

Using failure mode and effects analysis to plan implementation of smart i.v. pump technology

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Technologies are increasingly being introduced into health care to improve the efficiency and quality of care while decreasing medical errors. Because medication administration is a frequent source of medication errors and adverse drug events,¹⁻³ hospitals are expending considerable resources on sophisticated technologies in the form of bar-coding technology and smart i.v. pumps.^{4,5} I.V. medication administration is especially vulnerable due to the lack of built-in double checks and the low likelihood of event interception before the drug reaches the patient.^{1,6} In a systems analysis of error, misuse of infusion pumps and other parenteral delivery systems was identified as a common proximal cause of error.⁶ A new type of i.v. infusion pump, an intelligent or smart i.v. pump, has been created to decrease pump

Purpose. Failure mode and effects analysis (FMEA) was used to evaluate a smart i.v. pump as it was implemented into a redesigned medication-use process.

Summary. A multidisciplinary team conducted a FMEA to guide the implementation of a smart i.v. pump that was designed to prevent pump programming errors. The smart i.v. pump was equipped with a dose-error reduction system that included a predefined drug library in which dosage limits were set for each medication. Monitoring for potential failures and errors occurred for three months postimplementation of FMEA. Specific measures were used to determine the success of the actions that were implemented as a result of the FMEA. The FMEA process at the hospital identified key failure modes in the medication process with the use of the old and new pumps, and actions were taken to avoid errors and adverse events. I.V. pump software and hardware design changes were also recommended. Thirteen of the 18 failure modes reported in practice after pump

implementation had been identified by the team. A beneficial outcome of FMEA was the development of a multidisciplinary team that provided the infrastructure for safe technology implementation and effective event investigation after implementation. With the continual updating of i.v. pump software and hardware after implementation, FMEA can be an important starting place for safe technology choice and implementation and can produce site experts to follow technology and process changes over time.

Conclusion. FMEA was useful in identifying potential problems in the medication-use process with the implementation of new smart i.v. pumps. Monitoring for system failures and errors after implementation remains necessary.

Index terms: Computers; Devices; Dosage; Drug use; Errors, medication; Hospitals; Injections; Methodology; Team; Technology; Toxicity

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programming errors by providing a medication dose double check at the bedside.^{5,7-9}

A smart i.v. pump is equipped with a dose-error reduction system that detects and prevents programming errors.⁷ This system has a predefined drug library contained within software in the pump programming module. The drug library allows upper and lower dosage limits to be set for each medication and a distinct library or profile for designated patient-care areas of a hospital (intensive care unit [ICU] or operating room) or patient type (adult or pediatric). When a pump is programmed above or below a medication dosage limit, audio and visual alerts provide feedback that an error may have occurred. A soft alert can be overridden by the user to continue with the administration at the programmed rate. A hard alert does not allow an override and requires reprogramming within the defined medication limits for delivery of the medication.

Thus, the addition of the drug library and programming alert to the pump software has the potential to improve patient safety. However, they also introduce significant changes to the i.v. pump programming process and user interaction with the pump. Because of this, it is valuable to prospectively identify the unintended consequences that may occur with the introduction of the technology.¹⁰⁻¹³ Patient-safety experts recommend examining the technology and the related processes of care in order to identify system issues and threats to safety, redesign them proactively before errors occur, and train staff on avoidance of the errors.^{6,10,11,14,15} System issues may arise from the addition of technology and its interactions with other elements of the work system. The work system is made up of five elements: people, tasks performed, environment, organization, and tools and technologies used to complete tasks.¹⁶ With the addition of a new technology, the effects of the

work system on all elements should be considered.

Failure mode and effects analysis (FMEA) is a common human factors method used to prospectively identify and eliminate known and potential failures and errors from the system, process, or technology design before reaching the end user.¹⁷⁻²⁰ The use of FMEA is growing in health care organizations since the Joint Commission on Accreditation of Healthcare Organizations requires the performance of a yearly proactive risk assessment (e.g., FMEA) of one process or technology.²¹ In health care, FMEA is commonly used to evaluate high-risk patient-care processes such as medication use and blood transfusions, in addition to infant abduction and security risks.²²⁻²⁵ These prospective risk analyses are time-consuming and require tremendous resources.^{6,23,26} Likewise, there may be challenges when applying the classic models for analysis used in other industries to the health care setting.²⁶⁻²⁸ Health care organizations (HCOs) may use FMEA to determine failure modes that could be obviated with technology software and hardware solutions and work with device vendors to make these changes. Device vendors are required to perform FMEA on technology for Food and Drug Administration (FDA) approval of their device; however, many vendors do not include end users in this process and only test the technical capabilities of the system in a laboratory environment.²⁸ HCOs are best positioned to put the needs of end users and patients first and do not have conflicts of interest with the need to market or sell a technology.

