
Infusion Safety: Addressing Harm with High-Risk Drug Administration

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Philip J. Schneider, MS, FASHP, Editor

Medication Safety and Harm
Improving Medication Safety
Assessing IV Medication Harm
Using an IV Medication Safety System
Roundtable Discussion

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Inter-Professional Conference on Infusion Safety Technology:

Addressing Harm with High-Risk Drug Administration

The third invitational conference at the ALARIS® Center for Medication Safety and Clinical Improvement in San Diego, held on November 7, 2003, brought together a distinguished faculty from clinical practice, academia, organizations and government. 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 addresses harm with high-risk intravenous drug administration and provides actionable data for best practice improvements.

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Addressing Harm with High-Risk Medications

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Sharpening Our Focus

Medication safety has been at center stage for at least four years since the publication of "To Err is Human" by the Institute of Medicine.¹ Much of the information used in preparing this report came from the Harvard Medical Practice Study that was published in 1991.² The report indicated that the medical treatment most commonly associated with adverse medical events was medication.³ Even before that, in the early 1960's, pharmacists had found that approximately one in ten doses of medication administered deviated from the prescribed therapy.⁴ While some improvements have been documented in the past 40 years, recent evidence suggests these have not been sustained.⁵ Why is this?

Perhaps one of the reasons is that earlier efforts focused on errors, not harm. Many of the deviations from prescribed therapy, while common, did not result in harm to patients. The unit dose and intravenous (IV) admixture systems created to reduce these deviations were applied to all medications, not just to those that had the greatest potential for harm. Extensive and expensive systems were needed to prepare doses in the pharmacy that were ready to administer at the bedside and distributed in quantities of 24 hours or less. These systems were easiest to apply to low-risk medications used in low-risk patients. Preparing sterile doses that have

less standardization and are needed more immediately were difficult to fit into unit dose and IV admixture systems—and are increasingly so. The increase in the acuity of care in most hospitals has resulted in a need to have medications more quickly accessible at the point of care. This has resulted in the proliferation of point of care dispensing cabinets and IV systems that can be activated at the bedside.

This results in a second reason for an erosion in medication safety—technology. While technology is widely advocated to reduce adverse drug events,¹ there are often unintended and unexpected new problems ("side effects") that emerge.⁶ One of these "side effects" is the elimination of double checks within the medication use system when medications are so available in patient care areas. Other "side effects" include the need to calculate and prepare the dose at the bedside—a task performed by health care professionals who do not ordinarily perform this function, and are doing so in a hectic environment.

The new JCAHO patient safety standards require that health care professionals focus more attention on managing risk, not just waiting for errors to happen. One way to do this is through the use of Failure Mode and Effects Analysis (FMEA). This method focuses on three aspects of a process: likelihood of failure, chances of failure resulting

in harm, and the likelihood of the failure being undetected. Common failures that are likely to cause serious harm and not be detected and prevented are the ones on which improvement efforts should focus. Hospitals are required to do at least one FMEA per year, but we can apply the thinking behind this technique to our everyday thinking. What failures are common? Which ones seem to have the potential to cause the greatest harm? How can failures in a process be made more visible, so that detection and correction are increased?

Focusing on both high-risk medications and high-risk methods of administering these medications can narrow the scope of work. Cohen has an excellent chapter titled "High-alert medications: safeguarding against errors" in his text *Medication Errors*.⁷ Sixteen medications or drug categories are listed, 14 of which can be or are administered by the IV route. Kaushal, et al found that the IV route of administration was the most common in medication errors detected in pediatric inpatients.⁸ In their annual report, USP states that "the intravenous route of administration often results in the most serious medication error outcomes," based on the reports submitted to MED-MARXSM in the year 2002.⁹ We do not need a formal FMEA to know that IV drug administration is a high-risk area of medication use, and needs more of our attention.

The purpose of this conference was to address harm that results from high-risk drug administration. The content of the meeting and these proceedings outline the imperative to do this, the methods for identifying near misses and harm resulting from medications, emerging standards for improving medication use safety, and the role of new technology to improve the safety of IV medication administration in today's highly complex patient care environment. Participants reached consensus on the following points:

1. IV therapy needs to be a higher priority as a patient safety issue.

2. IV medication safety system is an effective way to improve and measure IV drug administration safety, with both error-prevention and process-improvement data-collection capabilities.

3. Improving the safety culture (especially with CEOs and nursing) in an organization is an important antecedent to adopting new technology such as smart pumps.

4. The organizational infrastructure to improve safety differs in many organizations, and different strategies to improve medication use safety may be needed.

5. The business case for investing in improvements in medication use safety may be intuitive in some cases and needed for quick decisions, but evidence to support the investment remains the ideal.

References

1. Kohn LT, Corrigan JM and Donaldson MS, eds. *To Err Is Human: Building a Safer Health System*. Institute of Medicine. Washington DC: National Academy Press; 1999.
2. Brennan TA, LL Leape, NM Laird, et al. Incidence of adverse events and negligence in hospitalized patients: results of the Harvard Medical Practice Study I. *New Eng J Med*. 1991;327:370-6.
3. Leape LL, TA Brennan, NM Laird, et al. The nature of adverse drug events in hospitalized patients: results of the Harvard Medical Practice Study II. *New Eng J Med*. 1991;327:377-84.
4. Allen EA and KN Barker. Fundamentals of medication error research. *Am J Hosp Pharm*, 1990;47:555-71.
5. Barker KN, EA Flynn, GA Pepper, et al. Medication errors observed in 36 health care facilities. *Arch Intern Med*. 2002;162:1897-1903.
6. Patterson ES RI Cook, and ML Render. Improving medication safety by identifying side effects from introducing bar coding in medication administration. *J Am Med Inform Assoc*. 2002;9:540-53.
7. Cohen MR and CM Kilo. High-alert medications: safeguarding against errors. In: Cohen, MR, ed. *Medication Errors*. Washington DC: American Pharmaceutical Association; 1999.
8. Kaushal R, DW Bates, C Landrigan, et al. Medication errors and adverse drug events in pediatric inpatients. *JAMA*. 2001;285:2114-20.
9. Hicks RW, DD Cousins, R Williams. *Summary of information submitted to MEDMARXSM in the year 2002. The Quest for Quality*. Rockville, MD: UPS Center for the Advancement of Patient Safety, 2003.

Conflicting Priorities for Addressing Medication Safety

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Key Points:

- Many organizations, including the Agency for Healthcare Research and Quality, the Massachusetts Hospital Association, the Joint Commission on the Accreditation of Healthcare Organizations, the American Society of Health-System Pharmacists, and the Leapfrog Group have published patient safety mandates.
- Recommendations are often consistent but sometimes conflict.
- A plan can be designed to achieve dramatic improvements in patient safety, despite the conflicting recommendations from various organizations.

Patient safety has been a focus of individual practitioners and institutions. The release of the Institute of Medicine's (IOM) first report,¹ *"To Err Is Human: Building a Safer Health System,"* and the media coverage of victims of medical errors have thrust patient safety into the public domain.

The IOM report estimated that deaths resulting from medical errors range from 44,000 to 98,000 per year, placing medical errors as the 8th leading cause of deaths in the United States. Although the accuracy of these estimates can be debated, the impact of the IOM report in mobilizing national patient safety efforts must be acknowledged.

Many organizations have published patient safety mandates. This overview identifies where those mandates can be consolidated, where they differ, and Tufts-New England Medical Center's (T-NEMC) plans to accomplish recommended improvements in patient safety.

Patient Safety Organizations

In response to the IOM report, many organizations were directed to formulate

action plans to improve patient safety. Federal, state, accreditation, professional, and private organizations directed their focus to patient safety. The Agency for Healthcare Research and Quality (AHRQ) was responsible for evaluating, prioritizing, and disseminating information about patient safety.² The AHRQ commissioned the Evidence-Based Center at the University of California in San Francisco to review the evidence. In total, 79 patient safety practices were evaluated and rated based on the potential impact of the practice, the strength of the evidence, and barriers to implementation. Eleven of the 79 practices were highly rated; however, none of these practices included computerized prescriber order entry (CPOE), the use of automated dispensing machines, or bar coding. Criticism of the AHRQ recommendations included its focus on individual practices versus system-related practices, its focus on the provision of optimal care versus the prevention of adverse events, and its failure to highly rate safety practices that were recommended by other patient safety organizations.

At the state level, the Massachusetts Hospital Association (MHA), in collabora-

tion with the Massachusetts Coalition of the Prevention of Medication Errors, has published several Best Practice Recommendations.³ The first list of Best Practice Recommendations was published in 1999,³ before the release of the first IOM report. These recommendations focused on hospital settings and included two basic principles, eight short-term recommendations, and four long-term recommendations. The basic principles of the recommendations were the need for creating a systems-oriented approach to patient safety and promoting non-punitive medication error reporting. The short-term recommendations consisted mostly of operational and educational strategies such as developing special procedures for high-risk drugs and educating both clinicians and patients about medication use. MHA's long-term recommendations were technology oriented and included implementing CPOE, adopting electronic medication administration records (eMARs), and initiating bar coding at point of care.

The 2003 Best Practices targeted reducing medication errors due to communication failures by reconciling medications.⁴ Reconciling medications is the process of comparing and resolving discrepancies between the patient's current medication list and that at time of admission, transfer or discharge. MHA is in the process of developing Best Practice Recommendations for the ambulatory setting. These recommendations will focus on obtaining a complete and accurate medical and medication history, reducing prescribing errors by encouraging the use of clinical decision support, and improving patient-provider communication.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has announced its 2004 National Patient Safety Goals.⁵ The medication-related

Conflicting Priorities for Addressing Medication Safety

TABLE 1.
Consolidating Medication
Safety Goals

- Culture and Education
- Infrastructure
- Practices
- Technology

TABLE 2.
Conflicting Priorities

- Evidence-based versus intuition-based
- Differing foci
 - Errors of omission versus commission
 - Operational versus clinical issues
- Patient safety recommendations versus institutional goals
 - Allocation of resources

TABLE 3.
Accomplishing
Institutional Change

- Build the necessary infrastructure
- Gather institutional-specific data
- Identify and prioritize patient safety goals
- Implement patient safety initiatives
 - Monitor and sustain progress
 - Learn from both successes and failures
 - Avoid moving in too many directions at once

goals include improving communication among healthcare providers by implementing a "read-back" process for taking verbal and telephone orders and by standardizing the abbreviations and symbols used throughout the institution. A second medication-related goal is improving the safety of high-alert medications by removing concentrated electrolytes from patient care units and by standardizing and limiting the number of drug concentrations available in the institution.

Professional organizations, including the American Society of Health-System Pharmacists (ASHP), have also focused attention on medication safety.⁶ ASHP has created a Center on Patient Safety with the goal of fostering "fail-safe medication use in health systems through the leadership of pharmacists." It developed an extensive list of responsibilities of the "medication-use safety coordinator" and has been active in supporting the adoption of bar coding and CPOE.

The Leapfrog Group, which also responded to the IOM report, consists of more than 145 public and private organizations that provide health care benefits to their employees. It will be evaluating hospitals that provide care to their employees and referring patients to hospitals based on performance in three areas: CPOE implementation, intensive care unit staffing with intensivists, and localizing high-risk procedures to high-volume centers.⁷

There are many other groups that have published patient safety mandates. Health care institutions and providers are under tremendous pressure to respond to these mandates.

Consolidating Recommendations

Consolidating the recommendations of many patient safety organizations can be accomplished by grouping these recommendations into four categories: 1) creating a culture of safety and providing education about medication safety; 2) building the necessary infrastructure to support patient safety; 3) implementing practices that reduce medication errors; and 4) adopting technological solutions for improving patient safety (Table 1). As recommended by IOM and MHA, there is a need to foster a nonpunitive approach for medication error reporting and to encourage an open dialogue about the causes of errors. A multidisciplinary medication safety committee that is responsible for prioritizing and coordinating safety practices is one component of the infrastructure that needs to be built to support patient safety initiatives. Practices such as the use of safety checks for high-alert medication, a pharmacy-based intravenous (IV) admixture program, and education of both patients and clinicians about medications need to be adopted.

Technology needs to be incorporated into each step in the medication-use process.

Conflicting Priorities

Despite attempts to consolidate the recommendations of the increasing number of patient safety groups, some differ and conflicting priorities remain (Table 2). Although the patient safety groups are well meaning in their intentions, the basis for their recommendations can differ. AHRQ uses scientific evidence as the basis for its recommendations, whereas JCAHO and MHA use intuition as the basis for theirs. Some recommendations highlight reducing errors of omission such as failure to provide peri-operative antimicrobial prophylaxis, whereas others focus on reducing errors of commission such as administering the wrong drug. JCAHO and MHA center their emphasis on operational issues, whereas others highlight clinical issues. However, the conflict between these groups' mandates and institutional goals is paramount. Reconciling these organizations' recommendations with institutional goals, specifically given the limited human and financial resources, is important.

