusion was the limit presented. Upon deciding to review their parameters, the nurse returned to the programming screen and found that the values they had entered were erased. This makes it difficult for nurses to compare what they entered with the value of the limit. Therefore, highlighting the value of the parameter that exceeded the soft limit will decrease the time it takes for nurses to determine what was inappropriate and make the necessary corrections.	✓		✓

Table 13 - Hard Limit Alert Findings

Design Feature	Findings*		Impact			Mitigation Strategy		
		Reference	Safety	Efficiency	Notes	Acquisition Consideration	Post Acquisition Consideration	
							Reconfigure with pump software	Training
Alert Confirmation	Hard limit alerts should stay present on the screen until users confirm them.	B		✓	Temporary "pop-up" alert messages may be missed if the user is not looking at the screen for a moment. While the objective of the hard limit can be achieved whether the nurse understands it or not, it may not be clear to the user what has happened. This recommendation will reduce inefficiencies related to nurses retrying the same programming parameters when it is unclear why it was not successful the first time.	✓		✓

* Findings are referenced according to this legend:
A = Finding is supported by statistically significant data in the experiment.
B = Finding is supported by human factors principles and/or strong inferences from the experiment.
C = Finding is supported by additional literature
D = Finding is supported by feedback from nurse participants in the experiment.

7.3 Methodology of Comparative DERS Design Experiment

This section describes the experimental methodology of the experiment comparing pump designs, on which section 3 is based. Additional details on the study can be found by reviewing Rothwell, 2009[11].

7.3.1 Participants

Twenty-four nurses participated in this experiment and were recruited from six clinical areas (i.e. post anaesthetic care unit, cardiovascular intensive care, coronary intensive care, general surgery, general internal medicine and transplant). Each nurse was remunerated for their participation. University Health Network Research Ethics Board (REB) approval was obtained.

The participants were in the following age ranges; fifteen were between the ages of 18 and 35, seven were between the ages of 36 and 45, and two were between the ages of 46 and 60.

7.3.2 Design

The participants delivered IV infusions with three different smart pumps under seven different infusion scenarios. Thus, the design was a 3 (pump model) x 7 (infusion scenario) repeated measures design. The order of the pump models and infusion scenarios were counterbalanced to avoid carry-over effects.

Pump Models

Three smart pumps currently available on the market were acquired from three different manufacturers. The pumps were selected based on the various design elements they possessed in hopes of comparing different approaches to infusion pump programming.

Infusion Scenarios

Nurses were asked to complete a series of IV infusion scenarios. These infusion scenarios were developed in consultation with nursing and pharmacist experts to ensure validity. All infusions were intended to be primary infusions unless otherwise indicated. The infusion scenarios are summarized here:

1. **Continuous first channel**: A primary continuous infusion performed on the first channel of the pump.
2. **Intermittent second channel:** A primary intermittent infusion performed on the second channel of the pump.
3. **Intermittent first channel:** A primary intermittent infusion performed on the first channel of the pump. The medication in this scenario is not in the pump's drug library.
4. **Continuous maintenance first channel:** A primary continuous infusion of a maintenance fluid on the first channel of the pump.
5. **Secondary intermittent infusion on first channel:** A secondary intermittent infusion on the first channel of the pump. Note that this scenario is always

paired with scenario #4 as secondary infusions require an association to a primary infusion.

6. **Intermittent second channel soft limit:** A primary intermittent infusion that exceeds the maximum soft limit performed on the second channel of the pump.
7. **Continuous second channel hard limit:** A primary continuous infusion with ordered parameters that exceed the maximum hard limit value performed on the second channel of the pump.

Physician orders were presented on an integrated computer physician order entry (CPOE) and electronic medication administration (eMAR) system to reflect how nurses in this study currently view physician orders, except in cases where paper orders were typically used in practice. Drug orders for continuous infusions provided dose-rate, rate and volume to be infused (VTBI). Drug orders for intermittent infusions provided dose, duration and VTBI.

7.3.3 Location and Apparatus

The experiment was conducted in labs that allow high fidelity re-creations of clinical environments. In order to simulate an inpatient unit environment a number of components were used including patient beds, furniture, CPOE and eMAR systems, IV infusion equipment (e.g., IV bags, tubing sets, labels), and paperwork. These labs were equipped with multiple ceiling-mounted cameras and microphones, had observational booths with one-way glass, and had full video and audio recording and editing facilities. No actual drugs or patients were used. Rather, water was used in place of drugs and mannequins were used in place of patients.

7.3.4 Procedure

Each participant was provided with a 15 minute training session on a given pump. The training covered the main programming tasks required in the experiment and was based on typical vendor instruction. Participants were then asked to complete various infusion tasks in the simulated clinical environment. When the experimental condition began, there were three patient mannequins in separate beds in the unit. Participants were briefed by a confederate nurse on the patients' medical histories, given physician orders for IV infusions, and asked to program the pumps accordingly. The confederate nurse remained present in the room to ensure participants conducted the tasks in the required sequence. If participants became stuck or confused they were asked to communicate with the confederate nurse. Participants then completed a post test survey on the pump they just used and began the procedure anew by receiving training on another pump. When testing sessions with all three pumps were completed, nurses responded to a final survey to rate their opinions on each of the three pumps and provide additional comments.

7.3.5 Metrics

A thorough account of how metrics were recorded can be found in Rothwell's thesis[11]. Short definitions are provided here.

