

# “SMART” Infusion Safety Systems

Averting the most critical and costly  
medication errors



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# Intravenous medication safety systems help prevent harm and career-ending mistakes

## Extensive nursing input helps design easy-to-use system that intercepts critical errors.

By Susan Thurman, RN, Mark Sullivan, PharmD, MBA, BCPS, Mary Anne Williams, RN, and Andrew Gaffney, MD, FACC

Medication safety at the point of care is a major concern of nurse administrators. Research has been directed toward determining where, when, and how medication errors occur. However, more than merely working to identify errors, we must work to *prevent harm*.

In the medication use process, the nurse at the bedside is the most vulnerable,<sup>1,2</sup> and intravenous (I.V.) drug administration often results in the most serious medication error outcomes.<sup>3</sup> Only a few high-risk drugs—for example, coumadin—are administered orally. A far greater number—heparin, insulin, morphine, fentanyl, propofol, and midazolam<sup>4-6</sup>—can be delivered intravenously.

“An infusion-related preventable adverse drug event (PADE) can have tragic results for the patient and be a career-ending mistake for a nurse,” says Susan Thurman, RN, Manager of the Inpatient Cardiology Patient Care Unit at Vanderbilt University Medical Center (VUMC). “A nurse would never give one hundred pills to a patient, but can all too easily program a general-purpose I.V. pump to deliver a comparatively massive overdose.” (See “High-risk-of-harm I.V. errors: examples.”)

VUMC, a 631-bed healthcare system in Nashville, Tenn., has decision-support computerized prescriber order entry (CPOE) and sophisticated pharmacy and dispensing systems as part of an integrated effort to prevent medication errors. “Nonetheless, we recognized that more was needed to provide support to the nurses at the point of care that would be comparable to what physicians have with CPOE,” says Mark Sullivan, PharmD, VUMC Pharmacy Manager.

### Room for improvement

I.V. medications are associated with 54% of potential adverse drug events,<sup>7</sup> 56% of medication errors,<sup>8</sup> and almost 61% of the serious and life-threatening errors. Double-checking, although desirable, is unlikely to occur.<sup>9</sup> Moreover, an infusion-related PADE may go unrecognized—its effect on the patient can be misinterpreted as being general deterioration.<sup>10</sup>

PADEs are also costly. In 1993 dollars, the cost per PADE at a 700-bed teaching hospital was \$4,685; the estimated annual cost, approximately \$2.8 million.<sup>11</sup> The adjusted cost per PADE is \$5,830.<sup>12</sup> These figures don't include the costs of injuries, malpractice costs, cost of admissions due to ADEs, or litigation.

Until recently, no technology had the capabilities to safeguard against patient harm for the nurses with regard to I.V. infusion delivery of high-alert medications.<sup>13,14</sup> In particular, verbal orders and the programming changes required for titrating medication aren't protected by most CPOE systems, pharmacy information systems, or bar code medication administration (BCMA).

Starting in 1993, VUMC was one of several institutions involved in the development of an I.V. medication safety system (Medley™ Medication Safety System with Guardrails® Safety Software, ALARIS Medical Systems, Inc., San Diego, Calif.\*) to help prevent high-risk medication errors at the point of care and to provide actionable data for best practice improvements.

### Safety system features

**“Final check” at the point of care:** After a nurse has programmed an infusion and pushed “Start,” the I.V. safety software checks whether the programmed dose is within hospital-determined limits. If so, the infusion begins. Programming infusion parameters below or above the pre-established limits results in an alert to the nurse, which must be addressed before infusion can begin. (See “I.V. medication safety system: averted errors.”) This can prevent an incorrect dose from being accidentally administered to the patient.

**Modular design:** This design allows various configurations of up to 4 modules with a computerized point-of-care unit. Large-volume pump, syringe, and pulse oximetry modules are available. Patient-controlled analgesia and end-tidal carbon dioxide monitoring modules are currently in limited release. A common user interface for programming and monitoring all modules helps to reduce complexity and improves ease of use.