Accomplishing Institutional Change

Given the number of recommendations published by patient safety organizations, healthcare institutions need to

Conflicting Priorities for Addressing Medication Safety

identify where to begin and how to proceed in implementing medication error reduction strategies (Table 3). A health-care organization needs to build the necessary infrastructure by obtaining the moral and financial support of its executive group. This infrastructure often includes a medication safety team consisting of representatives from management, clinical departments, laboratory, and information systems to identify and prioritize medication safety goals. Gathering institutional-specific data is also necessary since practitioners are more likely to respond to "local" rather than national data. Patient safety goals need to be identified, prioritized, and implemented based on both institutional and national information. Once improvement strategies are implemented, progress needs to be monitored. Both successes and failures need to be reviewed and analyzed.

Tufts-NEMC's Approach

The Medication Safety and Quality Committee at T-NEMC used MHA's 1999 Best Practice recommendations as the basis for patient safety initiatives. An initial goal was to improve medication error reporting to identify institution-specific medication error patterns. MHA's short-term recommendations, including standardizing the prescribing and concentrations of IV heparin, were adopted. The hospital's executive group has made a financial commitment to support the implementation of CPOE.

For 2003-2004, several new initiatives have been identified, including reducing medication errors that reach the patient, meeting MHA's 2003 Best Practice Recommendations, and meeting JCAHO's 2004 National Patient Safety Goals.

Drastic improvements in patient safety need to occur and can be accomplished despite the excessive number of patient safety recommendations. Each health care organization should be familiar with these recommendations and develop a plan based on those that best match their individual institutional needs and the needs of their patients.

References

1. Kohn LT, Corrigan JM and Donaldson MS, eds. *To Err Is Human: Building a Safer Health System*. Institute of Medicine. Washington DC: National Academy Press; 1999.
2. Agency for Healthcare Research and Quality. Making health care safer: a critical analysis of patient safety practices. www.ahrq.gov/clinic/ptsafety (accessed 2003 Nov 1).
3. The Massachusetts Coalition for the Prevention of Medication Errors. MHA best practice recommendations to reduce medication errors. http://www.macoalition.org/documents/Best_Practice_Medication_Errors.pdf (accessed 2003 Nov 1).
4. The Massachusetts Coalition for the Prevention of Medication Errors. Reconciling medication recommended practices. <http://www.macoalition.org/publications.shtml> (accessed 2003 Nov 1).
5. Joint Commission on Accreditation of Healthcare Organizations. 2004 national patient safety goals. http://www.jcaho.org/accredited+organizations/patient+safety/04+npsg/04_npsg.htm (accessed 2003 Nov 1).
6. The American Society of Health-System Pharmacists. Patient Safety Resource Center. <http://www.ashp.org/patient-safety/index.cfm?cfid=21981551&CFToken=96558264> (accessed 2003 Nov 1).
7. The Leapfrog Group. Patient safety. www.leapfroggroup.org/safety.htm (accessed 2003 Nov 1).

Focusing on Harm to Set the Patient and Medication Safety Agenda

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Key Points:

- *To improve patient safety, it is important to improve teamwork among health care professionals.*
- *Frontline staff has to assume responsibility for quality and safety, be educated to systems thinking, and commit together that "harm is untenable."*
- *Interventions require creating and using practical tools that are goal-directed.*
- *Hospital leadership needs to be actively involved.*
- *Results need to be documented and stories shared.*

Despite all the discussion and promotion of patient safety in recent years, frustration continues that relative little progress had been made in improving patient safety both locally and nationally. At The Johns Hopkins Hospital, many efforts have been initiated to improve patient safety, but they were not structured in a way that would allow the organization to cross the "quality chasm." Lessons learned from these experiences showed that improvement in teamwork among health care professions was needed.

Frontline staff has to assume responsibility for quality and safety, and contribute to these aspects of care at the bedside every day. Policies and procedures can be written to support these health care professionals, but safety and quality are not solely the responsibility of a process improvement or risk management department. The challenge is to make that concept of improved teamwork real for frontline staff—not just provide team training that is divorced from bedside care.

Creating a Culture of Safety: An Eight-step Program

The culture of an organization changes incrementally, not all at once. Large-scale efforts intended to make rapid changes in culture uniformly fail. Rather, one small unit at a time must be changed—one heart, one mind—and the change grows. Time and effort are required. The cultural changes must be concrete, or they will not be practiced when a team returns to the frontline. For interventions such as team training or crew resource management to work, they need to be goal-directed, so that people actually practice these tools in their daily work, with a focus on the patient and on safety. The results of these interventions need to be documented.

At Johns Hopkins, an eight-step program has been established that is evolving daily and is achieving dramatic results (Table 1).

1. *Measure the culture of safety.* The first step is to measure the culture of

safety. At Johns Hopkins, a survey instrument was developed to assess the culture of safety.

2. *Educate staff.* Next, the staff is educated about the "science of safety." To gain understanding of the need to focus on improving systems, a story is told about a child who pulls weeds by pulling off the tops, rather than by pulling out the roots. This does not eliminate the weeds. To improve performance, a new system of work is needed. Helping the staff understand systems is important, because this type of thinking has not been included in the education of health care professionals.

3. *Identify safety concerns.* A one-page survey asks, "Who was the last patient that would have been harmed by an error that you prevented?" This tool is specifically designed to identify heroes—those who work hard daily in healthcare environments to improve safety. The next question is, "How might the next patient be harmed by an error, and what can we do to prevent it?" Results are then summarized. Experience has shown that often about a year's worth of effort can be directed by the results of the survey. Incident reporting systems are important, but in healthcare the frontline staff knows of many things that are broken. It is not necessary to wait for a rare incident to emerge in an incident reporting system. Talking to caregivers will reveal what needs to be done.

4. *Assign executives.* The fourth step is to assign a senior executive to a service area in what is called "adopt a work unit." Executives meet monthly with the staff of their units, review what people have said is broken, and help decide what the staff wants to fix. The executives make sure resources are available to fix what the

Focusing on Harm to Set the Patient and Medication Safety Agenda

TABLE 1.
Creating a Culture of Safety

1. Measure the culture of safety
2. Educate staff
3. Identify safety concerns using uncomplicated surveys
4. Assign executives to "adopt a work unit"
5. Identify priority areas
6. Implement improvements
7. Share stories
8. Remeasure

staff has identified, and follow up every month. This experience has been very successful.

5. *Identify priority areas.* Originally the Veterans Administration model for identifying potential failure modes was tried, using a grid with a severity score and the probability of occurrence to identify priority areas for improvement. At Johns Hopkins, this approach was not successful, because reliability of the assessments was low. Instead, the unit managers, nursing leaders, physician leaders and executives now do the following:

- Evaluate what the staff has said are hazards to patient safety.
- Identify three changes that do not require any marginal resources and which can be implemented tomorrow, and focus on these changes.
- Select two or three changes that do require resources. These suggested changes are directed through the safety infrastructure, so that the staff knows what needs to be improved. Efforts can then be priority ranked so that the staff can be advocates for getting the resources needed to implement the changes.

Most of the resource requests are quite small and can be implemented within existing budgets. In many cases, the funds have already been allocated and

TABLE 2.
Team Factors: A Practical Framework

- First, create a culture of safety
- Second, eliminate complexity
- Third, create independent redundancies such as checklists for processes

were just was not being used.

6. *Implement improvements.* Once staff members decide what they want to do, they implement changes to make improvements. Every one of the changes needs a way to measure performance. In the Johns Hopkins culture, a suggestion for change will not be supported unless improvements can be documented.

7. *Share stories.* The seventh step is to share stories that demonstrate what has been learned and to help spread organizational learning.

8. *Remeasure.* The final step is to remeasure the culture to see if it has improved.

Team Factors: A Practical Framework

Improving teamwork provides enormous leverage in improving patient safety; however, much effort is required to make teamwork really effective. One reason is that healthcare professionals are not taught to work collaboratively but rather to work independently. Safety will only improve when clinicians learn how to interact with each other so that everyone is free to communicate and raise concerns.

When teams are asked to really think about preventing mistakes, they are given a very practical framework that includes

three components (Table 2):

- First, create a culture of safety.
- Second, eliminate complexity, because the more steps there are in a process, the greater the likelihood it will fail (see Meisel, these Proceedings).
- Third, create independent redundancies such as checklists for processes. Make certain that an independent checklist is used to ensure that all necessary steps have been taken before a procedure is begun. Tragic examples of errors resulting in harm that are reported by the press are often instances where there was not an independent check.

To make the idea of culture very real and not just jargon, care teams are asked to publicly commit together to the concept that "harm is untenable." Saying that everyone's efforts are focused on patient safety galvanizes the team. One of the principles of negotiation is to identify some common areas to which everyone can agree. In health care, there is no doubt that such an area is patient safety. That becomes the centering ground for everyone to focus their efforts. The team then works on assertiveness, teamwork, and situational awareness.

"Goal Sheet": Example of Successful Tool

An example of a successful communication tools has been the Goal Sheet. Communication has been identified as a problem in more than 90% of responses of units surveyed. Nurses do not know what the physicians are doing, and physicians do not know what their residents are doing. A one-page Goal Sheet was created that asks, "Do you understand what needs to happen for this patient today? What is this patient's safety risk, and how might we reduce it? What is your communication and care plan?"

To measure the results, before the project began caregivers were asked, "Do you understand the goals for this patient

for the day, and do you understand what work needs to be done to accomplish these goals?" Using a five-point scale, less than 10% of the physicians and nurses knew the work plan for the day.

Physicians were making "provider-centered rounds"—talking about evidence-based medicine and pharmacology and physiology but not asking, "What work is needed to get this patient to the next level of care?" Once this was documented on the Goal Sheet the staff clearly understood the goals of therapy. Length of stay has decreased to an almost unprecedented level of one day in a surgical ICU. This was accomplished by reducing complications and by making sure all staff members are working as a team.

Case Study: Transfer Orders and Medication Errors

These interventions were used to improve a common type of medication error. The nurses had identified that medication errors were often associated with transfer orders. An information-gathering sheet was created to evaluate this problem. A nurse leader in a patient care area was asked to review charts to answer three simple questions:

- Are the medications being administered after transfer the same as they were in the ICU?

- Are the patient's allergies listed the same in both areas?

- Did the patient start their home medications?

If any of these questions was answered "No," the nurses were instructed to ask the physicians, "Did you intend to make this change?" The definition of a defect was quite simply, "Did the physician change the order?" after having been asked.

In the first two weeks after this project began, 94% of orders were changed. Medication reconciliation was made part of routine discharge and now is done for every patient. Auditing error rates has shown that in three ICUs this type of defect has virtually been eliminated by changing the way transfer orders are handled.

An additional result is that in two ICUs the nursing turnover decreased. The organization is doing a lot to improve nurse retention, which is a strategic issue for every organization in this country. With this project, there has been an improvement in nurse retention.

Conclusion

The Johns Hopkins Hospital has developed a practical way to improve patient safety that makes cultural change goal-directed. Leadership support ensures that new behaviors are supported and realized. The program has been implemented one ICU at a time.

The process of building a medication safety agenda is still evolving and it is nowhere near finished. Sharing stories still requires work, and the training modules for assertive communication and teamwork are being developed for the education program. Finally, an entire curriculum is being developed for medical and nursing students to ensure that, at a very early stage, a culture of teamwork and safety are presented.

Using The Trigger Tool to Detect Potential Harm in Medication Management

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Key Points:

- *Assessing medication safety has relied on voluntary reporting, which captures a small percentage of actual errors, not all of which result in harm. The Trigger Tool identified adverse drug events (ADEs) in 24.9% of patient records, compared with 1.9% found through conventional systems.*
- *The Trigger Tool methodology screens patient records for laboratory values, interventions, and administration of reversal agents to identify possible ADEs; harm is assessed using the NCC MERP severity index.*
- *The Trigger Tool method measures total harm, goes beyond error but does not exclude error, is easy to use for sampling over time, and measures the results of patient safety improvement efforts.*

Need for Improved Assessment of Medication Safety

In January 2000, the Institute for Healthcare Improvement, a not-for-profit Boston-based organization, and Premier, a healthcare alliance for 1,600 of the nations' hospitals, convened a group of experts to develop a model for redesigning the medication system to achieve a level of safety in medication administration that would be tenfold greater than currently exists. The project was known as the Idealized Design of the Medication System (IDMS). Effective measurement of safety in medication use was critical to assessing the effectiveness of the new system in achieving this goal.

