Improving Safety of Medication Infusion Pump Through Simulation and Applying Systems Engineering Principles and Best Practices

Final Comprehensive Report

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EXECUTIVE SUMMARY

Medication infusion pumps (MIP) are important medical devices that allow for safe and controlled delivery of intravenous medications. They are prolific in healthcare; approximately 90% of inpatients receive intravenous (IV) medications.[1] While their benefits as a means of controlling and improving the safety of IV medication administration are many,[2] MIPs carry potential for harm. Medications administered through MIPs are potent, and the consequences of an error can be severe.[3] Recent reports of adverse events have made MIPs the target of close examination, with 87 pump recalls between 2005 and 2009. The Food and Drug Administration (FDA) contends that their operational complexity has led to 56,000 adverse drug events over 4 years, some of which have led to serious injuries and deaths.[4]

The FDA-sponsored Infusion Pump Summit (2010) identified poor human-machine interface design as a critical shortcoming of current MIPs.[5] Clinicians often find themselves adapting their workflow to the designs of the MIPs, as opposed to having access to MIPS that are designed to meet their needs and workflow.

To address this challenge, the Johns Hopkins University Applied Physics Laboratory (JHU/APL) and Johns Hopkins Medical Institute (JHMI) partnered to apply a systems engineering approach for enhancing and evaluating the safety of MIPs. The partnership was funded through the Agency for Healthcare Research and Quality (AHRQ) on April 22, 2011. The overall objectives of the project were to define user needs toward the design of a new human-machine interface for MIPs and develop a strategy for evaluating the infusion pump design using simulation as a usability test-bed environment.

The team sought to achieve these objectives through three specific aims (see Figure ES-1) to: 1) define clinician requirements in use of MIPs, 2) develop a rapid prototype environment to test the safety and usability of simulated infusion pumps and develop MIP prototypes based upon clinician requirements, and 3) measure the safety/usability profile of infusion pumps using high-fidelity simulation.

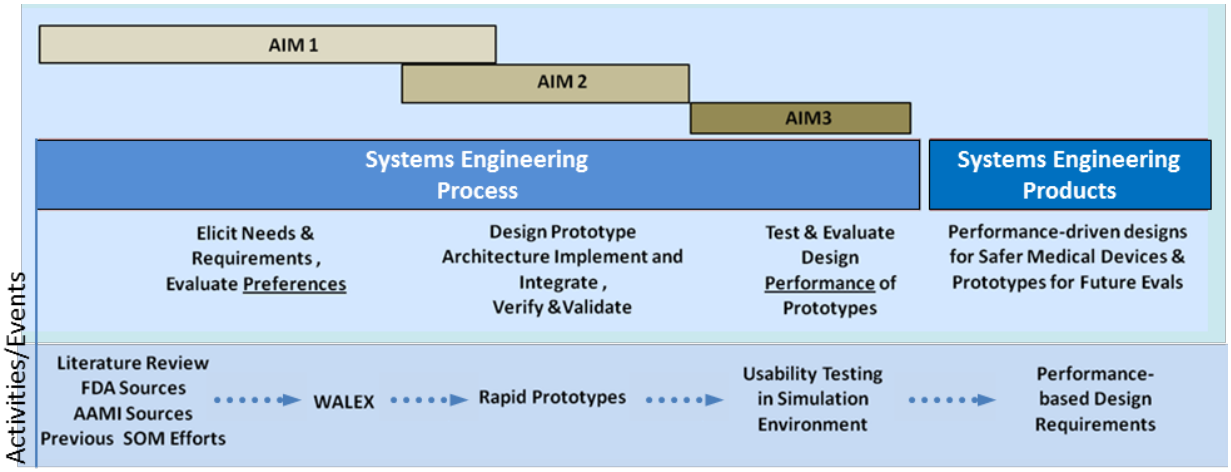

Figure ES-1. Specific Aims of the Project Aligned with the Systems Engineering Process

Specific Aim #1: To define MIP user needs

Through a survey of clinicians and one-day multi-disciplinary workshop, 25 requirements were elicited from a group of nurses, physicians, engineers, manufacturers, and regulators. The 25 requirements were summarized into five overarching themes:

- ***Systems Integration***
  MIP users strongly express a desire to see infusion pumps more tightly integrated into the larger health information technology (IT) enterprise. At the bed-side level, users express the benefits of pump designs integrating with medication orders, IV bags, IV poles and IV tubes.

- ***Programming Navigation***
  MIP users express frustration with the limitations in current MIP display interfaces, including the ability to effectively navigate through menus and option choices. This is especially important during stressful situations. Users desire a more user-friendly graphical user interface and sensible menu layouts that align more closely with their clinical workflows.

- ***Information Presentation and Prioritization***
  Users regularly express the difficulties of viewing pumps from a distance or certain viewing angles, and/or under various lighting conditions.

- ***Control Standardization***
  Users desire more consistency among the terminology and location of functions such as "Run," "Stop," etc. across pump designs. Variations in terminology use and controls placement between different pump designs lead to confusion.

- ***Context Awareness***
  Users express interest in a MIP that is more aware of the patient's condition and medical treatment. MIPs could know that other pumps are connected to the same patient, other pumps are flowing the same drug, or the relative orientation of one bag on a pole to the orientation of other bags on the same pole. MIPs could monitor the patient's clinical trajectory, the practitioner's identity, and the patient's allergies.

Specific Aim #2: To build a prototype using a software-based platform and an exploratory test environment for the rapid evaluation of infusion pumps.

The project team formulated a concept of operations for an improved MIP design based on clinician needs and key themes identified from Specific Aim #1. By integrating with hospital information and provider order entry (POE) systems, the MIP concept enables the clinician to manage the medication infusion process through an auto-programming mode that associates the device to a patient, medication infusion order and pump elements. The concept was materialized as a prototype and software-based platform through close collaboration with clinical subject matter experts. Additional activites were conducted in preparation for usability and validation testing in Specific Aim #3, such as developing the testing

protocol, identifying performance metrics, and generating clinical scenarios for training and testing sessions.

Specific Aim #3: To measure the safety/usability profile of infusion pumps using high-fidelity simulation.

The project team evaluated the safety and usability profile of the MIP prototype in a high-fidelity simulation environment. Comparative usability testing was conducted to evaluate the MIP prototype in manual and auto-programming modes. Forty-one participants became familiar with the MIP prototype by walking through a patient scenario in both modes. Participants were then instructed to operate the MIP prototype using a test scenario that required the participant to log in, start infusions, start/stop bolus, detect and resolve air-in-line alarm, perform secondary infusion, titrate medication and discontinue infusions. The scenario involved administration of lactated ringers, heparin, norepinephrine, and piperacillin/tazobactam and vancomycin in a high-fidelity simulation environment. Demographic characteristics, performance characteristics, and qualtitative feedback were collected.

Participants felt that auto-programming could prevent misinterpretation of physician orders (4.3 versus 3.1 on NASA Task Load Index, $p < 0.01$), reduce programming errors (0.2 versus 2.9, $p < 0.01$), and prevent errors in calculating conversions (4.3 versus 3.7, $p = 0.03$). Auto-programming was associated with less mental (33.8 versus 39.4, $p = 0.02$) and performance demands (20.7 versus 28.9, $p < 0.01$), but similar overall Task Load Index (28.3 versus 31.1, $p = 0.08$). There was no difference in proportion of tasks completed (97.9 vs. 97.2, $p = 0.17$) between the two modes.

Based upon testing in the simulated environment, auto-programming of MIPs was superior to manual programming in terms of perceived safety and mental load. Participants expressed concern about relying on auto-programming, however, and not being as vigilant in catching potential errors in physician orders. There was no measured difference in terms of task completion or overall task load.

Conclusion

In this project, challenges and user needs associated with large volume MIPs were identified. A prototype MIP interface allowing for usability testing of various functions and features was developed. Usability testing was performed comparing automated and manual MIP programming. Test participants found auto-programming to be potentially safer. They found it to be less mentally demanding and associated with better performance. However, they found manual programming to be easier to use, likely related to their familiarity with this process and the nature of the barcode device selected for use. Tasks were completed with equal likelihood in both modes.

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1. PHASE 1

1.1 PHASE 1 EXECUTIVE SUMMARY

Medication infusion pumps (MIP) are important medical devices that allow for safe and controlled delivery of intravenous medications. They are prolific in healthcare; approximately 90% of inpatients receive intravenous (IV) medications.[1] While their benefits as a means of controlling and improving the safety of IV medication administration are many,[2] MIPs carry potential for harm. Medications administered through MIPs are potent, and the consequences of an error can be severe.

During Phase 1, the project team developed a research protocol and obtained Institutional Review Board (IRB) approval for the user evaluation of the prototype medication infusion pump. The team defined a preliminary set of user needs for a Johns Hopkins University Applied Physics Laboratory (JHU/APL)/Johns Hopkins Medical Institute (JHMI) Workshop discussion related to usability challenges associated with the safe use of MIPs. A select group of MIP stakeholders were surveyed prior to the workshop to rank the importance and criticality of their usability challenges. The team conducted the one-day workshop, which was attended by approximately 40 MIP Subject Matter Experts (SMEs) from industry, government, healthcare and academia. Findings from the workshop were summarized into five overarching themes:

- ***Systems Integration***
  MIP users strongly express a desire to see infusion pumps more tightly integrated into the larger health information technology (IT) enterprise. At the bed-side level, users express the benefits of pump designs integrating with medication orders, IV bags, IV poles and IV tubes.

- ***Programming Navigation***
  MIP users express frustration with the limitations in current MIP display interfaces, including the ability to effectively navigate through menus and option choices. This is especially important during stressful situations. Users desire a more user-friendly graphical user interface and sensible menu layouts that align more closely with their clinical workflows.

- ***Information Presentation and Prioritization***
  Users regularly express the difficulties of viewing pumps from a distance or certain viewing angles, and/or under various lighting conditions.

- ***Control Standardization***
  Users desire more consistency among the terminology and location of functions such as "Run," "Stop," etc. across pump designs. Variations in terminology use and controls placement between different pump designs lead to confusion.

- ***Context Awareness***
  Users express interest in a MIP that is more aware of the patient's condition and medical treatment. MIPs could know that other pumps are connected to the same patient, other

pumps are flowing the same drug, or the relative orientation of one bag on a pole to the orientation of other bags on the same pole. MIPs could monitor the patient's clinical trajectory, the practitioner's identity, and the patient's allergies.

1.2 PHASE 1 INTRODUCTION

Clinicians, engineers, and medical care providers cite MIPs among the most problematic medical devices used today in the clinical setting.[6] According to a US Food and Drug Administration (FDA) report, the problems with these devices stem from poor software design/implementation and human factor considerations, among others.[4] "From 2005 through 2009, FDA received approximately 56,000 reports of adverse events associated with the use of infusion pumps, including numerous injuries and deaths. During this time period, 87 infusion pump recalls were conducted by firms to address identified safety concerns."[4]

A key shortcoming of current infusion pumps, based upon device error reports, is poor human-machine interface design. Clinicians often find themselves adapting their workflow to the design of the infusion pumps rather than operating a pump designed to meet their needs and clinical workflow. The mismatch is largely due to the limited pre-production usability testing and human/systems factors engineering in the design of infusion pumps.

In response to the challenge, JHU/APL and JHMI collaborated on exploring innovative technogical solutions to improve the safety of MIPs in clinical settings. The focus was on MIPs used for fluid delivery to patients in hospital settings. Toward this end, JHU/APL and JHMI received Agency for Healthcare Research and Quality (AHRQ) funding (1R18HS020460) in April 2011 to improve the safety and usability of MIPs using a simulated environment for rapid evaluation. The following subsections describe the methods used in Phase 1 of this project, which elaborates upon the pump issues discussed during the stakeholder workshop and user needs for developing the concept of operations (CONOPS) of a MIP prototype.

1.3 PHASE 1 METHODS

The project team used a systems engineering approach to produce performance-driven user needs for improving MIP safety. The first step was to elicit user needs to address the operational and technical gaps surrounding MIPs. This step ultimately drives the level of detail in defining the user needs and design features, an activity represented graphically in Figure 1. Specifically, the project team identified user needs from clinicians, pharmacists, engineers, vendors, regulatory and human factors personnel. The JHU/APL—JHMI workshop occurred in January 2012 at the JHU/APL Collaborative Analysis Center (CAC). The CAC facility (formerly the Warfare Analysis Laboratory or WAL) is equipped with extensive resources to foster open discussion and collaborative exercises. The collaborative exercise engages participants in a thoughtful examination of a problem or set of problems and solicits experiences, perspectives, and judgment from participants.[7]

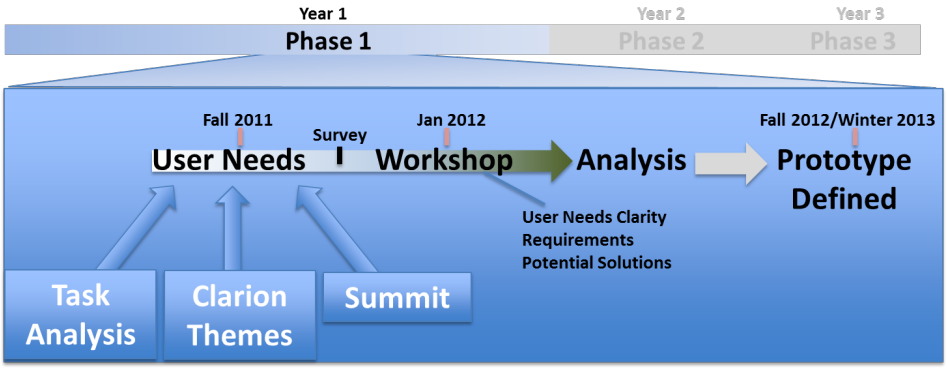


Figure 1. Description of Phase 1 (Specific Aim #1) Activities

Workshop attendees joined the facilitated discussions and participated in the CAL's electronic messaging system by entering comments. Participants used the messaging system to exchange candid opinions and open discussion in a non-attributed way. All of the comments were available for viewing in real time. Contents from both the oral discourse and messaging system were documented and served as a source of information for later analysis by the project team.

1.3.1 Project Team

The project team members prepared and executed the event with the assistance of a professional facilitator who guided stakeholders through the workshop discussions. The project team selected Mr. John Deadwyler as the workshop facilitator (Bernard Consulting Group, St. Louis, Missouri). His previous involvement as a facilitator included several infusion pump-related conferences and workshops, two of which representatives from JHU/APL and JHMI attended. The decision to employ Mr. Deadwyler as the workshop facilitator was driven by his familiarity with infusion pumps and patient safety topics, as well as the recognition and respect he commands from the infusion pump community as an effective facilitator.

The multi-disciplinary team was comprised of individuals having clinical, engineering, and project management expertise, including:

- JHMI
  - SMEs (nurse and physician)
  - Human factors engineer
  - Project analyst
- JHU/APL
  - Systems engineers
  - Project analyst and administrator

1.3.2 Participants

A critical component in executing a successful CAC exercise is hosting the right mix of participants to encompass multiple perspectives toward the common problem or set of problems. The objective is to

address the complex set of problems where no one participant has the complete view of the problem and its associated policy, operations, and technical issues.[7]

The workshop committee carefully selected and assembled a diverse group of 41 participants who were invited to solicit their experiences, perspectives, and judgment based upon planned discussions of the problem space. Representatives from academia and industry attended the JHU/APL-JHMI Workshop and consisted of manufacturers, clinicians, regulators, subject matter experts (SMEs), and engineers who volunteered their time for the seven-hour event. A distribution of the 41 invited participants and nine project team members by category of expertise is depicted in Figure 2.

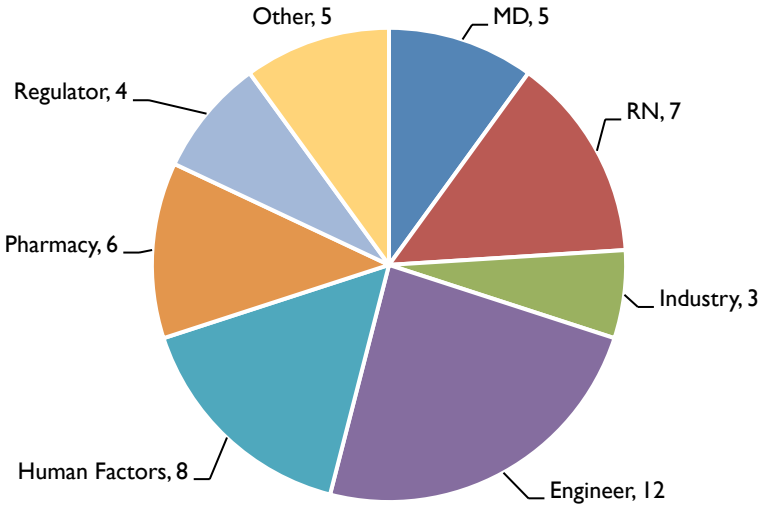


Figure 2. Attendees at the 2012 JHU/APL/JHMI Workshop (Categorized by Expertise)

1.3.3 Workshop Preparation

To prepare for the workshop, the committee solicited input from select participants on multiple occasions to identify issues, prioritize problems, and elicit information about best MIP practices. Additionally, workshop materials and displays were developed to facilitate discussions at the workshop. These topics are discussed more fully in the following subsections.

1.3.3.1 Preliminary Analysis for Issue Prioritization

An online survey was sent to invitees ten days prior to the event with the aims of refining the topics for in-depth discussions within the allotted seven-hour workshop session. Responses to the surveys provided the format for discussing workshop topics in the collaborative exercise. A comprehensive list of user needs, which was subsequently used to define design features, were compiled from the 2010 JHU/APL/JHMI Task Analysis study and 2010 Association for the Advancement of Medical Instrumentation (AAMI)/Food and Drug Administration (FDA) Infusion Pump Summit.[5] Findings from the latter study included the clarion themes and priority issues as topic areas for workshop discussion. The project team prioritized the user needs by soliciting feedback from workshop invitees in advance.

1.3.3.2 Issue Prioritization of Problem Statements

To determine the order of discussion topics at the workshop, the project team invited representative users from two cohorts to complete a survey during December 2011 and January 2012. The online survey was completed by 13 registered nurses, in addition to 37 of 41 registered workshop attendees prior to the event. The survey presented 25 questions relating to usability and user needs in the form of problem statements (i.e., root cause). Respondents were instructed to prioritize each problem statement by assigning it a ranking of either "Low," "Medium," "High," or "Unsure," according to the following criteria:

- How frequently does each problem occur?
- When the problem does occur, how severe is the outcome to patient safety?
- How likely is it that each problem statement will generate interesting discussion during the workshop?

The answer choices "Unsure," "Low," "Medium," and "High" were respectively assigned a score of 0, 1, 2, and 3. Each of the three questions were weighted equally, and the average composite score was generated (range 1 to 3); "Unsure" responses were not used in calculating the average. After assigning the final scores to each problem statement, the results were subsequently ranked from highest to lowest scores.

1.3.3.3 Best Practices Survey

Respondents were also asked whether a series of statements about MIP user interfaces were considered "best practices" for design using fundamental human factors design principles. The list of design features were derived from the needs list, which was down-selected by the project team based on expert opinion. Respondents were asked to indicate whether or not the statement of design features were indeed best practices.

Approximately 70% (n = 31) of the 41 invited attendees completed the best practices survey. The number of responses for each item were recorded and then analyzed to determine which design features were accepted as best practice. Design features were accepted as best practice when items received a majority vote consisting of at least 75% of the survey respondents. Results indicated 11 design features, meeting the 75% threshold criterion (Figure 3).

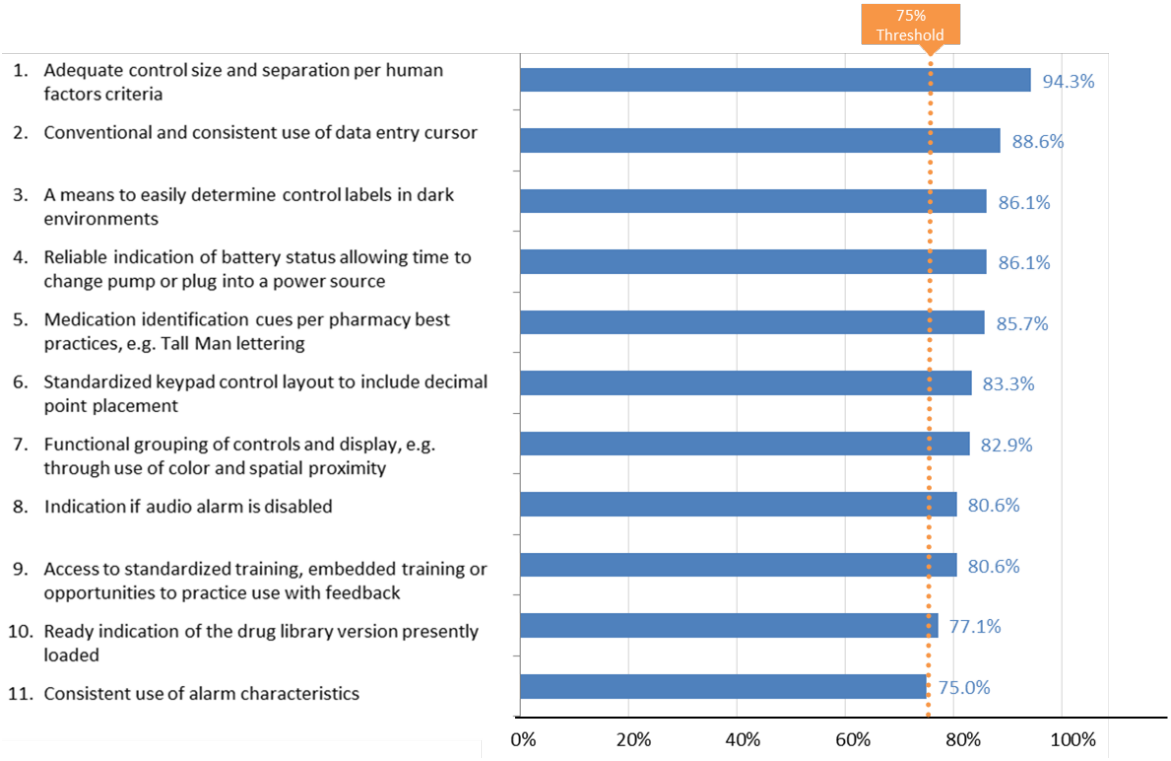


Figure 3. Summary of Design Features Accepted as Best Practices (Met 75% Criterion)

Consensus for best practices was not met for an air-in-line detector, consistency in labeling, force functions, alarm cues for occlusion, test features, and standardized units, as shown in Figure 4.

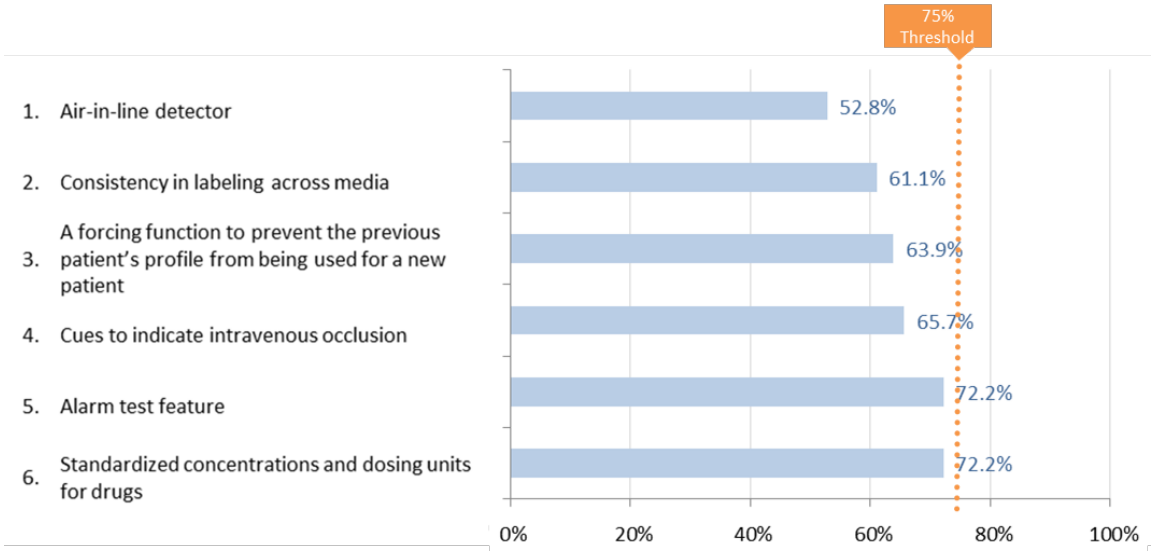


Figure 4. Summary of Design Features Not Accepted as Best Practices (Did Not Meet 75% Criterion)

1.3.4 Workshop Materials and Displays

The CAC facility for the JHU/APL/JHMI Workshop hosts a reception area for welcoming participants and collaborative area for open discussions. The CAC also boasts extensive resources for projection capability, in addition to hardware and software capabilities for collaboration through laptop computers. The layout of the workshop facility is shown in Figure 5.

