



IMPROVING INTRAVENOUS THERAPY: OPPORTUNITIES FOR
DESIGNING THE NEXT GENERATION INFUSION SYSTEM
PART 1 – SUPPORTING MEDICATION SAFETY

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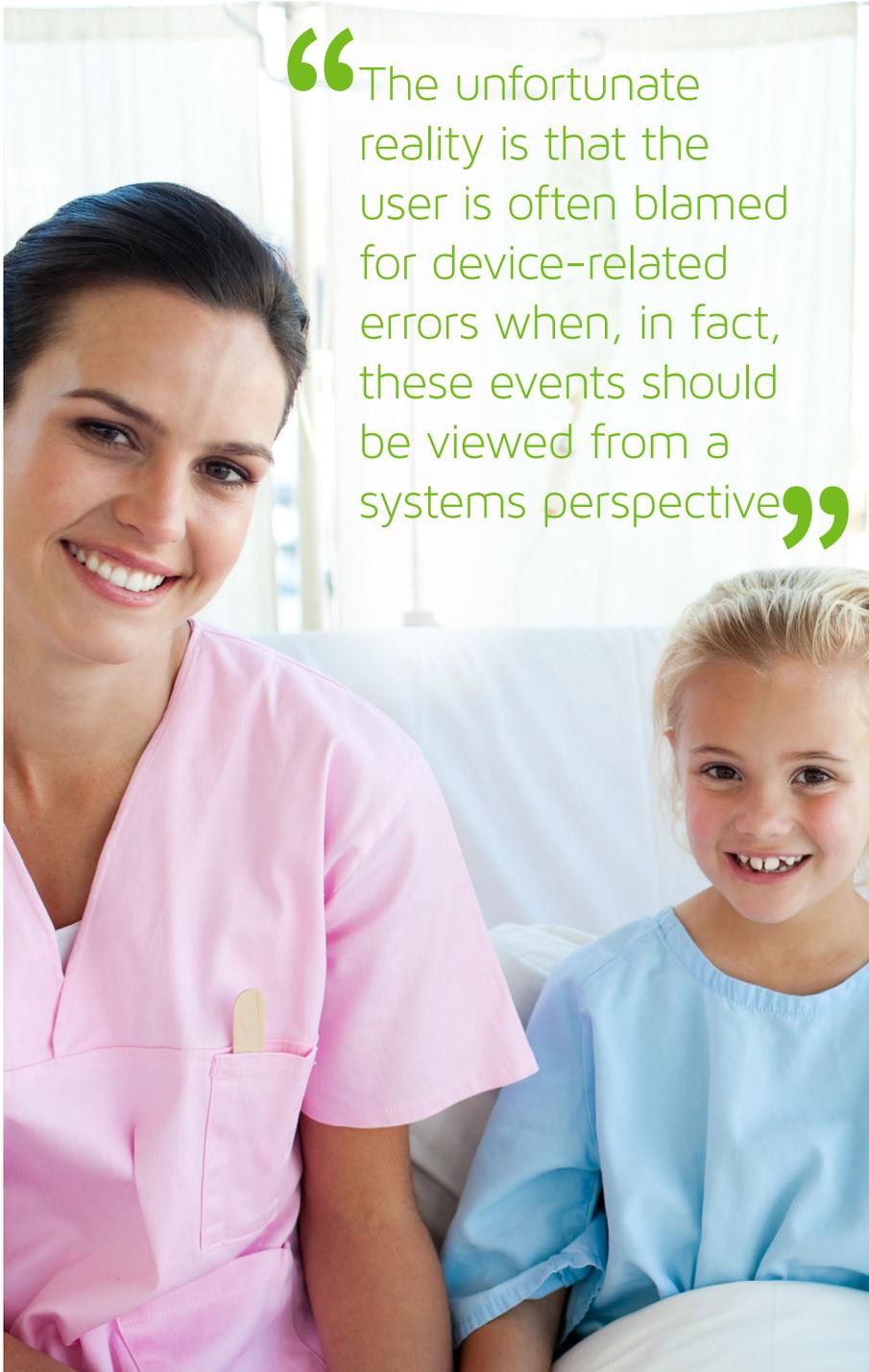
INTRODUCTION



