# Medication Error Reduction, Technologies, and Human Factors Final Report


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## A. STRUCTURED ABSTRACT

**Purpose:** The objective of this research was to examine the impact of the implementation of medication administration technology, namely Smart IV pumps and barcode medication administration technology, using human factors techniques.
**Scope:** Technology implemented to improve patient safety can introduce significant changes in workflow, tasks, and end-user worklife. Human factors techniques were used to plan and evaluate the technology design and implementation of these technologies at an academic medical center.
**Methods:** We studied the impact of Smart IV pumps and point-of-care barcode technology implementation on end users and medication safety. Event reporting data, pump log data, and medication administration audits were used to evaluate the effects on medication safety. Prospective risk analysis and usability testing were used to assess and remediate problems with the technology design and implementation. Observations, focus groups, and surveys monitored the technology change process' effects on nursing and physician technology use perceptions and quality of working life.
**Results:** Prospective risk analysis and usability testing greatly improved the implementation of the Smart IV pump technology. Perceptions related to pump functioning, interface, improving patient safety, and ease of use predicted pump acceptance. Medication administration errors decreased, and pump related errors were few.
**Key words:** Smart IV pump, barcode medication administration technology, medication errors, prospective risk analysis, human factors

## B. PURPOSE

**Specific Aim 1. To determine the effect of Smart IV pump and barcode technology implementation, supported by sophisticated human factors techniques, on the number and severity of medication errors**

**Specific Aim 2. To determine the impact of Smart IV pumps and the integration with barcode technology on nurses and physicians (end users)**

**Specific Aim 3. To describe a human factors prospective error analysis and to qualitatively evaluate its effectiveness on the implementation success of technology in an acute care hospital setting**

## C. SCOPE

### C1. Background

Medication errors are common, occurring in nearly 20% of inpatient medication doses (Barker, 2002) and accounting for 7000 deaths annually (Kohn, 2000). Nearly half of medication errors are preventable (Leape, 1995). The Joint Commission lists medication errors as the fourth most frequently reported sentinel event, thereby indicating the importance of improving the medication use process (JCAHO, 2003). The medication administration process is a vulnerable time for errors due to the lack of built-in double checks. Because these errors directly reach the patient with potential for great harm, improvements must be made to how medications are administered, a point stressed by AHRQ in the report,

*Reducing and Preventing Adverse Drug Event to Decrease Hospital Costs* (AHRQ, 2001). Three of The Joint Commission's National Patient Safety Goals for 2003 recommended ways to improve the medication administration process: (1) improve the accuracy of patient identification when administering medications, (2) improve the safety of using high-alert medications, and (3) improve the safety of using infusion pumps by ensuring free-flow protection.

**C2. Context**

We studied the implementation of Smart IV pumps and evaluated a barcode medication administration (BCMA) system in use at the University of Wisconsin Hospital and Clinics (UWHC). Smart IV pumps have a predefined drug library with built-in drug dose limits to avoid under and overdosing of IV medications. Most high-alert medications are administered through an IV pump. Also, the implementation of this technology allowed the University of Wisconsin Hospital and Clinics to standardize the IV pumps throughout the hospital and eliminate all IV pumps without free-flow protection. The use of BCMA technology further ensured accuracy in patient identification during medication administration. Evaluating these two technologies provided a better understanding of the technology's impact on medication safety, primarily at the administration phase, as well as the impact on the work system at UWHC.

**C3. Setting**

This study was conducted at the University of Wisconsin Hospital and Clinics in Madison, WI. It is a university based-hospital with 471 beds. It has a level-1 trauma center, has a 60-bed Children's Hospital, and is the second busiest organ transplant service in the United States. On average, the Department of Pharmacy Services processes over 4300 inpatient medication orders and dispenses over 10,000 inpatient medication doses daily. A web-based event reporting system (Patient Safety Net, PSN) was in place. PSN utilizes the National Coordinating Council for Medication Error Reporting and Prevention taxonomy of medication errors that provides a standardized language and structure for medication error-related data and severity of event reporting as a means to promote analysis of reports (NCC MERP, 1998).

**C4. Participants**

We studied the implementation of the Smart IV pump technology that was purchased by the UW Hospital and Clinics in June 2003. We also examined barcode technology use. Several methods were used to assess the impact of these medication administration technologies: (1) employee questionnaire, (2) observations of nursing interaction with the technology, (3) focus groups, (4) observation-based evaluation of medication administration errors, and (5) Patient Safety Net data, a web-based error reporting system. The purpose of the end-user (employee) questionnaire was to assess the end-user perceptions of the Smart IV pump implementation at UWHC. The use and acceptance of the pump were measured on the post-implementation surveys. The employee questionnaire was conducted at three points in time: 1 week before the implementation of the pumps, 6 weeks after the implementation, and 1 year after the implementation of the Smart IV pumps. Direct observations and semi-structured interviews of end users and others involved in the medication use process were performed as well. The pump observations occurred 1 month before Smart IV pump implementation and 5 months

after the pump implementation, and 1 month after integration of the technologies. The objective of the focus groups was to evaluate the following aspects of the Smart IV pump implementation: user acceptance, ease of use/design, impact on work, and training.

The study also proposed to assess the integration of point-of-care barcode technology with the Smart IV pumps. However, the respective manufacturers were unable to design a compatible product; thus, the technology integration never occurred.