Assessing medication use safety has been difficult because of reliance on traditional voluntary reporting of ADEs and medication errors using incident reporting systems. Organizations have used voluntary reporting systems to provide data as a measure of patient safety. Leape and others have found that voluntary reporting is unreliable and, at best, probably captures only 10 to 20 percent

of actual errors.¹ Most errors are intercepted before reaching the patient, do not result in ADEs, and are not even perceived by many to be worthy of report. In addition, studies suggest that only a small percentage of medication errors actually result in harm, and those that do not are not likely to be reported.

The redesign team required a better detection method, one that focused on ADEs, not errors, to measure the effectiveness of the new system. Classen in Salt Lake City used computerized screening of patient information using sentinel signals or "triggers,"^{2,3} but broad application of this automated screening methodology was unlikely to occur due to fiscal and technical constraints. The redesign team developed a "low-tech" version that could be widely applied in any institution. This method has since been used extensively by hospitals working with IHI on improving medication safety. Organizations now can use this Trigger Tool method to measure, monitor, and manage the safety of the medication use process.

Trigger Tool Method

The Trigger Tool method involves the

monthly examination of 20 randomly selected patient records with a minimum two-day length of stay to screen for the presence of triggers such as laboratory values, interventions, and administration of reversal agents (Table 1). If a trigger is found, the chart is examined further for evidence of an ADE.

The degree of harm associated with the ADE is classified using the severity index of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP).⁴ The five NCC MERP categories (E-I) that involve actual harm to patients range from category E, defined as contributing to or resulting in temporary harm that required intervention, to the most serious category I, defined as contributing to or resulting in the death of a patient (Table 2).

Results

As shown in Table 3, data collected from 86 organizations using the Trigger Tool revealed 720 ADEs in 2,837 patient records (24.9%). Total doses of medications administered in this population were 268,796, resulting in a calculated ADE per 1,000 dose rate for all 86 organizations of 2.67. Nine of the 86 organizations evaluated their traditional mechanisms for finding errors and ADEs. Of the 274 ADEs identified by the trigger tool in these organizations, only 5 (1.8%) were elicited.⁵

Conclusion

The use of the Trigger Tool appears to be more effective than traditional reporting methods for detecting medication-related harm. The methodology is reasonably inexpensive to institute and is sparing of quality- and safety-personnel time. The tool takes advantage of all types of events, including "near-miss" errors and

Using The Trigger Tool to Detect Potential Harm in Medication Management

TABLE 1.
Triggers for Identification of Possible Adverse Drug Events

Trigger	Process Identified
T1: Diphenhydramine	Hypersensitivity reaction or drug effect
T2: Vitamin K	Over-anticoagulation with warfarin
T3: Flumazenil	Oversedation with benzodiazepine
T4: Droperidol	Nausea/emesis related to drug use
T5: Naloxone	Oversedation with narcotic
T6: Antidiarrheals	Adverse drug event
T7: Sodium polystyrene	Hyperkalemia related to renal impairment or drug effect
T8: PTT >100 seconds	Over-anticoagulation with heparin
T9: INR >6	Over-anticoagulation with warfarin
T10: WBC <3000 × 10 ⁶ /μL	Neutropenia related to drug or disease
T11: Serum glucose <50 mg/dL	Hypoglycemia related to insulin use
T12: Rising serum creatinine	Renal insufficiency related to drug use
T13: Clostridium difficile positive stool	Exposure to antibiotics
T14: Digoxin level >2 ng/mL	Toxic digoxin level
T15: Lidocaine level >5 ng/mL	Toxic lidocaine level
T16: Gentamicin or tobramycin levels peak >10 μg/ml, trough >2 μg/mL	Toxic levels of antibiotics
T17: Amikacin levels peak >30 μg/mL, trough >10 μg/mL	Toxic levels of antibiotics
T18: Vancomycin level >26 μg/mL	Toxic levels of antibiotics
T19: Theophylline level >20 μg/mL	Toxic levels of drug
T20: Oversedation, lethargy, falls	Related to overuse of medication
T21: Rash	Drug related/adverse drug event
T22: Abrupt medication stop	Adverse drug event
T23: Transfer to higher level of care	Adverse event
T24: Customized to individual institution	Adverse event

TABLE 2:
NCC MERP Index Categories E through I

- Category E: harm that contributed to or resulted in temporary harm to the patient and required intervention.
- Category F: harm that contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization.
- Category G: harm that contributed to or resulted in permanent patient harm.
- Category H: harm that required intervention to sustain life.
- Category I: harm that contributed to or resulted in the death of a patient.

TABLE 3.
Multi-center Trigger Review

- 2837 charts reviewed using Trigger Tool
- 86 institutions
- 720 ADEs found on reviews
- 268,796 medications doses administered
- ADEs/1,000 doses = 2.67
- Admissions with ADEs = 24.9%

ADEs. The surveillance methodology implicit in the tool is more reliable than spontaneous reporting, and if the chart selection is properly randomized, the data over time generate statistically valid information untarnished by the limitations of spontaneous reporting. The data obtained are best used for internal comparison and measuring improvement. As a point of further development, over the past two years IHI has developed a similar tool for detecting ADEs in the intensive care unit. This tool is currently being used by more than 60 organizations.

Further information about the IHI Trigger Tool for Measuring Adverse Drug

Events is available at the following website: www.QualityHealthCare.org.

References

1. Cullen, DJ, Bates, DW, Small, et al. The incident reporting system does not detect adverse drug events: a problem in quality assurance. *Jt Com J Qual Improv.* 1995;21:541-8
2. Classen DC, Pestotnik SL, Evans RS, et al. Computerized surveillance of adverse drug events in hospital patients. *JAMA* 1991; 266:2847-51.
3. Classen DC, Pestotnik SL, Evans RS, et al. Using a hospital information system to assess the effects of adverse drug events. *Proceedings of the Annual Symposium on Computer Applications in Medical Care* 1993;161-5.
4. www.nccmerp.org/dangerousabbr.htm (accessed December 6, 2003).
5. Rozich, JD, Haraden, CR, Resar, RK. Adverse drug event trigger tool: a practical methodology for measuring medication related harm. *Qual Saf Health Care* 2003;12:194-200.

Complexity, Standardization, and Medication Safety

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Key Points:

- *Medication use safety is a problem in large part because of the complexity of the medication use process and a lack of standardization within it.*
- *Improving medication safety can be accomplished by taking steps out of the process, standardizing procedures, or both.*
- *Integrating steps in the medication use process is one way both to take steps out of the process and to increase standardization.*

The medication use process is extremely complex, involving both individuals and technology in a series of complicated steps. As organizations seek to make this process safer, much can be learned from complexity theory, human factors engineering (HFE), and findings from other industries such as nuclear power and aerospace. This article describes how key elements of complexity theory and HFE can be applied to the medication use process. Several case studies illustrate how simplification and standardization can reduce complexity to improve medication safety.

Medication Management

Medication management includes seven core processes: evaluation of a patient, decision to use a medication, drug ordering, order transcription, drug distribution, drug administration, and finally patient monitoring. No one person is responsible for the entire overall process. While nurses are primarily responsible for drug administration, patients still self-administer, and physicians, families, respiratory therapists and others may also administer medications. Similarly, physicians are primarily responsible for prescribing drugs, but pharmacists can prescribe, as do nurse practitioners, while patients will self-prescribe.

Creating an effective medication process requires the participation of members from every discipline involved with medication use. The medication process needs to be examined as a whole, not as subprocesses, so that improvements made in one area, such as drug distribution, will not adversely affect other areas, such as prescribing or drug administration.

Complexity Theory

Berwick has pointed out that systems produce precisely the outcomes they are designed to achieve. Understanding key aspects of complexity theory can help direct efforts to redesign the system to improve medication safety.

The overall failure rate of a complex system can be calculated based on the probability of error in each step and the number of steps in the system (Table 1).¹ If, for example, the one step in a one-step process fails 1% of the time, the system fails 1% of the time. If the same 1% failure rate occurs in a system with 25 steps, the system will fail 5% of the time; with 50 steps, 39%; and in a 100-step process, the system will fail 63% of the time. Thus, increasing complexity increases the likelihood of error.

At Fairview, the medication process has been calculated to have between 40

and 70 steps.³ To improve the process, efforts could be made to reduce the failure rate in every one of 50 steps from 1% to 0.1%, and thereby decrease the failure rate from 39% to 5%. However, reducing the number of steps from 50 to 25 achieves the same result. Simplification is a significant component of medication safety improvement.

Human Error Rates

Considering the nominal human error rates in the general population for performing particular tasks (Table 2)² also suggests ways to improve medication safety. An error of commission, such as misreading a label, occurs at a rate of 0.3%, or three times out of a thousand. An error of omission without reminders occurs at a rate of 1%; however, embedding the item in a procedure reduces the error rate to 0.3%

The rate for simple math errors with self-checking is 3%. A monitor or inspector fails to detect an error 10% of the time. Personnel on different shifts will fail to check hardware at a rate of 10%, if they are not required to use a checklist. Finally, the rate of general error in a high-stress situation where dangerous activities are occurring rapidly—e.g., a typical intensive care unit (ICU), operating room, or emergency department—is 25%, or one in four.

Error rates from the nuclear power industry further underscore the importance of checklists and simplicity.³ When working without a checklist, errors of omission occur at a 5% rate. Use of a complicated checklist with more than ten elements reduces the failure rate to 0.3%. However, use of a simple checklist reduces the error rate by an additional two-thirds, to 0.1%.

TABLE 1.
**Complex Systems:
Probability of Error²**

Probability of Error, Each Step

# Steps	0.05	0.01	0.001	0.0001
1	0.05	0.01	0.001	0.0001
25	0.33	0.05	0.005	0.0002
50	0.92	0.39	0.05	0.005
100	0.99	0.63	0.10	0.01

Human Factors Principles and Systems Design

Clergue has pointed out that the single limiting factor of human activity is that the brain cannot have multiple simultaneous foci of interest.⁴ Pilots in a cockpit are trained to look at four pieces of data, because the human brain cannot process more information at a given time. An ICU nurse is expected to keep in mind far more pieces of information, which is one of the reasons failures occur.

A system designed to overcome this limitation would avoid reliance on memory; simplify all tasks; standardize processes; use forcing functions, protocols and checklists wisely; improve access to information; decrease reliance on human vigilance; reduce hand-offs; decrease look-alike elements; and use automation carefully.

Frankel has said, "If there is a better way to do something, we should all do it that way because it's better. But if there is no known best practice, we should settle on one, because the system and its players cannot execute all of those practices without an unacceptably high failure rate."⁵

How many different sliding-scale insulin protocols are necessary in a hospital, health system, or even a country? How many surgeon-specific "recipe cards" are necessary in an operating room? Different methods of marking the surgical site? Of dosing warfarin? How many dif-

TABLE 2.
Nominal Human Error Rates⁴

Activity	Human error probability
Error of commission (misreading a label)	0.003
Error of omission without reminders	0.01
Error of omission when items embedded in a procedure	0.003
Simple math error with self-checking	0.03
Monitor or inspector fails to detect error	0.1
Personnel on different shifts fail to check hardware unless required by checklist	0.1
General error in high stress when dangerous activities occurring rapidly	0.25

ferent infusion pumps are necessary? How many different pediatric immunization protocols in the clinics? How many post-operative pain regimens, cardioplegia formulas, methods of administering pre-operative antibiotics, potassium replacement protocols, double-check policies and systems? Patient safety is improved by limiting the available options, as shown by the following case studies.

Case Study #1 – Standardizing Concentrations

A three-year-old child undergoes a liver transplant at a major university hospital. Because of very small blood vessels, there is concern about potential clotting. Heparin is prepared in the operating room and infused correctly. Some hours later on the general floor, the heparin runs dry. A new bag comes up from pharmacy, and in keeping with a hospital standard, is administered at the same rate that was previously programmed on the pump. Twelve hours later the discovery is made that the solution prepared in the operating room was ten times more dilute than the hospital standard, so that in the patient care area, the child received a 10-fold overdose for 12 hours and subsequently died.

In 1996, in one of the first Institute for Healthcare Improvement (IHI)

Breakthrough Series, a California hospital studied the preparation of pediatric standard dilutions.⁶ It was found that anesthesia was preparing the drips during an operation, then post-operatively the physician would order a different concentration that pharmacy would prepare and dispense. The nurses would change the IV bags and administer the medication. Opportunities for error were numerous.

