

# Measuring medication safety with smart IV systems



## Introduction

Inter-professional conference on intravenous medication safety:  
**Measuring medication safety with smart IV systems**

The fourth invitational conference at the Center for Safety and Clinical Excellence in San Diego, held on June 11, 2004, brought together a distinguished faculty from clinical practice, academia, organizations and industry. Philip J. Schneider, MS, FASHP, Director of the Latiolais Leadership Program and Clinical Professor at The Ohio State University, chaired the conference and moderated the roundtable discussion. Nationally recognized experts from different health professions focused on the use of an intravenous medication safety system that averts high-risk medication errors and provides previously unavailable data to measure medication safety and best practice improvements.

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# Putting the “I” into “IT”—the critical importance of information in the use of information technology

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When you read the Roundtable Discussion section of these proceedings, you will note that the theme of this introductory editorial can be attributed to a comment by Dr. Charles Denham. He was reflecting on his observation that Chief Information Officers are now beginning “to recognize the critical importance of the ‘I’ part of ‘IT.’” Let me start by acknowledging this valuable insight. Perhaps it has been too easy to consider technology a panacea for many problems, including those with patient safety. Certainly there are a plethora of new technologies that are being promoted and endorsed to improve medication use safety. These include computer prescriber order entry (CPOE), barcode medication administration (BCMA), robotic and point-of-care dispensing systems, “smart” IV pumps and integration of these technologies. Some of these technologies have been discussed at the previous CareFusion Invitational Conferences.<sup>1,2,3</sup>

What we have learned at these meetings is that the technologies are only a tool to improve system performance. Indeed, at one meeting it was noted that there are actually “side effects” or unexpected changes, that occur when technologies are introduced.<sup>4</sup> We need to be careful when investments are made in new technologies intended to improve medication safety, in order to realize their benefits. The most obvious features of these technologies are the decision support, forcing functions and alerts that are provided to clinicians at the point of care when performing a patient-specific activity. For example, through a CPOE system a prescriber might be warned or even prevented from ordering a medication to which a patient has a known allergy. When using a BCMA system a nurse might be warned when trying to administer

a medication to which the patient has a known allergy or if the dose is too high. The point-of-care features of these systems are merely design features of the technology that depend on Information to achieve their desired intent. Furthermore, most institutions have found that this Information must be customized to each organization to reflect the patient population, preferences and best practices. This means more is required than just buying technology. Time, effort and expertise are needed to use information to design decision support that really improves patient safety and achieves the desired impact.

The second and often overlooked benefit to medication safety technology is the storehouse of Information that serves as an electronic record of what actually happened at the point of care. As noted in the first article of these Proceedings, measuring medication safety has been notoriously difficult.<sup>5</sup> Making durable changes to improve medication safety requires more than preventing events at the point of care. It requires making system changes, so that events that occur more often or those that result in serious injury to patients don’t happen again. This means taking the time to select technology that can provide useful Information about medication safety events and providing reports that can be used to identify system failures that can be corrected.

Don’t fall into the trap of buying expensive technology and thinking that patient safety has improved. It requires the use of Information, both at the point of care and over time, to actually use technology to actually improve patient safety. Make sure you don’t forget what the “I” means in the acronym “IT.”

# Measurement as a component of system improvement

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## Key points:

- Improving system performance requires a way to measure system performance
- Commonly used methods for measuring medication system performance are not optimal
- Electronic tools will provide a more accurate and effective way to measure, monitor and manage medication use system performance

At The Ohio State University Medical Center, we monitor the quality of care using the “vital signs of quality.” Such “vital signs” include the rate of nosocomial infections, post-surgery mortality rate, frequency of unexpectedly taking patients back to the operating room, frequency of readmitting patients to the hospital for the same diagnosis within 60 days of discharge and the number of times that patients fall while they are in our hospital.

What is the vital sign for medication safety? I can tell you from personal experience and after 20 years of being asked by our Board—there isn’t one. Medication safety is very difficult to measure, monitor and manage.

The tool used in most hospitals and health-systems is a record of voluntarily reported errors and events (Figure 1). While this method is easy, it presents several problems.<sup>1</sup> It dramatically under-reports errors—perhaps as few as one in 100 are reported. It does not usually report events where an error is prevented, but from which we can still learn (the “free lessons” that occur so often). Finally, it does not identify dangerous conditions that create the possibility of error.

This method does offer some advantages, including staff participation and the qualitative information that often can be gleaned from a narrative, but clearly a better measurement system is needed.

## Underreporting: How big is the problem?

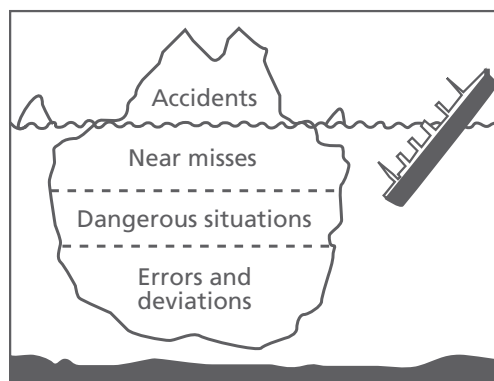


Figure 1.  
Detection rate depends on the intensity of surveillance.

## A better a method of measuring medication safety would achieve the following objectives:

- Detect errors at all steps in the medication use process, including prescribing, dispensing, administration and monitoring
- Detect all events that occur, providing a quantitative measurement that could be used to assess the impact of changes intended to improve medication safety
- Include qualitative information that would make it possible to learn from the events that transpired (the “story behind the story”)
- Not trigger false alerts where no error actually occurred
- Not be too expensive or require too much staff time to implement and maintain
- Measure medication safety from a number of perspectives to provide a clearer picture of how a system is performing

Measurement is a critical tool in systems improvement because every improvement requires a change. It is crazy

to think that things will get better by doing them the same way. Measurement allows you to confirm that you are doing things differently and achieving results.

A common approach to systems improvement uses “the Improvement Model,”<sup>2</sup> which asks three simple questions:

- What are we trying to accomplish?
- How will we know that a change results in improvement?
- What changes will we try to see if improvement results?

The improvement process is shown in the commonly used “PDSA cycle” [Plan-Do-Study-Act]. While the process starts with planning a particular change, then making the change, evaluating the results of the change and thinking about what to do next, it could just as easily start with a discussion of what changes are to be made (the “act”) step. Regardless of where one starts and how many times the cycle for learning and improvement is repeated, measurement is a central component of this model.

The Improvement Process and the PDSA Cycle are unified in Figure 2. The process starts with a clear idea of and agreement about the goal of the improvement effort.

**The improvement model<sup>2</sup>**

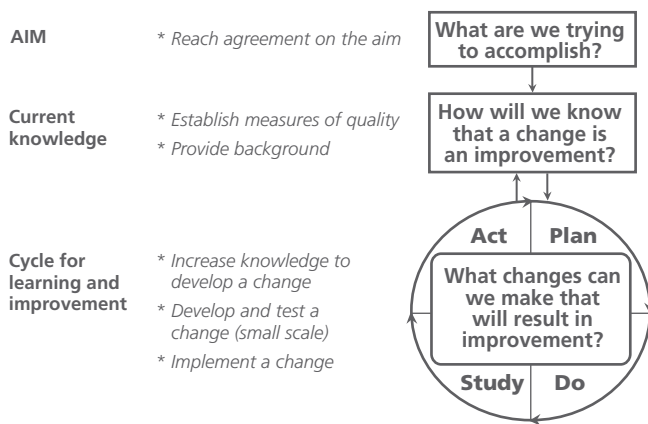


Figure 2.

This is followed by a thorough understanding of what is known about the current state and how to measure progress toward the goal. It is followed by repeated application of the PDSA cycle to achieve the goal. Implicit in this approach is that one change does not usually achieve the desired results.

Ideally, each reiteration of the PDSA cycle will result in

some improvement and progress toward the agreed-upon goal (Figure 3). As stated earlier, it is not common for a single change to result in the achievement of the intended goal. In fact, it has been argued that an organization should never be satisfied with performance, no matter how much it improves.

**Ramping up change<sup>2</sup>**

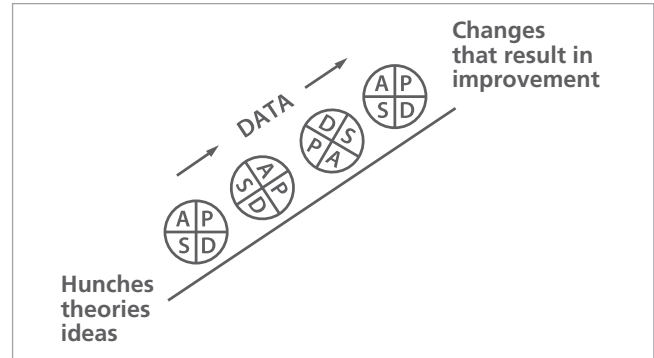


Figure 3.

Let’s take a closer look at the Improvement Model. The first question to ask is: What are we trying to accomplish? Do we even know if there is a need to make a change and whether change can, in fact, lead to improvement? How would we find out? Two suggestions for exploring such questions are:

- Review published information (e.g., Institute of Safe Medication Practices [ISMP], United States Pharmacopeia [USP], case reports)
- Review incident reports at your hospital

An example of an incident is administering IV vancomycin too rapidly, causing the “Red Man” syndrome. The goal might be to reduce the frequency of this adverse drug event, or even to eliminate it entirely.

The question then arises, if a change or changes are made, how will we know if the frequency of this adverse drug event (ADE) decreases? Are incident reports a sensitive enough measurement system to determine if our goal has been realized? Probably not. What measurement system might we use that would be better?

Possibilities for better systems to measure ADEs include 1) observation of drug administration and clinical response, and 2) chart review for evidence of adverse clinical event. Both methods are quantitative and qualitative and would be an effective ways to see if change results in

improvement. However, these methods are also expensive and time consuming.

Besides using a metric to measure performance, it is also important to use the information gathered effectively. Measuring performance over time is the most effective way to present the information (Figure 4),<sup>3</sup> because the impact of change on performance can clearly be associated.

The most creative step in making improvements is identifying changes that may result in improvement.

### Measuring performance over time<sup>3</sup>

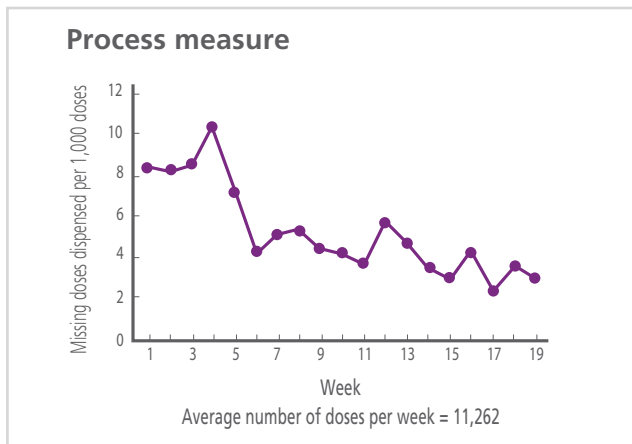


Figure 4.

These line (the so called “sharp end”). Administrative (“blunt end”) involvement is also needed because of the fiscal and changes need to come from people who are at the front political impact of making change in any organization.

To continue our example, changes that could improve the safety of vancomycin infusions include:

- Education of nursing staff about the association between infusion rate and adverse reactions
- Supplementary labeling alerting nurses about the importance of recommended infusion rates
- An elastomeric infusion device with a fixed administration rate that was lower than a rate that would cause a reaction

The temptation is to be too ambitious in setting the goal, i.e., trying to do too much at one time. A good axiom to

use in starting the process is to ask the group, “What can you try by next Tuesday? I will negotiate what you try, but not Tuesday.”

Another trap is to place too much emphasis on being quantitative. An improvement exercise is not research, and there is no need for a statistically valid sample. If a change results in improvement by the end of the week or in the next ten patients, adopt it, and then move to the next change concept.

It should be noted that several good experiences do not constitute an “evidence base” to support a change. Generalizability may be limited because circumstances may be different in another organization. This is not meant to criticize either qualitative or quantitative methods—both are needed. We ought not let an attempt to be too quantitative get in the way of making changes for improvement.

Leape and Bates have found that the drug administration step is the second most common point in the medication use process at which errors occur, with 38% of preventable ADEs occurring because of errors at this step.<sup>4</sup> In addition to the high frequency, it is also important to consider that errors at this step are rarely intercepted before a dose is administered to a patient.

Measurement of performance and safety traditionally have been done either by expensive observation-based studies or through voluntary reports. Technologies have been developed and advocated to provide double checks at administration to improve medication use; these could also play an important role in measuring medication safety.

While it is tempting to view technology as a panacea, experience from early adopters shows that there are some limitations.

- Practitioners find creative ways to bypass the safeguards in a system, creating new failure modes
- The frequency of alerts may significantly exceed the number of times an actual event occurs or a significant event is prevented
- Unless the system is properly configured, a lot of non-specific data are generated that make it difficult to extract the important information
- Data produced from electronic records rarely provide any narrative that might be needed to identify the root cause of an error
- If data are used to penalize staff, this may not support the culture of improvement needed to use such information for learning

As public attention focuses on the quality of healthcare, improving patient safety has become more important, both for healthcare providers and for those in academia who study healthcare. Both groups need a more quantitative method for measuring patient safety, in order to improve care at the bedside and to provide an evidence base to support improvements that often require changes in work and investment. Finding such a method is not an easy task, but it is likely that the introduction of new technology with a rich storehouse of electronic information will be a breakthrough in measuring medication safety. Smart infusion medication safety systems are being used by early adopters for exactly this purpose.

# Moving from infusion pumps to an intravenous medication safety system

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## Key points:

- Intravenous (IV) medication errors are associated with the greatest risk of patient harm
- General-purpose infusion devices can deliver medication over a wide range of doses and rates, without the capability of performing a “test of reasonableness”
- So-called “smart pumps” are large-volume pumps (LVPs) with dose-error reduction software to perform a “final check” to help avert IV medication errors
- An IV medication safety system offers a technology platform that:
  - Offers harm and dose-error reduction software across multiple types of infusion devices
  - Integrates infusion and patient monitoring devices using a common user interface
  - Can be networked with a hospital’s information technology systems, providing immediate access to data and accelerating best practice and process improvements

## Preventing harm

Since the Institute of Medicine report was published in 1999, several strategies to reduce medication errors have been advocated, including computerized prescriber order entry (CPOE), barcode medication administration (BCMA), clinical pharmacy services, automated drug dispensing cabinets and dispensing robotics. While these strategies can be effective in reducing the overall rate of medication errors, they have limited effectiveness in addressing intravenous (IV) medication administration errors, which pose the greatest risk of harm.<sup>1,2</sup> MEDMARX

2002 data showed that the IV route of administration for medications often results in the most serious medication error outcomes.<sup>3</sup>

IV infusions are administered to the sickest patients, often with a large number of infusions being administered simultaneously with frequent dosage adjustments. Compared to oral and non-IV parenteral medications, an IV infusion typically is not a single administration event, but rather a series of programming events at the “sharp end” of the medication use cycle, i.e., at the point of care, where the risk is greatest. In a seminal medication error study, Leape et al found that 38% of the preventable medication errors occur at the point of administration, and only 2% of these are intercepted.<sup>4</sup> IV medication is associated with 61% of the most serious and life-threatening potential adverse drug events.<sup>5</sup>

Together, these findings point to IV administration as the area in which errors have the greatest potential for patient harm. Consequently, implementing medication safety systems that can increase interception of IV administration errors has the greatest potential to reduce harm and provide a safety net for patients and nurses that is not available in many of the medication safety initiatives.

## Need for improved IV infusion safety

The increasing complexity of IV therapy has led to the development of sophisticated infusion devices designed to deliver accurately a wide variety of therapies. The infusion devices, commonly referred to as “pumps,” are the medical devices most widely used in hospitals today. Approximately 750,000 pumps are used to deliver over one million IV doses per day in United States hospitals. Unlike medications, which are ordered and dispensed

based on individual patient requirements, infusion devices typically are not configured for individual patient use. Rather, they are configured at the time of installation to cover the full spectrum of possible applications, from a pre-term 600-g baby receiving a fraction of a milliliter per hour to an 80-kg trauma patient receiving a liter per hour. These general-purpose infusion devices are designed to be easy to use, require no authorization to program, and have a 10,000-fold rate and dose range that can support a wide range of infusion orders. Until recently, infusion pumps had no capability to provide a “test of reasonableness” to the programming of an IV medication or fluid. These are reasons why IV medication errors often result in the most serious outcomes.<sup>3</sup>

### “Smart” infusion systems

A new generation of infusion devices introduced in May 2001 provides an IV safety net for nurses at the bedside. Although shipped to hospitals as “dumb” infusion devices with features similar to existing legacy pumps, these new “smart” (computerized) large-volume pumps (LVPs) incorporate software that can be customized for each hospital’s “best practices” for IV therapy. The best practices are incorporated in the safety software to create multiple patient-care-area libraries that include medications, concentrations, dosing units and dose limits. For the first time, hospitals can have the equivalent of ten infusion devices in one, with drug libraries and infusion rules designed for unique areas or patient types (referred to as “profiles”). Once a clinician identifies the profile for a particular patient care area such as neonatal intensive care unit (ICU), med/surg or adult ICU and selects a drug to be infused, the customized software applies hospital best practices to check device programming, thereby ensuring a new level of safety for IV therapy.

Standardized concentrations, non-editable drug dosing units and minimum and maximum dosage limits are among the safety elements of these new devices. In February 2002, the newsletter of the Institute for Safe Medication Practices described this new technology as a “smart” pump.<sup>2</sup> In addition to reducing the opportunities for programming errors through incorporating best practice guidelines and providing alerts when programming exceeds limits, some devices also maintain a log of the alerts

that can be downloaded for future analysis and process improvement. In October 2002, Health Devices, published by ECRI, evaluated all currently marketed general-purpose infusion pumps and concluded that only pumps that had “dose error reduction software” should be considered for purchase. The ECRI criteria are reviewed in Figure 1.

#### What makes a pump smart?

ECRI has established Smart Pump criteria:

- Minimum of 8 profiles or “areas of use”
- Comprehensive drug library including:
  - Drug names/concentrations
  - Dosing units
  - Hard and soft dose limits
  - Max weight, max rate, max volume per profile
- Forced function to select new patient and area of use
- Continuous display of drug name/dose on infusion pump
- Continuous indicator of doses infused outside of the limit (soft)
- Comprehensive log to record smart alerts
- Support structure to assist in smart pump implementation

Only 3 currently marketed infusion pumps and one syringe pump meet all ECRI Criteria

*Health Devices, October, 2002, October 2003*

Figure 1.

### Creating the best practice rules

Customization of the safety software database for the smart pumps is accomplished through review of existing IV practices and creation of an extensive drug library. A master drug library is created that includes the drug names and available concentrations. Appropriate items from this extensive library, which often numbers in the hundreds of entries, are then copied to each patient care area profile where a particular drug/concentration will be used. In addition, minimum and maximum dosage limits, including soft (can be overridden at clinician’s discretion) and hard limits (cannot be overridden), are added at the sub-library level for each profile.

For example, dopamine may have three concentration entries in the master library (400 mg/250 mL; 800 mg/250 mL and 1600 mg/250 mL). In a specific profile, dopamine may be available in one, two or all three

of the concentrations, or it may not be available if the drug is not used in that patient care area. All three combinations may be available in the adult ICU, only one in the step down unit and none in med/surg.

For each entry, minimum/maximum dosing units can also be customized according to how the drug is used. The maximum dose that can be programmed for dopamine before an alert is provided may be 20 or 22 mcg/kg/min in an adult ICU, whereas the maximum dose might be 5 mcg/kg/min in a step-down unit. The ICU dopamine limit may be designated as a “soft” limit, while the step-down limit may be a “hard” limit to reflect the different indications for the same medication.

The process for developing and approving the IV best practices varies among hospitals, but typically is pharmacy-driven with final approval by the Pharmacy and Therapeutics Committee or the Medication Safety Committee. Prior to loading the best practices into the infusion devices, a line-by-line signoff is required. The most advanced smart pumps utilize a CD-ROM with multiple levels of security, and the safety software and data set are transferred by biomedical engineers using a laptop computer.