## D. METHODS

Table 1 - Project Timeline, 2003-2005

| | Pre-grant | | | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| (Month) | J | J | A | S | O | N | D | J | F | M | A | M | J | J | A | S | O | N | D | J | F | M | A | M | J | J | A | S | O | N | D |
| FMEA IV pump | X | X | X | X | X | X | X | X | | | | | | | | | | | | | | | | | | | | | | | |
| FMEA AcuScan | | | | X | X | X | X | X | X | X | X | X | X | X | X | X | | | | | | | | | | | | | | | |
| Pump implementation | | | | | X | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Usability testing | | | | | | | | | | | | X | X | | | | | | | | | | | | | | | | | | |
| Focus groups | | | | | | | | | | | | X | | | | X | | | | X | | | | | | | | | | | |
| Pump survey | | | | | X | | X | | | | | | | | | | | | X | | | | | | | | | | | | |
| Pump observations | | | | | X | X | X | X | X | X | | | | | | | | | | | | | | | | | | | | | |
| BCMA observations | | | | | | X | X | X | X | | | | | | | | | | | | | | | | | | | | | | |
| Pump log data | | | | | | | | | X | | | | | X | X | | | | | | | X | X | | | | | | | | |
| PSN data collection | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Med admin audits | | X | X | X | X | | | | | | X | X | X | | | | | | | | | | | | | | X | X | X | | |

### D1. Aim 1. Smart IV Pump Implementation Impact on Medication Errors

#### D1.1. Medication administration audit data

Medication administration audits were used to supplement other sources of error data to evaluate actual pump programming accuracy. A trained pharmacist collected data by direct observation of the infusing medication pump programming, the IV bag label, and the medication order. Use of the smart pump safety features (the drug library) and the overriding of alerts were noted. These were analyzed using Microsoft Excel to identify medication errors (e.g., wrong dose, etc.) and potentially unsafe practices. Three observation periods occurred: before implementation and 6 months and 2 years after implementation.

#### D1.2. Pump log data

We evaluated downloaded data in the IV pump log that recorded alerts sent to users and the user response to the alert to evaluate the frequency and nature of (potential) programming errors as well as the errors avoided as a result of the error-checking mechanisms inherent in the technology. The pump sent alerts to users based on the user programming a medication dose or bolus rate above or below the upper and lower medication dosing limits preset in the pump drug profiles. Alerts were also sent if the same drug was infusing. The log collects pumping and programming module ID numbers, date and time of the actions, alert type, medication profile, medication name, programmed dose, action taken by end user (cancel, reprogram, or override alert), and intended dose if the action was to reprogram. The pump log data were transformed by the process of selection, abstraction, and recoding. *Selection* involved removing events or sequences that were not of interest for the analyses. *Abstraction* involved constructing new sequences for analysis based on the user performing multiple actions in a sequence that may account for one or more rows of data in the log, or

identifying data on the same patient. *Recoding* allowed analyses to be performed on newly generated data and sequences. Data were analyzed using SAS. Counts and summary statistics were performed by sequence length and type, alert type, action taken, profile, and patient. Potential harm severity to the patient by the medication dose programmed was determined for each medication by expert opinion, guided by literature review.

**D1.3. Hospital web-based event report data (Patient Safety Net [PSN] Data)**
We monitored hospital event reports to evaluate the nature and frequency of errors or pump problems reported at pre- and post-implementation times. All medication- and IV pump-related events were collected for analysis. Counts and descriptive statistics were used to analyze data by medication stage, error type, and harm score.

**D1.4. Pump event-reported data reported to pump nurse**
The web-based error reporting system also provided a mechanism for identifying IV medication incidents warranting follow up by the IV pump nurse. To ensure follow-up and documentation, the IV pump nurse maintained a log of pump-related incidents that may or may not have been reported through this formal incident reporting system. In conjunction with the SMArT-HF Research Team, summary reports were developed. They included event and follow-up dates; event notes; whether patient harm may have occurred as a result; the source of the problem, including equipment-related concerns (malfunction, tubing issue, air-in-line alarm/issue, pump design/performance), apparent inadequate/ improper training, a clinical practice issue, any questionable source (implying a "false alarm" related to the pump that, in hindsight, did not warrant reporting and follow up), and another "miscellaneous" source (these generally were still under scrutiny and were ultimately categorized to an aforelisted source); and what follow up occurred to resolve the issue. Over time, the incidents reported to the coordinator were summarized according to categories of the possible or probable source of the incident. Follow-up and other data were also included in the summary.

**D2. Aim 2. Smart IV Pump Implementation/Technology Impact on End Users**

**D2.1. Pump observations**
Observations of nurses and anesthesia staff programming IV pumps occurred both at pre- and post-implementation times of the Smart IV pumps. Similar observations were conducted on nurses using the barcode medication administration technology. The intent of the observations was to determine compliance with standard procedures, capture the amount of time spent using the respective technology, and both describe and identify work and workflow issues associated with use of the technology.

**D2.1.1 Pre-pump implementation**
Pre-Smart IV pump implementation observation data were collected by six people, all with an industrial engineering background, using a paper data collection instrument and an electronic timeboard. The observation environment dictated the number of observers, with pairs assigned to conduct observations in the intensive care units (ICU). In total, 52 observations were used in the analysis. The units where observations occurred were selected in an effort to capture a variety of patient

populations and the nurses' consequent uses of the pump. Patients on different units reflect varying types of IV medications used. Likewise, ICU patients generally have more IVs than patients cared for elsewhere in the hospital. Data collected were sequence of pump programming, medication(s) being programmed, length of time programming consumed, and work environment conditions.