A hospitalized patient, on average, is subjected to one medication error every day.^[1]

This distressing fact has prompted a great deal of research, summits, and reports on the topic, as hospitals and clinicians seek new technologies to address the issue. Because about 90% of hospitalized patients receive medications via the intravenous (IV) route,^[2] current infusion pump technology remains a significant contributor to unsafe medication practices. In hospitalized Australian patients receiving continuous intravenous infusions, there was an 18% incidence of error (most commonly wrong rate).^[3] In 2012, the ECRI Institute identified infusion pumps as one of the most dangerous and hazard-prone technologies in healthcare today.^[4] For example, a Bayesian analysis found that 73% of cases involving use of an IV pump produced at least one error.^[5] Recent recalls by the Food and Drug Administration (FDA), affecting nearly every major infusion pump company, and ample public attention^[6] further suggests that infusion technology lags behind other high-risk medical devices from a safety perspective.

The most commonly used infusion technology today is a “smart pump” so called primarily because the devices incorporate software, termed Dose Error Reduction Software (or DERS), intended to ensure that drug dosages fall within best-practices ranges, as defined by individual clinical facilities. Whereas earlier infusion pumps were programmable by flow rate alone, these devices allow drug specific dosing and can provide warnings and other information on the pump’s user interface (UI) screen when the user attempts to program a drug dose that falls outside limits identified in each hospital’s unique Drug Library. The implementation of DERS, however, has not eliminated IV medication errors. Further, smart pump technology has created new types of errors, for example, due to administrative errors (e.g., drug library set-up errors), lack of inter-connectivity between pumps and other health information technology, and warning/alarm fatigue.



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The FDA obtains more than 10,000 infusion device-related Adverse Event (AE) reports annually yet we know that most events go unreported. In a study at Northwestern Memorial hospital, 7 more pump related infusion errors were observed in a single day than were reported over 2 years in that hospital’s incident reporting system.^[7] Reported AEs vary in severity but many include significant patient injury and even death. There are numerous case reports in which clinicians made a simple usability error (e.g., misprogramming a pump to deliver a drug at ten times the intended rate) and caused irreparable patient harm.^[8] The unfortunate reality is that the user is often blamed for device-related errors when, in fact, these events should be viewed from a systems perspective.^[9] How do so many well-intended, well-trained clinicians make so many rueful errors, undeterred by the provision of a technology (DERS) specifically designed to prevent them? A recent survey of 400 nurses interviewed one year after their facility implemented smart pump technology found that 32% did not trust the smart pumps any more than they had trusted their traditional pumps without DERS.^[10] This suggests that current infusion pump interfaces have not been designed to be sufficiently user-centered and error tolerant.

In this three part series, we strive to provide an overview of the current status and apparent effectiveness from the user’s point-of-view of infusion pump design. We acknowledge the advances in the field while highlighting opportunities for future improvements. In focusing on some of the usability issues of current pump interfaces and insufficient interoperability, we highlight some of the existing pitfalls and offer human factors-based guidance for next-generation designs. Here, we define infusion pump usability as the relationship between the technology and clinicians’ ability to use that technology to attain their work goals effectively, safely, efficiently, and with both clinician and patient satisfaction.

This, the first of three parts, focuses on how infusion pumps can enhance medication safety through empowering clinicians’ use of the “Five Rights”.