The initial smart pump drug libraries were limited in capacity, and the drug data sets typically included 30 to 40 IV medications with standardized concentrations, dose limits, etc. The current software allows a much larger library, which includes multiple listings for the same drug with indications or other modifiers. For example, tPA (Activase, Alteplase, recombinant) may be listed as: tPA (stroke); tPA (MI) and tPA (PE) with corresponding concentrations, dosing units and limits appropriate for each application. This has resulted in making what initially were drug entity best practices into drug/indication best practices and tightening the limits accordingly.

**Logging the alerts.** Traditionally, there has not been a way to measure IV drug infusion practice. Short of actual observation studies, little information could be gleaned from the infusion devices with the exception of key press logs that were reserved for use in investigation of IV errors. Certain models of smart pumps maintain a log of all programming alerts, as well as the caregiver’s response to an alert. The logs capture the infusion device serial number,

care unit, drug name/concentration, initial programming and response to the alert. At the individual hospital’s discretion, a patient identifier (e.g., history number) can be entered in the smart pump as the device is assigned to the patient. If included, the logs of the alerts can be associated with a specific patient.

Smart pump logs have varying capacities, ranging from a day or two up to 6 months or more of data. Most hospitals download the logs at 3- to 6-month intervals. The data contained in the logs can be analyzed using a variety of bar, pie, run and other charts. Data can be segregated based on time of day, time of week, per patient care area and per drug. Risk management, medication safety officers, nursing management and medical staff and pharmacy all can use the data to track and trend prevented errors, determine where best practices may not match current practice and identify potential opportunities to improve IV drug administration. Individual hospitals have used the data in a variety of ways both to address areas of potential harm prevention and to improve therapy by implementing and measuring adherence to best practice guidelines.

### Smart medication safety systems

As shown in Table 1, in contrast to smart pumps, the modular design of an IV medication safety system incorporates multiple types of pumps—not just LVPs—as well as patient monitoring equipment. The integrated medication safety platform uses a single interface for all devices, which reduces training needs and opportunities for error.

An IV safety system provides more comprehensive CQI reporting and analytic tools. Wireless systems are beginning to be applied to IV medication safety systems and can provide near real-time data to allow clinicians to act on the data much more quickly. Networked systems also allow an organization to identify more quickly situations where someone may be operating outside of best practices and either to refine the dosing limits in the safety software or provide additional training regarding best practices.

Making IV devices “smart” is a tremendous advance; integrating smart IV safety systems with a hospital’s

information technology opens new opportunities to achieve even greater gains in medication and patient safety.

<b>From smart pump to smart medication safety system</b>	
<b>Smart pump</b>	<ul style="list-style-type: none"> <li>• A standalone infusion pump supported by dose error reduction software</li> <li>• Provides standardized concentrations and dosing limits at the bedside</li> <li>• Offers limited continuous quality improvement</li> <li>• (CQI) storage and reporting capabilities</li> </ul>
<b>Smart medication safety system</b>	<ul style="list-style-type: none"> <li>• Integrated medication safety platform that offers harm and dose error reduction safety software across all infusions on one platform and includes PCA, large volume delivery, patient monitoring and syringe delivery</li> <li>• Integrates patient monitoring using a common user and IT networked interface</li> <li>• Provides comprehensive CQI reporting and analytic tools that allow hospitals to more frequently improve best practices</li> <li>• Speed to impact through CQI reporting and analytic tools that are networked, providing immediate access to the data and accelerating best practice and process improvements</li> <li>• Networked for safety and workflow efficiency, providing a single gateway into hospital systems from multiple modalities</li> <li>• Only 3 currently marketed infusion pumps and one syringe pump meet all ECRI Criteria</li> </ul>
Health Devices, October, 2002, October 2003	

Table 1.

**Summary**

In less than three years since the introduction of the first smart pumps, advanced infusion technology has proven that the risk associated with IV infusions is very high and the number of “good catches” is significant. In one evaluation of pooled data from 18 hospitals using smart IV devices, the risk of a potentially life-threatening programming error is approximately one error/1000 patient days (Table 2).<sup>6</sup> Compared to other medication safety initiatives such as CPOE, BCMA and electronic medication administration records, smart pumps are quick to **Pooled**

hospital data—risk/1000 patient days<sup>6</sup>

<b>Harm potential</b>	7 hospital pool (3/03)	10 hospital pool (8/03)	18 hospital pool (2/04)
<b>MINIMAL</b> (No to minor clinical effect)	<b>2.6</b>	<b>2.2</b>	<b>1.9</b> (n = 810)
<b>MODERATE</b> (Probable significant clinical effect)	<b>0.8</b>	<b>0.8</b>	<b>1.5</b> (n = 626)
<b>SEVERE</b> (Potentially life-threatening)	<b>1.1</b>	<b>1.3</b>	<b>1.1</b> (n = 459)

Notes: 18-hospital aggregate data represents 425,000 hospital patient days  
Dose above maximum with reprogramming events only

Table 2.

implement, provide immediate safety, capture data related to IV risk of harm and force compliance with best practices.

IV medication safety systems incorporate not only smart pumps but also a technology platform that integrates multiple types of pumps, patient monitoring devices and networking interface. This advanced infusion safety technology holds the promise of accelerating the rate at which healthcare organizations can implement, monitor and continuously improve infusion therapy and overall patient care.

*Activase (Alteplase, recombinant) is manufactured and distributed by Genentech, South San Francisco, CA.*

# Developing the evidence for IV safety—preliminary report from a smart pump study

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## Key points:

- Smart intravenous (IV) infusion systems have great potential to reduce serious and life-threatening medication errors in critical care units
- Successful implementation of smart IV systems requires early evaluation of pump log data findings from newly implemented systems and assessment of pre-existing nursing practices such as infusion practice violations
- Successful integration of new technologies such as smart IV systems into nursing practices requires institutional leadership and local (e.g., unit-level) support in order to maximize the safety potential of these tools

The medication administration process is a complex series of events that includes many steps.<sup>1</sup> Medication errors are frequent and can lead to adverse drug events (ADEs).<sup>2</sup> The ADE Prevention Study found a rate of 6.5 ADEs for every 100 admissions, of which 28% were preventable or due to a medication error.<sup>3</sup> In the ADE Prevention Study, medication administration by nursing was the second most common stage (38%) associated with ADEs. The most common proximal causes of ADEs during the nursing medication administration stage were inadequate drug knowledge and problems related to intravenous (IV) infusion pumps and parenteral delivery problems.<sup>1</sup> Administration errors are also more difficult to detect, likely resulting in an underestimation of the true rate.

Intravenous (IV) medications are vital in the therapeutic management of hospitalized patients and are often delivered with infusion pump systems. Critically ill patients are particularly susceptible to ADEs<sup>4</sup> and frequently receive

potent IV drugs with narrow safety margins that require careful titration. While these medications can be lifesaving, errors in administering them have a high risk for severe adverse events, including fatalities.<sup>5</sup> Newly developed “smart” IV infusion systems have been designed to reduce the rates of these types of errors.

Few studies have evaluated the relationship of infusion pump use to medication errors. Therefore, we sought to study the impact of introducing a smart infusion system on serious medication error rates. This study also provided an opportunity to learn of some of the challenges associated with successful integration of new technology into critical care nursing practice. Caring for critically ill patients involves complex interactions between clinicians, patients and the many devices used for patient support.

## Study design

The study was supported by the Agency for Healthcare Research and Quality as part of a “Center of Excellence in Patient Safety” grant. This study was conducted at the Brigham and Women's Hospital in the cardiac surgical intensive care units (ICUs) and step-down monitored units. The study was originally planned as a randomized control trial. This design was not used due to logistical challenges in reliably identifying patients prior to initiation of cardiac surgical cases for assignment to control or intervention patient care units. Therefore, the study design became a non-blinded, prospective time series spanning four 8-week data collection periods, each separated by 2-week transition phases. The first and third period were control/off periods and the second and fourth periods were intervention/on periods. Pumps were reconfigured to

provide point-of-care, real-time decision support feedback for the intervention/on periods. The feedback feature was inactivated during the control periods.

The interface and design of the Alaris® System was upgraded from pumps used before the study and included a drug library. The library incorporated standardized concentrations for commonly used drugs, weight-based volume and rate calculations, dose and rate limits, and alerts based on predetermined limits. Alerts could be designated either as “soft,” allowing overrides, or “hard,” which cannot be overridden. Hard limits were not implemented during our study.

Nurses had the option to select a drug and concentration from the drug library list or could bypass the drug library by entering a drug as a non-specific or generic infusion. Generic infusion selections were meant for less commonly used drugs not included in the library and were not associated with predetermined dosing or rate limits and alerts. Programming for starting new IV medications with the early version of the system software used during the study required selecting additional prompts to move from the generic infusion mode to the drug library mode. These extra steps are important features with regard to library use compliance.

Medication error and ADE cases were found by several methods, including chart review, solicited staff reports, hospital incident reports, a computerized ADE surveillance monitor and alerts generated by pump log reports. Trained research nurses abstracted charts and created incident case summaries for presentations to physicians.

Two independent physician reviewers with expertise in judging adverse events rated cases. In addition, we detected several potentially risky practices:

- Bypassing the drug library knowledge base when the drug was in the library
- Overrides of warning alerts when judged clinically inappropriate
- Undocumented verbal orders for administered medications

Bypassing the library prevented the IV safety system from checking drug limits or providing feedback alerts. Overrides were defined as either a continuation of a medication at a rate higher than the preset alert limit or bolusing of

medications for brief periods at rates far in excess of the alert limit. Medication boluses (e.g., rates of 999 mL/hr) were considered violations if the practice was not consistent with hospital nursing guidelines and/or the bolus lasted longer than 15 seconds.

In light of these challenges, in addition to the intention-to-treat findings, we also assessed the potential impact of correctly using the system’s safety features on preventing medication errors resulting from rule violations. We re-rated the preventable ADEs and non-intercepted potential ADEs that escaped interception during the intervention bolusing of medications for brief periods at rates far in excess of the alert limit. Medication boluses (e.g., rates of 999 mL/hr) were considered violations if the practice was not consistent with hospital nursing guidelines and/or the bolus lasted longer than 15 seconds.

In light of these challenges, in addition to the intention-to-treat findings, we also assessed the potential impact of correctly using the system’s safety features on preventing medication errors resulting from rule violations. We re-rated the preventable ADEs and non-intercepted potential ADEs that escaped interception during the intervention period due to bolus and override violations. Excluding these violations provides an assessment of the system’s capabilities for preventing serious errors in an “ideal” setting.

### **Preliminary findings**

There were a total of 744 admissions, including more than 8,000 patient-pump days in the control and intervention periods. Overall, we found a total of 219 medication errors, including 25 preventable ADEs and 155 non-intercepted potential ADEs. There was no difference in the rate of serious medication errors between the control and intervention periods.

The most common types of error were incorrect dosing of titratable drugs and incorrect IV drug rates. The most common medications resulting in ADEs were vasopressors, electrolyte concentrations and diuretics. The most common injury resulting from ADEs were cardiovascular, especially hypotension, and metabolic derangements. Almost two-thirds of preventable ADEs were serious or life-threatening. Most of the potential ADEs were rated as having the potential for serious or life-threatening injury. Examples of intercepted potential ADEs, or near miss intercepts, are provided in Table 1.

**Case examples:  
IV safety software “near miss” intercepts**

- Vasopressin
  - entered at 1 unit/min instead of 0.1
- Dopamine
  - entered at 70 mcg/kg/min instead of 7
- Epinephrine
  - entered at 32 mcg/min instead of 2
- Heparin
  - entered concentration of 5 units/250 cc rather than 25,000 units/250 cc

**Table 1.**

Two problematic IV administration practices or violations occurred frequently during the study: bypassing of the drug library and overriding alerts, including the use of inappropriate boluses. During the intervention period, we found that among drugs preprogrammed in the drug library, 25% of programming bypassed the library either accidentally or intentionally. The most commonly infused medications bypassing the drug library during the intervention periods were propofol, continuous insulin infusions and vasopressors (Table 2). We also found that drugs were frequently given with no documented orders.

**Drug library bypasses during the intervention phase**

Drug category	Total drugs n	Bypass n (%)
Anesthetics (propofol)	676	246 (36)
Insulin	330	117 (36)
Pressors	645	113 (15)
Inotropes	57	5 (8)
All preprogrammed drugs	2,234	571 (25)
Total all drugs	5,364	571 (11)

**Table 2.**

The findings in the intention-to-treat intervention period were then reassessed to evaluate smart infusion system use if the safety features were correctly used during the intervention period. Examples of opportunities for interception of potential ADEs that were undetected in our study are provided in Table 3. After correcting for both library bypassing and alert overrides, the rates of preventable ADEs and non-intercepted potential ADEs

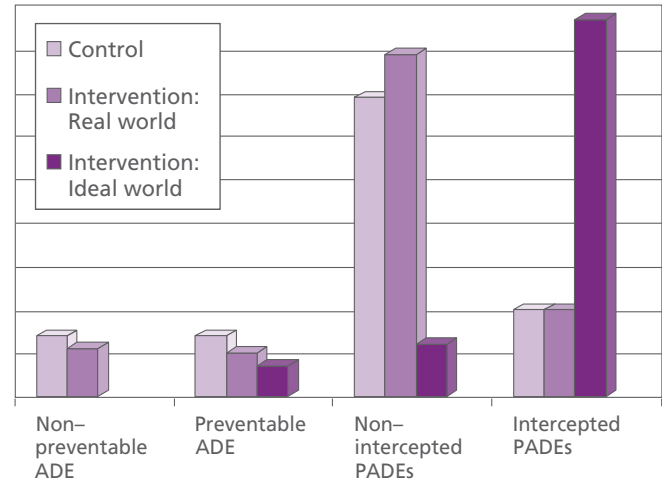
during an idealized intervention would have decreased by 36% and 82%, respectively (Figure 1).

**Case examples:  
Undetected opportunities for interception of potential adverse drug events**

- Heparin
  - *Bypassed* in drug library
  - 90,000 units/h for 10 minutes
- Nesiritide
  - New to formulary; *not yet entered* into library
  - Infused at twice the maximum dose
- Propofol
  - Soft Guardrails® limit *overridden*
  - Bolus infused at 999 for 2 minutes

**Table 3.**

**Drug library bypasses during the intervention phase**



**Figure 1.**

**Discussion**

We found that medication errors and ADEs associated with IV infusion pumps in cardiac surgical patients were common and not infrequently hazardous. While smart IV systems with decision support capabilities have the capacity to intercept many dangerous medication errors, and allowed detection of many errors that would have been difficult to find through other mechanisms, in this study smart pumps did not reduce the rate of serious medication errors. This was probably the case because the initial version of the infusion system made it easy for nurses to bypass the drug library and because overrides were frequent. The

more recent version of this technology has been improved. We believe that our inability to show a favorable effect of smart IV systems on safe infusion practice was due to both the system design at that time and the unforeseen clinical practices, which included many violations.

On the other hand, we were able to uncover correctable unsafe practices, such as administering many potent medications without documentation of physician verbal orders and the use of very high rates for certain drugs that were difficult or impossible to measure through other means. A surprising unintended consequence found in this study was the infrequent use of the drug library. At the beginning of the study, the default setting was not to use the drug library, and in fact nurses only used it 75% of the time in the intervention group. As a result of these data, the drug library was subsequently made the default setting and the library was expanded.

The capture of bedside medication programming history in log records is an extremely important benefit of smart IV systems, because this allows objective measurement of infusion practices, which can then be used to provide staff feedback. Logs can serve as “black-box” flight recorders used to capture aviation-related incidents and can provide data to analyze sentinel events due to infusion therapy. Logs can also be used to monitor several nursing practices including compliant use of the drug library, reducing overrides of drug dosing alerts and bedside drug administration behavior such as insulin titration.

Our analysis of the potential impact of smart IV systems used under more “ideal” conditions is an additional important analysis. In response to the study findings and after learning of nursing practice violations, we have been able to address some of the contributing factors to violation behaviors.

Interventions to improve our infusion practices included: educating nurses and physicians to eliminate undocumented verbal orders; providing education to increase user knowledge about the library and the safety features of the decision support software; changing the workflow to make it easy to use the library, including a new pump interface; upgrading the software so that clinicians automatically encounter the drug library rather than having to seek the library with additional keystrokes; expanding the library from 40 to 100 drugs for each

clinical service; adding an anesthesia mode for seamless transfer from the operating room to the ICU without reprogramming; the addition of an “indication for use” to the drug selection mode and additional clinical advisories during drug selection; changing the application to decrease the likelihood of programming errors that were more common with the new pumps and expanding the pump’s capability to better handle boluses.

Successful adoption and correct use of the safety features is critical to systems’ effectiveness in improving medication safety. Nurses need to be able to use these devices seamlessly and quickly in order to make sudden changes in infusion therapy for unstable patients. In an effort to perform better while providing care to many acutely ill patients, nurses may be taking shortcuts, or work-arounds, that violate safe IV infusion practice.

Successful strategies for implementation of smart IV systems into critical care nursing practice include the following:

- Standardization of concentrations across clinical units
- Review of the existing nursing practices and violations prior to installation of the new pumps
- Obtaining ground level support and buy-in from influential staff and leadership
- Early review of findings and providing user feedback following smart system implementation
- Targeting high-risk medications for early analysis and library maintenance on a scheduled basis in order to add new medications or upgrade alert limits

## Conclusion

In this study we found that there were many problems with infusion safety in critically ill patients that were under- or unrecognized before implementation of smart pumps. While we found no impact on the serious error rate, we did identify important errors. To substantially improve infusion safety, it will be necessary to continue to refine the technologies involved and carefully consider human performance aspects of the IV infusion process. Smart IV safety systems have the potential to substantially improve safety; the extent to which refined technology and lessons learned contribute to achieving that potential remains to be determined.

# A framework for analysis of medication events using infusion safety CQI technology

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## Key points:

- Intravenous (IV) safety system data of averted medication errors is a powerful tool to explore medication administration practices
- Review of continuous quality improvement (CQI) data will take time, knowledge and skills
- Review of IV safety CQI data has fostered collaboration between pharmacy and nursing
- Clinical staff should be included in the evaluation of CQI data to increase understanding of data and to help implement the system, knowledge and cultural changes needed to reduce IV medication errors

To address medication administration safety, organizations need to focus not only on medication errors but also adverse events resulting from errors. An adverse drug event (ADE) includes both reactions to the appropriate use of drugs and events that occur as a result of errors.<sup>1</sup> ADEs can be classified as “potential” (events with the potential for injury) and “preventable” (events due to an error that could have been prevented by any means currently available).<sup>2</sup> Information about medication errors and ADEs typically come from self reports. Leape, et al, found that voluntary reporting is unreliable and at best probably captures only 10% to 20% of actual medication errors.<sup>4</sup> Healthcare professionals rarely report preventable or potential ADEs.

As healthcare organizations move from risk management to improving risk prevention, documenting potential or preventable ADEs can help identify system and practices issues in their organizations. Technology can be a useful

tool for collecting this information by automatically recording information on actual, potential or prevented ADEs. For example, a smart intravenous (IV) medication safety system (the Alaris System with the Guardrails Suite, CareFusion, San Diego, CA) not only helps avert IV programming errors, but also automatically records information about errors associated with the administration of IV medications. For the first time, an IV safety system allows an organization to collect information on infusion medication administration practices from more than just a convenience sample and voluntary reports.

The software in this IV medication safety system allows an organization to build a drug library that provides decision support for the nurse at the point of administration to ensure that the medication is administered safely and correctly. The drug library is created through a collaborative effort among physicians, pharmacists and nurses and is customized for a specific patient population and types of IV medications administered. As the drug library is built, each member of the multidisciplinary team needs to understand how other members evaluate and manage medications, to ensure that the drug library incorporates the organization's best practices for administration of IV medications.

When a nurse administers an IV medication, the safety software captures data about the alerts provided based on the decision support, and what action the nurse takes after the alert. These continuous quality improvement (CQI) data can be downloaded and reviewed to identify and track trends, allowing organizations to have a first-hand look at possible IV medication events.