**D2.1.2 Post-pump implementation**

Post-Smart IV pump implementation observation data were collected by primarily one individual with an industrial engineering background. (There were instances when this individual was paired with a healthcare provider as part of a training process.) A paper data collection instrument was used initially but was later replaced by a tablet PC-based data collection instrument. The pre-implementation observation sheet was used as the starting point and was completely re-designed for post-implementation observations due to significant differences between the Smart IV pumps and previous pumps in terms of programming. Data collected during the observation were again aimed at identifying the sequence followed when programming the Smart IV pump; visual or audio signals noting an advisory, alarm, error or prompt; and various other pump-, workflow-, and environment-related issues. When the staff nurse had time, an observation was followed by a short interview that captured various aspects of pump use, working conditions, as well as time pressure and mental workload assessments using the NASA TLX (Hart & Staveland, 1988).

**D2.2. BCMA observations**

Nurse use of BCMA technology for medication administration was also observed. A naturalistic, undisguised observation design with time-based elements was used. A human factors engineer paired with a pharmacist performed the observations in seven adult inpatient units that had been using BCMA for at least 6 months, including three ICUs. The observation tool utilized was a modified version of the paper document used for the pre-implementation IV pump observations. The elements of interest were based on the work-system model and included the 1) tasks performed: sequence of medication administration steps from the time the nurse entered the medication room until the administration task was completed, handoffs, and obvious errors or unsafe acts; 2) work environment: shift (am/pm), location of tasks, lighting, noise level, neatness; 3) technology: automation surprises and alarms; 4) people: nurse and patient comments; and 5) organization: interruptions of activities. Sample size was determined by the theoretical saturation principle. The final data were analyzed by three human factors engineers, a nurse, a pharmacist, and a physician.

**D2.3. Pump survey questionnaire**

To assess the impact of the technology and its implementation process on end users, we distributed questionnaires assessing these issues 1 week pre-implementation and 6 weeks and 1 year post-implementation. The questionnaires included questions that have been shown to be valid and reliable in previous research studies. Many of the questions used in the questionnaire have been used by the PI in previous research, in particular research studies on the effects of various forms of technology on jobs and quality of working life (Carayon 1994; Carayon, Schmitz et al. 1998;

Carayon and Karsh 2000). The questionnaires *before implementation* and *1-year post implementation* contained the following sections: Section A is about your job: job title, tenure and experience on the job, unit, and shift. Section B covers technology issues (from the Questionnaire for User Interface Satisfaction version 5.0): (1) information received about the system, (2) inputs regarding decisions and implementation, (3) system effect on job, (4) attitude toward system, (5) overall reaction toward system, (6) learning, and (7) system capabilities. Section C covers characteristics of work environment: (1) role ambiguity, (2) quantitative workload, (3) uncertainty, (4) challenge, (5) task control, (6) decision control, (7) resource control, and (8) general job control. Section D covers the quality of working life (QWL): (1) organizational commitment, (2) fatigue, (3) tension, (4) facet-free job satisfaction, and (5) burnout. Section E covers self-rated performance. Section F is about demographics and background variables: gender, education level, and age. The *right-after-implementation* questionnaire had 50 questions: full questions from sections A, B, E and shortened question lists from sections D (fatigue and tension) and E. This survey was sent to nurse users only.

The before-implementation questionnaire was administered in paper mode at the time that the nurses and anesthesiologists were trained on the Smart IV pump. The training was 1 week long; it began on Monday, October 13, 2003, and ended on Sunday, October 19, 2003. Nurse users were approached for participation by CQPI-trained research staff and the PI immediately after training and were given the survey and an addressed campus-reply envelope. Anesthesia users were hand distributed the questionnaire by the Co-PI at training sessions. She also stuffed their mailboxes and put follow-up reminder signs up. The *right-after-implementation* and *1-year-post-implementation* questionnaires were web based and sent to users by email address lists obtained through human resources at the hospital. Three follow-up reminder emails were sent to increase the response rate. All data analyses were performed using SPSS software. After descriptive statistics were performed, various regression analyses were used to identify predictors of technology acceptance (evaluating demographics and technology characteristics) and quality of working life (evaluating technology characteristics). ANOVAs and post-hoc tests were performed to compare user perceptions and user acceptance of the Smart IV pump across the three surveys.

**D2.4. Focus Groups**

As the research study progressed, healthcare providers experienced with both the “old” IV pumps and the new Smart IV pumps participated in homogeneous focus groups. The objective of these groups was to assess user acceptance (ease of use, impact on work and training), concerns, and satisfaction with the Smart IV pumps. The five groups included representative pediatric nurses, intensive care nurses, staff anesthesiologists, resident anesthesiologists, and certified registered nurse anesthetists. Due to the difficulty associated with recruiting and convening a focus group composed of medical/surgical nurses, individual interviews were conducted with two such nurses. Individuals were given a stipend for participating during nonworking hours.

## D3. Aim 3. Human Factors Prospective Risk Analysis

### D3.1. Failure mode and effects analysis

We conducted two failure mode and effects analyses (FMEAs), one addressing the Smart IV pump implementation and the other evaluating the current use of BCMA. Both FMEAs used the five steps of the Healthcare FMEA™ process to complete the prospective risk analysis. First, a topic was chosen; then, a multidisciplinary team was assembled. All team members underwent training in the use of the Healthcare FMEA. Third, the teams completed a process map of the entire medication use process with specific emphasis on the technology use and related steps. Fourth, a hazard analysis was conducted to identify failure modes, assign a hazard score, and determine causes. Last, actions and outcome measures were determined for failure modes that proceeded. Team member interviews were performed separately for a qualitative evaluation of the processes and outcomes of both FMEAs.

