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The urgent need for innovation in I.V. infusion devices

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More than a decade ago, the introduction of smart I.V. pumps with drug libraries and dose error reduction systems (DERS) provided an unprecedented means of reducing I.V. medication infusion errors. However, even with the availability of smart pumps, errors continue to occur in every clinical setting. A benchmark 2005 study found a staggering 67% error rate with the administration of I.V. infusions on an ICU.¹ Common sources of error included overriding dose error alerts and, even more concerning, using basic programming to bypass the smart pump's drug libraries and DERS completely.^{2,3}

This article provides an overview of the major I.V. infusion device user issues so that nurses can be better prepared to facilitate technology innovation in this important area of patient safety.

The problem

Smart I.V. infusion safety systems utilize drug libraries and DERS to reduce the chances of a programming error. Reasons that nurses bypass the drug libraries and DERS include both the complexity of the user interface and the time needed to program the DERS.⁴ Although some programming automation exists, the vast majority of smart pump programming is still completely manual.⁵ For nurses, this often results in a clinical conundrum when appropriate and timely medication administration is literally a matter of life and death.

The complexity of I.V. medications and the multiple steps involved in their preparation, administration, and monitoring create a scenario that demands close attention to detail and relies heavily on human intervention to detect and mitigate errors. The clinician at the point of care, most often a nurse, is accountable for the final step of ensuring that the correct I.V. medication or infusion fluid is delivered. Although the use of smart infusion technology reduces error in the administration of I.V. medication, I.V. infusion continues to be associated with 54% of potential adverse drug events, 56% of medication errors, and 61% of serious and life-threatening errors. Data support that up to 58% of all I.V. errors occur during actual drug administration, reinforcing the notion that the end user at the human-device interface is the final gatekeeper of safety.⁶

Summary of FDA recall database⁹

- extreme flow rate inaccuracies in both the high and low flow rate ranges
- sudden unattended halting of infusions while the run indication is still active
- pumps suddenly shutting off without warning, occurring across a number of different pump platforms and manufacturers
- incorrect medication dosing due to technical issues such as key bouncing (when the device mistakenly registers two button pushes)
- unintended drug delivery during priming, leading to overdose
- numerous technical issues such as faulty free flow safeguards, leading to increased and serious risk of drug overdose
- poor design, leading to frequent I.V. pump occlusions
- numerous battery issues, leading to a host of pump malfunctions
- touch screen programming failures.

Another important point is that even with programming within the DERS, smart pumps have no ability to detect a dosing error that falls within the recommended infusion dosing, even when the dosage isn't correct for the patient to whom the medication is being administered. This is where current smart pump technology falls particularly short and may be one of the reasons why infusion devices account for up to 35% of all medication errors that result in significant harm.⁶ Clinicians report that pump programming is frequently rushed and they often feel forced to make hasty decisions about overriding alerts because of time constraints and other demands placed on them.^{6,7}

Significant issues

The safety issues and problems with I.V. infusion devices (most of which are smart pumps) are well recognized and are a top priority for the FDA, which received 56,000 reports of infusion pump incidents (including 710 deaths) and issued 87 infusion pump recalls between 2005 and 2009.⁶ Since that time, the number of adverse events associated with I.V. infusion devices has only increased, especially in the most serious cases. (See *Summary of FDA recall database*.)

Class 1 recalls are defined by the FDA as "situations in which there is a reasonable probability that use of the recalled device will cause serious adverse health consequences or death."⁸ After adjusting for duplicate database entries, a recent review of the FDA infusion device recall database indicated an unprecedented total of 24 Class I recalls for I.V. infusion devices involving virtually every infusion device manufacturer on the market.⁹

Both the ubiquitous nature and severity of this issue have caught the attention of several organizations committed to improving patient safety. The Association for the Advancement of Medical Instrumentation and the FDA cosponsored a summit in 2012 to make safe I.V. infusions a top priority.¹⁰ Also in 2012, the National Quality Forum conducted an environmental analysis that resulted in 13 recommendations for improving safety during I.V. infusion administration.⁶

Finally, the top two hazards on the 2014 ECRI Institute's Top 10 Health Technology Hazards list are related to I.V. infusion pumps.¹¹ According to the ECRI Institute, the purpose of this list is to raise awareness of the potential dangers associated with the use of medical devices to help health-care providers minimize the risk of technology-related adverse events. Number one on the 2014 list was alarm hazards, including alarm fatigue, which cuts across many devices but is a common problem with I.V. infusion pumps. The second hazard on the list is infusion pump medication errors, a problem explicitly related to I.V. infusion devices, as previously discussed.¹¹

Impact of current hardware and software

One of the fundamental reasons for the pervasive quality and safety issues inherent in current I.V. infusion devices comes from the legacy designs that support their hardware and software. In the age of advanced computers, tablets, and touch screen operating systems, the look and feel of current I.V. devices and software are antiquated; they don't meet user needs for today's complex medication and fluid delivery, and aren't intuitive for the upcoming generation of clinical users. In addition, numerous hidden acquisition and operational costs associated with these designs make this outdated "classic" appearance quite costly.