This article describes the use of FMEA to evaluate a smart i.v. pump as it was implemented into a redesigned medication-use process. The outcomes of the FMEA and the implementation process are presented and discussed.

Background

The hospital, a midwestern, ter-

tiary care, academic medical center, had previously implemented robotic dispensing and point-of-care bar-coded medication administration to improve the medication-use process.

A multidisciplinary committee was assembled to evaluate i.v. pump technologies that could improve pump programming accuracy and decrease i.v. medication errors. The i.v. pump used by the hospital at that time (hereafter referred to as the old pump [Deltec 3000, Deltec Inc.; Deltec Inc. is now Smiths Medical MD, Inc.]) was a single-channel all-purpose infusion pump with a display that allowed trailing zeroes and did not have a built-in dose-error reduction system. By majority consensus, the committee identified 29 desired functionality criteria for a new i.v. pump. These criteria included a built-in dose-error reduction system, free-flow protection, certain alarm types (e.g., air in line, upstream and downstream occlusion, low battery, infusion complete alarm and an alarm interface with the nurse call system), operating-room use features, use of leading zeroes and avoidance of trailing zeroes on the pump programming screen, easy starting and stopping of infusions, and dose-rate calculation.

Only one pump (from ALARIS Medical Systems [now Cardinal Health] Guardrails, version 5.0) was identified that met a majority of the criteria and had the desired safety features. Most importantly, the pump had drug-library programming with dosing alerts based on customer preset limits and did not use trailing zeroes on the pump interface. The committee participated in a vendor demonstration of the pump and arranged for pilot testing. A decision to purchase the pump was made, and an FMEA of the i.v. medication administration process and the new technology was planned.

Experience with FMEA

A multidisciplinary team was as-

sembled to perform an FMEA of the i.v. medication administration process incorporating pump technology and to report its findings to the hospital performance-improvement coordinating committee.²⁶ The 22-member team included representatives from anesthesiology (resident and staff physicians, equipment engineer), biomedical engineering central supply, industrial engineering, internal medicine, nursing, pharmacy, and quality improvement. Few of the team members were end users of the i.v. pump, but all were involved in the medication-use process or in technology maintenance, except for the industrial engineers. The team underwent training in the use of Healthcare FMEA (HFMEA), developed by the Veterans Administration National Center for Patient Safety.²⁹ The steps in the HFMEA process include (1) team selection, (2) process identification, (3) process mapping, (4) failure-mode identification and scoring, and (5) determination of actions and outcome measures. This form of FMEA was thought to be easier to apply to health care situations due to a modified hazard matrix scoring system for failure modes based on health care outcomes.²⁹ HFMEA uses a 4-point scale to rate severity (minor, moderate, major, catastrophic) anchored to patient outcomes and a 4-point scale for probability (remote, uncommon, occasional, frequent).²⁹ The product of these two scores creates a hazard score. The failure mode then follows a decision tree to assess criticality, existing control measures, and detectability. Failure modes with high criticality that do not have effective control measures in place and are not easily detectable are prioritized for further action. The FMEA start date was three months before the planned i.v. pump implementation date.

Multiple data sources supplemented the team's work to gather input on process mapping and potential failure modes for the new i.v. pump as the pump had only been

implemented in 60 U.S. hospitals at the time of the FMEA. Online list-server discussions from an academic hospital organization identified issues with hardware breakage of pole clamps and pump handles and a possible free-flow event at a children's hospital. FDA's Manufacturer and User Facility Device Experience database (MAUDE), which provides reports about adverse events involving medical devices, was searched for events involving the new i.v. pump. The vendor's technology FMEA, a report on i.v. pumps from ECRI, and other relevant literature were reviewed.⁷ Nurse-user survey data from the i.v. pump pilot showed general satisfaction with pump use except for frequent air-in-line alarms.

Observations of the i.v. medication administration process with the old pumps supplemented information from end users about the variations in practice during the administration process, and workarounds to facilitate process mapping and failure-mode generation provided information.^{30,31} Medication administration and i.v. pump events reported with use of the old pump were identified and retrieved from the hospital's Web-based event reporting system.

The team mapped the entire medication-use process with the old i.v. pumps and then repeated the mapping process with the new i.v. pumps, including the process of obtaining the pump from central supply. Understanding that there are variations in the process based on the patient-care area (e.g., ICU, general care, emergency department, operating room), and also by patient population (pediatrics or adults), the team first mapped a single process for adult patients on a general medical unit. Steps were identified in the mapping process where variations may occur by care area or patient population, and they were later addressed during the FMEA. To aid the process mapping, end users demonstrated pump programming

on the old and new pumps for team members.

