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Intravenous Medication Safety and Smart Infusion Systems

Lessons Learned and Future Opportunities

Abstract

The Institute of Medicine report To Err Is Human: Building a Safe Health System *greatly increased national awareness of the need to improve patient safety in general and medication safety in particular. Infusion-related errors are associated with the greatest risk of harm, and "smart" (computerized) infusion systems are currently available that can avert high-risk errors and provide previously unavailable data for continuous quality improvement (CQI) efforts. As healthcare organizations consider how to invest scarce dollars, infusion nurses have a key role to play in assessing need, evaluating technology, and selecting and implementing specific products. This article reviews the need to improve intravenous medication safety. It describes smart infusion systems and the results they have achieved. Finally, it details the lessons learned and the opportunities identified through the use of smart infusion technology at Brigham and Women's Hospital in Boston, Massachusetts.*

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• THE NEED TO IMPROVE MEDICATION SAFETY

The 1999 Institute of Medicine report estimated that medical errors kill approximately 44,000 to 98,000 people per year.[1] Although there has been considerable controversy about these figures,[2] a 2004 report by Health Grades, Inc. that evaluated 37 million patient records reached an even higher estimate, maintaining that 195,000 people in the United States died in 2000, 2001, and 2002 as a result of potentially avoidable medical errors.[3] The general public's experience with medical errors is also alarming. In a nationwide poll conducted by Lou Harris and Associates released in 1997 by the National Patient Safety Foundation, 42% of Americans reported either personally experiencing or having a family member or friend experience a medical mistake.[4]

Complications from medications are the most frequent cause of adverse events.[5] To understand the incidence of adverse events stemming from the use of medications, it is important to understand how these events are defined. Researchers at the Division of General Internal Medicine at Brigham and Women's Hospital (BWH) recently published a report on the detection and classification methods used to investigate the incidence, type, and preventability of adverse drug events (ADEs) and medication errors. In their report, an incident was defined as "any irregularity in the process of medication use," including "ADEs and medication errors."[6] An ADE was considered to be an injury attributable to a medication. A medication error can occur at any stage in the medication use process (ie, ordering, filling, dispensing, administering, or monitoring).

A *potential* ADE (PADE) is a medication error that has the potential to cause harm, but does not actually do so because of circumstances, chance, or someone intercepting and correcting the error before it reaches the patient.[6] An example of a potential ADE is a threefold overdose of morphine sulfate that fortunately resulted in no apparent harm.

A *preventable* ADE is an injury that occurs as a result of an error. An example of this would be an error by a nurse in administering a drug that causes harm to the patient. For example, if nipride is programmed to infuse at a rate of 4 mcg/kg/min instead of 0.4 mcg/kg/min, a patient could experience hypotension, a nipride-related adverse drug event, which is preventable.

A *nonpreventable* ADE is defined as an injury that is not the result of a medication error. Nonpreventable ADEs also are commonly referred to as adverse drug reactions (ADRs).[6] An example of a nonpreventable ADE is seen in the case of a patient given an antibiotic for a bacterial infection who subsequently experiences diarrhea attributable to *Clostridium difficile*.

The Adverse Drug Event Prevention Study examined medical and surgical patients in two tertiary care facilities in the United States and found an overall rate of 6.5 ADEs for every 100 nonobstetric admissions, 28% of which were preventable or attributable to a medication error.[7] In the study, 56% of preventable ADEs occurred during the ordering stage and 34% during administration. The authors pointed out that 48% of drug-ordering errors were intercepted. However, 0% of administration errors were intercepted. Whereas nurses may intercept physician and pharmacist errors, no one is positioned to intercept nurses' administration errors except, on occasion, the patient or family. The most common causes of errors occurring at the medication administration stage were inadequate drug knowledge, problems related to infusion pumps, and parenteral delivery problems.[8] Infusion administration errors can be difficult to identify and may not be reported, so it has been difficult to ascertain the true frequency of their occurrence.