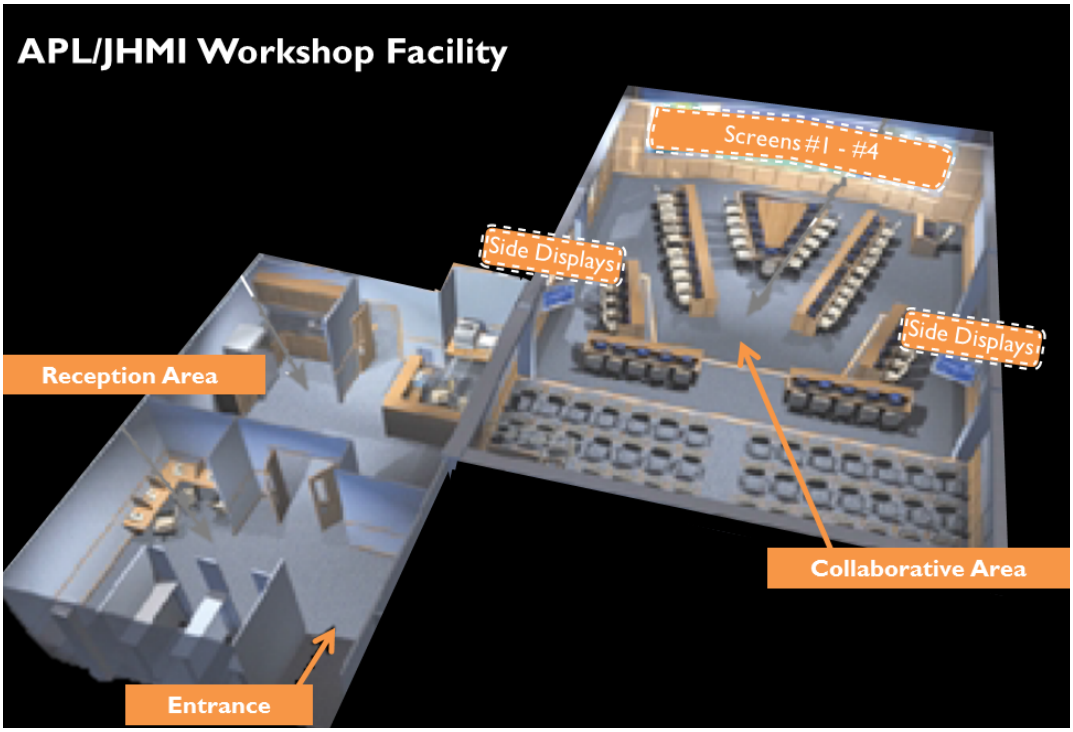


Figure 5. CAC Facility for the 2012 JHU/APL/JHMI Workshop (Modified from Nolen, 2000)

Display materials for the workshop were prepared in advance by the project team to present the topic areas of discussion. Each discussion slide consisted of the problem statement along with the clinical context, failure mode, result, and preliminary user need to provoke additional thought, opinions, and judgment. The format of the discussion slide is shown in Figure 6.

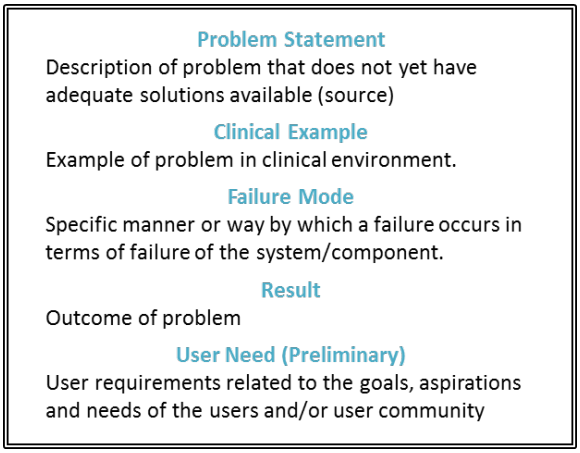


Figure 6. Format of Problem Statement Discussion Slides

1.3.5 Workshop Execution

Eliciting meaningful and fruitful discussion from stakeholders required structure in the planning and preparation of presentation materials as well as a careful strategy for information collection as stakeholder discussions were directed toward the objectives of the workshop. During the January 2012 JHU/APL/JHMI Workshop, a total of 41 attendees included representatives from within and outside of Johns Hopkins. Each attendee received a name badge and was asked to select the category that best described his/her area of expertise. Attendees received a corresponding sticker to affix onto the back of the name badge—the stickers within each category were pre-printed with an incremental number. For example, nurses received stickers with "RN1, RN2," etc. Similarly, pharmacists received stickers that read "Pharm1, Pharm2," etc. These category assignments served as the participants' username when logging into the CAC electronic messaging system, known as "Think Tank." The basis for using the messaging system anonymously was to promote the exchange of open discussion and opinions.

After a 30-minute check-in period, CAC staff instructed attendees to log in to the CAC system. Once the attendees successfully logged in, Dr. Pham (JHMI) set the context for the attendees by presenting the evolution of infusion pump design and history of clinical use leading up to today. Next, Mr. Ravitz (JHU/APL) provided a stage-setting briefing to the attendees that included a description of the AHRQ-sponsored project and how the workshop's objectives and execution plans fit into the project plan.

Mr. Deadwyler then led the facilitated discussion. For each of the discussion topics, four large projection screens displayed the following information:

Screen #1: Think Tank electronic messaging

- Screen #2: Problem statement slide
- Screen #3: Problem statement discussion notes
- Screen #4: Same as Screen 1

Screens 1 and 4 represented the continually flowing electronic messages the attendees typed into the laptop computers at their respective seats.

The problem statements, which spanned a range of topics as summarized in Figure 7, were displayed one at a time on Screen #2. The specific problem statements formed the basis for developing user need statements that inform a better design and cover a wide range of topics ranging from discrete issues to wider themes. Problem statements are presented along with the workshop discussion results in APPENDIX B.

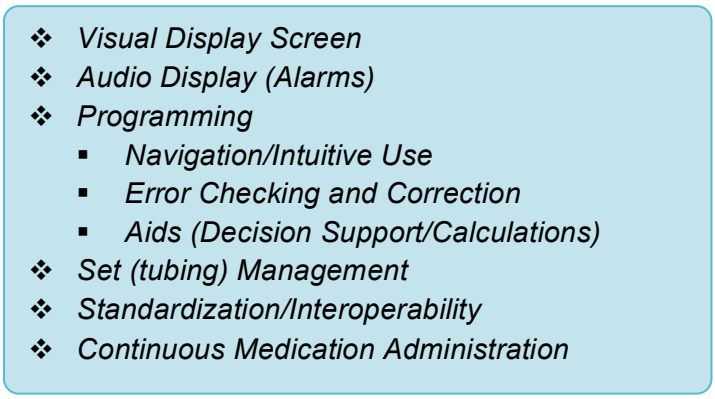


Figure 7. Emerging Themes from Preliminary Analysis of Issue Prioritization

An example of the problem statement discussion slide is shown in Figure 8. The problem statement discussion slides included a succinct statement of a root cause usability problem along with a reference to the source of the statement (CT = Clarion Theme, Sum = Summit notes, TA = Task Analysis). Next, the slide included a clinical example to provide context for the problem statement. For this context, the project team turned to two JHMI nurses with extensive experience using MIPs in hospital settings for a short (2–3 minutes) discussion of how this particular problem statement manifests in the real world.

The discussion then moved into the user need topic, where gravity of the facilitated discussions evolved. Mr. Deadwyler urged the attendees to voice their thoughts regarding user needs, design requirements, and creative solutions to the specific problem statement highlighted. The amount of information the project team elicited during these discussions was limited by the time constraints of the event. Mr. Deadwyler conferred with the project team leads, Dr. Pham, Dr. Doyle, and Mr. Ravitz, to determine whether indeed the moment was right to move on or to continue probing on a given topic.

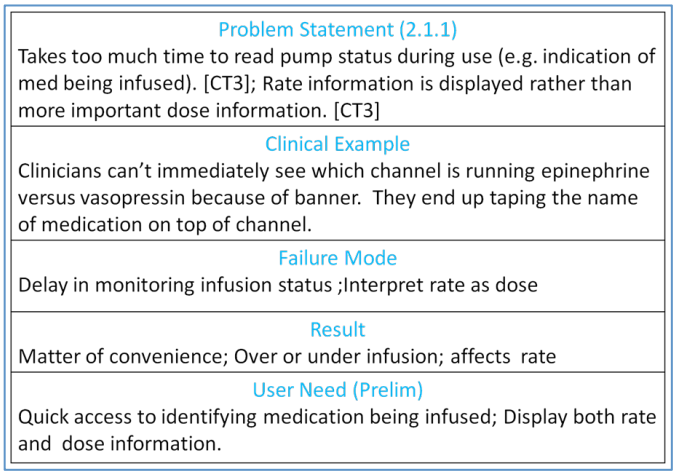


Figure 8. Sample Problem Statement Slide from the Workshop

The attendees provided feedback on all 25 problem statements by expressing their most significant challenges and user needs, and presenting potential solutions to mitigate these challenges. One specific problem statement generated additional discussion and prompted the facilitator to administer a poll survey. In an open-ended format, participants were asked to indicate critical MIP design features, such as location and terminology of user controls and graphical user interface features, in need of standardization.

Dr. Pham then reviewed results from the best practices survey that was administered online prior to the workshop. At the conclusion of the workshop, the project team assembled for a 30-minute debrief to review the day, discuss immediate impressions of the event, and assess how well the event addressed the objectives.

1.4 PHASE 1 RESULTS

The project team analyzed content from both the oral and electronic messaging discussion forums to identify common themes and uncover clusters of information that provided a closer look into issues with MIPs in real-world healthcare environments. Stakeholders revealed potential risk factors as a result of unaccounted processes and practice deviations (otherwise known as workarounds) due to deficiencies in the system or workflow design. The disregard for behavioral and/or cultural factors relating to the clinical workflow were also noted as potential risks.

1.4.1 Qualitiative Analysis of Discussion Forums

Qualitative analysis of the discussion content was achieved through an independent review of the problem statement discussions by the project team leaders. The process required a framework, to which the reviewers characterized each workshop comment into one of the following categories:

- User Needs
- Potential Technical Solution
- Potential Policy Solution
- Potential Training Solution
- Potential Research Topic
- Noteworthy Comment
- Miscellaneous Comment

Details of the report can be accessed in the MIP pump Workshop Summary Report at http://www.aami.org/htsi/infusion/Materials/Medication%20Infusion_Pump_Workshop_JohnsHopkinst_092812.pdf.

Based on the review process and qualitative analysis of the discussion content, the project team focused on capturing user needs and potential technical solutions to inform the design features in Aim #2. A list of user needs was defined for MIP devices (APPENDIX B) and the resultant themes are summarized below:

- **Systems Integration**
  Infusion pump users strongly express a desire to see infusion pumps more tightly integrated into the larger health information technology (IT) enterprise. At the bed-side level, users express the benefits of pump designs integrating with medication orders, IV bags, IV poles and IV tubes.

- **Programming Navigation**
  Especially when routine care can become stressful situations, infusion pump users express frustration with the limitations in current MIP display interfaces, including the ability to effectively navigate through menus and option choices. Users desire a more user-friendly graphical user interface and sensible menu layouts that align more closely with their clinical workflows.

- **Information Presentation and Prioritization**
  Users regularly express the difficulties of viewing pumps from a distance or certain viewing angles, and/or under various lighting conditions.

- **Control Standardization**
  Variations in terminology use and controls placement between different pump designs lead to confusion. Users desire more consistency among the terminology and location of functions such as "Run," "Stop," etc. across pump designs.

- **Context Awareness**
  Users desire pump designs that provide information relating to other pumps connected to the same patient, such as notifying users if administering the same drug is intended. Another example is having the pump determine the relative [orientation of one bag on a pole to the orientation of other bags on the same pole]. Context awareness, which edges into systems integration, would enable users to be more aware of the patient's condition, [the practitioner's identity], and other context-related items.

1.4.2 Results from Ad-hoc Survey on MIP Design Features to Standardize

One problem statement in particular generated additional discussion and prompted the facilitator to administer a poll to identify MIP design features in need of standardization. Participants indicated critical MIP design features, such as location and terminology of user controls and graphical user interface features. Due to the open-ended format, the project team first characterized the responses and established categories to assign each comment to a category. A total of 28 categories were identified and summarized by frequency count for each category, as shown in Table 1.

The results are displayed by the overall number of attendees who participated in the exercise and category of expertise represented. The percentage in parentheses denotes the percentage of total respondents

within the respective category. Results achieving counts of 10% or more from the total respondents are summarized in Figure 9.

Table 1. Summary of Poll for MIP Features in Need of Standardization

#	MIP Feature to Standardize	Overall (N = 31)	Engineer (n = 7)	HFN (n= 5)	Industry (n = 3)	MD (n = 3)	Pharm (n = 6)	Regulator (n = 1)	RN (n = 6)
1.	Power On/Off controls	17 (55%)	2 (29%)	3(60%)	1(33%)	2 (67%)	4(67%)	0 (0%)	5(83%)
2.	Start/Run controls	16 (52%)	4 (57%)	2 (40%)	2(67%)	0 (0%)	4(67%)	0 (0%)	4(67%)
3.	Controls placement (keys/ keypad numbers, bolus, power, start/pause)	13 (42%)	3 (43%)	2(40%)	2(67%)	1(33%)	1(17%)	1 (100%)	3(50%)
4.	Stop/Halt	11 (35%)	4 (57%)	3(60%)	1(33%)	1(33%)	1(17%)	0 (0%)	1(17%)
5.	Pause	9 (29%)	2 (29%)	3(60%)	0 (0%)	1(33%)	2(33%)	0 (0%)	1(17%)
6.	Battery	5 (16%)	1 (14%)	1(20%)	0 (0%)	0 (0%)	2(33%)	0 (0%)	1(17%)
7.	Placement of decimal point	5 (16%)	0 (0%)	1(20%)	0 (0%)	0 (0%)	2(33%)	0 (0%)	2(33%)
8.	Bolus	4 (13%)	1 (14%)	1(20%)	0 (0%)	1(33%)	0 (0%)	0 (0%)	1(17%)
9.	Silence alarm	4 (13%)	1 (14%)	0 (0%)	0 (0%)	1(33%)	1(17%)	0 (0%)	1(17%)
10.	Dose (and position), rate,	3 (10%)	1 (14%)	1(20%)	0 (0%)	0 (0%)	1(17%)	0 (0%)	0 (0%)
11.	Sequence/order of data entry	3(10%)	1 (14%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2(33%)
12.	Terms: Run, Pause, Bolus, On/Off buttons (size, color, label)	3 (10%)	1 (14%)	1(20%)	0 (0%)	1(33%)	0 (0%)	0 (0%)	0 (0%)
13.	Back(undo)	2 (6%)	0 (0%)	1(20%)	0 (0%)	0 (0%)	1(17%)	0 (0%)	0 (0%)
14.	Cancel	2 (6%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1(17%)	0 (0%)	1(17%)
15.	Drug library	2 (6%)	1 (14%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1(17%)
16.	Scroll buttons	2 (6%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1(17%)	0 (0%)	1(17%)
17.	Care area	1 (3%)	1 (14%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
18.	Drug class	1 (3%)	1 (14%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
19.	Generic Drug name	1 (3%)	1 (14%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
20.	Piggyback	1 (3%)	1 (14%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
21.	Alarms (frequency, characteristics, and sound)	2 (6%)	0 (0%)	2(40%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
22.	Alarm types	1 (3%)	0 (0%)	1(20%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
23.	Clock time	1 (3%)	1 (14%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
24.	Control to change an infusion parameter	1 (3%)	0 (0%)	1(20%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
25.	Internal fault indication	1 (3%)	1 (14%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
26.	Override safety	1 (3%)	1 (14%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
27	Process of start new patient vs. Start new protocol on same patient	1 (3%)	0 (0%)	1(20%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
28.	Running indicators	1 (3%)	0 (0%)	1(20%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

Features with the highest frequency counts (representing 10–55% of overall respondents) included user controls (i.e., "Start/Stop, On/Off, Pause, Bolus," etc.), controls placement (including keyboard and keypad numbers), status notifications (i.e., silence alarm, battery), and order information (such as dose, rate, and volume to be infused [VTBI]), as shown in Figure 9. More specifically, "Power On/Off" and "Start/Run" controls were noted as the most important MIP features in need of standardization.

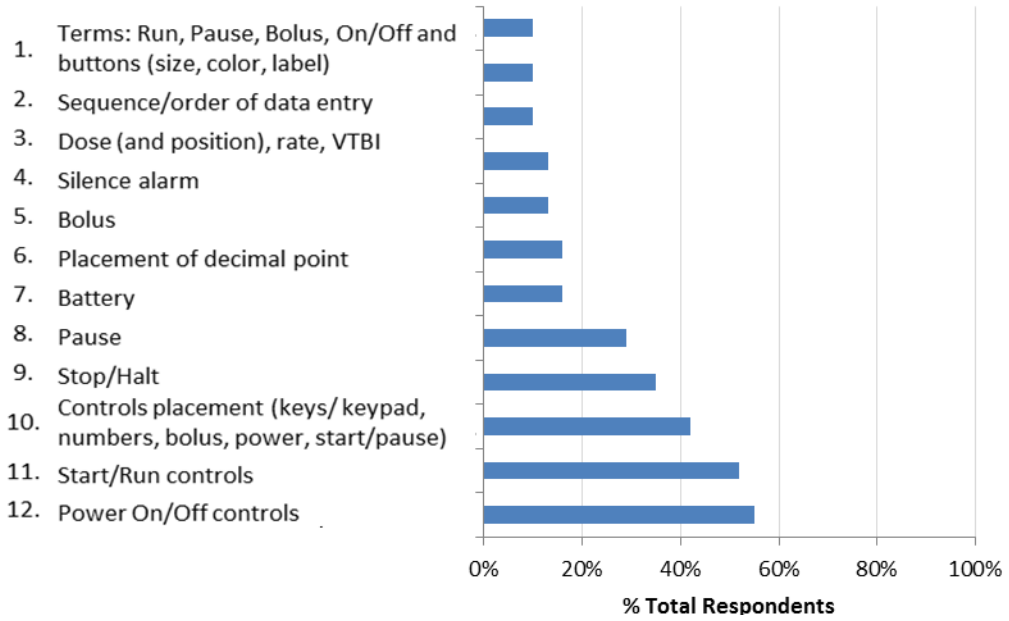


Figure 9. Polling Results on Top MIP Features to Standardize (Responses from 10% or Greater of Total Respondents)

1.5 PHASE 1 DISCUSSION

Responses during the workshop discussions reflect the general preferences within the broader group and across user groups. Analysis of the data obtained from the workshop helped inform the design features for the CONOPS and prototype interface in the second phase of this AHRQ-sponsored project.

Although proprietary differences exist in current MIP designs, standardization of MIP features (such as controls design and placement) would enable users to readily operate any MIP devices based on a common understanding and easier identification of fundamental user controls. The ability for users to operate MIP with confidence would also suggest an improvement in the usability and safety of MIP designs. While excessive standardization does not facilitate the emergence of innovative designs, participants agreed that a set of fundamental controls (i.e., power, start, stop, and keypad controls) should be standardized.

2. PHASE 2

2.1 PHASE 2 EXECUTIVE SUMMARY

Continuing the systems engineering approach in this phase, the project team used the problem statements and key themes to develop a set of user needs useful in formulating a CONOPS for an improved MIP design. The concept was co-developed and vetted by clinical SMEs, and subsequently a prototype MIP was designed and developed. Development of training and test infusion scenarios were initiated in parallel with these activities for the purpose of exercising the prototype in Phase 3 to assess benefits afforded by the CONOPS. Once implemented, the prototype and associated software to conduct test scenarios was tested during verification and validation stages. Means for remote observation and recording of scenario results were also developed during this phase.

2.2 PHASE 2 INTRODUCTION

In Phase 2, the project team developed a CONOPS specifying a pump design concept that addressed a subset of the problem statements identified in the CAC exercise. Alternative architectures and technology solutions were evaluated to meet the user needs and address the priority problems. The project team selected a tablet-based platform for the prototype interface to enable evaluation of novel pump features at the key stroke level. The team also developed a simulated test environment for evaluation of the prototype features in Phase 3. A summary of Phase 2 (Aim 2) activities, shown in Figure 10, highlights the development process based on the user needs and high-level requirements from Phase 1.

Hardware components to carry out the functions of a MIP prototype in the medication administration process included a laptop to simulate presentation of Provider Order Entry (POE) orders to the pump, a network server, a wireless network router, and the use of a smartphone to support auto-progamming inputs via optical imaging technology. To facilitate the medication infusion process in auto-programming mode, the project team explored various optical imaging techniques for transfering programming information to the prototype. This information included patient and nurse ID, medication bag attributes, route, and provider order information. The Quick Response (QR) Code™ system was selected for its advantages over conventional barcodes. The two-dimensional QR code enables reading in either the vertical or horizontal direction and decoding if the label is damaged. It also requires less display space, and contains more storage capacity. The prototype was developed with feedback from clinical SMEs. Once the prototype and its simulated environment were developed, the functionality of the system was validated with nursing and physician oversight prior to the Phase 3 formal evaluation.

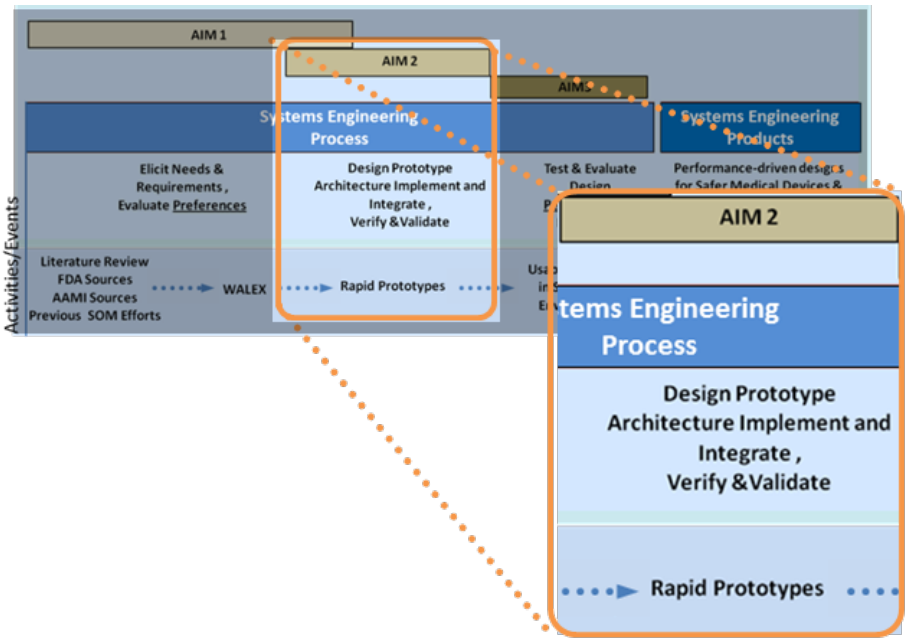


Figure 10. Summary of Activities in Phase 2

2.3 CONCEPT DEVELOPMENT

To address the key themes, the project team developed a CONOPS for a prototype that would enable evaluation of design solutions at the system level. The goals and objectives of the new CONOPS were to improve the usability, performance, and safety of large volume MIPs in a hospital-based environment by: 1) automating point-of-care programming at the bedside and 2) associating MIP components (links) in the medication administration process. This would ensure that the right medication is administered at the right dose, volume, and concentration; via the right route to the right patient.

Mapping the key themes to selected problem statements from the CAC exercise, the project team developed a prototype interface to address a selected set of the identified problem statements. This subset of problem statements is shown along with associated user needs in Table 2.

Table 2. Selected Problem Statements Addressed by Design of the Prototype Interface

Problem Statement	User Need
Misinterpretation of a physician's order	Ability to download order directly from POE; Automated reporting and charting
Bypassing and forgetting to reset programming after a bolus	Reliable cue to reset programming.
Errors in calculating conversions	Appropriate assistance with conversion.

Problem Statement	User Need
Pump workflow doesn't match the user workflow. The sequence for programming the pump differs from the user's sequence of tasks for medication delivery.	Programming configurable with medication tasks (e.g., loading doses, bolus infusions, and titrations) and work flow options.
Inadequate display field sizes, line break position, and use of bolding to differentiate selection options	Better and standardized cues to differentiate drug classes (e.g., display background color).
Prompts to enter rate or volume to be infused (VTBI) come before prompts on dose	Means to prevent confusion between rate and dose prompts.
Insufficient alerts when input errors have been made	Improved monitoring, prediction and checking of errors with associated alert.
Pump interface features associated with high risk control functions are not standardized across pumps (e.g., control and label placement, color coding or order of data entry)	Standardization of high risk functions within and across pumps
Use of weight data that varies from the primary source (medical records vs. bed scales vs. memory)	Access to and reliable input of weight data.
Lack of forcing function to confirm and check important data entries	Better confirmation of data entry and programming inputs.
Program too much Volume To Be Infused (VTBI)	Means to better predict end of infusion process.
Display content and format make it difficult to read in different settings (e.g., lighting, distance, angles)	Improved readability in various environmental conditions

The central theme of the system concept is that the constituent elements of medication administration should be viewed as a system, and the medication administration process itself should be a systematic one in which the workflow process and the system itself collaborate to prevent or mitigate risk of error. This would formalize the identification and association of the various elements, or links, in the medication administration chain. As illustrated in Figure 11, the links in this chain include the provider, patient, drug, bag, dose, route, and pump channel.