#### D3.1.1. IV Pump FMEA

The hospital's performance improvement coordinating committee defined the FMEA topic as the "medication administration process using the Smart IV Pump." A 22-member team included representatives from anesthesiology (housestaff, staff, and engineering), biomedical engineering, central supply, industrial engineering, internal medicine, nursing, pharmacy, and quality improvement. All were involved in the medication use process or in technology maintenance except the industrial engineers, and many were end users of the IV pump. The team made short-term (training and process redesign) and longer-term (technology software and hardware redesign) recommendations. Forty-six hours of meeting time occurred over 4.5 months, representing 600 person-hours of time.

#### D3.1.2. BCMA FMEA

The five steps of the Healthcare FMEA™ were again used to complete the prospective risk analysis. First, the hospital's performance improvement coordinating committee defined the FMEA topic as the "medication administration process using the BCMA." A 13-member team included five pharmacists, four nurses, two physicians, one quality improvement facilitator, and a human factors engineer. The medication use process map from the IV pump FMEA was modified to include BCMA technology and related steps, for a total of 80 steps. Failure modes were divided into two groups: failure modes that were resolved through BCMA software upgrade and those that were not. The team focused efforts on those failure modes that would require further solutions beyond the planned software upgrade. Approximately 600 person-hours of time were spent over 7 months.

#### D3.1.3. FMEA team member interviews

We sought to evaluate FMEA team members' perceptions of FMEA team performance with the primary aim to provide recommendations to improve the FMEA process. Email invitations were sent to all members of both the IV pump and BCMA teams to participate in face-to-face interviews. Questions addressed issues related to team processes and performance. Data captured during the interview (primarily qualitative in nature) were transferred from the handwritten to typed notes. These notes were then content analyzed and assigned to a node structure using QSR NVIVO©. Nodes were

defined by two of the researchers who had reviewed a significant number of the comments to achieve consistency in coding.

### D3.2. Usability testing

Schroeder et al. (2006) write of a free-flow incident attributable to the pump. The nature of the free flow had previously been identified by the IV pump FMEA team; however, the team was unable to create the (at that time) hypothetical incident. Subsequent to the incident, usability analyses were conducted that focused on a technology upgrade aimed at ensuring a safe redesign that specifically addressed the free-flow incident.

A team of representatives from Biomedical Engineering, Medicine, Nursing, Patient Safety, Pharmacy, and the Research Team convened to determine the objectives of the testing as well as to provide input to scenario designs. The testing team, composed of the IV Pump Coordinator, a Biomedical Engineering Technician, and a Research Scientist, ultimately conducted two rounds of testing, because findings from the first round warranted further re-design by the manufacturer. The second round of usability testing occurred with what was ultimately the final pump.

The testing team developed the full protocol, including script, data collection instrument, and user questionnaire, to accompany each session. Each of the usability sessions began with the distribution of an IRB-approved information sheet ensuring participant confidentiality. Subsequently, each participant completed a pre-study questionnaire that evaluated pump performance. Throughout testing, participants were instructed on how to interact with and program the pumps. Some instances/scenarios were more prescriptive than others. They were asked to "think aloud" as they interacted with the pumps. The data collection instrument ensured consistency between observers for those aspects of the pump under scrutiny. Data collected included the occurrence (or not) of a free flow, any error or warning message displayed on the pump, and the gap measurement between the door and unit. Notes reflecting actions or comments made by the participant and/or responses of the pump were also collected by the observers. At the conclusion of each session, the participant was asked to again complete the (same) questionnaire – using a different-colored ink pen – to rate the same aspects of the pump as previously noted, although this time based on their interaction with/performance of the newly designed pump.

## E. RESULTS

### E1. Aim 1. Smart IV Pump Implementation Impact on Medication Errors

### E1.1. Medication administration audit data

We conducted over 900 observations of IV medications administered with the pump (300 pre-, 300 6 months post-, and 300 2 years post-implementation) to compare actual pump programming with the medication order and IV bag label. Use of the pump drug library with dosing limits was high at 6 months and remained >95% at 2 years. Many medication use practice issues were identified, including non-labeled IV bags from the operating room, missing medication orders for infusing medications, and IV protocols not being followed by the user.

**E1.2. Pump log data**

In total, 579 pumps (89% of pumps) had the log data from the first 8 months of use downloaded for analysis. This represented an average of 264 days use per pump. A total of 20,680 unique events or rows of data represented the initial dataset, and 12,519 rows remained after the selection process. There were 11,253 single sequences (rows of data) and 572 multiple sequences. Most multiple sequences had two event rows of data (range 2-8). There were 11,825 total alert events, which represented 45 alert events per pump day of use. Of these 11,825 events, 11% were near misses, in which the user either reprogrammed (9%) or canceled (2%) the infusion. Also, 10,568 alerts (89%) were overridden (end user proceeded with infusing the programmed dose above or below the limit); 52% of overrides were for an alert for a dose or bolus above the upper (maximum) limit. When considering all doses-above-maximum alerts, 1% were canceled, 13% were reprogrammed, and 86% were overridden. The programmed dose above maximum was 1-1.1 times over the limit in 24% of alerts, 1.2-1.5 times over the limit in 25% of alerts, 1.6-2.0 times over the limit in 14% of alerts, 2.1-4.0 times over the limit in 9% of alerts, and 4.1-999 times over the limit in 27% of alerts.

The limitations of these data include the need for significant transformation of the data to ready for analysis, lack of contextual information about the event, the experience level of the user, the condition of the patient factor and whether they required dosing outside of set medication limits, and the lack of actual patient harm data. The generalizability of these results to other hospitals are unknown.