**Patient care area “profiles”:** A hospital can configure up to 10 customized hospital profiles in the software to meet infusion requirements for particular patient care areas, with unique operating parameters, programming options, and drug libraries. A clinician can configure the system for a particular patient care area with a single key press.

**Drug libraries:** Each drug library contains institution-determined maximum and minimum dosing limits, with a combined total of up to 1,000 drugs. Clinicians can override “soft” limits, but not “hard” limits. Creation of drug library data sets helps to drive standardization (drug concentrations and dosing limits), which also contributes to improved practice.

**Ease of use:** Extensive staff input from nursing, pharmacy, biomedical engineering, and medicine, as well as human factors engineering, was used to design a system that streamlines workflow, decreases training time, and decreases the potential for error

## High-risk-of-harm I.V. errors: Examples

### Continuous insulin infusion: inadvertent weight-based programming

- Adolescent, 67 kg
- Dose limit – 0.1 units/kg/hr (7 units/hr)
- Initial programmed dose – 7 units/kg/hr (67x overdose)

### Error averted by I.V. safety system “final check”

- 7 units/kg/hr – resulted in alert
- Dose corrected to 0.1 units/kg/hr (7 units/hr, not 7 units/kg/hr)

### Nipride infusion: potential “death by decimal”

- Infant, 3.3 kg
- Dose limit – 8 mcg/kg/min
- Initial dose – 205 mcg/kg/min (82x overdose)

### Error averted by I.V. safety system “final check”

- 205 mcg/kg/min – resulted in alert
- Dose corrected to 2.5 mcg/kg/min (not 205)

Source: Hatcher, I., Sullivan, M., Hutchinson, J., et al.: “An intravenous medication safety system: preventing high-risk medication errors at the point of care,” *Journal of Nursing Administration*. 34(10):437-439, 2004.

when devices are used by staff, agency, registered, or travel nurses.<sup>15</sup>

**CQI data:** Logs in the continuous quality improvement (CQI) software record the “near misses” (programming errors) averted by the new system, thus providing clinicians with a previously unavailable tool to improve medication administration. CQI data can be used to assess current safety levels and guide improvements to optimize care and reduce costs, as well as to report prevented errors to the Joint Commission on Accreditation of Healthcare Organizations and other regulatory institutions.

**Networking capabilities:** Finally, I.V. safety systems can function as standalone devices or can be networked with hospital information systems. Wireless networked connectivity allows hospitals to more frequently and easily analyze CQI data and upgrade the safety software to reflect improved best practices, thereby further improving patient and medication safety.

**Implementation:** The average time for implementation, including data set customization and nurse training, is 67 days. Installation can be accomplished in a matter of hours.<sup>16</sup>

## Results

CQI data documented the potential medication errors averted by the new safety system, many of which could’ve resulted in significant harm if they hadn’t been averted by the new system. During beta testing, nurses reported that trauma patients transferred from the ICU often required a prolonged period to become responsive enough to start rehabilitative therapy. CQI data analysis showed that sedative dosing could be more closely tailored to an individual patient’s condition. CPOE guidelines were changed so that

## I.V. medication safety system: Averted errors

### Beta testing: 8 months on 2 units (60 beds, 50 systems)

- 900 alert messages
- 99 “events” (programming changes) – 9.4/1,000 patient days

### Serious events

- 33 events: initial programming was  $\geq 2.5x$  upper dosing limit
- 9 events: 2.5-5x upper limit
- 9 events: 5-10x upper limit
- 10 events: 10-20x upper limit
- 5 events:  $\geq 20x$  upper limit

Source: Hatcher, I., Sullivan, M., Hutchinson, J., Thurman, S., et al.: “An intravenous medication safety system: preventing high-risk medication errors at the point of care,” *Journal of Nursing Administration*. 34(10):437-439, 2004.