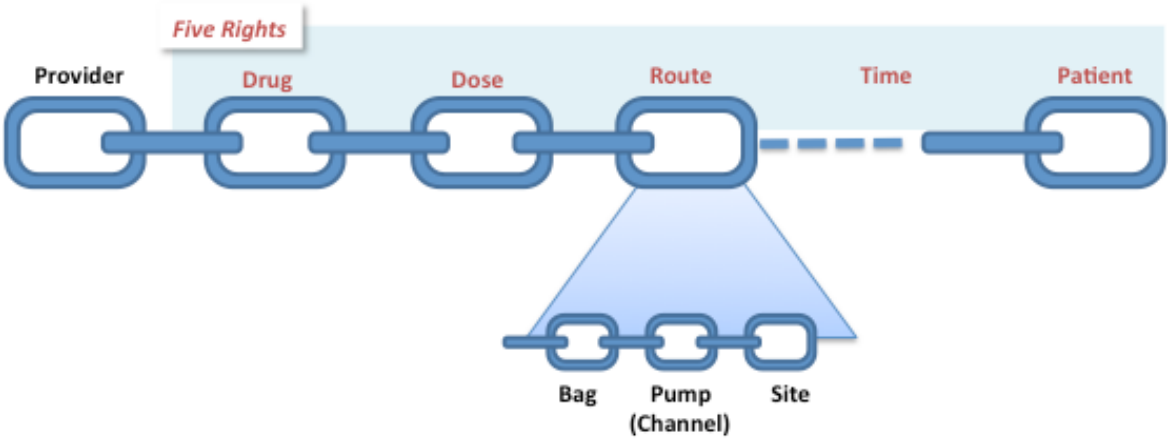


Figure 11. Conceptual Description of Medication Administration

A further extension of this model would include links to other subsystems in the overall infusion domain such as the patient's Electronic Medical Record (EMR), Computerized Provider Order Entry (CPOE), Pharmacy Information Systems (PIS), and so forth, as seen in Figure 12. Inclusion of those systems in the present project would require extensive modelling and integration efforts, which were deemed beyond the scope of the current effort. Accordingly, the team turned its attention to medication administration processes bounded by the elements depicted in Figure 11.

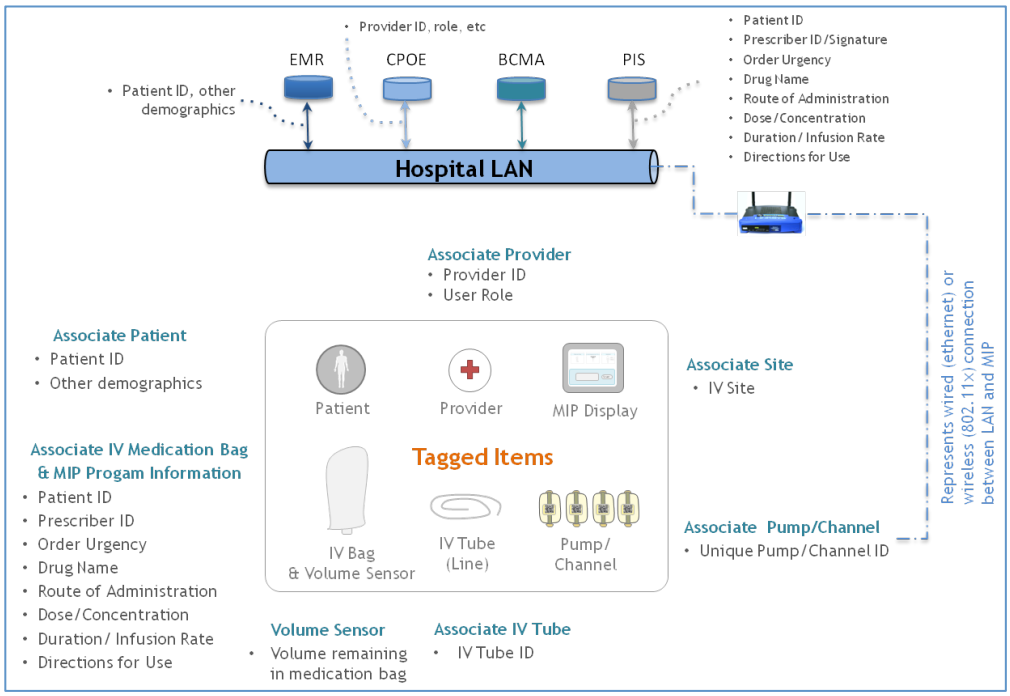


Figure 12. MIP as Part of the Hospital IT Enterprise

The transition from user needs (as manifested by the problem statements) to a CONOPS required the

attention of systems engineering, clinical (physician and nursing infusion experts), human factors personnel, and a smaller subset of workshop attendees. An iterative process was employed to refine the workshop artifacts and focus-group-type discussions were held to help shape the CONOPS. Once sufficient refinement was reached, the project team advanced through the process toward the prototype design, implementation, test, verification, and validation stages during Phase 2.

To address a multitude of the problems and user needs, the project team developed a concept of automating steps in the infusion chain that are susceptible to error. The team selected a QR coding approach as a means to more accurately and more reliably associate the links in the infusion process. This enabled an auto-programming mode which could be compared to the typical manual method of pump programming. A tablet device served as the MIP interface and offered, in addition to the autoprogramming feature, a flexible environment to evaluate a novel interface design. By keeping the MIP interface separate from the mechanical pump assembly, a tablet device enabled a larger display space to host a more user-friendly graphical user interface and implement design solutions that address user needs. As such, the CONOPS provided the basis for the design of the prototype interface. The prototype interface developed in Phase 2 included capabilities for the user to verify the correct association of critical infusion parameters by scanning the:

1. Provider badge to verify the clinician administering the medication
2. Patient to ensure the proper patient
3. Route (e.g., via a route label)
4. Medication order, which consisted of a pre-printed label on the IV bag with a QR code that could be read from an imaging device such as a smartphone camera. The QR code contained data pertaining to the order and included drug, dose, rate, volume, and concentration associated with the proper bag and patient.
5. Pump channel

2.3.1 Conceptual Approach

The prototype concept allows both manual programming and automated point-of-care pump programming through the barcode approach. The concept assumes that drug orders generated at the pharmacy-level will be pushed to the prototype interface through the electronic Medical Administration Record (eMAR). Upon receipt of the medication order to the unit, the provider uses the barcoding method to submit the medication order to the MIP. This enables the clinical user to directly transfer programming information into the MIP, minimizing risks for error such as manual data entry, misinterpretation of orders, numerical calculations, and visual checks.

The barcoding capability is hypothesized to reduce cognitive workload demands, which would enable bed-side providers to direct more attentional resources toward patient-centered activities and less attention to activities requiring manual checks and processes. The design concept, as shown in Figure 13, illustrates the scanning elements of the verification process.

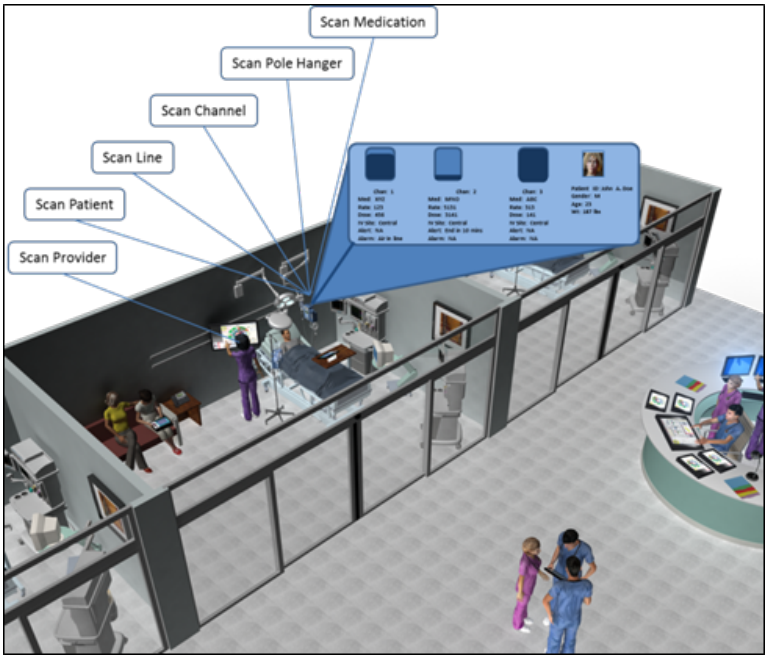


Figure 13. Design Concept of MIP Auto-Programming Smart System

A mock-up of an earlier prototype is shown in Figure 14.

Figure 14. Early Prototype Concept Following Workshop

2.4 PROTOTYPE DEVELOPMENT

Using the systems engineering approach, the project team, consisting of two human factors engineers, a systems engineer, and clinical experts, developed infusion display and control requirements for the software engineer to develop the prototype. These requirements addressed both manual and auto-programming task objectives and requirements to meet human factors design objectives for navigating, programming, monitoring, and controlling the infusion process.

The prototype interface evolved through iterative design and development by the project team. This included frequent reference to clinical SMEs. Multiple trade-off decisions were made to optimize the interface design within the constraints imposed by hardware and software. The interface was subsequently verified through iterative testing and refinement with clinical SMEs.

Once the team was satisfied that the prototype interface, simulation engine, and supporting components (i.e., prototype system) were sufficiently complete to support evaluation of the primary evaluation measures, the prototype system was subjected to a series of end-to-end evaluations with clinical users.

Concurrently, human factors engineers worked with clinicians to develop test and training scenarios to exercise a set of infusion tasks with a range of medications. These scenarios appear in the test session moderator scripts provided in APPENDIX D, APPENDIX E, and APPENDIX F. The infusion tasks in these scenarios include:

1. Log in
2. Start infusions
3. Start and stop bolus
4. Detect and resolve air-in-line alarm
5. Set up a medication as a carrier for an infusion
6. Start secondary infusion
7. Titrate medication
8. Discontinue specific infusion
9. Discontinue all infusions

Scenarios guided these evaluations along with a moderator script to ensure that the prototype functioned in a manner that integrated with clinical workflow and that the typical clinician specifically recruited for the evaluation would be able to complete the scenario within a 30-minute period. Clinician feedback from the evaluative sessions was used to improve upon the user interface, moderator scripts, and the moderator interface. Additionally, an inspection of the test environment layout was conducted by the study team to ensure that the environment test, which was only available for the 5-day evaluation, did not introduce unwanted influences.

2.4.1 Overview of Prototype Functional Design

The physical setup of the MIP prototype, as shown in Figure 15, consists of the prototype infusion pump interface hardware in the form of a Samsung S4™ tablet. for display and control of pump operation. A

smartphone was selected as the image device to support auto-programming and tasks requiring QR code scanning. Additional equipment to support the MIP prototype consisted of IV bags with pre-printed labels containing information about the medication order in the QR codes, and panel with pre-printed QR codes to identify pump channels. Speakers used in the test assembly augmented the alarm signals presented in the test scenario. The mechanical pump, conceived as a separate subassembly, is not represented as part of the MIP prototype setup.

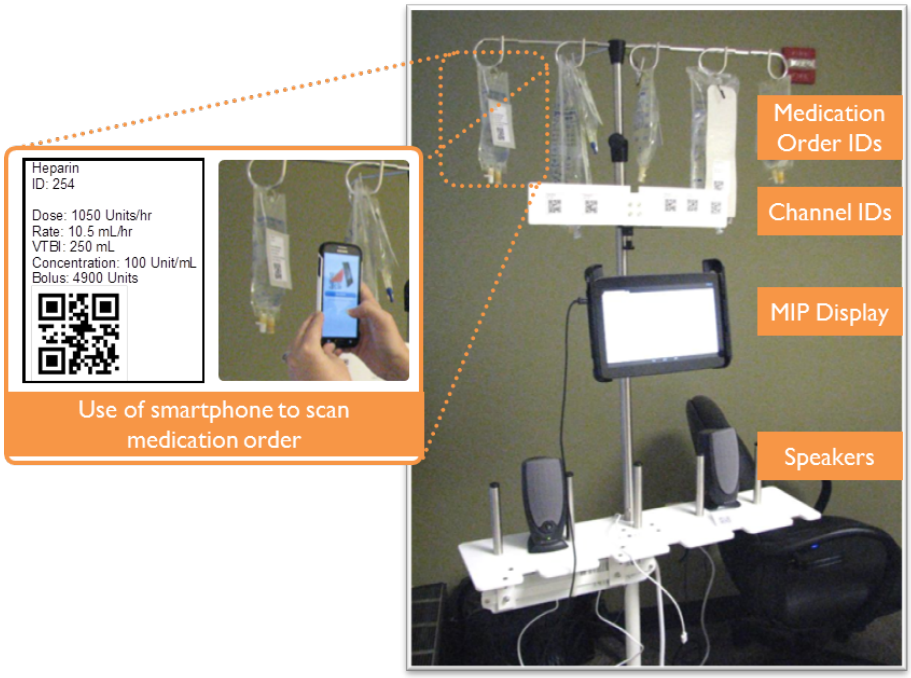


Figure 15. Final Set-up of MIP Prototype Display with Smartphone Scanner and Supporting Equipment

The prototype interface simulates two operational modes: an auto-programming mode and a manual mode. In the auto-programming mode, the user scans QR codes to identify the user, patient, medication, infusion route, and pump channel. This mode promotes accurate completion of four of the five rights: right patient, right medication, right dose, and right route. Right time of day was not evaluated. The scanning application translates the QR codes on the RN's badge, patient, medications, and channels with the intention of speeding the processes of login, treatment, and charting. In the auto-programming mode, selected subtasks such as titrations are executed manually. In the manual mode, programming is performed by touchscreen entry of data via menus and an alpha-numeric keypad. These two design approaches allowed the project team to evaluate solutions that addressed the key themes generated during the workshop. The prototype enabled the user to operate up to six separate channels concurrently, start and stop a bolus on each channel, titrate medications, and receive alerts for different alarm conditions.

The project team for Phase 2 consisted of a multi-disciplinary team made up of clinicians, human factors engineers, a systems engineer, and software engineer. The team collaborated closely in the ongoing development of design efforts by adhering to existing human factors precepts and standards while

meeting clinical workflow needs. The effort included numerous user feedback sessions with clinicians who routinely use infusion pumps. Using low- and medium-fidelity prototyping tools, the iterative design process helped build upon the initial navigation and graphical user interface (GUI) features including screen layout, color, labels, and text size, all with the objective of assuring safe use. The project team focused prototype development efforts on the comparison between manual and auto-programming modes and the assessment of selected human factors design features. While the intent was to develop capabilities to rapidly test alternative MIP designs and usability of discrete GUI design features (e.g., navigation, legibility and readability of font characteristics and buttons), the project team focused on the functional design of the MIP system to establish the concept design in the prototype environment.

2.4.2 Operational Sequence of Use

This section describes the operational sequence for using the prototype in manual and auto-programming modes. The high-level steps for the manual mode are described first, followed by a description of the operational differences in the auto-programming mode.

2.4.2.1 Operation Sequence in Manual Mode

In the manual mode, the user first logs in as a user and then enters a user ID and password, followed by entering the patient ID using an alphabetic keypad (as shown in Figure 16 and Figure 17).

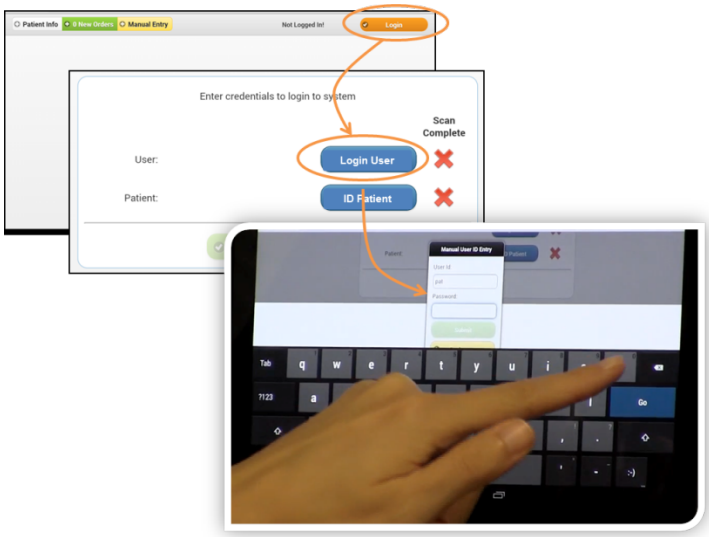


Figure 16. Prompts to Log in and Manually Identify the User

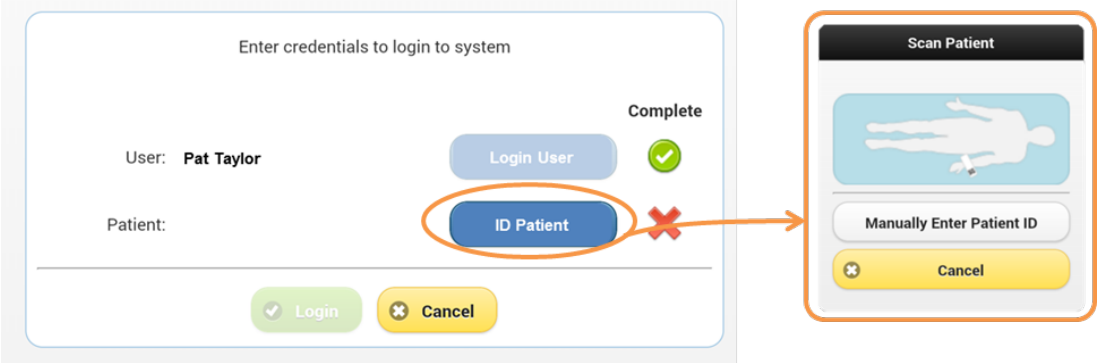
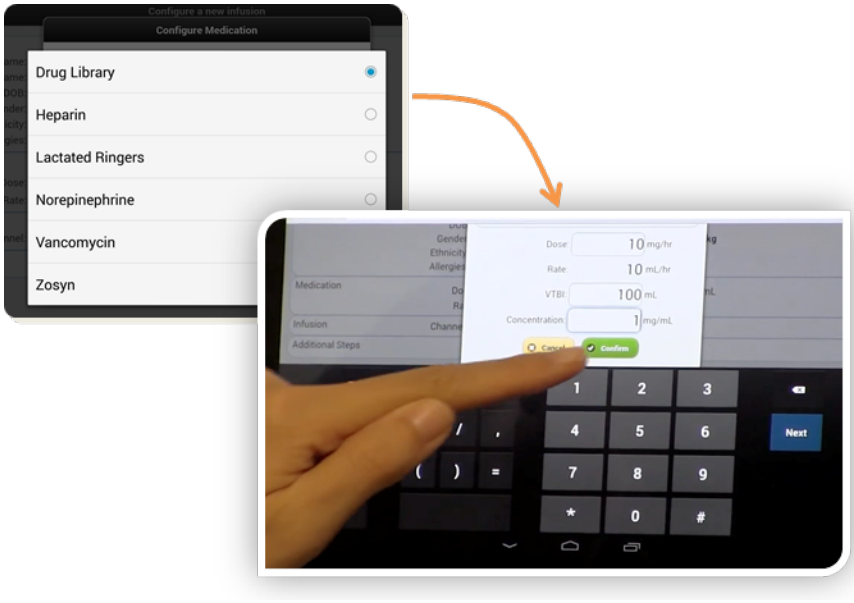


Figure 17. Prompts to Identify the Patient and Enter Patient Identification in Manual Mode

Next, the user selects the ordered medication from a drug library menu and enters dose, rate, VTBI, and concentration via the numeric keypad (Figure 18). The user has the option to bolus the medication following start of administration.



Note the numeric keypad arrangement.

Figure 18. Manual Infusion from the "Configure Medication" Selection Pop-up Window

The user then selects a pump channel for the specific medication hung (Figure 19), confirms the order as entered, and starts the infusion (Figure 20).

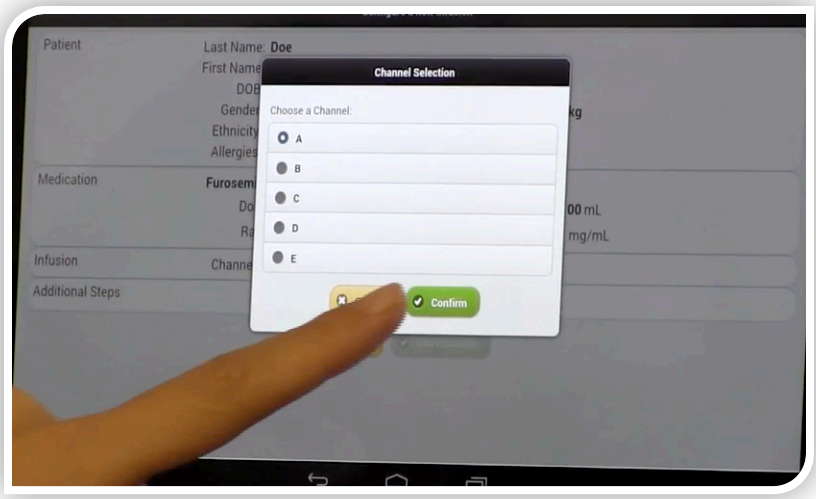


Figure 19. Selecting a Pump Channel

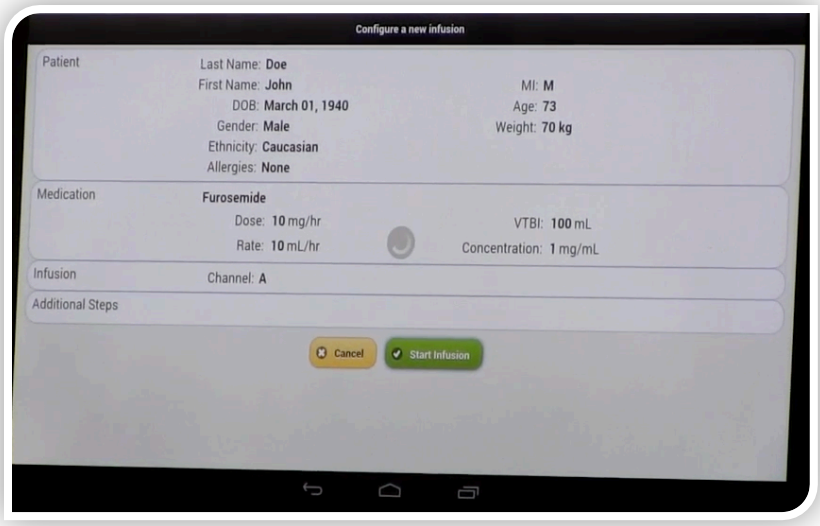


Figure 20. Prompt to Start Infusion

Selected infusions require a second nurse to verify the information. This manual step is shown in Figure 21.

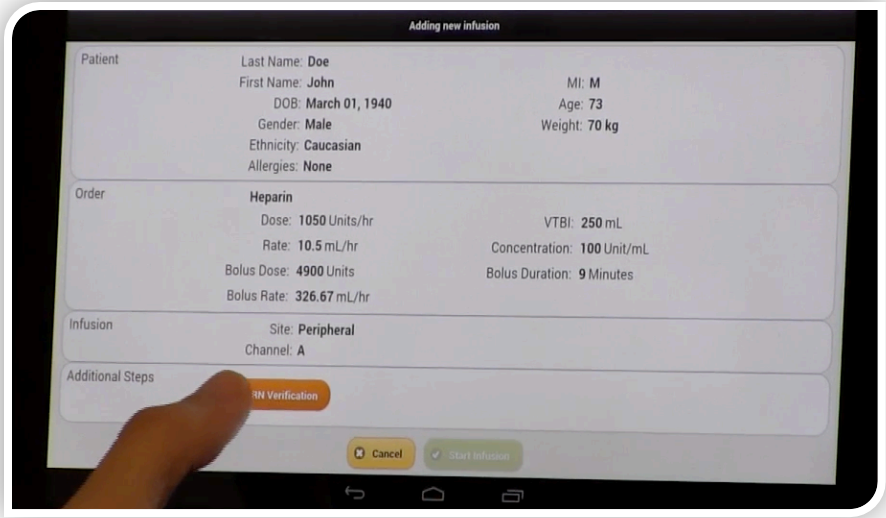


Figure 21. Function Requiring Second RN Verification

Once the infusion has started, the user may select a medication to see an expanded status display of infusion parameters and control options to change infusion parameter values (Figure 22).

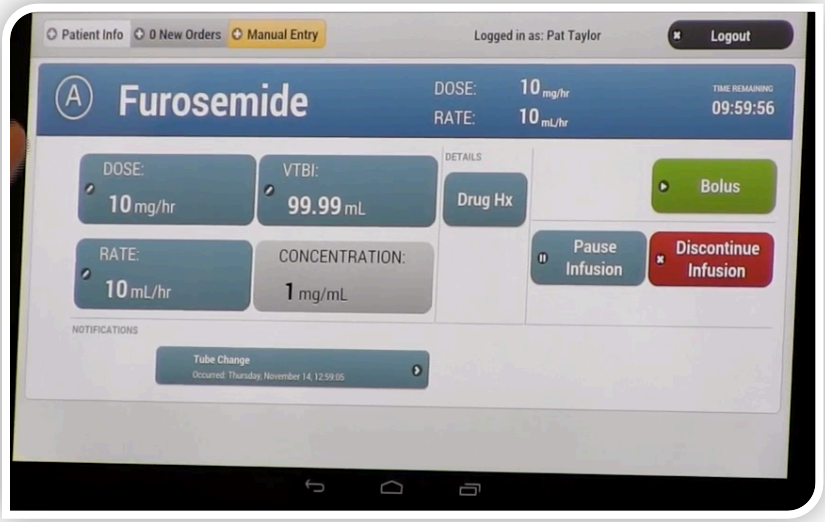


Figure 22. Infusion Status and With Expanded Display from Training Scenario

Infusion parameters may be modified at any time during the infusion (Figure 23).

