Using Data to Improve Smart Intravenous Infusion Pumps

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In 2002, Alaris Medical Systems, Inc., now part of CareFusion, launched a new era in intravenous (IV) infusion therapy with its introduction of so-called “smart” (computerized) pumps for large-volume and other IV infusions. These new devices were designed to improve medication safety by making it harder for clinicians to do the wrong thing and easier for them to do the right thing in programming the administration of high-risk IV medications. The dose-error reduction software (DERS) in the new smart pumps included drug libraries with dosage-limit and other alerts that helped intercept potentially fatal medication programming errors. Continuous quality improvement (CQI) logs in the software automatically collected data that previously were not available either to individual hospitals or to the pump manufacturer, including the programming that led to an alert and the user’s response to the alert.

The company’s design process, which began in the late 1990s, included usability testing with simulation of the clinical environment and the application of human factors engineering (HFE) principles such as using forcing functions, simplifying all tasks, standardizing processes, avoiding reliance on memory, decreasing reliance on human vigilance, improving access to information, and using automation carefully. In developing the new pumps the company drew on extensive experience in creating new safety enhancements, a clinical staff with hundreds of years of collective experience in practice and industry, and expert input from highly experienced practicing clinicians and biomedical engineers. Studies showed that implementation of the new smart pumps provided a rapid, effective, and cost-effective means to improve patient safety and quality of care.

The company also sponsored creation of a starter set of drug libraries through an extensive review of the literature and by combining the drug libraries from a number of early adopters of the smart pump system. The starter set was independently reviewed by physicians, pharmacists, and nurses with expertise in each of the key areas such as intensive care, obstetrics, and neonatal intensive care. The set was made available to hospitals in August 2002, but by October 2002 it was apparent that, because of the tremendous variability in IV practice within and among hospitals, hospitals preferred to develop their own drug libraries rather than use the carefully vetted starter set. A study published in 2005 documented the enormous intra- and inter-hospital variability in how IV drugs were ordered, dispensed, and administered, and showed how this variability presented numerous safety risks that had not been identified when the smart pumps were first designed.

The latest smart pumps now have expanded coverage to include almost every IV medication and fluid infusion, a variety of new types of safety alerts, and wireless connectivity that allows for easy transfer of DERS library updates to every device in a hospital and frequent collection of the CQI log data. This article is a case study of how one smart pump company used the CQI data from the DERS safety logs to iteratively improve its products, add safety enhancements, and ultimately further help reduce IV pump programming errors.

Iterative Safety Improvements

To understand the need for post-introduction, iterative smart pump improvements, one should keep in mind that early usability testing was conducted with nurses who for the most part had never seen a smart pump. The idea that an infusion pump could identify doses that were out of range was well received, and in simulation testing the
nurses responded as anticipated by reprogramming doses that were out of range. The usability testing did not include every possible IV drug or real patients.

Once a significant number of the pumps were in clinical use, retrospective review of the CQI logs revealed a number of issues that were not previously identified. These included compliance issues in using the DERS safety system, frequent overrides of soft minimum and maximum dose alerts, and drug administration practices that often were not in compliance with established hospital policies.

For example, hospitals typically had specific policies that covered how bolus drug doses were to be administered during continuous infusions. These policies called for administration of the bolus dose using a separate drug source such as a vial. The CQI data revealed an alarming frequency of high rate infusions with soft alerts that were overridden as bolus doses were being administered from the continuous infusion containers. The administration of drugs at what often was “wide-open” rates of infusion was unanticipated and a surprise to physicians, pharmacists, and nurse administrators. Today these practices are known and can be tested in specific scenarios, but early on such practices were not known and were not anticipated. In addition, much of the smart pump development work was initiated in the 1990s when usability testing was not as mature as it is today, academic and hospital simulation centers were few and limited, and the discipline of HFE was not nearly as robust and comprehensive as it is today.