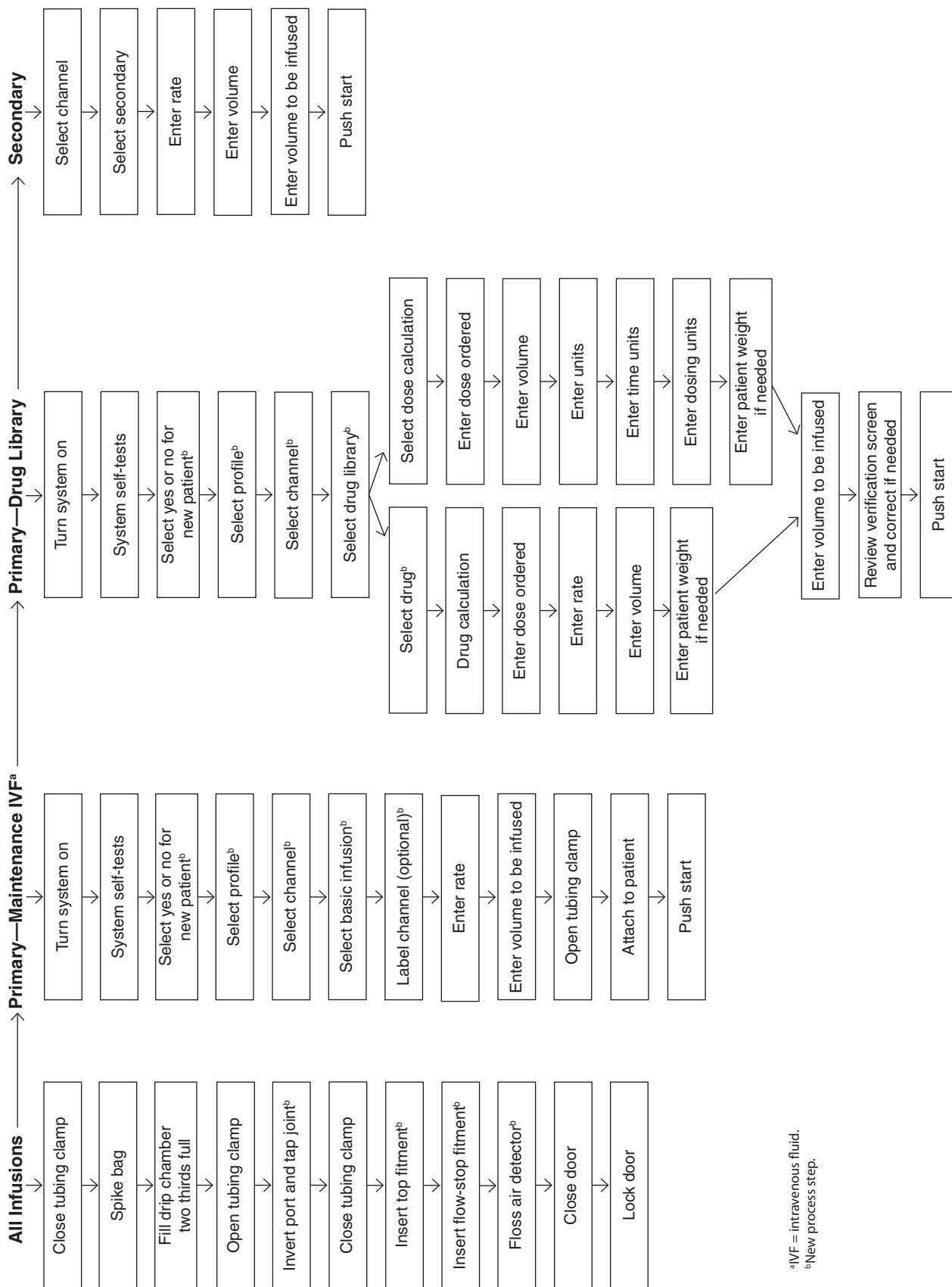
The FMEA team met for 46 hours over four and a half months. This resulted in a one-month delay of i.v. pump implementation.

Process mapping. Seven main process steps (i.e., patient assessment, prescription, transcription, preparation and dispensing, administration, monitoring, and pump acquisition) and 33 substeps were outlined and are available for viewing.³² The medication-administration substeps that directly focused on end-user interaction with the old pump were further divided into 10 steps for retrieving the medication and tubing and 24 steps for pump programming. Fourteen unique pump programming steps were identified for the new pump (Figure 1). The extra programming steps involved navigating pump menus for choosing new patient or not, choosing a drug profile (library) appropriate to the patient setting, and selecting the mode of infusion programming (basic infusion or drug library). If using the drug library, a medication and concentration are chosen from the library list. For basic infusions, a channel label could be chosen from a preset list.