To simplify the procedure, key steps were moved to the pre-operative setting. Before surgery, a physician uses a weight-based protocol to order medications. Pharmacy generates a worksheet and labels based on the order. Anesthesia still prepares the drips, but based off the pharmacy protocol and preprinted labels. Postoperatively, the physician only had to order the dose to be administered with everyone using the same standard concentration.

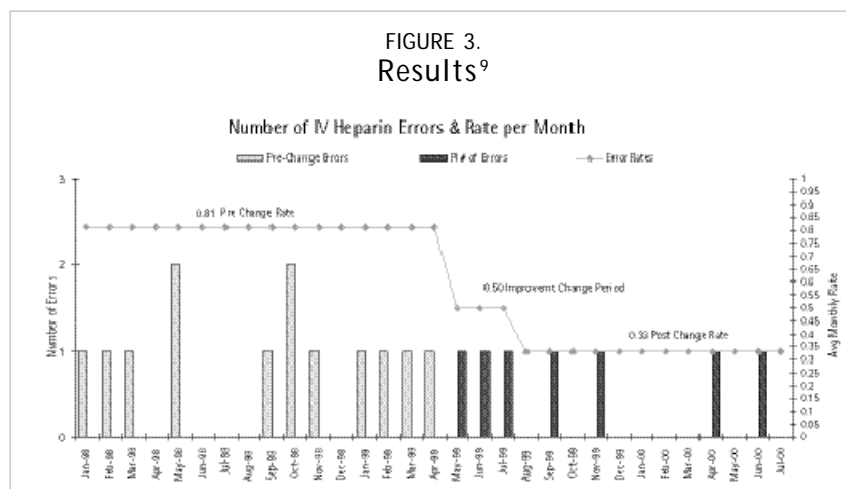
Case Study #2 – IV Pump Programming

A hospital uses IV medication safety system with dose calculation software. The system requires that a nurse select the name of the drug from a library, then enter the amount of the drug in the bag, the volume in the bag, patient weight, desired dose, and units. When programming heparin, the nurse mistakenly enters 2,500 units in 250 mL, instead of 25,000 units in 250 mL, which results in a 10-fold overdose.

IV medication safety system has standard concentrations and dose limits preprogrammed. A nurse only has to select the name of the drug, the weight and the desired dose. If the programming is outside of those limits, an alarm is given. Simplification and standardization improve medication safety.

Case Study #3 – Prescribing

A physician handwrites sliding-scale insulin orders, using his own parameters. The orders are manually transcribed onto to the medication administration



record (MAR). However, the order is misread, and an order for 12 units of insulin is transcribed as 120 units, resulting in severe hypoglycemia.

What if the hospital had agreed on a single sliding-scale protocol? What if the protocol had been pre-typed? What if there were pre-typed medication administration records to go along with it? What if a computerized prescriber order entry (CPOE) system populated an electronic MAR? All these actions would have resulted in simplification, which would have improved patient safety.

Case Study #4 - Evaluation and Monitoring

A patient undergoes cardiac valve surgery. His care is managed by the cardiac surgeon, cardiologist and internist. While in the hospital he suffers a transient ischemic attack, is seen by a neurologist and placed on warfarin. About a week later the patient is discharged with multiple prescriptions, including warfarin, but no firm visit is scheduled for an INR.

Each physician involved in the case assumed one of the others was monitoring the INR. Two weeks later, the patient presents to the emergency department with an INR > 10 and what is later diagnosed as a retroperitoneal bleed.

What if there had been an inpatient anticoagulation service; if referrals to this service had been automatic; if the service had had full accountability for evaluation, monitoring, dosing and scheduling follow-up; or if the patient had been referred to an outpatient anticoagulation clinic?

Case Study #5 - Dispensing

A pediatric patient is admitted for chemotherapy, enrolled in an investigational protocol. The physician writes orders that are correct for the protocol and patient characteristics. However, the protocol contains certain dilution and volume specifications. The dose and dilutions are calculated incorrectly by the pharmacy, and the error is not caught when the order is double checked. The pharmacy dispenses a dose 50% higher than prescribed, which results in neutropenia and sepsis.

What if the hospital settled on a single, simple dilution method and the hospital requested and received a waiver from the researchers for these dilutions? And what if these dilutions were pre-loaded into the pharmacy computer? Calculations would not be necessary, mistakes would not be made and these kinds of errors would not happen.

Case Study #6—Combined Order Form/MAR for Heparin

A hospital with a pharmacy-based heparin dosing service had numerous problems because of the number of transcriptions and handoffs that take place after a dose has been selected. To simplify this procedure, a combined MAR-order form document was designed, so that when a pharmacist writes an order (e.g., for a heparin bolus), it is written on the same document that the nurse uses for medication administration and documentation. This approach, whereby a prescriber writes orders directly onto the MAR, has been used in England for years. As shown in the Figure, implementing this change to simplify the process reduced the error rate from 0.81/month to 0.33/month.⁷

Conclusion

Simplification and standardization can improve medication safety.

References

1. Communication with Tom Nolan in December 1999.
2. Salvendy G (ed.). *Handbook of Human Factors and Ergonomics*. New York, NY: John Wiley and Sons, Inc; 1997.
3. Philippe Garnerin. Thinking simple. Presentation at IHI 14th Annual National Forum, Orlando, Florida. Dec 8, 2002
4. Communication with Francois Clergue in December 2002
5. Communication with Allan Frankel in December 2002.
6. Leape LL, Kabaceni A, Berwick DM, and Roessner J. *Breakthrough Series Guide: Reducing Adverse Drug Events*. IHI. Boston MA 1998:24
7. Meisel S, Schultz J, and Graf K. An Interdisciplinary Model for Reducing Intravenous Heparin Errors. Solutions Conference, sponsored by the Joint Commission on the Accreditation of Health Care Organizations and the National Patient Safety Foundation, Chicago, Illinois, October 6, 2000.

Improving Drug Order Entry Turnaround

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Key Points:

- *Failure to evaluate the medication use process before implementing point of care medication storage cabinets that do not allow nurses to obtain medications before a pharmacist review led to unacceptable delays in drug administration.*
- *A Six Sigma project led to the implementation of several changes, each of which contributed to significant improvement in service delivery, such as limiting a pharmacist to ICU activities and alerting nurses when and where medications were delivered.*
- *Evening-shift turnaround time was identified as particularly problematic, and resistance had to be overcome to include experienced pharmacists on the evening shift.*

At the request of the Director of Critical Care, a Six Sigma project was begun to improve the turnaround time for medication order fulfillment between pharmacy and a surgical intensive care unit (SICU). The project was conducted at a 330-bed acute-care facility located in an urban community in the southwestern United States. The SICU was a 16-bed, multi-specialty unit that included cardiac surgery, trauma, and an active ventricular assist device program.

The turnaround issue had a long-standing history. Recent changes included the implementation of point of care medication storage cabinets. These cabinets were configured in a way that prevented nurses from obtaining medications before the prescription was reviewed by a pharmacist. Before this change was made, nurses easily could obtain the medications prescribed from medication cabinets that were not linked to pharmacy. Creating a link to pharmacy, which prevented retrieval of medications before the pharmacist review, was not accomplished effectively, and order processing delays resulted in delays in administration of

essential medications (Figure 1). This resulted in an evaluation of the medication use process.

The first attempt to solve this problem was to allow the nurse to "override" the safety check, so that urgent medications could be obtained before the pharmacist review. There were still unacceptable delays with other medications.

Because of the difference between an "open-cabinet," available medications system and a "locked down" medications system with a double check, one would expect staff resistance to a change from one to the other, because of the added inconvenience of having to wait for the pharmacist review. In hindsight, the medication use process should have been studied before implementing the double-check system to ensure that medications were available to administer in a timely fashion. During the first four months after implementing the new restricted-access system, tension developed between nurses and pharmacists. The Critical Care Nursing Director requested assistance from corporate Clinical Effectiveness, because the nurses were

"ready to quit." The pharmacists were similarly disgruntled.

Definition Phase

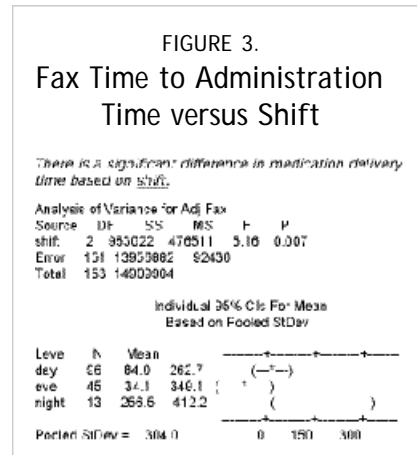
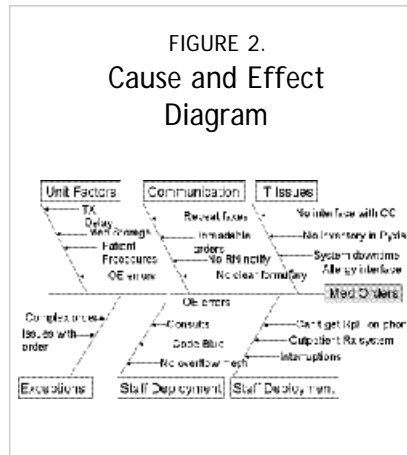
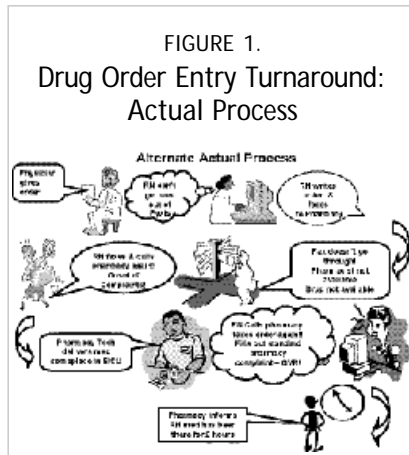
The first step in the project was to define the service delivery area, list the medications prescribed in the SICU, and develop a map of the medication use process. The SICU was the area with the strongest complaints. Many variance reports documented medication delays that occurred on all days of the week and at all times of day. These delays resulted in significant dissatisfaction among both nurses and pharmacists. Adverse effects resulting from these delays on the patients were not measured, but anecdotal evidence suggested there were some negative clinical events.

Initial discussions with the pharmacy staff led to the development of a cause and effect ("fishbone") diagram (Figure 2) that revealed several procedural issues. These included problems with inbound communication (failed faxes, faxed orders that did not get processed), outbound communication (no way to let a nurse know a medication was available), and production issues (a production line that was not maintained at all times). Pharmacists would often leave their work station to do pain consultations, attend codes, and eat lunch, but with no process in place to cover the unstaffed periods.

Measurement Phase

All new medications ordered for seven consecutive days were recorded. The data were collected from faxed orders to the pharmacy and electronic files from both the pharmacy system and the point of care system. The physician orders were entered into the pharmacy system by

Improving Drug Order Entry Turnaround



pharmacy staff after the orders were received via fax. The orders were also entered into a nursing point of care information system by the ward clerk or nurse. The nursing point of care information system provided the medication administration record.

The medication orders were recorded and time intervals were determined using fax time, order entry time, verification time, and administration time. PRN medications were not included in the study. Intravenous continuous infusions were also not included, because they were documented differently. With these exclusions, there were 154 usable orders. The data showed substantial delays in medication order processing and a high variability in turnaround times.

Analysis Phase

The turnaround time data were evaluated using analysis of variance (ANOVA). Results were significant for shift ($p=0.007$), with the evening shift demonstrating the most variance from the other data (Figures 3-4). The data were not significant for order status (stat, now, and routine), suggesting there was poor differentiation of orders based on their priority.

Despite having worked with the pharmacy staff to describe the medication use process design, the data suggested

the actual process functioned differently. Rather than the pharmacist verifying the physician order followed by the nurse administering the drug, the data suggested the process was reversed almost half the time. Medications were being administered up to 500 minutes before the pharmacy reviewed the orders.

Individual and Moving Range (I and MR) control charts documented the erratic variability in the entire medication use process but demonstrated a rather consistent pharmacy processing time. Unfortunately, the mean pharmacy processing time was 69 minutes, which exceeded the desired time to get "now" order medications to the nurse. The upper specification limit for administering drugs was considered to be 15 minutes for "now" orders and two hours for routine orders. The number of medication orders processed per hour was analyzed for seven days. There was a bimodal distribution with peak order times between 0800 to 1300 and 1700 to 2300 (Figure 5). Analysis of the results associated with the evening shift and the staffing pattern identified some issues.

While day-shift turnaround time was inadequate, the evening shift was unacceptable. Staff meetings with the SICU and pharmacy staffs provided additional insight:

1. New staff members were consis-

tently scheduled to work the evening shift (the least popular shift).