Clinical usability issues to support optimal patient care

- Current infusion devices have a limited ability to communicate with one another. Pumps need to provide cross-pump guidance; that is, smart integration across devices to avoid overdoses for the duration of patient therapy.
- Pumps typically don't make use of patient information on the healthcare enterprise, making patient-centered guidance virtually impossible. Interoperability with other systems that provide pertinent patient-specific information (such as physiologic and lab parameters) would enable profile-based and seamless patient-care management.
- Autoprogramming is ideal but, until those capabilities are more widely available, manual programming must be simplified and require fewer steps. Most pumps are programmed through a series of nonobvious button pushes. 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 can't see information that supports infusion delivery.

- Devices should be lighter, more portable, more rugged, and usable at eye level. Most pumps today are large, heavy, and not designed with transportability in mind.

In one example related to hardware, a large teaching hospital in the Northeast purchased 250 new infusion pumps in 2012. When the preventive maintenance period arrived in 2013, a third of the fleet had cracked tops, requiring a minimum of 1 hour of repair each. When queried about the frequent fail rate of the external housing, the vendor's support representative noted that the pump was based on a 15-year-old design and continued to use construction materials of that same vintage. In this case, the manufacturer documented that modern cleaning methods can actually damage the pump, although it was unwilling to assume any of the associated costs. Instead, the hospital incurred a substantial and unbudgeted cost in labor and parts, and the clinical users had to work around longer-than-expected periods of I.V. infusion device down-time.

An occurrence at a different facility illustrates the impact of older software. In this case, an infusion pump in use was behind by four software releases and the vendor was adamant about the need to upgrade to the most recent software—an upgrade that had been promoted as “free” to customers. The clinical users were in no particular rush to upgrade because the end-user functionality of the new software wasn't different with regard to any of the pertinent clinical functions, and they didn't want to take on the workload of learning new software or delays associated with pump downtime without any obvious benefits. However, after much discussion, the upgrade was planned. It had to be done in stages and, most notably, at a dual expense to the facility. The first cost was a per-unit cost to get another device to replace the original because a new main board in the device was needed to upgrade the software. The second was a cost to be paid by the customer to the vendor if all of the pumps weren't found and replaced.

These are just two examples of the significant investment in time and money that's often required to keep these old platforms operational. In order to address the substantial cost and usability issues of current devices, new design considerations should be included in all future next-generation I.V. infusion device platforms. (See *Clinical usability issues to support optimal patient care*.)

The role of nursing leadership

The responsibility for manufacturers of I.V. infusion devices to build safer and more user-friendly systems can't be overemphasized, and nurse leaders are in an ideal position to play a significant role by requiring manufacturers to move more quickly on these important issues. Although clinical processes and changes in workflow can help address some of the problems that contribute to I.V. medication infusion errors, many of the fundamental issues will need to be addressed through innovation and the development of new technology.

The status quo and slow pace of change is simply no longer acceptable; it's imperative that manufacturers begin to address these problems in earnest. Both patients and clinical users rely on the expertise and integrity of the small number of large, global companies that

provide the vast majority of I.V. infusion devices for the acute care environment. Overall, known deficits in the technology must be improved. It's essential that I.V. infusion pumps adapt to the clinical environment rather than requiring the environment to adapt to the pumps.

Because nurses are the primary users of I.V. infusion devices, nurse leaders are in a key position to advocate and promote improvements in this very important area of patient safety. It will take a village of clinical users, pharmacists, human factors experts, and I.V. infusion device manufacturers working together to adequately address the multiple and complex issues associated with improving the ease of use and safety of I.V. infusion devices. This process must be combined with a disciplined and ongoing program of clinical outcomes research to generate credible peer-reviewed evidence to measure how well we're progressing. These research findings then need to swiftly make their way into clinical practice. Only then are meaningful and lasting improvements achieved in this important area.

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