Organizations that have implemented this technology

quickly learn that the amount of CQI data captured by the IV safety system may be overwhelming. The data must be evaluated carefully, keeping in mind the need to focus on risk prevention while maintaining a blame-free culture. Evaluating the data also requires not only a review of the nurse who is programming the infusion device, but also of the entire medication process.

Access to these data creates new possibilities for most organizations. Analyzing the data using a framework that helps to identify system, knowledge and cultural issues can improve understanding of medication events and practices. This is also useful when discussing CQI data with members of the organization who may not be intimately involved in medication practices but are required to be aware of the organization's CQI activities. At City of Hope, the following framework has been useful in analyzing IV safety software data on "good catches" (averted errors) to improve best practices for infusion therapy.

### System issues

Systems issues are operational issues that affect medication management across the continuum of care. Examples of system issues that may be identified through the evaluation of infusion safety CQI data include:

- **Drug library modification.** As an organization builds its customized drug library, it may be difficult to accurately define various medication administration practices. Event information captured in the CQI software will help to identify the need to re-evaluate and modify the drug library, if rate ranges were set too conservatively or did not truly describe the organization's practices regarding IV medication administration.
- **Dosing units.** CQI data can help identify situations in which pharmacy, nursing and physicians view an issue from different perspectives. For example, many drugs are dosed based on weight; however, at the point of administration, a nurse usually calculates the dose over time. Heparin is commonly ordered in units per kilogram; at the point of administration, the nurse administers heparin in units per hour. In establishing the drug library, staff must be aware of both perspectives to establish a safe range for administration. However, the dosing unit that is commonly used by the nurse at the point of administration should be what

is displayed when the device is being programmed. Similarly, if a drug library includes medications such as phosphorus, which are dosed as mEq/hr, the physician's order should be written using the same dosing units, or the pharmacist should convert the order to the dosing units used in programming the infusion device at the point of administration.

- **Workload practices.** The most exciting CQI capability is the safety software's ability to graphically display medication events by time of date and day of week. These time-sensitive event data can be evaluated from a global or drug-specific perspective. By identifying peak periods for certain high-risk medications, an organization can re-examine workload practices or routines in order to identify ways to reduce the potential for medication events.
- **Staffing and scheduling.** CQI data also can be used as an organizational tool to help with staffing and scheduling, not only in the patient care units but also in the pharmacy. The safety software provides hard data, so that decisions about IV medication administration and the medication use process can be based on objective evidence, not just staff opinion.

### Knowledge issues

In a study of ADEs, Leape et al. concluded that the lack of knowledge about medications contributed to the most frequent cause of errors.<sup>3</sup> Reviewing CQI data can help an organization to identify where staff may have knowledge gaps about medications or the operation of the infusion device. The CQI data may also alert the organization to instances where staff is not following organizational policies or guidelines for the administration of certain medications.

One example is the use of sedatives in the ICU setting. If an organization has a defined sedation protocol, the CQI data may identify situations in which the staff is practicing outside the defined protocol guidelines. Discussing this type of data is much more powerful than simply doing a skills exercise in which a nurse is asked to perform a single task in order to be validated as competent. The CQI data provide an ongoing record of the types of medication administration practices that are occurring daily, and provide opportunities to assure that practice is consistent with policy.

The CQI data may be used as a part of an annual needs assessment to help plan orientation, in-service or continuing education sessions. The CQI data may also be used to evaluate the possible impact of temporary or registry staff on an organization. Although the CQI software does not yet track events by individual nurse, when infusion events are correlated with past unit staffing patterns, the data may help identify potential risks.

**Cultural or attitudinal issues**

Healthcare professionals do not come to work intending to make errors. They focus on not doing harm. However, the intensity and complexity of healthcare, as well as human factors, put every healthcare professional at risk for making an error at some point in their career. The safety software CQI data help to identify potentially risky habits that staff may have developed in programming the administration of IV medications.

The data will also identify peak periods of medication administration, which allows an organization to stress the need for a nurse to pay particular attention to decreasing the distractions when programming an infusion system. Because the IV safety software captures both alerts and response to alerts, the organization now has the ability to identify and trend potential risks to the nurse, pharmacist and physician. This ability to capture and trend the potential or preventable events can help open the door to greater opportunities for staff to explore and change the organizational culture to assure safe IV medication practices.

**Responsibility of evaluating and trending data**

When an organization decides to implement smart pump technology, it must also assign responsibility for review and management of the CQI data, as well as determine how and when the data will be reported. Although medication administration is a nurse responsibility, the data obtained from the CQI data can also affect pharmacy and physician practice. Thus, it is important to ensure that the data are reviewed by a multidisciplinary team, which at least includes representatives from nursing and pharmacy. The team will be responsible for analyzing the overall CQI data and identifying priority medications for more detailed investigation. Based on their analyses, the team can identify system, knowledge and cultural issues and then

establish a plan of action to address these issues through CQI activities.

**Establishing priorities to evaluate CQI data**

Analyzing CQI data in terms of risk and harm can help to establish priorities in evaluating medication-specific events. Considering a drug’s inherent risk as described in the literature or by the organization helps to identify which medications in the library have the greatest potential for adverse outcomes, if administered incorrectly. Harm is defined by the extent to which a programmed dose exceeds the maximum dose limit established by the institution, using the following scale:

**Minimum risk of harm**

- 1 to 1.5 times the maximum dose

**Moderate risk of harm**

- 1.5 to 2.5 times the maximum dose

**Severe risk of harm**

- Greater than 2.5 times the maximum dose

After rank-ordering events, an organization can perform more detailed analyses of medication-specific data to identify system, knowledge and cultural issues. For example, using the risk and harm index, a review the first 10 months of IV safety software data at the City of Hope National Medical Center identified potassium as a priority

**City of Hope CQI data high risk/harm medications**

	Minimum harm	Moderate harm	Severe harm
High risk medications	1 - 1.5 max dose	1.6 - 2.5 max dose	>2.5 max dose
Heparin	47	3	7
Hydromorphone		1	2
Insulin			1
Lorazepam	1	1	1
Magnesium sulfate	57	1	5
Morphine	2	1	4
Potassium	166	42	15
Propofol	3	1	9
Tacrolimus	23	7	3

**Table 1.**

drug for further investigation (Table 1). Our detailed review of potassium event data identified system, knowledge and cultural opportunities to help reduce risk (Table 2).

**Issues identified through analysis of potassium events**

System issues	<ul style="list-style-type: none"> <li>• High number of events occurring at 7 a.m. and 1 p.m. suggested the need to evaluate the time electrolyte replacement is initiated</li> </ul>
Knowledge issues	<ul style="list-style-type: none"> <li>• Data suggested inconsistent awareness of staff regarding hospital policy issues for potassium administration</li> <li>• Data helped identify opportunity to increase staff knowledge regarding programming of infusion by dose over time vs. volume over time</li> </ul>
Cultural issues	<ul style="list-style-type: none"> <li>• Data increased awareness of staff regarding the number and times events were actually occurring when potassium was infused</li> <li>• Data identified peak administration times, and the need for staff to decrease distraction factors when programming the infusion device during those times</li> <li>• Data prompted acknowledgement of staff when reprogramming and prevention of an event occurred</li> </ul>

Table 2.

**Conclusion**

As summarized in Table 2, IV medication safety systems can become a powerful tool for organizations to evaluate medication practices. The implementation of this technology assists in establishing organizational “best practice” guidelines, and the CQI data obtained from the safety software will help an organization to identify and avert potential ADEs. Through the use of a framework for evaluation of the CQI data, an organization can reduce risk by identifying system, knowledge and cultural issues that affect IV medication delivery.

# The Nebraska Medical Center experience with smart infusion systems

*Joe Graham, Senior Vice President and Chief Operating Officer,  
The Nebraska Medical Center, Omaha, NE*

## Key points:

- The risk of serious infusion medication errors and adverse drug events (ADEs) is high without the use of infusion safety technology
- An intravenous (IV) medication safety system helps avert infusion medication errors
- The cost of IV safety technology is less than the cost of ADEs
- The value of protecting the second victim of infusion device errors—the nurse—is also important

The Nebraska Medical Center (NMC) is a 680-bed teaching hospital for the University of Nebraska Medical Center, with 950 private practice and faculty physicians providing primary, maternity, and tertiary/quaternary care. Specialized treatments available at NMC include solid organ transplantation, burn care, wound care, geriatrics, bone marrow transplantation, radiation therapy and oncology. Oncology services include:

- National Cancer Institute (NCI) Designated Clinical Cancer Center
- One of 14 founding members of the National Comprehensive Cancer Network
- One of 14 NCI-funded bone marrow transplant centers
- NCI Special Program of Research Excellence (SPORE) in pancreatic cancer

**Safety is a major focus.** At every meeting with a formalized agenda, in any department, the first agenda item is always safety. New technologies and treatments present many opportunities to improve the quality of care. The challenge is to fund these improvements. One approach is to generate capital internally by eliminating

waste, and there is nothing more wasteful—in both financial and human terms—than adverse drug events (ADEs).

Many NMC patients are seriously ill and are being treated with high-risk IV drugs. Starting in 1997, NMC became aware of the availability of an intravenous (IV) medication safety system (the Alaris System with the Guardrails Suite, CareFusion, San Diego, CA) that was designed to help avert IV programming errors. The system offered a modular platform and one operating system for large-volume pumps (LVPs), syringe pumps and patient-controlled analgesia (PCA). In 1999, NMC became a beta site for the IV medication safety system with LVPs.

Human factors engineering tools and techniques were used in analysis, design, testing and evaluation of the IV medication safety system to reduce the likelihood of use errors that could lead to death or injury, and avoid creating a system so complex that it would not be used. The system was introduced commercially at the American Society of Health-System Pharmacists meeting in December 2001. In 2003 NMC installed syringe modules on all devices, completed hospital-wide implementation of the IV safety system with LVPs and began exploring use of PCA modules.

## IV medication safety study

To evaluate the effectiveness of the IV medication safety system, NMC conducted an 8-month study in three patient care areas (oncology/hematology, adult intensive care unit [ICU], and a pediatric ICU) to determine the number and kinds of infusion device errors averted and recorded by the safety systems, and the nurse satisfaction with this technology. The results from approximately 14,000 patient days were evaluated. The most significant finding was that on 157 occasions the IV safety system alert resulted in a reprogramming of the device to a different rate of infusion (Table 1). While this error rate was small compared to the

total number of medications administered during the study, a review of those 157 events determined that “a potentially life-threatening dose had initially been programmed in 17 different events analyzed.”<sup>1</sup>

<b>Medication errors averted by IV safety system</b>
<ul style="list-style-type: none"> <li>• 3 units (oncology/hematology, adult ICU, PICU)</li> <li>• 8 months, approximately 14,000 patient days</li> <li>• 2,038 safety system alerts (dose exceeded hospital-established limits)</li> <li>• 157 alerts resulted in reprogramming the dose (averted errors)</li> </ul>

Table 1.

### The financial cost of poor quality

While the imperative to provide a safe environment for patients was the driving purpose in pursuit of smart infusion technology, analysis of the financial impact of a decision to replace the pumps currently in use with new, smart technology was also an important element in getting approval for purchase and implementation. At the time of the study, the hospital had a long-term arrangement that required a significant buy-out of the lease in order to replace existing devices with smart systems. The results of high-level financial analysis supported the decision to purchase the new technology and should also be applicable to other facilities.

The NMC Department of Pharmacy had recently completed a three-year study of the incremental expense of ADEs at the hospital. Results showed that the average incremental expense was approximately \$8,000 per ADE. Annualizing the 157 reprogramming events in the 3-unit, 8-month study showed an expected 235 events (averted medication errors) during a one-year period. The hospital’s experience is that approximately 38% of medication errors result in ADEs. Thus, on an annualized basis, the hospital could expect approximately 89 ADEs (235 x 38%) in those units. The annual incremental expense would be approximately \$712,000 (\$8,000 x 89) for the three nursing units involved in the study (Table 2).

No attempt was made to estimate the medication error rate on the other 17 units; the financial result based on

3 units was sufficient to support hospital-wide implementation of smart infusion systems as a financially positive decision. Most importantly, having previously unavailable, documented evidence of high-risk medication errors, as well as the technology to avert such errors, made implementation of the IV safety systems imperative.

<b>Financial impact of averted errors</b>
<ul style="list-style-type: none"> <li>• 157 averted errors in 3 units over 8 months = 235 averted errors in 3 units on an annualized basis</li> <li>• 38% of errors result in an adverse drug event (ADE)</li> <li>• Cost of ADE shown by 3-year study = \$8,000</li> <li>• Annual cost avoidance of using IV safety system: <math>236 \times 38\% \times \\$8,000 = \\$712,000</math> on 3 units</li> </ul>

Table 2.

### Protecting staff (the 2nd victim of an infusion error)

One of NMC’s Leadership Priorities is to be a desirable place for healthcare professionals to work. Using technology to create a safer environment for the nurse in which to practice is an important way to help achieve that goal. A survey was distributed to all users of the IV medication safety system to determine their level of satisfaction with the technology and their perceptions of the contribution of the safety software to the prevention of medication errors. Responses from nurses on the three units involved in the study are shown in the Figure 1. More than 90% of users “agree” or “strongly agree” that the IV safety system provides a valuable safety at the point of care, that they prefer the safety system instead of other devices currently available at NMC and would recommend the IV safety system to other hospitals and institutions.

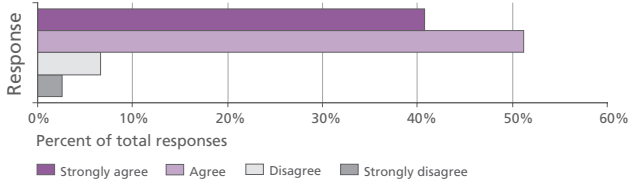
### Summary

An evaluation of smart infusion technology at NMC demonstrated that:

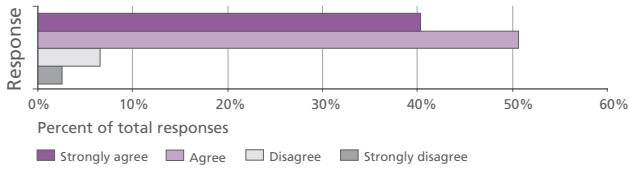
- IV medication safety systems can significantly reduce the number of drug infusion errors
- The incremental hospital costs of treating those errors would have significantly exceeded the cost of the IV medication safety systems
- Nurses valued the added protection from error and the ease of use of the multi-channel IV medication safety systems

**Nursing satisfaction with IV safety system**

*"I feel the Alaris System and Guardrails Suite of safety software provide a valuable safety net at the point of care."*



*"I prefer to use Alaris System and Guardrails Suite instead of other infusion devices currently available in this institution."*



*"I would recommend the Alaris System and Guardrails Suite to other hospitals and institutions."*

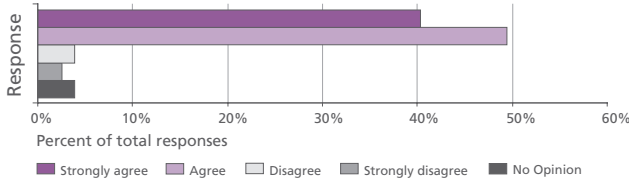


Figure 1.

# Infusion safety findings from a children's hospital—a road map for continuous quality improvement

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## Key points:

- Experience at Children's Hospital San Diego with both large-volume and syringe pumps shows that an intravenous (IV) medication safety system can effectively help the hospital to:
  - Identify and prevent high-risk IV medication programming errors
  - Identify opportunities for change
  - Monitor the effectiveness of interventions, and thereby facilitate the process of change
  - Foster nursing acceptance, change attitudes and promote compliance
- Wireless networking and data links may provide additional critical safeguards and information to further improve patient and medication safety

Quality Improvement is rarely a single-step process, and should more appropriately be likened to a voyage in which different organizations find themselves at different points in their journey. For Children's Hospital and Health Center in San Diego (CHSD), an important milestone in their journey toward intravenous (IV) medication safety came in January 2002 with their decision to invest in an IV medication safety system (the Alaris System with the Guardrails Suite, CareFusion, San Diego, CA). The initial implementation was for large-volume pumps (LVPs). More recently, syringe pumps were added to the medication safety system throughout the hospital.

From a perspective spanning nearly two years, the implementation and the subsequent operation of systems, including both type of pumps, was an unqualified success

and exceeded all expectations. An IV safety system was originally perceived as a means to help prevent patient harm resulting from medication errors. In addition, however, the data collected by the systems are used by CHSD personnel to actively inform and support performance-improvement activities across the organization. The continuous quality improvement (CQI) logs in the safety software opens a window into processes that previously could not be readily or reliably assessed. The rich stream of data that is captured in these logs becomes the foundation for performance improvement efforts.

While the work described in this article took place in a pediatric hospital, it speaks to the importance of the ability for any system to respond to patient-specific concerns, whether they are related to size, maturation, physiologic maturity or varying degrees of organ dysfunction. These concerns are not unique to the discipline of Pediatrics. They unite all organizations that care for diverse patient populations. As such, the lessons learned at CHSD should have relevance for all organizations where infusion devices are used.

## Achieving high compliance

A guiding philosophy of the CHSD implementation program was the belief that in order to realize the benefits of the medication safety system, nurses and physicians needed to be able to understand and articulate the personal value that the safety software provided to them and to their patients. Initial data analysis and compliance efforts therefore focused on reprogrammed events (i.e., errors that were caught), for two reasons. First, reprogrammed events are self-declared errors, so that there

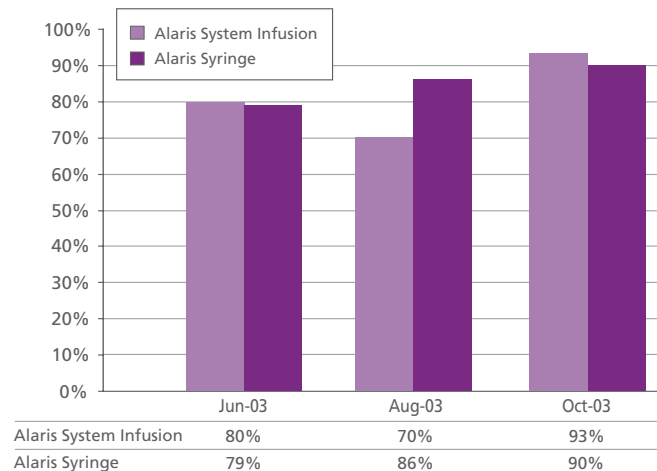
is no question an error was made in programming the infusion device. Second, reprogrammed events document that a nurse took appropriate action to avert a potential medication error. As a result, CQI data were cast in a non-threatening light—the kind of light most likely to foster compliance and sustain gains among staff.

The data not only captured staff members’ attention, but it also secured their commitment to using the technology. Focusing on reprogrammed data specifically demonstrated the personal value of the system and why the safety software dosing limits should be used. Improving medication safety is about winning hearts and minds—having nurses and physicians understand the personal value of this technology to them. When they can articulate this value, an organization has taken a major step forward with respect to safety.

In addition to building an awareness of the personal value derived by use of the safety system, it was equally important to make it as easy for clinical staff to do “right thing.” For example, by evaluating the process of the IV medication administration, it became apparent that the existing pharmacy labels for IV bags did not present information in the same order that was required to program the system. To facilitate system use and promote accurate infusion programming, the pharmacy labels were redesigned to present data in exactly the same manner and order as a nurse would enter the infusion information into the device. This one change improved both the accuracy of data entry and reduced a barrier to a nurse’s engaging the software.

An indication that nurses were cognizant of the personal value derived from engaging the IV medication safety software was vividly demonstrated when the pediatric intensive care unit (PICU) nurses began to audit themselves with respect to how often the safety software was engaged versus the times when it could have been used. That was a very important step. Data collected by the nurses on their own initiative showed that compliance steadily increased with respect to the use of both the LVPs and syringe infusion pumps (Figure 1). The most recent study period revealed that compliance in excess of 92% had been reached—i.e., when a medication could be infused using IV safety software dosing limits, approximately 92% of the time the software was engaged.

