The Guardrails® Suite MX software—an innovative safety solution to address infusion medication errors

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Impact of intravenous (IV) infusion medication errors

The publication of the Institute of Medicine report entitled To Err is Human has focused the attention of the healthcare industry on medication errors.1 One chapter in this report uses infusion pumps as an example of device-related errors. Studies indicate that the overall rate of medication errors in hospitals is 5.3 to 5.7 per 100 admissions, with approximately 1% of errors leading to adverse drug events (ADEs) or potential ADEs.2,3 Medication errors resulting in preventable ADEs (PADEs) occurred most often during ordering (56%) and administration (34%).3 Possibly the most commonly quoted study of error incidence and classification is the 1995 study conducted by Lucian Leape and colleagues.4 This study demonstrated that prior to administration, Pharmacists caught 6% of the ordering errors and Nurses intercepted an additional 42%. Nurses also intercepted 33% of all transcription and dispensing errors. However, only 2% of drug administration errors were intercepted. The errors made during administration almost always result in an ADE, while errors made earlier in the medication use process are less likely to reach the patient undetected. A study by Kaushal, Bates et al documented that 54% of potential ADEs were associated with IV medications.5 According to a communication with D.W. Bates in October 2001, 61% of the most serious and life-threatening potential ADEs were associated with IV therapy. Ross et al, in a study conducted in the United Kingdom, reported that 56% of medication errors were associated with intravenous medications.6 As a group, IV medication errors are among the most serious, and IV medications typically are administered with infusion devices. It is accepted in the medical community that IV devices, while usually not blamed for the errors, are associated with PADEs, which typically involve programming incorrect infusion parameters. Reports to manufacturers, the FDA, The Institute for Safe Medication Practices and other agencies document infusion device-related medication errors, which frequently are published as case studies or anecdotal reports, thus increasing their visibility.

Objectives of this report

The objectives of this report are twofold: The first is to review the current situation with respect to infusion devices and some of the reasons why IV medication errors occur. The second objective is to describe an integrated medication safety software platform that has been introduced to address many of the current issues and to provide safer IV therapy.

Evolution of intravenous infusion pumps

The first infusion devices were marketed in the late 1960s in response to the increasing complexity of intravenous drug infusion and nutrition therapy. These devices had very limited functionality and were used primarily in intensive care units. Over the past 30+ years, infusion devices have evolved in application, functionality and safety. What started out as a limited-function infusion device that could deliver only clear fluids, had a rate range of 1-299 mL/hr and provided limited safety features has become a distinct market segment of more than a billion dollars. Today’s devices can deliver all IV fluids, drugs, nutrition and blood products. The average hospital patient receives two or more IV infusions, with some patients receiving 10 or more simultaneously.
This has led to the availability of multi-channel devices that can infuse up to four IVs from the same device. IV therapy also has expanded beyond the traditional hospital, and patients are taught to use portable or wearable IV devices in their homes for a variety of different therapies. Current devices include features such as the following:

- General-purpose infusion devices have a 10,000-fold rate range from 0.1 to 999 mL/hr; some of these devices can be programmed in 0.01 mL/hr increments.
- In response to hospital preferences, the same infusion device now can be used anywhere within the hospital or hospital system with only a simple cleaning required between patients.
- To meet the varying needs of different patient populations, the same infusion device can be configured to function for patients with weights ranging from 600 grams up to 200 or more kilograms.
- Advanced programming features to calculate dosages, preprogram infusion delivery and administer complex, multi-step infusions are available for use in every patient care area.
- Medications that formerly were considered to be “safe” for infusion only in an intensive care unit are now infused by patients in their homes via devices they have been taught to program themselves.

Increasing sophistication of infusion devices

The infusion device industry has responded to the increasing sophistication of IV therapy in two ways. First, the definition of a general purpose infusion device has changed dramatically over the years, as technology has advanced in response to the needs and desires of clinicians. One example is the development in the late 1980s of infusion devices designed for pediatric and neonatal use. These devices provided highly accurate infusions capable of delivering as little as 2 drops of fluid over a 1-hour period. To meet the low-end performance requirements, these devices could not infuse above 100 mL/hr. Thus, in a typical hospital that treated both adult and pediatric patients, two separate types of infusion devices were required to meet infusion needs. It was not long before the infusion device industry responded with infusion devices that provided both the low-end performance needed for pediatrics with the higher volume capability needed for adults. The resulting one-size-fits-all devices solved the problem of performance limitations, but created a new potential for programming errors. Nurses caring for adult patients now had 0.1 mL/hr programming capability, and decimal errors that previously could not have happened now began to appear. In the pediatric and neonatal units, the 10-fold greater infusion range allowed the devices to be inadvertently programmed to rates far higher than the previous 100 mL/hr limit.

The second industry response has been to develop therapy-specific infusion pumps. An example is the pain-control infusion device. In response to rethinking postoperative pain management, the traditional intramuscular injections that were administered in response to patients’ requests have evolved into patient-controlled IV injections administered via devices designed for just this purpose. The general purpose infusion devices could not provide for this special need; however, the “rethinking” has expanded to other modalities of narcotic delivery, including continuous IV and epidural infusions that often are administered with the general-purpose pumps.