Fortunately, in designing and developing the smart IV infusion pumps, the company included a comprehensive CQI log in its devices. The logs captured all programming data preceding an alert, including the time and date, drug, concentration, and programmed parameters including dose and type of alert. Following the alert, the logs also captured the user’s response to the alert, such as overriding and continuing with the programmed parameters, reprogramming the value that was out of range, or in some cases cancelling the programming and starting over. The cancellation of the programming following certain alerts suggested a work-around, especially following “hard” alerts that halted the programming and required reprogramming. It is also important to note that the alerts (e.g., for a dose that was too high) were not presented to the user until the programming had been confirmed and the infusion “start” key had been pressed.

Initially, collecting data from the CQI logs required manually downloading each pump’s log using a laptop computer. Prior to introduction of infusion pump wireless connectivity, this manual process was performed infrequently, often during the annual preventive maintenance cycle. As described below, observation of clinical use and analyses of pooled data on six to 12 months of pump use collected from hundreds of infusion systems helped individual hospitals identify safety risks and practice issues. Individual hospitals also granted the company permission to analyze the data, and since the first pumps were implemented in 2001, data from hundreds of hospitals have been evaluated.

In addition to helping individual hospitals identify safety risks and practice issues, analyzing the data from the logs has enabled the company to iteratively develop multiple safety features and interface adjustments. The company’s field-based clinical pharmacists and nurses, who work with individual hospitals to help create the drug libraries and interpret the CQI data, also have been an excellent source of potential product enhancements. The following examples illustrate the types of enhancements that have been made.

Improving Compliance

Early adopters of smart pump technology often struggled with achieving clinical staff compliance in using DERS safety features. Although the DERS CQI logs did not provide true compliance rates, it was still apparent that in many patient care areas the use of the safety software was not optimal. Bedside compliance rounds often revealed that high-risk medications were being infused outside of the safety system. Since the technology was implemented to improve the safety of IV infusion programming and to provide a safety net for clinicians, investigating the factors that led to poor compliance was a priority for both hospitals and the manufacturer. Clinicians’ reasons for poor compliance were many and varied, and often included resistance to changing the way physicians’ orders for IV medications were calculated and programmed. Nurses were comfortable with the way they had always done things and felt the new pumps had too many programming steps.

Earlier, some general-purpose pumps had included a generic drug calculator (not drug-specific) that allowed a clinician to enter a drug concentration, patient’s weight (if used for dosing), and dose ordered. The pump then automatically converted the dose to a rate in mL/hr. Since this onboard calculator was used only occasion-
ally, it was included in the Options menu. With the early smart pumps, initiating the new safety features also required use of the Options menu. To improve compliance and make it easier to do the right thing, an early change in the user interface simplified selection of the DERS system by placing it on the page that immediately followed selection of an infusion pump channel. While the generic drug calculator remained in the Options menu, the user interface was changed so that the DERS system was immediately available (Figure 1) and the user no longer had to go to the Options menu.

Adding Both Soft and Hard Dose Limits
Prior to the implementation of smart pumps, most hospitals had not established drug dosing limits. Official compendia of drug information typically did not provide guidance on what low and high limits should be for most IV drugs. Thus, the early adopters of smart pumps were true pioneers who used their best judgment and clinical experience to set the dose limits in their drug libraries. In the first-iteration smart pump, each drug in the library could have either a soft or a hard maximum limit. Hospitals were reluctant to set hard limits for any drug, because hard limits did not allow the administration of doses that were larger than typical but clinically necessary. Analyses of the DERS CQI data identified frequent soft-alert overrides, with some doses significantly outside the soft-alert limits.

Analyses of the CQI data also helped identify several possible explanations for the high incidence of soft-alert overrides, including limits that were too tight, misalignment between current practice and the DERS “best practices,” patients who required extraordinary doses of certain medications, and clinicians who apparently overlooked the significance of the alert. Further analysis identified that an alarmingly high percentage of the overrides occurred in less than two seconds following the posting of the soft alert.