Dr Kenneth Barker has published extensively on the use of direct observation methods for detecting medication errors at the administration stage. Using observation, Barker's group studied the prevalence of medication administration errors in 36 institutions and found a 19% rate of error.[9] In this study, administration errors were defined as doses administered differently than ordered. The most common categories of error were wrong time (43%), drug omission (30%), wrong dose (17%), and unauthorized drug administration (4%). Of these errors, 7% had the potential for harm.[9]

In a study by Benner et al,[10] 21 case studies of nursing errors from nine State Boards of Nursing were analyzed in an effort to develop a taxonomy of nursing errors. The study identified eight categories of nursing errors. One of these categories consisted of medication errors. The seven subtypes of medication errors recognized include: "missed doses of medication; wrong time of administration of medication, either more frequently or less frequently than ordered; IV infusion rate too fast, delivering too much medication, wrong concentration or dosage of medication delivered IV; wrong route of administration (eg, oral solution, given intravenously); wrong medication administered; and wrong medications delivered due to misidentifying the patient."[10]

Much research has been directed toward determining where, when, and how medication errors occur.[11] In 1998, the United States Pharmacopeia (USP) introduced MEDMARX, an anonymous, confidential medication reporting system accessible to hospitals via the Internet. The goal of this program is to enable hospitals to report, track, and share medication error data in a standardized format.[12] However, beyond identifying errors, efforts must be directed toward preventing harm.[11] Many medication errors can be prevented by system improvements. Top priority must be given to averting errors associated with the greatest potential for patient harm.

• IV MEDICATION ERRORS: GREATEST RISK OF HARM?

Intravenous medications are vital to the management of hospitalized patients. The treatment of certain disease states often requires that multiple powerful, high-risk IV medications be administered simultaneously, particularly to critically ill patients. Such medications include heparin, insulin, morphine, potassium chloride, propofol, and midazolam.[12-14] Because of the high potency and rapid onset of infusion medications, their potential for harm is great compared with that of oral medications.

Intravenous administration is a highly complex process that often requires multiple steps for completion. In a study by Kaushal et al,[15] investigators found that IV medications were involved in 54% of potential ADEs in the pediatric inpatient setting.

An analysis of data from 65 hospitals showed a wide variation among institutions with regard to dose limits, concentrations, and even drug names[16] (see Figures 1 and 2 for examples[17]). Many institutions have not compared practices, and there exists little or no rationale for these major differences. This in turn creates many opportunities for error.

Greatly contributing to the possibility of error is the enormous complexity of the nursing environment. Demands often exceed the individual's capacity to function without error, even highly experienced clinicians.[11] A system approach is necessary to avoid errors and improve safety.

- KCl (central) 10 mEq/100 mL
- KCl (central) 20 mEq/1,000 mL
- KCl (central) 40 mEq/1,000 mL
- KCl (central) __ mEq/ __ mL
- KCl (peripheral) 10 mEq/100 mL
- KCl (peripheral) 20 mEq/1,000 mL
- KCl (peripheral) 40 mEq/1,000 mL
- KCl (peripheral) __ mEq/ __ mL
- KCl 10 mEq/100 mL
- KCl 10 mEq/500 mL
- KCl 20 mEq/1,000 mL
- KCl 40 mEq/1,000 mL
- KCl 5 mEq/250 mL
- KCl __ mEq/ __ mL

FIGURE **1**.
Multiple line items for single drug, single hospital. (Personal communication, R. Crass, Cardinal Healthcare, August 12, 2005.)

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

FIGURE **2**.
Alteplase: drug names variations. (Personal communication, R. Crass, Cardinal Healthcare, August 12, 2005.)