Other changes in process involved the new tubing setup and insertion. The old pump had an easy-to-insert tubing set that could only be inserted in one manner. Correct insertion of the tubing in the new pump required three separate sequential actions: (1) placement of the tubing top fitment into the pump, (2) insertion of a plastic side clamp into the pump to disengage the anti-free-flow mechanism, and (3) flossing of the tubing through an air-in-line sensor at the bottom of the inside of the pump. The top fitment could be easily misplaced at the top of the new pump, a scenario that was more likely to occur if the tubing insertion steps were completed out of order.

Mapping the entire medication-use process identified several issues beyond medication administration

Figure 1. Programming process for new i.v. pumps.



^aIVF = intravenous fluid.

^bNew process step.

to be addressed before implementation of the new i.v. pump. First, differences in prescribing across disciplines added to the complexity of choice of drug or dosage units in the drug library. For example, nitroglycerin was ordered based on weight in micrograms per kilogram per minute by the anesthesia and surgery department but not by internal medicine physicians. Many drugs in the library also had more than one entry due to the different concentrations available. However, only two drugs, nitroglycerin and alprostadil, had entries with different dosing units. Second, even though our institution had defined standard concentrations for adult i.v. medications, further refinement was needed for drugs used in pediatric patients. A subcommittee was appointed to develop the drug library and achieve consensus across user disciplines. Third, medication labels needed to be changed to match drug library information so that the end user could easily choose the correct medication and concentration from the drug library. Fourth, because the new i.v. pumps had separate programming and pumping modules (one programming module supports four pumping modules), there was a need to change pump acquisition screens and educate end users and unit clerks on ordering the separate modules. Fifth, because the modules communicate through connection by radio frequency, other radio frequency operating devices in the hospital were evaluated for interference potential. If used in close proximity, the security team's walkie-talkies could interfere with the i.v. pumps, causing cessation of pumping. Sixth, the pumps' air sensors required special cleaning during reprocessing to increase the sensitivity of the air-in-line alarm. Finally, returning pump modules was identified as a potential problem as patients may need multiple pumping modules for medication delivery, but unused and unneeded pumping modules may not be promptly disconnected and returned.

Failure-mode identification and scoring. Hazard analysis followed process mapping and focused on the medication-administration process step due to time constraints before implementation. Over 200 failure modes were identified and assigned a risk priority number or hazard score, which takes into account the severity and probability of failure-mode occurrence. Severity and probability of failure modes for the new i.v. pump were ranked as low, moderate, or high, because knowledge about the pump and its use was inadequate to use the 4-point scale defined by HFMEA. Low was defined as unlikely to cause harm or to occur, high was defined as likely to cause significant harm or very likely to occur, and moderate is a rating between low and high. Again, the product of the severity and probability of occurrence ratings was used as a hazard score. Failure modes with low or low-moderate hazard scores were assessed for detectability, and only nondetectable failure modes were considered for further action. All moderate-to-high scoring failure modes proceeded to action. Known and potential causes of the failure modes were then identified and actions determined to prevent failure-mode occurrence. The team categorized solutions into five categories related to the work system¹⁶: (1) policy and procedure, (2) training or education, (3) environment, (4) people, and (5) technology software or hardware change. Technology changes were further classified as short-term or long-range improvements. A comparison of high hazard score failure modes in pump programming identified with the old and new pumps is presented in Table 1. The new i.v. pump removed causes of wrong dose or rate errors and decreased the severity of pump programming errors but introduced new failure modes due to additional pump features. During the process to determine failure modes, the pump vendor alerted the institution to a new source of infusion rate error

caused by tubing fitment misplacement that could result in underinfusion or overinfusion. Aware of these reports and anecdotal reports of a free-flow event from another hospital, the team's biomedical engineers performed infusion-rate testing and confirmed the underinfusion error with the tubing misplacement. The team unsuccessfully attempted to create a free-flow event by manipulating the i.v. tubing and the pump door closure.

FMEA team recommendations and actions taken. The FMEA team recommended mandatory end-user training before using the new pump in patient care based on the significant changes in pump programming as compared to the old pump. Recommended training topics included proper tubing installation to avoid issues with underinfusions and overinfusions and air in line, the air-in-line removal techniques, the correct pump channel, the drug profile and medication selection, the use of channel labels for basic infusions, the difference between drug-library programming and using channel labels (there is no dose-error protection with channel labels), the continued use of double checks for high-risk medications, and the procedure for obtaining pumps. Nurses were required to program the volume to be infused with the new pump to allow for close management of infused volume, which may allow for recognition of potential underinfusions and overinfusions. A nurse was hired to guide pump implementation and coordinate training and troubleshooting postimplementation. She performed problem identification and resolution for pump users, ensured user training completion and retrained users on new functions during the implementation phase.

Eighty percent of nurse users and most anesthesia users underwent hands-on skills-based training for one week before implementation. Nurse superusers (nurses who received initial intensive training on

Table 1.