**Guardrails Suite of safety software in use**



**Figure 1.**

**Extending the IV medication safety platform to other pumps**

The successful LVP conversion and the reported number of averted medication errors underscored the need to extend the same safety technology to the other infusion devices used at CHSD. Syringe pumps typically are used to infuse small, highly regulated amounts of potent medications. As a result, syringe pump infusion errors were perceived to carry an especially high risk of harm. Therefore, the decision was made that syringe pumps would be converted next, followed by patient-controlled analgesia (PCA) devices.

From a nursing perspective, the ability to add syringe pumps to the same technologic platform as the LVPs reinforced the value of having adopted an integrated infusion system. Nurses no longer had to remember different programming schemes for different devices. Instead, they were able to use a single interface—a common technologic platform. The increased ease of use, along with reduced training needs and opportunities for error, further helped the CHSD nursing staff realize the personal value of implementing smart infusion safety technology.

**Syringe pump findings**

The number of dosing limit events (when a dose exceeded dosing limits, producing an alert) showed no increase when the syringe pumps were installed. This confirmed the nurses’ perception that minimal additional training

was necessary and that their experience with the LVPs facilitated their use of the syringe pumps.

**Using CQI data to identify training needs.** The number of alerts did not prove to be a useful indicator of training needs, since alerts also included instances when a practitioner overrode dosing limits based on the clinical need of seriously ill patients. A more sensitive indicator of a knowledge-training deficit may be the number of times a pump needed to be reprogrammed before the programmed medication dose fell within acceptable dosing limits (Figure 2). To use an analogy, how many times would you continue to bump into the car ahead of you or behind you, before finally getting the car into a parking spot? Using reprogramming as an indicator, successful training and learning is evident as a reduction in the number of reprogramming attempts necessary to reach an appropriate dosing range. As shown in Figure 2, this gap did narrow over time.

**Number of futile programming episodes ending in reprogramming or cancellation**

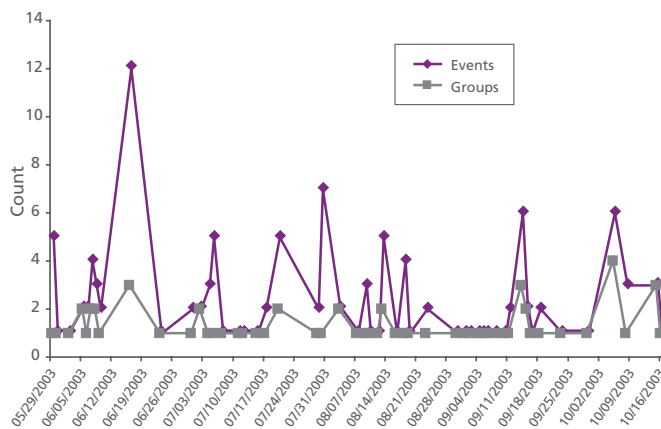
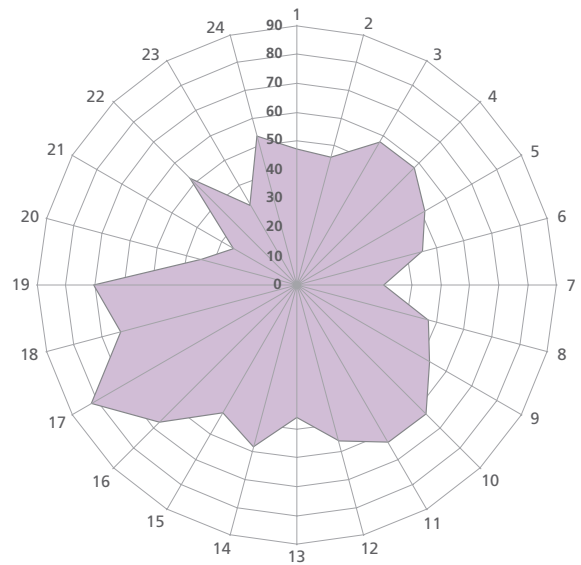


Figure 2.

**Chronogram.** The chronogram (Figure 3) shows that the pattern that emerges from syringe pump data is similar to that for LVP data, namely, that alerts are not randomly distributed around the clock but rather have peaks and valleys, suggesting that certain time periods are more error-prone than others. This awareness becomes the foundation for further investigation and ultimately for informed interventions. At CHSD, the period with the greatest number of alerts correlated with fixed (end of school day) and variable factors (change of shift, elective admissions, medication delivery).

**Chronogram of syringe pump alerts**



Children's Hospital data.

Figure 3.

**Frequency of alerts and reprogrammed "good catches" sorted by medication.**

The greatest numbers of alerts were associated with overrides of the usual and customary doses of fentanyl, midazolam and heparin. At the present time, the general alert data lack sufficient granularity to further assess or distinguish the significance of a particular override alert. By way of contrast, reprogrammed alerts or "good catches" resulted in reprogramming or cancellation in response to a signaled alert. Among the self-declared errors involving syringe pumps, the most frequent averted errors were associated with potassium chloride infusions.

**Harm potential of averted errors.** Overall, doses that were reprogrammed or cancelled ranged from 1 to 100 times the upper dosing limit. The Table summarizes likely "harm potential" that was averted through the use of the IV medication safety system. Many of the averted errors involving fentanyl, heparin or potassium chloride would be categorized as severe, underscoring the value of the use of the medication safety system.

**Decimal-point errors.** The data for the syringe pumps show 121 averted errors, including numerous 10- and 100-fold errors. As with LVPs, the syringe pump CQI data suggest that decimal point errors made either in writing, interpreting or programming a medication order continue to exist.

### Future opportunities

While the current medication safety system has led to important safety gains, continued opportunities exist. In terms of IV medication safety, ongoing challenges include:

- Overrides—further effort will be needed to determine how many overrides of “soft” alerts are based on clinical judgment and how many represent as yet unidentified errors
- Retrospective data analysis versus prospective error interdiction or mitigation—to have optimal value, medication error alerts need to be analyzed and acted upon in real time
- Development of a comprehensive, fully-integrated program for error prevention

The current medication safety system can help prevent many of the errors involving improper weight-based medication dosing. In spite of this significant advance, patients remain vulnerable to errors related to inadequate monitoring, incorrect medications, drug allergies/adverse drug reactions and omitted medication orders or doses. The system does, however, carry the potential to address these concerns. More than likely, the solution to these residual vulnerabilities will evolve as connectivity is established between the medication safety system and the hospital's information system/databases. Specifically, with the necessary data linkages, weight-based dose checking can be expanded to body surface area-based dose checking, patient identity verification, drug identity verification, drug indication verification, medication reconciliation, allergy/adverse drug reaction prevention and dose-response monitoring. Wireless networking to link the IV safety systems to a hospital's information system to automate the infusion programming process is currently undergoing beta trials at the Hospital of the University Pennsylvania (see article by Smith in these Proceedings). Linking the IV medication safety system to other safety technologies and data sources holds the promise of achieving further gains in patient and medication safety.

# Patient safety and smart infusion technology—18 months' experience at the VA San Diego Healthcare System

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## Key points:

- Despite a barcode medication system, computer prescriber order entry system and computerized patient records, intravenous (IV) medication errors were occurring in the administration phase of the medication use process
- Smart (computerized) infusion pumps with medication safety software have helped prevent these IV medication errors
- Ongoing interdisciplinary analysis of data is important to realize maximal benefits from use of smart infusion technology
- Providing safety systems such as smart infusion technology can play an important role in the protection of patients

VA San Diego Healthcare System (VASDHS) was a beta test site and implemented smart (computerized) infusion technology (the Alaris SE single/dual channel pump with the Guardrails Suite, CareFusion, San Diego, CA) in September 2002. This article presents highlights of 18 months' experience with this infusion safety technology, including key findings and recommendations.

## Patient safety landscape

The Veterans Affairs (VA) was an early adopter of barcode medication administration (BCMA), computerized patient records and computer prescriber order entry (CPOE). Although these safety systems help address some issues related to medication errors, they do not address errors that may be made in the programming of an infusion pump.

IV medications are associated with 54% of potential adverse drug events (ADEs),<sup>1</sup> and 56% of medication errors.<sup>2</sup> Smart infusion technology provides a "final check" to ensure that programmed infusion parameters do not exceed institution-established limits. In this way, even in the presence of the above safety mechanisms at VASDHS, smart pumps with safety software offered additional protection not provided by the other systems.

Before smart pump technology can be implemented, the safety software must be customized by creating "profiles" for different patient care areas, establishing drug libraries with upper and lower limits for infusion parameters and standardizing concentrations of IV medications to be used. At VASDHS, physicians, nurses, pharmacists and biomedical engineers participated in this process. Soft limits (alerts that can be overridden) were established for the critical care unit, operating room and the emergency room. Hard limits (alerts that cannot be overridden based on clinical judgment) were used for all other areas.

The quantity of the data downloaded from the infusion pumps was initially overwhelming. It was difficult to know where to focus attention and how to extract the important information from the data, recognizing the importance of the errors averted by the safety software.

New terminology was learned during the process of analyzing the data. "Alerts" were not necessarily errors; they were "events" that required further investigation. A continuous quality improvement (CQI) process was used to review the data, which prompted important questions (Table 1). Data from 183 pumps over an 18-month period were analyzed to determine the number of alerts and

Table 1.

**Drug(s) with most frequent dose limit alerts**

Pareto Table
PHENYLephrine
nitroPRUSSide
heparin
fentanyl
midazolam
insulin
DOPamine
nitroGLYcerin
morphine
pantoprazole
diltiazem
AMIODArone
eptifibatide
esmolol

averted errors (near misses) and to identify patterns and trends.

Having all disciplines at the table during this review is invaluable; many of us have gained insights that may not have been revealed if fewer disciplines were represented.

**Results**

Over a period of 18 months, 59% of all reprogramming alerts occurred in the intensive care unit (ICU) and 20% in the operating room. Less than 5% occurred in the medical/surgical areas, probably because there are fewer IV drips being administered in these areas.

There was a pattern of increased alerts on Fridays and Saturdays. This may be the result of educational efforts occurring more often during the week that do not affect staff that works primarily on weekends. Significant increases in alerts were also noted during July and December. Possible reasons for this include being an academic institution where medical and pharmacy residents change during July, with an increased number of new graduate nurses also present during this period. Staffing patterns may contribute to the increased number of alerts in December; however, no firm conclusions have been reached.

Drugs associated with the most frequent dose limit alerts

are consistent with those reported by others (Table 1). A secondary review of infusion safety software data is currently underway to categorize potential causes of alerts as cognitive, visual or tactile in nature.

The data revealed several examples of dopamine infusions well over the 20 mcg/kg/min limit that is accepted as standard in the industry, e.g., dopamine administration at 36 mcg/kg/min (Table 2). The practitioners chose to override the warnings, which were soft alerts. These instances and several others involving different medications have prompted reconsideration of the decision to make all alerts in the critical care areas “soft” alerts that can be overridden.

**Override soft limit in ICU**

Snapshot table	4:47 6/22/2003	4:47 6/22/2003
Profile selected:	ICU	ICU
<b>Drug name:</b>	<b>DOPamine</b>	<b>DOPamine</b>
Concentration:	400 MG/250 mL	400 MG/250 mL
<b>Dose:</b>	<b>36.04 MCG/KG/MIN</b>	<b>36.04 MCG/KG/MIN</b>
Max dose limit:	20	20
Min dose limit:	1	1
Patient weight:	74 kg	74 kg
<b>Rate:</b>	<b>100 mL/h</b>	<b>100 mL/h</b>
Profile max rate limit:		
VTBI:	177.7 mL	177.7 mL
Prog to limit	1.802	1.802
Prog to res	1	1
Snapshot status	DOSE above soft limit	RES: OVERRIDE_HI

Table 2.

**Recommendations**

Lessons learned from VASDHS include the importance of establishing a CQI process early in the implementation of infusion pumps with safety software. Analyzing data is important to identify and address the factors that may be contributing to potential errors. A reporting mechanism that reaches the clinicians as well as administration is important to communicate process improvements made and potential errors averted with the infusion safety software.

Identifying 'key events' to be tracked is important; initially starting with basic data may avoid overwhelming the individuals involved. The use of a harm assessment model such as the *IV Medication Harm Index*<sup>3</sup> should be considered in developing a CQI process, since data on medication or dose alone are not sufficient to predict harm for the patient or meaningful outcomes for the institution.

Observation of repetitive data patterns (e.g., a dose alert occurring multiple times) may indicate that drug profile adjustments are needed. After establishing a core set of key events to be tracked, a secondary data review may be recommended. For example, low-dose alerts have not been addressed sufficiently. Potential causes for these can include drug profiles that need to be changed or lack of practitioner education regarding efficacious dosing of medications.

Education of all practitioners who use the pump and software cannot be overemphasized. Instances were identified where the safety software was not used. In other examples, a pump was converted to a primary mode after multiple alerts were received, thus effectively bypassing the safety software. Initial and ongoing education regarding the value of the safety software is important. Policy statements mandating use of the safety software are now being written.

### **Conclusion**

The use of infusion pumps with safety software plays a valuable role in patient safety. CQI results at VASDHS have shown that this technology helps protect nurses from making critical errors in infusion programming, thus protecting patients from potential harm.

# ICU sedation—an analysis of intravenous dose limit overrides

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## Key points:

- An intravenous (IV) medication safety system provides comprehensive continuous quality improvement (CQI) data that can help to identify medication safety issues for drugs given by the IV route
- Although clinical practice guidelines for intensive care unit (ICU) sedation have been developed by the Society of Critical Care Medicine, they may not be used consistently in many clinical settings
- Propofol is a widely used, highly effective IV sedative for ventilator-assisted patients in the ICU
- CQI data demonstrate a significant overuse of propofol in these patients that may be associated with iatrogenic consequences not previously recognized and that prompted changes to improve patient care

## St. Joseph's/Candler Health System

In October 2002 the St. Joseph's/Candler Health System (SJCHS) in Savannah, Georgia implemented a computerized ("smart") intravenous (IV) medication safety technology to improve the safety of medications with the highest potential to produce harm. The safety software incorporates a data set with SJCHS-defined dosing limits for IV medications commonly infused to patients in our hospitals. These limits are designed to alert caregivers that a specific programmed dose of a medication is outside a minimum effective or maximum safe dose for the drug. The alert must be addressed before infusion can begin. A "soft" limit can be overridden by a clinician, whereas a "hard" stop cannot. The intent of the software dosing limits is to prevent IV medication errors.

A total of 525 IV medication safety systems were installed

in our two tertiary-care referral hospitals. Each instance of a programmed dose less than or greater than the pre-established dosing range is electronically recorded in the computer "brain" in each infusion device as an "event" for continuous quality improvement (CQI) purposes. Events are stored by the device until purged at designated times. The use of IV medication safety systems at SJCHS has provided a mechanism to recognize and capture information that documents actual drug administration data at the bedside. This technology allows us to identify and prevent potential medication errors, record infusion programming steps that occurred before the alert, record all actions taken by the nurse even if he/she continued the administration process after having been "warned" that a system programming instruction was outside of the dosing limits and implement corrective actions to reduce the potential for future medication errors.

## IV medication safety

The use of technology to improve medication safety is an important development for patient care. Medication errors associated with high-risk drugs have the greatest potential to cause significant patient harm. Many IV infusion medications are high-risk-of-harm drugs,<sup>1,2</sup> and administration is the stage most vulnerable to error.<sup>3</sup> For these reasons, the prevention of IV medication administration errors at the point of care, particularly those involving continuous drug infusion programming errors, should be a primary initiative to prevent patient harm. The introduction of IV medication safety systems provides a technology that can help safeguard patients and caregivers against IV administration errors. These systems also provide previously unavailable data on the frequency and characteristics of these high-risk medication errors that

were averted by the use of this technology.

Analysis of aggregated data from smart pumps at 18 institutions—community and regional hospitals, as well as major medical centers—shows that in an average 350-bed hospital, IV medication safety systems avert one potentially life-threatening IV programming overdose every 2.6 days and an additional, potentially significant IV error every 1.9 days.<sup>4</sup>

Some IV errors may be detected even without IV safety technology, since many patients are closely monitored in the intensive care unit (ICU). Other errors may go undetected for extended periods, depending on the location of the therapy and the likelihood that the error will be discovered. In an acutely ill patient, an infusion-related preventable adverse drug event (PADE) can easily be misinterpreted as being the progression of disease. The longer an error goes undetected, the greater the likelihood may be of increased length of stay, hospital costs and patient harm.

Initial CQI data have been synthesized for an analysis of our initial experience with the IV safety software at SJCHS. The data indicate that most alerts were warnings of the possibility of drug overdose. The data also indicate that 7.2% of all events resulted in the nurse canceling the administration process or resetting the infusion device. These cases are thought to represent “near misses” in which a potential medication error was prevented by the IV medication safety system. Warnings involved multiple medications, including some of those identified by the USP as being associated with the highest liability for harm.<sup>1</sup> An example of one area where we are using CQI data for further investigation is ICU sedation.

**Sedation of ventilator-assisted patients**

Maintaining optimal comfort and safety for critically ill patients who require mechanical ventilation is an important goal. The Society of Critical Care Medicine has developed clinical practice guidelines to assist clinicians in the use of sedatives and analgesics for these patients (Table 1).<sup>5</sup> Indications for sedative agents are not well defined. They are, however, commonly used adjuncts for the treatment of anxiety and agitation in the ICU.<sup>5</sup> Several drugs, including the benzodiazepines (diazepam, lorazepam, midazolam), propofol and centrally acting-agonists (clonidine,

**ICU sedation guidelines**

- A sedation goal or endpoint should be established and regularly redefined for each patient. Regular assessment and response to therapy should be systematically documented.
- The use of a validated sedation assessment scale is recommended.
- The titration of the sedative dose to a defined endpoint is recommended with systematic tapering of the dose or daily interruption with retitration to minimize prolonged sedative effects.
- The use of sedation guidelines, an algorithm or a protocol is recommended.

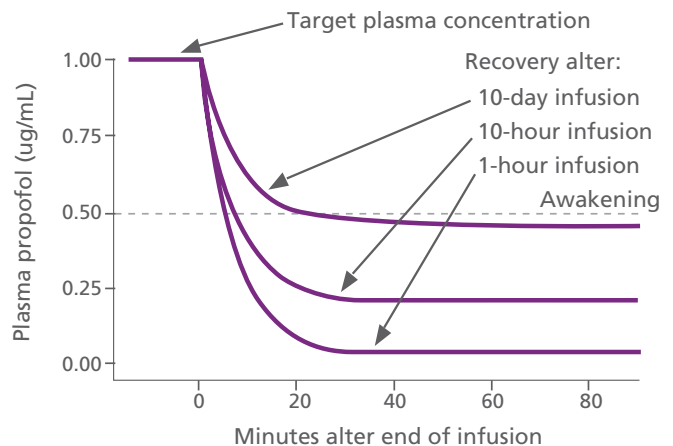
*Society of Critical Care Medicine. Clinical practice guidelines for sustained use of sedatives and analgesics in the critically ill adult. Critical Care Med; 2002, 30:119-41.*

**Table 1.**

dexmedetomidine), are used to sedate a mechanically ventilated patient.

**Propofol.** Among the commonly used agents, propofol has been favorably compared to the benzodiazepines, particularly midazolam, because it reduces the time needed for recovery of spontaneous respiration and successful weaning of patients from a respirator.<sup>6-8</sup> It has a rapid onset and short duration of sedation once discontinued (Figure 1).<sup>9</sup> Propofol (2,6-diisopropylphenol) is available as an emulsion in a phospholipid vehicle, which provides 1.1 kcal/mL from fat and is an important caloric source for patients receiving a continuous infusion.<sup>10</sup>

**Fall of plasma propofol levels following ICU sedation infusions of various durations**



**Figure 1.**

In spite of the availability of clinical practice guidelines for the use of sedatives including propofol in the critically ill adult patient, physicians routinely order this medication as “Propofol drip,” “Titrate propofol” or “Sedate with propofol.” Since ICU patients are mechanically ventilated, clinicians typically titrate patients to a desired level of sedation with minimal concern for the quantity of drug infused per unit of time and for the potential of overdose or adverse effects. Serious adverse events can occur with propofol and include a number of metabolic,<sup>11-14</sup> neurologic,<sup>15-16</sup> cardiac,<sup>17-19</sup> infectious,<sup>20</sup> pulmonary<sup>21</sup> and local reactions.<sup>10</sup> Propofol can also cause anaphylactoid type reactions,<sup>22, 23</sup> and tachyphylaxis<sup>24</sup> has been documented.