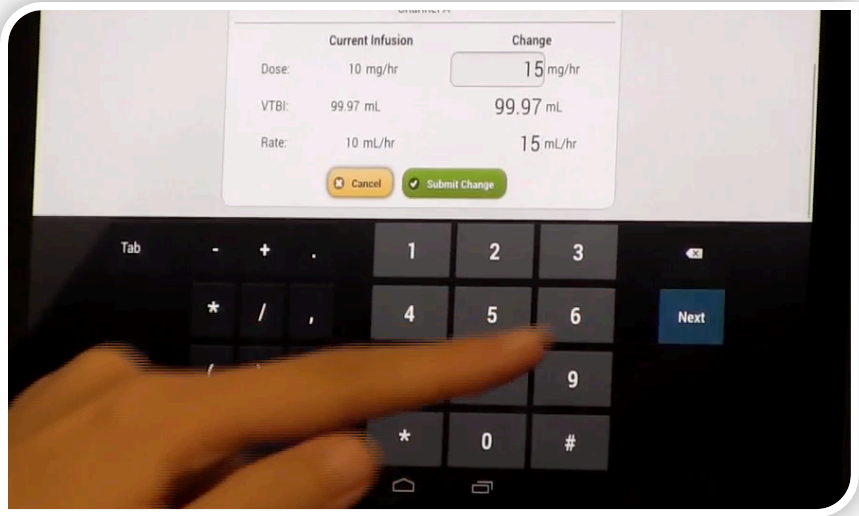
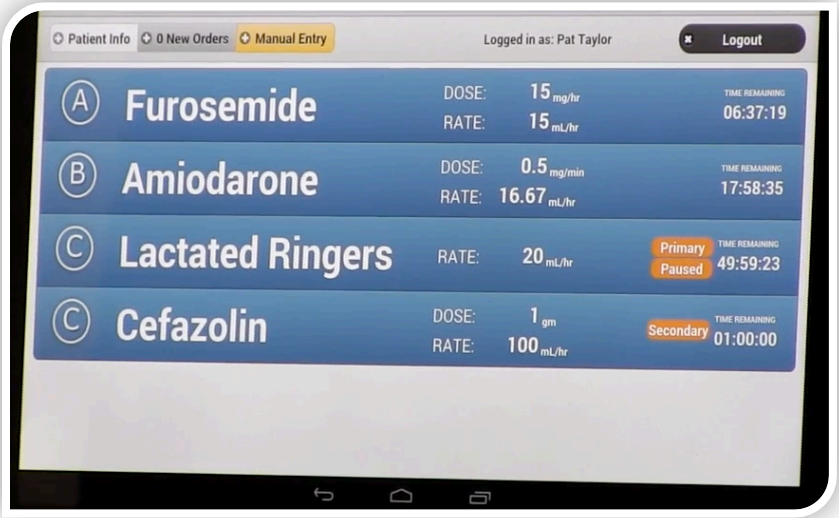


Figure 23. Changing Infusion Parameters (e.g., Dose)

An example of a summary display of multiple infusions, including Cefazolin as a secondary infusion, is shown in Figure 24. Options to change drug parameters are made possible in the expanded view of Cefazolin, as shown in Figure 25.



Note: Cefazolin is a secondary infusion on Channel C.

Figure 24. Sample Display of Multiple Infusions for Training Sccenario

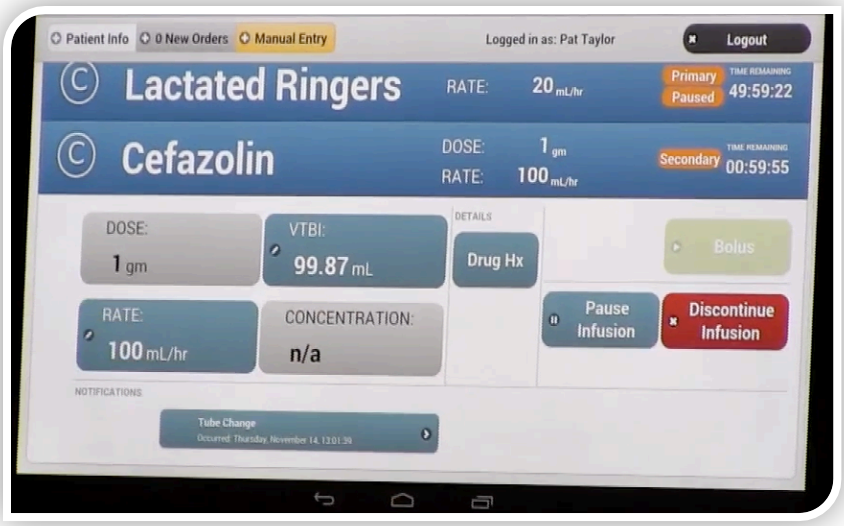


Figure 25. Expanded Cefazolin View Showing Options to Modify Drug Parameters

Figure 26 shows the visual indication of an occlusion alarm and schedule-based notification to change tubing with prompts to respond. The prototype also provided an audible signal for alarms during the test sessions.

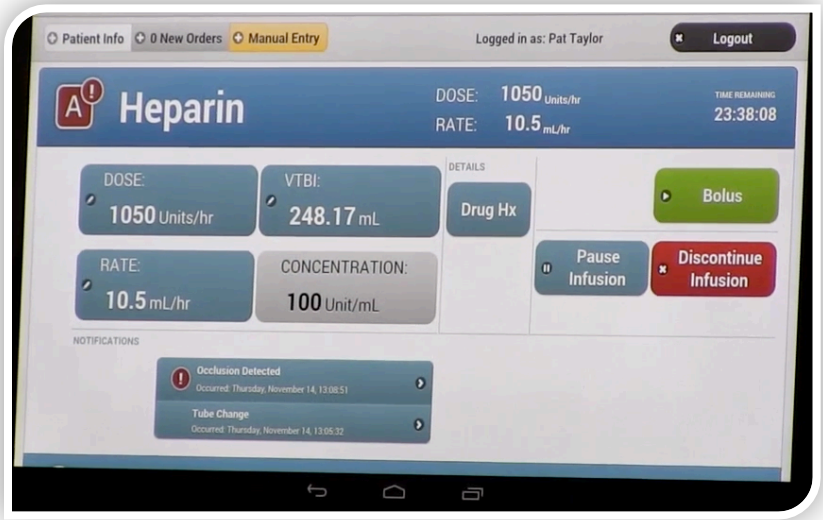


Figure 26. Visual Alarm and Notification Indications for Occlusion and Tube Change

A feature was also provided to discontinue all medications at once (Figure 27).

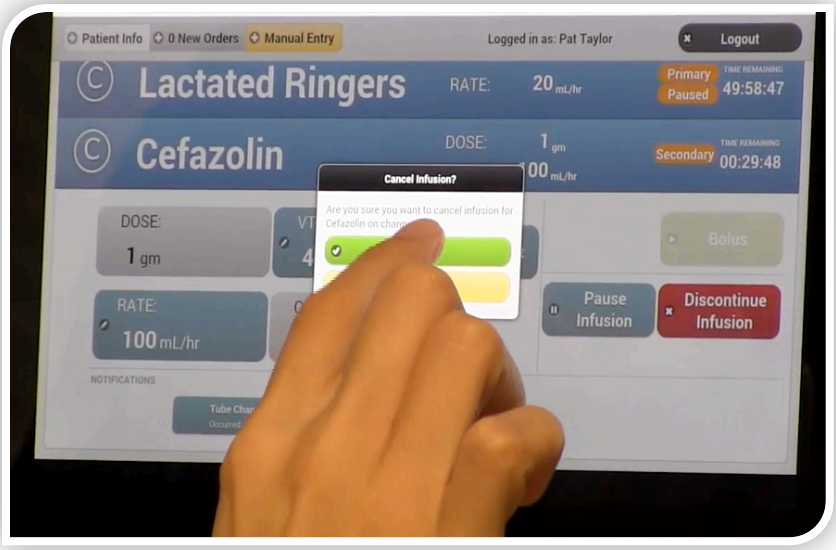


Figure 27. Option to Discontinue All Medications (Training Scenario Shown)

2.4.2.2 Operation Sequence in Auto-programming Mode

In the autoprogamming mode, users scan QR codes as a means of inputting selected information into the prototype (RN ID, patient ID, medication, dose, rate, volume, concentration, and route). Certain subtasks, such as titrating doses, are still conducted manually via manual touchscreen entries. However, the use of auto-programming should address a number of error types otherwise performed manually. Login and patient identification via the scanner are the first subtasks (Figure 28 and Figure 29).

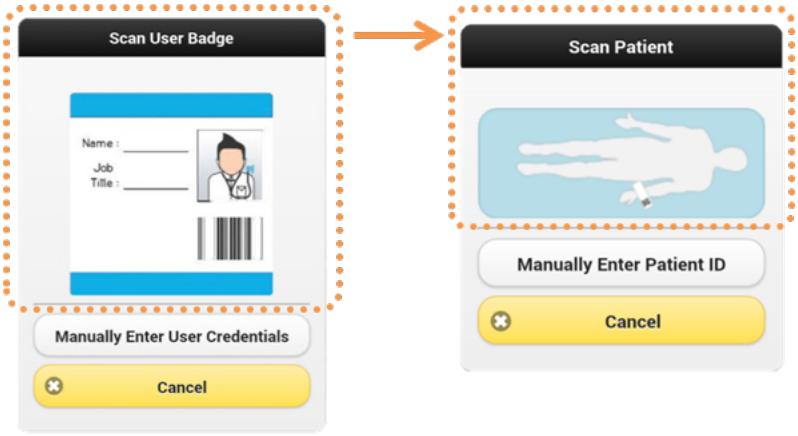


Figure 28. Prompts to Scan User Badge and Patient ID

Jean Smith, RN

Username: jean
Password: jean

Pat Taylor, RN

Username: pat
Password: pat

Figure 29. Quick Response Codes Used for RN Identification During the Prototype Evaluation

The user then selects "New Order" to display the order(s) sent from the eMAR and selects an order from the menu listing (same as used in the manual mode). This is shown in Figure 30.

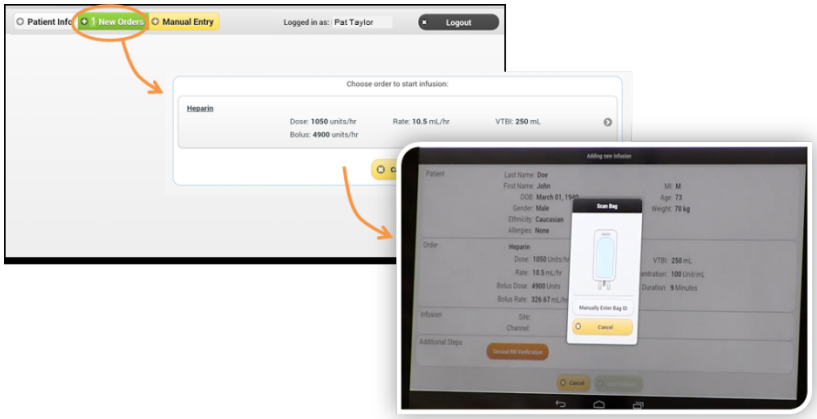


Figure 30. Prompts to Select New Order and Scan Bag, Including Option to Manually Enter the Bag ID

Then the user scans the bag to verify proper association of the bag (medication, volume, and concentration) with the order (Figure 31 and Figure 32).

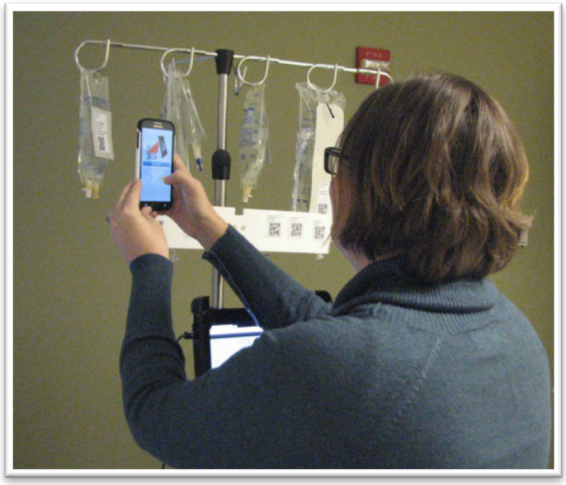


Figure 31. Participant Scanning Medication Bag

Heparin ID: 254 Dose: 1050 Units/hr Rate: 10.5 mL/hr VTBI: 250 mL Concentration: 100 Unit/mL Bolus: 4900 Units	Lactated Ringers ID: 255 Rate: 120 mL/hr VTBI: 1000 mL	Lactated Ringers ID: 255 Rate: 20 mL/hr VTBI: 1000 mL

Figure 32. Sample QR Codes Used to Identify Medications Infused During the Test Session

The user then scans the infusion route (in the simulation, a QR code on a wristband for a peripheral infusion site) and pump channel (see Figure 33 through Figure 35).

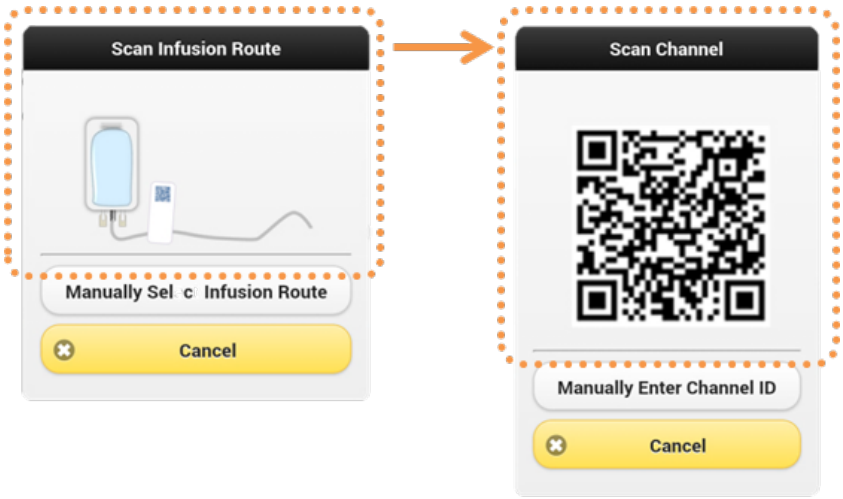


Figure 33. Prompts to Scan Route and Channel

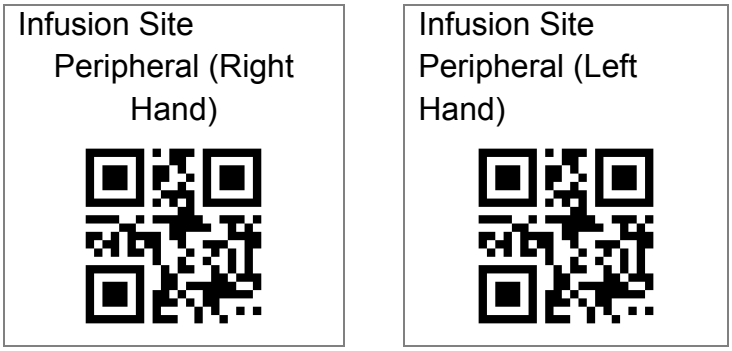


Figure 34. QR Codes Used for Infusion Site Identification

Figure 35. QR Codes for Channel Identification

In cases requiring verification by a second RN, practice is enforced through the clinical requirement for the second RN to scan his or her badge before proceeding further (Figure 36).

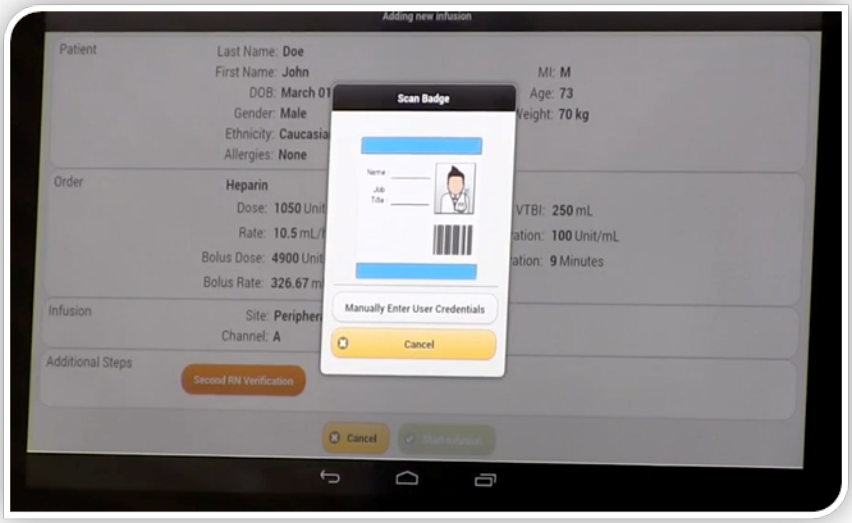


Figure 36. In Auto-programming Mode, a Verification Dialog is Displayed and Requires a Second Nurse to Scan His/Her ID Badge

The user can then start the infusion (Figure 37).

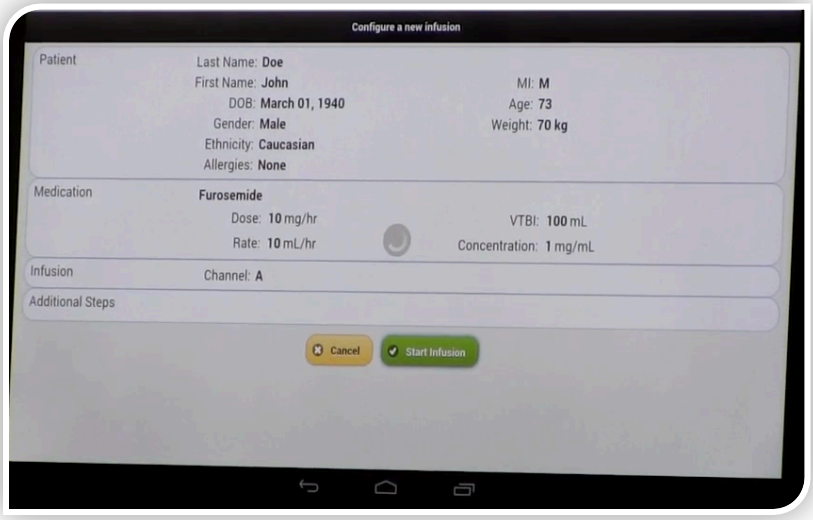


Figure 37. User Verifies the Programming Information and Must Press Start to Initiate the Infusion

2.4.2.3 Observer's Scenario Control

Development of the prototype included the functionality for a remotely located observer to initiate training and test sessions. A laptop was used by the observer to start and stop sessions, provide simulated

eMAR orders in the auto-programming mode, and inject notifications such as “air in line” and “occlusion.” Figure 38 to Figure 40 provide sample pages for these control functions.

Figure 38. Observer Control Panel – Top-Level Page

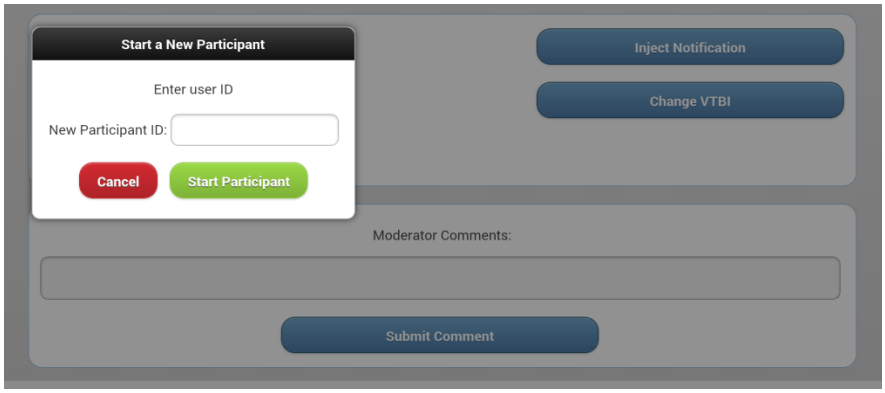


Figure 39. Observer Control Panel – Start a New Participant Pop-up Window

Figure 40. Observer’s Interface to Simulation Engine – Send Orders Interface

2.4.3 Description of Test Environment Architecture

As seen in Figure 41, the prototype MIP system includes four hardware components and two computer software applications (i.e., MIP user interface and a simulation engine) that were developed to facilitate Phase 3 usability evaluations. The main hardware components that supported prototype user interface evaluation included a computer tablet, a laptop computer, a smartphone (functioned as a QR code scanner), and a wireless router. The software applications include the MIP user interface application, which comprises three subcomponents and a simulation engine. The simulation engine simulated certain infusion pump actions based upon user interactions with the prototype.

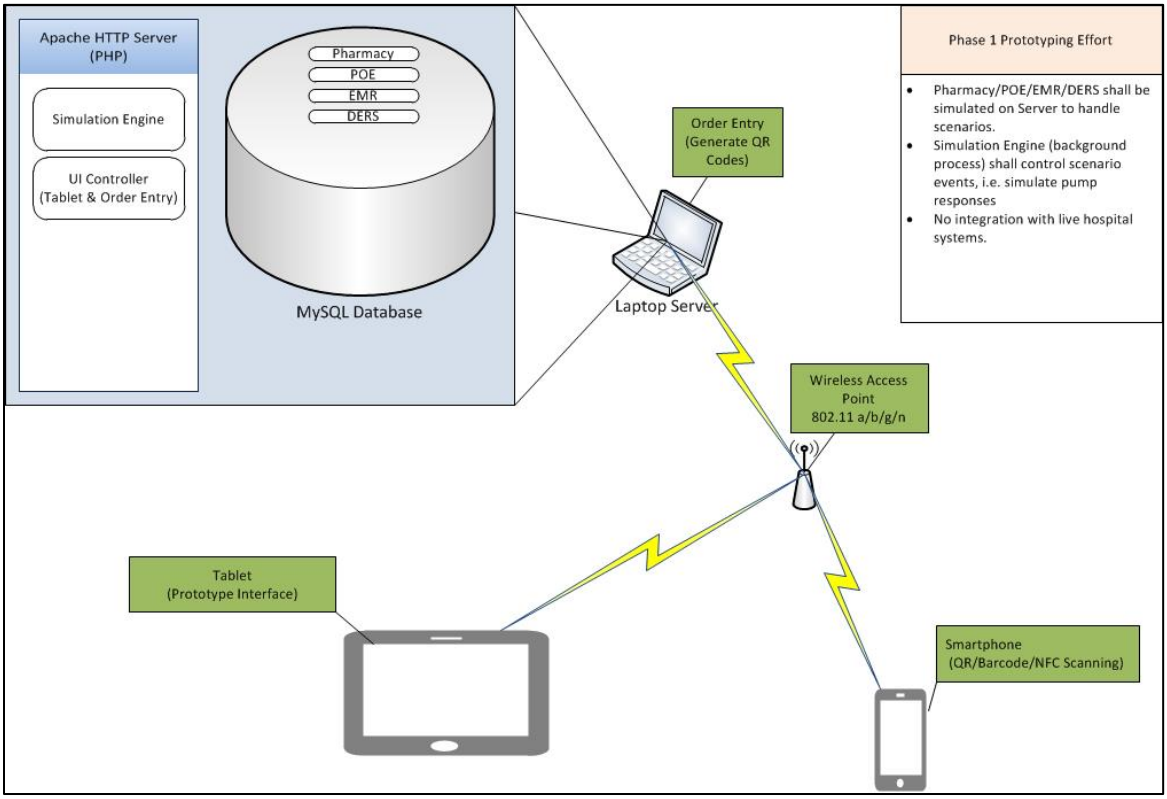


Figure 41. System Technical Interfaces and Data Flow Supporting the Prototype Evaluation in the Test Environment

The following subsections describe the prototype architecture, technologies, and systems that provided the platform for the evaluation. These commercial components were chosen not only for their ease of access and development for this study but also for possible future enhancements by other investigators.

2.4.3.1 Hardware Components

The hardware components included a Samsung 10-inch computer tablet to display the MIP user interface, a Dell laptop computer to function as the server and host the database, the observer's user interface as well as the simulation engine, a Samsung smartphone, which functioned as a QR code scanner, and a

wireless router.

2.4.3.2 Wireless Network

The database and software application components communicate over a closed wireless network. For this prototype, a static Internet Protocol (IP) address is assigned to the laptop. The SmartPhone scanning application uses this IP address in its internal configuration.

2.4.3.3 Database Connections

The database is used as a resource by the prototype infusion pump application to store information about current infusions and pending infusion orders, as well as information about notifications and patient and login information. The simulation engine and the scanning application also connected to the database to translate QR codes and update notifications, the VTBI, and time left for infusions to complete.

2.4.3.4 Browser-based Application Interfaces

A browser-based application was developed with three subcomponents: an observer control panel, order entry screen, and prototype infusion pump application (referred to throughout this report as the prototype). The observer's interface was used to simulate the presentation of orders to support the tasks during the infusion scenario. This very basic simulated POE functionality on a laptop was used by the observer to add an infusion order to the pump prototype. The screens subsequently produced on the prototype step the participant through a series of pop-up windows for selecting different properties about the infusion, such as the infusion site and channel and, in the case of manual infusion, which drug will be infused. At the end of the process of setting up the infusion, there is a confirmation screen that includes all of the infusion information. Refer to Figure 16 through Figure 40 for selected images of the user interface.

Other functions at the observer's workstation include presentation of appropriate pump cues for the user and the ability to reset and reinitialize the simulation for the next participant. The observer typically uses the control panel and order entry screen (Figure 38 to Figure 40) remotely from a desktop or laptop.