High Hazard Score Pump Programming Failure Modes for Old and New I.V. Pumps and Recommended Actions from the FMEA Team^a

Failure Mode	Cause(s)	Old Pump	New Pump	Recommended Action(s)
Enter incorrect rate	Keypad not backlit; zero and decimal close together; misread order—illegible; processing more than one order at a time; lack of drug knowledge; misread display because trailing zero displayed for all drip rates under 100	Yes	Yes ^b	Implement new technology that has backlighting for keypad and will alert nurse when rate or dose is out of range
Select incorrect dose or rate calculator mode	Lack of knowledge and training	Yes	No	Implement i.v. infusion system that will eliminate need to perform calculations by the nurse; train nurse to use calculator on pump
Select incorrect status for patient when asked if patient is new (pump memory retains weight of patient)	Patient new to pump versus hospital; interunit transfers; unclear phraseology; patient not identified on pump	No	Yes	Train nurses to answer yes when unclear about patients' status; use policy and procedure to set clear parameters for the process and roles; encourage vendor to rephrase question in next version
Select incorrect profile	Nurse unclear about available profiles or what profile to use for her or his unit; incorrect profile selected postoperatively from operating room; profiles sequenced alphabetically and not by most common; cannot select new profile while pump is running	No	Yes	Include profiles in education and training; encourage vendor to sequence profiles by most used; develop a profile for code situations; train nurses to run medications in basic infusion mode until patient is stable, then switch mode to library
Select incorrect channel	Nurse running multiple infusions at once; look-alike tubing and bags; tubing not labeled	Yes	Yes	Enforce double checks throughout the process; use preprinted drug labels to identify tubing above and below the i.v. pump; create interface with bar-code technology; use tubing separators
Select incorrect drug or drug concentration	Multiple concentrations in the drug library; medication with multiple concentrations on more than one page	No	Yes	Standardize concentrations whenever possible; place all concentrations on one screen; provide prompt when all concentrations will not fit on one page; use fonts and Tall Man letters to differentiate concentrations and drug names

^aFMEA = failure mode and effects analysis.

^bFor a misread or an illegible order and when processing more than one order at a time.

the use of the new pump to be able to teach other users) and vendor representatives performed the training. Supplemental computer-based training was also available at all hospital computer workstations. The training was mandatory and well publicized by administration. Additional training of end users occurred during

pump implementation by nurse superusers, and the remaining users received on-the-job training over the following two months.

Many recommendations identified short-term and long-term software and hardware changes to address failure modes with the understanding that technology changes could elimi-

nate certain failure modes or provide fail-safe design.^{14,33} These recommendations often complemented other proposed training or policy and procedure changes recognizing the limitations of consistent human function given the complex and ever-changing work environment and the need to adapt to patient-care situations. For

example, although hardware redesign of the pump to eliminate tubing misplacement or to ensure alarms if the tubing was misplaced (fail-safe) was noted as the ideal solution, end users were also trained on correct tubing insertion. A summary of recommended technology solutions is found in Table 2.

At the end of the general-process FMEA, the team identified hospital-site and patient-specific considerations for i.v. pump implementation. Common to all sites was the use of the appropriate site-specific drug profile and the subsequent need to change profiles if the patient changed his or her care setting. However, changing the drug profile requires power-down of the i.v. pump and reprogramming of the infusion. There were particular concerns about the procedure to follow during patient resuscitation. For example, the i.v. pump may already be infusing in the medical-surgical drug profiles, but the medications needed to stabilize blood pressure are either not in this drug profile or the programmed drug limits are set lower than necessary for resuscitation. The team considered multiple options for these occurrences, including powering down the pump and changing to the ICU drug profile (which takes one to two minutes), delivery of a new pump programming module that could be powered up into the ICU drug profile, and the use of anesthesia mode, which would make most ICU drugs available but would deactivate audio alarms. The team determined that the ICU profile should be used during codes or patient deterioration, and powering down was preferable to programming the infusion without the use of the drug-library limit protection when feasible. In addition, when patients transfer across settings of care (e.g., ICU to the medical-surgical unit), the i.v. pump should be changed to the appropriate drug profile for that specific unit when patient stability allows powering down of the pump.

Table 2.