**E1.3. Hospital web-based event report data (PSN data)**

All medication errors reported via the hospital's anonymous web-based event reporting system 21 months before smart pump implementation and 5 months after implementation were retrospectively reviewed to identify events involving IV medications. The data were further subdivided into those IV medications that required an IV pump to deliver. Overall, 2171 reports were reviewed pre-implementation, and 499 records were reviewed post-implementation. The number of IV administration errors accounted for 58% and 92.5% of all medication administration errors reported pre- and post- implementation, respectively. IV medications requiring an IV pump accounted for 35.5% of the pre- and 18.6% of the post-administration error events. The most common error reported pre-implementation was wrong dose (17%), followed by wrong drug (8.4%), wrong rate (6.1%), and wrong concentration (3%). Wrong dose (18%) and wrong drug (5.4%) were the most commonly reported errors post-implementation. Most of the errors were given harm scores of C and D (reaching patient, causing temporary harm). More serious harm scores of E (19.5%), F (2.7%), and H (0.5%) were assigned to 19.5%, 2.7%, and 0.5% of the medication errors pre-implementation versus 22.5%, 1%, and 0% for the respective scores post-implementation.

**E1.4. Pump event reported data reported to pump nurse**

Overall, 58 discrete events/issues were summarized over the first 12 months post-implementation of the smart pump. This summary report facilitated organized follow up when recurring incidents or types of problems arose. Examples of follow up included

formal training sessions with particular groups of nurses, one-on-one follow up with staff nurses or nursing managers, coordination with the biomedical engineering department to better understand instrument design, and formal and informal communication with the product vendor. Table 3, "Problems Reported after Implementation of Smart I.V. Pump," in Wetterneck et al. (2006) provides a summary of the types of problems that arose in the first 3 months after implementation, the manner in which they were reported, and the follow-up action taken. Of note is the complementary nature of the reporting mechanisms used to identify issues and problems.

## E2. Aim 2. Smart IV Pump Implementation/Technology Impact on End Users

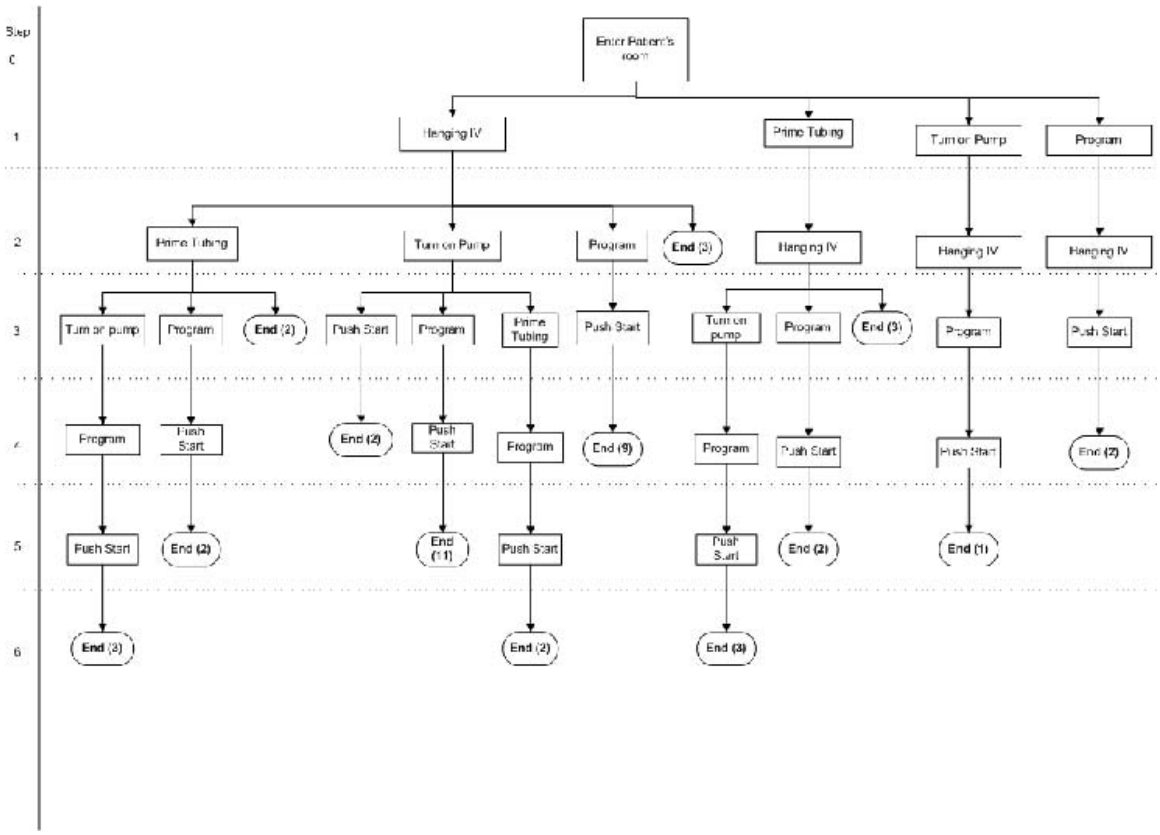
### E2.1. Pump observations

#### E2.1.1. Pre-pump implementation

Task Sequence of Medication Administration Process

In total, 52 observations conducted between 7 a.m. and 11 p.m. over 3 weeks were used in our analysis. There were nine different units and the emergency department on which the observations occurred. Thirty different IV medications were administered. Observations lasted between 1 minute and 30 minutes, with a mean duration of 5.6 minutes and a median of 3.5 minutes. Forty-five observations (of the 52 total) were considered when analyzing the task sequencing of the IV medication administration process. There were 13 different task sequences performed by nurses to complete an IV medication administration process. These task sequences are shown in Figure 1. The frequency of the task sequences is shown in the corresponding end box of each task sequence.