Case examples

This increasing sophistication of IV infusion devices, however, has not been without cost in terms of increasing IV medication errors. The following medication errors are examples that have been published in safety alerts or newspaper articles, or reported in presentations at professional meetings.

Example 1: A Neonatal Nurse responded to an Infusion Complete alarm on an IV device; the rate of infusion was 0.8 mL/hr. The Nurse refilled the volume control burette with several hours’ worth of fluid, then reprogrammed what the nurse thought was the Volume to be Infused with a small volume. Unfortunately, the Nurse pressed the Duration key on the pump instead of the Volume to be Infused key and thus programmed a very short duration. When the infusion was started, the inadvertent switching of the time for the volume recalculated the infusion rate to 189 mL/hr, or approximately 200 times the ordered rate.

Example 2: Heparin for infusion typically is dispensed from the pharmacy in 500 mL bags containing 25,000 units, an amount sufficient to provide a therapeutic dose for a 24-hour period.
In this case, the nurse programmed the Volume to be Infused as 500 mL and inadvertently also programmed the rate as 500 mL/hr, rather than the 14 mL/hr that was ordered. The device infused for 1 hour as programmed, which resulted in the patient receiving the entire 24-hour dose in 1 hour.

**Example 3:** The Physician ordered a nitroglycerin infusion for a patient in an adult medical unit with the dosing units specified as micrograms/minute (μg/min). The Nurse programming the infusion pump was accustomed to delivering nitroglycerin in μg/kg/min. The Nurse programmed the infusion device using weight, and the 70-kilogram patient received a 70-fold overdose.

**Example 4:** The infusion rate for a neonate was ordered to be increased from 3.2 to 3.4 mL/hr. The nurse unintentionally pressed the “0” in place of the decimal point, resulting in an infusion rate of 304 mL/hr.

**Example 5:** During the setup of drug calculation, the amount of morphine was entered as 100 mg in 100 mL; the actual amount was 1000 mg (1 gram). The infusion device calculated the infusion rate based on the wrong concentration, and the patient received a 10-fold overdose.

In each of these cases, there are three common threads. First, the infusion devices were capable of delivering exactly what was programmed, regardless of what was ordered. Second, there was no way for the device to perform a test of reasonableness to alert the Nurse at the bedside that the infusion was not appropriate prior to delivery to the patient. And third, in each case the patient died.

Fortunately, these “single button press” mistakes often are caught as the Nurse reviews the programming before pressing the start key. However, this is not always the case, and the above examples illustrate how easy it is for tragic misprogramming to occur.

**Infusion device design**

Infusion devices are especially vulnerable to error, since they have been designed with few controls, are programmed at the bedside by a single caregiver and frequently are used in life-threatening situations when seconds count. More extensive control systems exist in other areas of the drug delivery process, including computerized physician order entry, use of clinical pharmacists on patient care units and barcoding and robotics for drug dispensing. Little attention has been focused on supporting the Nurse at the bedside, the final point of IV medication delivery.

To illustrate this point, a study reported on one hospital that was using eight different types of infusion devices. Each type had a unique user interface for programming the infusion, different terminology and nomenclature and device-specific disposable administration sets. Other factors that lead to medication errors associated with infusion devices include the limited availability of training time, infrequent use of some devices and temporary agency Nurses who use different equipment as they move between hospitals.

Adding to the complexity of IV therapy are reduced Nursing staff and the frequency with which infusion devices are adjusted, making the probability that mistakes will occur very high. Without decision support tools at the point of care, Nurses are highly vulnerable to the occurrence of serious ADEs.

**Innovative approach to addressing IV infusion errors**

To address the need to provide support at the bedside to reduce IV medication errors, CareFusion has introduced a proprietary IV infusion safety net called Guardrails Suite MX software. CareFusion has long been recognized as an innovator in the industry and developed some of the first infusion devices in the late 1960’s. Many of the firsts in IV therapy originated with Alaris® products, including free-flow protection, volumetric accuracy, computer-controlled infusions and pressure and resistance IV site monitoring. CareFusion has developed the Guardrails Suite MX software to address many of the issues discussed previously, including the need to provide a test of reasonableness prior to medication delivery, customization to overcome the one-size-fits-all device configuration and safeguards against the “one button press from disaster” programming.

**The concept of Guardrails Suite MX software**

To illustrate how the Guardrails software will make IV therapy safer in much the same way that highway engineers make driving safer, consider the following: The highway department assesses each road, identifies the potential danger points and develops a complete
set of “guardrails” to protect the driving public. These guardrails include steel barriers, lane markers, reflectors, signs, sand barrels, rumble strips and the like to set limits and to warn about potential conditions that could lead to accidents. Driving safety would most certainly be lessened if these guardrails and other safety systems were removed from the roadways. We use some of the highway safety guardrails every day, while others are seldom used. But we can take comfort in the fact that they are there, and we are safer because of the preplanning and implementation that resulted in their presence.