UNRESOLVED PROBLEMS WITH IV THERAPY – ADDRESSING MEDICATION SAFETY



In an effort to reduce medication errors, most health care providers, and especially nurses, have learned the importance of the “Five Rights” of medication safety – right patient, right drug, right dose, right route, and right time. The goal of this process-based approach is to significantly limit the number of Adverse Drug Events (ADEs) that reach the patient. Unfortunately, to date, this approach has failed to have a substantial impact on infusion safety, in part because of an excessive reliance on nurse’s performance at the bedside, where they often employ paper or electronic checklists along with use error-prone pump and medication safety (e.g., bar-code reader) technology. As a result, clinicians are too often blamed for ADEs when they are simply following organizational policies and procedures to the best of their abilities. National and international medical device usability standards state that whenever there is a device-related use error, the design of the device’s user interface should be considered contributory until proven otherwise through a formal investigation.

Although many smart pump manufacturers have attempted to integrate the Five Rights into their devices primarily through DERS, they have generally done so incompletely and/or ineffectively. As recently as 2012, a medication error was still being reported in nearly 1 in 133 cases that utilized an anesthetic drug.^[1] The successful integration of a Five Rights protocol into a truly intelligent pump will require a user-centered design approach to assure that all of the Rights integrated into the device function with the natural clinical workflow of medication administration in all clinical contexts of use.

We will discuss how these ‘Rights’ are (or are not) achieved with current smart pump systems and their limitations.

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Wrong Dose at the Wrong Time

Hospitals may be investing three or four times as much to purchase smart pumps with their associated 'safety software' compared to the cost of traditional pumps despite insufficient consistent demonstrable safety benefits for the additional technology. In fact, the implementation of smart pumps can create new failure modes that lead to patient harm.^[2] Dosing errors during smart pump use are still quite common and may include miscalculations, unit errors, push-button mistakes, and multiple-of-ten errors. Although many wrong dosages go unreported, there are numerous examples of ADEs involving smart pumps.

As but one example, a nurse accidentally programmed an infusion of parenteral nutrition at 457 mL/hour rather than 45.7 mL/hour. The infusion ran for 2 hours before discovery causing acute hyperglycemia with the patient being transferred to the ICU.^[8] While the pump generated a soft-limit alert in response to the 10-fold overdose, the nurse bypassed the alert and administered the programmed dose. Unfortunately, such 10-fold overdoses appear to be common with smart pumps. The DERS may be less effective in these cases because clinicians have to appropriately override the software so frequently to accomplish intended correct therapy.

Another smart pump study in the ICU setting provides further evidence of insufficient safety impact of current smart pump technology.^[12] Of the 46,000 patient-pump encounters studied, 100 preventable adverse drug events occurred, 29 of which involved overdoses. Cases of wrong duration and wrong drug were also observed. Only 4% of all ADEs were intercepted by the smart pumps. A more recent study in a simulated inpatient unit similarly reported that the ability to remedy "wrong drug" errors between smart and traditional pump types was insignificant.^[13] Soft limit alerts had no impact on the nurses' ability to identify and correct overdose errors.

In a study performed for the FDA more than a decade ago, numerous types of intravenous medication errors were described by 49 inpatient pharmacists and critical care nurses during 8 focus groups. For the 47 different types of errors, the full implementation of smart pumps alone could only have prevented about one-quarter of the events. A comprehensive re-engineering of medication processes, including full integration of a comprehensive suite of institutional medication management software, appeared required to prevent all of the reported errors.





Right Patient-Device Association

Currently, the accuracy of information entered into the pump is critically reliant on correct manual data entry of the medication, its dosing, patient weight, etc. Bypassing of extant DERS eliminates whatever benefit such software provides to notify the user of potential errors. Errors in patient identity, although infrequent, can be dangerous and sometimes fatal. Most commercially available infusion pumps either do not permit or have time-consuming manual methods of entering patient name (and/or identification numbers) or other patient information. To confirm patient identity during the medication administration process, informatics systems have been developed called bar-code medication administration (BCMA). Although BCMA technology can decrease patient misidentification, these systems also appear to create new types of administration risks.^[14] Furthermore, because of faulty user interfaces and the inherent inefficiency of most BCMA systems, many nurses develop process workarounds that partially or completely offset any safety benefits.^[15]

An alternative approach to addressing this Right would be the direct point-of-care association of the patient, the pump, and patient-specific orders. Here, the pump would be 'aware' of its precise hospital location (e.g., through linkage of hospital census software and pump location-awareness technology). The nurse programming the pump at the bedside would confirm the location and patient identity. Then, he or she would choose that patient's current infusion order from a list of pending medication orders downloaded to the pump from the hospital's electronic health record (EHR) system as entered electronically by the prescribing clinician. The chosen order, already checked by a pharmacist, would be automatically programmed into the pump.