Fine-tuning the drug library could reduce the alerts that users found to be annoying and might lead them to overlook really significant alerts. However, hospitals clearly wanted to have the option to have an early warning (a soft alert), as well as a hard stop. One of the early iterative enhancements allowed both soft and hard maximum limits. (Note: Despite the current availability of both soft and hard limits, ongoing analyses of drug libraries reveal a continued reluctance in many hospitals to use the hard limits, even for high-risk drugs such as insulin, heparin, and narcotics.)

Selecting the Right Version of the Drug
The pumps were designed so that selecting a drug to be administered required a caregiver to scroll through a list to select the correct drug. In hospitals’ highly variable drug libraries, drugs such as dopamine could have multiple concentrations in the drug list. As a result, caregivers could scroll down one drug at a time to the first “dopamine” entry and choose it, without realizing that two more concentrations would be the next two selections, if they continued to scroll. For example:

- Dopamine 400 mg/250 mL (first selection in the dopamine list)
- Dopamine 800 mg/250 mL
- Dopamine 1600 mg/250 mL

This variability became apparent in the evaluation of early DERS CQI data, which showed that in some cases the first drug listing was selected and confirmed as the right drug, even though this was not the intended concentration. The results of confirming incorrect selections varied, depending on whether the error was recognized before infusion was begun. In some cases the infusion programming was cancelled and the correct selection was made; in other cases selection of a wrong concentration resulted in a potential medication error, if the dose infused was calculated from the incorrect concentration. For drugs with multiple concentrations, data analyses
also revealed instances when a wrong drug-concentration selection was corrected by reprogramming the concentration (which created additional opportunity for error, as discussed below).

Analyses of these types of error led to a redesign of the drug selection process for drugs with multiple concentrations, so that caregivers would be presented first with only the drug name, for example, dopamine. Selecting and confirming the drug brought up a separate page that listed the various versions of dopamine in the library. This rather simple change in the user interface effectively helped to resolve the unanticipated programming risks created by how hospitals were building their drug libraries.

Selecting the Right Drug by Therapy

The limited drug library capacity of first-generation smart pumps forced hospitals to make a difficult choice. For example, Activase® is used to treat clots associated with myocardial infarction (MI), pulmonary embolism (PE), and stroke. Each application has different treatment protocols. A hospital could include Activase in the library as a single drug listing with limits wide enough to cover its range of therapeutic applications, or it could include a different Activase listing for each of its three different clinical uses. The safety of Activase programming could be improved by adding safeguards to protect the drug based on the therapeutic application. Analysis of DERS data revealed that many hospitals had chosen the latter approach and had three different library entries for Activase, with drug and application listed together in consecutive entries (Activase [MI], Activase [PE], and Activase [Stroke]), each with unique dosing limits. As with multiple concentrations discussed above, this created the possibility of a clinician incorrectly selecting the first “Activase” to appear in the drug library.

To address this issue, the company added a separate programming screen for “Therapies,” so that a clinician first selected only the drug (Activase) and then on the next programming screen selected a particular therapy. Since many IV drugs have multiple therapeutic applications with varying dose ranges, adding “Therapies” as a separate screen was key to moving smart pumps from IV drug safety to IV drug application safety.

Setting Limits Around Custom Concentrations

Professional organizations and regulatory agencies encourage hospitals to recognize that drug concentration standardization is essential to improving medication safety. A long-standing practice in pediatrics and neonatal intensive care units (ICUs) was to prepare a patient-specific concentration for each IV infusion based on an individual patient’s weight. The drug selection required programming of the drug amount and the volume it was mixed in to allow the pump to calculate the drug concentration. The widespread use of non-standard concentrations increased the risk that the final concentration could be programmed incorrectly. In addition, as discussed above, one response to selecting the wrong drug concentration from a list of standard concentrations was to reprogram the concentration. DERS CQI data analysis revealed that sometimes, rather than cancelling a wrong selection, clinicians merely edited it to create a new concentration. This carried the risk of introducing a new error if the concentration was not edited correctly. In addition, the drug was identified on the pump’s electronic display by the drug nomenclature that had been selected (not as edited). Thus, if a drug library listed “Dopamine 1X, Dopamine 2X, Dopamine 4X”, selecting “Dopamine 1X” and then reprogramming the concentration to equal 2X changed the dose calculation but left the display showing “Dopamine 1X.” A solution to these opportunities for potential programming errors was to introduce concentration limits (both low and high) for non-standard concentrations and make standard concentrations a non-editable field. Users are forced to cancel the programming and reselect the correct drug entry.