2. The ICUs had a dedicated pharmacist on days, but during the evening shift one pharmacist covered the main pharmacy and the ICUs.

3. There was little awareness of the need to maintain the production line.

4. Inbound communication of orders was very unreliable.

5. Outbound communication was non-existent.

6. Medications delivered to the unit were left in inconsistent places.

7. There was no interface between the electronic information systems.

Improvement Phase

Potential changes intended to improve medication turnaround time were evaluated using in Impact/Risk/Cost analysis tool. A schedule for implementation of the changes agreed upon was established. The team agreed to implement and test the following changes:

1. Limit the ICU pharmacist to ICU activities.

2. Schedule more experienced pharmacists to the ICUs.

3. Move an experienced pharmacy technician to the evening shift.

4. Provide a "status board" to alert a

Variability in IV Therapy: A 65-hospital Analysis of IV Best Practices

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Key Points:

- *The intravenous (IV) route of administration for medications often has the greatest potential for patient harm.*
- *An IV medication safety system incorporates customized software that applies hospital best practices for IV therapy, including medications, concentrations, dosing units, and dose limits; and maintains a log of "near misses" that can be used for analysis and process improvement.*
- *A review of IV medication safety system data sets from more than 65 hospitals revealed large variations in all aspects of IV therapy best practice rules, both intra- and inter-hospital.*
- *Standardizing concentrations, drug names, dosing units, dose limits, maximum infusion rates, weight limits and volume limits may help to improve patient safety.*
- *In improving IV medication safety, a safety system's data collection capabilities may be as significant as their capability to intercept IV medication errors.*

Since the Institute of Medicine report was published in 1999,¹ several strategies to reduce medication errors have been advocated, including computerized prescriber order entry, bar code medication administration, 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 arguably pose the greatest risk of harm. MEDMARXSM 2002 data showed that the IV route of administration for medications often results in the most serious medication error outcomes.²

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 under cir-

cumstances where the risk is greatest.

In a seminal medication error study, Bates et al found that 38% of the preventable medication errors occur at the point of administration, and only 2% of these are intercepted.² IV medications represent 61 % of the serious and life-threatening errors.³ Together, these findings further reinforce the fact that IV administration is an area where errors have the greatest potential for patient harm. Consequently, implementing medication safety systems that can increase interception of the IV administration errors has a high potential to reduce harm and protect both patients and nurses—a strategy that is unique compared to other medication safety initiatives.

Intravenous Delivery Devices

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 most widely used medical

devices in hospitals today. Approximately 750,000 pumps are used to administer more than one million IV doses per day in United States hospitals. Unlike medications, which are prescribed and dispensed based on individual patient requirements, infusion devices typically are not configured for individual patient use by Biomedical Engineering departments. Rather, they are configured at the time of implementation 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 as much as a liter of fluid 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, the infusion pumps had no capability to provide a "test of reasonableness" to the programming of an IV medication or fluid. Consequently, infusion devices have been associated with some of the most serious medication errors.

IV Medication Safety System

A new generation of infusion devices introduced in May 2001 comprises an innovative medication safety system that provides an IV "safety net" for nurses at the bedside. Although shipped to hospitals as a "dumb" system with features similar to existing legacy pumps, these new infusion safety systems 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-specific libraries that include medications, concentrations, dosing units, and dose limits. Hospitals can now have the equivalent of 10 infusion devices in one, with drug libraries and infusion rules designed for unique areas or patient types (referred to as "Profiles"). After a clinician identifies the Profile for a

Variability in IV Therapy: A 65-hospital Analysis of IV Best Practices

TABLE

Infusion Therapy: Variation in Practice from 65 hospital data sets:

- Average of 64 drugs per hospital
 - Average of 279 drug/concentrations per hospital
- Multiple names for same drug
 - Average of 4 names per drug
- Inconsistent continuous dosage units for same drug
 - 60% have more than one continuous dosage unit (Range = 1-8)
 - Average of 13 unique dosage units/hospital (Range = 3-19)
- Does not include bolus dosing—typically different from continuous dosing
- Multiple concentrations per drug
 - Average of 1.5 per drug, per hospital (Range = 1-9)
 - 7.5 per drug in all data sets (Range = 1-13)
- Minimal concentration standardization in peds/NICU
 - 67% of entries are “fill in the blank” concentrations

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 practice rules to check device programming, and alerts the clinician if the programming exceeds the rules. This “test of reasonableness” thereby ensures 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 this new system. In addition to reducing the opportunities for programming errors through incorporating best practice guidelines and providing alerts when programming exceeds limits, an IV medication safety system also maintains 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 systems and concluded that only pumps that had “dose error reduction software” should be considered for purchase.⁴

Creating the Best Practice Rules

Customization of the software database for an IV medication safety system 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 1,600 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 a med/surg unit.

For each entry, min/max 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 the adult ICU, whereas the maximum dose might be 5 mcg/kg/min in the 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 is typically pharmacy-driven, with final approval by the Pharmacy and Therapeutics Committee or the Medication Safety Committee. Before loading the best practices information into an IV medication safety system, a line-by-line signoff is required. The most advanced systems utilize a CD-ROM with multiple levels of security, and the safety software and data set are transferred by the biomedical engineers using a laptop computer.

Unexpected Findings

One evaluation criterion noted in ECRI's Health Devices for selecting smart infusion technology is consultative support from the vendor to guide hospitals through the development of the best practices drug library data set.⁴ ALARIS Medical Systems initially approached this consultative support through the development of a peer-reviewed “starter” drug library data set. However, despite the collective wisdom and experience of a blue ribbon panel of clinical experts representing multiple disciplines, this data set was found to be of minimal value. The reason for this became obvious during a review of more than 65 individual hospital data sets: there is large variability in all aspects of the best practice rules (see Table). This variability is found in 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.

Further investigation focused on the variability in drug names. A surprising finding in examining the 65 data sets was that the average drug entity had four different names. Some of this variability was to be expected and included generic, trade and “local” names. Another source for variability was the creative use of the drug names to include indication for use, as illustrated by the various creative names used for tPA. In the 65 hospitals, tPA has been given 20 different names (e.g., alteplase, tPA, and Activase®). In all but two entries, the indication or another modifier (e.g., tPA–stroke, Activase®–MI, alteplase–PE) has been added.

Variability in IV Therapy: A 65-hospital Analysis of IV Best Practices

Expansion of the capacity of the drug library from the initial 40 entries to 100 and then to as many as 1,000 per patient care area has provided hospitals with the necessary flexibility to add the indication to the drug names. The addition of the indication or other modifier such as "weight based" (heparin) or "central line" (potassium) has allowed the best practices to be made indication-specific and to significantly tighten the safe software dose limits to match the intended use.

A second unexpected finding was the large variability in drug concentrations. On average there were 65 drug entities per hospital data set. (A drug entity is defined as the drug only, e.g., dopamine or dobutamine. If a hospital used both generic and trade names for the same drug, this was counted as a single drug entity.) Further analysis determined that there were 279 drug/concentration combinations for these 65 drug entities. Many of the drug library entries had "fill in the blank" concentrations, including 67% of the NICU and pediatric profile entries. The large number of drug/concentration combinations conflicts with the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) 2003/2004 safety initiative for reducing the number of concentrations (discussed by Schafer in these Proceedings). Data sets from the 65 hospitals included 18 different tPA concentrations and 17 fentanyl concentrations. One hospital had 15 different KCl concentrations listed in their data set; another had five epinephrine concentrations. While not all of these drug/concentration entries were available in the same profile, the large number of concentration options was unexpected.

A third unexpected finding was the variability in dosing units, e.g., mg/hr, mcg/kg/min, and units/hr. The range per drug entity over the 65 hospitals was 1 to 8, and 60% of drug entities were associated with 2 or more dosing units. The average number of unique dosing units per hospital data set was 13, with a range from 3 to 19. The smart infusion devices being used in these hospitals had 42 possible dosing

units, including nanograms, micrograms, milligrams, grams, units, milliunits, and milliequivalents. As expected, the dosing units for NICU and pediatrics were the most standardized, since most medications in these profiles are set up as weight-based infusions. Examples of the dosing unit variability included amiodarone (6 different dosing units), calcium gluconate (7), and magnesium sulfate (8). The 44 different amiodarone drug name entries had the following dosing units: mcg/kg/hr; mcg/kg/min; mg/day; mg/hr; mg/kg/hr; mg/min. Another surprise was to find 64 continuous delivery IV medications that had 2 dosing units in the same patient care area profile. It should be noted that this analysis did not include bolus dosing, PCA or epidural drug infusions.

Implications of Data Set Variability

In many cases, the introduction of an IV medication safety system resulted in the development of the first comprehensive drug library intended to set forth a hospital's best practice guidelines for IV infusion therapy. Evaluating the best practices data sets from 65 hospitals has revealed variability in IV therapy that may not have been previously recognized. Intra- and inter-hospital variations are a significant and consistent finding. Several of the clinical experts who participated in the peer review process to define the "starter" data set were surprised by this variability, which explains why a peer-reviewed data set was not effective, even as a starting point. It should also be pointed out that these 65 hospital data sets were the result of extensive internal review by each hospital, and often represent significant reduction in variability from pre-IV medication safety system use.

At this point it is not clear what impact this variability has on medication safety, but it may well be a critical factor. For example, using or not using a weight in a drug calculation in a 70-kg patient represents a potential for a 70-fold under or

over-dose. The variability revealed in analysis of the drug library data sets from 65 hospitals provides unexpected support to the 2004 JCAHO National Patient Safety Goal requiring organizations to standardize and limit the number of drug concentrations available in the organization. JCAHO's requirement for limiting concentrations, as well as principles of complexity theory and human factors engineering (HFE), and findings from other industries (see Meisel in these Proceedings), suggest that standardizing drug names, dosing units, dose limits, maximum infusion rates, weight limits and volume limits may also help to improve patient safety.

Conclusion

An IV medication safety system provides both a safety net for nurses that can detect and prevent IV drug administration errors, and a database to measure, monitor, manage, and improve infusion safety. Since this route of administration is the most dangerous and there are infrequent and often cursory double checks at the drug administration step of medication use, an IV medication safety system would appear to have an excellent impact when considered with other patient safety technologies.

References

1. Kohn LT, Corrigan JM and Donaldson MS, eds. *To Err Is Human: Building a Safer Health System*. Institute of Medicine. Washington DC: National Academy Press; 1999.
2. Hicks, RW, DD Cousins, RL Williams. *Summary of Information Submitted to MEDMARXSM in the Year 2002. The Quest for Quality*. Rockville, MD: USP Center for the Advancement of Patient Safety; 2003.
3. Communication with DW Bates, October 2001.
4. Emergency Care Research Institute, *Health Devices*; 2002;31(10):353-87.

Activase® (Alteplase, recombinant) is manufactured by Genentech.

The JCAHO Focus on Limiting Concentrations of High-Alert Medications: Opportunities and Potential Impact

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Key Points:

- A 2004 JCAHO National Patient Safety Goal requires organizations to standardize and limit the number of drug concentrations available in the organization; this conflicts with the widely used Rule of 6, which results in the use of varied drug concentrations.
- The JCAHO Standards Interpretation Group has stated that the Rule of 6 is not acceptable in meeting their standards.
- The majority of institutions surveyed in 2003 still used the Rule of 6; those that had changed to standardized concentrations felt the change was useful.
- Issues of concern include administration rates with standardized concentrations, half-life of drugs delivered at very slow infusion rates, and the learning curve in making the transition from the Rule of 6 in pediatric practice.

New JCAHO National Patient Safety Goals

Healthcare, public and private organizations continue to focus intently on the reduction of adverse events that patients may experience. The 2004 National Patient Safety Goals (NPSG) of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) outline requirements that organizations must comply with or they will "receive a special requirement for improvement for that goal" (a Type I recommendation). One of these new goals is to "Improve the safety of using high-alert medications"; specifically, to "standardize and limit the number of drug concentrations available in the organization." The measurement system suggested for meeting this standard can be found in the new Medication Management (MM) chapter of the JCAHO accreditation manual in section 2.20. The new MM standards are effective January 1, 2004.

New requirements included in these patient safety goals can conflict with wide-

spread current practices. Resolving such conflicts will be challenging, yet critically important to improving patient safety.