2.4.3.5 Simulation Engine

The simulation engine is used to move time forward in the application as if the infusions were actually occurring, including reducing VTBI, incrementing bolus progress, shutting off bolus when appropriate, resuming primary infusions, and triggering notifications for low VTBI and no VTBI. The simulation engine is a windows service running on the MIP server. The interface to the simulation engine is shown in Figure 42.

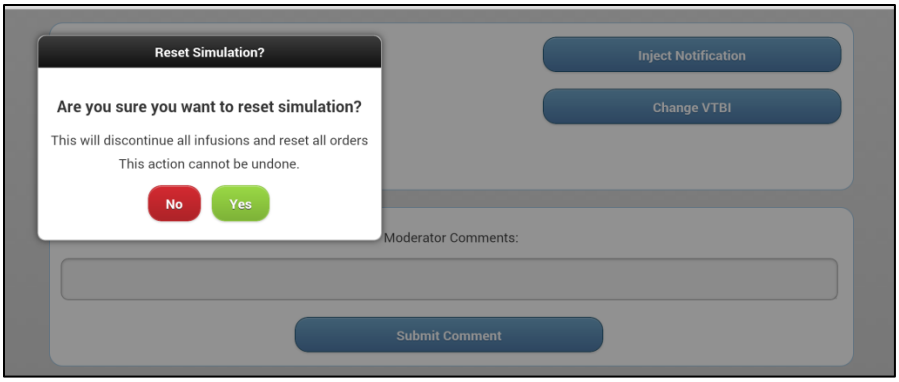


Figure 42. User Interface for Simulation Engine

2.4.4 Summary of Software Technology Used in Application Development

This section briefly describes each of the technologies used in the development of the MIP application as well as its interaction with other hardware and software components that supported the evaluation.

- MySQL 5 – Relational database engine used to house all information related to an infusion pump instance
- PHP 5.3.13 – Server-side scripting language used for both the prototype user interface (web browser) application and as a communication bridge for the Android SmartPhone Application (Scanner)
- jQueryMobile 1.3.1 – JavaScript library used in both the prototype infusion pump application and scanner that provides enhancements and support for mobile devices
- jQuery 1.8.2 – JavaScript library used in both the main application and scanner
- Apache Cordova 2.9.0 – set of application programming interfaces that allow mobile applications to access native mobile device functions, in this case, the smartphone camera for barcode/QR scanning
- Java 1.6 – Used by the Simulation Engine sub-component. It runs as a background service to prototype infusion pump actions, specifically reducing the volume of medication left to be infused, based upon the configured dose and rate.

The JHU/APL Office of Technology Transfer (OTT) offers academia, business and industry streamlined access to APL technology. The OTT operates as a single point-of-contact to identify available technologies and research capabilities at the Laboratory and to secure both licensing and industry Rearch & Development agreements. The OTT should be contacted to request the MIP software source code. The APL OTT can be reached at 443/778-3541, techtransfer@jhuapl.edu, or http://www.jhuapl.edu.

3. PHASE 3

3.1 PHASE 3 EXECUTIVE SUMMARY

The project team evaluated the safety and usability profile of the MIP prototype in a high-fidelity simulation environment. Comparative usability testing was conducted to evaluate the MIP prototype in manual and auto-programming modes. Forty-one participants became familiar with the MIP prototype by walking through a patient scenario in both modes. Participants were then instructed to operate the MIP prototype using a test scenario that required the participant to log in, start infusions, start/stop bolus, detect and resolve air-in-line alarm, perform secondary infusion, titrate medication, and discontinue infusions. The scenario involved administration of lactated ringers, heparin, norepinephrine, and piperacillin/tazobactam and vancomycin in a high-fidelity simulation environment. Demographic characteristics, performance characteristics, and qualitative feedback were collected.

Testing results suggested that participants felt that auto-programming could prevent misinterpretation of physician orders (4.3 versus 3.1 on Likert Scale, $p < 0.001$), reduce programming errors (4.2 versus 2.9, $p < 0.001$), and prevent errors in calculating conversions (4.3 versus 3.7, $p = 0.03$). Auto-programming was associated with less mental (33.8 versus 39.4 on NASA Task Load Index, $p = 0.02$) and performance demands (20.7 versus 28.9, $p < 0.01$), but similar overall Task Load Index (28.3 versus 31.1, $p = 0.08$). There was no difference in proportion of tasks completed (97.9 vs. 97.2, $p = 0.17$) between the two modes.

Based upon testing in the simulated environment, auto-programming of MIPs was superior to manual programming in terms of perceived safety and mental load. There was no measured difference in terms of task completion or overall task load.

3.2 PHASE 3 INTRODUCTION

In this final phase, the project team recruited 41 ICU nurse participants of varying experience to use the prototype in the two modes. The team installed the prototype and data recording equipment in two lab areas and pilot tested the test sessions to verify reliable operation of equipment for conducting scenarios and recording data. The team conducted training and tests sessions for both manual and auto-programming modes with the participants, documenting results with videos of test sessions and manual recording of observations. The resultant data were then analyzed as described in the sections that follow.

3.3 PHASE 3 METHODS

To assess the benefits of auto-programming technology in reducing errors related to manual programming tasks and its effect on perceived workload, 41 nurses used a tablet-based infusion pump prototype in both manual and auto modes. An incentive of $150 was provided for one hour of participation. Participants reviewed and signed a consent form upon arrival. The availability of one substitute nurse to participate between scheduled sessions enabled data collection from 41 participants.

3.3.1 Equipment

In addition to the prototype system described in Section 2, additional equipment was used to support the evaluation. This included an IV pole to mount the prototype, video cameras to record test sessions for later analysis, two mannequins, IV bags and tubing, IV bag labels and placards for IV sites on the mannequins, and finally nurse badges (see Figure 43 and Figure 44). The study team used the existing wireless system in the test facility after ensuring compatibility with the test system.

Figure 43. IV Bag Medication Used in MIP Evaluation

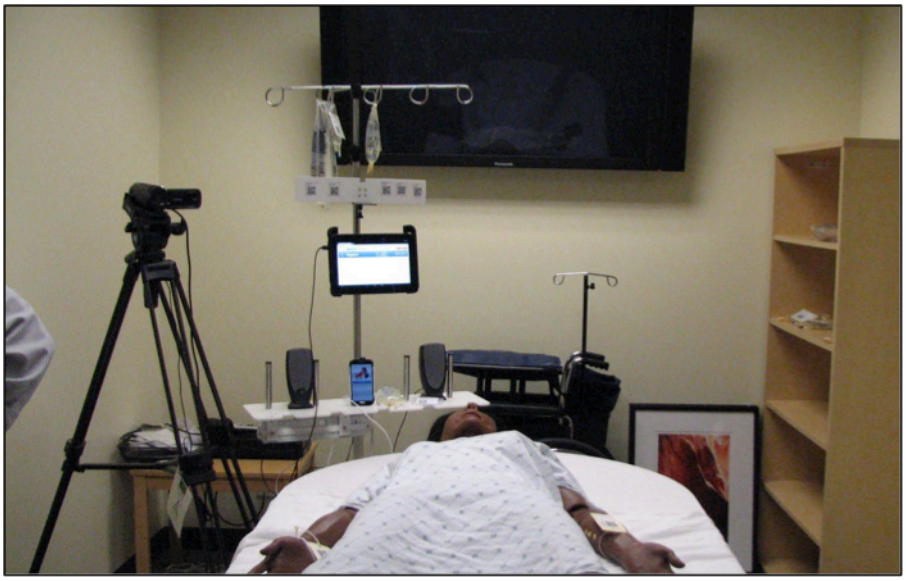


Figure 44. Equipment Used in MIP Evaluation

3.3.2 Participants

Nursing members of the team recruited participants for the study through postings on nursing listservs and social media and via word of mouth from the Johns Hopkins Hospital (JHH) Intensive Care Unit (ICU) staff. Criteria for selection included: more than six months of ICU experience, currently caring for patients on a regular basis (i.e., not primarily an administrative role), and regular use of medication infusion pumps. The goal was for equal distribution of participants from a variety of years of experience, academic and non-academic environments, and experience with various MIP types. Institutional Review Board (IRB)-approved recruitment literature provided participant candidates an overview of the study and the experience required to participate. Project team members contacted candidates to screen them against participation requirements.

3.3.3 Test Sessions

A nurse moderator conducted training and test sessions in one of two usability laboratory spaces, one with a one-way observation window. Both labs utilized Laerdal simulated patients (mannequins) with scannable labels on wristbands and infusion route sites, as well as the simulated pump mounted on an IV pole and medication bags (saline) as needed to simulate the medications. Both labs enabled remote video viewing of pump manipulations for scoring purposes by a remote observer. The lab environment can be seen in Figure 44.

Participants underwent a training session to become familiar with the MIP prototype in each mode prior to testing. During training and test sessions, a nurse moderator followed a prepared script to assure consistency of scenario presentation across participants. The training scenario included logging in, infusing four medications, and concluding the infusion process in both manual and auto-programming modes. Medications to be administered included lactated ringers, heparin, piperacillin/tazobactam, vancomycin, and norepinephrine. Specific medications were chosen due to the high frequency of their use, their status as high-risk medications, and the complexities in their administration. Training for the two modes was provided and the moderator freely discussed aspects of pump use until the participant was comfortable to proceed with testing.

During testing, the nurse moderator presented the scenario tasks one by one to the participants who conducted the same test scenario in separate manual and auto mode sessions, randomized for sequence effects (Figure 45). The test scenario simulated an infusion sequence of 12 tasks involving five medications: heparin, lactated ringers, vancomycin, piperacillin/tazobactam, and norepinephrine. These medications were chosen because of their frequency of use in clinical practice, status as high-risk medications, and complexity in administration and titration. Tasks included the initiation and conclusion of the simultaneous infusion of multiple fluids, a secondary infusion, bolus, and titration tasks; and comprise 78 subtasks in the manual mode and 64 in the auto-programming mode. After completion of one mode,the participant repeated the scenario in the opposite mode (manual then autoprogamming or vice versa). An observer remotely monitored the participant's touch screen actions via camera to a large display (Figure 46). The observer also inserted air-in-line faults into the simulator at a specific time to assess the reaction to the means for alert notification. Any deviation from the correct action was scored incomplete for that subtask.

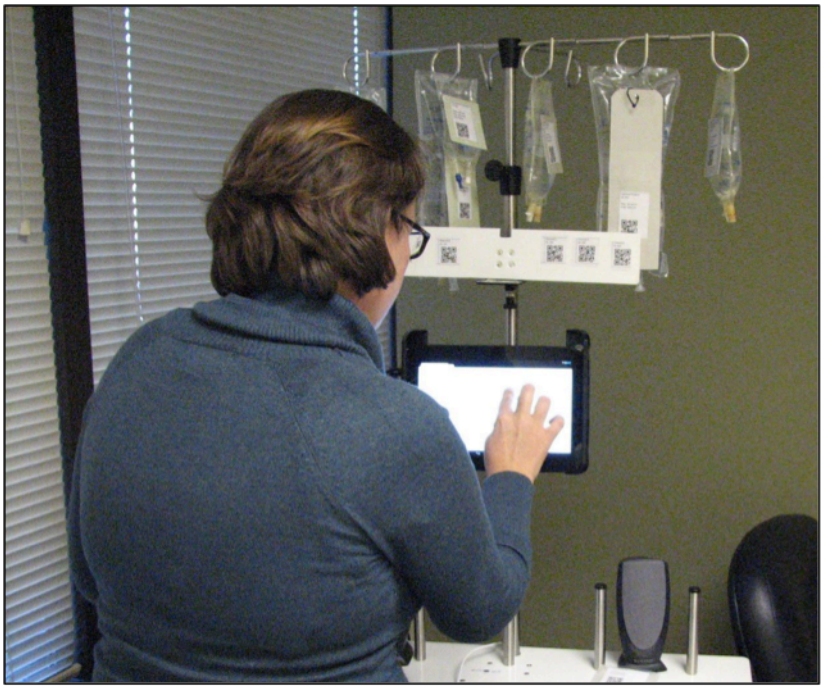


Figure 45. Pariticipant Interacting with Prototype Interface

Figure 46. Study Observer Monitoring a Participant's Action

Test sessions were video-taped for later validation of scoring. The participant's subtasks, as reviewed by a human factors engineer, were scored "Complete" or "Incomplete", yielding completion scores for each subtask. The subtask was scored as incomplete if there was significant delay, need for prompting from the moderator, execution of a task in a manner other than specified (e.g., using manual mode when

prompted to use auto mode), or multiple attempts for completion of the task. Certain errors in subtask completion were categorized as "high risk". High risk errors include errors that resulted in actual delivery of incorrect medication, dose, or volume to the patient; delivery of correct medication to the incorrect patient; and delivery of correct medication via an incorrect route.

3.4 SCORING METHOD

One of several alternate observers scored task and step completion in each test session. A review and discussion of the scores recorded by different observers indicated variability in scoring practices. For example, some scored 'incomplete' if there was a typing error even if corrected while others did not. This prompted the team to more closely define the criteria for scoring as shown in the section below and to rescore the steps by reviewing the test session videos. Using the improved scoring criteria, a human factors engineer then reviewed all the videos and rescored all steps. Notable variances were found between the scores conducted real time during the sessions and the newly assigned scores. Because of the ability to stop and replay the action, the post test-scoring was thought to be more accurate. To check the scoring reliability of the post-test scoring, a second human factors engineer independently scored a sample of ten videos, representing five participants in each of the two modes – manual and auto-programming. To avoid bias effects in the set to be rescored, the videos were sampled across four of the five test days, both labs, and five different test moderators. The project team decided that a scoring variance between the two human factors engineers exceeding 10% would require further analysis until a 90% level of agreement was achieved. Scoring variances between the two scorers were summed for all of the 73 auto mode session subtasks and then for all of the 100 manual subtasks. The variance rates found between the two engineers were 2.19% and 1.20% for the auto and manual modes, respectively. Because both are well within the 90% criterion for agreement and because the difference between the two modes is less than 1%, it was decided to proceed with the scores as assigned by the first human factors engineer.

3.4.1 MIP Scoring Criteria

A task (e.g., start Vancomycin 1 mg stat) typically comprises several steps (e.g., select Vancomycin, enter 1 gm, or enter 250 mL). The project team developed the following criteria for scoring completion at the subtask level.

Score Incomplete

Participant did not perform correct action for a subtask on first attempt:

1. Started in wrong mode
2. Entered wrong data via the keypad including:
    a. Entries that had no effect on ultimate delivery of medication (e.g., keypad entries corrected before "entered" into the system)
    b. Errors that resulted in incorrect delivery of medication (wrong medication, patient, route, dose, volume, or rate)

3. Encountered significant delay in subtask completion (> approximately 15 seconds)
4. Conducted wrong sequence to complete a task or skipped a subtask
5. Selected Norepinephrine before Lactated Ringers as a carrier
6. Experienced any instance of retyping with exception of 1st letter of input for user ID as often happened

Score Complete

1. Participant performed subtask:
   a. Accurately as required in the moderator/observer guide and
   b. Within approximately 15 seconds
2. Exception made in Task 4 (Pipericillin administration) where participants put the medication on channel D as a primary instead of channel B as a secondary. Exception made because not all participants were familiar with using secondary infusions.

Steps Not Scored

1. Steps where the moderator prompted the participant or prematurely gave the participant advice to subtask completion
2. Option not available for participant's action (e.g., login prompt not active) (coded light red)
3. Conducted manually by participant because order not sent
4. Not tested (e.g., moderator skipped step)
5. Wrong order sent by observer
6. Instances where moderator inadvertently assisted the participant by actually making a selection on the screen

The team collected the following demographic information from the participants (APPENDIX G): age, sex, height, current use of various mobile technology devices, years of ICU experience, current employment in an academic versus non-academic environment, and familiarity with different medication infusion pump types. After the test session for each mode, the participant was interviewed by the observer using a structured interview form (APPENDIX H) to learn about the acceptability and safety of the prototype pump features. The participant also completed a post-task survey to collect subjective feedback (APPENDIX I) and a NASA Task Load Index (NASA-TLX) form (APPENDIX J) to assess perceived workload.

After each test scenario, participants completed a self-administered fifteen-question survey of their perceptions of the particular programming mode (APPENDIX I). Responses to the post-task survey for the first eleven questions were scored on a five-point Likert scale where 1 = "Not at All" and 5 = "Great Degree." Scales for the remaining questions follow:

- Question #12: 1 = "Too insensitive" and 5 = "Too sensitive";
- Question #13: 1 = "Difficult" and 5 = "Very easy;"
- Questions #14 and #15: 1 = "Not confident" and 5 = "Very Confident."

After completion of the self-administered questionnaire, participants completed the NASA-TLX. The higher the score on the NASA TLX, the higher the workload. Individual components of the NASA-TLX scores were combined to create a single composite score to represent workload. Questions were assigned different weights in the composite score to reflect varying contribution of mental demand, physical demand, temporal demand, performance, effort, and frustration as it relates to administering medications using an MIP. The weighting scheme was determined by group assignment of the study team to comparative values, as described by Hart et al.[7] The weight for the domains are shown in Table 3.

Table 3. NASA TLX Composite Score Weights by Domain

Domain	Weight
Mental Demand	0.2
Physical Demand	0
Temporal Demand	0.067
Performance	0.333
Effort	0.133
Frustration	0.267

Statistical Analysis

Demographic and experience characteristics of participants were summarized using counts and percentages for categorical measures and means and standard deviations (SDs) for continuous measures. The responses to individual questions as well as the NASA-TLX scores for manual data entry and automated data entry were summarized using means and SDs, and were compared across methods using paired t-tests. Analysis was performed using SAS version 9.3 (SAS Institute, Inc., Cary, NC). All tests were two-sided, and significance was set at $p < 0.05$.

3.5 PHASE 3 RESULTS

3.5.1 Quantitative Results

The following tables present results of the prototype testing. The prototype is presented as "automated" programming. Participants had an average age of 32 years ± 7.5 years and were predominantly female (83%). Participants had a median of 6 years of professional experience, 4 years employed at current institution, and 6 years of pump experience. Approximately 90% of the participants work in an academic institution, use infusion pumps daily, and 85% reported familiarity with the Alaris infusion pumps over other infusion pumps. Participants also had smartphone (34%) and/or tablet experience (61%). A summary of the results is shown in Table 4 below.

Table 4. Demographic and Experience Characteristics

Characteristic	All Participants (n=41)
Age in years, mean (SD)	32.0 (7.5)
Age > 29 years, No. (%)	21 (51)
Male gender, No. (%)	7 (17)
Height in inches, mean (SD)	66.5 (3.6)
Height ≤ 65 inches, No. (%)	17 (41)
Electronic Personal Devices Used, No. (%):	
Cell phone only	1 (2)
Cell phone + tablet	1 (2)
Smart phone	14 (34)
Smart phone + tablet	25 (61)
Years of Experience, median (IQR)	
Professional	6 (3.5-12)
At current institution	4 (2-7)
With pump	6 (3.5-12)
Vision, No. (%):	
No assistive devices	16 (39)
Distance only	22 (54)
Reading	3 (7)
Takes medication that might cause drowsiness, No. (%)	1 (2)
Pump experience, No. (%):	
< 2 years	2 (5)
2-5 years	17 (41)
> 5 years	22 (54)
Academic institution, No. (%):	37 (90)
ICU experience, No. (%):	
< 2 years	9 (22)
2-5 years	15 (37)
> 5 years	17 (41)
Pump use frequency, No. (%):	
2-3 times per month	1 (2)
2-3 times per week	1 (2)
Daily	39 (95)
Pump type, No. (%):	
Alaris	35 (85)
Baxter	1 (2)
Plum	2 (5)
Alaris and Baxter	3 (7)

Results from the post-task survey are shown in Table 5. Participants reported that the MIP prototype in auto-programming mode had a higher degree of preventing misinterpretation of medication order information than manual mode ($p<0.001$) and higher degree of reducing programming errors compared to manual mode

(p<0.001). Although the graphical user interface was the same in both modes, participants felt that the auto-programming mode displayed options for correct selection of drug concentration more prominently (p<0.001).

Table 5. Participant Perception of Medication Infusion Pump, by Mode

Question	Likert Rating		
	Manual Programming (SD)	Automated Programming (SD)	P value*
1. To what degree does the simulated pump prevent overriding of safety features?	3.2 (1.3)	3.5 (1.0)	0.14
2. To what degree does the simulated pump prevent misinterpretation of a physician's order?	3.1 (1.4)	4.3 (1.1)	<0.001
3. To what degree does the simulated pump reduce programming errors?	2.9 (1.1)	4.2 (0.9)	<0.001
4. To what degree does the simulated pump prevent the need to reprogram the pump after a bolus?	4.2 (1.2)	4.4 (1.1)	0.35
5. To what degree does the simulated pump prevent errors in calculating conversions?	3.7 (1.2)	4.3 (1.1)	0.03
6. To what degree does the simulated pump provide a workflow that matches the user workflow?	4.0 (0.8)	3.7 (1.1)	0.10
7. To what degree does the simulated pump display easy to read content and format?	4.5 (0.9)	4.4 (0.9)	0.26
8. To what degree does the pump control accuracy of weight data derived from primary source?	4.1 (1.1)	4.3 (1.0)	0.11
9. To what degree does the pump provide adequate visual cues for selection options?	4.4 (0.9)	4.4 (0.8)	0.69
10. To what degree does the pump prominently display drug concentration options?	3.5 (1.4)	4.2 (1.1)	<0.001
11. To what degree does the pump provide adequate cues to read pump status during use?	4.4 (0.8)	4.5 (0.9)	0.25
12. Please rate the sensitivity of the touch screen compared to current methods of infusing medications.	2.7 (0.8)	2.5 (0.8)	0.13
13. Please rate the overall ease of using this mode compared to what you currently use at your hospital?	4.1 (0.9)	3.4 (1.4)	0.01
14. Please rate your degree of confidence in administering infusions with what you currently use at your hospital?**	4.7 (0.5)	4.7 (0.7)	0.80
15. Please rate your degree of confidence in administering infusions with this mode of the simulated pump.	4.2 (0.7)	4.2 (0.9)	0.99

Values are shown as mean (standard deviation)
Responses were completed on 5-point Likert rating scale where
- *1 = Not at All; and 5 = Great Degree (Questions 1-11)*

- *1 = Too insensitive; and 5 = Too sensitive (Question 12)*
- *1 = Difficult ; and 5 = Very easy (Question 13)*
- *1= Not confident; and 5 = Very Confident (Questions 14-15)*

** P value from paired t-test*
*** Same question for both modes; expected same response*

Results from the NASA-TLX survey are shown in in Table 6. Participants rated a higher performance ("How successful were you in accomplishing what you were asked to do?") in auto-programming mode than in manual mode ($p<0.01$).

Table 6. NASA Task Load Index Scores by Method

NASA Task Load Index	Manual Programming (n=40)	Automated Programming (n=41)	P value*
Composite (weighted), mean (SD)	31.1 (15.4)	28.3 (15.7)	0.08
Mental Demand	39.4 (21.2)	33.8 (18.6)	0.02
Physical Demand	21.8 (18.1)	23.8 (20.1)	0.47
Temporal Demand	31.4 (19.8)	31.0 (21.8)	0.76
Performance	28.9 (19.7)	20.7 (15.9)	<0.01
Effort	35.3 (18.3)	32.6 (22.7)	0.24
Frustration	25.5 (19.1)	30.9 (27.5)	0.17

**P value from paired t-test for n=40 with both types of entry*
- *Composite: weighted summation of mental, physical, temporal, performance, effort, and frustration.*
- *Performance is reverse coded where 0 = Perfect Performance; and 100 = Failure*

Composite NASA-TLX scores were also analyzed by subject charcteristics, as shown in Table 7. Height effects were observed wherein taller participants (> 65 inches) indiciated lower workload demands in the auto-programming mode compared to MIP use in the manual mode ($p<0.01$). Although not statistically different, shorter participants (≤ 65 inches), on the contrary, reported higher workload demand in the auto-programming mode.

Table 7. Composite NASA Task Load Index, by Method, Stratified by Subject Characteristics

Characteristic [mean (SD)]	NASA – TLX (composite)		
	Manual Data Entry	Automated Data Entry	P value*
Age:			
20-29 years	30.2 (12.1)	27.2 (14.7)	0.24
30-53 years	32.0 (18.4)	29.4 (17.0)	0.22
Sex:			
Males	26.0 (20.7)	24.9 (23.0)	0.59
Females	32.2 (14.2)	29.0 (14.2)	0.10
Height:			
> 65 inches	29.0 (14.8)	23.1 (11.8)	0.004
≤ 65 inches	33.9 (16.1)	35.6 (17.9)	0.56

Characteristic [mean (SD)]	NASA – TLX (composite)		
	Manual Data Entry	Automated Data Entry	P value*
Electronic Personal Devices Used:			
Cell phone only	12.3 (**)	13.0 (**)	**
Cell phone & tablet	13.0 (**)	10.0 (**)	**
Smart phone	26.8 (13.5)	23.8 (11.4)	0.27
Smart phone & tablet	35.1 (15.5)	32.1 (17.1)	0.20
Years of Professional Experience:			
<2 years	27.5 (8.7)	17.2 (4.0)	0.20
2-4 years	29.1 (13.6)	23.5 (13.2)	0.05
> 4 years	32.7 (17.1)	32.2 (16.8)	0.64
Years of Experience at Current Institution:			
<2 years	30.6 (14.6)	28.2 (19.8)	0.61
2-4 years	28.2 (13.1)	22.4 (12.2)	0.06
> 4 years	33.7 (17.7)	32.9 (15.9)	0.59
Vision:			
No assistive devices	37.6 (17.6)	33.1 (15.0)	0.08
Distance only	26.9 (11.9)	25.6 (16.7)	0.40
Reading	25.4 (17.2)	22.7 (4.7)	0.80
Takes medication that might cause drowsiness:			
Yes	40.0 (**)	34.0 (**)	**
No	30.9 (15.5)	28.2 (15.9)	0.10

Values are shown as mean (standard deviation)
** P value from paired t-test within each characteristic.*

*** Response from only one participant; result could not be analyzed.*

Comparison of auto-programming and manual modes were analyzed by the number of subtasks completed and duration, as shown in Table 8 and 9. The manual mode required participants to complete 180 steps, which included any single key input or scanning action. In the auto-programming mode, participants were required to complete 89 steps, which included 68 manual inputs and 21 scanning actions. Time to completion was statistically different; results yielded a longer time to complete in the auto-programming mode ($p<0.001$).