• SYSTEM APPROACH TO SAFETY

Since the Institute of Medicine's landmark report in 1999, many articles have been published on the causes and contributing factors associated with medical errors. Recent patient safety research and increased public awareness are helping to create a shift in the way clinicians and researchers approach understanding how and why medical errors occur. This shift involves focusing on potential breakdowns in systems that allow errors to occur rather than on individuals. There is a move away from the "name, blame, and shame" approach common in years past.

One of the best-known experts and thought leaders in the study of human error is Professor James Reason. According to Reason,[17] "the basic premise in the system approach is that humans are fallible and errors are to be expected, even in the best organizations. Errors are seen as consequences rather than causes, having their origins not so much in the perversity of human nature as in the upstream systemic factors."[17(768)] Reason's system approach to human error has served as a basis for many research efforts currently underway to identify, evaluate, and mitigate the causes of medical errors.

IV Medication Safety Systems

In 2002, ECRI (formerly Emergency Care Research Institute) evaluated general purpose infusion pumps in an Executive Summary published in *Health Devices*. The article evaluated 26 models and the degree to which each of

these systems helps to ensure patient safety by providing protection in the form of preventing pump programming errors and other events that can lead to IV medication errors. It also recognized the models that guarantee free-flow protection.[18]

In its review, ECRI determined that only 5 of the 26 models contained a safety feature that "warns" the user when a programmed dose falls outside predetermined "safe" limits. The models rated as "preferred" in this review include three Alaris (Cardinal Health, Alaris Products,* San Diego, Calif) pumps: the Medley MSS and the Signature Edition Gold 7130 and 7230 modules equipped with the optional Guardrails software. The article also noted that two other models from Baxter (Deerfield, Ill), the Colleague CX and 3CX, are considered worthy of consideration. However, their dose error reduction system was not as comprehensive as those noted as "preferred." This article also rates the Abbott (Abbott Park, Ill) OmniFlow 4000 Plus model. However, this model is rated as "unacceptable" in this Executive Summary because the administration sets "may not prevent unintended flow under all circumstances."[18]

The national mandate for reform of systems to reduce error involves multiple disciplines. Hospitals, vendors, physicians, patient safety researchers, frontline nursing staff, pharmacy, and biomedical engineering must work together in new liaisons. Creation of a safe medication delivery system depends on communication involving all members of the healthcare team. The implementation and management of computerized infusion systems—so-called "smart technology"—signify one example of system reform that requires a multidisciplinary approach. Smart infusion systems represent innovative technology that can assist in averting IV medication errors at the point of care, thus creating an additional layer of safety for patients.[19]

The role of the smart technology is to "remember" whatever rules apply (eg, dosing limits and clinical advisories) for a particular patient care area by incorporating them into the safety software. The clinician's role is to make clinical observations and to verify that the rules applied by the system make sense.[20] An individual patient's condition might necessitate that the rules either should not be applied at all or should be altered in their application (eg, a "soft" alert for dopamine may be overridden if a patient's hypotension is refractory to usual dosing). Additionally, reaching the limit on the dosing of any single medication can trigger critical thinking about whether other agents or treatments are needed. A rule cannot account for all of the factors that actually are affecting an individual case.[20] Critical thinking will always be necessary.

As compared with a smart pump, an IV medication safety system offers a technology platform that can provide harm and dose-error reduction software across multiple types of infusion devices (Figure 3). The IV medication system also integrates infusion and patient monitoring modules using a common user interface. It also may be networked with a hospital's information technology systems, providing immediate access to data and accelerating best practice and process improvements. Smart technology at the bedside has been designed to reduce the necessity of relying on memory for mixtures and formulas, and to standardize infusion administration, reduce programming errors, and streamline processes for IV administration by forcing many functions.[21]

- 100 mg of morphine reprogrammed to 5 mg
- Heparin errors with extra zeros
- Potential amiodarone errors that clearly show confusion between bolus, peripheral, and central infusion rates

FIGURE **3.**
Examples of errors averted by IV safety system.