Data from a 9-month period in our hospitals indicate that the average dose of propofol was 100 mcg/kg/min for patients given continuous infusions. The recommended maximum rate of infusion for this indication is 80 mcg/kg/min when given for sedation in the critically ill adult patient receiving mechanical ventilation.<sup>5</sup>

Discussions with colleagues at other institutions in community and university hospital settings indicate that our experience is not unique. It is likely that physicians’ orders for and ICU nurses’ administration of propofol often exceed the maximum recommended dose per unit of time. It is possible, perhaps likely, that unrecognized adverse outcomes are occurring in patients receiving this medication.

**Using safety system CQI data to improve practice**

CQI data from our IV infusion system that indicate a potential problem with the safe dosing of propofol are now being used to answer important questions about the administration of propofol in our ICU setting (Table 2). Pharmacists, nurses and physicians have implemented clinical practice guidelines for the use of propofol and are performing an evaluation of data associated with its administration in ventilator-assisted patients in the ICU. Our study will evaluate the effect of using these guidelines on patient safety and clinical outcomes. It will also demonstrate how data obtained from the IV medication safety system can be used in a multidisciplinary collaborative process to correct clinical problems. We hope our results can positively influence

the vigilance of clinicians who administer this drug and help to improve the care of these patients.

Questions that need answers
<ul style="list-style-type: none"> <li>• Are there differences in outcomes among patients being treated with/without sedation guidelines in place (toxicities, vent days, ICU LOS, infectious complications, etc.)?</li> <li>• Is there a difference in the number and type of dose-limit events?</li> <li>• Is there a difference in the amount and cost of propofol administered?</li> </ul>

**Table 2.**

# Using real-time data to improve patient safety

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## Key points:

- The University of Pennsylvania Health System (UPHS) has taken major steps in creating a culture of safety through organizational initiatives as well as technical innovations
- Real-time data from electronic patient-care systems can facilitate early intervention and improve care
- As more electronic patient-care technologies are implemented, departmental and technical silos must be torn down and systems integrated, so that clinicians are not overwhelmed by the “noise” of competing clinical rules
- As biomedical equipment and software applications continue to converge, cooperation between vendors is critical to the successful integration of various systems for optimal clinical use

## The change mandate

Over the past century, the eradication of many diseases, such as smallpox, and other major advances in medical care have changed and reordered the leading causes of death (Table 1). In the decades to come, medical technology and advances that today are only on the horizon will again reorder the leading causes of death and bring other medical issues to the forefront. Such advances will require commitment and funding from all areas of healthcare. They may not even be technologies that require major changes, but rather simple shifts in how care is provided. At a time when budgets are tight, reimbursement is constantly under pressure and almost all areas of operating a hospital are in need of capital spending, the University of Pennsylvania Health System (UPHS) is committed to crafting a culture of safety and using technology as a tool to improve the delivery of care.

### The change mandate leading causes of death

1900	1940	2000
Pneumonia/flu	Heart disease	Heart Disease
Tuberculosis	Cancer	Cancer
Diarrhea/enteritis	Stroke	Stroke
Heart disease	Nephritis	Chronic resp. illness
Stroke	Pneumonia/flu	Accidents

### Where will future progress come from?

Source: Wall Street Journal Almanac, 1998 and National Center for Injury Prevention and Control 2000, 2001.

Table 1.

## Developing a culture of safety

When accidents happen in a hospital, they often are not the result of one person’s lapse or mistake but of many incidents occurring in sequence. Analyzing a system for failure modes often illustrates where safeguards should be placed to ensure a safer environment for patient care. This analysis can also identify where technology should be applied for building new, safer processes, including changes in how people work and provide care. Continuous multidisciplinary review of patient safety data is needed to turn the data into actionable information that can be used to make priority decisions about the allocation of resources to improve patient care.

Throughout the UPHS hospitals, many programs have been implemented to increase awareness of safety measures and to recognize those taking exemplary steps to improve patient safety. Programs have included quality and safety awards, peer education, annual quality fairs, an online incident reporting system and close and continuous communication with the senior leadership of the hospital

about quality. Each year the quality department also facilitates over a dozen multi-disciplinary failure mode and effect analyses (FMEAs). Approaches such as these have significantly improved patient safety and created a culture of safety where staff feel confident about the way they perform their jobs for the benefit of their patients. UPHS hospital has been nationally recognized for quality improvement and increased staff and patient satisfaction.

Over the last five years, UPHS has made a major financial and staff commitment to build a continuous quality improvement (CQI) process for improving patient safety by improving the processes of care. The quality department staff has led multi-disciplinary efforts to implement major systems changes, including computer prescriber order entry (CPOE), blood glucose testing devices, computerized (“smart”) intravenous (IV) medication safety technology and monitoring safety measurements using data from electronic patient-care systems.

### Use of technology

**CPOE.** Many organizations view CPOE as the gold standard of technical innovation and improvement in care. UPHS has experienced major process improvement from the CPOE system that has been in place at HUP for the last seven years. The system requires continuing, major commitment of financial and other resources that other healthcare systems may not be able to afford. As a result, CPOE penetration is growing but still represents only a small percentage of U.S. hospitals. While this technology is an important building block for creating a safe clinical environment for patient care, it is just one of many possible approaches.

**Real-time data analysis for early intervention.** An important component of developing a culture of safety is the information that has become available through the use of electronic systems. Over the last five to ten years, UPHS has implemented many new electronic technologies in clinical settings. The data captured by these systems in real time supports clinical and operational review of patient-care events that can identify significant opportunities for safety improvements. The goal of using patient safety data is to create an iterative process identifying patient safety vulnerabilities, creating intervention plans and subsequently evaluating the impact of the intervention.

For example, analysis of real-time information from the laboratory, radiology and communication systems has made it possible to notify clinicians of patients whose symptoms indicate a high probability of acute lung injury.

Providing such early warning can improve treatment, which is good for patients, and decrease the intensive care unit (ICU) length of stay, which is good for patients and the financial margin of the hospital. Other examples are shown in Table 2.

#### UPHS examples of real-time clinical decision support

- Licensed drug interactions (CPOE, Pharmacy System, Amb EMR)
- Medication administration process (infusion pump, advanced administration calculations for neonatology and hematology/oncology)
- Rules and triggers (CPOE) around:
  - Patient identification (multiple checks)
  - Clinical protocols (care in appropriate setting)
  - Administrative protocols (costs, appropriate billing)
  - Compliance with standards (immunizations and test in Amb EMR)
- Abnormal results (ancillary and CPOE)
- Patient access (portal for patient tracking)
- Advanced protocol management (diabetes in Ambulatory EMR)
- Diagnosing and treating acute respiratory distress and acute lung injury

**Table 2.**

**IV medication safety systems.** Another exciting example of using information for real-time or near real-time interventions is the use of an IV medication safety system (the Alaris System with the Guardrails Suite; CareFusion; San Diego, CA—Table 3). Nursing staff has enthusiastically embraced this medication management technology and has communicated that they now feel safer. Some of the results of the use of this system are shown in Table 4.

The alerts produced by the system’s safety software whenever programmed infusion parameters exceeded institution-established limits were analyzed. Patterns of increased potential medication administration errors were identified. It was noted that increased errors and risk of

**IV medication safety system**

- Leverages our wireless investment for real-time information
- Brings data to the operation never before captured
- 157 computerized point-of-care units at HUP (560 pumps)
- Plan is for 645 point-of-care units (915 pumps)
- Early results reveal safer drug administration

**Table 3.****IV safety system outcomes**

- Development of IV Medication Harm Index
- Applications of IV Medication Harm Index findings and PADE patterns in development of clinical advisory software to further ensure patient safety
- Confirmation of patient census data based on day of week
- Investigation of relationship between time of day and day of week and PADEs
- Monitoring of IV medication harm risk and cardiac arrest/stat call occurrences
- Statistically significant reduction in MICU and CT/SICU length of stay

**Table 4.**

harm were associated with certain days of the week. Based on this finding, staffing patterns were modified during those days. The results of these changes are being monitored, and other adjustments to clinical operations will be made as necessary. A statistically significant reduction in the length of the stay in the participating ICU was also identified in this study. These examples are exciting because they demonstrate the use of technology and process changes to improve patient care in qualitative and quantitative ways.

**Convergence—the next step**

In the future, the convergence of biomedical equipment with clinical application software and the resulting opportunities for real-time and retrospective analyses could produce dramatic improvements in care. A major

impediment to creating a culture of safety and using technology most effectively is the lack of integration of patient information and clinical decision support. Caregivers use dozens of different software applications that may contain different clinical information for the same patient. The software may also have clinical rules with varying degrees of complexity, communication routes and levels of rigidity that create electronic “noise” (competing rules or irrelevant information) for busy care providers already confronted by human noise and perpetual distraction. The amount of information generated is voluminous, especially in an intensive care setting, yet this information must be carefully monitored for that one indicator that identifies a potentially life-threatening situation.

As technology evolves, the amount of information and rules is increasing rapidly. Care must be taken to avoid having clinicians become overwhelmed and the value lost in the clutter of noise. Clinical information and decision support needs to be better integrated to minimize “noise” and the risk of critical information being lost.

The medication administration process is a good example of competing rules. When the medication is selected, rules in the CPOE system take into account possible drug-drug interactions, body weight for appropriate dosing and other clinical algorithms. The medication order then is sent to the pharmacy, which has another set of rules. These may be aligned with the CPOE system or may be slightly different. The order then may be forwarded to a robot or a dispensing machine and returned to the nurse’s medication administration record and a barcode medication administration (BCMA) system. The information also may be sent to another medical device, such as an infusion system. All of these electronic transfers may result in a prescription being evaluated using different rules and parameters that must be continually reviewed and maintained for appropriateness. Clinicians may start to ignore the various alarms, some of which would be unnecessary if electronic systems were tied more closely together.

Because these various systems are not interfaced, application vendors and hospital providers must develop rules that are consistent among these systems, not just develop progressive rules for improving the diagnosing and

treating of patients. Care providers and technologists must challenge and influence the thinking of the technology vendors to work cooperatively instead of competitively within the care process and to keep providers' and patients' interests foremost in their thinking. Technology has contributed to major advances in healthcare, and greater cooperation will produce maximum improvement over time.

# Intravenous medication safety wireless data system

*Nancy Pratt, MSN, Senior Vice President, Clinical Effectiveness, Sharp HealthCare, San Diego, CA*

## Key points:

- Sharp HealthCare purchased and deployed an intravenous (IV) medication safety system as a key component of its safety strategy; wireless data transfer was added to optimize the use of the system and to maximize the safety benefit
- Regular analysis of data from the IV medication safety system provides insight into avoiding harm, determining where learning needs exist with respect to IV medication safety, and better understanding current practices in the administration of continuous IV drug infusions
- There is confidence at Sharp that the IV medication systems with safety software and wireless connections not only have reduced harmful events associated with IV drug infusions but also have provided tremendous insight into the administration of IV drugs

In 2003, Sharp HealthCare installed an intravenous (IV) medication safety system (the Alaris System with the Guardrails Suite, CareFusion, San Diego, CA) in five acute care hospitals. The following year, the company approached Sharp about testing a wireless solution for connecting the intravenous (IV) safety systems to the health system's information technology (IT) network. The wireless server enabled the health system to download alert data from the devices and to upload software configuration changes without having to physically touch all 1,064 IV safety systems used throughout the organization.

The use of IV medication safety systems and wireless network connection are a part of an organizational transformation to make Sharp HealthCare the best place to work, the best place to practice medicine and the best place to receive care. To achieve this mission, Sharp must

be a safe place for the delivery of healthcare. Part of the strategic approach to patient safety at Sharp includes the use of technology that provides a significant safety benefit. To this end, Sharp implemented pharmacy-linked point-of-care dispensing cabinets, hired safe-medication-practice pharmacists, implemented a Safe Medication Hotline, subscribed to an online medication error reporting system, implemented an automatic electronic triggering system to identify adverse drug events and initiated Six Sigma performance-improvement projects related to medication dispensing and administration. Sharp also purchased IV medication safety systems as a key component of the safety strategy. Wireless data transfer was added to optimize the use of the IV medication safety systems and to maximize the safety benefit.

Alerts are provided to clinicians when programmed parameters exceed institution-established limits. The most compelling reason to evaluate the software alerts is to enable the organization to make sound decisions about adjusting the software parameters that stimulate an alert. Leaders can gain insights about avoiding harm, determine where learning needs exist with respect to IV safety system utilization and better understand current practice in the administration of continuous IV drug infusions.

Our objective in evaluating the data was first to determine whether the software parameters were properly set to maximize the specificity of the alerts. Maximizing the specificity (increasing the number of "true positives") leads to a circumstance in which a minimal number of false alerts occurs and, ideally, stimulates a nurse to pause when the safety system does produce an alert. The objective is to give a nurse a high degree of confidence that an alert is associated with risk and, therefore, should be carefully assessed.

The wireless capability enables analysis of the total sample at one time. The data are available on a near real-time basis, as the infusion safety systems send information to the network server each time they are in use. This makes monthly evaluation of safety data reasonable. The quality of the decisions resulting from a review of a total sample of the data are much more methodologically sound than decisions rendered from the download of data gathered from a convenience sampling. Adjusting and configuring the systems to provide the greatest impact on safety can best be done within the context and understanding of how they are actually being used while providing patient care. Making configuration changes using a wireless connection is substantially faster and more economical than making these changes on each device individually.

**Wireless data acquisition**

The wireless data acquisition system (510K cleared medical device) consists of a network server and a wireless communication card installed in the point-of-care unit (computerized “brain”) of the IV medication safety system (Alaris System). The IV medication safety systems automatically upload alert data to the network server and receive downloads of software and configuration changes. The network server includes a browser application installed on a desktop computer that automatically transfers data into a relational database and sorts the data into standardized reports.

**Data analysis**

The new wireless connection was installed and tested in Spring 2004. The following information is the initial evaluation of the results of alert data obtained on the total sample of IV safety systems at one of the acute care hospitals. The alerts occurred during a two-month period from February to April 2004.

The initial data set included 1,117 alert events. Ninety-five percent of the alerts were overridden by the clinician. The majority of the events (61%) occurred in the intensive care unit, with the next highest group of events (22%) occurring in Med/Surg. The event category “dose above maximum” was of particular interest and was the largest individual category of alerts (33%). A thorough analysis of the data was conducted to try to determine:

1. What environments experienced the largest number of alerts?
2. What types of drugs generated the majority of alerts?
3. Were the configuration settings appropriate?
4. Was harm avoided?

The analysis was begun by evaluating the alert events in which the clinician stopped to reprogram the pump, as well as “dose above maximum” alerts.

**Reprogramming alerts**

Alerts that led to reprogramming of the infusion were regarded as successful alerts in that the clinician responded with a change in the infusion parameters. There were 57 of these events (Table 1), of which 13 involved avoidance of harm. The drugs associated with the greatest number of reprogramming events are shown in Figure 1.

Averted IV medication errors	
•	One complete hospital data set
•	Inclusive dates 2/10/2004 - 4/23/2004
•	Total number of events: 1,117
•	95% of events overridden
•	Number of multiple events at same time: 42 (3.8%)
•	Average number of events when in multiples: 2.3
•	Alerts that led to reprogramming: 57
–	Potentially harmful events: 13

Table 1.

**Reprogrammed by drug**

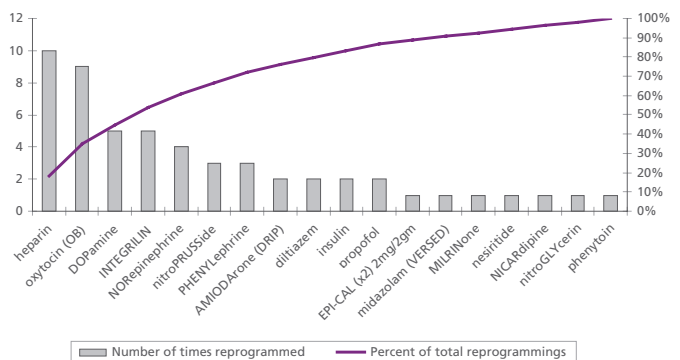


Figure 1.

Heparin and oxytocin were the most commonly reprogrammed drugs. The likely reason is the availability of many concentrations of heparin, which adds to the confusion of programming the pumps. A standardized concentration and volume were proposed to resolve this problem. The oxytocin errors involved user data entry mistakes that were likely promoted by the “wildcard” selection feature on the IV medication safety system. Rather than prompt the user to select a standard concentration of oxytocin, the “wildcard” selection (which is a blank field), was listed as the first option. Staff sometimes entered the dose and volume data inaccurately into this “wildcard” field. This led to a recommendation for a software change to place the “wildcard” selection as the last option. Printing barcodes on the IV bags and having the IV safety systems recognize this barcode is another way to prevent erroneous data entry.

Examples of the harm avoided are shown in Figure 2. Most of these involved decimal point errors. The determination of harm avoidance was a clinical judgment based on a patient experiencing an adverse response within a short period of time of a pump being started at the initially programmed rate and the clinician walking away from it. Most of these drugs would cause clinically significant hemodynamic changes within minutes. The heparin and insulin infusions would cause physiologic changes that could easily go undetected until they became clinically severe (e.g., gastrointestinal hemorrhage, severe hypoglycemia). These adverse effects were avoided by feedback from the pump prompting the clinician to make a correction.

**Warnings reprogrammed**

		Initial programming				Subsequent programming	
		GR limit	Amount +/-		Times the limit		Times intended dose
			+	-			
DOPamine 400 mg/250 mL	106.67 mcg/kg/min	SOFT+	20	86.667	5.333 mcg/kg/min	96.9697	11
DOPamine 400 mg/250 mL	106 mcg/kg/min	SOFT+	20	86	5.3 mcg/kg/min	7	15.4
Heparin 25000 unit/500 mL	12000 unit/hr	SOFT+	25000	95000	4.8	12000 unit/hr	10
Heparin 25000 unit/500 mL	6000 unit/hr	SOFT+	25000	35000	2.4	100 unit/hr	60
Heparin 25000 unit/500 mL	8000 unit/hr	SOFT+	25000	55000	3.2	800 unit/hr	10

Figure 2.

**“Dose above maximum” alerts**

The drugs involved in the majority of the “dose above maximum” alerts events are shown in Figure 3. Many of these alerts were for very small maximum-dose violations. For example, Integrilin (eptifibatide) programming often resulted in an alert at 1.001 times the maximum dose limit. These alerts are typically overridden and form a background of “noise” for the clinician. Adjusting the upper limits to a broader but still safe maximum amount was recommended. Sixty percent of the alerts could be eliminated with broader maximum drug limits.

Another issue that was identified was the use of bolus and loading doses. High-dose alerts were most commonly associated with the following drugs:

- Morphine
- Propofol
- Amiodarone
- Heparin
- Integrilin (epitibifide)
- Oxytocin

These are drugs often administered in bolus and loading doses. There is the likelihood that clinicians were infusing bolus doses through the IV medication safety system but not using the bolus feature, thereby prompting an alert. Additional in-service education about the bolus feature in the system is planned, in order to ensure that it is properly configured and available in the cases where bolus dosing is used.