Table 8. Scenario Requirements and Time to Complete Medication Infusion Pump Simulation

	Manual Data Entry	Automated Data Entry	P value*
Time to scenario completion (start to end), seconds	515.6 (80.9)	648.6 (130.2)	<0.001
Total Number of Subtasks	100	73	
Total Number of Steps	180	89	
Total number of keystrokes	180	68	
Total number of scanning actions	0	21	

Values are shown as mean (standard deviation).

- *Subtask: action required to achieve task (row of scoring table). Multiple subtasks make up a task.*
- *Step: Any single keystroke or scanning action (sum of keystroke and scanning action).*
- *Scanning action: instance that requires scanning QR code.*
- *Keystroke: any touch of the screen.*

Although the number of total errors during testing was similar between the two modes, a higher number of high risk errors were observed in the manual mode. A statistical difference was observed for the initial login process where 95% participants successfully completed the task in manual mode compared to 89% participants in auto-programming mode (p = 0.02). There was no difference between modes for the proportion of tasks completed. The results are shown in Table 9.

Table 9. Medication Infusion Pump Simulation Task Completion, by Method

	Manual Data Entry	Automated Data Entry	P value*
Total Number of Errors (summation from all 41 participants)	84	85	-
Total Number of High Risk Errors	8	6	-
Percent of all subtasks completed	97.9% (2.0)	97.2% (3.4)	0.17
Percent completed, by Task			
Initial Login	95.2% (6.8)	89.0% (13.7)	0.02
Task 1: Administer Heparin	97.8% (3.9)	96.7% (11.8)	0.55
Task 2: Administer Lactated Ringers	100% (0)	98.8% (4.4)	0.08
Task 3: Administer Vancomycin	98.5% (4.2)	98.4% (5.0)	0.85
Task 4: Administer Perpacillin	97.6% (4.4)	97.6% (4.9)	0.99
Task 5: Bolus Heparin	98.5% (5.3)	99.0% (4.4)	0.66
Task 6: Discontinue Piperacillin	99.2% (5.2)	99.2% (5.3)	0.99
Task 7: Increase Lactated Ringers	97.6% (7.5)	96.3% (10.5)	0.42
Task 8: Setup Lactated Ringers as Carrier	99.1% (3.3)	98.9% (9.7)	0.05
Task 9: Administer Norepinephrine	97.6% (4.9)	98.0% (5.5)	0.68
Task 10: Change Norepinephrine Dose to 0.04 mcg/kg/min	98.8% (5.5)	98.2% (6.6)	0.66
Task 11: Change Norepinephrine Dose to 0.12 mcg/kg/min	97.6% (7.5)	98.2% (6.6)	0.66
Task 12: Discontinue all medications	95.1% (21.8)	97.0% (16.0)	0.47
Percent Completed. by Action Type			
Login	87.2% (23.1)	86.2% (18.2)	
Submit/Confirm	98.8% (3.5)	99.0% (3.7)	
Select Patient	93.9% (20.0)	96.3% (13.2)	
Navigate Menu	98.3% (4.0)	96.5% (6.2)	
Input Medication Name	98.5% (3.5)	97.2% (5.5)	
Input Dose	95.7%(7.2)	99.2% (5.2)	
Input Volume	98.4% (5.0)	-	
Input Concentration	97.6% (10.9)	-	
Select Bag	-	98.4% (5.0)	
Input Route	-	94.3% (16.9)	
Select Channel	98.4% (5.0)	98.4% (5.0)	
2nd RN Verification	-	95.1% (21.8)	

	Manual Data Entry	Automated Data Entry	P value*
Start infusion	98.4% (5.0)	79.5% (3.1)	
Stop infusion	98.4% (7.3)	98.4% (7.3)	
Input Rate	96.0% (6.5)	96.3% (10.5)	
Set up Secondary Infusion	100.0% (0.0)	0.0% (0.0)	
Respond to alert	100.0% (0.0)	97.6% (10.9)	
Change dose	93.9% (16.6)	93.9% (16.6)	

Values are shown as mean (standard deviation).
** P value from paired t-test.*
- *High Risk Error: errors that resulted in actual incorrect delivery of medication, dose, or volume to the patient; delivery of correct medication to the incorrect patient, and delivery of correct medication via an incorrect route.*
- *Task: administering specific drug.*

3.5.2 High-Level Themes from the Debrief Interviews

A large number of observations and insights were provided about the two pump modes (APPENDIX K). Many of the inputs addressed discrete issues concerning control, display, and editing designs. This section discusses the more common themes derived and those of greater interest to safety.

In discussing safety for the two modes, 44% of participants offered that the scan mode would be the safer mode, while only 7% offered that the manual mode would be safer. The reasons offered were based on the auto-programming features, which preclude pump programming errors.

The general approach to the tablet-based interface design was well accepted from a usability standpoint. It was seen as easy to navigate, user friendly, and intuitive to use.

Comments regarding the means to enter and edit data highlighted the importance of design features that support error-free programming. Users pointed out the need for standard decimal point placement, as well as easy and reliable means of cursor control. The importance of proper touchscreen sensitivity to avoid input errors was well noted.

The concept and means for providing allergy and tube change alerts was well accepted, and additional alerts were suggested (e.g., running two incompatible medications, doses out of range, confirmation that Rx has been contacted for a new bag, and even alerts for dressing changes).

The design for infusion status information (see Figure 24 to Figure 26) was well received, and a number of individual suggestions was provided for the display of additional information.

3.5.3 Discussion

This section provides discussion of the results in view of the CAC exercise problem statements that the project team addressed with the design of the prototype interface. Individual subsection headers describe

specific problem statements.

3.5.4 Safe Use

An important motivation for this project was the safe administration of medications using MIPs. The prototype MIP was developed with this in mind. A discussion of the results pertinent to the safe use of the prototype are provided first.

3.5.4.1 Misinterpretation of a Physician's Order (and Misprogramming Infusions)

One of the problem statements identified during the MIP workshop (Phase 1) was that misinterpretation of a physician's orders and misprogramming of MIPs could potentially lead to medication errors. To address this concern, the auto-programming mode enables the user to transfer drug parameters from the physician order directly to the infusion pump. The automated approach is a means to prevent human error due to incorrect entry, miscalculation, or misinterpretation of the physician's order. In addition, the system verifies other user inputs in the infusion pump process, such as route and channel.

In both manual and auto modes, users have the ability to enter drug parameters into the pump interface in the event verbal orders or immediate changes are necessary.

Results from the testing (Table 5) suggests that the perceived accuracy of entering the physician order is higher in the automated mode. Participants felt that the automated mode was more likely to prevent misinterpretation of a physician's orders (4.3 versus 3.1, Post-Task Survey Q#2) and programming errors (4.2 versus 2.9, Post-Task Survey Q#3). The results for both questions were statistically significant.

3.5.4.2 Lack of Forcing Function to Confirm/Check Important Data Entries and Ability to Easily Override Safety Features

A challenge identified during the MIP workshop (Phase 1) was the lack of forcing functions to confirm and check important data entries. Furthermore, the ability to easily override safety features could lead to medication errors. Test results suggest that the two modes (i.e., manual and auto-programming) were similar in their ability to prevent overriding of safety features (3.2 versus 3.5, Post-Task Survey Q#1). Five times (1.1%) in the manual mode, users failed to confirm their entries for channel, volume to be infused, and dose (once each); and twice for confirming receipt of alerts. This failure rate might present appreciable safety concerns for a hospital's fleet of pumps. As implemented, automated programming of the infusion order did not include a manual confirmation step for selecting channels, volume, dose, or rate information derived from the system (though it could have for manual rate changes, for instance) as there is no need for the user to check one's programming accuracy. Note, however, that with automated programming, 15 of 41 nurses (37%) indicated they would be less likely to double check whether scanned orders were appropriate for the patient. Those nurses had concerns about the loss of prompts for nursing to evaluate the accuracy of orders and auto-programming instructions.

3.5.4.3 Errors in Calculating Conversions

A problem identified during the MIP workshop (Phase 1) was that calculating conversions might potentially lead to errors. Participants felt that the automated pump was more likely to prevent errors in calculating conversions (4.3 versus 3.7, Post-Task Survey Q#5). Participants did not feel there was a difference between the two pump modes in terms of accuracy of weight information (4.3 versus 4.1, Post-Task Survey Q#8); the project team did not expect a difference because this functionality was not designed in either mode. Participants did not need to make any conversions; thus, any data reflects participant opinions regarding the value of automating conversions.

3.5.4.4 Bypassing and Forgetting to Reset Programming After a Bolus

One issue raised at the MIP workshop (Phase 1) was the possibility of forgetting to reset a continuous drip after a bolus. As designed for both modes, the simulated pump continues the infusion after the bolus, requiring no action of the user. Therefore, it was expected that participants felt that both manual and auto-programming modes were similar in their ability to prevent the need to reprogram the pump after a bolus (4.2 versus 4.4, Post-Task Survey Q#4).

3.5.4.5 Inadequate Display Field Sizes, Line Break Position, and Use of Bolding to Differentiate Selection Options

One issue raised at the MIP workshop (Phase 1) was that current MIPs had inadequate display field sizes, line break positions, and use of bolding to differentiate selection options. For the prototype MIP display, a tablet device defined the display's real estate and aspect ratio. This resulted in a GUI design that enabled users to easily reference drug information and navigate between screens.

Results from the post-task survey indicated that the MIP display was easy to read (4.4 and 4.5, Post-Task Survey Q#7) and provided adequate visual cues (4.4 and 4.4, Post Task survey Q#9) in both modes. Because the displays were very similar in both modes, a difference in responses was not expected.

There were no differences in these responses between participants of different personal device use, although the majority of participants (39 of 41) used smartphones.

3.5.4.6 Reliance on Automation

Transferring physician orders directly to pumps via autoprogramming can reduce risks associated with manual pump prgramming. However, this could invite a sense of complacency, leading users to forego manual verification tasks that help assure safe use. Study participants expressed the risk of relying on the automated method and not being as vigilant in catching potential errors originating from the physician's order.

3.5.5 User Satisfaction

Another important motivation for this project was the need for a MIP that is user-friendly. In some

instances, users are forced to adapt their workflow to the design of the MIP. The prototype was developed the goal of creating a more user-friendly MIP. A discussion of the results pertinent to satisfaction of use is now provided.

3.5.5.1 Pump Workflow Does Not Match the User Workflow

Another challenge raised at the MIP workshop (Phase 1) was that the MIP workflow does not always match the user workflow. Although the risk for human error remains inherent, the MIP consisted of an interface design that aligned with user workflow based on SME feedback. For example, the display included drug input parameters in a particular order such as drug, rate, concentration, and VTBI.

The testing results suggest that auto-programming did not match user workflow more than the manual programming (3.7 versus 4.0, Post-Task Survey Q#6). However, in debriefing interviews, both modes were reported to be user friendly. Users reported that auto mode reduces double checking and documentation and that manual mode required reading the order and more programming effort.

The NASA TLX scores suggest that auto mode is more efficient than manual mode. Mental demand was lower (33.8 versus 39.4, $p = 0.02$) and perceived performance was higher [reverse coded] (20.7 versus 28.9, $p < 0.01$) for the auto compared to the manual mode (Table 6). These results were noted despite a smartphone being used as a scanning device, which presented scanning frustrations. Use of a different scanner would seem to increase speed and satisfaction of the auto mode.

3.5.5.2 Takes Too Much Time to Reach Pump Status During Use (e.g., Indication of Med Being Infused)

One issue raised at the MIP workshop (Phase 1) was that it takes too much time to read the MIP status during use. For example, some pumps use a scrolling banner type display to economize space. Users need to wait several seconds until the information they need appears on the banner. Participants found both auto and manual programming modes provided adequate visual cues to read the pump status (4.5 and 4.4, Post-Task Survey Q#11). The project team did not expect to find a difference between the two modes because the displays were very similar.

3.5.5.3 Display Content and Format Make It Difficult to Read in Different Settings

Another challenge raised at the MIP workshop (Phase 1) was that the display content and format of MIPs sometimes make it difficult to read in different settings (e.g., lighting, distance, angles). MIP display accounted for design based on human-computer interaction (HCI) and usability guidelines for tablet-based information. The physical setup of the infusion pump consisted of good ergonomics practice by including an adjustable tablet mount to allow users to modify the display as needed to reduce glare and accommodate the appropriate viewing angles. Results from the post-task survey indicated that the MIP display was easy to read in both auto and manual modes (4.4 and 4.5, Post-Task Survey Q#7). The project team did not expect to find a difference between the two modes because the displays were very similar.

3.5.5.4 Post-Test Survey Results: Ease of Use and Sensitivity of Controls

Participants found the manual programming mode easier to use than the auto mode (4.1 versus 3.4, Post-Test Survey Q#13). This likely represents participant familiarity with the manual programming mode because most participants had never used auto-programming before (95% use Baxter or Alaris pumps, Table 4**)**

Observations led the project team to believe that challenges using a cell phone as a scanning mechanism negatively affected the perceived ease of use for the auto-programming mode. On the other hand, participants had equal confidence in administering medications with both modes (4.2 versus 4.2, Post-Test Q#15).

Participants found the sensitivity of the touch screen, both in auto-programming and manual modes (2.5 and 2.7, Post-Test Survey Q#12) to be quite poor. One participant consistently had challenges with the keypad. This may have been due to the adaptation of a tablet computing device for the MIP interface.

3.5.5.5 Workload

Overall, the participants found the workload associated with using the MIP prototypes in both auto-programming mode and manual mode to be similar (Composite NASA TLX 28.3 versus 31.1, $p = 0.08$, Table 6). The participants indicated that the manual mode imposed a higher mental demand than the auto-programming mode (Mental Demand NASA TLX 39.4 versus 33.8, $p = 0.02$). This likely represents the automation provided by auto-programming. Moreover, participants believed that their performance was better with the auto-programming mode compared to manual (Performance NASA TLX 20.7 versus 28.9, $p < 0.01$). Performance is reverse coded; 0 = perfect performance, and 100 = failure.

On subgroup analysis (Table 7), participants that were taller (Composite NASA TLX 23.1 versus 29.0, $p < 0.01$) or had fewer years of professional experience (Composite NASA TLX 23.5 versus 29.1, $p = 0.05$) found auto-programming to be less burdensome than manual mode. Subjects with fewer years of professional experience might have been more flexible and open to the new concept of auto-programming, thus finding it to have lower task load index. It is unclear why taller subjects found the auto-programming task load less burdensome than the manual mode, while shorter subjects perceived no significant task load difference between modes.

3.5.5.6 Meeting User Requirements (from Specific Aim #1)

During Aim #1 of the project, the project team identified five broad themes of user requirements:

1. Systems Integration
2. Programming Navigation
3. Information Presentation and Prioritization
4. Control Standardization
5. Context Awareness

During Aim #2 of the project, a prototype MIP was developed that, in concept, would address many of these requirements. The fundamental concept of this prototype MIP was to integrate the MIP, hospital information system, and computerized order entry system (automatic programming). During Aim #3 of the project, the team tested whether or not the prototype MIP would meet some of these user requirements. It was found that the auto-programming indeed met the user requirements of systems integration and context awareness. Users found this system to be easy to use and less error prone. Though not directly tested, users reported in both debriefings and surveys that the program navigation and information presentation of the prototype MIP was acceptable. Control standardization was not directly evaluated with the testing.

4. CONCLUSION AND RECOMMENDATIONS

In this project, challenges and user needs associated with large volume MIPs were identified. A prototype MIP interface allowing for usability testing of various functions and features was developed. Usability testing was performed comparing automated and manual MIP programming. Test participants found auto-programming to be potentially safer. They found it to be less mentally demanding and associated with better performance. However, they found manual programming to be easier to use, likely related to their familiarity with this process and the nature of the barcode device selected for use. Tasks were completed with equal likelihood in both modes.

4.1 SIGNIFICANCE

Though these findings are based upon a small sample size performed in a simulated setting, they have some potential implications. Automated programming can potentially lead to safer administration of medications. There appears to be a learning curve, as participants had a natural preference to manual programming due to increased familiarity. Further research in this area should provide clearer evidence of the value of automated MIP programming.

4.2 NEXT STEPS

4.2.1 Recommendations for Improvement of Pump Designs

The product of the Phase 1 workshop offered a multitude of recommendations for improvement of infusion pump safety. This is evidenced by the results compiled from workshop discussion of problem statements, from the ratings for both feature standardization and best pump design practices and from design suggestions participants offered after prototype use. The CONOPS that drove the prototype design addressed many of those issues by integrating infusion information within a hospital network (e.g., EHR and CPOE) to promote positive control of pump programming.

One theme obtained from participants was that a hybrid design including both scanning and manual modes would be more favorable than either mode alone. This would minimize the potential risks for error, allow bypassing of possible system constraints for emergency use, and maintain vigilance by requiring some manual data inputs. Examples of such manual inputs include selection of channel and route.

4.2.2 Further Investigation

Opportunities remain to further investigate this approach through more comprehensive integration of the prototype with other elements of a hospital LAN, e.g., CPOE, pharmacy, and EMR systems. Additional opportunities exist to investigate how alternative prototype designs may produce other solutions to address the problem statements. Those problem statements include:

- Specific display issues
    - Frequent alarms that fatigue users

    - Use of the same alarm cues for critical and non-critical events
    - Drug concentration options that are not prominently displayed
    - Use of inadequate or non-standard visual cues for different classes of drugs
    - Inadequate notification of conditions approaching out-of-tolerance limits
    - Time required to read pump status during use (e.g., indication of medication being infused)
    - Adequate indication of need for additional medication product in time for pharmacy to provide it
- Control and programming issues
    - Ability to easily override safety features
    - Ability to edit the rate even if pulled from the library
- Other safety controls
    - Need for a maximum rate feature for bolus dosing specific drugs
    - Safe management of multiple infusion lines
    - Controlling use of two bags of the same drug on multi-channel pumps
    - Ready replacement of failed pumps

Further opportunities are presented to conduct comparative studies of specific human factors features that affect both usability and safety. Such studies may examine alternative designs of features such as:

- Navigation between operational modes
- Manual entering and editing of orders and data
- Numeric keypad designs
- Text character size and font style
- Drug labeling conventions in view of space provided
- Visual and auditory cues for alarm information
- Use of color and other cues to indicate infusion status
- Control button and widget designs

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APPENDIX A. REFERENCES

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APPENDIX B. PROBLEM STATEMENTS AND DISCUSSION RESULTS

#	**Problem Statements and Discussion Results** (Problem statements shown in bold; source of problem statements shown in brackets).
1	**Frequent alarms fatigue users**. [Summit] *Workshop Results:* • MIPs designed so that alarms/alerts include the drug name • MIPs designed to send alarms/alerts to specific clinical team members on their notification devices • MIPs designed with coded alarms (e.g., sound) based upon what caused the alarm • MIPs designed with graduated alarms and alarms differentiated based on clinical factors • MIPs designed using standardized alarms
2	**Ability to easily override safety features** [Summit] *Workshop Results:* • Safety features that address clinical needs of each individual patient; pumps that are more patient-aware • Need unique safety features that allows for variance of practice. • Alerts that safety feature has been overridden (currently relies on intuition or memory of user)
3	**Difficult to manage multiple infusion lines** [Summit Clarion Theme 4] *Workshop Results:* • Pump design requires the nurse to confirm that set-up has been done correctly • Location information regarding each system component (drug, line, etc.) • Centralized display of information • Use of colors to differentiate bags, lines, etc. • Use of barcodes to link system components together
4	**Same alarm cues for critical and non-critical events** [Task Analysis] *Workshop Results:* • (Not discussed in workshop due to similarities with 2.2.1)

#	**Problem Statements and Discussion Results** (Problem statements shown in bold; source of problem statements shown in brackets).
5*	**Misinterpretation of a physician's order** [Task Analysis]; 7.1-1 Most pumps are not interoperable with a host of data systems, including medication orders, drug library, electronic medical administration (eMAR) records, bar code medication administration (BCMA) and reporting. [Summit Clarion Theme 2] *Workshop Results:* Manual verification of the Five Rights was identified in separate problem statement. User needs and solutions discussed included: • Mismatches between the medication order entry and the nurse's programming of the MIP. MIPs designed for automated programming • Take away the ability and need for the nurse to perform drug calculations • Implement order verification at the pump • Leverage 2005 standard for rich barcode for pharmacy labels that contain all the data necessary to program a MIP • Implementation of automated dispensing cabinet can produce the patient-specific label • MIPs designed to handle infusion rate changes which cause an initial pharmacy-generated label to be inaccurate. A solution may be: titration change on the pump; pump sends the info to the server; and system checks to ensure titration range is within the order • Use of social networking to catch programming issues
6*	**Bypassing and forgetting to reset programming after a bolus** [Summit] *Workshop Results:* • SMEs discussed the fact that not all pumps have a dedicated bolus feature and for those that do, the function is sometimes not easy to use. • MIPs designed to require double-keyed override for bolus; bolus termination when one is released • MIPs designed with bolus features that have the ability to check the appropriate sources to ensure the bolus is administered properly to the right patient. For example, the SMEs noted that a Symbiq MIP model verifies the patient's weight against the bolus administration.
7*	**Errors in calculating conversions** [Summit] *Workshop Results:* • The discussion regarding this problem statement did not stimulate lengthy conversation. Many smart pumps on the market perform calculations already. As well, it was noted that this topic was covered during discussion of other problem statements.

#	**Problem Statements and Discussion Results** (Problem statements shown in bold; source of problem statements shown in brackets).
8	**Drug concentration options are not prominently displayed (e.g., need to scroll down for some). User reverts to non-DERS (Dose Error Reduction System) administration by bypassing safety functions** [Summit Clarion Theme 3] *Workshop Results:* • Driving issue associated with this problem statement is the initial selection of the concentration from the drug library when programming the pump. The SMEs noted the inconsistency of navigation approaches across models and also the fact that an AAMI working group is charged with looking at ways to structure a drug library to make these libraries easily navigable. User needs and solutions discussed included: • MIPs designed to support automatically pre-populating the drug concentration choice through barcode readers or cameras that do optical character recognition • MIPs that utilized keyword functionality that self-populate when a few characters are entered (similar to word recognition used on smart phones and tablet computers) • MIPs that utilized voice recognition to specify the concentration and MIP-generated audio that echoes the selected concentration back to the nurse to confirm the selection. • MIPs that utilize a configuration similar to the "newsstand" Apple uses on the iPad: a visual display of the concentration options available. Also, use of a touch sensitive color screen that possess orientation sensitivity and uses graphically rich (high resolution) displays that utilize icons and graphical representations more than text.
9	**No maximum rate feature for bolus dosing for specific drugs** *Workshop Results:* • The SMEs restated this Problem statement as: "MIPs need to provide more entry options (spaces) for types of maximum settings and the ability to look at them concurrently." The SMEs went on to discuss the need to change the user interface to accommodate resolving this problem as well as the need to ensure clear display of trigger limits and the need to display units for some drugs of weigh and non-weight-based regardless of the limits with the limits based on kilograms, total dose, and rate. The SMEs also noted that there are not many drugs that warrant a maximum setting. • No specific user needs or solutions emerged during the user needs portion of the discussion during this Problem statement topic. Instead, one very noteworthy comment that emerged during the discussion of this Problem statement captured the general sentiment expressed: "…do we want a smarter pump or a smarter clinical network…" Though this comment was raised specifically during this Problem statement conversation, it was implied throughout the day even if not mentioned explicitly.

#	**Problem Statements and Discussion Results** (Problem statements shown in bold; source of problem statements shown in brackets).
10*	**Pump workflow doesn't match the user workflow. The sequence for programming the pump differs from the user's sequence of tasks for medication delivery.** [Summit] *Workshop Results:* The SMEs slightly reworded this Problem statement to: "Lack of standardization on field type, order of fields, terminology to describe the field, and consistency between ordering, the pump and pharmacist." The new statement reflected the notion of standardizing the sequence of data entry whereas the original intent of the statement was a broader issue involving the whole concept of a bedside pump and manual programming. The ensuing discussion touched on a few interesting items in terms of potential solutions. **User needs and solutions discussed included:** • Prototyping entry sequences to assess the occurrence of errors (would want to perform this under a range of environmental conditions i.e., low/high acuity, emergencies, etc.) • Prototyping pump programming methods that involve little to no bedside data entry but rather the pump is programmed via the Pharmacy and the bedside caregiver validates the settings. Accommodation of bedside operation is a must in case of emergencies or problems with the network which could degrade or eliminate communication between the Pharmacy and the pump. • An important concept from the Think-Tank notes is the notion of a validation step (by a person) involved in the programming. Essentially, one person programs the pump and another follows entering the same information – differences would be noted and need resolution before proceeding with the infusion.
11	**Inadequate/non-standard visual cues for different classes of drugs** [Summit] *Workshop Results:* The SMEs noted that different drug classes look alike and scrolling marque-style displays on some MIPs make it hard to see what drug was selected for infusion. The display size on some MIPs and the size of the information displayed were also noted as issues. The ensuing discussion ranged beyond visual cues for different classes of drugs to include alarms and visibility of pertinent information. Though not specifically related to this Problem statement, this ranging discussion provided insightful information regarding issues, challenges, and potential solutions that spanned a number of the Problem statements discussed at the Workshop. **User needs and solutions discussed included:** • MIPs designed to support cues for the nurse walking past the room to interpret an alarm • MIPs designed to provide information and context about the infusion while the pump is operating • MIPs designed in recognition of the need to read the MIPs display at a distance (20-30 feet and outside the patient's room) and in varying lighting environments and the need to determine nature of alarm quickly at a distance • Research is needed to identify the essential non-negotiable information that needs to be displayed at all times: MIPs designed balancing safety and convenience: what info needs to be available from a distance, what information needs to be available at bedside, at the pump; recognition that the information required might be different based on patient At the conclusion of the discussion of this problem statement, the SMEs noted that many of the issues and challenges just discussed have been faced and addressed in the design and implementation of other medical devices and systems outside the healthcare field. These other applications should serve as lessons learned which could be used to address MIP issues.

