Published in final edited form as:

Nurs Manage. 2015 March ; 46(3): 17–19. doi:10.1097/01.NUMA.0000461066.79777.06.

The urgent need for innovation in I.V. smart pumps

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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 a means of reducing I.V. medication infusion errors that hadn't been previously available. However, even with the availability of smart pumps, errors continue to occur in every clinical setting. A 2005 study found a staggering 67% error rate with the administration of I.V. infusions on an ICU.¹ Common sources of error include overriding of dose error alerts and, even more concerning, using basic programming to bypass the smart pump's drug libraries and DERS completely.^{2,3}

We provide an overview of the major I.V. smart pump user issues so that you 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 narrow 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 it takes 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 because, in some cases, 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 is being delivered. Although the use of smart infusion technology has been shown to reduce the incidence of error in the administration of I.V. drugs, 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 the actual drug administration step, again relying on the human end-user at the human-device interface as the final step in ensuring safety.⁶

Another important point to note is that even with programming within the DERS, there's no ability for smart pumps 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. Repeatedly, 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 demands placed on them.^{6,7}

Significant issues

The safety issues and problems with I.V. infusion devices are well recognized and have become 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 continued to increase, especially in the most serious cases. Class 1 recalls are defined by the FDA as "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."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 spanning virtually every infusion device manufacturer on the market.⁸ (See Table 1.)

Both the ubiquitous nature and severity of this issue have garnered the attention of several organizations tied to patient safety. The Association for the Advancement of Medical Instrumentation and the FDA cosponsored a summit in 2012 to make the issue of patient safety and I.V. infusions a top priority.⁹ 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. 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 healthcare providers minimize the risk of technology-related adverse events. Number one on the 2014 list was alarm fatigue, which cuts across many devices but is a frequent problem with I.V. infusions. The second hazard on the list is infusion pump medication errors, a problem explicitly related to I.V. infusion devices.¹⁰

Impact of current infusion pump hardware and software

One of the fundamental reasons for the pervasive quality and safety issues inherent in the I.V. infusion devices currently on the market comes from the legacy designs that support their hardware and software. In the contemporary age of advanced computers, tablets, and touch screen operating systems, the general designs, as well as the “look and feel,” of current I.V. devices and software are antiquated in both their appearance and function, 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, there are numerous hidden acquisition and operational costs associated with these designs that make this “classic” appearance quite costly.

In one example related to hardware, a large teaching hospital purchased 250 new infusion pumps in 2012. When the preventive maintenance period arrived in 2013, a third of the fleet came up with fractured top cases, 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 are actually considered damaging to 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 larger-than-expected periods of I.V. device downtime.

An occurrence at a different facility illustrates an example of the impact of older software. In this case, an infusion pump in use was currently four software releases back 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 functionality and they didn’t want to take on the workload and 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 Table 2.)

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 this is a place where nurse leaders are in an ideal position to play a significant role by requiring manufactures 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 are able to adapt to the clinical environment versus requiring the environment to adapt to the pumps.

Because nurses are the primarily users of I.V. infusion devices, nurse leaders are in a key position to 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. medication infusion devices. This process must be combined with a disciplined and ongoing program of clinical outcomes research to generate credible evidence that can stand up to peer review to measure how well we're progressing. These research findings then need to swiftly make their way into clinical practice. Only then will meaningful and lasting improvements in this important area likely be achieved.

References

1. Husch M, Sullivan C, Rooney D, et al. Insights from the sharp end of intravenous medication errors: implications for infusion pump technology. *Qual Saf Health Care*. 2005; 14(2):80–86. [PubMed: 15805451]
2. McAlearney AS, Chisolm DJ, Schweikhart S, Medow MA, Kelleher K. The story behind the story: physician skepticism about relying on clinical information technologies to reduce medical errors. *Int J Med Inform*. 2007; 76(11–12):836–842. [PubMed: 17112779]
3. Kirkbride G, Vermace B. Smart pumps: implications for nurse leaders. *Nurs Adm Q*. 2011; 35(2): 110–118. [PubMed: 21403484]
4. Carayon P, Hundt AS, Wetterneck TB. Nurses' acceptance of Smart IV pump technology. *Int J Med Inform*. 2010; 79(6):401–411. [PubMed: 20219423]
5. Evans RS, Carlson R, Johnson KV, Palmer BK, Lloyd JF. Enhanced notification of infusion pump programming errors. *Stud Health Technol Inform*. 2010; 160(Pt 1):734–738. [PubMed: 20841783]
6. National Quality Forum. Critical paths for creating data platforms: patient safety: intravenous infusion pump devices. http://www.qualityforum.org/Publications/2012/10/Critical_Paths_for_Creating_Data_Platforms__Patient_Safety__Intravenous_Infusion_Pump_Devices.aspx
7. McAlearney AS, Scheck A, Vrontos J, et al. Strategic workarounds to accommodate new technology: the case of smart pumps in hospital care. *J Patient Saf*. 2007; 3(2):75–81.

8. FDA. Medical device recalls. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm>
9. Association for the Advancement of Medical Instrumentation. Infusing patients safely: priority issues from the AAMI/FDA infusion device summit. http://www.aami.org/publications/summits/AAMI_FDA_Summit_Report.pdf
10. ECRI Institute. Top 10 health technology hazards for 2014. https://www.ecri.org/Resources/Whitepapers_and_reports/2014_Top_10_Hazards_Executive_Brief.pdf

Table 1

Summary of FDA recall database

•	Extreme flow rate inaccuracies in both the high and low flow rate ranges
•	Sudden unintended 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
•	Unintended drug delivery during priming, leading to overdose
•	Numerous technical issues, 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
•	Touchscreen programming failures

Table 2

Clinical usability issues to support optimal patient care

•	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 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) 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 made more simple 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, smaller, more portable, more rugged, and usable at eye level. Most pumps today are large, heavy, and not designed with transportability in mind.