

# Intravenous Smart Pumps

## Usability Issues, Intravenous Medication Administration Error, and Patient Safety



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### KEYWORDS

- IV infusion/medication error • IV smart pump • Patient safety
- Medical device usability

### KEY POINTS

- Although the use of intravenous smart pumps has been associated with reductions in medication error rates, they have not eliminated error.
- Current data do not support that the use of intravenous smart pumps has had a measurable impact on decreasing adverse drug events.
- The administration of multiple intravenous infusions, secondary infusions, intravenous boluses, and titrated doses are particularly prone to errors.
- Intravenous smart pump programming errors often result from use errors related to the infusion device interface.
- There is a clear need for innovation in intravenous smart pumps to address usability and safety challenges.

### INTRODUCTION

Intravenous (IV) infusion pump systems are among the most frequently used technologies in health care. An estimated 90% of hospital patients receive IV medications via infusion pumps,<sup>1</sup> an indication of how pervasive these devices are in patient care, particularly in critical and acute care settings. Clinical use of IV smart pumps with built-in dose error reduction systems (DERS) began at Massachusetts General Hospital in 1996 and has since become widely accepted as a standard of care for the reduction of infusion-related medication error.<sup>2</sup> A 2012 national survey by the American Society of Healthcare System Pharmacists found a 77% adoption rate of IV Smart

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pumps by US hospitals.<sup>3</sup> Although the use of IV smart pumps has been associated with decreases in medication error rates, they have not eliminated error.<sup>4–6</sup> Furthermore, current data do not support that the use of IV smart pumps has had a measurable impact on decreasing adverse drug events (ADEs).<sup>4,7,8</sup>

Common sources of user error include overriding dose error alerts and, even more concerning, manually bypassing the drug libraries and DERS completely.<sup>9,10</sup> The complexity of the device user interface, the time required to program the DERS, and incomplete drug libraries are among the most frequently cited reasons that nurses bypass IV smart pump safety features.<sup>11</sup> The complexity of IV medication administration and the multiple steps involved demands close attention to detail and ultimately relies heavily on human–device interaction to detect and mitigate errors. Clinicians in the busy critical care and medical-surgical clinical environments are frequently interrupted and rushed during IV smart pump programming. As a result, the overriding of alerts and programming outside of the DERS owing to time constraints and competing work demands are recognized as a part of daily clinical practice.<sup>9,12–15</sup> Despite an increasing focus in health care on patient safety and quality of care, and despite improvements in technology, medication errors and usability issues with IV smart pumps are a significant patient safety issue.<sup>16</sup> A recent review of the US Food and Drug Administration (FDA) Manufacturer and User Device Experience database for 2015 to 2017 revealed more than 23,000 submitted reports of malfunction and injury for the 3 most commonly used large volume IV smart pumps (Alaris, Baxter, and Hospira).

The ubiquity of IV smart pumps, along with a sense of urgency to address IV medication safety, has garnered the attention of several organizations focused on patient safety. The Association for the Advancement of Medical Instrumentation (AAMI) and the FDA cosponsored a summit in 2010 to prioritize patient safety related to IV infusions as a national concern.<sup>17</sup> In 2012, the National Quality Forum conducted an environmental analysis that resulted in 13 recommendations to improve safety of IV infusion devices.<sup>12</sup> The 2014 Emergency Care Research Institute identified alarm hazards and infusion pump medication errors as priorities that need immediate attention.<sup>18</sup> In 2015, Association for the Advancement of Medical Instrumentation initiated a multiyear national coalition to address IV infusion device safety.

## OVERVIEW: INTRAVENOUS INFUSION ERROR

IV medication administration is a complex, multistep process that provides numerous opportunities for error, with administration at the point of care as the part of the process most vulnerable to errors.<sup>19,20</sup> Medication error is a general phrase that encompasses multiple and distinct ways in which IV infusions can go wrong at virtually every stage of the medication delivery process. A failure modes and effects analysis of the set of processes used to deliver continuous drug infusions at an 11-bed pediatric ICU identified 6 elements of the process: (1) selecting the drug, (2) selecting a dose, (3) selecting an infusion rate, (4) calculating and ordering the infusion, (5) programming the infusion pump, and (6) delivering the infusion. The last 3 elements of the process had the highest risk profiles.<sup>21</sup>