The "smart" infusion safety system implemented hospital-wide at BWH is a modular computerized system that integrates infusion and clinical best practice guidelines on a single technology platform.† The point-of-care unit contains the computer "brain" with customized safety software, which provides decision support to nursing personnel and real-time user feedback. Our next step is to add a patient-controlled analgesia option to our module. A common system that can be wirelessly networked to hospital information systems is also part of the future strategic plan for the medication administration system.

The safety software can be customized with up to 10 hospital "profiles" to meet infusion requirements for particular patient care areas such as the neonatal intensive care unit (NICU), the adult intensive care unit (ICU), and oncology. Each profile contains a unique drug library, programming options, and operating parameters including air-in-line alarm sensitivity, available optional programs, and maximum infusion rate. Using the appropriate profile, a clinician in hematology/oncology can configure the system for the special needs of this area (chemotherapy, palliative care medications) with a single key press. If the system is moved to another clinical setting such as an ICU, a clinician can select the appropriate profile for this area. In this way, one infusion safety system can be used throughout the hospital.[11]

Drug libraries in the point-of-care unit software contain institution-determined, preset maximum and minimum dosing limits for each profile for a combined total of up to 1,000 drugs.[11] Clinical advisories that reflect institutional best practices are also contained in the drug libraries.

When a nurse is using the safety software and programs to give an infusion, the safety software "checks" whether infusion parameters are within the preestablished limits. If so, the nurse simply proceeds with the infusion. Program-

*Formerly known as Alaris Medical Systems, Inc.

†The Alaris® System with Guardrails® software was formerly known as the Medley™ System with Guardrails Safety Software.

ming that exceeds the limits results in an alert that must be addressed *before* infusion can begin. Depending on the drug, warnings are programmed as either "soft" or "hard" warnings. Soft warnings can be overridden by a clinician, whereas a hard limit does not allow the clinician to continue. Another advantage of smart pumps is their ability to record administrations and when alerts result. Automatically, CQI logs in the software capture data to document every "event" (ie, when an alert has been produced as well as subsequent action taken by the nurse). Alerts that result in reprogramming are considered averted errors ("near misses" or "good catches"). The CQI data provides clinicians with a previously unavailable tool for assessing current practices and identify opportunities to improve medication administration.[11]

• RESEARCH AND CLINICAL USE

Safe Intravenous Infusion Study

In an attempt to improve medication safety, investigators at BWH received funding from the Agency for Healthcare Research and Quality for the Safe Intravenous Infusion Study. This project examined the incidence and epidemiology of serious medication errors associated with infusion pump delivery systems. In collaboration with the Alaris Corporation, the project aimed to develop prevention and safety strategies while evaluating the impact of smart infusion technology on the incidence of serious medication errors among critically ill patients. Serious medication errors are defined as preventable ADEs and nonintercepted potential ADEs.

Early findings suggest that critical drug infusion therapy is a complex process. Patient handoffs from one clinical area to another are frequent and multifaceted. One example is a surgical patient's transition from the operating room to the recovery area to the ICU setting. The programming of infusions often varies on the basis of a patient's clinical status and the particular clinical settings.

The Safe Intravenous Infusion Study investigated the cardiac surgical service consisting of cardiac anesthesia and four clinical units: two ICUs and two step-down units. Patients admitted or transferred to other areas of the hospital (eg, overflow) remained on current pump technologies used in those patient care areas.

Study staff collected data on the incidence and nature of medication errors and ADEs through chart review using the "smart" multichannel infusion safety system. All medication transactions programmed into the infusion safety system were stored electronically within the device and could therefore be retrieved for analysis. Research staff reviewed these log reports along with a patient's medical records to elucidate bedside administration practices.

