

## F E A T U R E

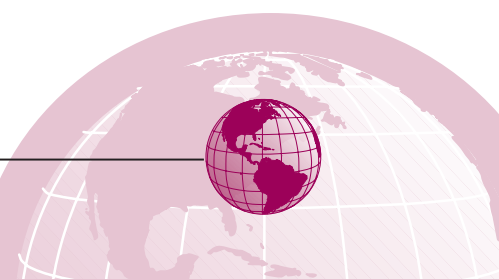
## A R T I C L E

# Smart Pump Technology

## What We Have Learned

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Intravenous infusion may present the greatest preventable medication administration error risk to hospitalized patients. Smart pumps can provide clinical decision support at the bedside for nurses who are administering intravenously administered medications with the potential to significantly reduce medication errors and subsequent patient harm. However, implementations of smart pumps have yielded mixed results and mixed perceptions of their ability to actually decrease error. To realize the potential of smart pumps, there must exist a clear understanding of how these devices are being integrated into healthcare organizations, specifically nursing practice. The purpose of this article was to describe current smart pump evaluation studies and to suggest areas of future evaluation focus.

### KEY WORDS

Evaluation • Medical devices • Medication errors •  
Nursing practice • Smart infusion pumps

### MEDICATION ERROR

In their report, “Preventing Medication Errors” (2007), the Institute of Medicine brought the problems associated with medication error into sharp focus and into the forum of public discussion.<sup>1</sup> The problems associated with medication error go beyond the potential harm to patients and the financial cost incurred by errors that are not averted.<sup>2</sup> The trust that patients have in their caregivers can also be seriously damaged once news of a preventable event causing patient harm is made public.

Intravenous (IV) infusion, both bolus and continuous, may present the greatest preventable medication administration error risk to hospitalized patients.<sup>3</sup> In a study of the IV medication administration process and error rates in ICUs, nurses cited several types of errors associated with the use of IV pumps such as setting the wrong rate, mistaking one drug’s pump for another, and adjusting the rate on the wrong medication. They also indicated that they were more likely to make these errors when unfamiliar with the drug or the patient population or when they were particularly busy or stressed.<sup>4</sup> Another study found that a lack of drug knowledge accounted for 10% of administration errors, while slips and memory lapses caused approximately 40% of errors.<sup>5</sup>

Innovations such as bar-code scanners, drug-dispensing cabinets, and smart pumps are among the new generation of medical devices intended to reduce healthcare errors, specifically medication administration error. As with many new devices designed for use in healthcare, medication administration devices are incorporating information technology that is intended to provide decision support at the point of care. The unintended consequences of the implementation of these devices are not always apparent, and prior to their use in practice, a thorough understanding of

how they affect patient outcomes is needed. Methods used to study medical devices in practice include such methods as failure mode and effects analysis (FMEA), heuristic evaluation, observation, and surveys. The purpose of this article was to describe current medical device evaluation methods using evaluation studies of smart pumps as a model and to discuss the strengths and weaknesses of various approaches.

### SMART PUMPS

Smart pump technology has the potential to significantly reduce medication errors and subsequent patient harm.<sup>6,7</sup> Smart pumps provide clinical decision support at the bedside for nurses who are administering IV medications; however, the implementation of smart pumps has yielded

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DOI: 10.1097/NCN.0b013e3181fcb66d

mixed results and mixed perceptions of their ability to actually decrease error.<sup>8-10</sup> To realize the potential of smart pumps, a clear understanding of how these and other medical devices are being integrated into healthcare organizations, specifically nursing practice, must exist.

As standard infusion pumps that control drip rate and set infusion volume were an advance over thumbwheel drip rate control, smart pumps represent an evolutionary step in IV medication administration technology. Smart pumps integrate information technology with elements of standard infusion pumps to provide clinical decision support for nurses at the bedside. Smart pumps are equipped with an IV infusion drug library that contains data on dose ranges, infusion rates, and dilution factors for infusion medications. Hospitals can customize these libraries to better fit their specific patient populations and local conventions for medication administration.