“titrate to sedation” was replaced by titration to a specified sedation scale.<sup>17</sup>

In addition, staff education focused on monitoring patient response to sedation more closely within the scale. Implementation of these changes led to decreased patient recovery time, decreased length of stay, and decreased potential for sedation-related complications.<sup>18</sup>

Even in the presence of a fully mature CPOE system to intercept errors during order entry, the “smart” I.V. medication safety system intercepted infusion administration errors at the point of care. This new I.V. medication safety system allows nurse administrators to help nursing staff avoid serious errors and career-ending mistakes, track errors that have been avoided, and obtain previously unavailable data to monitor safety and improve best practices.

“Most importantly, the new infusion technology provides us with tools to *prevent harm*,” emphasizes Thurman. “By identifying areas at highest risk for PADEs, nurse administrators can target those areas and thus implement improvement strategies most effectively to have the greatest impact on improving medication safety.”

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\*The Medley™ System with Guardrails® Safety Software is now known as the Alaris® System with the Guardrails® Suite of safety software. ALARIS Medical Systems, Inc., is now Cardinal Health.

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## Prioritizing safety technologies

### I.V. medication safety system offers greatest "speed to impact."

By Sharon K. Steingass, RN, MSN, AOCN

City of Hope (COH) Cancer Center is one of the world's leading research and treatment centers for cancer, diabetes, HIV/AIDS, and other life-threatening diseases. Most medication is delivered via intravenous (I.V.) infusion, which must be dosed and administered correctly for effective treatment and patient safety. I.V. programming errors, which can result in significant overdose, pose the greatest risk of patient harm. (See "Average 350-bed hospital critical infusion errors.")

#### Product selection

To replace existing I.V. pumps, a multidisciplinary team considered which safety technology would offer the most rapid, significant impact. COH staff chose to implement an I.V. medication

safety system before either computerized prescriber order entry (CPOE) or bar coding. Following a two-week clinical trial of two different products, the COH team selected the Medley™ Medication Safety System with Guardrails® Safety Software (ALARIS Medical Systems, Inc., San Diego, Calif.\*). (See "Key deciding factors in system selection.")

#### Results

In less than four months, the COH team customized data sets to adapt the software to chemotherapy, conducted staff training, and went live with the project. Installation took approximately seven hours.

Informal reports by staff members confirm that the new technology has helped them avert potentially serious medication errors. "The I.V. safety system has made a huge improvement, because now a nurse can't administer a wrong dose. It's a night and day difference," says Robert Cuthbertson, Director, Materials Services. Nurses find the system easy to use and the software

highly intuitive. Patients have expressed appreciation for the additional safety features of the new system.

The lightweight, modular design of the Medley™ System makes ambulation easier for both patients and transport personnel. Expandable technology platform allows for integration of both infusion and monitoring modules, as well as future integration with other safety technologies. Cuthbertson explains, “We encourage our patients to get moving. Now they aren’t ‘chained’ to a massive amount of equipment. With the Medley™ System, it’s much easier for patients to go outside of our campus, which is designed to encourage ambulation.”

“Our nurses really embraced the change to the I.V. safety system,” says Sharon Steingass, RN, MSN, AOCN, professional practice leader of hematology and bone marrow transplant at COH. “This allowed us to introduce culture change in incremental steps and to achieve the greatest impact on improving medication errors in the shortest amount of time.”

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## **Average 350-bed hospital critical infusion errors**

### **In an average 350-bed hospital, I.V. medication safety systems avert**

- a potentially life-threatening I.V. programming error every 2.6 days.
- an additional, potentially significant I.V. error every 1.9 days.