### Warnings reprogrammed

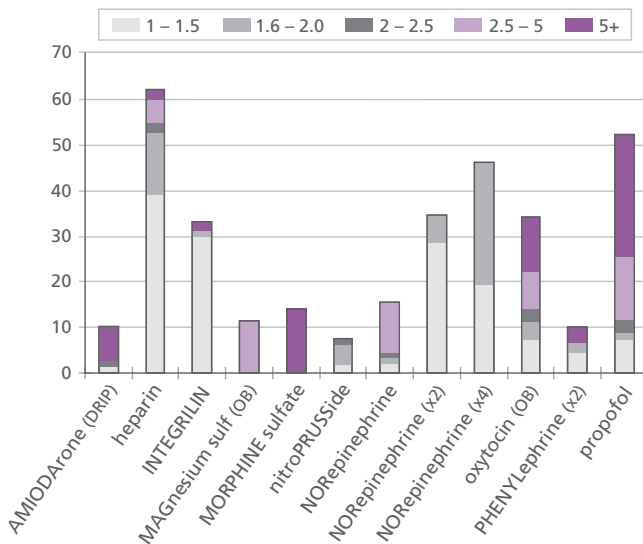


Figure 3.

The drugs that were administered below the limit are another source of “noise” or unnecessary alerts. Except for drugs that require a base-line blood level to be effective, most of these alerts were felt to be not useful. Lower limits will be removed in all cases except for those drugs requiring a minimum blood level for effectiveness.

### “Proceeded anyway”

If one can assume that the majority of “proceeded anyway,” or alert overrides, resulted in safe administration of medication, then the dose warning configuration settings are too tight and the resulting alerts too sensitive. Since 13 potentially harmful events were avoided, one can only wonder how many of the 95% of overridden alerts potentially resulted in adverse effects. It is difficult to tell from the current data which circumstances involved a therapeutic bolus and which were potential programming mistakes. Currently the data are not connected to patient-specific information, so the ability to evaluate the clinical circumstances under which an alert was provided is limited. One additional data element that would be useful is the duration an infusion was running at a particular rate. Certainly more information is needed to evaluate alert overrides to distinguish between proper therapeutic use of the drugs and device programming or drug administration errors.

### Summary

We learned that most of the alerts were overridden, that

data-entry errors persist in the set-up of some drugs, that alerts from under-dosing are difficult to assess and probably not very useful, that loading and bolus doses commonly cause alerts for exceeding the dose, and that there were at least 13 harmful events avoided in two months at a single hospital. In any of these 13 cases, if the infusion had been started and the clinician had walked away, there is little doubt the patient would have had an adverse event.

### Recommendations

Based on the analysis of the data from this sample, the following recommendations were made:

1. Set the drug limits wider to increase specificity
2. List “wildcard” concentrations last
3. Evaluate human factors interface with bolus dose feature
4. Ensure proper configuration of bolus and loading dose parameters in the software
5. Barcode IV medication labels to prevent data entry error and assure that the drug matches the programming of infusion pumps
6. Capture the duration of an infusion following an alert condition in the database

### Conclusion

There is confidence at Sharp that the IV medication system with safety software and wireless connection have not only reduced harmful events associated with IV drug infusions but have also provided tremendous insight into the administration of IV drugs. This is not an area where historically we have had a lot of information in the form of variance reports or documented adverse drug events. Previously, if clinicians had problems with the user interface, the only source of information was clinician complaints. Now, a tool is available that provides much better insight into the usability of the equipment and the general practices associated with IV drug infusions. With wireless connectivity, health systems can fully leverage their investment in safety technology by adjusting the allowable infusion setting promptly and evaluating the alerts regularly.

Based on the inherent risks, greater standardization should be used in IV medication therapy to improve patient safety.

The unnecessary variations that clinicians are confronted with while treating their patients should be minimized. In addition to averting high-risk medication errors, the safety software in the IV medication safety systems enables this standardization.

*Integrilin (eptifibatide) is manufactured by COR Therapeutics, Inc., South San Francisco, CA, and distributed by Key Pharmaceuticals, Inc, Kenilworth, NJ.*

# Integrating barcode medication administration and intravenous medication safety systems

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## Key points:

- Barcode medication administration (BCMA) technology does not detect or prevent intravenous (IV) infusion programming errors
- Integration of BCMA with IV medication safety systems can further improve medication administration accuracy and documentation
- Integrating these two systems provides a “window to the bedside” with real-time visibility of the status of IV infusions

Ohio Valley General Hospital (OVGH) is a tax-exempt, not-for-profit, acute care, community-owned hospital located five miles outside Pittsburgh. It has 119 beds, including 64 medical/surgical beds, 8 critical care beds, 18 intermediate care beds, 13 OB/GYN beds and 16 acute rehabilitation beds. The medical staff includes nearly 300 physicians in 36 different medical specialties. This article briefly describes how implementation of barcode medication administration (BCMA) at the point of care and computerized (“smart”) intravenous (IV) medication safety systems led to the integration of the two patient safety technologies to achieve further benefits.

## Patient safety initiatives

A medication safety taskforce was formed in the summer of 2000 to analyze various technologies to improve patient safety. At that time physician order entry was in development but was not viewed as a short-range strategy to improve medication safety. Pharmacy challenges included limited hours of services (15 hr/day, weekdays; 8 hr/day, weekends) and pharmacist shortages. The pharmacy-generated computerized medication

administration record (MAR) was printed daily with hand-written documentation of doses administered by nursing.

With the support of the board of directors, decentralized pharmacy services utilizing automated dispensing cabinets and barcode medication administration (BCMA) at the point of care (POC) were implemented in 2001. It was felt that these two changes improved medication turnaround time while maintaining patient safety. BCMA verifies that the right medication is given to the right patient at the right time in the right dose by the right route, and reduced medication administration errors from 76% in 2000 to 34% in 2004.

About 60 to 80 wrong patient “near misses” are intercepted by the BCMA system each month. However, BCMA does not detect or prevent infusion programming errors. This shortcoming was identified during a root-cause analysis of an IV medication error in which a 4-fold dose of neosynephrine was given for 1.5 hours. Some of the factors that were identified as contributing to IV infusion medication errors are outlined in Table 1.

### Factors that contribute to IV infusion medical errors

- Illegible order (Eptifibatide 2 mcg/kg/min read as 7 mcg/kg/min)
- Incorrect dose prescribed
- Pump programming errors
- RN distracted or fatigued
- Math error converting mcg/kg/min to mL/hr
- Inadequate staffing for double check
- Pharmacy not available 24 hours

Table 1.

Many medication errors are the result of system problems. To improve medication use systems, tasks and processes need to be designed to minimize reliance on memory, especially when the staff is fatigued and working in a high-activity area. Technology is now available that can prevent errors before they happen.

In October 2003, OVGH implemented an IV medication safety system (the Alaris System with the Guardrails Suite, CareFusion, San Diego, CA.) throughout the hospital. The system required standardizing IV medication infusion concentrations, establishing minimum and maximum dose limits for bolus and continuous infusions, defining hard stops and soft alerts for each drug, and revising physician preprinted order forms and protocols to coincide with the new standard concentrations. Standardizing all IV infusion concentrations was a critical factor in reducing opportunities for error among nurses selecting a drug concentration in the safety software.

CQI data gathered during the first two months documented that 12.4% of all warnings resulted in averted errors from reprogrammed and cancelled processes. The IV safety system prevented 26 overdoses that involved high-risk and moderate-risk medications (Table 2). One near miss involved a 3.5-fold overdose of Integrilin (eptifibatide). In this case, the nurse initially tried to program the pump with a 7 mcg/kg/min infusion. After the safety software alert, she double checked the order, realized that the physician’s order was actually for 2 mcg/kg/min, and corrected the programming.

**Overdoses prevented**

**(OVGH experience 2 months CQI event report)**

Eptifibatide	2
Heparin	2
Insulin	10
Propofol	1
Retepase	2
Diltiazem	6
Lidocaine	1
Norepinephrine	1
Oxytocin	1

**Table 2.**

CQI data also identified areas of noncompliance in the emergency department with the use of the safety software and underuse of the bolus dose feature. Nursing education was provided, and managers monitored compliance.

The vision was to expand barcode technology to include IV medication safety technology, so that the physician’s order would be directly transferred from the pharmacy information system to the IV infusion device to further decrease the chance of infusion programming errors.

**Joint product: BCMA and IV medication safety system**

On Dec. 2, 2003 OVGH implemented the use of IV Right and Connect IV, a barcode and a wireless infusion system in a critical care suite (CCS). The CCS consists of 8 ICU beds and 18 step-down telemetry beds. Order sets were developed and entered into the pharmacy computer system to assure consistent practices. The pharmacy must enter the infusion rate for all IV infusions. Titrations of doses are entered at a low-dose starting point established by the medical staff. Nursing is warned of potential errors from the IV safety software for doses that are titrated. Data are transferred in real time (Figure 1).

**Real-time data transfer**

**(OVGH experience 2 months CQI event report)**

Eptifibatide	2
Heparin	2
Insulin	10
Propofol	1
Retepase	2
Diltiazem	6
Lidocaine	1
Norepinephrine	1
Oxytocin	1

**Figure 1.**

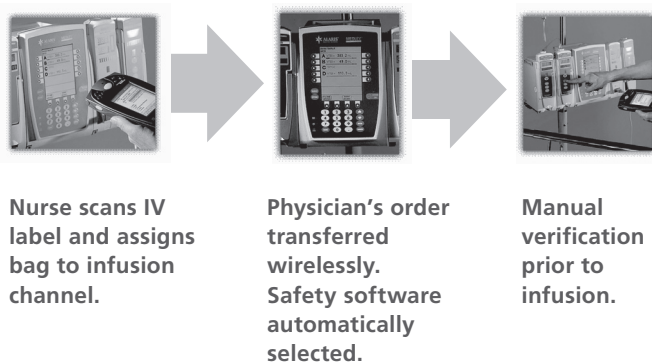
The first step in the IV medication infusion process is to associate an infusion device with a patient by scanning the patient’s barcoded wristband and the barcode on the Alaris unit. Pharmacy transcribes the physician’s order into the pharmacy computer system, which interfaces with the BCMA system that the nurse uses. The nurse scans the barcode on the IV medication label and assigns

the medication to an infusion channel. The physician's order is transferred wirelessly to the BCMA and IV medication safety systems, and the IV safety software is automatically selected. The nurse verifies the medication, solution concentration and infusion rate before starting the infusion. After starting the infusion using the IV medication safety system, the nurse selects "Chart" on the handheld BCMA device to chart the time and rate of infusion. Subsequent infusion rate changes are charted on the electronic MAR (eMAR) by the nurse using the auto-reconciliation function on the handheld BCMA device.

This integrated system provides an independent double check for pharmacists and nurses for high-risk medications. For example, if a pharmacist enters "heparin" into the pharmacy computer system in units/kg/hr, but the medication label prints the order in mL/hr, a nurse can confirm the physician's order written in units/kg/hr using the smart IV system with the corresponding rate of mL/hr on the IV label. This saves nurses several steps in the medication administration process, many calculations and multiple opportunities for errors.

Integrating the technologies reduced the risk of programming errors, as shown by a 12% decline in averted medication errors documented by CQI data from December to April 2004. The joint product also provides electronic documentation of all IV rate changes. Overall benefits are summarized in Table 3.

**Joint product benefits**



**Table 3**

Pharmacists now have real-time availability of the status of all IV infusions through the exchange of information. The pharmacist can see when an IV infusion was started, the current infusion rate and the time remaining on the

infusion. These data can be used for planning workload. A report can be generated to identify all infusions that will need to be prepared within a defined time period. It is expected that this will reduce Stat orders called to the pharmacy and reduce drug waste. Pharmacists also have direct access to patient infusion medication status to assist them with physician consultations. The IV safety system automatically transmits alerts/overrides to the pharmacy, so the pharmacist can respond to potentially critical events in a more timely fashion. The eMAR documentation of all IV rate changes prevents and defends denial of payment when managed care organizations audit drug administration records.

**Lessons learned**

Being a beta site for the development of new technologies is an exciting opportunity for a small community hospital to demonstrate leadership and commitment to patient safety. Radio frequency (RF) connectivity issues were a significant challenge. The server and RF cards on the infusion systems were upgraded to improve the signal strength, which was necessary to keep the communication line open between the server and pump.

Before integrating BCMA and IV medication safety technologies, nursing workflow was cumbersome and time-consuming, because order reconciliation by nurses was required. Reconciliation is defined as the process whereby a nurse associates an unknown infusion with a known pharmacy-generated order. Now the process of reconciliation takes place using the integrated technology.

Because the pharmacy does not provide 24-hour services, when the pharmacy opens, all IV infusions orders started during the off hours must be reconciled to the order entered. To streamline this process, an internal ID has been created which now passes to the BCMA system, so that events can be grouped and the number of reconciliations and confirm rate changes reduced.

Ease of use for nurses in scanning barcodes on IV solutions has also been a challenge. There are two barcodes on IV solutions, one containing the NDC number and the second, the lot number and expiration date. This is confusing for nurses. The pharmacy-prepared IV solutions also have a barcode on the IV label. The barcode on the IV medication label contains the medication order number, patient

account number and bottle number. The barcode on the IV medication label is large, and the label curves around the IV bag, making scanning at the point-of-care troublesome. In the future, the adoption of reduced space symbology (RSS) should resolve this problem.

### **Future plans**

OVGH plans to implement the integrated system on all inpatient patient care units during the next two to three months. We anticipate further reduction in averted medication errors with hospital-wide implementation. This will also allow for wireless upload of data set changes and real-time surveillance of CQI data. In the near future, as wireless transfer of information becomes more sophisticated, the physician order entry process will directly program the IV safety systems. Integrating IV infusion systems with bedside monitoring systems will provide clinicians with the ability to make recommendations for dose changes based on physiological changes. With wireless technology, the future possibilities are endless.

*Integrilin (eptifibatide) is manufactured by COR Therapeutics, Inc., South San Francisco, CA, and distributed by Key Pharmaceuticals, Inc., Kenilworth, NJ.*

# Industry-healthcare synergies—applying “lean” methodology to intravenous medication processes

C. Gamble Heffernan, VP Professional and Consulting Services, CareFusion, San Diego, CA

## Key points:

- Hospitals are looking to industry for proven solutions for maximizing process improvement and eliminating waste.
- “Lean” thinking is a proven solution and a core competency of CareFusion where this methodology is employed daily to reduce waste, increase cost savings and produce the highest quality product—with documented annual savings of \$12 million
- CareFusion now brings this service to their customers to achieve measurable process improvements in safe medication use
- “Value stream mapping,” a key tool in this methodology, seeks to identify activity that is not valued (or would not be paid for) by the customer, i.e., anything that does not directly contribute a patient’s getting well and out of the hospital is non-value-added
- Eliminating non-value-added activity can help healthcare providers optimize the impact of technology implementation

## Industry-hospital collaboration

“Lean” means “operating without waste.” Lean thinking has been applied successfully for years by leading companies such as General Electric and Johnson & Johnson. Now, hospitals have begun to turn to other industry leaders to help them understand and improve healthcare processes using tools such as these. Recently a Wall Street Journal article described how Virginia Mason Medical Center in Seattle learned from Toyota how to use these tools to improve financial performance as well as quality of care.

**CareFusion core competency synergies.** Lean thinking is a core competency of CareFusion. Introduced in 1997, this methodology, including value stream mapping (Table 1), has led to \$12 million in savings annually and is applied to both process improvement and new process development in operations, professional services, marketing and customer care to ensure that all processes produce only value for customers.

### CareFusion experience: Lean results

- \$12 million annualized worldwide savings
- Order fulfillment: 99.5%
- Inventory accuracy: 99.5%
- Documentation reduction: 70%
- Productivity improvement: 24%
- Improved morale, teamwork and customer satisfaction

Table 1.

CareFusion also has a core competency in safe intravenous (IV) medication administration processes. At the request of customers who observed this expertise in lean thinking and value stream mapping, the company has developed a professional service product that brings operations and clinical staff members trained and experienced in this methodology to apply lean principles and do value stream mapping on site at the customer location.

## Lean thinking and value stream

Lean thinking, also known as “Toyota production principals,” is a process improvement tool and way of working that focuses on identifying and eliminating waste by looking at an entire system—not just individual “boxes”

(tasks or departments). Lean thinking emphasizes the customer’s view of value and recognizes that all materials are “pulled” through a process by a customer, not “pushed” through by providers.

“Value-added” versus “non-value-added” are basic tenets of lean. If a customer would not be willing to pay for something, it is non-value-added. It may be required (e.g., a legal requirement), but it is not value-added. In the case of healthcare, the patient is the customer, and anything that does not directly relate to a patient’s getting well and getting out of the hospital is not value-added.

A “value stream” is all activities in a process that flow to the customer. Value stream mapping (VSM) provides a system-level view of a process that:

- Identifies all value-added and non-value-added activities, time elements and resources in a process
- Identifies flows and processes, not people
- Identifies not only process steps but also material, information and activity flows
- Crosses functional boundaries

**Example 1.** Table 2 summarizes one application of lean thinking and value stream methodology that CareFusion performed with a large West Coast hospital. As shown in this example, VSM is the first step in the process, which involves the development of a current state to look at the elements that can lead to waste, including:

- Time (travel, wait, searching)
- Distance traveled
- Whether found at first attempt
- Information flows
- Confirmation steps
- Interruptions to process

All these items are measured, then determined to be “value-added” or not. Multiplying items by the number of times they happen during a given time period shows the cumulative impact of waste. In the case of this institution, 85% of the activity in the IV medication administration process (nurse process) was non-value added. Our subsequent engagements have shown us that this number typically falls between 60% to 80%. Causes of non-value-

**Hospital A: West Coast**

- Current state value stream
  - 800-bed facility—medical/surgical unit mapped—24 beds, high census
  - IV medication delivery process observed
  - Total process time = 81 minutes, 23 seconds
  - **Total non-value-added (NVA) time = 69 minutes, 55 seconds (85%)**
- Non-value-added example—recommendation for process improvement
  - Centralize preparation and labeling materials
    - Avoid “hunting and seeking” stickers, addressograph card, tubing, etc., none of which are located near one another
    - Avoid traveling back and forth across area to label, get printout, materials
  - **Current NVA time to complete this task = 2.3 minutes**
  - Multiply the NVA time by number of times IV delivered in unit (14,053) =
    - **30% of an FTE**
    - **54 shifts saved per year**

***Simple re-design and placement of material = 539 hours/year gained for patient care***

**Table 2.**

added activity include the poor location of necessary items, which necessitates “hunting and gathering” to locate what is needed. For this hospital, simply placing materials in more convenient locations resulted in savings of 54 shifts per year—all of which could be used for direct patient care.

**Example 2.** In a recent engagement with an East Coast hospital (Table 3), waste was generated by an extra “confirmation” step that occurred because the staff knew that the fax machine used to send an order to the pharmacy was not always reliable. Consequently, the staff also phoned the pharmacy to make sure an order was received. While the action may have taken only a minute, when that length of time was multiplied by the number of times orders were faxed per year, it easily justified the small dollar amount needed to replace the fax machine. This

**Hospital B: East Coast**

- Current state value stream
  - 120-bed facility—intensive care unit mapped—8 beds, medium census
  - IV medication delivery process observed
  - Total process time = 31 minutes (if all went well)
  - **Total non-value-added time in 31-minute process = 18 minutes, 18 seconds (59%)**
- Non-value-added example—recommendation for process improvement
  - Centralize supplies and get a better fax machine
    - Walking to two different areas on opposite sides of nursing station to obtain supplies = 2 minutes
    - Re-faxing orders to pharmacy due to non-functioning fax/non-receipt = 2 minutes
  - **Current NVA time to complete this task = 4 minutes**
  - Multiply the NVA time (4 minutes ) by number of times IV delivered in unit/day (50) =
    - 3 hours/day saved, 122 shifts/year
    - 68% of an FTE

***Reduction of small amounts of waste in process add up to big opportunities = 1,217 hours/year gained for patient care***

CareFusion is committed to the comprehensive delivery of medication safety that takes into account the need for process improvement prior to technology adoption. The combined application of lean thinking and value stream methodology has been shown to have measurable positive impact on customers’ clinical and operational efficiency.

**Table 3.**

time-saving solution added the equivalent of 122 shifts per year back into the process for direct patient care.

**Maximizing processes for technology adoption**

CareFusion is dedicated to developing performance partnerships with its customers utilizing its expertise in medication safety and process improvement. Our core competencies in medication administration processes and lean thinking comprise an effective combination in driving not only technology implementation but also process improvement and technology adoption. Hospitals have implemented technology in many cases without looking at core systems and processes already in place to make sure they are not wasteful. If a bad process is automated, the only result is an accelerated bad process.