I.V. Pump Software and Hardware Design Changes Proposed by the FMEA Team^a

Design Change	Hospital	Vendor
<i>Short-Term Goal</i>		
Drug library list		
Addition of Tall Man (capital) letters to distinguish between similar drug names	X	
Maintenance infusion channel labels		
Channel labels consistent with i.v. bag labels	X	
Most frequently used solutions at top of list	X	
<i>Long-Range Goal</i>		
Drug-library list capabilities		
Put all drugs with multiple concentrations on the same screen		X
Prompt for additional screens if multiple drug concentrations extend to more than one screen		X
Adjust fonts based on user input for drugs with multiple concentrations		X
Profile list—most frequently used at top of list		X
Tubing installation		
Tubing fitting colors to indicate correct placement		X
Technology redesign to prevent incorrect placement		X
I.V. tubing—place preprinted drug name labels above pump and close to patient	X	
Menu phrasing—clarify that new patient means the first use of pump for this patient		X
Multiple channels—i.v. pole rakes to separate and hang infusions over respective pumping modules	X	
Consider addition of a patient resuscitation mode		X
Consider including pumps on patient resuscitation carts	X	
Consider the feasibility of elevator modifications to better accommodate the increasing amount of equipment (i.v. pumps and other) accompanying patients	X	
Disable maximum rate feature for bolus dosing		X
Allow soft and hard limits for each medication in the drug library		X

^aFMEA = failure mode and effects analysis.

The main site-specific recommendations involved the operating room and use of pumps by anesthesiology staff. A number of issues were identified. The anesthesia mode setting, which turns off audio alarms and allows an extended pause without an alarm, was programmed for use in each drug profile and staff was informed that the anesthesia mode would cease when the pump is unplugged from the electrical outlet. An additional team was assembled to address labeling of i.v. bags prepared in the operating room. Also, the new pumps were larger than the old pumps and there was a concern for space in the operating room and the elevators used for patient transfer. Therefore, a mock transport of a patient with multiple infusions from the operating room to the ICU was

performed. Because space was tight during transport, the anesthesia engineer designed a new pole system for transport. For the emergency department, it was recommended that the ICU drug library should be used for all infusions unless it was known that the patient would be placed on a medical-surgical unit. With regard to patient-specific recommendations, for pediatric patients, the syringe pumps would continue to be used for low-volume infusions; syringe pumps compatible with the new i.v. pump should be purchased to add the protection of programming with the drug-library limits.

Drug library creation. A committee composed of pharmacists, nurses, an anesthesia engineer, and physicians created the pump drug library. Six libraries were created based on care

area: medical–surgical, intermediate care, cardiac care, adult ICU, pediatric ICU, and general pediatrics. The anesthesia ranges for medications were available within the respective drug library when the pump was set in anesthesia mode. All continuous infusions that were approved for use in the care area were included in the specific library. The pharmacy and anesthesia literature was reviewed for common medication dosing ranges, and the upper and lower limits for a medication were set considering the acceptable range limits for the patient population and common dose ranges in a care area. Patient safety and the potential for medication dosing outside of literature-based ranges were used to set the final limits. All limits were soft, allowing override based on user judgment, except for a hard upper limit on heparin in the pediatric libraries. Standard concentrations were determined for each medication; however, about one third of the medications had multiple concentrations listed to decrease the need for concentration programming by users. Consensus was achieved after review by all disciplines, with outstanding issues resolved in consultation with the chair of the pharmacy and therapeutics committee. Users were required to use the drug library when programming medication infusions and bolus doses.

Postimplementation outcomes. Specific measures were used to determine the success of the actions that were implemented as a result of the FMEA. These measures included (1) conducting audits of pump programming to evaluate use of the drug libraries, correct patient profiles, channel labels, and tubing placement, (2) monitoring of mandatory end-user training, and (3) monitoring and recording all i.v. medication administration event reports and informal and formal complaints about pump functioning or events for three months postimplementation. Three months is the typical period after technology implementation during

which the users are experiencing the effects of the technology change.³³⁻³⁵ The team used the event reports data to gain a descriptive sense of what problems occurred and used the pumps' event log data for a quantitative analysis of user response to dosing alerts and programming errors that were averted. Patient resuscitation events were also observed for problems using the new pumps.

Several problems were noted in the first three months postimplementation (Table 3). Five of the problems were not anticipated by the FMEA team during failure-mode generation, including three free-flow events, one of which was related to tubing misplacement.³⁶ Two problems were related to unintended consequences of implementing the new i.v. pump (loss of rate-taper function and incompatibility of tubing with a desired needleless injection port).

Audits of pump use were conducted at various times during the first three months after implementation. Two weeks after implementation, a 475-infusion audit found the drug library was used in 99.6% of medication infusions, channel labels in 80%, and the correct profile in 97%. One infusion had incorrect tubing placement. Six weeks later, in a 485-infusion audit, 99.6% of medication infusions used the drug library, 76% used channel labels, and 96% had the correct profile. Table 3 outlines the events and problems reported in the three months after i.v. pump implementation, how the events were reported, if patient harm occurred, and the actions taken.