One example of an intercepted error identified during this data collection process occurred with a patient ordered to receive 80 mcg/min of IV nitroglycerin. In this case, the nurse programmed the pump for 80 mL/hour of nitroglycerin, or 533 mcg/min. A dosing limit alert warned the nurse that the dose was outside the acceptable range for infusion of this medication based on the drug library limits. The nurse acknowledged the warning and subsequently reprogrammed the pump to deliver the medication correctly at 80 mcg/min. Study data are being aggregated and analyzed in further detail by study investigators at the BWH Center of Excellence for Patient Safety Research and Practice.

As important as the quantitative study findings will be to the impact of "smart" infusion technology, equally important are the qualitative lessons learned in the incorporation of this technology into standard nursing practice. Also crucial are the descriptive data gathered during regular clinical use.

In the development of systems to improve the medication delivery process, the appropriation of educational resources needed to implement this new technology became a paramount issue. The time it takes for staff to become comfortable with the new system, the impact of this technology on the day-to-day workflow of nurses, and the function of the new technology in relation to the previous system all have an impact on the success of implementation. The remainder of this article discusses the approach used by leaders at BWH to address these challenges as well as preliminary CQI data on averted errors.

• IMPLEMENTING INFUSION SAFETY TECHNOLOGY FOR CLINICAL USE

For any patient safety improvement process to be successful, it is of vital importance that the institution first establish a culture in which frontline staff views safety as a priority. This needs to be done months before implementation of any technology that will have a significant effect on practice patterns. To facilitate development of a culture of safety, leaders at BWH have defined patient safety in a way that places emphasis on a systems approach to addressing error. The goal is to implement systems to prevent errors from occurring, to identify errors when they do occur, and to reduce the untoward effects of errors that are not intercepted.

Establishing a system-wide change of this magnitude in a large tertiary care facility is difficult, although not insurmountable. At BWH, a multidisciplinary approach was adopted to meet this challenge. Leaders in medicine, nursing, and pharmacy met regularly to improve the medication administration process and incorporate systems to prevent errors at the stage of administration.

They sought to identify safety devices with the capacity not only to address current safety concerns, but also to adapt to future needs. Establishing an ongoing relationship with the vendor providing this support was critical, so that the selected system could be continually assessed and updated.

In January of 2000, this matter was addressed with the formation of a Medication Use Process Improvement Team consisting of an external facilitator; nurse managers; members of the medical, nursing (including infusion nurses and the Critical Care Program Coordinator), and pharmacy staffs; bioengineering technicians; and information systems and quality improvement managers. The team was co-chaired by the Director of Nursing Practice and the Director of Pharmacy Services.

The team met weekly for several months and reported its progress to the Vice President of Patient Care Services and the BWH Care Improvement Council. Its objectives were to discuss the current BWH medication use process, to identify the strengths and weaknesses in the current system, to identify opportunities for improvement, and to design software and process solutions.

Early work showed a common perception of the "need for speed" among staff when delivering medications to patients. Current clinical support systems were not optimally integrated with other systems, and as a result, "work-arounds" were common. Systems developed in previous years had decreased the amount of face-to-face communication among disciplines, and recently implemented computerized systems did not alleviate this issue. Among other plans, the group considered implementing a wireless technology to automate programming to new infusion pump technology.

The plan for adopting a new infusion system involved multidisciplinary staff at all levels of the process, including development, education of frontline staff, and review of existing data. A challenge specific to the use of infusion systems is the integration of multiple information sources needed in programming the infusion pumps. Current feedback mechanisms often are very limited or not well designed. This, along with the complexity of the environment, increases the potential for programming errors. Unfortunately, some strategies used in other patient safety efforts, such as the use of "double checks," are not realistic for this process of care because they are very labor intensive.

Another limitation of infusion safety systems is that infusion devices often are stand-alone systems with little connection to other medication systems. Complementary technologies such as barcode scanning, electronic administration records (eMAR), and computerized drug dose checking are additional technologies currently being studied to address this issue.

The multidisciplinary team reviewed existing data on various models of infusion pumps and chose the Alaris Medley systems because of the additional safety features available with this product. Infusion nurses at BWH were intricately involved in the evaluation and selection process.