Managing IV infusions with smart pumps is essentially the same as managing infusions with regular IV pumps. The nurse enters the volume of fluid to be infused and the rate to infuse the medication. When using the smart pumps, however, the nurse also selects the name and concentration of the medication to be administered from the onboard menu-driven drug library so that the pump can deliver medication-specific messages and alerts. Alerts are generated when the parameters entered into the pump for the medication selected from the drug library do not fall within the guidelines for that drug.<sup>11</sup> Some pumps can also perform drug dose calculations, relieving the nurse of the time this task would take as well as the stress and danger of a possible miscalculation of correct dosage delivery rates.<sup>12</sup>

Smart pump alerts form two lines of defense. Soft alerts, the first line of defense, can be overridden, and the pump reprogrammed once the alert is acknowledged. One example of a soft alert is when a medication is programmed to be given at a slightly higher rate than what is generally recommended for that drug, as defined by the pump's drug library. The second line of defense against error that the smart pump provides is known as a hard alert; these alerts cannot be overridden. An example of a hard alert is when a medication is programmed to be infused at a much higher and more dangerous rate than what is specified in the drug library.<sup>13,14</sup> Hard alerts will not allow the medication to be administered, resulting in the need to verify the drug and ordered rate of infusion with the medication administration record, pharmacist, or physician.

The rationale for having both hard and soft alerts is that drug libraries cannot substitute for clinical judgment when adjusting medications for a particular patient. A reduction in reported errors of 73% was seen when implementation of smart pumps was combined with standardized concentrations for IV medications.<sup>15</sup> A fourfold reduction in heparin infusion-related FMEA risk-priority score (210 pre, 56 post) was reported after

the implementation of smart pumps as part of an IV medication safety system in three hospitals.<sup>16</sup>

In addition to identifying the impact of smart pumps on known causes of error, evaluation methods such as FMEA and heuristics have found new causes of error introduced by the pumps. One area of concern is the complexity of the drug libraries, primarily due to differences in dosing across a hospital. Differences in dosing patterns across different specialty units increase the risk that a nurse will select an incorrect concentration.<sup>17</sup> Targeted libraries that are specific to a unit could address this concern, but would limit the ability to keep pumps with a patient during and after transfers.

From a systems perspective, one barrier to maximizing the potential of smart pump technology to decrease error is the lack of integration of the pumps with other safety technologies such as electronic prescribing and bar-code medication administration systems. However, few hospitals report having implemented all components that would be required to link to other medication administration technologies and form a closed-loop system.<sup>18</sup> The development of interfaces that integrate these tools will take error prevention to the next level.<sup>13</sup> The keyboard and display of smart pumps constitute another area of concern. Poor legibility due to small screen size and fonts, insufficient backlighting and visibility, and small keypads can result in incorrect programming and error.<sup>19</sup>

## PREIMPLEMENTATION EVALUATION METHODS

Methods used to evaluate the potential effect of smart pump functionality on medication administration error rates include such techniques as FMEA, heuristic evaluation, observation of practice, and surveys.<sup>17,20</sup> The use of methods such as these can help organizations evaluate, in a cost- and time-effective manner, pump features, potential new sources of error, and usability of smart pumps prior to selection of a vendor and a particular pump product. Moreover, these analyses can contribute to the successful implementations of smart pumps by providing the necessary information to support nurses in the use of all smart pumps features and to avoid introduced errors. The findings of the analyses can also be important for vendors who can make use of them to guide further development of smart pump features and functionality.