# Enhancing patient safety with a standard taxonomy for CPOE and a smart intravenous medication safety system

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## Key points:

- Substantial variability exists in all aspects of infusion best practice rules—e.g., in drug names, concentrations, dosing units and dosing ranges, as well as in other performance limits such as maximum infusion rates, weight limits and volume limits—between institutions, within institutions, and even within care areas
- Unnecessary variability increases opportunities for errors; standardization of ordering, preparation and administration is vital to reducing variability
- Advanced technology—while intended to increase safety—can actually cause harm, if not carefully integrated
- Multidisciplinary communication and collaboration are important factors in successfully integrating medication safety technologies to avert errors and prevent harm

Aggregate data from 90 hospitals using an intravenous (IV) medication safety system (the Alaris System with the Guardrails Suite, CareFusion; San Diego, CA) reveal intra- and inter-hospital variability in IV therapy as a significant and consistent finding. The underlying reason is an enormous variability in all aspects of the hospitals' best practice rules—e.g., drug names, concentrations, dosing units and dose limits, as well as in other performance limits such as maximum infusion rates, weight limits, volume limits, etc. Such variability may play a critical role in medication safety by increasing opportunities for errors to occur. For example, having the option to either use or not use a weight in a drug calculation for a 70-kg patient creates the potential for a 70-fold under or over-dose.

The 2004 Joint Commission National Patient Safety Goal

requiring organizations to standardize and limit the number of drug concentrations available in an organization, as well as principles of complexity theory and human factors engineering (HFE) and findings from other industries, suggest that standardizing drug names, dosing units, dose limits, maximum infusion rates, weight limits and volume limits may help reduce process variation and thereby improve patient safety.

This article includes a brief review of variability findings and reports on experience at Vanderbilt University Medical Center (VUMC) in enhancing patient safety by using a standard taxonomy for computerized prescriber order entry (CPOE) and smart (computerized) IV medication safety systems.

## Infusion therapy best-practice variability

The 90-hospital data set shows that variability exists in all aspects of infusion therapy: drug names, drug concentrations, dosing units, dosing ranges and, for drugs such as dopamine, in the specific “steps” involved in titrating. Variability included generic, trade and “local” names, as well as the creative use of the drug names that included indication for use (e.g., tPA -stroke, Activase—MI, alteplase—PE).

Dosing units were also inconsistent, e.g., 94 drugs had two different dosing units per drug—even within the same profile. Concentrations also differed, with an average of 119 different drug-concentration combinations per hospital, with each drug having an average of 1.3 concentrations. Neonatal and pediatric intensive care units (ICUs) sometimes had only patient-specific concentrations, so that in theory, every patient could receive a different concentration.

<b>Alteplase: Names</b>	
Activase	alteplase - IR
Activase (tPA)	alteplase - TPA/Occlus
alteplase	alteplase - vascular
alteplase (tPA)	alteplase - intra-art
alteplase (Activase)	alteplase (MI/PE/CVA)
TPA (alteplase)	alteplase - MI < 67
alteplase - PE	alteplase - MI > 67
alteplase - MI	ALTEPLASE (mg/kg/hr)
alteplase - stroke	alteplase - (tPA) bolus
alteplase - low dose	alteplase drip

*Data on file at CareFusion*

**Table 1.**

Many drugs had multiple names for the same drug. For example, alteplase was called by 18 to 20 different names, including descriptors based on brand name or indication (Table 1), was available in multiple different concentrations (Table 2) and could be administered in seven different dosing units for a variety of indications. Each indication (e.g., stroke, myocardial infarction (MI), pulmonary embolism, etc.) had different dosing units and dose limits (Tables 3-5). Finally, a large category labeled “none of the above” still had multiple different opportunities to provide different doses and different concentrations.

<b>Alteplase: Concentration</b>
• 0.02 mg/mL – 10 mg/500 mL
• 0.05 mg/mL – 12.5 mg/250 mL
• 0.01 mg/mL – 10 mg/100 mL – 50 mg/500 mL
• 0.286 mg/mL – 20 mg/70 mL
• 0.375 mg/mL – 30 mg/80 mL
• 0.4 mg/mL – 20 mg/50 mL
• 0.5 mg/mL – 50 mg/100 mL
• 1 mg/mL – 50 mg/50 mL – 100 mg/100 mL

*Data on file at CareFusion*

**Table 2.**

These examples underscore the significant variability in IV drug administration that exists within and among hospitals and even within a patient care area. Such variability can result when one physician wants a certain dosing strategy that is totally different from what another physician wants. Such variability increases opportunities for errors.

Integrating technologies to provide a seamless transition between CPOE, pharmacy systems and infusion systems is key to reducing errors and improving outcomes. Creating independent systems contributes to inconsistent practice patterns and significantly increases the likelihood of medication errors.

**Overdoses prevented**

Indication	Dosing unit	# of hospitals	Min	Max
Vascular	mg/hr	3	1	5 - 100
Stroke	mg/hr	2	0.9 - 30	81.1 - 90
	mg/kg/hr	1	0.1	0.9
MI	mg/hr	1	1	60
	mg/kg/hr	1	0.25	1.52

*Data on file at CareFusion*

**Table 3.**

**Alteplase: Dosing**

Indication	Dosing unit	# of hospitals	Min	Max
PE	mg/hr	4	10 - 49.9	50 - 51
CVA	mg/kg/hr	1	0.1	0.75
IR	mg/kg/hr	1	0.02	0.1
Intra-arterial	mg/hr	1	1	4
“Low-dose”	mg/hr	1	0.4	3

*Data on file at CareFusion*

**Table 4.**

**Alteplase: Dosing**

Indication	Dosing unit	# of hospitals	Min	Max
None of the above	mg/hr	16	0.01 - 49.9	2 - 100
	mg/kg/hr	8	0.025 - 0.1	0.05 - 1.5
	mg/min	1	0.1	0.6
	mg/kg/min	1	0.003	0.025

*Data on file at CareFusion*

**Table 5.**

**VUMC**

In 1994 Vanderbilt developed and implemented a CPOE system called WIZ Order (subsequently purchased by McKesson and marketed as Horizon Expert Order

System). Use of this technology resulted in increased standardization, because the CPOE system does not allow the unlimited operations for ordering that was possible when every physician order was handwritten.

When the smart IV medication safety systems were implemented in 2002, a multidisciplinary team was formed to determine best practice parameters, with pharmacist oversight of dosing limits. The safety software was customized by establishing drug libraries with dosing limits for individual care areas based on existing drug libraries within WIZ. Individual care areas were allowed to make additions to the system. In an attempt to accommodate individual needs and preferences, multiple dosing options were available. Not all units were utilizing CPOE, and units were asked for their individual wish lists. Those requests were granted without being validated against the existing drug libraries. Also, an anesthesia profile was created that allowed a clinician to bypass the IV safety software dosing limits in the operating room (OR).

Following implementation of the IV safety systems and on subsequent software upgrades, the multidisciplinary staff recognized a need to limit dosing options and to incorporate the anesthesia profile into existing drug libraries, in order to align CPOE with infusion systems and standardize practice across the organization.

Pharmacy and nursing worked closely together to establish the drug libraries for both systems. Customizing the IV safety software was made easier by having a drug library already available in the CPOE system. After implementation of smart infusion technology, given that CPOE was already well established, the number of medication errors due to interpretation and transcription errors decreased. The opportunity still exists for transcription errors to occur when medication orders are copied onto the medication administration record (MAR). However, this represents a time-limited error and should be noticed when orders are reconciled by nursing staff during routine chart checks and when new MARs are printed by the pharmacy. Currently, updated pharmacy software will have the option to "demand print" MARs, which will eliminate the need for hand transcription. Also, electronic documentation systems (e.g., eMAR) are currently being evaluated, so that technology implementation remains a work in progress.

## Aligning CPOE and IV safety systems

**Amiodarone.** A few medications can serve as examples of how the current CPOE system has been aligned with the smart IV system to improve medication safety. One such example is the use of amiodarone. When a clinician wishes to enter an order into the CPOE system and types in "amiodarone," options such as "bolus" or "continuous infusion" appear on the screen, and the clinician selects the desired option. Selecting "amiodarone drip" (infusion) brings up two possible doses: "0.5 mg/min" and "1 mg/min." The clinician may select one of these options or type a different dose into the free text; however, whatever dose is entered needs to be in milligrams per minute. The next option is when to start: "STAT" (the default option), "Next scheduled dose" or "Now." Selecting STAT enters the order to start infusing the desired dose in mg/min now.

Upon receiving the medication order, a bedside nurse accesses the IV safety system screen, which shows the standard concentration of amiodarone as 450 mg in 250 mL. The screen shows that weight is not used, that the time is in minutes and the dose is in milligrams per minute. The VUMC dosing limits are a minimum of "0.5 mg/min" and a maximum of "5.0 mg/min." Once that information is confirmed, the dose is entered, e.g., 1 mg/min, and the safety software populates the screen with the rate. The clinician can now press "Start."

Multiple options are not available. For both ordering and administration, only "mg/min" is available for dosing. Limiting the available options reduces the need for decision-making on the part of the clinician and increases the likelihood of doing the right thing.

**Heparin.** This medication is another example of variability in how it is dosed, how it is administered and indications for therapy. As with the above example, if a physician goes into the CPOE system and types in "heparin," the screen displays different options. One feature of the Vanderbilt CPOE system is a decision support screen that opens and guides the clinician in selecting appropriate therapy based on clinical indications. This screen also guides the clinician in selecting appropriate corollary orders to monitor outcomes of therapy.

Once the indication for therapy is selected, the system

will direct the user to a web-based application that is a decision support screen or a treatment advisor. At this point, the screen will ask the clinician to review clinical data and then pick an indication. Based on that indication, the system then proceeds to prescriber information. For example, if the user selects the “acute coronary syndrome indication,” the system will proceed to the appropriate decision support screen and provide the clinician with options for hourly dosing or weight-based dosing.

Another feature of this CPOE system is that in designated care areas with certain patient populations, nurses can enter adjustments to the heparin dose using these same treatment advisors. While weight-based dosing is an option within the CPOE system, a unique feature is that the printed order will ultimately be dosed in units/hr. This standardizes the administration process and decreases the likelihood for administration errors should the nurse inadvertently select “units/kg/hr” rather than “units/hr.” In addition, the treatment advisor screens include corollary orders such as “Check stool for occult blood,” orders for coagulation studies, platelet counts, etc.

**Potassium chloride.** In electrolyte replacement, potassium chloride (KCl) is another area where a lot of variability exists, along with frequent dose-limit overrides and an increased potential for errors. VUMC uses a couple of standard concentrations for KCl. In the adult population, KCl appears in the system either as “10 milliequivalents in a 50-mL bag” or “50 milliequivalents in a 100-mL bag,” but the concentration is the same—only the volume changes. A clinician can select the desired dose in units of 10 or can enter a different dose. However, the software drug libraries dictate that whatever dose is entered must be in milliequivalents, not some other unit of measure.

At the point of administration a nurse selects “KCl” from the drug library. After the correct dose and rate are confirmed and prior to infusion start, a clinical advisory screen appears alerting the nurse to “Watch IV site carefully for signs of extravasation.” Thus, multiple layers of information serve not only to avert errors but also to optimize care.

**Alteplase.** The final example is TPA or alteplase. The current CPOE drug library has multiple dosing options for different clinical indications. One such indication is

acute myocardial infarction (AMI), listed as “Acute MI Accelerated Infusion.” Selecting this option leads a clinician to the next screen, where a pop-up screen appears outlining the 3-step process for administration of alteplase for AMI in which a 15 mg bolus dose is administered (using bolus option on IV safety system), followed by 50 mg over the next 30 minutes, with the remainder of the standard 100 mg dose administered over the next 60 minutes. The infusion system is aligned with the CPOE system so that the drug is delivered in mg/hr. As a result, even though weight was used to determine the correct dose to give, the dose is administered consistently each time.

### Summary

As we continue to learn, it is important to remember that advanced technology, while intended to increase safety, can actually cause harm if it is not carefully integrated. Experience at VUMC has shown that we have integrated technologies well and have achieved a certain degree of consistency. Aligning CPOE and the IV safety system in every aspect continues to be a work in progress. But customizing the system to decrease options (e.g., dosing heparin in units/hour only) significantly decreases opportunities for errors to occur. Standardization in ordering, preparation and administration is vital to decreasing net variability, and implementation and integration of advanced safety technology can play a vital role in improving not only standardization but also collaboration and quality of care.

# Implementing a medication safety and management strategy—clinical, operational and financial impact

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## Key points:

- Improving medication use safety in the hospital setting can not only save money but also save lives
- There are technologies that can improve the safety and efficiency of prescribing, dispensing and administration of medications
- These need to be implemented in a stepwise fashion, but with a strategic aim to integrate the technologies
- Cost savings from improvements in efficiency and safety can exceed those of the acquisition of the technologies

Spartanburg Regional Health System (SRHS) is an integrated healthcare system comprising three hospitals, with 730 beds, 510 staff physicians and gross annual revenues of \$1 billion. As a result of being a very early adopter of innovative technology in implementing a comprehensive medication safety and management strategy since 1995, SRHS can now demonstrate that the use of integrated, innovative medication safety technology (Figure 1) not only can improve patient care, but also can realize cost-savings to help fund technology acquisition and other continuing improvements. Ultimately, the decision to integrate technology is about much more than saving money—it is about saving lives.

The problems associated with medication errors have been widely publicized: thousands of deaths per year, the difficulty of identifying and preventing medication errors and the economic impact of such errors on care delivery organizations. A major challenge is reducing variability in care. Lack of standardization to experience-based best practices leads to significant variation in quality and in cost. While this is true in many industries, in healthcare

## Closed-loop medication management

- Physician
  - Information access
  - Clinical decision support
  - Order initiation
- Pharmacist
  - Work queue
  - Verification
- Dispensing
  - Barcode packaging
  - Centralized robotics
  - Decentralized cabinetry
- Nursing
  - Point-of-care scanning
  - IV safety system
  - “Near miss” reporting
- Patient monitoring
  - Rules-based alerts
  - Escalation

Figure 1.

the enormous volume of new treatments and evidence—numerous new medications and tens of thousands of new journal articles every year—presents a significant challenge for healthcare professionals to remain current and to incorporate new developments into the care decisions made every day.

In 2000, in response to the occurrence of a fatal morphine overdose, the board of directors challenged the entire executive staff of SRHS, including the information technology (IT) department, to improve patient safety. A major management goal was to eliminate variation, both to improve clinical care and to be able to implement

technology much more rapidly. In terms of technology, the goal has been to automate all phases of patient care through a closed-loop medication environment, so that a clinician can access clinical information in real time or near real time from anywhere in the system (Table 1).

**Spartanburg’s medication safety and management technology plan**

- 1996: Pharmacy dispensing robot
- 1997: Barcode scanning of medications at bedside
- 1998: Electronic monitor integration
- 1999: Unit-based medication cabinets
- 1999: Electronic pharmacy distribution
- 1999: Electronic medical supply distribution
- 2002: IV medication safety systems
- 2004: Pharmacy system with decision support
- Today: CPOE
- Today: Integration of electronic systems

**Table 1.**

In 1996, SRHS was the sixth hospital in the United States to implement an automated robotic pharmacy technology, which automates the storage, dispensing, returning, restocking and crediting of barcoded inpatient medications. This resulted in a reduction of four full-time equivalent (FTE) technician positions, better inventory control, reduced order-to-administration time and downtime of less than 1%. In 1997, a nursing clinical documentation system was implemented that uses barcode scanning of drugs and IVs at the point of administration to ensure the “five rights.” This technology reduced medication administration errors, improved on-time medication administration, reduced nursing documentation time and improved nursing satisfaction.

In 1999, variation was further reduced by using medication cabinets in patient care areas that interface with the dispensing robot. This change improved inventory control and monitoring and reduced costs by eliminating excess inventory. Signing a contract with a new pharmaceuticals distributor reduced costs by \$500,000, and a 99.99% fill rate eliminated the need to use a secondary vendor. Changing the medical supply distributor and linking systems for totally electronic ordering resulted in recorded

savings of over \$1.1 million, redeployment of 6 FTEs and freight savings over \$45,000. These savings were then invested in other improvements.

In 2002, the implementation of an IV medication safety system (the Alaris System with the Guardrails Suite, CareFusion; San Diego, CA) was easy to justify on a cost-benefit analysis, since the cost of the lawsuit from the morphine overdose far exceeded the cost of the IV safety systems. Installation of 565 IV safety systems was completed over the course of one weekend. Nursing acceptance and satisfaction was very high, and several letters were sent to the administration, thanking them for providing nurses and patients with that protection. As shown in Table 2, use of the safety software and the number of events (instances in which the software produced an alert) increased, and patient safety was improved.

**IV medication safety systems**

- First review of data from 100 of the 556 pumps
  - 65% of nurses used the safety software
  - 550 events logged
- Second review of data from all 556 pumps
  - 86% of nurses used the safety software
  - 1,423 events logged
- Conclusion:
  - Intervention occurred prior to med administration
  - Discrete data available to P&T committee for ongoing review
  - Improved patient safety

**Table 2.**

In 2004, a pharmacy information system designed to enable electronic receipt and processing of medication orders from computerized prescriber order entry (CPOE) system was implemented and integrated with other IT systems. The goals were to provide a rules- and knowledge-based system, to improve medication safety with end-to-end electronic order processing and to improve workflow and efficiency. CPOE was implemented in 2004 to enable the best, most efficient decision making by physicians, as well as to standardize patient care and eliminate handwritten orders. The overall impact of these

changes has been to reduce expense budget by over \$4.2 million, improve patient safety and patient care and improve access to clinical information.

To increase efficiency by avoiding a need for multiple sign-ons, a single-point, single sign-on “portal” provides all nurses in the system access to not only the acute care systems of the hospital but also some physician office systems and national databases. The system provides visual integration of multiple information sources, personalized presentation and navigation, and is accessible anywhere, anytime. Clinicians now can access any historical data since 1995, when the electronic medical record was implemented, as well as laboratory results, vital signs, patient charts and medical images.

As stated above, the decision to integrate technology is about much more than saving money—it is about saving lives. In particular, implementation of the IV medication safety system has had positive effects in many areas of patient safety (Table 2). In terms of capturing and analyzing data, about 12 nurses serve on a data advisory committee that reports to the board of trustees’ quality council monthly. Nursing satisfaction has improved tremendously. Capturing data in real time or near real time has improved care and the hospital’s bottom line.

One area not yet fully addressed is the need to integrate all existing medical software systems. More data are available than ever before, but there are still gaps between different products that must be addressed and the systems integrated. Achieving full integration will achieve even greater gains in patient and medication safety.

# Roundtable discussions

## Implementation of infusion safety systems

*Participants were asked to share their experiences in implementing an infusion safety system in terms of a business perspective, ease of use, staff training, durability of training and compliance with the use of the devices.*

From a business perspective, is technology a method of assuring the safety of care without necessarily burdening an already-stressed work force?

**Ms. Obsheatz:** Administration will support technology in our hospital, and they're less likely to give me more people; man-hours are harder to come by than technology. That's an interesting philosophy at our institution, and (implementing barcode medication administration and smart infusion technology) has really helped us get through Joint Commission surveys. It also enables me to sleep at night, because I'm ultimately responsible for everything that goes on with medications. We're not there 24 hours to see everything. I need to know that we are doing our best to provide a safe environment.

### Ease of use

**Ms. Pratt:** With respect to convenience—using the IV safety system versus a barcode—there are light years of difference in the obstacles that are presented to the nurse. With respect to using a barcode solution, they have to perhaps carry a portable, heavy, bulky barcode reader, which may be dropped. It's another thing they have to carry along. There are issues around how fast or how accurately it scans the barcode, how smoothly it documents the drug. There is a huge number of variables that are different than going into the IV safety software to pick a drug. You pick an item off the menu, and the software pulls up the information on the pump. I don't think they're close in terms of the obstacles.