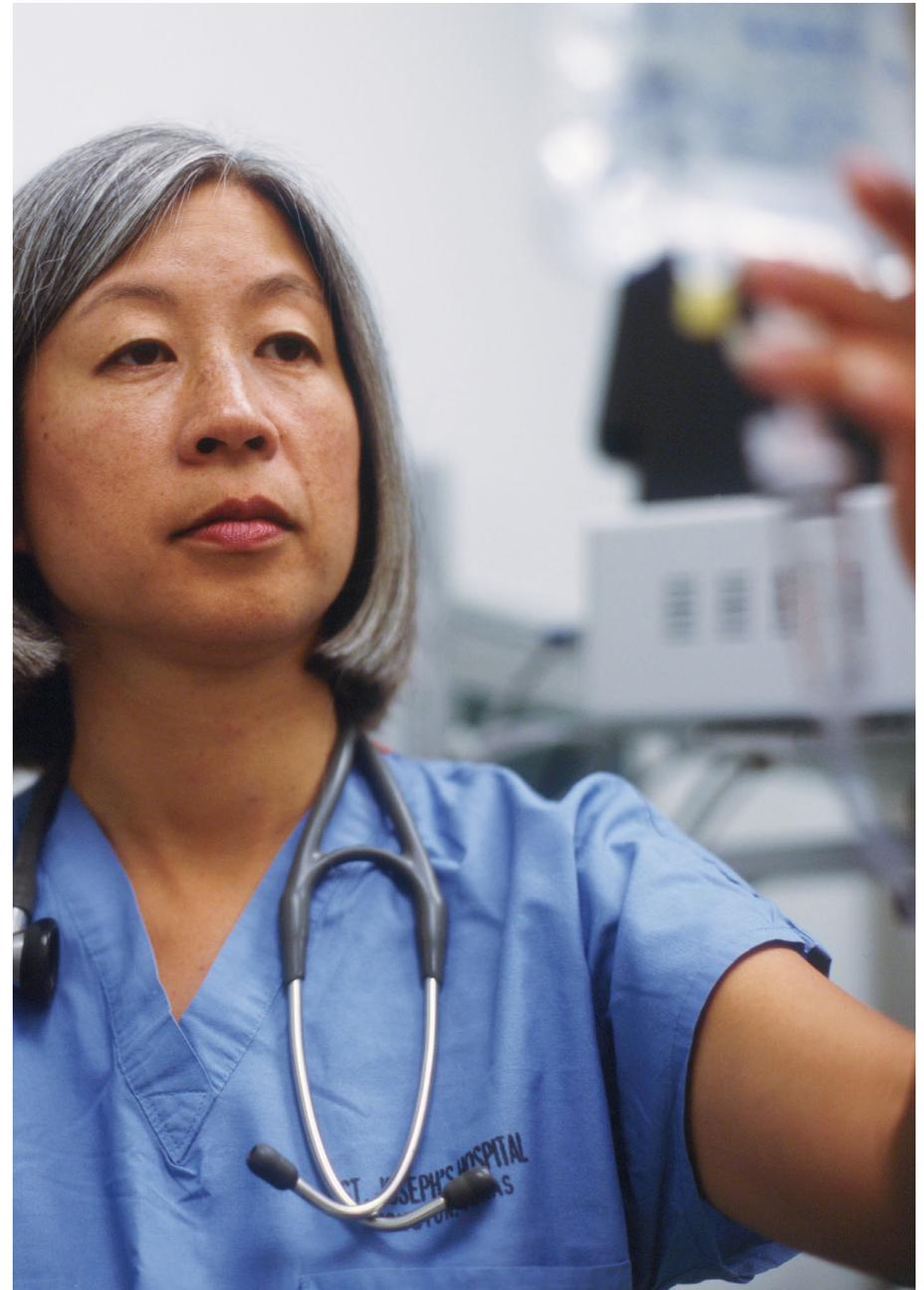




Right Drug

Ensuring that the correct drug is administered to the patient is obviously critical. Wrong drug administration accounts for about one in seven medication-related deaths.^[17] The wrong drug can be given for many reasons. The administration of the wrong drug can be affected by many “performance shaping factors” (or PSFs) ranging from the individual clinician (e.g., inexperience, fatigue), the work environment (e.g., noise, distraction, poor workflow), technology (inadequate labeling, confusing UIs), and organizational factors (e.g., lack of training, production pressure, misplaced priorities).^[18] Currently, the administration of the wrong drug via an infusion pump can only be prevented by the clinician noticing on the pump display that they are about to give the ‘wrong’ drug. The use of drug-specific programming and the large display of drug name can facilitate error recovery. However, if the clinician is misinformed as to what drug is to be administered, there is little the smart pump can do. In the rare situation when the dose of the intended drug falls outside the DERS limits for the programmed drug, the clinician may be prompted to double-check the original medication orders. What needs to happen is a ‘closing of the loop’ between the medication ordered, the medication dispensed, and the medication loaded into the pump. This process would be best facilitated by fully communicating CPOE, BCMA, and pump software when the infusion pump is programmed and/or the infusion is started.

A variant of ‘wrong drug’ error is when a drug is administered to which the patient is known to be allergic. This error typically happens at the ordering step but should be caught either by the pharmacist prior to dispensing or by the nurse prior to its administration. In the latter case, it requires point-of-care knowledge of the patient’s allergies. Since no current smart pump contains this information, successful prevention would be best facilitated by fully communicating EHR and pump software.





Right Dose