**Table 1** provides an example that outlines and compares the required steps for programming a normal saline infusion at 125 mL/h within the medical-surgical drug library on 3 widely used large-volume IV smart pumps: BD/Alaris, Baxter Sigma, and Hospira Plum A+. These 3 manufacturers represent approximately 88% of the large-volume IV smart pumps in current clinical use in US hospitals, with Alaris as the most widely used.<sup>22</sup> Each pump requires between 11 and 17 steps to program an normal saline infusion, making it easy to see that even low risk infusions are not simple to program.

| Step | Sigma (SW Version v6.02.07)                                 | Alaris (SW Version 9.19)   | Plum A+ (SW Version 13.41.00.002)                           |
|------|---|--|---|
| 1    | Push "ON" button  | Push "ON" button   | Push "ON" button  |
| 2    | New patient? Hit YES  | New patient? Hit YES   | New patient? Hit YES  |
| 3    | Brings up library list, use arrow key to choose M/S library | Displays profile used last. Hit NO   | Brings up library list, use arrow key to choose M/S library |
| 4    | OK  | Brings up drug library list, select M/S library                              | ENTER   |
| 5    | Enter IV  | CONFIRM  | Hit Arrow up "A"  |
| 6    | Use arrow to scroll down to IV Fluids                       | Asks for patient ID, Hit EXIT  | Arrow/Page down to IV Fluids                                |
| 7    | OK  | Brings up list of available channels (up to 4), select channel               | ENTER   |
| 8    | Choose PRIMARY or SECONDARY                                 | Chose from Guardrails drugs, Guardrails IV fluids, or basic, Chose IV FLUIDS | Enter RATE  |
| 9    | OK  | Select alphabet range that includes the letter "N"                           | Hit ARROW DOWN BUTTON                                       |
| 10   | Enter RATE  | Select the letter "N"  | Enter VTBI  |
| 11   | OK  | Select NS  | Hit START   |
| 12   | Enter VTBI  | Correct? Hit YES   |   |
| 13   | OK  | Hit RATE ARROW KEY   |   |
| 14   | Confirm volume given as 0                                   | Enter rate using keypad  |   |
| 15   | Hit RUN   | Hit arrow key to chose VTBI  |   |
| 16   |   | Enter VTBI   |   |
| 17   |   | Hit START  |   |

*Abbreviations:* IV, intravenous; M/S, medical-surgical; NS, normal saline; VTBI, volume to be infused.

An analysis by the Emergency Care Research Institute patient safety organization of medication errors at 80 health care organizations—including acute care and pediatric hospitals and long-term care facilities—categorized the medication use process as having 4 stages, or "nodes": prescribing, dispensing, administering, and monitoring. Of 695 ADE submitted by participating health care organizations over a 5-week period in 2011, the majority (67.7%) occurred during medication administration, followed by dispensing (16.1%), prescribing (8.5%), and monitoring (7.8%). IV-related errors, the most frequent occurrences of medication errors reported, represented 36.9% of administration-only ADE reported in this analysis. Some ADE involved errors at multiple stages of the process. The most commonly reported types of IV administration errors included drug not given (22.9%), due to failure to open the tubing (especially when a secondary infusion was administered) or to connect the IV line to the patient to allow the drug to be infused; wrong pump rate (20.3%); wrong drug (16.9%); and wrong dose (13.6%).<sup>20</sup>

Programming errors are known to contribute to medication errors involving IV infusion devices, because data support that the majority of ADE are the result of incorrect

programming.<sup>12</sup> Examples of programming errors include incorrectly entering (or selecting from menus of) drug names, doses/concentrations, rates, and times<sup>23</sup>; bypassing the drug library (either accidentally or intentionally)<sup>7</sup>; and administering an incorrect or unauthorized medication, and overriding drug limits or alerts.<sup>7</sup> Programming errors can result from incorrect clinical decisions, mental computation errors, keystroke errors, or use errors related to the infusion device interface (eg, entering information into the wrong field).<sup>24</sup>