Current Practice: The Rule of 6

The "standardization of drug concentrations available within the organization" has particular relevance in the pediatric patient population. Pediatric practitioners have utilized the Rule of 6 to calculate continuous medication infusions by varying the concentration while keeping the rate of infusion standard. The prescriber calculates the desired concentration of drug based on individualized factors, including patient weight, desired drug amount, and solution infusion rate:

$$\frac{6 \times \text{desired dose (mcg/kg/min)} \times \text{patient wt}}{\text{desired fluid rate (mL/hr)}} = \frac{\text{mg of drug to be added to}}{100 \text{ mL solution}}$$

Using the Rule of 6 to calculate how much medication to use in preparing an infusion, the practitioner varies the concentration of the drug while keeping the rate of infusion

standard, as shown in the following examples:

- 2-kg infant to receive dopamine
5 mcg/kg/min to run at 0.5 mL/hr

 $\frac{6 \times 5 \text{ mcg/kg/min} \times 2 \text{ kg}}{0.5 \text{ mL/hr}} = 120 \text{ mg of dopamine in } 100 \text{ mL of solution}$
- 20-kg toddler to receive dopamine
5 mcg/kg/min to run at 1 mL/hr

 $\frac{6 \times 5 \text{ mcg/kg/min} \times 20 \text{ kg}}{1 \text{ mL/hr}} = 600 \text{ mg of dopamine in } 100 \text{ mL of solution}$

Medications that are commonly prepared and administered using the Rule of 6 include vasoactive medications (e.g., dopamine, epinephrine, dobutamine, milrinone), antiarrhythmic agents (e.g., lidocaine, amiodarone), central nervous system medications (e.g., opioid agonists, benzodiazepines), and other medications requiring continuous intravenous administration.

JCAHO Clarification

Due to the scope and widespread use of the Rule of 6 in pediatrics, clarification of JCAHO's position on standardized drips was requested (Table 1). The response provided in October 2003 read:

"The Rule of 6 is not acceptable. When trying to determine how to give a medication as an infusion ordered at a certain milligram per hour or microgram per kilogram per hour, one can keep the rate of infusion standard (e.g., 1 milliliter/min) and vary the concentration (milligrams per milliliter) of the drug, or one can vary the rate of infusion while keeping the drug concentrations standard. The National Patient Safety Goal requirement 3b (scored on MM 2.20, EP #8) states that the latter (keeping the drug concentration standard and varying the rate of infusion) must be used.

The JCAHO Focus on Limiting Concentrations of High-Alert Medications

TABLE 1.
Standardized Concentrations
vs. Rule of 6

- "If we are using the Rule of 6 for drips for our pediatric patients, are we non-compliant with NPSG #3b?"
- JCAHO's response (October 30, 2003):
 - *"The Rule of 6 is not acceptable. When trying to determine how to give a medication for infusion ordered at a certain mg per hour or mcg per kg per hour, one can keep the rate of infusion standard and vary the concentration of the drug, or one can vary the rate of infusion while keeping the drug concentration standard. The NPSG #3b states that the latter (keeping the drug concentration standard and varying the rate of infusion) must be used.*
 - *"The Rule of 6... allows for infinite number of drug concentrations and is directly opposed to the NPSG and 2004 standard MM2.20..."*

"The Rule of 6, commonly used in pediatrics, is just one of many methods of quickly calculating a concentration of the drug needed to achieve a given dose, while keeping the rate of infusion constant (1 milliliter/min). This allows for an infinite number of drug concentrations and is directly opposed to the NPSG and 2004 standard MM.2.20, EP #8 requirement of having the number of concentrations standardized and limited.

In many hospitals, the pharmacy department has developed charts/tables that allow nurses to quickly determine the proper rate of infusion to achieve a desired mg/kg/ hour using different standardized concentrations of the drug. In addition, 'smart' infusion pumps can assist in this calculation, too."

Teresa Stewart, RN, MJ
Associate Director, Standards Interpretation Group, JCAHO

TABLE 2.
Rule of 6: Why a Major
Issue?

- Historical precedence (1981 Harriet Lane)
 - Formula to assist with unit conversions along with limited pump technology of infusion rates
- Pediatric Advanced Life Support (PALS)
 - "Gold Standard" for educational purposes
- References
 - Harriet Lane Handbook
 - NeoFax
 - Pediatric Dosing Handbook
- Standard of Practice?

Controversies and Opportunities

The enforcement of this new standard is being scrutinized by the pediatric community for several reasons (Table 2). The Rule of 6 has been a standard of practice for approximately 25 years and was originally intended to provide a simplified calculation of doses and infusion rates. Since the smallest infusion rate that most infusion pumps could deliver was 0.5 mL/hr, the Rule of 6 helped determine the individualized concentration of medication needed to deliver the prescribed dose. As a result, most pediatric healthcare practitioners have been trained to utilize the Rule of 6.

A survey conducted by Morgan showed that while most centers still used the Rule of 6, those that had changed to standardized concentrations all felt that the change was useful (Table 3).

Citing the historic precedence of Rule of 6, pediatric practitioners at centers using Rule of 6 stated that a change in practice could adversely affect patient safety by introducing a new "standard" to which professionals are not accustomed.

TABLE 3.
Survey of Existing Practices

- Douglas Morgan MS, RPh Children's Hospital of Iowa, University of Iowa Hospitals and Clinics
- Survey completed in July 2003 and again in October 2003.
- Results
 - 30 respondents: 15 MD, 5 RN, 7 RPh, 3 Unknown with 27 centers
 - 18 of 27 centers use Rule of 6
 - 2 of 18 were planning to change to standard concentrations only
 - 9 of 9 centers that changed to standard concentrations felt change was useful; use 2-4 concentrations

Centers using standard concentrations acknowledged that education was of paramount importance in the successful conversion from the Rule of 6 but that pediatric practitioners were satisfied after the conversion.

The Rule of 6 also is commonly discussed in pediatric references. For example, Pediatric Advanced Life Support (PALS) describes the Rule of 6 as one method for calculating medication drip calculations. The Harriet Lane Handbook, NeoFax, and Pediatric Dosage Handbook all describe the Rule of 6 as a useful calculation method for continuous medication infusions. The JCAHO standard will require revision of these frequently used references.

Another concern with standardized concentrations is variation in the rate of fluid administration needed to provide the prescribed therapy. There is wide variation in the weight of patients between a 24-week gestational age neonate and an 18-yr old adolescent. If too much fluid is used to administer the prescribed dose of a medication, pediatric practitioners are concerned that the use of standardized concentrations might result in fluid

The JCAHO Focus on Limiting Concentrations of High-Alert Medications

imbalances. Institutions that have adopted standardized concentrations have been able to create 2 to 4 different concentrations for vasoactive medications that are based on patient weight. Practitioners are concerned that smaller patients may receive too much fluid when being given vasoactive medications, particularly if they are also receiving total parental nutrition. In this situation, medications may need to be prepared in concentrations that result in extremely slow infusion flow rates that may be unachievable with current infusion pumps.

There have been considerable advances in infusion pump technology since the inception of the Rule of 6. Current technology including smart pumps can be programmed to deliver medication at very slow rates. Practitioners must be aware that while a pump can be programmed to deliver such rates, there is a point beyond which medication delivered at these very slow rates can have little pharmacological effect.

Consider the following example: With microbore tubing, a rate of 0.1 mL/hr will deliver one drop of medication fluid to the patient end of the microbore tubing every 13 to 14 minutes. Since the half-life of dopamine is 2 to 4 minutes, this low rate of administration may produce a diminished or variable response,

because the pump cannot deliver medication at a rate close to the rate the patient eliminates it. One reason a patient might appear to need a higher dose or have a variable blood pressure response is that the drug simply is not being delivered reliably. This illustration demonstrates another aspect that a pediatric practitioner must consider: does the concentration (whether standardized or individualized) and mechanism of administration provide the optimal pharmacologic action intended?

One criticism that JCAHO has received in its publication of this standard is the lack of evidence to support a reduction in medication errors. One aspect being overlooked is the number of medication errors attributed to the Rule of 6 kept in the "file drawer." Although the Rule of 6 is the standard of practice in pediatrics, the infinite number of individualized concentrations that can be created suggests an exponential increase in the possibility of medication errors even in the same patient, who may receive variable concentrations of the same medication. Unless there are collaborative data suggesting that the Rule of 6 results in decreased errors as compared to standardized concentrations, the evidence-based approach discussed by opponents to JCAHO's position is invalid.

Conclusion

The NPSG and JCAHO's position in standardizing medication concentrations and eliminating the Rule of 6 have led to a great deal of controversy in the pediatric community. Although the Rule of 6 is a standard of practice in both the educational and clinical setting, the infinite number of individualized concentrations that could be created with the Rule of 6 appears to increase opportunity for medication errors compared to a limited number of standardized concentrations. Pediatric practitioners should examine existing resources (both technologic and educational) in their application of these new standards until evidenced-based medicine demonstrates the superior safety of one method over the other. Regardless, the debate over standardized concentrations versus the Rule of 6 can be expected to continue for the foreseeable future.

Intravenous Medication Safety Errors

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Key Points:

- Administration errors may be particularly hazardous, because most are not intercepted with traditional approaches.
- Intravenous medication safety represents a particularly vulnerable area, especially in the ICU.
- An IV medication safety system has the potential to substantially improve safety, but studies will be needed to determine the extent to which it will achieve that potential.

Medication safety is an important problem, as illustrated by the Adverse Drug Events Prevention study.¹ In that study, there were 6.5 adverse drug events for every hundred admissions, and about a third of these were preventable. Serious medication errors are the errors that either harm someone or have the potential to do so. While the largest proportion of serious medication errors occurs at the ordering stage, the second greatest proportion occurs at the administration stage.

A major finding is that errors occurring late in a process are less likely to be intercepted. The medication use process is no exception: in one study, about half of ordering errors were caught before they reached the patient vs. only 2% of administration errors.²

Intravenous (IV) medications are vital in the therapeutic management of hospitalized patients, yet administering medications via this route is a vulnerable area (Table). Inpatients often receive several IV medications concurrently, and these often are delivered with infusion pump systems.³ Critically ill patients often receive potent IV drugs that have narrow safety margins and require careful titration. These patients, who are sicker than patients not requiring intensive care, may

be more vulnerable to adverse effects of medications. While IV medications are undoubtedly beneficial and can be life saving, errors in administering them have a high risk for severe adverse events and have caused many fatalities.⁴

New infusion systems incorporate significant technologic improvements.³ One important safety advance has been the development of mechanisms that can nearly eliminate the risk of free-flow, which has caused many fatalities. Other features include enhanced functionality, convenience and portability. Additional features, however, can also add complexity. To attempt to "engineer out" errors, some of the newest infusion systems have features including drug/dose calculations, programmable volume and time calculations, improved alarms and indicators, and most recently, inclusion of drug or patient-specific decision support capabilities. All such systems should be designed using human factors techniques, which include both adherence to certain precepts and actual testing of interfaces and the devices themselves to assess what can go wrong.⁵

Medication Errors (MEs) associated with the use of IV systems have received attention most often as individual case reports, sometimes related to machine

malfunctions. An even bigger problem, which has resulted in a number of fatalities, has been the administration of overly high doses, often ten-fold more than prescribed. Many of these events have been related to human calculation errors and not to machine malfunctions.

There are few prospective data regarding the incidence and nature of serious MEs associated with IV infusion pump delivery systems.^{3,4} It is important to note that while such data are important, the FDA does not generally require them before approving devices, and thus such studies are rarely performed.

Current Study

We recently received support from the Agency for Healthcare Research and Quality to establish a Center of Excellence in Patient Safety. One of the initial efforts has been to perform a prospective study to assess the impact of an IV medication safety system that has both error-prevention and process-improvement data-collection capabilities. Our study had the following goals: 1) to assess the incidence and epidemiology of serious MEs associated with IV infusion pump delivery systems in critically ill patients; 2) to evaluate the impact of an IV medication safety system on the serious medication error rate; and 3) to assess the impact on resource utilization of the device by comparing the length of stay and costs between the intervention and control groups.

The study has only recently been completed, and we are still finalizing the data collection. Nonetheless, some early qualitative findings are apparent. Early in the study, it became clear how complex critical drug infusion can be. Patients included in this study were in the cardiac

TABLE
Intravenous Drug Safety

- Intravenous delivery a vulnerable spot
 - Hard to detect—true rate higher than realized
 - Very high severity level
 - Hard to intercept without changing systems
- Effective interfaces will be key because integration critical
- Expertise in “engineering out” errors pivotal
 - Need to build approaches that help clinicians do what they intend, don’t rely on training

surgical intensive care unit (ICU), where multiple infusions were the rule. Handoffs occurred when patients came from the operating room to the ICU via the recovery room or directly, and their treatments were more complex than anticipated. The study was to be performed as a randomized controlled trial, but this proved impractical, because it could not be determined at the outset of an operation to which cardiac surgery ICU the patient would go at its conclusion. Instead, an “on-off” methodology was used.