Giving the wrong dose of a drug can also be catastrophic. Toxicity or injury can result from too high a dose (e.g., potassium or heparin) whereas too low of a dose can delay or even preclude needed therapy (e.g., antibiotics). Similarly, drugs given faster or slower than intended by their manufacturer can cause harm (e.g., vancomycin given too quickly causes “Red Man Syndrome” with associated hypotension). Current smart pumps’ DERS prompts users when dosages exceed proscribed limits, as established by local pharmacists and other clinical leaders. DERS typically have both soft (a warning that can be over-ridden) and hard (cannot be over-ridden) limits. Although current DERS can decrease dose-related ADEs, it has shortcomings. DERS’ drug-specific limits are not patient-specific; instead, drugs are programmed based on standard dosing ranges, sometimes adjusted by the patient’s weight. Thus, when patients are old or frail, the upper limits may be too high and the lower limits may not be low enough.

Furthermore, soft limits are routinely (and almost always correctly) overridden, causing clinicians to suffer from ‘alert fatigue.’ As a result, users are more likely to inadvertently override the few “correct” alerts, leading to patient harm.^[19] Clinicians also complain about the rare situations when pump hard limits do not allow for a drug to be administered at an otherwise “excessive” dose when doing so is essential in that case (e.g., in a ‘code’ situation).

To support DERs, an on-pump drug library is uploaded (preferably wirelessly) from an institutional drug library residing on a central server. Maintaining this institutional drug library, typically the responsibility of inpatient pharmacists, is a resource intensive task. Assuring that all pumps contain the latest version of the drug library, the responsibility of healthcare technology management (HTM) personnel (previously called clinical engineers), is also resource intensive.

Thus, an effective infusion management system must closely integrate on-pump safety features with the off-pump infusion system software that allow the pharmacists to create and maintain the institutional drug library as well as provide quality assurance (QA) and pump fleet management applications to monitor the institution’s infusion therapy use and safety.