*Source: Cardinal Health, Alaris® Products data, aggregated from 18 institutions, including community and regional hospitals, and major medical centers. Findings presented by Cardinal Health, Alaris® Products to the National Patient Safety Foundation 5th Annual Congress, March 14, 2003.*

## **Key deciding factors in system selection**

- Availability of safety features such as drug libraries, channel labels, and CQI data logs
- Ease of use
- Expandable platform that can accommodate other modules such as patient-controlled analgesia and syringe pumps
- Potential for future integration with other medication safety technologies
- Modular, lightweight design that meets patients’ mobility needs\*

*\*Bone marrow transplant patients can have 10 or more I.V. lines running simultaneously. The Medley™ System can accommodate up to 12 lines on one I.V. pole.*

## **Case study: Salinas Valley Memorial Healthcare System**

# **Achieving rapid implementation without disrupting workflow**

## **Medication administration technology meets nurses’ need for “perfect” technology.**

By David Perrott, MD, MBA, FACS

Salinas Valley Memorial Healthcare System (SVMHS) is a 266-bed community hospital in the central coast region of California. As part of its ongoing partnership under a signed Space Act Agreement with the National Aeronautics and Space

Administration (NASA), SVMHS was one of three medical facilities in the world to work with NASA to form the first collaborative clinic with Stanford and Cleveland Research Clinic. SVMHS recently selected new “smart” intravenous (I.V.) medication safety systems to improve medication safety and patient care.

### **Searching for a better way**

Infusion devices installed at the hospital only 18 months earlier didn’t meet clinicians’ needs. In addition, installation proved dis-

ruptive and time-consuming. Ann Kern, RN, MBA, senior administrative director of resource management and project manager, notes, “The nurses were receptive to having new pumps, with one requirement—they had to be perfect.”

After evaluating several possible systems, SVMHS concluded that an I.V. medication safety technology (Medley™ Medication Safety System with Guardrails® Safety Software, ALARIS Medical Systems, Inc., San Diego, Calif.\*) would set a new standard of safety by helping nurses avert high-risk medication errors and providing data on “near misses” for best-practice improvement.

### Implementation

To ensure a positive staff experience and to expedite hospital-wide change with minimal disruption to workflow, SVMHS used professional services provided by the company, including:

◆ **pharmacy data set customization.** Sample data sets were used to create dosing limits based on SVMHS’s own best-practice guidelines. “We matched and verified the sample dosing limits with our formulary drugs and developed limits for any drugs that were still needed,” says Terry Pettitt, RPH, pharmacy clinical specialist. “It didn’t make sense to re-invent the wheel; we wanted to get it right the first time.”

◆ **nurse education.** Classroom training lasted five days, with classes offered day and night. One-hour classes were scheduled for regular nursing staff, and longer classes were scheduled for “superusers,” those who would serve as resource persons. Most classes had 30 nurses, each of whom had an I.V. safety system on which to practice. The clinical consultant was a registered nurse

with ICU and specialized I.V. medication delivery experience.

◆ **actual installation.** The vendor provided three nurses, and SVMHS provided one nurse each for ICU, the step-down unit, and the med/surg unit, since outside personnel weren’t allowed to attach the new infusion lines to patients.

### Outcomes

Participants completed customization of the SVMHS data set, including three profiles with dose limits for 96 drugs in each drug library, in approximately 30 days. More than 400 of the organization’s 600 nurses attended training classes. Conversion of the entire hospital to the 240 I.V. medication safety systems took 3-1/2 hours, with the exception of two patients still in surgery.

The use of professional consulting services allowed SVMHS to begin receiving the clinical and financial benefits of the I.V. safety systems as rapidly as possible with minimal disruption to hospital staff. “We’re clearly committed to being a leader in the area of patient safety,” says Sam Downing, MPH, MBA, president and chief executive officer of SVMHS. “This underscores our dedication to providing innovative, high-level healthcare. Using consulting services to support our own staff ensured that everything worked extremely well, right from the start.”