Event log data were downloaded from two thirds of the i.v. pumps after three months of use. This revealed 301 separate dosing alerts that led to reprogramming of the infusion rate when the initial programming was for a dosage outside the set limits. A total of 187 dosing alerts (62%) occurred for doses programmed above the upper limit. Of those, 72 were at least 10 times above the programmed limit. Approximately 3 dosing alerts

per day resulted in reprogrammed doses, within drug library limits, which prevented potential pump programming errors from reaching patients.

Discussion

The FMEA process at our institution identified key failure modes in the medication process with the use of the old and new pumps, and actions were taken to avoid errors and adverse events. We previously described challenges encountered when performing this FMEA.²⁶ Particularly challenging were the time and resources needed because of the complexity of the medication-administration process and the incorporation of a new technology into the process. However, team members remained devoted to the completion of the project, and the hospital supported member participation. A pharmacist team facilitator who had a full understanding of the medication-use process, FMEA, human factors, and technology was critical for the team to remain on task and function effectively. The team also had difficulty with the hazard scoring system presented in the HFMEA technique, particularly the use of a 4-point scale for severity and probability of occurrence scoring. It did not allow sufficient specificity in scoring to prioritize the large number of failure modes in the FMEA, as most harm was considered major or catastrophic (3 or 4) and most probabilities were rated frequent (4) due to the human element in the process. Our institution has since returned to using the classic risk priority number scoring that uses 10-point scales for severity, probability of occurrence, and likelihood of detection.¹⁸

External and internal sources of information were critical to the success of the FMEA. Online technology user groups, listservers, and FDA's MAUDE database provided information about device implementation problems and potential adverse events that organizations and vendors may not otherwise pub-

Table 3.
Problems Reported after Implementation of Smart I.V. Pump

Problem ^a	Reporting Mechanism ^b	Temporary Harm	Action(s) Taken
Anticipated by FMEA ^c team			
Wrong weight entered for infusion	R	No	Training and education
Incorrect drug profile used	A	No	Training and education
Channel labels not used	A	No	Training and education
Drug library not used for infusion	A, R	No	Training and education
Drug library not used for bolus infusion	I	No	Training and education
Wrong rate programmed and alert overridden (10-fold overdose)	R	Yes	Education about alert overriding
Wrong rate programmed and drug library not used	R	Yes	Education about drug-library use
Air-in-line alarms or clearing air	C, R, N, I	Yes	Training and education
Wrong channel programmed	R	Yes	Education, move toward integration with point-of-care bar coding
Pole clamp breakage	A	No	Replacement of all pole clamps
Pump handle breakage	A	No	Replacement of all handles
Unused pumps not returned for reprocessing before patient discharge	C	No	Education, process change
Needle puncture of needleless tubing valves	C	No	Education
Not anticipated by FMEA team			
Free-flow event from tubing misplacement	C, R	Yes	Redesign of i.v. pump
Cyclosporine infusions with excessive air	R	No	Change preparation of drug
Tubing connection not secure due to Luer-Lok on new tubing (caught prior to implementation)	I	Not applicable	Change to less desirable flow-stop valve
Loss of rate-taper function on new i.v. pump	R, C	No	Education, process change
Propofol bolus dosage units unfamiliar to nurse users	C, I	No	Education, change drug library

^aEach listing may be as a result of one or more events or problems.

^bA = audit, C = call to i.v. pump nurse, I = informal, N = reported via toll-free vendor telephone number, R = Web-based event reporting system.

^cFMEA = failure mode and effects analysis.

licly acknowledge. Internal sources of data were also needed because end-user attendance at the FMEA meetings was inconsistent due to work schedules and time commitments. End-user input was supplemented by data from observations of the medication-administration process, which brought to light potential or actual failure modes and guided the process mapping.^{30,31} Hospital event reports also provided information on potential failure modes and contributing factors to adverse events and errors. Users of the i.v. pump performed pump programming for team members, which added a richer understanding of the process and potential failure modes. We also took advantage of engineering expertise to encourage technology redesign suggestions for the ultimate elimination of failure modes. The inclusion of engineers was previously reported to

encourage infusion pump redesign and was important with our own redesign issues.³⁶⁻³⁹

It is important for hospitals to be able to judge the success of their FMEA efforts and learn from the process. FMEA is very time-consuming and resource-consuming for a hospital,^{21,26} so the return on this investment must be measured. FMEAs are supposed to identify and reduce risk from potential or known failures. Traditional methods to judge the success of FMEAs in health care have focused on reporting that the FMEA process has decreased hazards by recalculating the risk priority number of the redesigned process step failure mode and showing that it has greatly decreased.^{24,40,41} This technique does not objectively judge whether the system is safer when the actions are implemented. Also, most FMEA studies that measure outcomes do

not report the occurrence of unintended consequences of change and technology implementation or unanticipated failure modes.²²⁻²⁵ In addition, using data from event-reporting systems to assess outcomes may be misleading because data are subject to voluntary reporting biases. For example, there may be an increase in reports because of increased awareness of the need to report errors when technology is implemented, or a decrease in events may occur due to fear of increased scrutiny of errors and fear of punishment.