It was also found that physicians and pharmacists often did not understand programming the systems and moving them from place to place, but that nurses had a better understanding of this. While issues around the initial programming of the systems were targeted initially, it quickly became apparent that this did not represent most of the programming. Issues related to reprogramming the systems were found to be as or more important.

The strategy from the beginning was to use the IV medication safety system logs to identify events, to determine what alerts were being provided by the safety software, and what the responses to the alerts were. Data were downloaded from

the systems regularly to obtain this information. The early version of the software did not include a patient identifier, which made it difficult to associate the data with a patient, although it was possible to do this in the study setting. It became clear that for this information to be most useful for quality improvement, it should be linked both with a patient identifier and a nurse identifier. These data could then be used in follow-up evaluation of specific cases for quality improvement.

These log data may be useful in a variety of ways. For example, it will be important to assess how often warnings are given, and whether some warnings should be removed or changed with respect to level of severity. In particular, for some medications “low end” warnings may not be useful, as “taper to off” continuous infusion orders are common and it is unclear what dose is too low before medication should be discontinued. It will also be possible to ask questions such as whether some clinicians are more likely than others to override the alerts, though this may raise concerns to many about “big brother.” While nursing may raise legitimate concerns regarding this approach, and malpractice protection in particular is important, this will represent an extremely valuable resource from the safety perspective.

Another interesting preliminary finding related to identifying dose limits. It was found that there was wide variation with respect to dose limits for IV medications, but in order to use the safety system, hospital-wide consensus dose-limit standards had to be reached. This issue clearly presents opportunities for error.

A number of issues remain. It is clear that greater degree of agreement about maximal doses for IV medications is needed. Some areas appear to be particularly challenging: for example, oncology, in which a large number of different types of highly toxic infusions are used, and experimental protocols with atypical dosing

ranges exist. Developing alerts for bolus IV doses is also difficult. It was also apparent that software and technology to make it possible to transfer orders from computerized ordering and pharmacy applications to the IV medication safety system might make it possible to reduce error rates even further. Forcing functions—while very powerful—must be used sparingly and judiciously.

Conclusions

IV drug safety represents a particularly vulnerable area, especially in the ICU. Administration errors are especially hazardous compared to other stages of the medication process, because most are not intercepted with traditional approaches. IV medications are risky compared to other routes, because of the high toxicity of the medications involved and the rapid bioavailability when drugs are delivered via this route. An IV medication safety system has the potential to substantially improve safety, but the extent to which it will achieve that potential remains to be determined.

References

1. Bates DW, Cullen D, Laird N, LA, et al. Incidence of adverse drug events and potential adverse drug events: implications for prevention. *JAMA* 1995; 274:29-34.
2. Leape LL, Bates DW, Cullen DJ, et al. Systems analysis of adverse drug events. *JAMA* 1995; 274:35-43.
3. Schneider PJ. A review of the safety of intravenous drug delivery systems. *Hospital Pharmacy* 1999; 34:1044-1056.
4. Bates DW, Cousins DD, Flynn E, et al. Consensus Development Conference Statement on the Safety of Intravenous Drug Delivery Systems: Balancing Safety and Cost. *Hospital Pharmacy* 2000; 35:150-155.
5. Gosbee J. Human factors engineering and patient safety. *Quality & Safety in Health Care* 2002; 11(4):352-354.

Potential for Harm in IV System Programming: A 10-Hospital Analysis

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Key Points:

- *Detecting and analyzing "near misses" achieves an acceptable standard of patient safety as recommended by a recent Institute of Medicine report.*
- *Analysis of near misses may provide a link between actual failures that are highly visible but rare, and latent conditions that are very common but nearly invisible. This might help to develop a predictive model for recognizing emerging errors and preventing them from occurring.*
- *A new IV Medication Harm Index, which is being developed to help analyze intravenous (IV) medication near misses, estimates the potential harm averted through the use of an IV medication safety system.*
- *Analysis of 10-hospital aggregated data from an IV medication safety system shows that IV medication near misses occur at the following rates:*
 - *Minimal harm potential = 2.2 per 1,000 patient days*
 - *Moderate harm potential = 0.8 per 1,000 patient days*
 - *Severe harm potential = 1.3 per 1,000 patient days*

director in JCAHO's Division of Research recently said, "Because of the abundance of near misses, data from analyzing them may provide the means to distinguish random fluctuations from actual trends, and therefore will be useful for statistical monitoring purposes and developing useful interventions to enhance patient safety." He goes on to state that near miss analysis may provide a linkage between highly visible yet rare actual failures and very frequent but nearly invisible latent conditions. Such a linkage would help in developing a predictive model that could be used to recognize emerging errors and prevent them from occurring.²

IV Medication Safety System

A new tool for active surveillance and analysis has become available with the introduction of an IV medication safety system designed to avert IV medication errors. An IV medication safety system enables a hospital to define best infusion practices, including dosing limits, and to incorporate rules based on these practices into safety software that can perform a final "test of reasonableness" within the infusion system at the point of care.

When an IV medication safety system is programmed to deliver a drug outside of best dosing practices, the safety software provides an alert when the "start" key is pressed. Infusion cannot begin until the alert is addressed. The alert gives a clinician an opportunity either to adjust the dosing parameters or to override the alert and proceed. Other conditions may also lead to an alert. For example, if a channel on a multiple channel infusion is programmed to deliver a drug already infusing on another channel, a "Same Drug Infusing" alert is provided. In this way, programming steps that otherwise might

The recently published Institute of Medicine (IOM) Report, "Patient Safety: Achieving a New Standard for Care," details a plan for the collection, coding, and classification of patient safety information.¹ To achieve an acceptable standard of patient safety, it is recommended that comprehensive patient safety programs that include adverse event and so-called "near miss" detection and analysis be established.

Near Miss Analysis

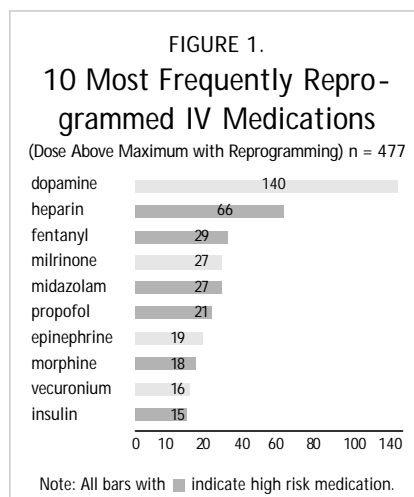
The importance of near miss analysis is the subject of an entire chapter in the IOM report. Near misses are relatively frequent compared with actual errors and represent circumstances in which potential adverse effects have been avoided. For both reasons, they represent rich learning opportunities.

As other industries including aviation have realized, near miss analysis provides a method of understanding underlying system weaknesses and root causes of error, so that systems can be redesigned and simplified to prevent adverse events and improve safety. The new medication management standards of the Joint Commission on the Accreditation of Healthcare Organization (JCAHO) reinforce the importance of active surveillance and reporting systems to achieve a better understanding of medication errors.

Analysis of near misses has the advantage of fewer barriers than the reporting of actual adverse events. Near misses cause less concern about potential issues of blame or malpractice litigation, compared with actual adverse or sentinel events.

Andrew Chang, JD, MPH, project

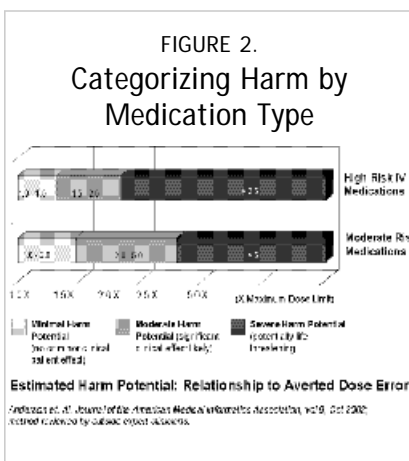
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lead to a medication error are brought to a clinician's awareness and corrected as they occur, thereby improving patient safety and reducing the potential for harm.

More than just a smart pump, an IV medication safety system includes continuous quality improvement (CQI) logs that record each programming alert, so that aggregate data can be collected within an institution to analyze the averted errors and to gain a deeper understanding about when and why they occur. All events associated with an alert are logged for subsequent retrieval and analysis. Some system programming events that do not lead to an alert but that may also be instructive in learning how medication errors occur are also logged. For example, if a drug is selected from the library to initiate an infusion and then the selection cancelled, this event is logged. The safety system company often works with hospitals employing the safety software to create an aggregate database of alerts associated with the use of this technology.

Several of the other articles in these Proceedings discuss the individual experience of hospitals employing an IV medication safety system and lessons learned from analysis of CQI data. The remainder



of this article will focus on the findings from the 10-hospital, aggregated from an IV medication safety system CQI data.

Aggregated Data on Near Misses

Figure 1 lists the top 10 most frequently reprogrammed IV medications where the initial alert was "Dose Above Maximum Limit." The list contains several entries common to other lists of problem-prone medications: drugs such as opiates, sedatives, heparin and insulin.³⁴ Many types of near misses associated with programming errors have been seen, including programming the mL/hr infusion rate or volume to be infused as the dose, programming a "0" instead of a decimal point, factor-of-10 errors, and extra digits that are deleted when the infusion is reprogrammed following an alert.

Assessing Averted Harm

A question frequently asked in hospitals during the review of their CQI data is "Are all near misses created equal, or are there some averted IV medication errors more likely to be associated with harm than others?" To answer this question, a project was begun in the first quarter of 2003 to create a harm potential model that could be applied to near-miss events

recorded in the safety software CQI logs.

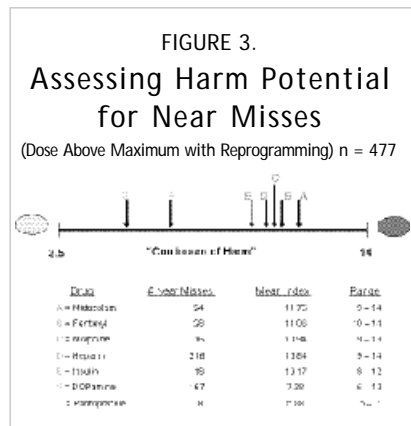
Although there are tools that can be used to define harm from adverse drug events that actually occur (e.g., the National Coordinating Council for Medication Error and Prevention [NCC MERP] tool), there has not been a tool to assess harm for medication errors that are prevented and therefore never actually occur. Using an adaptation of a concept put forth in an article from the medical informatics literature,⁵ a proposed harm index model was developed that uses the magnitude of the dose at the time of a "Dose Above Maximum Limit" alert (e.g., 2.5 times, or 5 times upper limit) as the basis for stratifying averted IV medication errors into three categories: minimal harm potential, moderate harm potential, and severe harm potential (Figure 2).

This model was applied to "Dose Above Maximum Limits" alerts in the 10-hospital database. The results indicated that 51.3% of near misses had minimal harm potential, 19.3% had moderate harm potential, and 29.4% had severe harm potential. Based on the number of patient days during which alerts were provided in the 10 hospitals, the rate of events with minimal harm potential is 2.2 per 1,000 patient days, 0.8/1,000 for events with moderate harm potential, and 1.3/1,000 for events with severe harm potential. Although the minimal-harm-potential events typically would not be expected to result in a need for additional medical intervention or costs, the moderate- and severe-harm-potential events could be expected to affect patient status and costs if the error had not been averted by the safety software. A previously published white paper describes this model and its application to some near miss data from CQI data.⁶

IV Medication Harm Index

In July 2003, an interprofessional group of clinicians with experience with

Potential for Harm in IV System Programming: A 10-Hospital Analysis



patient safety and medication errors programs was convened for a conference on IV medication harm. Representatives from medicine, nursing, pharmacy, and national groups with a stake in patient safety (e.g., the Institute for Healthcare Improvement and the American Hospital Association) reviewed the harm model described above and proposed enhancements to it. The outcome of this meeting was the proposed *IV Medication Harm Index* that can be applied to evaluate IV medication near miss data.

This new harm index uses information about the drug, its inherent risk, the magnitude of the averted dose error, the patient's acuity as determined by using the patient care area location as a surrogate marker, and the likelihood of detection of an adverse drug event, if a medication error had reached a patient. Using the IV Medication Harm Index results in a single number score for each near-miss event. The range of possible scores is 3.5 for near misses with the least harm potential to 14 for near misses with the greatest harm potential.

The Harm Index calculation has been performed for the near miss data for "Dose Above Maximum Limits" for seven drugs 10-hospital data (Figure 3). Additional work is underway to pilot the use of the Harm Index.

Dr. Sullivan describes this conference and the resulting Harm Index in greater detail in her article in these Proceedings.