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## Case study: Spartanburg Regional Healthcare System

# Correcting risk of harm from I.V. medication errors

## Explore safety, financial, and community benefits.

By Raymond A. Shingler

Spartanburg Regional Healthcare System (SRHS), with three hospitals, 730 beds, 510 staff physicians, and gross annual revenue of \$1 billion, is ranked as one of the 100 most-wired hospitals in the United States. When existing infusion pumps required replacement, SRHS focused on selecting technology that would

provide safeguards against intravenous (I.V.) medication errors, which pose the greatest risk of harm to the patient. At the conclusion of a two-week clinical evaluation, SRHS selected a modular system with continuous quality improvement (CQI) logs (the Medley™ Medication Safety System with Guardrails® Safety Software\*) for hospital-wide implementation.

### Results

Implementation of 556 I.V. medication safety systems was completed in less than six weeks; installation took approximately 7

hours. Facility personnel decided to enlist the assistance of consulting services, but no additional full-time equivalents were required.

Patients experienced heightened medication safety almost immediately. “The max-min dosing limits in the Guardrails® Software are extremely important,” says George Reid, PharmD, director of pharmacy at SRHS. “In the past, you depended on pharmacist-nurse communication, or nurses looking up information in texts. This technology provides a safeguard that dramatically improves patient safety.”

CQI data show that the new technology quickly achieved significant improvement in medication safety. “The early CQI data confirmed that we had made the right decision in implementing the Medley™ Medication Safety System with Guardrails® Safety Software,” reports SRHS’s Chief Information Officer Raymond Shingler.

Denise Taylor, RN, I.V. team coordinator, praises the technology’s safety checks: “Nobody wants to make a mistake. We always double-check, but the I.V. safety system gives you tremendous

peace of mind. The software dosing limits provide you with a back up, that extra assurance that the device is programmed correctly. I wish it had been there when I was doing bedside nursing.”

Allen Pendergrass, director of purchasing, claims that the benefits of the system “far outweigh any additional cost,” which proves well worth the difference. Shingler adds, “The ALARIS ‘smart pump’ technology can be implemented in a very short amount of time. Daily interaction with patients allows nurses, physicians, and pharmacists to quickly see the benefits of this technology. With the resulting error prevention data, we can easily demonstrate to the community our improvements in and commitment to quality patient care.”

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### **Case study: Children’s Hospital and Health Center, San Diego**

## **Evidence-based improvements prevent high-risk errors**

### **Harm isn’t random.**

By Glenn Billman, MD

The rate of adverse drug events (ADEs) in pediatrics is three times higher than in adults. Intravenous (I.V.) medications are involved in 54% of potential ADEs in pediatric inpatients.<sup>1</sup> Thus, I.V. medication safety needs to be a top priority when investing in safety technology.

Children’s Hospital and Health Center, San Diego (CHSD) is an independent, 238-bed, not-for-profit health care organization that offers comprehensive pediatric medical care. Until recently, staff used several different types of infusion devices, each with a different user interface. Pumps could be programmed to deliver doses ranging from a few drops to almost one liter per hour, with no “final check” and no easy way to track I.V. medication errors.

#### **Necessary changes**

A multidisciplinary team that included 15 senior nurses evaluated

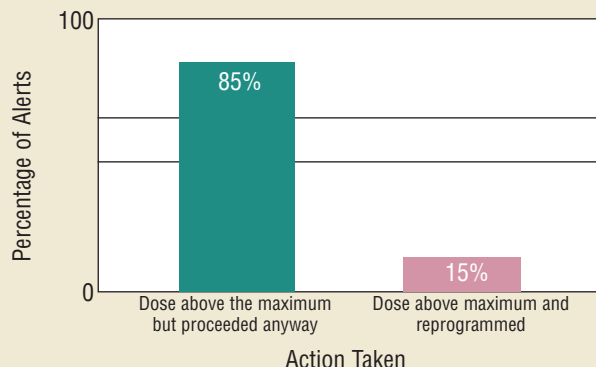
and selected new infusion technology for hospital-wide use. The team presented two products to the general nursing staff review, which yielded additional information and helped to engage the entire nursing staff in the decision-making process. The team selected I.V. safety technology (Medley™ Medication Safety System\*) for hospital-wide implementation.