Once the decision was made to implement the modular smart infusion technology, the BWH team held a series of meetings to create best practice guidelines and incorporate these guidelines into the forcing functions of the smart pumps. Pharmacists and nurses collaborated in developing the data sets for the drug libraries specific to each clinical area. These data sets were based on hospital drug administration guidelines and reviewed by service line experts. Once complete, the data sets were approved by the Drug Safety Committee, and the software containing this information was uploaded into the smart pump infusion system. Education involved classroom training, simulated training at the Harvard Center for Medical Simulation, and computer-based-training modules. A comprehensive usability testing process was performed to ensure that the systems were user friendly. Failure mode and effects analyses also were performed.

Specialized software in the infusion safety system records all transactions associated with the use of each infusion pump. Subsequently, CQI data can be downloaded into a desktop computer, and a report may be generated to serve as a tool for monitoring the effectiveness of interventions. The CQI data can be aggregated and analyzed to report medication dosages used by clinical care areas, the number of alerts and averted-error events per area, and staff responses to software alerts, including instances in which the pumps were reprogrammed or the alerts were overridden. Also, CQI logs document when the infusion safety system has averted administration errors that would have been significant had they not been averted. Typical "near misses" include extra zeros, missing or misplaced decimal points, transposition of rate and dose (mg and mL), and 10- and 100-fold errors. The CQI data reporter can also provide information as to the types of error, the medications involved, and the dates, locations, and times of the events. The CQI data are shared regularly with nursing clinical leaders and staff to raise awareness regarding common averted-error events, augmenting the individual and cultural surveillance for safe practice. The Critical Care Program Coordinator and other hospital educators are able to use information gleaned from these reports to identify practice pattern trends and determine the alignment of evidence-based clinical guidelines with current practice patterns. The data then serve as a vehicle for quality improvement efforts, ongoing staff education and training, and risk management. Figure 4 contains an example of trended information obtained from the CQI logs.

• NURSING SATISFACTION

At the time of this writing, the infusion safety systems at BWH had been fully operational for more than a year. In

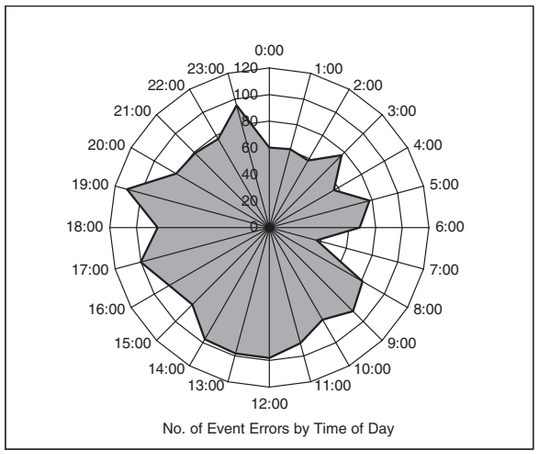

FIGURE **4**.
Infusion-related event errors by time of day. A review of 3 months of data captured by the IV safety technology shows that the least number of error events (37) occurred at 7:00 AM whereas the highest number of error events (111) occurred at 7:00 PM.

collaboration with the BWH Department of Nursing, study investigators conducted a survey of nurses from the cardiothoracic surgical unit to determine nursing satisfaction with the use of the infusion safety systems. The surveys were distributed to 150 nurses, 84 of whom completed the survey, for a response rate of 56%. Of these 84 nurses, 42 had more than 5 years of clinical experience at BWH. More than 80% of the respondents had used more than three different infusion pumps during their nursing careers. Overall, 89% of the respondents reported ease with programming the infusions, and 59% reported that they felt dosing limits and safety software helped prevent medication errors and adverse drug events (Figure 5).