- **Success:** Nurses either passed (success) or failed an infusion task. Nurses passed if the infusion was started with the correct parameters selected and

entered into the pump as displayed on the medication order. Nurses were allowed to receive hints. Failure was the result of either:
    - The infusion not being started.
    - The infusion being started with parameters different from those on the medication order.
    - Nurses requiring explicit instructions on how to continue.
- **Success rate**: The success rate represents the proportion of nurses that successfully completed the entire infusion scenario or sub-tasks.
- **Deviations:** Deviations refers to occasions where nurses did not follow the optimal programming path, as determined by experimenters prior to the testing sessions. The frequency and type of deviations provide insight into what design elements may be problematic.
- **Task time:** Task completion time was recorded for the entire infusion scenario as well as sub-tasks.
- **Survey results:** A post-test survey was provided to nurses assessing their perceptions of usability and performance of each smart pump model. A five point Likert scale (Strongly Disagree – Disagree – Neutral – Agree – Strongly Agree) was used.

7.4 Methodology of Education Experiment

The following sections outline the experiment on education in more detail. For more information, consult Fan, 2009[61].

7.4.1 Participants

Fourty-seven nurses were recruited from seven clinical areas (i.e. post anaesthetic care unit, cardiovascular intensive care, coronary intensive care, general surgery, general internal medicine, emergency department, and transplant). Each nurse was remunerated for their participation. University Health network Research Ethics Board (REB) approval was obtained.

The participants were split into two groups for the mixed factors experiment design. The first group of 24 participants were in the following age ranges: thirteen were between the ages of 18 and 35, five were between the ages of 36 and 45, and six were between the ages of 46 and 60. The second group of 23 participants were in the following age ranges: sixteen were between the ages of 18 and 35, two were between the ages of 36 and 45, and four were between the ages of 46 and 60; one nurse did not answer the question.

7.4.2 Design

A mixed factors design was used. Participants in group one received traditional vendor based training (VBT) while participants in group two received human factors and education informed training (HFET). Participants in each group were asked to complete the same set of seven IV infusion scenarios. Therefore, the between group variable was the training protocol, and the within subject variable was the infusion scenario.

The VBT group participated in the study first so that human factors analysis of the pump could be conducted. These findings were paired with recommendations from an education expert to develop the HFET training protocol, which was then used to train the second group of participants.

Training Design

The participants in the first group received vendor based training (VBT). This protocol was designed based on direct observation of vendor training sessions specific to the smart pump used in the study, as well as literature and training documents from other vendors. The VBT protocol utilized a guided training approach covering the tasks required of nurses in the infusion scenarios. Time constraints forced training sessions to be approximately 10-15 minutes.

After analyzing safety and efficiency metrics from nurses trained with the VBT method, a new training curriculum was developed with consultation from human factors and education experts. This new HFET method provided greater emphasis on topics identified to be problematic from the first group. It made use of an acronym to assist nurses in remembering the correct sequence of tasks, and also was restructured to involve case based situations nurses would attempt on their own, with minimal guidance.

Infusion Scenarios

The infusion scenarios utilized in this study are the same as those presented in section 7.3.2, but because only one test condition was required (i.e., no counterbalancing), the specific infusions are presented in the order participants complete them:

1. Continuous infusion of heparin
2. Intermittent infusion of potassium phosphate with drug order designed to trigger soft limit alert
3. Continuous infusion of maintenance fluid
4. Secondary intermittent infusion of dimenhydrinate (on the maintenance fluid above)
5. Continuous infusion of insulin with drug order designed to trigger hard limit alert
6. Intermittent infusion of danaparoid (rare drug intended not found in the drug library)
7. Intermittent infusion of morphine

7.4.3 Location and Apparatus

The location and apparatus were identical to the setup discussed in section 7.3.3.

7.4.4 Procedure

The procedure is identical to that presented in section 7.3.4 with the exception that each participant completed only one set of infusions on one pump, and received only one type of training (i.e., VBT or HFET).

7.4.5 Metrics

A thorough account of how metrics were recorded can be found in Fan's thesis[61]. Short definitions are provided here (brackets indicate analysis topic):

- **Failed infusions (safety):** Nurses either passed (success) or failed an infusion task. Nurses passed if the infusion was started with the correct parameters selected and entered into the pump as displayed on the medication order. Nurses were allowed to receive hints. Failure was the result of either:
  - The infusion not being started, or being started but not connected to the patient.
  - The infusion being started with parameters different from those on the medication order.
  - Nurses requiring explicit instructions on how to continue.
  - Starting a drug order despite hitting a soft limit (changing the drug order to fall within soft limit parameters was considered acceptable)
  - Bypassing a hard limit by resorting to generic programming
- **Task time (efficiency):** Task completion time was recorded for the entire infusion scenario as well as for each section of programming.
- **Deviations (efficiency):** Deviations refers to occasions where nurses make an action that takes them away from the goal of a correctly programmed and started infusion. Deviations provide insight into where a mismatch between user expectations and pump design exists and therefore is more descriptive than straight measures of task completion time. Therefore, additional measures were devised to provide more detail:
  - The section of programming deviations occurred in.
  - The amount of time users spent deviated.
  - The number of key presses nurses made while deviated until returning to the intended programming path or until the end of the infusion scenario.
  - The proportion of task time spent deviated.
- **Hints provided (efficiency):** The number of hints provided to nurses suggests lack of understanding of the pump programming process. Furthermore, the section of programming nurses required hints in was also recorded.