#	**Problem Statements and Discussion Results** (Problem statements shown in bold; source of problem statements shown in brackets).
12	**Can hang two bags of the same drug on pumps with more than one pump channel.** [Task Analysis] Inability to know total dose of medication being infused if two or more pumps are infusing the same medication *Workshop Results:* The SMEs noted that there is no association of the patient-specific order to a particular pump channel which permits duplication of medication dosing. User needs and solutions discussed included: • MIPs designed with a holistic view of the infusions
13	**Inadequate notification of approaching out-of-tolerance conditions** *Workshop Results:* • The SMEs expressed the inclination to allocate the notification of and/or response to approaching out-of-tolerance conditions to something other than the infusion pump such as a decision support algorithm "outside" the MIP that sends commands to the MIP to achieve a desired clinical result). Such a MIP would be designed to respond to externally generated instructions to change the infusion parameters. The reprogramming (or programming adjustment) response could come from either a remote clinical order or from another medical system in an automated close loop fashion (with a clinician in the loop for verification).
14*	**Inadequate display field sizes, line break position, and use of bolding to differentiate selection options** [Summit] *Workshop Results:* • During the workshop the project team decided to skip this problem statement because the topic was discussed during discussion of other problem statements.
15*	**Prompts to enter rate or volume to be infused (VTBI) come before prompts on dose** [Summit Clarion Theme 3] *Workshop Results:* • During the workshop, the project team decided to skip this problem statement in the interest of time since the topic was discussed during discussion of other problem statements.
16	**Takes too much time to read pump status during use (e.g., indication of med being infused)** [Summit Clarion Theme 3]; Rate information is displayed rather than more important dose information. [Summit Clarion Theme 3] *Workshop Results:* • During the Workshop, the project team decided to skip this problem statement in the interest of time since the topic was discussed during discussion of other problem statements.

#	**Problem Statements and Discussion Results** (Problem statements shown in bold; source of problem statements shown in brackets).
17*	**Insufficient alerts when input errors have been made** [Summit] *Workshop Results:* The SMEs discussed the importance of addressing this issue particularly for high risk drugs such as Heparin. User needs and solutions discussed included: • MIPs designed with special alerts when input errors occur when administering high risk drugs. • MIPs designed to mitigate entering the correct data into the wrong field; a SME suggested that rotary knobs such as those called "jog knobs" rather than screen (keyboard) entry may address entry errors. • MIPs designed with a "summary page" where MIP operators would be required to review and confirm before administration begins. • MIPs designed with the ability to track errors to identify issues that can be addressed via training.
18*	**Pump interface features associated with high risk control functions are not standardized across pumps (e.g., control and label placement, color coding or order of data entry)** [Summit] *Workshop Results:* • This specific problem statement generated additional discussion which prompted the need to ask attendees to break down user controls and interface features to another level. The facilitator capitalized on the ThinkTank system by instructing attendees to use the electronic discussion board to identify the most critical MIP features in need of standardization. Participants reflected results in an open-ended format, in which the number of responses differed among the number of respondents.
19*	**Use of weight data that varies from the primary source (medical records vs. bed scales vs. memory)** *Workshop Results:* Administration of medications where the dose is patient-weight-dependent represents a challenging type of infusion in terms of safety. The SME's discussion, however, steered toward means for determining how much medication volume remains in the bag. **User needs and solutions discussed included:** • Instead of a battery charge "bars left" type of indication of how much medication remains in the bag, use a clock to count down the amount of time remaining; must take into account infusion rate changes, pauses, etc.; utilize a nurse callback and/or a prompt to pharmacy when a bag is nearing completion. • A special sensor to determine how much fluid remains in the bag as the infusion progresses.

#	**Problem Statements and Discussion Results** (Problem statements shown in bold; source of problem statements shown in brackets).
20	**Pump does not provide adequate indication of need for additional medication product in time for pharmacy to provide it.** [Task Analysis]; 8.1.2. Sometimes notifications from the pump indicating infusions are nearing completion do not occur until after infusion is complete, interrupting continuous medication delivery [Task Analysis] *Workshop Results:* The discussion surrounding this problem statement focused on the fact that near-end-of-infusion alerts or alarms are not universally implemented and in some cases where they are used, they are not considered accurate. Accordingly, nurses tend to utilize workarounds involving programming the pump such that an alert is triggered well in advance of the end of the infusion. **User needs and solutions discussed included:** • Instead of solely relying on the flow parameters of the pump during the infusion to determine how much fluid remains, utilize a sensor to measure the weight of the fluid in the bag.
21*	**Lack of forcing function to confirm/check important data entries** [Summit Clarion Theme 3] *Workshop Results:* • During the workshop, the project team decided to skip this problem statement because the topic was discussed during discussion of other Problem statements.
22	**Some pumps allow users to edit the rate even if pulled from the library** [Summit] *Workshop Results:* • The SMEs discussed the desire to have the MIP program pre-populated with the desired infusion rate rather than to have it manually entered. A non-technical policy-related suggestion raised included the ability to give hospitals customizable functionality for pre-populated dose rates and the ability for the clinician to deviate from the pre-populated rate if necessary.
23*	**Program too much Volume To Be Infused (VTBI)** *Workshop Results:* This problem statement stimulated a short discussion among attendees how this issue largely centers on practice rather than technology **User needs and solutions discussed included:** • Association of bag-rate-patient addresses this issue • A separate sensor that senses what is in the medication bag

#	**Problem Statements and Discussion Results** (Problem statements shown in bold; source of problem statements shown in brackets).
24*	**Display content and format make it difficult to read in different settings (e.g., lighting, distance, angles)** [Task Analysis] *Workshop Results:* Discussions among groups over the best means for displaying information often lead to widely ranging concepts and the workshop discussion on this problem statement is evidence of this. With the wide range of personal opinions, operational conditions, and definition of "the best means", it is not surprising that the discussion that ensued with this problem statement involved a number of different suggestions for solutions. The discussion over this topic, however, was shortened due to the recognition that much can be learned from other industries regarding these issues and in fact recognized standards exist for many. **User needs and solutions discussed included:** • MIPs designed with configurable lighting options and brightness controls operated manually and/or controlled by a sensor that detects the environment and optimize the settings. • Research is required to assess the range of viewing angles and distances to consider when designing a MIP user interface.
25	**Pump fails and a replacement is not available** [Summit] *Workshop Results:* The SMEs discussion of this topic centered less on general pump failures and more so on failures related to battery discharge. **User needs and solutions discussed included:** • Improved technology to predict battery life • MIPs designed with the ability to "fail operative" in other words, if the battery fails, certain features and functions should remain operative for a pre-specified period of time. • MIPs designed to support hot-swappable battery replacement that does not require reprogramming the pump once the MIP operator completes the battery swap.

[Summit]: AAMI/FDA Infusion Pump Summit (2012)
[Summit Clarion Theme #]: Clarion Theme from AAMI/FDA Infusion Pump Summit
[Task Analysis]: Performed by APL/JHMI or AAMI/FDA Infusion Pump Summit
** Challenges that can potentially be addressed by automated programming*

APPENDIX C. PUBLICATIONS AND PRODUCTS

The project team produced three manuscripts stemming from research associated with this grant. These include:

- *Infusion Pump Workshop 2012: A Systems Engineering Approach for Human Factors Solutions*, JHU/APL REDD-2012-251, September 2012
- Ravitz, A.D., Sapirstein, A., Pham, J.C., Doyle, P.A., *Systems Approach and Systems Engineering Applied to Healthcare: improving patient safety and healthcare delivery*, submitted for publication October 2013.
- Pham, J.C., Doyle, P.A., Ravitz, A.D., Sultana, N., Gurses, A.P, Pronovost, P.J., *Examining User Needs for Safe Medication Infusion Pumps*, American Journal of Health-system Pharmacy, submitted for publication December 2012.

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APPENDIX D. MODERATOR SCRIPT – MANUAL MODE

Participant# _____ Date: _____ Room A or B Session Time: _____

This simulation has the following sequence of infusions:

Task 1. Heparin bolus 4900 U/hr followed by a drip of 1050 U/hr.
Task 2. IVF (Lactated Ringers) 120cc/hr.
Task 3. Vancomycin 1 g IV stat
Task 4. Piperacillin/tazobactam 3.375 g IV as secondary to Lactated Ringers
Task 5. Rebolus of Heparin 2450 U/hr
Task 6. Discontinue piperacillin
Task 7. Order to infuse remaining Lactated Ringers at 999cc/hr
Task 8. Norepinephrine for a MAP goal of 60 mm/Hg (2.63 mL/hr calcs automatically) with a Lactated Ringers infusion at 20 cc/hr as carrier
Task 9. Start Norepinephrine at 0.02 mcg/kg/min to achieve the MAP goal
Tasks10 -11. Two Norepinephrine increases to achieve the MAP goal
Task 12. Discontinue all infusions

The following text provides highlighted script for moderators to read to participants *directions and notes to the moderator in Italics*, and notes to the observers in blue.

Observers will record observational data.

Observer startup/initiation of scenario:
- Control Panel
- Login

Start as logged out
- Observer Login/Password: their name/their name
- [Start Participant]

Moderator:
Assure patient info tab is "up" on left side of MIP screen!
Participants login as Jean/Jean or Pat/Pat
The patient ID is 524837
Participants select manual entry

Scenario
Now we will start the infusion scenario. In this scenario, you will enter information manually and will not use the scanner. Please remember that in cases where a 2nd RN verification is needed, I will role play the 2nd RN.

You have just received report from the ED on a patient that came in with acute shortness of breath and was found to have low O2 saturations on arrival to the ED. He is being ruled out for PE and is being admitted to the ICU for management. Mr. John Doe is a 73 year old, 70 kg male with no known allergies.

Task 1.

On arrival to your ICU, the patient's preliminary diagnostic tests indicate he is positive for PE. The patient needs to start on heparin. A continuous heparin drip of 1050 U/hr. with concentration is 100 U/mL followed by a bolus of 4900 U. Please start these infusions on Channel A.

Observer: Sub-tasks for Heparin on Channel A

1. Select Login Y / N
2. Select Login user Y / N
3. Provide User ID Y / N
4. Select Submit Y / N
5. Select Pt. ID Y / N
6. Select Submit Y / N
7. Select Login Y / N
8. Select Manual Entry Y / N
9. Select Heparin Y / N
10. Enter 1050 U/hr. Y / N
11. Enter volume 250 mL Y / N
12. Enter concentration 100 U/mL Y / N
13. Select Channel A Y / N
14. Confirm 2nd check Y / N
15. Start infusion Y / N
16. Select Heparin Y / N
17. Select bolus Y / N
18. Enter dose 4900 Y / N
19. Select yes Y / N
20. Confirm Y / N (it starts)

Task 1.1

Moderator: Once the heparin infusion is started, verify the information is correct, then ask the Participant (P):

How would you stop the bolus? Go ahead and do so.

Observer:

Select Bolus Y / N
Select Stop bolus Y / N
Select Yes Y / N

This prevents having to run the bolus 9 min and initiates the continuous heparin infusion. The Heparin infusion will run at normal speed.

Observer: Next order is for Lactated Ringers (Task 2).

Task 2.

Additional admitting orders include maintenance IVF of lactated ringers (LR) at a rate of 120 cc/hr. Hang an IV bag of lactated ringers now on Channel B.

Observer: Sub-tasks for Lactated Ringers

1. Manual entry Y / N
2. Select drug menu Y / N
3. Select LRs Y / N
4. Enter rate 120 Y / N
5. Enter volume 1000 Y / N
6. Confirm Y / N
7. Select Channel B Y / N
8. Confirm again Y / N
9. Start Y / N

Observer: Next order is for vancomycin (Channel C) and Piperacillin/tazobactam (Channel B) (Task 3).

Task 3.

Your patient is now looking septic with hypotension and febrile indicators. Stat orders are placed for antibiotics - vancomycin and Piperacillin/tazobactam. Pharmacy has verified this vancomycin as 1 g IV stat. Start the vancomycin on Channel C.

Observer: Sub-tasks for Vancomycin

1. Manual entry Y / N
2. Select drug menu Y / N
3. Select Vancomycin Y / N
4. Enter 1 gm Y / N
5. Enter VTBI 250 mL Y / N
6. Confirm Y / N
7. Select Channel C Y / N
8. Confirm again Y / N
9. Start infusion Y / N

Observer: Next order is Piperacillin/tazobactam (Channel B) (Task 4).

Task 4.

Now start piperacillin/tazobactam – 3.375 gm IV Stat as a secondary to the ringers.

(*Moderator: If P is not familiar with hanging a secondary, use next open channel as a primary for Piperacillin/tazobactam)*

Observer: Sub-tasks for Piperacillin

1. Manual entry Y / N
2. Select drug menu Y / N
3. Select Piperacillin Y / N
4. Enter dose 3.375 gm Y / N
5. Enter VTBI 100 mL Y / N
6. Confirm Y / N
7. Select Channel B Y / N
8. Set as Secondary: YES Y / N
9. Confirm again Y / N
10. Start infusion Y / N

Observer: Initiate an occlusion alarm for Heparin.

1. Participant selects Heparin to expand Y / N
2. Participant sees notification for occlusion Y / N
3. Selects the notification Y / N

Task 5.

It is now 6 hrs. later and the aPTT result is low and requires a rebolus heparin dose of 2450U per protocol.

Observer: Sub-tasks for Heparin on Channel A

1. Select Heparin Y / N
2. Select bolus Y / N
3. Enter dose 2450 Y / N
4. Enter Yes Y / N
5. Confirm bolus: Yes Y / N

Observer: After Piperacillin/tazobactam is started, use the "Change VTBI" prompt to reduce the VTBI to 2 mL to accelerate the infusion and enable notification to appear regarding infusion end.

Task 6.

Discontinue the Piperacillin/tazobactam as if it had finished.

Observer: Sub-tasks for Piperacillin on Channel B/D

1. Selects piperacillan Y / N
2. Selects discontinues P/T infusion Y / N
3. Cancel infusion: Yes Y / N

Task 7.

A verbal order is given to infuse the remaining LR at a rate of 999 cc/hr.

Observer: Subtasks for Lactated Ringers on Channel B

1. Select LR Y / N
2. Select rate Y / N
3. Enters 999 Y / N
4. Submit change Y / N

Moderator: A "new" LR channel will be used with LRs later as carrier for Norepinephrine.

Observer: Next order is for Lactated Ringers and Norepinephrine.

Task 8.

There is no improvement in blood pressure. The provider orders Norepinephrine for a map goal of ≥ 60 mm Hg. Start an infusion of LR at 20 cc/hr. as a carrier on Channel D.

Observer: Subtasks for LR on Channel D

1. Manual entry Y / N
2. Select drug menu Y / N
3. Select LR Y / N
4. Enter rate 20 cc mL/hr Y / N
5. Enter 1000 Y / N
6. Select Channel D Y / N
7. Confirm Y / N
8. Start infusion Y / N

Task 9.

Start Norepinephrine drip on Channel E using a patient weight of 70 kg and dose of 0.02mcg/kg/min. Use a peripheral concentration dosing of 32 mcg in 100 mL.

Observer: Subtasks for Norepinephrine on Channel D

1. Manual entry Y / N
2. Select drug menu Y / N
3. Select Norepinephrine Y / N
4. Enter dose 0.02 mcg/kg/min Y / N
5. Enter concentration 32 mcg/mL Y / N
6. Enter volume 250 mL Y / N
7. Confirm Y / N
8. Select Channel E Y / N
9. Confirm Y / N
10. Start infusion Y / N

Task 10.

Moderator: Instruct the RN to increase Norepinephrine as follows:

Patient BP is 70/40 with a MAP of 50 mm Hg. Titrate Norepinephrine up to 0.04 mcg/kg/min.

Observer: Subtasks for Norepinephrine on Channel D

1. Select Norepinephrine Y / N
2. Select dose Y / N
3. Change dose to 0.04 mcg/kg/min Y / N
4. Submit change Y / N

Task 11.

Moderator: Instruct the RN to increase Norepinephrine as follows:

Patient MAP is 59 mm Hg. Titrate Norepinephrine up to 0.12 mcg/kg/min.

Observer: Subtasks for Norepinephrine on Channel D

1. Select Norepinephrine Y / N
2. Select dose Y / N
3. Change dose to 0.12 mcg/kg/min Y / N
4. Submit change Y / N

Patient Map has reached 63 mm Hg and is now at goal.

Task 12

The patient's condition has improved. Discontinue all infusions.

Observer: Subtasks to discontinue all:

1. Select patient information Y / N
2. Discontinue all Y / N
3. A warning prompt selects OK Y / N
4. Selects confirmation Y / N

Observer:

- Follow instructions in Tasks 12 if participant does not do so or data will get confounded with next participant.
- To end Scenario, select "Stop participant/Reset Simulation" to prep for next participant.

APPENDIX E. MODERATOR SCRIPT – AUTO-PROGRAMMING MODE

Participant #_____ Date: _____ Room A or B Session Time: _____

This simulation has the following sequence of infusions:

Task 1. Heparin bolus 4900 U/hr followed by a drip of 1050 U/hr.
Task 2. IVF (Lactated Ringers) 120cc/hr.
Task 3. Vancomycin 1 g IV stat
Task 4. Piperacillin/tazobactam 3.375 g IV as secondary to Lactated Ringers
Task 5. Rebolus of Heparin 2450 U/hr
Task 6. Discontinue piperacillin
Task 7. Order to infuse remaining Lactated Ringers at 999cc/hr
Task 8. Norepinephrine for a MAP goal of 60 mm/Hg (2.63 mL/hr calcs automatically) with a Lactated Ringers infusion at 20 cc/hr as carrier
Task 9. Start Norepinephrine at 0.02 mcg/kg/min to achieve the MAP goal
Tasks10 -11. Two Norepinephrine increases to achieve the MAP goal
Task 12. Discontinue all infusions

The following text provides yellow highlighted script for moderators to read to participants , *directions and notes to the moderator are in Italics*, and notes to the observers in blue.

Observers:
Observers will record observational data but will also assist the scenario at appropriate times as shown in the sequence below by sending the medication orders from the eMAR (laptop in the scenario control room/area).

Observer startup/initiation of scenario: 3 3creens are used:

- Send orders screen
- Control panel
- Login screen

Observer Login as their name/their name

Moderator:
Assure patient info tab is "up" on left side of MIP screen!
Participants login as Login as Jean/Jean or Pat/Pat
The patient ID is 524837

Scenario Begins:

Now we will start an infusion scenario where we will use scanning in some of the tasks. Please remember that in cases where a 2nd RN verification is needed I will role play the 2nd RN.

You have just received report from the ED on a patient that came in with acute shortness of breath and was found to have low O2 saturations on arrival to the ED. He is being ruled out for PE and is being admitted to the ICU for management. Mr. John Doe is a 73 y.o. 70 kg male with no known allergies.

Observer: Select start participant and send the order for heparin as in item 1 below.

TASK 1.

On arrival to your ICU the patient's preliminary diagnostic tests indicate he is positive for PE. Pt. needs to start on heparin. A heparin bolus of 4900 was ordered to be followed by initiation of a continuous drip of 1050 U/hr. Please start these infusions on channel A.

Metrics: after starting participant –

a) Select Login Y / N
b) Login user/scan badge Y / N
c) ID patient/scan badge Y / N
d) Login Y / N
e) Select new order Y / N
f) Select Heparin Y / N
g) Scan bag Y / N
h) Scan route Y / N
i) Scan channel A Y / N
j) Select 2nd RN verification Y / N
k) Scan 2nd RN badge Y / N
l) Start infusion (bolus starts) Y / N

Moderator: Once the heparin infusion is started, verify the information is correct then ask the Participant (P): How would you stop the bolus? Go ahead do so. *(Note: This prevents having to run the bolus 9 mins. and enables starting the* continuous heparin infusion. The Heparin infusion will run at normal speed.)

a) Select Heparin
b) Select stop bolus Y / N
c) Select Yes

Observer: Send the order for Lactated Ringers as in item 2 below

TASK 2.

Additional admitting orders include maintenance IVF of lactated ringers (LR) at a rate of 120 cc/hr. Start the lactated ringers now on channel B.

a) Select new order Y / N
b) Select order details LR Y / N
c) Scan ringers bag Y / N
d) Scan route Y / N
e) Scan channel B Y / N
f) Start infusion Y / N

Observer: Send the order for vancomycin and Piperacillin/tazobactam as in item 3 below

TASK 3.

Your pt. is now looking septic with hypotension and febrile indicators. Stat orders are placed for antibiotics - vancomycin and Piperacillin/tazobactam. Pharmacy has verified this as vancomycin - 1 g IV stat. Start the vancomycin on channel C.

a) Select new order Y / N
b) Select order for vanc Y / N
c) Scan vanc bag Y / N
d) Scan route Y / N
e) Scan channel C Y / N
f) Start infusion Y / N

TASK 4.

Now start Piperacillin/tazobactam – 3.375 g IV stat. as a secondary to the ringers (*Moderator: If P is not familiar with hanging a secondary, use next open channel as a primary for Piperacillin/tazobactam)*

a) Select new order Y / N
b) Select order for piper Y / N
c) Scan piper bag Y / N
d) Scan route Y / N
e) Scan channel B Y / N (If not familiar with secondaries, they can use a free Channel)
f) Setup secondary Y / N
g) Start infusion Y / N

Observer: Initiate an occlusion alarm for Heparin.

a) Select Heparin to expand Y / N
b) P sees notification for occlusion Y / N
c) Selects the notification Y / N

TASK 5.

It is now 6 hrs. later and the aPTT result is low and requires a rebolus heparin dose of 2450U per protocol.

a) Selects Heparin Y / N
b) Select bolus Y / N
c) Enter 2450 Y / N
d) Enter Yes Y / N
e) Confirm bolus Y / N

Observer: Shortly after the Piperacillin/tazobactam is started, use the "Change VTBI" prompt to reduce the VTBI to 2 mL to accelerate and finish that infusion and to enable the notification to appear regarding infusion end is pending.

TASK 6.

Discontinue the Piperacillin/tazobactam as if it had finished.

a) Selects piperacillin Y / N
b) Selects discontinue P/T infusion Y / N
c) Cancel infusion Y / N

TASK 7.

A verbal order is given to infuse the remaining LR at a rate of 999 cc/hr.

a) Select ringers Y / N
b) Select rate Y / N
c) Enter 999 Y / N
d) Select Submit change Y / N

(Moderator: A "new" LR channel will be used with LRs later as carrier for Norepinephrine)

Observer: Send new order for Lactated Ringers and Norepinephrine per items below.

TASK 8.

There is no improvement in blood pressure and the provider orders Norepinephrine for a map goal of ≥ 60 mm Hg. Start an infusion of LR on channel D at 20 cc/hr as a carrier.

a) Select new order Y / N
b) Select Lactated Ringers Y / N
c) Scans bag Y / N
d) Scan route Y / N
e) Scan channel D Y / N
f) Start infusion Y / N

(Moderator: once the LRs are started instruct the participant as follows)

TASK 9.
Start Norepinephrine drip on channel E using a patient weight of 70 kg and a dose of 0.02mcg/kg/min. Use a peripheral concentration dosing of 32 mcg in 100 mL

a) Select new order Y / N
b) Select Norepinenphrine Y / N
c) Scan bag Y / N
d) Scan route Y / N
e) Scan channel E Y / N
f) Start infusion Y / N

TASK 10.
(*Moderator: Instruct the RN to increase Norepinephrine as follows:*)
Pts. BP is 70/40 with a MAP of 50 mm Hg. Titrate Norepinephrine up to 0.04 mcg/kg/min.

a) Selects norepinephrine Y / N
b) Selects dose Y / N
c) Change to 0.04 Y / N
d) Submit change Y / N

TASK 11.
(*Moderator: once done proceed with the instructions for participants below)*
Pts. MAP is 59 mm Hg. Titrate Norepinephrine up to 0.12 mcg/kg/min.

e) Selects norepinephrine Y / N
f) Selects dose Y / N
g) Change to 0.12 Y / N
h) Submit change Y / N

Pts Map has reached 63 mm Hg and is now at goal.

TASK 12.
Now the patient's condition has improved. No further infusions are necessary. Please discontinue all infusions.