Both FMEA and the heuristic evaluations have identified trouble with usability as a primary problem associated with smart pumps. Nurses who were part of the preimplementation evaluation teams had difficulty navigating the complex menus, reading the pump display, and with selecting the correct drug and concentration from the drug library. These usability issues, in turn, can create additional problems if nurses' perceptions are that they

will spend more time initiating an infusion, and consequently avoid the use of smart pump features. The result can be that nurses may develop negative attitudes toward the pumps and develop the habit of using them in standard mode without their decision support features.

Preimplementation FMEA and heuristic evaluations can provide valuable data for those considering the implementation of informatics tools such as smart pumps by studying and understanding how these devices will fit in and work in a particular setting. Being able to evaluate, ahead of purchase, how well a device such as a smart pump may affect known causes of medication administration error can support not only the decision to implement, but also the selection of the most appropriate vendor product. In addition, understanding the potential causes of introduced error from a particular device can help with the development of training and quality measures to minimize or avoid those new sources of error. The use of root-cause analysis methods, such as FMEA (now part of Six Sigma), can also be part of a larger methodology for process and quality improvement and management in healthcare.<sup>21</sup>

Given their use in formative studies, these methods can be used to avoid patient harm. Failure mode and effects analysis and heuristic preimplementation evaluation methods are an important component in a comprehensive evaluation tool kit. They can guide organizations to informed decision making by providing a framework and processes that have been shown to contribute to successful implementation and effective use.

## Failure Mode and Effects Analysis

Failure mode and effects analysis is an evidence-based, systematic method, originally developed by the US military. Failure mode and effects analysis involves the assembly of a multidisciplinary team to proactively identify the ways failure could occur in a proposed new process or with the introduction of a new device. The team also identifies and quantifies the effects of that failure, the severity of the effects, and the underlying causes.<sup>22</sup> One measure used by the team to understand the postimplementation impact of the new process or device is the risk-priority score. To determine risk-priority scores, the team first assigns a Likert scale rating to several factors associated with the causes of failure. The score itself is then generated by multiplying the individual scores for probability, severity, and detectability of errors together. Scores are then compared between the devices preimplementation and postimplementation periods.

In one preimplementation evaluation of smart pumps using FMEA, the evaluation team identified the majority of points of failure for smart pump processes (13 of 18 failure modes reported after implementation).<sup>17</sup> Several of the points of failure that were not anticipated related to

tubing connections and misplacement. These points of failure were addressed by changes to the pump design and training. It can be argued that these points of failure were not particular to smart pumps, but would have occurred with any new pump whose tubing setup was significantly different from the standard pump. Furthermore, the formation of a multidisciplinary team to perform the FMEA evaluation supported the successful implementation of the smart pumps. This team broke down barriers that typically exist between professional groups and guided the organization effectively toward change in their medication administration processes.

## Heuristic Evaluation

Adapted from human factors engineering for the evaluation of medical devices, heuristic evaluation also makes use of a team of experts who, in this case, work with guidelines about usability, also known as heuristics. Heuristics are adapted from commonly accepted usability principles that contribute to good design, such as the ability of a person to view the current state of a device, while using it, and a minimalist approach that avoids the display of unnecessary data that might distract the user.<sup>23</sup> The team then uses the heuristics to proactively evaluate a device, identifying design features that violate usability principles that could contribute to medical error.

In a preimplementation heuristic evaluation of smart pumps, a four-member panel consisting of usability experts and an ICU nurse, who had experience using the pumps, was assembled.<sup>20</sup> Smart pumps were evaluated according to 14 heuristic rules, such as consistency, language, and how well the device corresponds to the environment in which it will be used. In this study, 231 violations were discovered, including nine catastrophic ones, across all 14 rules, with consistency (14%) and language (12%) having the highest number of violations. The primary menu presented the highest number of rule violations (42%), followed by the options screen (17%) and physical interface (12%).

The most severe and serious violations were found to have violated multiple heuristic rules, a minimum of 8, perhaps indicating a snowball effect with certain initial violations. As with FMEA, the results of this evaluation contributed information that is important to improving the design of the pumps as well as highlighting pump use practices in the clinical units that warranted further evaluation.