### Education—how long does it take to really get your staff fully trained with this?

**Dr. Rothschild:** Well, when we did our study, there was a two-week period for training before we actually started the control phase. I should mention that there were some real, cultural acceptance issues, and the reality was that for years the nurses on this floor were using a type of pump that was very small. The pumps were breaking down and probably creating more problems than they should have, yet when the nurses saw these new larger pumps, the overwhelming majority of the nurses were really upset. It actually took a while before they realized that there's a reason these are larger than their old ones, and they took a while before they understood the reason we brought these pumps in and how valuable they were for the care of their patients.

So there were cultural issues up front, and as I mentioned, about a quarter of the time they did not use the library for drugs that were in the library. I don't know if that was anything different at the end of the study than at the beginning of the study. But again, this was the version of the pump that did not have the default library appearing when the pump was turned on.

**Ms. Almandinger:** Nurses can get an overview from the computer-based training, but I think it takes at least 45 minutes for a nurse to sit down with the pump and really go over the profiles and the Guardrails, and this is how you put the

tubing in and don't do it this way, and what do you do about an air-in-line alarm and they just don't get that from the computer based training (CBT).

**Ms. Heffernan:** What we've learned from 200 implementations is that you start with the computer information as the premise, the overview, but you do not depend on that as the primary way to educate. You use the skills lab, but the use of the super-user or train-the-trainer is a great reinforcement tool. So that is pretty much our standard approach, regardless whether it's 200 nurses or a thousand nurses going forward. We got there by working with you and finding out what was the best way. Now we also measure the rate of adoption to compare what percentage compliance with CBT training classes has to occur to achieve that high rate of compliance with using the technology following implementation.

**Mr. Carr:** At the time we implemented, we actually had classes around the clock, and it was mandatory that every nurse attend. So that was the hands-on training with the pump set, to go through and learn the operation.

As we've had subsequent software upgrades, we have had mandatory sessions. But we train super-users and then made them responsible at the unit level. Then everyone had a checklist that they went through. When we recently upgraded, we created a step-by-step checklist, and everybody had to go through, even though they'd been using the pumps for over a year, to make sure they understood the new software upgrades. So we do have that documented competency assessment that goes into their education file.

**Ms. Steingass:** If you have nurses coming in the room, they need to have a device in front of each one of them. Don't try to put 30 nurses in a room with 15 devices. That doesn't help the training. Each person needs to have their own hands-on experience.

**Ms. Long:** I just want to say that peer pressure is one of your best tools to achieve compliance. There's really a climate now where, if a nurse comes on and the previous shift's nurse has not been using the safety software, it's kind of a big deal.

## Durability of this training?

**Ms. Steingass:** We reinforce our learning every six months when we do a mandatory education express. That is a brief 10- or 15-minute session where they have to program something that we have seen from our CQI data that they're doing wrong on a consistent basis or from our audits. Then we use that to refresh.

As you look at your CQI data, you will begin to discern those things that the nurses are still doing that are potentially risky behavior.

Even though they learned and are adopting and using the technology, your training becomes different because you're identifying different things. Now it's not so much how to press the buttons and operate the infusion device; the training now goes to, so what else are you doing to medication delivery that potentially may not be the best?

**Mr. Donnelly:** It's not so much the technology that they need to be re-educated on. It's that we see practice change throughout the year. For example, IV Protonix is a proton pump inhibitor they give to bleeding-ulcer patients. About 90 days ago we changed our formulary to allow more doctors to prescribe it in different areas in the hospital. Our rates for reprogramming events shot up, so we educated med/surg floors and postop surgical floors on this drug to drive those prevented ADE's back down.

## Compliance

**Ms. Steingass:** The amount of time necessary to go from a facilitating process to where the staff is really held accountable for taking advantage of the technology really depends on the organization. If they're learning new equipment as well as

the technology, it may take as much as six months. If they're familiar with the piece of equipment, and now you're just adding the software feature, you can maybe shorten that time a little bit. You also have to look at the age of your staff and how willing they are to make a culture change.

We said to the staff, "It's okay; it's a learning curve, and we'll have opportunity to mentor you," but we also said to them, "Over time, if you choose not to adopt, this can become a performance issue for you." We built that in upfront in our policy and procedure issue. So the requirement was, "I'll give you a couple of times that you need to learn, but eventually it's not going to be a learning issue anymore; it's going to be a performance issue."

**Mr. Donnelly:** We took a much more aggressive timeline. We've had the Alaris System for 14 months, and we took a 30-day timeline. We felt compelled to do that, because this is an error-defense system. It's really indefensible to have a system in place, from a risk standpoint, from a safety standpoint, where you're not using a technology.

We have a multidisciplinary group that meets every month. It includes pharmacy, biomed, all nurse managers, clinical quality folks, and we sit down and go through the entire technology management for the organization. Nurse managers are compelled to go through once a week and sample 10% of the infusions on their floor to make sure that the nurses are using the safety software. Because they have to come and report that, they really enforce the idea that you must use the safety software.

**Dr. Maddox:** A reasonable goal is 100%. Seatbelts don't work unless you use them. Compliance in our institution is between 98% and 100% with our nursing staff. The primary reason is that the process by which the decision was made to use the system incorporated nurses from the outset. They very clearly understand what this does for their practice in the patients they're taking care of.

If I'm a patient lying in a bed in my hospital or yours, I want this system in place. So a reasonable goal for us who are responsible for delivery of that care is 100%.

## Measuring safety

*It was agreed that in addition to the value of providing alerts that prevent errors at the point of care, the infusion safety system also provides a system for measuring medication safety, so that system and best practice changes can also be made to help prevent errors in the future.*

**Ms. Foley:** It's not just medications. This is very exciting because it is about making smart decisions—either staffing or workflow or scheduling and skill and expertise. It's a very nice use of information generated by your CQI reports.

I had the privilege of visiting San Diego Children's yesterday. They told me about having looked at some of their data. An expert nurse team, by looking at the information, uncovered the finding that 6 p.m., which is the traditional time at which they made all of the changes in their lines, there was a huge peak in error reports.

Looking at the work environment of a 12-hour nurse, 6 p.m. is when you're ready to wrap up and you're pretty fatigued. They've changed that practice so that line changes are now initiated at the start of the night shift, when the team is fresh, alert, checking the orders, getting ready for their full shift. They've already seen a change in the mistakes being caught.

**Dr. McCarter:** In regard to the sedation discussion, I would also think that the error rate with the medication itself might not be the only endpoint. I would anticipate that, as this is studied further, that by optimizing sedative practice in the ICU, your length of stay in the ICU will go down; your event days will go down. Therefore, your nosocomial infection rate will go down, your catheter days will go down and your UTI rates will go down. So measuring just the event rate and monitoring that over time may not be the endpoint that I would be looking for.

**Dr. Classen:** We published an article in the New England Journal in 1988 on a journey we took to improve medication safety in the ICU. A program that was initiated to improve medication safety and did prevent 70% of ADE's in the ICU

became a program that improved medication use and had the benefits you outlined.

The economic benefits of preventing ADE's were completely dwarfed, by several orders of magnitude, by the economic benefits of reduction in resource use, length of stay, nosocomial infections and total hospital length of stay.

So what started as medication safety became a whole lot more, and maybe that's another way to think about this as we take this journey. Maybe we should increasingly focus our measurement, not just on medication errors or adverse drug events prevented, but on these other outcomes.

## Improved care

**Dr. Rothschild:** The process of implementing and using IV safety systems really has improved care. Within that one area, there's been dialogue between physicians, nursing and pharmacy, which I think has streamlined the process. The other challenge as we move forward is developing libraries we can use across different areas of the hospital. Brigham's is a fairly large institution; it has about a dozen different ICUs, and I think it's been a good outcome for the different directors of the ICUs at both the nursing and physician level, to sit down at the table and agree on some common doses and concentrations for drugs. I think it really has helped.

## Alerts: soft limits vs. hard limits; alerts vs. actual events

*Decision support in infusion safety systems can be designed to prevent an action entirely ("hard limits" that cannot be overridden) or to provide a warning ("soft limits" that can be overridden) that can enable the administration of an IV medication to proceed, based on clinical judgment. Participants were asked to discuss their experience with using both types of warnings, so that the value of decision support to caregivers is optimized.*

## Hard limits

**Dr. Billman:** An important consideration is that hard limits are developed in a multidisciplinary and collaborative fashion. Most of the organizations that have already deployed the Alaris System have, in fact, used hard limits. We've had no problems whatsoever with our use of those, as long as the caregivers, the opinion leaders, had the chance to agree to those in advance. I have most of my heartburn around the overrides, because we don't have the hard limits. I very much advocate for getting both the hard limits and the soft limits, because I need that certainty that certain barriers are not going to be violated.

**Dr. Rothschild:** I think this process is very analogous to that of the adoption of guidelines. We look at guidelines that are evidence-based, supported by national organizations and everyone can agree are of value. Yet when you bring them into your institution, they're usually not adopted unless you have local leaders who go over the guidelines and make some subtle changes to match the unique practices of that institution. If you take a standard library as sort of a guideline, clearly you need to then take that to your institution, get input from clinical leaders in a multidisciplinary setting and then modify it to the needs of your institution in order to get acceptance. I think this is very similar to the guidelines challenge.

## Overrides

**Mr. Donnelly:** If you have too many overrides, you kind of eliminate the sentry function of these systems. As managers of these systems, it becomes our priority to reduce the number of times the system cries wolf.

**Dr. Maddox:** Overrides are about 50% of the things that are happening here. I'm convinced there are some things going on in those overrides that are important for us to know about that we don't yet and haven't talked about. The point is

that, while the technology is a heck of a lot easier to use, nurses are still overriding a lot of alerts, and I'm not sure what all the reasons are.

**Ms. Pratt:** I am a nurse, and I will tell you you're entirely correct. When I looked at the data that the nurse overrode the alarm, you could see it coming in sequence where it was the same drug and the same everything. I couldn't tell you with certainty that this clump of alarms was all on the same patient, but I could tell you intuitively it was. And if I re-presented the data on that basis, you'd see much, much higher yields.

**Ms. Steingass:** You really have to go back to those bedside nurses, show them the data and have them explain to you what is it that they are doing, so you can understand what that override data means. Maybe they're overriding it for a very good reason. So you have to maybe rethink how you're setting up your drug library.

**Mr. Schneider:** Overrides are not necessarily a bad deal in terms of white noise. The positive aspect is that they might identify people who shouldn't be overriding. It reflects a bad practice. Ray's presentation about the propofol infusion rates was a good example of an override that's actually telling you something. So that's an important thing to think about, before you look too negatively on the value of overridden alerts.

**Dr. Vanderveen:** One of the things that we're finding is that so many of the overrides are due to the fact that the rules don't match practice, as we've heard several times this morning. As the rules begin to match practice or as practice changes, the number of overrides comes down. When there are 2.3 million programmings, a percentage of those are always going to be just mistakes. In the data we've seen, those seem to be pretty consistent. It's a consistent low level of programming errors. But the number of overrides is what tends to drop over time.

**Mr. Donnelly:** There is a minimum noise level of errors that are always going to be there, but you've got to pay attention to them, and it should be a fairly changeable defense set. The practice in the clinical environment constantly changes. We'll always provide you with that new error data set, and you need to address it.

**Dr. Maddox:** The point is that the minimal baseline rate is a rate not of error but a rate of prevented error. That information can be used for process improvement. But the continual introduction of new drugs or new doses of old drugs continually changes what we are doing in practice. That's going to have an error production capability associated with it that the system will continue to tell us about, that will allow us to continually improve the process. But still knowing that there is going to be a base rate of error interdicted by systems like this, which is a primary purpose of their being in place.

## Decreasing overrides from 80% to 15%—3 years

**Dr. Classen:** We always found as we put a new program in place that the overrides start at about 80%. After an arduous process over what often was two or three years, we'd get it down to about 15%. It never went any lower than that in many different, unrelated processes. So we developed a methodology where we would study the overrides on a monthly or every-second-month basis, look at the process and at the overrides, and evolve both the process and the overrides. Because overrides take a lot of worktime, there's no doubt that they block efficiency. In doing that, we had an intentional approach to narrow our choices so that, by the end of this process, there were far fewer overrides and much more limited choices. But we found that if we ever stepped in at the beginning of a process with the limited choice that we came out with at the end, it exploded in our faces. So it was an iterative process where you had to learn along the way. The overrides were a learning opportunity to further standardize processing, to come up with a process that actually had much less choice and much less variability.

The natural course of time involved in going from 80% to 15% was three years. We tried to shorten the process, but there were so many political issues in measuring, vetting, changing, especially with the medical staff, that we found that we couldn't shorten that. Even though the medical staff had done it before, every time we came to a new clinical issue, we'd have to repeat the process. Very often we were dealing with standard-of-care issues in what we were doing.

**Mr. Donnelly:** In my organization you're trying to influence 700 nurses, 500 physicians and I don't know how many pharmacists. To influence a collective like that, you have to educate them, you have to give them time to learn.

**Mr. Schneider:** At a previous conference, Dr. Pierce said that in terms of the diffusion of innovation, two or three years is a reasonable time line. He pointed out that the fastest patient safety innovation that he was aware of that had ever been adopted within healthcare was pulse oximetry, which took two or three years.

The experience that Cedars-Sinai had with the CPOE system is sort of a diffusion of innovation "stall." They tried to implement too fast, they lost the aerodynamic lift and the project collapsed.

So in thinking about all of the frustrations and challenges we have in terms of trying to improve care and get people to change what they do, I think it requires a lot of time and effort and patience. Three years is probably a good period of time to really think about when you're changing what people do in their daily work.

## Do you think that the safety systems in these new technologies make some of the Joint Commission requirements less important?

*Public demand for improvements in patient safety is being reflected by increasing scrutiny of hospitals by organizations such as The Joint Commission. Participants were asked if infusion safety systems would affect medication safety standards or the survey process.*

### Double checks

**Dr. McCarter:** Operationally, for us to stop delivery of care and wait for a second RN to come to the room to verify every titration or any change in the dose, we felt would paralyze areas like our emergency room and intensive care unit. So we actually responded with a request to the Joint Commission to reconsider the use of technology in place of that human factor double-check.

I'm also not convinced that a human factor double-check is better than technology in that situation. Coming into a room with a patient that you may or may not know and just visually looking at someone else's work and verifying it—I'm not sure that is the double-check that I would prefer in that situation.

**Ms. Long:** Heparin and insulin are two drugs that we had been trained as nurses to double-check, and I can guarantee you that's not happening. At the VA, we actually took away at the requirement to do that. Nobody ever double-documented that there was a second check, so there was no follow-up. It really got back to the nurse's conscience.

**Ms. Dang:** Until we are able to moderate nurses' workloads and not give them 18 things to do simultaneously, the thought of another nurse doing an independent check provides a false sense of security. Because what we find happening is that the nurse will take the insulin order and say, "Okay" and you're in the middle of something else, and you say, "Yeah, that looks good; order okay, move ahead." So the whole purpose of the independent check, which is to carefully look at that order, doesn't happen, because the work environment is so complicated and so intense. I would echo what Rebecca was saying; I think technology is a good alternative.

### Standardization

**Dr. Vanderveen:** The Joint Commission is focusing primarily on concentrations, but if you look at the data that was presented by Devin, that's the most standardized right now of all the variables in drug in IV drug administration. This technology helps to increase standardization.

**Ms. Obsheatz:** The Joint Commission followed the whole administration process when they were at our hospital. So I felt like they surveyed us last time like they're going to survey us this time, because they were so interested in how that worked. They wanted to see every step along the way of the medication process. We are up for a survey in January 2005, so I will see how their thought process has changed since we've adopted the Alaris technology.

## Have the safety benefits flowed over to affect physician-ordering practices?

*Nurses derive much of the benefit from infusion safety systems. Participants were asked if these systems would also affect physician ordering practices.*

**Dr. Maddox:** The short answer is yes. My experience with physicians, not only in the practice that I'm in now but every practice that I've been in, is that you can talk and talk and talk about, "This is what we think you need to be doing, Doctor, to improve patient care." But when you show physicians, for the most part, objective data that says, "This is what's going on in our practice associated with how you are writing orders, and we believe we can improve that process on the basis of the data that's real, appropriately distilled, filtered and analyzed," you get a positive response greater than 95% of the time. That's clearly been the case in our institutions.

**Ms. Almandinger:** Our early data showed that in the ICU we were frequently overriding our upper limits on dopamine. We even were going above 30 micrograms, and we took that back to our P&T committee and did some physician education, and those overrides have decreased considerably.

**Dr. Rothschild:** The practices of bolusing medications has improved dramatically since we have been studying that, at least in the cardiac surgical units where the study was conducted. I don't have the hard numbers, but I know that propofol bolusing has improved dramatically.

There were some other dangerous bolus practices that they were using. They were bolusing insulin, so patients were on an insulin drip, and they would turn it up to 999 for a couple minutes. That makes no clinical sense whatsoever, but it was easy, and it was a work-around, and it was not uncommon. We learned of these practices, and those have almost disappeared.

So the CQI reports have been very valuable. Just to emphasize what was mentioned before, I think that if you develop reports by units, you can get enough of a granular level of information that you can come back to the unit as a whole. Without picking out individuals, you can say, "Let's compare our floor to the other floors of the institution, and we can show how much better or not better we're doing and at least drill down to that level."

We can, of course, drill down to individual events by looking at the date of the event and the time of the event. If there was a very dangerous event in which an individual nurse does need to be informed about their practice, one can do that by going back to the specifics and getting back to the chart.

## Impact on medication safety (putting the “I” into the “IT” equation)—how do we use the data that this technology has the capacity to produce in a way that’s meaningful, useful and can enable us to improve the quality of care?

*Technology is often acquired as a “quick fix” and the full benefits of it never realized. Participants discussed the importance of using the decision-support and continuous quality improvement (CQI) information that resides in infusion safety systems to realize the full value and benefit of the investment.*

**Dr. Denham:** I was recently with 150 leading CIOs with an organization called the Health Technology Center, which forecasts the impact of technology for the next five to eight to ten years. It was so exciting to see the country’s best CIOs start to recognize the critical importance of the “I” part of IT. Up to this point, their role has been 10% “I” information and 90% “T” technology. In the future when technologies are highly reliable and deployed their role will be 90% “I” and 10% “T.” I think you all have a wonderful opportunity to engage them now, because they’re starting to recognize that clinical process re-engineering and that what must be done to deliver patient-centered care is critical for them to succeed in IT. This was a resonant theme all the way through a two-day meeting. The other thing that was kind of interesting was that they were a little surprised at the eerie nature of their successful IT implementations in the ICU because there was significantly less noise than what is typical for a busy ICU. They wondered what was wrong. “The “big aha” was that the most robust groups that had really mapped the care processes, had taken process steps out of their workflow. Their ICUs were running much more smoothly with less auditory alarms. The length of stay was shorter with fewer adverse events and with far less rework. So I think it’s an ideal time to start bringing the IT people in on the information side, and not just for the “T” piece, because they can help with the dissemination of information dependent innovations across the organization.

### Real-time data

**Ms. Russell:** The next big push is for every one of you to network the technology. We have to get these data, and the information to be live, and you have to be able to act on it when it’s appropriate for use. We’re at the infancy of that, but as that capability becomes more available, then I think we’re going to be able to take and iterate more quickly. So the way you provide drugs and doses will be more accurate, more quickly. You’ll get feedback if you’re operating outside of your best practices, you’ll actually get alerts within a time frame that you can act upon the data. You’ll connect the information to the patient in a timely fashion. So as we talk about Smart pumps, it’s great that we put the smarts into the device, but if the devices stay only islands of information separated from the rest of the care process, they won’t really be smart at all.

**Ms. Obsheatz:** One of the future things that I would like to see come down the road is a flow chart that maps all the information that our hospital-based IS system collects and all the monitors we have on patients, that we actually have a flow chart with the SpO<sub>2</sub> monitors, the blood work, wedge pressure, and all the drugs and their rate changes. So we really have actionable clinical data on hand at all times that interface with the smart pumps in that they are now collecting all those rate changes. They have SpO<sub>2</sub> monitors, so hopefully in the not too distant future, we’re actually going to see other data elements being collected and put on a flow chart together.

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