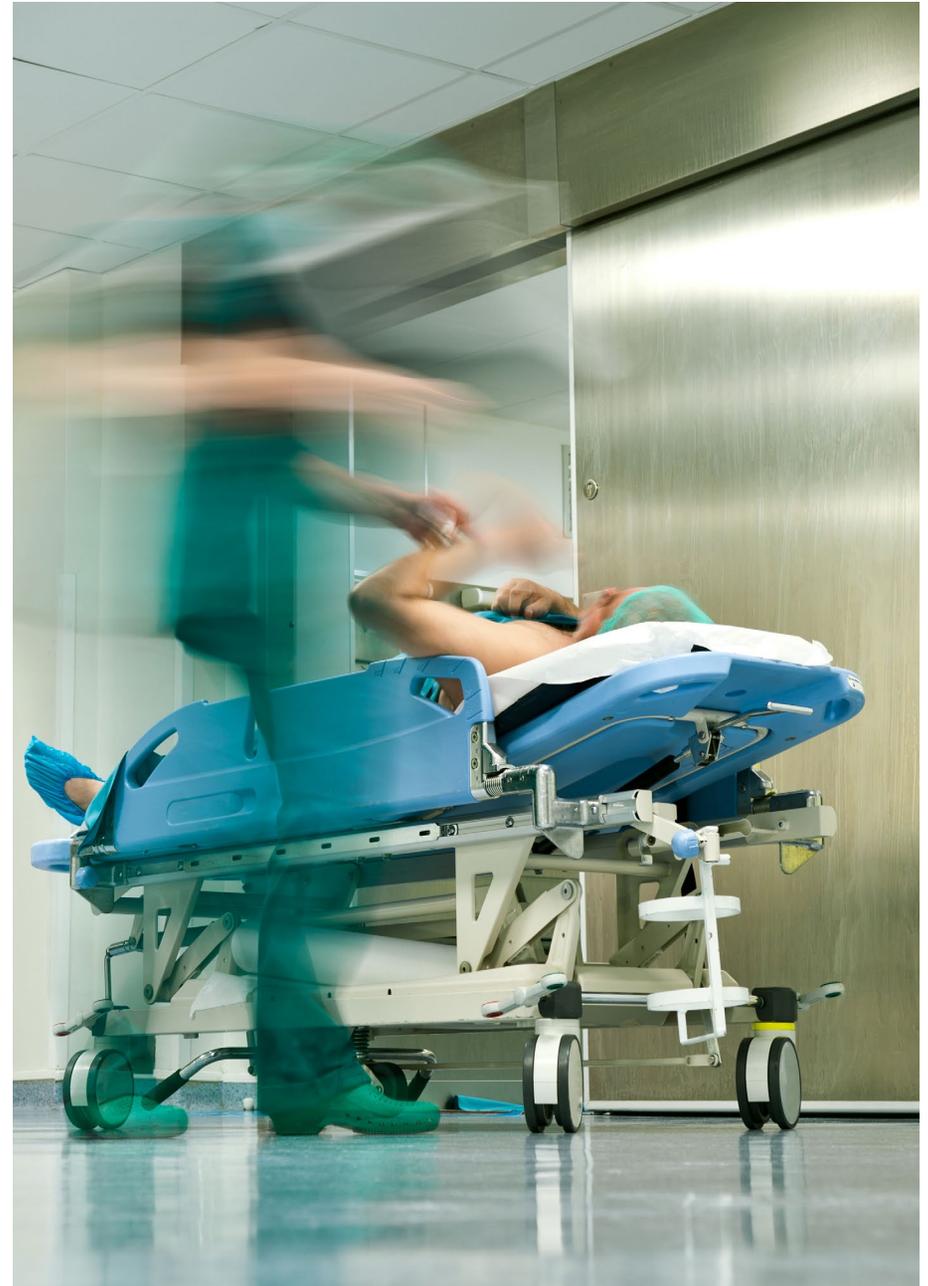
“A key value of any smart pump is the elimination of human mental calculation to ascertain correct dose or rate.”