## POSTIMPLEMENTATION EVALUATION METHODS

Postimplementation evaluation studies have focused on outcomes using smart pump logs, self-reports of medication

administration error, and chart reviews. These studies have described both increased rates of averted medication administration errors and reductions in reported errors after the implementation of smart pump technology. Studies that evaluate self-reports of medication administration error can identify the causes of medication error and are important not only to understand how devices such as smart pumps affect those causes, but also to identify new causes of errors, workarounds, and barriers to effective use. Studies using observational methods and chart review are challenging to conduct, in terms of time and effort, but they are necessary additions to a comprehensive evaluation toolbox, a toolbox that must include methods for understanding after implementation how smart pumps are actually being used at the bedside in the hands of nurses.

## **Error-Reporting Data Analysis**

Quantitative and qualitative data related to IV-related medication administration error were collected over the course of 1 year as part of the MEDMARX, a national medication error-reporting program. The MEDMARX registry collects data on adverse drug events for more than 400 healthcare organizations across the United States, to support patient safety and quality improvement. An analysis of quantitative data collected from MEDMARX participants found that 5.03% of IV medication errors resulted in patient harm. Analysis of narrative data, describing the causes of error, suggests that the majority (89%) could be attributed to three factors: performance deficit, procedures not followed, and errors in transcription.<sup>3</sup>

Secondary data analysis of medication error reporting can be limited by two factors: the number of actual errors reported represents a small percentage of those errors actually committed, and analysis is restricted to the variables collected in the database. Error reports often fail to provide the level of detail necessary to determine which device features could have been responsible for the error occurring. For example, onboard drug libraries and dose calculators are two pump features that provide the most support for reducing two of three factors that contribute to dosing errors, procedures not followed and performance deficit; how these features contribute to medication error are not included as data collected in most error-reporting databases.

Getting an accurate assessment of the actual impact of smart pump technology on medication error rates is also complicated by the frequent lack of complete and accurate data on medication administration errors prior to smart pump implementation.<sup>8</sup> Comparing rates across studies can also be complicated by the varied levels of information technology in use at the study sites, the different implementation processes, and the different methodologies used to evaluate the level of risk reduction.

Chart review is also limited in the sense that secondary data analysis can be done only retrospectively. The primary purpose of a patient chart is to provide data for patient care, not to provide data for research. The chart may not contain complete data or the data required for a comprehensive study. However, chart review allows for retrospective preanalyses and postanalyses and can give us an understanding of the effect of a particular type of error on a particular patient over his/her time on a unit.<sup>24</sup> This study has determined that the more significant contributors to preventable error include failure to monitor, failure to intervene, and incorrect or no rate specification on the medication label. Thus, smart pumps not integrated with other medication safety technologies that address these specific types of problems stand little chance of affecting preventable errors. With the medical and nursing information that chart review has available, the impact of smart pumps can be seen in the context of the full patient experience over time.

## **Observational Studies**

A postimplementation observation study also suggests that current smart pumps lack design features that would further reduce certain common causes of error, such as variability in medication administration processes, delays in medication administration, patient identification errors, and inattention to alerts.<sup>13</sup> Only one of the 389 documented errors, with 426 observed medication administrations, would have been prevented by current smart pump features. Incorporating additional medication administration safety components, such as bar-code medication administration, and developing interfaces with other hospital information systems were identified by this study as additional requirements for reducing error.

## **Postimplementation User Perception Evaluations**

User acceptance and satisfaction evaluations evaluate the thoughts and perceptions of the largest group of smart pump users, nurses. Not only are nurses the main users of smart pumps, they also do the final check for safe medication administration at the bedside. Without an understanding of how nurses think and feel about the pumps, we will be unable to ensure that the pumps reach their full potential to reduce patient harm. Experiences with pumps that have design or functionality problems can result in negative perceptions of smart pumps, even 1 year after implementation.<sup>25</sup> Positive experiences, often the result of inclusion and careful planning, can increase the level of confidence nurses feel in their own ability to safely use the technology, which in turn can help nurses



feel that pumps can have a positive impact on patient safety.