Figure 1




**E2.1.2. Post-pump implementation**

Seventy-six observations of 41 different medications programmed for use with the Smart IV pump on 16 hospital units occurred during a total of 51.75 observation hours. Six programming sequences accounted for 53 of the 76 observations. Approximately two thirds (49) of the IVs programmed were basic infusions, whereas one third were IVs included in the pre-programmed drug library and thus programmed according to the respective procedure. An area of significant interest – based on past research findings as well as user feedback – was the frequent sounding of alarms. Detailed data were collected regarding alarm type: 13 were advisory in nature (e.g., low battery, close door, restart channel), and 13 were alarms associated with potential errors (e.g., air in line, occlusion in line). These results confirmed suspicions related to the alarms and helped identify means of modifying the procedure related to "threading" the IV tubing in the pumping module. Because of concerns expressed by the manufacturer associated with the manner in which IV tubing were loaded, this aspect of the procedure was also audited, with feedback provided to the pump nurse and all nurse managers. Twenty-six instances of incorrect loading were identified. There was one instance in which the nurse incorrectly placed the tubing in the pumping module. This was pointed out to her by the observer and immediately corrected.

Fourteen of the individuals being observed had time and were willing to participate in the interviews. Eight of the participants considered their work day to be “unusually busy,” whereas the remaining six felt it was a “normal” day. Using the NASA TLX scales (0-100), both mental activity and time pressure were rated on the low end of the scale. The mean and median mental activity scores were both 40, and the mean and median time pressure scores were 23.85 and 15, respectively.

**E2.2. BCMA Observations**

In total, 62 observations of the med administration process were completed, witnessing the administration of 225 medications; 45% were on first shift, and 29% were in the ICU setting. The mean time of the observations was 7.7 min (sd, 5.9; range, 0-29), and the mean number of medications administered per observation was 3.9 (sd, 3.8; range, 1-19; five observations were excluded because they were not recorded (2) or were incomplete observations (3). The standard process included eight to nine steps: scan self ID, obtain meds, check meds vs. list, scan med, (double check), enter patient (pt) room, scan pt ID, admin med, document admin. Sequencing of task steps showed 18 different sequences in 57 observations. Only two sequences were “per policy” and represented 39% of observations. The most common deviation from protocol was documenting administration before actual administration (36%); 34% of observations had at least one medication given without full scan verification for the following reasons: the barcode was not in the database (nonformulary), no barcode was on the medication, the barcode could not be scanned (crinkled, ripped), there wasn’t a medication order for the patient, and the medication size dispensed was different than the ordered size. There were 10 observations with other unsafe acts, including not scanning the patient ID before administration, scanning a patient ID not physically on the patient, not documenting a medication that was administered, and administering the wrong dose despite an alarm. Thirty-two percent of observations had at least one interruption, commonly by physician rounds, patient questions/issues, or the need to retrieve equipment or further prepare medications. Automation surprises were noted in 10 observations (16%) due to device freezing, losing wireless connection, ‘time out’ of computer log-in, screen out of alignment, multiple scans required to read barcode, or an unfamiliar screen. These surprises resulted in response to the surprise and continuation of the process in seven observations, a discontinued process (1), and potentially unsafe actions (2). Patient contact isolation was associated with four handoffs/sharing of tasks in which one nurse scans and another administers or in which scanning and documenting occur outside the patient room. Nurses commented that they rely on technology to alarm if there is a problem, that its easier to document administration before actually doing it, and that the machines time out too soon. These data were used for the prospective risk analysis and vendor discussion for process and technology redesign; (re)training; and updating procedures to support safe, efficient technology use.

**E2.3. Pump survey questionnaire**

*Before implementation*

In total, 190 nurse responses were received from this questionnaire (response rate, 32%); 91% were women, and 69% were under the age of 45. The average length of time working for the institution was 7.4 years.

With regards to QWL, nurses reported high levels of workload, medium-high levels of role ambiguity, high challenge, medium job control, and high levels of job uncertainty. Twenty-five percent of nurses reported symptoms of burnout. Predictors of burnout included age, role ambiguity, and job control ($R^2$=23%; p<.001). Increasing levels of role ambiguity (beta coefficient=.24; p<.001) and decreasing job control (beta coefficient=-.21; p<.01) were associated with higher levels of burnout. Other job characteristics were not associated with burnout. Predictors of satisfaction with care provided included role ambiguity, uncertainty, and challenge ($R^2$=17%; p<.001). Low role ambiguity (beta coefficient=-.22; p<.01) and uncertainty (beta coefficient=-.19; p<.05), and high challenge (beta coefficient=.20; p<.05), were related to satisfaction with care provided. Predictors of time pressure included role ambiguity, uncertainty, and job control ($R^2$=28%; p<.001). Decreasing levels of role ambiguity (beta coefficient=-.30; p<.001) and uncertainty (beta coefficient=-.21; p<.01), and increasing job control (beta coefficient=.26; p<.001), predicted more perceived time available to complete tasks safely.

*6 weeks post-implementation*

The nurse response rate was 31% (322 responses received).

Stepwise regression analysis was used to identify technology characteristics associated with pump acceptance at 6 weeks. Six characteristics explained 64% of the variance. Perceptions of enhanced job effectiveness, the job being easier, improved patient safety, and the pump functioning as expected were associated with higher acceptance. Perception that the alarm messages for pump functioning were frustrating and that the pump interface was rigid predicted lower satisfaction.

*One year post-implementation*

Overall, 399 nurses responded (38% response rate). Age distributions were 45% under the age of 34 and 29% aged 45 and older; other demographics included 76% educated in a BS program and 44% worked in current job position for 6 years or longer.