Right Time and Duration

By far the most common IV pump related error, the timing of drug administration can be critical to the medication administration process as a whole.^[20] Too often the prescribed drug is not started on time or is administered over the correct duration. As many as 50% of all medication-related errors are time-related.^[21] Although starting an individual dose 10 minutes late in one patient is unlikely to be harmful, a pattern of late doses points to system deficiencies at the hospital level. Contributory factors to drug timing errors may include, delayed delivery of medications to the point of care, unrealistic 'standard dosing schedules' (e.g., too many medications need to be given at 9 am for the nursing staff available to do so), insufficient staffing, and/or inefficient bedside processes (e.g., BCMA technology that substantially increases the time required to 'check' the medications or burdensome pump programming requirements). The use of policy enforcement to reduce wrong time errors will invariably lead to workarounds that erode patient safety.^[22] Because of their frequency, dose-timing errors often go unreported,^[23] especially when there is no perceived patient harm. Yet, during times of high workload or in an emergency, patient outcome may depend on the efficiency of the administration process (e.g., antibiotics in sepsis).^[24] Next generation infusion pumps must facilitate efficiency as well as safety, particularly in emergency situations.

It is also common for the rate and duration of infusions to be incorrectly programmed.^[25, 26] Similar to the errors associated with dose-based programming, incorrect entry of infusion rate or duration can lead to multiple-of-ten entry errors and soft limits, if they are present, can be overlooked. Once again, through patient-specific and situation-specific functionality at the user interface, some of these pitfalls can be addressed.





Failed/Wrong Documentation – the Sixth “Right”



A failure to correctly and completely document medication administration can also cause patient harm. For example, if a dose of medication is given but not charted, there is a risk of duplicate dosing. Thus, all IV pumps should capture a comprehensive ‘audit trail’ of what was done when and by whom. This audit trail should document the patient, the medication parameters, and the clinician(s) responsible for the pump’s programming and administration. The Association for Advancement in Medical Instrumentation (AAMI), during their FDA-sponsored Infusion Device Summit in 2010, highlighted the difficulty of determining the cause of events and the necessity of this information for continuous quality improvement (CQI) of medication processes. Indeed, it’s well documented that the data currently collected from smart pumps do not reliably elucidate the patients harmed nor the clinicians involved.^[27] The FDA, along with some Patient Safety Organizations (PSOs), have begun to create a path to a centralized database for collating and analyzing medication safety data. The prospective analysis of a large number of event reports along with pump logs can identify areas for clinical improvement and cost savings. Smart pump implementations have generally improved medication safety and documentation thereby decreasing inaccuracies but have not done enough yet to create robust audit trails. Developing a more comprehensive documentation system that will facilitate data analysis without placing extra burden on clinicians will facilitate continuous system improvements.

“Prospective analysis of a large number of event reports along with pump logs can identify areas for clinical improvement and cost savings.”

DESIGN RECOMMENDATIONS – ADDRESSING THE FIVE RIGHTS OF MEDICATION SAFETY

- *Confirming the rights.* Pumps should be designed so that every “Right” can be confirmed by the clinician via the pump’s user interface.
- *Up-to-date drug libraries.* Infusion pumps must be rigorously maintained through wireless interoperability features, ensuring an up-to-date drug library and associated dose-error reduction software; this will promote a safety culture and clinician buy-in.
- *Quality improvement processes.* Pump systems’ drug administration databases must be developed whereby organizations can systematically collate ADE “big data” for analysis.
- *User centered design.* A user-centered design (UCD) approach must be utilized so that the Rights become part of a clinician’s natural workflow and not perceived as a hindrance.
- *Software integration.* Infusion systems must seamlessly integrate with other medication management software (CPOE, pharmacy systems, BCMA) to assure that relevant patient and clinical contextual information is available at the bedside during pump programming and use.



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