### **ERROR PRONE PROGRAMMING TASKS: MULTIPLE INFUSIONS, SECONDARY INFUSIONS, AND BOLUS DOSING**

Administration of multiple IV infusions, secondary infusions, IV bolus, and titrated doses are particularly prone to errors. Landmark studies by the University Health Network in Toronto<sup>25,26</sup> examined the types of reported incidents and errors associated with both sequential infusions through the same channel of a single infusion pump and concurrent infusions using separate channels on the same IV pump or on multiple pumps. Incidents reported and analyzed from the Institute for Safe Medical Practices in Canada for almost a decade (May 2000 to April 2010) indicated that incidents occurred during all methods of multiple IV infusion administration—sequential, concurrent, or a combination of both. Given that some patients can receive as many as 10 to 15 IV infusions at 1 time,<sup>26</sup> via different methods of administration and multiple pumps and lines, the potential for mix-ups and errors is very real. Multiple infusions place additional cognitive demands on clinicians, are not well-standardized, have many associated failure modes, and errors are not easily detected.<sup>25</sup>

Medication administration by secondary infusion is the most common method for administering IV medications ordered for 1-time or intermittent dosing, especially IV antibiotics. Secondary administration is designed to allow the primary continuous infusion to resume automatically once the secondary infusion is complete. To ensure that the secondary medication infuses as intended, most IV smart pumps (with the exception of the Hospira Plum series) require the nurse to manually increase the secondary IV bag height, so that the secondary hydrostatic pressure differential is great enough to prevent flow of the primary infusion until the secondary infuses completely. If the bag height differential is not great enough to prevent flow of the primary infusion, the secondary may not infuse at all, or both bags may infuse concurrently at unpredictable rates. This will occur even if the pump is programmed correctly.<sup>25</sup> Either situation leads to a medication administration error that is rarely identified or reported. The need for bag height differential for most IV infusion pumps, the complex acute care environment, the high cognitive load required for IV medication administration, a high frequency of interruptions, and a lack of standardized training and education regarding the relevant principles for secondary infusions all contribute to increased human error during secondary medication administration.<sup>25</sup>

During their field study, Cassano-Piché and colleagues<sup>25</sup> identified the following issues related to secondary infusion as having the potential to lead directly to patient harm: secondary medication is connected to a high-alert primary medication infusion; secondary medication is a continuous infusion of a high-alert medication; insufficient bag head height differential between primary and secondary infusions; secondary tubing is connected to the wrong port along the primary tubing; secondary IV tubing remains clamped after the secondary infusion has started; the secondary IV tubing is connected to a primary infusion set with no back check valve; and the infusion pump does not support the administration of a secondary infusion on a primary line

programmed using the drug library. The following case study on error with secondary infusion was included in their report:

*An experienced nurse worked on a general ward that rarely ran secondary infusions. She was not trained specifically on this feature of the infusion pump, but was able to figure out how to use it. Her patient was receiving D5W mixed with half-normal saline via an infusion pump at 40 mL/h. She had orders to administer morphine prepared in a 100 mL bag. She administered it as a secondary infusion on the D5W– half-saline primary line at a rate of 2 mL/h. The nurse was caring for several other patients and wanted to receive an alert after 5 hours to check on the morphine infusion before the end of her shift, so she (deliberately) set the volume to be infused (VTBI) to 10 mL instead of the 100 mL bag volume, expecting the pump to stop and sound a volume-complete alarm, as it does in the primary mode. However, the secondary mode is not designed this way on all pumps. After 5 hours, the pump automatically switched from the secondary to the primary mode, resulting in the remaining 90 mL of morphine in the secondary bag being infused at 40 mL/h. The nurse went home at the end of her shift not having noticed the error, and several hours later the patient was found dead in bed.<sup>25(p35)</sup>*

As a single dose of medication administered in a short period of time for a therapeutic purpose, medication administration by IV bolus dosing has the potential to cause more serious harm to patients than infusions administered at slower rates. In an observational study of IV medication preparation and administration in an ICU of a teaching hospital, the most common type of error was the injection of bolus doses faster than the recommended rate.<sup>27</sup> In another observational study of IV medication administration in 6 wards across 2 teaching hospitals, administration by bolus was associated with a 312% increased risk of error.<sup>28</sup>

Cassano-Piché and colleagues<sup>25</sup> observed 3 methods that were used for IV bolus dosing when not using the IV smart pump bolus feature: temporarily increasing the rate of a currently infusing medication, preparing an IV syringe with the bolus dose and administering the bolus as a manual IV push, and preparing an IV bag with the bolus and administering the bolus as a secondary infusion. Of the 3, only the latter two were considered safe.<sup>25</sup> It is important to note that regardless of which method is used, the dead volume contained in the primary infusion tubing will be flushed as the bolus is administered, making it unsafe to use any method of IV bolus dosing in an IV line, which contains high-alert medications.