Several studies that have examined nurses' satisfaction with and acceptance of pumps have yielded mixed findings. High levels of satisfaction and positive attitudes toward smart pumps were associated with the involvement of nurses in the process of evaluating causes of medication administration error, inclusion of nurses in all phases of implementation of the pumps, supportive changes identified and made to workloads and processes prior to implementation, and adequate training on smart pump use as well as on potential new sources of error.<sup>14,20,26</sup> A high level of compliance (98%–100%) with the use of smart pump features was attributed to the positive contributors, as well as the perception that the pumps promoted safe nursing practice.<sup>27</sup>

The lack of nursing involvement in the evaluation and implementation of smart pumps has resulted in nurses developing workarounds to bypass smart pump features, including decision support.<sup>7,28</sup> Work processes that were not reengineered effectively, inadequate training, and unanticipated problems introduced by poor pump design or minimal drug libraries led to feelings of frustration and a lack of acceptance of the pumps.<sup>28</sup> One study attributed the lack of real reduction in error, 2.03 errors per 100 patient-pump-days for the control period and 2.41 during smart pump use, to the ineffective use of smart pump features.<sup>9</sup>

With user satisfaction surveys as a postimplementation evaluation tool, we can clearly identify human-computer interaction problems and interface design problems that can be seen only in the clinical arena. We can also attempt to identify less well-defined problems that may have more to do with feelings and perception than a poorly designed menu or screen. These can be important contributors to workarounds and ineffective use, potentially contributing to the error rather than reducing it. Evaluative methods such as user satisfaction surveys are another valuable component in our evaluation tool kit because of the importance of those who will be using the smart pumps.

## ADVANTAGES AND DISADVANTAGES OF EVALUATION METHODS

### Failure Mode and Effects Analysis and Heuristics

Failure mode and effects analysis is an effective evaluation method for detecting causes of error and understanding the effects of those errors. By assigning risk-priority scores to the causes of error and ranking them, attention can be focused on serious errors and what changes are needed for their risk to be eliminated or minimized. Failure mode

and effects analysis is limited in that it is not typically able to detect errors that have complex multifaceted causes. While FMEA is a highly structured evaluation method, as its name implies, it is intended, whether used preimplementation or postimplementation, to detect modes of failure rather than develop a comprehensive understanding of how a medical device exists and is used in situ.

Heuristic evaluations are flexible in that they can be designed to be inexpensive and simple or more complex, depending on the resources available. However, that flexibility can be said to be a lack of rigor, with the result that a medical device may not be evaluated at the level of detail required for safe and effective use. Heuristic evaluation can be described as an inspection of the usability of a device and may not include an examination of the system the device will be used in or be able to suggest means for addressing usability problems. Identifying and including enough subject matter experts who have expertise in usability engineering, information technology, and the area of clinical practice that the device will be used in can also be challenging even for large healthcare organizations. The experts who form the evaluation team also emulate actual users and may not be able to fully predict all uses of the device.

In addition to these constraints, FMEA and heuristic evaluation designs are fairly static, adapting their design to evaluate different clinical scenarios or to test device redesigns requires changing the evaluation protocol, a time- and resource-intensive process. This lack of flexibility limits the number of testing scenarios that can be accomplished with these methods and potentially limits the likelihood they will be used over the life cycle of a medical device. While both these methods have limitations, they have a distinct benefit in that they can be conducted before a device is introduced into clinical practice and can therefore prevent error and reduce the potential for patient harm.