Stepwise regression analysis was used to identify pump technology characteristics that were associated with various QWL measures. The explanatory variables were six questions on learnability, 11 questions on efficiency, one question on memorability, five questions on errors, five questions on user satisfaction, six questions on technical performance, and one question on technology acceptance. Nurses who perceived the pump to be more reliable had higher organizational commitment (adj $R^2$=.027; β coeff=.173; p<.01). Nurses who believed that the pump drug library prevents errors had lower daily life stress levels (adj $R^2$=.01; β coeff=-.111; p<.05). Nurses who perceived the pump to be more reliable had higher job satisfaction (adj $R^2$=.018; β coeff=.113; p<.05). Nurses who perceived that alarm messages for pump functioning were frustrating were more likely to be burned out (adj $R^2$=.01; β coeff=-.106; p<.05).

Nurses who perceived the exploration of new pump features by trial and error was difficult were more likely to be satisfied with quality of care they provide (adj $R^2$=.01; β coeff=-.11; p<.05).

*Comparisons across surveys*
Nurse *user acceptance* of the Smart IV pump technology was positive (means varying from 6.53 to 7.20 on 10-point scales). Overall, *user acceptance* significantly increased 1 year after implementation compared with 6 weeks after implementation (p<.001). User experience with pump *reliability* and *noise* significantly changed from pre-implementation to 1-year post-implementation (p<.05 and p<.001, respectively). Compared with their expectations of pump *noise* before implementation, more negative responses were given in both the 6-week post-implementation survey and the 1-year post-implementation survey (p<.001 and p<.001, respectively). Respondents' perceptions of pump *reliability* 1 year after implementation were significantly lower than before implementation. Responses to the item, "*pump is designed for all levels of users,*" were more positive 1 year after implementation than before or 6 weeks after implementation (p<.05 for both comparisons). Responses tended to be positive for two questions on *efficiency* related to patient safety (means varying from 4.87 to 5.36) and for the question on the drug libraries and Guardrails® (mean 5.30), but responses were less positive for the question on *ease of use of the pump in emergency situations* (mean 4.03) (Note: this question was added in the 1-year post-implementation survey.)

For seven of eight questions on *efficiency*, perceptions improved from pre- to 1-year post-implementation: "*enables me to accomplish task more quickly*" (p<.001), "*improves the quality of care I provide"* (p<.01), "*improves the safety of care I provide*" (p<.01), "*enhances my effectiveness on the job*" (p<.01), "*makes it easier to do my job*" (p<.001), "*increases the safety of care provided to our patients*" (p<.001), and "*pump functions as I expect*" (p<.01). Responses to the question "*task can be performed in a straightforward manner*" did not change over time. Six weeks after implementation, the respondents reported less positive perceptions of *alarm messages for pump functioning* than they expected before implementation (p<.01), which remained less positive on 1-year post-implementation surveys. User perceptions of *alert messages for the drug library* became significantly more positive 1 year after implementation compared with 6 weeks after implementation (p<.01).

### E2.4. Focus groups
In general, issues associated with the smart pump varied by user type. This variance resulted in varied follow up with each of the respective groups, including changes/ additions to content of user manual, expansion of a "frequently asked questions" reference, clarifications with pertinent staff (generally through their manager), changes to new user training, and follow up with biomedical engineering staff. Some issues raised were also included in the post-implementation questionnaires distributed to all pump users.

## E3. Aim 3. Human Factors Prospective Risk Analysis
### E3.1. Failure mode and effects analysis
#### E3.1.1. IV Pump FMEA
Over 200 failure modes were identified. Major issues were identified with pump acquisition, proper tubing installation, air-in-line removal, drug profile selection, labeling

channels, and patient transfers. The team made 10 major recommendations, including changing pump acquisition as well as return and pump reprocessing, education about radiofrequency interference, 100% training and competency assessment, IV bag labeling to match drug library, standard concentrations and dosing, and pump use changes (including education about tubing insertion, clearing air-in-line alarms, and programming changes). Pump implementation was delayed by 1 month for actions to be completed and recommendations implemented. Reports were made to the hospital leadership and the pump vendor. After pump implementation, the pump use and related events were monitored by audits and analysis of event reports. Five new events were identified post-implementation that were not anticipated by the team, including a free-flow event related to improper tubing insertion (see E.3.2. Usability testing).

### E3.1.2. BCMA FMEA

In total, 202 failure modes were identified, and 91 completed the hazard score analysis and had solutions identified for them. The transcription and administration processes accounted for more than 80% of failure modes. The highest hazard score (100) was determined for 18 failure modes, and 83% of these occurred in the administration process. An average of 1.9 solutions was determined per failure mode (mode 1; range 1-5); 23% of failure modes had a solution in the new upgrade. Process and technology redesign solutions were suggested and implemented. For example, the failure mode "Medication does not have barcode" for the process step "Scan the medication barcode" was identified for action, as this process step is a technology safety check. Medications that frequently did not have a barcode included bulk products, metered-dose inhalers, IV fluids, and multidose insulin vials, and these were targeted by pharmacy for barcode development and placement before dispensing.

### E3.1.3. FMEA team member interviews

Twenty-four of the 39 members consented and participated to be interviewed concerning the FMEA team on which they participated. Content analysis of comments, grouped according to an input, process, outcome model, resulted in comments related to an "effective" FMEA as ensuring:

*Input*: inclusion of different disciplines, knowledgeable team members related to the process being reviewed, familiarity between members, process owner membership on the team, knowledge of the FMEA process, clarity regarding team objectives and a limited scope, sufficient organizational support;

*Process:* communication and participation among members, management of team members (to prevent grouping and dominating), efficient team processes, consistent attendance, inclusion and participation of all members in the process, measurement of progress, acknowledgment of time commitment;

*Output:* ability to measure team and individual accomplishments, value of FMEA.