Determining factors in the selection of the Medley™ system included the pump’s spatial configuration (horizontal versus vertical stacking), ease of setup, screen navigation and readability, the ability to configure alarm settings, ease of trouble-shooting, the ability to record and document alerts and operator responses, and the capability of adding syringe and patient-controlled analgesia pump functionality at a later date.

#### **Findings**

The time interval from selection of the smart I.V. system to the installation of 450 new systems was approximately two months. In the first six months of use, approximately 15% of the alerts led

### Action when programmed dose exceeds software limit



to the reprogramming of the infusion device.<sup>2</sup> (See “Action when programmed dose exceeds software limit.”) Some averted errors would’ve resulted in overdoses of high-alert medications at several times the dosing limits.

Time-based data revealed that dosing errors occur in identifiable patterns, peaking significantly during busy times such as shift change, high admission volumes, and activities requiring drug distribution. (See “Hourly distribution of reprogrammed alerts.”) As a result of these findings, the units were closed during shift change, and the timing of several elective activities was changed to reduce distractions. Since these changes, pump alerts are much less frequent and all of the former error peaks have been eliminated. (See “Hourly distribution of reprogrammed alerts.”)

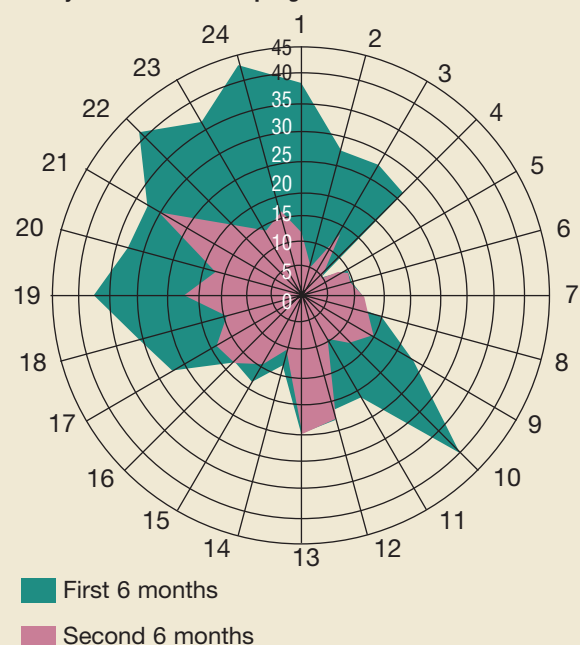
### Lessons learned

Bedside nurses’ ownership of the selection and implementation process, ongoing involvement with continuous quality improvement (CQI) data has been key. By focusing on averted errors (reprogrammed events), the CQI data present non-threatening information—the type of information most likely to sustain improvements in care.

Performance improvement requires strategic thinking. Not all lines of defense are equally effective in preventing serious medication error. I.V. safety technology offers the critically important advantage of being positioned immediately adjacent to the patient and thus positioned to integrate information and to provide a final check of all earlier steps in the medication use process.

The technology platform integrates various types of infusion and patient monitoring modules with a single interface. The platform also allows for additional modules to be integrated in the future. Based on initial positive results from beta-testing at the Hospital of the University of Pennsylvania, CHSD is planning to network the I.V. safety systems with the hospital information system.<sup>3</sup> This will allow for real-time data evaluation and rapid soft-

### Hourly distribution of reprogrammed alerts



ware upgrades to further improve patient and medication safety.

### Future direction

Smart I.V. systems can be the “canary in the mine” to identify where nursing workload issues exist and to target quality improvement to patient safety, best practices, and nursing satisfaction. These factors act synergistically and ideally position this medication safety system to function as an information hub, capable of integrating future innovative technologies and data. This holds the potential of further dramatic improvements in patient and medication safety.

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