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,[1] 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.[2] 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.[3] Although the use of IV smart pumps has been associated with decreases in medication error rates, they have not eliminated error.[4–6] Furthermore, current data do not support that the use of IV smart pumps has had a measurable impact on decreasing adverse drug events (ADEs).[4,7,8]

Common sources of user error include overriding dose error alerts and, even more concerning, manually bypassing the drug libraries and DERS completely.[9,10] 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.[11] 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.[9,12–15] 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.[16] 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.[17] In 2012, the National Quality Forum conducted an environmental analysis that resulted in 13 recommendations to improve safety of IV infusion devices.[12] The 2014 Emergency Care Research Institute identified alarm hazards and infusion pump medication errors as priorities that need immediate attention.[18] 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.[19,20] 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.[21]

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.[22] 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.