Adding a Loading/Bolus Dose Option

Early analyses of DERS CQI data revealed a common practice that presented previously unrecognized, serious safety risks. Numerous IV medications are administered initially with a loading dose to quickly establish a therapeutic level of drug, followed by a continuous infusion to maintain the therapeutic drug level. During the continuous infusion, increasing the therapeutic level involves periodic administration of a bolus dose. Most hospitals have policies that require caregivers to use separate vials—not the continuous infusion container—as the source of the loading or bolus dose. The reason for such policies is that resetting the infusion pump parameters to provide the higher dose could result in a variety of errors, such as failing to reduce the infusion dose following the bolus delivery.

Despite such established policies, the early DERS CQI data revealed a surprisingly high incidence of high-rate infusions with soft-alert overrides. One drug that
stood out was propofol, which is widely used in ICU patient sedation (Figure 2). The drug is administered as a continuous infusion, with frequent bolus doses to rapidly increase sedation in agitated patients who, for example, might be attempting to pull out a tube or climb out of bed. DERS CQI data analyses provided evidence of a widespread practice of reprogramming the pump to very high rates (often the maximum rate of the pump) and not setting a limit on how much drug would be administered. Caregivers apparently had adopted this practice long ago, and the soft alerts they received were just considered a nuisance. In most cases the soft alerts were overridden in less than two seconds; as few as 4% resulted in reprogramming.

The availability of such data helped hospitals to accept the addition of hard limits on the continuous dose and the addition of a loading/bolus dose programming option with soft and hard limits around the drug amount and the minimum time over which the bolus could be administered. These enhancements added a new level of safety to the frequent bolus/loading doses, while keeping the convenience of infusing these doses from the continuous infusion container.

Adding Point-Of-Care Drug Information
The amount of information printed on a 250-mL IV container of a pre-mixed drug such as heparin is substantial. However, beyond the drug name and concentration, the information is of no real benefit to a clinician. There is essentially no information on the drug, dosing instructions, precautions, etc. Although some additional information could be added to the pharmacy-applied IV container label, many hospitals now use pre-mixed IV medications (which have no pharmacy-applied labels) that are dispensed through controlled-access cabinets on nursing units. This approach has many advantages, including rapid availability of the medication, but fails to provide important auxiliary drug information for clinicians.

To address the lack of point-of-care supplemental drug warnings or cautions on IV containers, some smart pumps now include clinical advisory screens that follow the selection of certain medications from the library. For example, when the library includes a drug with two or more dosing-unit selections, adding a clinical advisory screen provides a second warning to double-check the selection. With heparin, one dosing method calculates the dose as units/hr and the second uses the patient’s weight and calculates the dose as units/kg/hr. Selection of the wrong heparin listing in the library can potentially result in a large under- or overdose. Creating clinical advisories to follow each selection provides an additional safeguard to help ensure selection of the right drug/dosing unit.
combination. Figure 3 shows an example of a free-text clinical advisory for heparin.

Transferring Programming Information to IV Labels
At some hospitals the analysis of DERS CQI data revealed a consistent set of programming parameters that triggered alerts. Comparing the data from programming errors with the information on the pharmacy-applied IV label showed that a nurse could misinterpret the information on the label. For example, a chemotherapy drug might be prepared using the instructions on a computer-generated label produced by the pharmacy computer system. But a pharmacy technician compounding the IV admixture and a nurse administering it require different information presented in a different order. Information intended for the pharmacy technician may lead to pump misprogramming if used by the nurse. In addition, the information on the label could lead to programming errors when it was not consistent with the order used to program the pumps.