• CONCLUSIONS

The study findings suggest that as an institution moves toward implementing technology such as smart infusion safety systems, it is important to review the literature

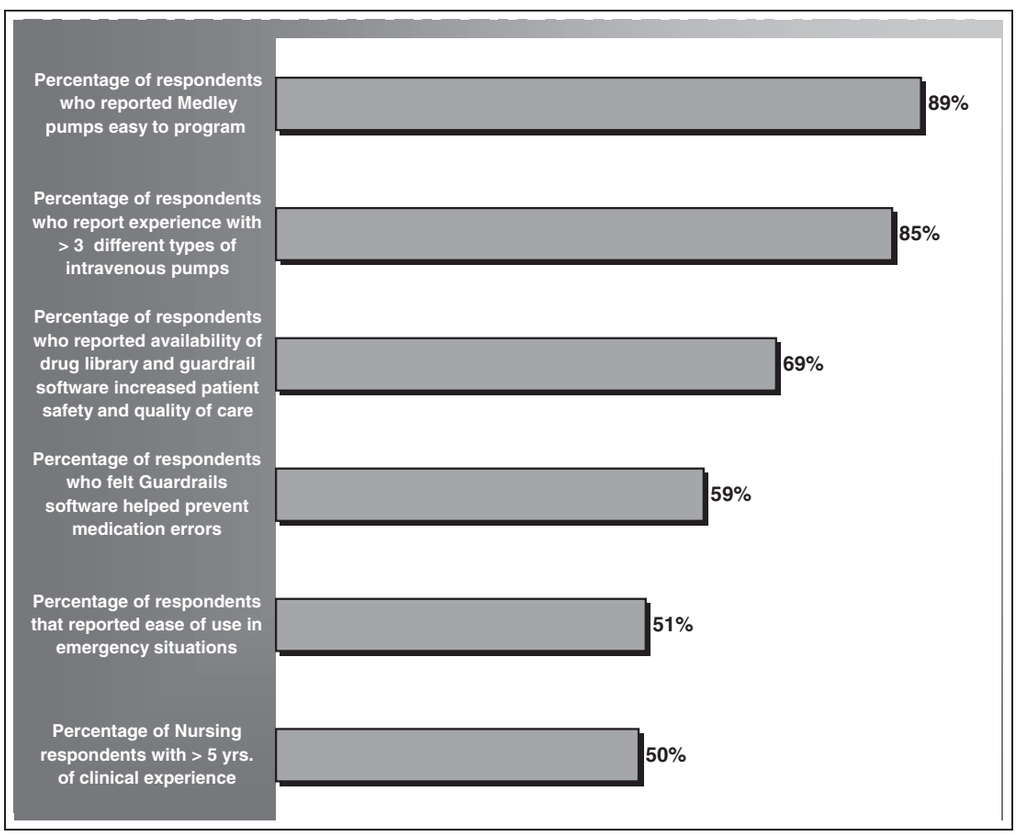

FIGURE **5**.
Nursing usability survey results. Nurses surveyed reported greatest satisfaction with the ease of programming the Medley pumps. More than half of the respondents also concur that the drug library and safety software improve patient safety and quality of care.

with each deployment of the systems to each clinical area, to review the current practice and common errors noted in the institution's healthcare system, to assess the organization's readiness, and to identify key stakeholders and owners. It is of paramount importance to create a culture of competence and safety among staff. The technology must be easy to use because technology is "useless if not used." The upgrade for such technology should not be viewed as a "one-time purchase." Rather, a continuous and ongoing relationship with the vendor must be established so that dialogue regarding software and hardware can remain open and current. The commitment to maintaining the collaborative effort established when purchasing decision was made must remain constant for all disciplines involved.

Infusion nurses have a critical role in this process and should be included in the decision-making processes when new technology is acquired. Their input regarding the selection, implementation, and ongoing evaluation of "smart" infusion technology will be vital to an institution's success in improving IV medication safety, reducing the risk of patient harm and using CQI data for continuous improvement of infusion best practice.

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