This analogy also applies to IV therapy except that, until now, there has been no equivalent of highway guardrails. If Nurses have the time, take the time, are experienced and are not interrupted or distracted, chances are the IV infusion will be delivered exactly as ordered. However, as has already been established, one wrong button press or a wrong concentration can lead to a serious, potentially life-threatening mistake.

**Guardrails Suite MX software from CareFusion**

Guardrails Suite MX software from CareFusion provides the hospital with two critical capabilities:

- The first is a method of predetermining exactly how an infusion device will function in a given patient care area
- The second is a drug library that limits how medications can be programmed and sets limits on the rates, volumes and doses that are appropriate for a given patient care area

The Guardrails Suite MX software utilizes an extensive library of drug dosing information, which is customized to meet the needs of the individual institution or hospital system. A multidisciplinary oversight committee generally is established to decide the hospital’s (up to 10 currently) unique infusion needs. For example, medication dosing and flow rates differ greatly between the neonatal intensive patient care unit and the adult surgical patient care unit. Dosing guidelines determined by the institution staff are established for each patient care area and become part of the information library used by the Guardrails Suite MX software. Likewise, the performance characteristics of the infusion devices, such as air detection limit and maximum infusion rate, are established and become part of the database used by Guardrails Suite MX software. This is a dynamic database that can be changed as necessary by the oversight committee. Once the Nursing staff is trained in programming the Guardrails Suite MX software, the safety system can be implemented virtually overnight.

**How the Guardrails Suite MX software works**

When the infusion device is being programmed for use, the Guardrails Suite MX software asks the caregiver if this is a new patient since the infusion device was last used and in which patient care area of the institution is it being used. Using the drug library option, selection of the drug to be infused accesses both the dosing guidelines previously established (which can contain “hard” or “soft” limits depending on the drug and the care unit) and safety reminders for drug monitoring. These boundaries function as an important verification test of reasonableness at the bedside that the caregiver has programmed the device correctly for both the care site and the specific medication. If the infusion specifications do not fall within the established parameters, an alert message results and the infusion cannot proceed until the issue is addressed. A log is kept of all programming and alerts, which later can be used to monitor the effectiveness of the system.

**Impact of the Guardrails Suite MX software**

If the Guardrails Suite MX software had been operating in each of the infusion devices associated with the errors discussed earlier, the results could have been dramatically different. Consider the impact of the test of reasonableness that the Guardrails Suite MX software would provide:

**Example 1:** With the Guardrails Suite MX software, the IV device would “know” it was being used in the neonatal ICU and the predetermined rate limits would not allow the high infusion rate of 189 mL/hr. The maximum infusion rate of 20-25 mL/hr for NICU applications would flag this error.

**Example 2:** Using the information in the drug library, the Guardrails Suite MX software would alert the Nurse that heparin should not be administered at a rate of 500 mL/hr and the infusion would not proceed until the rate was corrected. For example, a hard limit of 2000 units/hr could be predetermined in the data set used by the Guardrails Suite MX software.

**Example 3:** The nitroglycerin dose mistakenly entered as
The potential for the Guardrails Suite MX software to prevent intravenous medication errors is significant.

- Offers comprehensive, unit-specific intravenous infusion capabilities that allow standardization within an institution or hospital system
- Avoids the one-size-fits-all limitations of current devices
- Provides a test of reasonableness at the bedside, immediately prior to initiating the infusion
- Allows a reduction in IV infusion PADEs, protecting patients from potential serious harm
- Following the development of the data set, the Guardrails Suite MX software can be implemented in a day or less, unlike computerized physician order entry and barcode medication administration systems
- Does not change workflow associated with drug infusion
- Can be used as a performance measurement and clinical quality improvement tool

The Institute of Medicine report stressed that the focus must shift from blaming individuals for past errors to a focus on preventing future errors by designing safety into the system.1 CareFusion has pioneered the first and most comprehensive solution to dramatically reduce IV medication errors. The Guardrails Suite MX software makes it possible to bring a new level of safety to patients’ bedsides, making infusion systems even more valuable to caregivers. This state-of-the-art system is available for healthcare providers to use to support their patient safety initiatives.

Example 4: The Guardrails Suite MX software would not allow the Nurse to program a neonatal infusion rate of 304 mL/hr. The infusion would not continue until the infusion rate was within the limits set for this patient care area.

Example 5: Standard concentrations of medications such as morphine would be a part of the data set, and concentration programming errors such as this one would be prevented. A morphine concentration of 1000 mg/100 mL would not be a selection in the drug list.

Summary

References

Tim W. Vanderveen, PharmD, MS is currently Vice President of the Center for Safety and Clinical Excellence. He is responsible for ensuring the CareFusion commitment to education to help reduce the risk of harm from medication errors at the point of care, and supporting hospital’s patient safety initiatives.

This is the first in a series of white paper reports prepared by CareFusion to introduce our portfolio of products and services developed to address medication errors in hospitals and protect patients from harm.

For more information, contact your CareFusion Sales Consultant at 800.482.4822, in Canada at 800.387.8309, or visit our website at carefusion.com/alaris.