Issues identified as contributing to error with IV bolus dosing on IV smart pumps included IV smart pump does not have a bolus feature, the bolus feature may not be enabled for every relevant medication, a lack of familiarity with programming the bolus, and complexity of the bolus feature leading to excessive amounts of time required to execute the programming sequence.<sup>25</sup> Additionally, the FDA recall database includes several class I recalls related to bolus features and functionality. The following case study provides an example of why it is unsafe to administer IV bolus doses using temporary primary infusion rate increases<sup>25</sup>:

*During a shadowing session, a nurse described a past incident during which she was administering a bolus by programming the primary infusion to run at the fastest possible rate. She intended to specify a VTBI to limit the bolus; however, she became distracted by a patient across the hall who was self-extubating. She pressed the start button without changing the VTBI from the previously programmed value (entire bag volume); while she was assisting the patient across the hall, the first patient received a very large dose of morphine. The patient was not seriously harmed, but the nurse was so upset*

*that she no longer administers bolus infusions by changing the primary infusion rate.*<sup>25(p71)</sup>

## USABILITY ISSUES AND CLINICAL USE

As illustrated by the previous examples, medication errors should be considered failures in the drug delivery system, not human errors by front-line staff.<sup>21</sup> The 2010 Association for the Advancement of Medical Instrumentation/FDA summit on infusion device called for mitigating use errors with infusion devices by developing “design safety features that make it easy for the user to do the right thing.”<sup>17</sup> In a presummit survey, clinical, pharmaceutical, engineering, academic, and regulatory professionals identified a number of usability and user interface challenges with infusion devices, among many other challenges. Examples of the most troublesome issues cited by summit participants included the following.

- Programming features that require multiple screens to properly program devices, pushing of several buttons for programming, and pumps that are “incredibly difficult to program.”
- Confusing software menus and selection keys, and the use of numeric key pads, which result in “predictable” data entry errors.
- Screens that are difficult to read and that are at improper heights.
- Devices that are too big and too heavy, and that must be moved from IV pole to IV pole when patients are in transit.

In busy, stressful clinical settings, usability challenges contribute to IV medication errors, even by highly experienced clinicians.<sup>11,29</sup> Usability issues are compounded when multiple devices, and different brands of devices are in use. To safely deliver IV medication using multiple infusion devices, clinicians are required to master different pumps, different user interfaces, different accessories and supplies, and distinguish the most appropriate time for each to be used. A single patient can receive multiple infusions from different devices at the same time, and a single clinician can work in multiple settings of care. Variations in the standards of care for IV infusion therapy, different patient populations, transitions in care, and different environments of care can also increase the potential for error.<sup>15</sup>

## HUMAN FACTORS DESIGN AND INTRAVENOUS SMART PUMP USABILITY

The FDA has been advocating for the inclusion of human factors engineering as part of the medical device design process since the release of their guidance document in 2000.<sup>30</sup> The FDA now requires that potential hazards related to medical device use be addressed during device development, with user testing as the foundation at each stage of the product development process. Ongoing documentation of these efforts and adequate mitigation of all identified risks is now required as part of the regulatory approval process. The goal is to minimize use-related hazards, and to ensure that users are able to use medical devices safely and effectively in the environment for which they are intended.<sup>30</sup> Although these requirements exist for any new devices being introduced into the market, most of these requirements did not exist when some of the infusion devices in current clinical use were first introduced.

Over the past decade, the safety and usability challenges associated with IV smart pumps have resulted in numerous FDA recalls. When recalls occur, they are classified by the FDA into 1 of 3 possible classes according to the degree of associated health hazard.