**E3.2. Usability testing**

Participants in usability testing included four staff nurses, three nurse "super users," two nurse anesthetists, and two faculty and two resident anesthesiologists. All the participants from round 1 also participated in round 2. Round 1 compared the original pump with redesign version 1. Round 2 compared the original pump with both redesign versions 1 and 2.

*Round 1*

The first objective of this round was to assess whether it was more difficult to close the pumping module door of redesign version 1. Results were inconsistent and inconclusive. There was no universal agreement whether the new pumping module doors were either more or less difficult to close than the current module doors.

The second objective was to evaluate user perceptions of intentional misloads when the "top fitment" extended above the normal recess. Because there were no alarms or error messages and what appeared to be normal flow resulted, staff assumed the misload was indeed a correct loading of tubing. Staff were unaware and surprised that an UNDER-infusion most likely occurred in these cases.

The third objective was to assess the flow outcome and any messages/alarms that resulted from intentional misloads occurring after users followed a carefully crafted scenario. Of the 16 misload instances using the redesigned modules, three free flows occurred with error messages of "check IV set," "fluid side container empty," and "occluded fluid side" (one each). Four "drip-drip-gush" instances with NO error messages/alarms resulted. Door measurements of the free flows were 7.0 mm (2) and 6.5 mm. Door measurements of the drip-drip-gush instances were 6.5 mm (3) and 6.0 mm.

The fourth objective was to determine the resulting flow (if any) when additional tubing was placed both under as well as over the door platen (with the intended tubing accurately loaded). Tubing loaded under the platen resulted in a free flow, sometimes with but other times without alarms. Tubing loaded above the platen rarely resulted in a free flow.

The fifth objective was to observe users when loading pumps following their respective pump-loading practices. Overall, good practice was demonstrated, although some staff nurses were directed to refine their respective practice.

This round demonstrated that the redesign version 1 did not correct the ability to create free flows. Results of the questionnaire confirmed continued concern and dissatisfaction with the redesigned pump's performance.

*Round 2*

The first objective was to assess the flow outcome and any messages/alarms that resulted from intentional misloads. In each test, each module was misloaded once with a "front load" and once with the tubing cocked backward. Problems persisted with both the

original and redesign 1 versions of the pump. One free flow occurred for the second redesign version pumping module; however, an immediate alarm and an error message resulted. The “front loads” were sometimes corrected with the redesign version 2, most likely due to the manufacturer’s change in the recess/drive screws. The doors were more difficult to close and/or couldn’t close with front loads.

The second objective was to determine the resulting flow (if any) when additional tubing was placed both under as well as over the platen (with the intended tubing accurately loaded). Once again, tubing loaded under the platen resulted in a free flow, sometimes with but other times without alarms. Tubing loaded above the platen rarely resulted in a free flow.

The fourth objective was to observe users when loading pumps following their respective pump-loading practices. Most users displayed good practice; however, some anesthesia staff were unaware of the practice of threading the tubing through the air sensor and pressing it in place. The IV pump nurse followed up with these individuals.

Questionnaire results showed no difference in perceptions of performance between the “old” and final (redesigned) pumps’ performances; however, users felt that the final redesign pump contributed to safer patient care. Ultimately, the hospital elected to convert all the pumping modules to the final re-design based on the results of the usability testing.

**F. Publications**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2. Carayon P, Wetterneck TB, Hundt AS, Enloe M, Love T, Rough S, Schroeder M. "Continuous technology implementation in health care: The case of advanced IV infusion pump technology," presented at HCI 2005, Reno, NV, July 2005.

3. Carayon P, Wetterneck TB, Hundt AS, Ozkaynak M, Ram P, DeSilvey J, Hicks B, Roberts TL, Enloe M, Sheth R, Sobande S. "Assessing nurse interaction with medication administration technologies: The development of observation methodologies," presented at the WWCS 2004 Conference, Kuala Lumpur, Malaysia, June 29-July 2, 2004.

4. Carayon P, Wetterneck TB, Hundt AS, Ozkaynak M, Ram P, DeSilvey J, Hicks B, Roberts TL, Enloe M, Sheth R, Sobande, S. "Observing nurse interaction with infusion pump technologies," In: Henriksen K, Battles JB, Marks ES, Lewin DI, editors. *Advances in Patient Safety: From Research to Implementation.* Vol. 2, Concepts and methodology. AHRQ Publication No. 05-0021-2. 2005. p.349-64.
5. Carayon P, Wetterneck TB, Hundt AS, Ozkaynak M, Ram P, DeSilvey J, Ludwig B, Ram P, Rough S. "Evaluation of nurse interaction with bar code medication administration (BCMA) in the work environment," forthcoming in *Journal of Patient Safety*.

6. Carayon P, Wetterneck TB, Hundt AS, Schroeder M. "Human Factors in the Design and Implementation of Patient Safety Technologies," presented at ESCTAIC 2004.

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8. Hundt AS, Carayon P, Wetterneck TB, Love T, Haack B, Schroeder M, Enloe M. "Evaluating design changes of a smart IV pump," presented at HEPS, Florence, Italy, April 2005.

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14. Wetterneck TB, Skibinski K, Schroeder M, Roberts T, Carayon P. "Challenges with the performance of failure mode and effects analysis in healthcare organizations," *Proceedings of HFES 48th Annual Meeting 2004,* pp. 1708-1712.

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