In these cases the CQI data helped staff to identify the cause of certain programming errors. Changing the information presented on the pharmacy-generated IV container label eliminated the potential confusion in pump programming. In one case, information was added to clarify what was pharmacy compounding information and what was nursing programming information. In a second example, the hospital pharmacy modified the order in which information was displayed to match the order in which the pump was programmed.

Automatic Identification Using Bar Code Technology
Analyses of DERS CQI data showed a significant number of cancelled infusions, some of which were thought to be associated with incorrect drug selection from the increasingly complex drug library. One solution was to add image recognition to the infusion system, so that scanning a bar code label on an IV container automatically selects the correct drug/concentration. For manufacturer-supplied IV infusions, the label includes the drug name and concentration. For individual hospital-supplied, patient-specific IV admixtures, the bar code label can include additional information such as the patient identifier.

The advantages of using bar code technology include reducing the number of programming steps, increasing the safety of the drug/concentration selection, and ensuring that patient-specific IV infusions are administered to the right patient. Two other advantages are that DERS CQI data can be associated with a specific patient and a specific caregiver. While the patient and caregiver association are of some value for DERS CQI data analysis, they are mandatory for the seamless integration of smart pumps with the electronic health record.

Ability to Review Safety Alerts During Infusion
IV therapy is unique among the various types of drug administration in that it is typically a “process,” whereas
administration of tablets and injections are discrete “events.” The administration of an IV drug often involves multiple clinicians, can take place over hours or days, and is frequently modified to meet changing patient conditions.

Although programming of an IV pump may lead to an alert, as already established the alert may be overridden, typically for sound clinical reasons. If related to the dose being out of range, the override is indicated on the pump. For example, the drug name and dose can be preceded with up arrows, indicating that the dose is above the range for typical use. The early generation of smart pumps did not have a way to easily determine what led to the alert if a second nurse assumed responsibility for the patient’s care. Clinician input and HFE analyses led to the addition of an alert inquiry icon and soft key to identify the nature of the alert. Previously this information for doses out of range required the clinician to reprogram the pump to the current settings in order to receive and evaluate the alert.

As there are multiple types of alerts, such as concentration alerts, the alert inquiry key allows the clinician to view previously overridden soft alerts not associated with the dose. Without this alert override icon, the fact that an alert had previously been overridden would only be visible on the DERS CQI data.

Discussion
The early design process did not anticipate the tremendous complexity and variability in IV infusion practices both within and among hospitals. Smart pumps forced hospitals to create drug libraries based on their best knowledge of current practices. However, as smart pumps became more widely adopted, analyses of individual hospitals’ CQI data and pooled CQI data from large numbers of hospitals uncovered numerous issues, patterns of practice, and potential safety risks that provided opportunities for iterative enhancements.

The ongoing refinement of “smart” IV infusion safety systems to help avert the highest-risk medication errors provides an excellent example of continuous quality improvement based on repeated analyses of use data. While most medication safety technology enhancements—such as computerized prescriber order entry (CPOE), electronic medication administration records (e-MAR), and bar code medication administration—are new developments that have not been previously employed, infusion pumps and infusion practices have a long history. Until the early 21st century there were essentially no limitations and virtually no feedback on how infusion pumps were used. Bringing new DERS IV infusion safety systems to the market was a major safety advance. The CQI data logs in the pump software have provided previously unavailable data that have been used to help identify unrecognized risks and to develop the necessary safeguards.

Conclusion
It is essential that vendors and clinicians continue to work together to continuously monitor technology use, in order to identify previously unrecognized opportunities for errors and to develop new solutions in the well-known process of CQI. The ongoing refinement of “smart” IV infusion safety systems to help avert the highest-risk medication errors is an excellent example of CQI. Analyzing the extensive data automatically collected by the smart pump logs provides actionable information that can help improve IV medication safety and further establish IV infusion best practices. ■

References