Class I: a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

Class II: a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

Class III: a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

A review of the FDA recall database for large volume IV smart pumps between the dates of January 1, 2015, and October 9, 2017, revealed a total of 37 recalls of large volume IV infusion pumps, tubing and/or software for Alaris, Baxter and Hospira. Five of these recalls (14%) were class (Table 2).<sup>31</sup>

|         | Total | Class 1 | Class 2 | Class 3 |
|---------|-------|---------|---------|---------|
| Alaris  | 17    | 4       | 13      | 0       |
| Baxter  | 8     | 1       | 7       | 0       |
| Hospira | 12    | 0       | 12      | 0       |

Additionally, 2 highly publicized recalls resulted in IV smart pumps being permanently removed from the market. In 2010, the Baxter Colleague was discontinued. The FDA gave Baxter 2 years to complete their recall of between 200,000 and 250,000 IV smart pump channels in the US health care market. Customers were given the opportunity to transition to the Baxter Sigma IV Smart Pump, or receive a refund.<sup>32</sup>

In 2015 after multiple recalls, the Hospira Symbiq was permanently discontinued for sale. Because infusion devices are potentially life-saving, removing them from clinical use cannot happen immediately. It requires planning and a sequential approach. Unfortunately, shortly after the Symbiq was discontinued for sale, the FDA, the US Department of Homeland Security's Industrial Control Systems Cyber Emergency Response Team, and Hospira became aware of cybersecurity vulnerabilities associated with the Symbiq Infusion System. Hospira and an independent researcher confirmed that Hospira's Symbiq Infusion System could be accessed remotely through a hospital's network, allowing an unauthorized user to control the device and alter IV medication infusions. Although the FDA and Hospira were not aware of any ADE or unauthorized access, the Symbiq Infusion System removal needed to be accelerated to mitigate for this very serious risk.<sup>33</sup>

## NEED FOR INNOVATION

According to Nathaniel Sims, a well-known inventor and creator of the DERS, a broad view of the future of innovation in IV smart pumps would include<sup>34</sup>:

- Elimination of manual order entry and transcription;
- Patient-aware clinical support;
- Assisted caregiver programming;

- Autoprogramming, in which medication orders are sent directly to the infusion pump from a verified provider or pharmacy information system and then confirmed by a clinician before an infusion is administered;
- Autodocumentation of infusion pump programming, status, and alerts in electronic information systems; and
- Enhanced alerts and second checks.

An infusion pump workshop convened by the Applied Physics Laboratory at Johns Hopkins University in 2012 focused on a systems engineering approach to human factors solutions to most effectively address usability challenges.<sup>35</sup> Specifically, workshop participants cited the need for improvements in:

- System integration at the health information technology level—for ordering, pharmacy supply and control, documentation, and adherence to safety control—and at the bedside level for pumps and accessories;
- Programming navigation with better designed user interfaces;
- Information presentation and prioritization, with better ergonomics and visual and audio displays of critical information;
- Control standardization to minimize confusion and variation of controls and function representation on products from different pump manufacturers; and
- Context awareness, with information about all pumps, IV bags, and drugs for a single patient to provide a more comprehensive look at a patient's condition.

Finally, a review by Giuliano and Neimi (2015) lists several additional innovation needs<sup>16</sup>:

- Current pumps have a limited ability to communicate with one another.
- Pumps need to provide cross-pump guidance for the entire patient therapy.
- Pumps typically do not make use of patient information on the health care enterprise, making patient-centered guidance virtually impossible.
- Interoperability with other systems that provide pertinent patient-specific information (such as physiologic and laboratory parameters) that allows for profile-based and seamless patient care management is needed.
- Autoprogramming is ideal but, until those capabilities are more widely available, manual programming must be simplified. Most pumps are manually programmed through a series of nonobvious button pushes, do not use touchscreen technology, and the navigation to the DERS is often difficult and time consuming.
- The visibility of screens must be improved. Because of a small screen size and the limited capabilities of the pump, users are not able to see information to support optimal infusion delivery.
- Devices should be lighter, smaller, more portable, more rugged, and usable at eye level. Most pumps today are large, heavy, and not designed with transportability in mind.

## SUMMARY

There is a clear need for innovation in IV smart pumps to address usability and safety challenges. Although it is possible to address some of the issues with changes in clinical processes, the most fundamental challenges need to be addressed through innovation and the development of new technology using a human factors approach. As the primary users of the most complex configurations of IV infusion devices, critical care nurses are in the key position to guide innovation and conduct outcomes



research to measure the impact of innovation in this very important area of patient safety.

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