### Secondary Analyses and Observation Evaluations

Evaluations based on secondary analyses are limited by the purpose and method for the primary data collection and by being a retrospective method, which cannot be completely controlled. The questions they can answer can depend on whether the data are robust enough to support secondary analyses and can result in an incomplete picture of a medical device. The usefulness of secondary analysis for understanding the causes of medical error and medication error, in particular, cannot be argued; however, secondary analyses of devices ask more specific questions than the original study design may be able to support.

The main strength of observation and medical chart review evaluations is that they can more directly look at

the use of medical devices as they are being used in the clinical environment, by actual users. The understanding that can come from these methods can be an invaluable contributor to effective device use as well as in assessing the overall impact of a device as it is used in the real world. Disadvantages include the relatively low numbers of observations that can be made or charts that can be reviewed because, in part, of the significant time and effort required. Observation is also subject to the Hawthorne effect, with participants adjusting their behavior because they are being observed.

While secondary analyses, observation, and chart review can be effective evaluation methods, they are possible only after implementation, after error has occurred, and are not predictive in nature. They are at their most useful after a medical device has been implemented. Similarly, user acceptance evaluations are typically conducted postimplementation. While understanding the contributors to user acceptance and satisfaction can help support a successful implementation if rejection is averted, they are not intended to formally identify failure modes or causes of error or to suggest solutions for failures or error.

## Recommendations for an Evaluation Tool Kit

A comprehensive evaluation tool kit would ideally include a variety of formative, summative, and hybrid evaluation tools for all phases of a device's life cycle. Tools included would be able to fit small to large organizations and include human factors tools and tools for process improvement and error investigation. Particularly important to develop are evaluation methods that can identify causes of error ahead of time. Methods that make use of heuristics and FMEA evaluations using expert teams can provide valuable guidance for implementation; however, they do not allow us to see what will happen in the complex clinical setting.

In the past, healthcare organizations have generally used simulation for educational purposes, improving patient safety indirectly through expanding the knowledge and preparation of individual healthcare workers.<sup>29</sup> Simulation, however, is being increasingly used as a tool in healthcare for research and evaluation of new technologies and processes prior to implementation.

Recent work by Trbovich et al<sup>30</sup> has demonstrated the effectiveness of using clinical simulation to evaluate the impact of smart pumps on medication administration error. Surprisingly, the study's findings suggest that soft alerts did have a significant impact on rates of medication error and that secondary infusion error rates were not different between smart and standard infusion pumps. The development of evaluation methods that make use of clinical simulation can clearly provide unexpected and

valuable information that may not be gleaned from other methods.

Our recommendations are that an evaluation tool kit be developed to support the successful integration of informatics devices into healthcare, the effective use of these devices throughout their life cycle, and that the tool kit include clinical simulation evaluation methodologies (CSEM). Developing CSEM can help prevent error by allowing mistakes to be made, analyzed, and evaluated without the risk of patient harm. Clinical simulation evaluation methodologies can include a rapid application development approach, long used in software development, which uses an iterative process for development and prototyping, refining in cyclic phases to ensure accurate and effective simulations. Developing methods that organizations can use to include clinical simulations in their evaluation tool kits is the first step to having clinical simulation evaluations be available to small clinics as well as academic research medical centers, which are typically equipped for high-fidelity simulations.

Challenges will include finding low-cost means to provide high-fidelity, modular components to allow for simple or complex simulation scenarios and flexible analytic methods for simple or complex data. The benefits to CSEM would include a holistic approach that ranges from human factors to device features as well as the complex interactions between all aspects of the clinical environment.

## CONCLUSION

By reviewing the evaluation tools in use today and identifying gaps, we can work toward developing a comprehensive evaluation tool kit that will contain tools for all phases of a device life cycle. Life cycle-focused evaluation tools can also identify contributors to effective use in nursing practice. Including clinical simulations of IV medication administration at the bedside by nurses as one of these tools can bridge the evaluation gap between preimplementation feature and function analyses and postimplementation bedside use, bringing the benefits of summative evaluation methods into the preventive world of formative evaluation.

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