Too discontinue all: (Note: If discontinued one by one it does not discharge patient and the data will get confounded with next P – be sure at end you follow instructions below if P does not do so.)

a) Select pt. information Y / N
b) Discontinue all Y / N
c) Warning prompt displays, selects OK Y / N
d) Selects confirmation Y / N

Observer : To end scenario

1) Be sure all infusions discontinued as noted above then

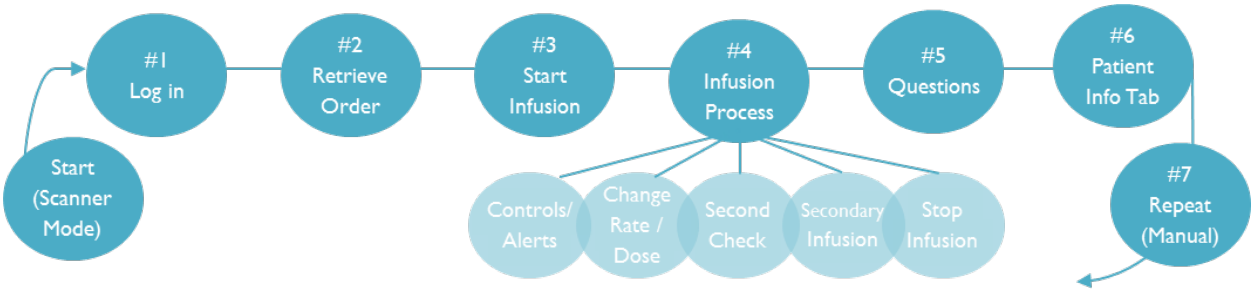
2) select Stop participant/Reset Simulation to prep for next P.

APPENDIX F. MODERATOR SCRIPT – TRAINING MODE

Introduction to Training

Explain Study / Instructions

"During this session, we will be having you test a simulated medication infusion pump. First, I will train you on the simulated pump in both scanner and manual modes, in which you will have the opportunity to practice using the display and ask any questions. Then we will ask you to use the simulated pump. Afterwards, we will have a debrief to ask you questions about your experience on the simulated pump system in both scanner and manual modes." (Allow participant to touch the display [i.e., "Go ahead and touch the Start button"]).



#1. Log in

"Dr. Pham has placed an order to initiate a furosemide infusion at 10mg/hr. Please initiate this infusion on Channel A."

#2. Retrieve Order

#3. Start infusion

#4. Explain how to manipulate infusion

a. Explain the controls and displays on the status screen
b. Indicate where notifications and alarms would appear.
c. Change rate of infusion and/or dose

"The patient's urinary output is still low. Dr. Pham gives a verbal order to increase the furosemide infusion to 15 mg/hr."

d. Perform second check

"The patient has a new onset arrhythmia of SVT, fever, elevated WBC and suspected wound infection. Dr. Pham has ordered Amiodarone 0.5mg/min for the next 18 hours. Please initiate Amiodarone continuous infusion on Channel B. This drug will also require a second RN verification."

e. Secondary infusion

"The patient requires a carrier fluid. Please start infusion of LR at 20 mL/hr on Channel C."

"…An additional order has been placed to initiate Cefazolin 1gm IV Q6 hours. Please initiate Cefazolin 1gm to infuse over 30 minutes as a secondary infusion on Channel C."

f. Stop infusion through Channel

"Patient develops an allergic reaction to the Cefazolin. Please stop the infusion for Cefazolin."

#5. Ask for any questions

#6. Explain Patient info tab and how to stop all infusions

"…to stop all infusion, select the "Stop all infusions" button."

#7. Repeat for manual mode

APPENDIX G. PARTICIPANT QUESTIONNAIRE

* Required

1. **Participant ID** * _____

Part I - Background

2. **What is your age in years?** *

_____

3. **Please select your gender** *
(Mark only one oval.)

- ( ) Male
- ( ) Female

4. **What is your height?** *

_____

5. **What type of personal devices do you use?** *
(Check all that apply)

- [ ] I do not use any personal devices
- [ ] Cell phone (i.e., flip phone)
- [ ] Smart phone (i.e., iPhone, Samsung SIII, Motorola Razr)
- [ ] Tablet (i.e., iPad, Samsung Galaxy)

6. **Years of professional experience** *

_____

7. **Years of experience at current institution** *

_____

8. **Years of experience with medication infusion pumps** *

_____

9. **How would you describe your current place of employment?** *

(Mark only one oval.)

- Academic
- Non-academic

10. Do you currently work in an ICU? *

If so, how many years of ICU experience do you have?

(Mark only one oval)

- No, I do not have any ICU experience.
- Less than 2 years
- 2 - 5 years
- Greater than 5 years
- Other: _____

11. At work, how often do you use a medication infusion pump? *

(Mark only one oval))

- Daily
- About 2- 3 times a week
- About 2 -3 times a month
- Very rarely
- Other: _____

12. If you use a medication infusion pump on a daily basis, which of the following do you use? *

Please check all that apply.

- ☐ I do not use infusion pumps on a daily basis
- ☐ Baxter BBraun
- ☐ CareFusion
- ☐ Alaris Plum
- ☐ Symbiq
- ☐ Other: _____

Part II - General Health and Vision

13. Do you wear glasses or contacts? *
If yes, please select all that apply.

- [ ] No
- [ ] Contacts
- [ ] Bi-focal glasses
- [ ] Distance glasses
- [ ] Reading glasses

14. Do you currently take any prescription or over the counter medication that might cause drowsiness and/or affect the way you think? *
Mark only one oval.

- ( ) Yes
- ( ) No

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APPENDIX H. POST-TASK STRUCTURED INTERVIEW FORM

Participant ID:_____ Date: _____Session: ☐ AM ☐ PM Room: ☐A ☐ B

Thank you for showing us how you would use the simulated pump in the scenarios. Now we'd like to ask you some questions about your experience with the pumps.

1. What was your overall assessment of the pump designs?

Automated Entry	Manual Entry

2. Probe topics regarding: screen and button design – size, arrangement, colors, icons, audio alerts, etc.

Automated Entry	Manual Entry

3. **Can you identify anything about the design that could result in errors?**

Automated	Manual

4. **If we could improve anything about the steps to operate the pump what would you suggest?**

Automated	Manual

5. **Is there anything else you would like to comment on about the pump designs?**

Automated	Manual

APPENDIX I. POST-TASK SURVEY – AUTO/MANUAL MODE

Participant ID: _____ **Date:** _____ **Session:** ☐ AM ☐ PM **Room:** ☐ A ☐ B

Section A: Please provide your response on a scale from 1 to 5 (where 1 = Not at All; and 5 = Great Degree) when considering use of the scanner mode compared to what you currently use at your hospital.

1. To what degree does the simulated pump prevent overriding of safety features?	1 Not at All	2 Some Degree	3 Neutral	4 Moderate Degree	5 Great Degree
2. To what degree does the simulated pump prevent misinterpretation of a physician's order?	1 Not at All	2 Some Degree	3 Neutral	4 Moderate Degree	5 Great Degree
3. To what degree does the simulated pump reduce programming errors?	1 Not at All	2 Some Degree	3 Neutral	4 Moderate Degree	5 Great Degree
4. To what degree does the simulated pump prevent the need to reprogram the pump after a bolus?	1 Not at All	2 Some Degree	3 Neutral	4 Moderate Degree	5 Great Degree
5. To what degree does the simulated pump prevent errors in calculating conversions?	1 Not at All	2 Some Degree	3 Neutral	4 Moderate Degree	5 Great Degree
6. To what degree does the simulated pump provide a workflow that matches the user workflow?	1 Not at All	2 Some Degree	3 Neutral	4 Moderate Degree	5 Great Degree
7. To what degree does the simulated pump display easy to read content and format?	1 Not at All	2 Some Degree	3 Neutral	4 Moderate Degree	5 Great Degree
8. To what degree does the pump control accuracy of weight data derived from primary source?	1 Not at All	2 Some Degree	3 Neutral	4 Moderate Degree	5 Great Degree
9. To what degree does the pump provide adequate visual cues for selection options?	1 Not at All	2 Some Degree	3 Neutral	4 Moderate Degree	5 Great Degree
10. To what degree does the pump prominently display drug concentration options?	1 Not at All	2 Some Degree	3 Neutral	4 Moderate Degree	5 Great Degree
11. To what degree does the pump provide adequate cues to read pump status during use?	1 Not at All	2 Some Degree	3 Neutral	4 Moderate Degree	5 Great Degree

Section B: Please select your response on a scale from 1 to 5 when considering use of the scanner mode compared to what you currently use at your hospital.

12. Please rate the sensitivity of the touch screen compared to current methods of infusing medications.

1	2	3	4	5
Too Insensitive	Somewhat Insensitive	Just Right	Somewhat Sensitive	Too Sensitive

13. Please rate the overall ease of using the manual entry compared to what you currently use at your hospital?

1	2	3	4	5
Difficult	Somewhat Difficult	Neutral	Somewhat Easy	Very Easy

14. Please rate your degree of confidence in administering infusions with what you currently use at your hospital?

1	2	3	4	5
Not Confident	Less than Confident	Neutral	Somewhat Confident	Very Confident

15. Please rate your degree of confidence in administering infusions with the manual entry of the simulated pump.

1	2	3	4	5
Not Confident	Less than Confident	Neutral	Somewhat Confident	Very Confident

APPENDIX J. POST-TASK SURVEY – NASA TASK LOAD INDEX

Participant ID: _____ **Date:** _____ **Session:** ☐ AM ☐ PM **Room:** ☐ A ☐ B

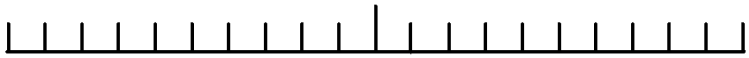
Mental Demand — How mentally demanding was the task?

Very Low — Very High

Physical Demand — How physically demanding was the task?

Very Low — Very High

Temporal Demand — How hurried or rushed was the pace of the task?



Very Low — Very High

Performance — How successful were you in accomplishing what you were asked to do?

Perfect — Failure

Effort — How hard did you have to work to accomplish your level of performance?

Very Low — Very High

Frustration — How insecure, discouraged, irritated, stressed, and annoyed were you?

Very Low — Very High

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APPENDIX K. QUALITATIVE THEME ANALYSIS FROM PARTICIPANT INTERVIEWS

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1.0 Comparison of Scan vs. Manual Modes

Table 1. Comparison of Scan and Manual Modes: Post Trial Interviews

Scan Mode	Manual Mode
Safer than manual mode: (18) reported scanning safer than manual mode due to built-in features: 1. Orders come in automatically from the system 2. Prevents wrong patient or meds, helps infuse exactly what ordered (2) 3. Double checks before medication starts 4. Provides real time feedback for errors 5. Forces accountability	Safer than scanning mode (3): 1. Felt more comfortable/safer than going through the motion in purely scanning mode 2. Helps you think about the dose, more of a safety check 3. No worries about success in scanning However 4. Manual entry could lead to entry errors or wrong information (14) or workarounds 5. No automatic error checking in manual mode (1) or reminder to check the patient (1)
Ease of Use / Workload 1. Straightforward and hard to err (4) 2. Easier than manual mode (4) 3. Easy to learn (2) 4. Do not need to remember patient ID (1) 5. Reduces double checking 6. Scanning reduces the need to document manually (1) 7. Like it – in favor of scanning (1) However: 8. Scanning would get annoying and it is so much scanning I would do a workaround (2)	Ease of Use: (18) reported it was easy to use 1. Login was easy (2) drug selection easy 2. The flow was easy, Logical and pretty user friendly, intuitive 3. Very clear, straightforward (1), Good (1) 4. "Configure a new infusion "is good; (1) 5. Like that manual entry calculates rate and concentration (2) However 6. Harder overall with the typing 7. Have to read the order (1); cannot remember information about meds or patient ID (2) 8. Not as user-friendly as scan (1)

Speed of use 1. (4) report scanning is quicker than manual mode but 10 claim it takes more time to scan However: 2. (6) Too many things to scan 3. (4) Concerned about quick use in emergency	Speed of use: 1. Faster (6) Do not need to scan patient ID (1), Fewer steps in manual vs. scanning However 2. Slower (7) takes a lot of steps; more time-consuming ; concerned about quick use in emergency; In case of emergency, login could take time and be frustrating
Communicates well: 1. All the information comes up 2. 2nd RN name is displayed and documented – if you do it yourself it records it so" 3. Like scanning and seeing the route 4. "Love that scan bag shows any error"	Communicates: No Comments
Reduces Likelihood of Critical Thinking 1. Less likely to double check information scanned in is correct (15)	Reduces Likelihood of Critical Thinking No comments
Scanning site/route 1. Not sure how it would work in real life especially in ER (20) 2. One would need a QR code at each possible site 3. Consider selecting route via a body icon on the screen 4. Must enable nurse to move the site to another compatible site	Scanning site/route N/A
Scanning Channels 1. (6) do not care for scanning channels 2. (1) prefers to use button for channel selection	Scanning Channels N/A

Tool Used for Scanning	Tool Used for Scanning
1. Not easy to use, tedious (11) some things were difficult to scan requiring repetition (6) 2. A gun (laser-based scanner) would be better than phone scanner (15); 3. If phone used for scanner provide a strap against dropping it (1) 4. Use of a phone as personal scanner would be beneficial to provide audible alerts with text 5. Required me to hold too much stuff (1)	N/A

Overall comment: "Need to find happy medium between scanning and manual modes" in view of all features/characteristics (1)

2.0 Functional Enhancements for Safety

1. Assure there is a means to start meds if the system (e.g., computer, internet, intranet) is down? (2)
2. Provide a means to recall patient's medication or start the pump quickly if one discontinues all meds by accident (1)
3. Control cross-association of a patients data if taking a pump from one patient to another
4. Provide a manual override feature in scan mode(7) with a separate intentional control action(2) and provide a warning confirmation step if you accidentally revert from scanning to manual mode so you know you are in manual, Can make mistakes when making manual edits in scan mode (1)
5. Provide a logout that prevents patients from programming the pump but allows status info to remain (3)
6. Enable the scan activity to check drug compatibility (1)
7. Provide message/warning to indicate route compatibility (4)
8. Include functions for the new RN to check at shift change (1)
9. Provide limits on all manually entered values to prevent unusually large numbers (2)
10. Labeling Tubes: One nurse comments that all tubes are labeled in ICU; not necessary to label the top part of the tube
11. Automatically integrate changed doses in the EMR record(1)

3.0 Human Factors Design Observations (Note that many of the comments were directed at human factors characteristics controlled by native features of the tablet design and that we were unable to change those features.)

Comments about the general approach to the interface design were positive:

1. Easy to navigate (8)
2. Like it (7)
3. Steps were what I do naturally (5)
4. Layout is intuitive (4)
5. User friendly (3)
6. Like the interface (2)
7. Like the flow of bag to channel to route (2)
8. Like the tabs approach (2)
9. No unnecessary steps (1)
10. Like the prompts (1)
11. **L**ikes use of 5 channels (1)

3.1. Navigation Recommendations

As indicated above, the interface characteristics were generally well-received. However, the following recommendations were offered for consideration.

3.1.1 Navigation, General

1. Add a tab for drug reference (2)
2. Indent secondary titles/labels (1)
3. Put control buttons around the perimeter of the screen and status info inside the center of the screen (1)
4. Editable fields for bolus could be more evident
5. Make the discontinue all button easier to find (2)

3.1.2 Navigation, Orders:

1. Drug library menu:
    a) Arrange by alphabetical categories (7)
    b) Arrange by categories for crystalloids and blood products with items alphabetically within
    c) Should have search feature
    d) Provide soft limits (2)
    e) Enable frequently used items to come up first for long stay patients the (1)
    f) Identify drugs relevant to the patient

2. Order Summary:
   a) Provide ability to edit order summary before starting infusion (1)
   b) "Choose order to start infusion "prompt not evident what to do with it (1)
   c) After selecting new order the options should be more apparent (2);
   d) Provide easy access to common protocols for unit and routine drugs (3); this would affect attention to messages/alerts – for instance, fentanyl dosing would not apply to unit if it is too high. Input floor protocol for second infusion tubing

3.1.3 Navigation, Editing Orders

1. After expanding drug and changing drug parameter, the display should go back one page instead of minimizing screen to monitor mode (5)
2. When cancelling drug edit, system goes back 5 steps instead of 1 (1),
3. If accidentally discontinue I wish to back up and restart without redoing all
4. After clicking rate on the current infusion, page one should be able to return to dose without going back several screens. (1)

3.1.4 Navigation, Status

1. Drug history can go on tube change page (1)
2. Put rate next to dose, concentration on left bottom and VTBI right bottom (1)

3.2. Operational Sequence:

1. Force a double check by 2nd person which is especially needed for Manual mode. Use password or fingerprint rather than 2nd RN badge which can be loaned (5)
2. Prevent from proceeding until 2nd check is done (1).
3. Logging in each time might not work in real life (2) Logging in is bothersome (2) it is an extra step (press screen, then scan). Would be better to scan in an active system (i.e., like RFID) rather than 2-step process (2)
4. Starting an infusion first to get a bolus option is confusing (2)
5. Entering concentration is an extra step (1)
6. Add a confirmation step for cancelling meds (2)
7. Confirmation Message for high risk drugs needs stronger forcing function/checks.

3.3 Controls

3.3.1 Control Options/System Features:

1. Provide a basic infusion capability in case a medication is not listed in the library (1)

2. Should be able to pause all infusions at once as well as stop them (3)
3. Provide "volume duration" feature – you put in volume then the time to infuse – an easier way of entering rate. (1)
4. Should have a "restore" or "quick start" function (1)
5. Provide call-back feature (2): (e.g., with 50 cc remaining)
6. Would like to be able to sign off as given through pump (2)

3.3.2 Control Buttons:

1. Button size:
   a) Increase the button size (11) make 2nd check button, button to cancel individual infusion, login and delete buttons bigger; Rate should be a larger button to stand out from the rest (1)
   b) Size is good (5); The big buttons are good (1)
2. Provide more space between buttons (5), channel buttons blend together (1)
3. Provide more space for choosing channels (3);
4. Login should be more evident on the front screen (3)
5. Conflicting comments were provided for audible feedback: Don't provide a "beep" for every input (1) vs. Would be nice to have auditory feedback to know that a button was pushed (1)

3.3.3 Data Entry/Editing:

1. Eight participants found it easy to change dose, rate, etc. (8)
2. One found it difficult to see where entering data for dose and rate (1)

3.3.3.1 Decimal Point:

Change location of the decimal - Needs to be with the numbers (2) should have decimal point where the "#" is (2); should be at asterisk spot (1)

1. Make the decimal image larger – almost missed it and erred (1)

3.3.3.2 Cursor:

1. Cursor is difficult to use for editing (5); blue touch-point could be larger; Misplaced the cursor; could provide a magnifier feature or set the cursor to a default place (1)

3.3.3.3 Backspace/Delete Button:

1. A large group (26) of participants requested an easier capability to use the delete button to clear the whole data field
2. Two considered editing numbers not obvious or difficult
3. Two indicated editing is easy and

4. One recommended delete should occur to the right of the digit
5. One offered that when changing dose etc., "backspace" and "next" could be better distinguished from the background

3.3.3.4 Numeric Keypad:

Note that like several of the interface design features the keypad design is a native characteristic of the tablet used.

1 Four found it very annoying that the keypad obscured part of the information
2 Two found the extra symbols on the keypad are irrelevant and distracting (+, -, /, *&#etc.) (2)
3 Two found the button size small for numerals or too close

3.3.4 Touchscreen:

1 A concern for many is touchscreen sensitivity:
   a) Touchscreen not responsive or too sensitive (20)
   b) Sensitivity may induce errors (1)
   c) Prefer real buttons to touch screen (1)
   d) A stylus might be helpful (1)
2 Some liked the touchscreen approach (4) - familiarity with tablet and smart phone interfaces facilitated use (2)
3 Concern about effect of touchscreen exposure to medication, body and cleaning fluids (7)
4 Provide appropriate levels of brightness for situational factors(1)

3.4 Displays:

3.4.1 Status Indications:

1. Well-accepted features:
   a) Visual indicator for channels (3)
   b) Simultaneous indication of all meds administered (1)
   c) Visibility of label and dose from distance equivalent to the patient's door (1)
   d) Bolus indicator is nice (1)
   e) Time remaining display good (1) could be more prominent (1);
   f) Source for weight comes from the "system" (1)
   g) Order history is great because it records it for EMR (1)
   h) Detailed provided in status screen is good (1)
   i) Display makes it easy for family to know what is going on
   j) Would be nice if the time to administer the medication was in the system as well (1)

2. Patient information [7]:
   a) Provide critical information (i.e., patient name, weight, allergies, etc.) visible at all times; would like the weight displayed on all screens (4);allergies too (1)
   b) Would be nice to have patient information shown on the header (1)
   c) Weight: Make weight more obvious (1); indicate source of weight as actual vs. ideal (1)
3. Infusion status information:
   a) Provide better indication of primary and secondary infusions together (and primary/bolus) (1)
   b) "Choose order to start infusion "screen should have concentration and could say e.g., : "Norepinephrine peripheral strength" (1)
   c) Should provide reminder if med volume is low (1)
   d) Indicate whether route is peripheral or central (1)
   e) Provide option to view remaining volume instead of time when surveying room.
   f) Secondary Infusion: Would not remove indication of secondary infusion from the display after its completion since secondary bag remains hung and not removed until another replacement is in place. Nurse would backflush everything. The tubing could be labeled "Carrier KVO/ABx")
4. Display design:
   a) Increase the size of the screen and all the displays
   b) Weird that status is stacked horizontally (1)
5. Feedback:
   a) Provide better feedback for buttons selected (1), Once a channel is selected highlight that bar in the list (1)
   b) Provide error Message for wrong ID (1)

3.4.2 Alerts:

1. Good features: Allergies (2); tube change(4);
2. Audio alert is good (1); easy to find (1) and Alert as too small (2)
3. Good that you must select the alert to learn the nature of it (1)
4. Easy to clear alarms (2)
5. Add alerts:
   a) Should warn you if running 2 incompatible meds(8)
   b) Should provide alert for unreasonable doses/out of range (6)
   c) For secondary infusions any alert should affect the whole channel (both lines) (1)

d) Dressing Changes**:** Similar to tube change – dressing change would be helpful to Include date/time, site

6. Sound a tone 2 min. after pausing an infusion as cue to restart (1)
7. Audio alert should sound more frequently (less off time in the duty cycle) (1) louder (2)longer (1)
8. Use more effective pop up alerts you have to close (1)
9. Change Tubing [3]: Additional questions should be displayed with tubing; should match with unit or hospital protocol; need to capture start time of tube ID as some are re-used, especially after secondary infusions. . Have questions related to tubing upon start of new infusion.
10. Provide RN or unit ability to edit time settings for alerts
11. Provide confirmation that Rx has been contacted for new bag (automatically or manually), also for STAT orders (10-15 minutes).

3.4.3 Color:

1. Colors are appropriate (8);
   a) Like alarms in red (3)
   b) Like the blue status bar (2) e.g., the blue/white contrast;
   c) Green for new orders is good (2)
   d) Provide different alert color for new orders (e.g., red) (1)
   e) Gray interface is intuitive for disabled Features
2. Use color to differentiate high risk meds (pressers, narcotics, etc.) (4)
3. Use more color or other cues to differentiate, blue for everything makes it all blend together (2)
4. Use red text for meds requiring 2nd verification;
5. Dose should be highlighted a different color so it is not mistaken for concentration (1)
6. Rate should be a different color so it can be seen more easily (1)
7. Login should be different color (1)
8. Screen may be too bright in dark room (1)

3.4.4 Font:

1. Large font size is good where used (1)
2. Font size OK (3)
3. Font too small (6), could be larger (make it 1 size up for new orders screen); font size OK for me but others may have trouble;
4. Icons too small (1)
5. Dose and rate info is a little small – would like to be able to see from the doorway (4)

6. Bold: Better if more bold letters (2), Bold all titles; bold all high order meds and put them in color (1)

3.4.5 Readability/Language:

1. Easy to read (2); nothing confusing; like the primary drug status row in blue; Drug label is easy to read (1)
2. "Enter Route" is not intuitive (2)
3. Prompts can be more specific e.g., "Route: Scan IV" (1)
4. Reduce reading required by using simpler terms e.g., "bag" or "chnl" (1)

4.0 Operating System

1. Reduce lag time between order entered and it appearance on the screen (2)
2. Logout occurs too soon (1)

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APPENDIX L. GLOSSARY AND ACRONYMS

Bolus: Single dose of a drug or other medicinal preparation administered to the patient all at once.

Channel Labels: Electronic message that scrolls on the MIP screen for the medication being infused (i.e., carrier fluids) as well as the location of infusion (i.e., blue port, peripheral).

Concentration: Ratio between amount of drug (mg or mc) and volume of bag (cc).

Dose: Quantity of drug taken or recommended to be taken at a particular time. Dose units are typically in milligrams (mg) or milligrams per patient weight (mg/pt wt). When qualified by time, the rate of giving dose can be referred to as milligrams per patient weight per unit time (mg/pt wt/unit time). Dose is also accompanied with a frequency, e.g., Q 6hr, where drug orders not complete without a frequency of administration.

Dose Error Reduction System (DERs): Preventive measures that control dosing by limited menu options and checking permissible doses against an established library

Dosing: Weight per unit time or volume per unit time, e.g., Mc/kg/min for some drugs, could be mg.hr.

Soft Limit: Pre-programmed dose limit that may be overridden by the clinician. When a soft limit occurs, the operator is asked to review and approve the infusion rate to assure that an error has not been made before overriding the DERs limit. A visual prompt will display continuously across the pumping module, indicating that the infusion is being delivered above or below the DERs limit.

VTBI: Volume To Be Infused