We report anticipated failure modes that occurred postimplementation despite the implementation of our recommended actions. Most of the listed failures are unintended consequences of the new technology, and it is unknown if our efforts decreased the frequency or severity of these events (air-in-line alarms,

needleless valve puncture, issues with incorrect use of new pump programming features), as we recorded events during the technology change period after implementation. However, to our knowledge, most resulted in temporary harm or no harm to the patient. Because of the short period between the FMEA team process completion and pump implementation, there may not have been enough time to fully address failure modes such as the return of unused equipment. However, the team identified a mechanism to deal with the problem when it arose. In addition, appropriate overriding of dosing alerts was not highlighted in pump training; however, review of our override alert data showed that these events are more common than previously thought and therefore users would benefit from a stepwise decision-making approach to overriding alerts. Many failure modes with a high likelihood of occurrence or high severity if they occur were seemingly averted from occurring. Specifically, radio-frequency interference with walkie-talkie devices and problems with pump use in patient resuscitation situations have not been reported. Therefore, the goal of reducing risk to patients from potential or known failure modes appears to have been achieved.

Failure modes also occurred that were not anticipated by the team. These were used as learning opportunities for the team for future FMEAs. Four of the five were related to unanticipated technology issues, two of which would have been reasonable for our team to have identified (rate-taper function, unsecured tubing connection). The issue with propofol dosage unit configuration in the drug library may have been averted with more end-user input into the drug library creation. Free-flow events are perhaps the most hazardous of all i.v. pump infusion errors. Prior knowledge of a potential free-flow event at another institution facilitated vigi-

lance on the part of the FMEA team; when a free-flow event occurred, the team was able to investigate the event, determine the root cause, and seek a hardware redesign fix. FMEA teams should recognize that it is impossible to identify all failure modes prospectively to the change occurring. This obviates the need for a combined strategy of prospective risk analysis along with continuous monitoring after technology implementation.

Perhaps the biggest successes of the FMEA were related to end users consistently using the pump features and responding to dosing alerts to reprogram erroneous pump programming. Workarounds commonly identified at other institutions (i.e., not using the drug library⁸) were rarely found on hospitalwide audits and were infrequently noted in event reports. We believe our consistently high rates of drug library use for pump programming were related to the initial intensive training efforts and the training follow-up of our i.v. pump nurse. These were specific recommendations of the FMEA team and, therefore, a major success for the team. Also, the user input into the design of the pump drug libraries ensured a fit with clinical practice. Maximizing the use of technology of this type is important for hospitals to realize the full return on investment through decreasing medication errors. From a business perspective, to maximize the return on investment for the pump purchase, the drug library safety features must be consistently used in practice.

There are limitations to the use of FMEA. First, FMEA focuses on optimizing processes and often recommends training or education of staff and technology implementation as solutions to failure modes. However, these actions may be only partly effective unless organizational and environmental issues that promote unsafe conditions and deter quality are also addressed (culture of fear, lack of teamwork, inadequate re-

sources, poor communication, lack of performance standards, lack of feedback).^{16,42} We had very few solutions that recommended organizational or environmental change. Perhaps the most important was the recommendation for mandatory pump training. Second, the breadth and depth of FMEA team recommendations directly relate to the knowledge, skills, and attitudes of people on the team. Therefore, involving multiple disciplines and systems thinkers, providing team training on FMEA, and supplying data to inform team decision-making are critical for success.

Implementation of technology to improve patient safety must be carefully planned and managed in order to achieve desired results. New sources of error can and do occur following new technology implementation. This hospital, its end users, and its patients benefited from the use of FMEA to plan the implementation of a new i.v. pump with built-in safety features. In particular, FMEA helped with process redesign and made recommendations for mandatory user training, training elements, and technology software and hardware redesign. This resulted in consistent use of the new pump safety features and averted pump programming errors and harm. We reported both anticipated and unanticipated failure modes that occurred postimplementation and highlighted unintended consequences of the new i.v. pump that could lead to failure. This provides a reality-based perspective on the usefulness and success of FMEA. Perhaps the most beneficial outcome to this hospital was the development of a multidisciplinary team that provided the infrastructure for safe technology implementation, effective event investigation after implementation, and communication with device vendors regarding future technology changes. With continual updating of i.v. pump software and hardware after implementation, FMEA can be an important starting

place for safe technology choice and implementation and can produce site experts to follow technology and process changes over time.

Conclusion

FMEA was useful in identifying potential problems in the medication-use process when planning the implementation of new smart i.v. pumps. Monitoring for system failures and errors after implementation remains necessary.

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