References

1. *Patient Safety: Achieving a New Standard for Care*, Washington, DC. National Academy Press; 2003.
2. Pew C, ed. *Patient Safety Taxonomy: One Step to Reducing Errors*. Oakbrook Terrace, IL: Joint Commission Perspectives on Patient Safety. 2002;2(8):3.
3. Cohen MR and CM Kilo. High-alert medications: safeguarding against errors. In Cohen, MR, ed. *Medication Errors*. 1999; Washington DC, American Pharmaceutical Association; 1999.
4. Hicks RW, DD Cousins, R Williams. *Summary of information submitted to MEDMARX™ in the year 2002. The Quest for Quality*. Rockville, MD: UPS Center for the Advancement of Patient Safety, 2003.
5. Anderson JG, Jay SJ, Anderson M, et al. Evaluating the capability of information technology to prevent adverse drug events: a computer simulation approach. *J Am Med Inform Assoc*. 2002;9:479-490.
6. Crass R. Improving intravenous (IV) medication safety at the point of care: retrospective analysis of pooled data using an innovative IV Harm Assessment Index. ALARIS Medical Systems, Inc.

IV Medication Harm Index: Results Of A National Consensus Conference

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Key Points:

- A conference of national experts in intravenous (IV) medication safety was convened to design an evidence-based tool to measure the clinical severity of prevented IV medication errors identified through previously unavailable data from an IV medication safety system.
- The newly developed IV Medication Harm Index consists of three sub-scales that estimate risk of harm and clinical severity of potential and preventable IV medication errors.
- Specific drugs having known high risk for harm through clinical experience, expert opinion, or available evidence corroborate high IV Medication Harm Index scores.

Advances in Intravenous Medication Safety

Computerized intravenous (IV) infusion devices—so-called “IV medication safety systems”—incorporate institution-established dosing limits and other parameters to provide a final check at the point of care to help prevent IV medication errors. In addition, safety software automatically records data on the “near misses” (programming errors) averted by the safety system. Most importantly, the new infusion technology provides clinicians with tools to help prevent harm, which can now be part of the research focus and continuous quality improvement (CQI) efforts with regard to infusion therapy.¹

Error vs. Harm

The National Coordinating Council for Medication Error and Prevention (NCC MERP) approved the following working definition of medication error: “... any preventable event that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the health care professional, patient, or consumer.”² The NCC MERP

definition of harm is “...death or temporary or permanent impairment of body function/structure requiring intervention. Intervention may include monitoring the patient’s condition, change in therapy, or active medical or surgical treatment.”³ Since medication errors do not necessarily correlate to patient harm, a new assessment tool was needed to evaluate the severity and potential harm of averted IV medication errors. Harm was defined conservatively, i.e., only in terms of whether a serious error would potentially be life-threatening.

Harm Assessment

In July 2003 a consensus conference was convened with nationally recognized experts in IV medication safety, including physicians, nurses, and pharmacists, to develop such a tool. Conference participants focused on four main areas: identification of the content domain for potential and preventable IV medication errors based on newly available real-time clinical data; assignment of evidence-based degrees of severity to this clinical measurement index; development of validity and reliability as initial respectable psychometric properties for

this tool; and finally, application of the newly developed IV medication harm index to a limited data set as a pilot test.

Methods

As described below, standard methods in instrument development were used in designing the IV Medication Harm Index.

Identification of Content Domain. Under the direction of a facilitator, conference participants reached consensus regarding the content domain of potential and preventable IV medication errors. Consensus was based on available data acquired from an IV medication safety system, state-of-the-science evidence, and expert opinion. The conceptual definition for IV Medication Harm Index was then determined to include specific drug risk, degree of overdosing of specific drug, level of care as an indirect measure of patient acuity, and detectability of adverse event based on specific drug. An IV medication safety system readily provides all data items needed for defining the index.

Based on expert and evidence-based decisions regarding content domain and conceptual definition, the current version of the IV Medication Harm Index consists of three sub-scales (Table 1). As the risk of harm or clinical severity of potential medication error consequences increases, the sub-scale scores and the total summated score for the measurement index increase in quantified values.

The Drug Risk/Overdosing sub-scale is based on the combined consideration of drug risk and degree of overdosing, and has a quantified severity score range of 1.5 through 9. As reference guides for scoring, keys providing information on drug risk and overdosing ranges, based on

IV Medication Harm Index: Results Of A National Consensus Conference

TABLE 1.
**IV Medication Harm Index–
Sub-scales**

- **Three Sub-scales based on:**
Drug Risk/Overdosing Range
 (Score Range = 1.5-9)
Level of Care
 (Score Range = 1-3)
Detectability of Adverse Event
 (Score Range = 1-2)
- **Summarized Score Range:**
 3.5-14

* Higher score = Greater Harm/Risk

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TABLE 2.
**IV Medication Harm Index–
Clinical Example**

- **Heparin administered to an adult ICU Patient at 4 times over the maximum dose (High Overdosing Range):**
 - Drug Risk/Overdosing Range (High/High) = **9**
 - Level of Care (Adult ICU) = **2**
 - Detectability (Unlikely) = **2**
 - **Summated Score = 13**

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instrument for use, are used as reference guides for scoring.

Summated scores increase as the degree of potential clinical severity, risk, and harm increase. The total summated score of the IV Medication Harm Index has a potential range of 3.5 through 14.

Application of the IV Medication Harm Index was demonstrated with a clinical case abstracted from de-identified real-time clinical data. For CQI data that document an attempted delivery of heparin to an adult ICU patient at four times over the maximum dose, the following sub-scale score ranges are assigned. Based on reference keys, Drug Risk/Overdosing Range are both rated as high with a sub-scale score of 9. Level of Care sub-scale, using the rating for an adult ICU, is assigned a score of 2. Since heparin is rated as a drug whose detectability of adverse events is unlikely, based on previously described reference keys, the Detectability of Adverse Event sub-scale score is assigned a score of 2. Adding these three sub-scale scores results in a total summated score of 13 for the IV Medication Harm Index for this potential and prevented IV medication error (Table 2). Since clinical experience and published literature confirm the high degree of risk associated with IV heparin medication errors, this clinical demonstration preliminarily corroborates the logic of this scale application.

TABLE 3.
**IV Medication Harm
Index–Total Summated Score**

Heparin	Range: 7 - 13 Mean: 12.25
Propofol	Range: 10 - 13 Mean: 11
Vasopressin	Range: 5 - 9 Mean: 7

Development of Operational Definition. Both numerator and denominator sub-scales are used in operational definition for the IV Medication Harm Index. The number of potential and preventable IV medication errors comprises the numerator, which may be further described based on severity ranges and specific drug. Based on expert opinion, available data, and current national trends in quality data management, the denominator selected for the index is 1,000 patient days.

Establishment of Initial Psychometrics. Initial content validity for the IV Medication Harm Index was established using the technique of quantification of content validity, as described by Lynn.¹ The multidisciplinary experts at the conference independently rated each sub-scale and the tool in its entirety using a Likert scale ranging from 1 = not relevant to 4 = very relevant. The initial content validity score established by the 20 experts using this technique is quite respectable with a total mean quantified score of 3.451.

Inter-rater reliability for the IV Medication Harm Index was also quite promising with a Pearson r correlation coefficient of 0.9295. Inter-rater reliability was established by comparing agreement between consensus panel experts

expert opinion and available evidence, accompany the instrument.

The Level of Care sub-scale is based on the patient care unit where the specific event was prevented and has a quantified severity score range of 1 through 3. Since available evidence indicates that pediatric and neonatal intensive care units (ICUs) have the highest degree of risk associated with IV medication errors, these units have an assigned score of 3. Adult ICUs have relatively high degree of risk associated with IV medication errors and have an assigned score of 2; intermediate care units, a moderate degree of risk with an assigned score of 1.2; and general care units, a lower risk with an assigned score of 1.

The Detectability of Adverse Event sub-scale is based on the likelihood that an error will be detected and has a quantified severity score range of 1 through 2. Specific drugs whose adverse events are likely to be detected are scored as 1, while those whose adverse events are considered less likely to be detected are scored as 2, i.e., are associated with high risk. Drug-specific keys provide information on detectability of adverse events and are based on expert opinion and available evidence. These keys, which accompany the

IV Medication Harm Index: Results Of A National Consensus Conference

TABLE 4.

Summary and Conclusions

Iterative combination and refinement of innovative safety technology with advanced analytical strategies:

- Can effectively measure the clinical severity of potential and preventable IV medication errors
- Can increase our knowledge and understanding of IV medication administration and the associated risks
- Can make a significant contribution to IV medication safety and quality improvement efforts
- Offer unprecedented opportunities to learn from mistakes before they are made

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during independent application of the tool to eight identical clinical cases from a de-identified data set.

Test-retest reliability for the IV Medication Harm Index was also quite impressive with a Pearson r correlation coefficient of 0.9695. Test-retest reliability was demonstrated by having each individual panel expert apply the instrument to the same eight clinical cases on two separate administrations spaced by a two-week interval. Expert ratings were compared between the first and second administration to determine the scale's stability and consistency in evaluation over time.

Pilot Testing

The newly developed IV Medication Harm Index was pilot tested during application to a limited data set. The measurement index was applied by a single researcher to software-acquired data downloaded from 45 IV medication safety systems currently in use in a medical ICU and a cardiothoracic surgical ICU of a tertiary-care academic health center. These IV systems had been used daily in both ICUs without interruption for four consecutive months. Table 3 lists three of the

most frequently occurring potential and preventable IV medication errors identified through software data with application of their associated harm index ranges. Importantly, specific drugs known through clinical experience, expert opinion, and available evidence to have a high risk for harm have corroboratively high IV Medication Harm Index scores.

Future Applications

Further refinement of this newly developed instrument has the potential to improve safety and quality in IV medication administration. Plans include:

- Employment of 1,000 patient-days denominator
- Correlation of the IV Medication Harm Index with a cost index
- Establishment of advanced psychometric properties
- Development of computerized automation of IV Medication Harm Index

Conclusions

Advances in IV medication safety system now can prevent potential dose-related IV medication errors and automatically gather real-time data describing these near misses. A new assessment tool is required to accurately assess the severity of harm that has been averted through the use of this technology. The IV Medication Harm Index has been shown in pilot testing to effectively measure the clinical severity of potential and preventable IV medication errors. Ongoing refinement and use of the measurement index in analysis of real-time clinical data can increase our knowledge and understanding of IV medication administration and the associated risks (Table 4).

The availability of a standardized tool at the earliest stages of an IV medication safety system data collection and analysis can make a significant contribution to IV medication safety and quality improvement efforts. Unlike earlier error-prevention efforts that had to rely on retrospec-

tive data, IV medication safety system and its associated CQI data offer unprecedented opportunities to learn from mistakes *before* they are made.

References

1. Wilson K, Sullivan S. Preventing medication errors with "smart" infusion technology. *Am J Health-Syst Pharm.* 2004;61:177-83.
2. <http://www.nccmerp.org/aboutmederrors.htm>
3. Cited in: USP, *Summary of the 1999 Information Submitted to MedMARxSM*, Glossary:19.
4. Lynn M. Determination and quantification of content validity. *Nurs Res.* 1986;35(6):382-5.

Using IV Medication Safety System Logs — A New Tool for Identifying Averted Harm

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Key Points:

- *St. Joseph's/Candler Health System selected an intravenous (IV) medication safety system for its initial investment of funds for hospital-wide implementation, having concluded that this technology, which incorporates dosing limits to avert intravenous medication errors, would have the greatest potential to reduce risk of harm to patients.*
- *Data logs in the IV medication safety system documented a 7.2% rate of pump reprogramming (i.e., "near misses"), which suggests that a significant potential for harm is being averted through the use of this technology.*
- *The safety software in this IV medication safety system is providing not only interdiction of untoward events but also information through its data storage and retrieval characteristics that is useful to continuous quality improvement of medication use at St. Joseph's/ Candler Health System.*

St. Joseph's/Candler Health System (SJC) is a three-hospital system comprised of two acute-care, tertiary referral centers in Savannah and one rural hospital located in an outlying community. The Savannah facilities include St. Joseph's Hospital, which has 304 beds made up of various adult medical and surgical specialties, and the Candler Hospital, which has 340 beds and provides adult and pediatric care. Candler is also the primary maternity facility in the city. This paper briefly describes the implementation of the Medley™ Medication Safety System with Guardrails® Safety Software at these two hospitals and preliminary results from the analysis of data derived from event logs that accumulated automatically during use of the system.

During the last four years SJC has been actively engaged in assessing new technology designed to improve medication safety for its hospitalized patients. This assessment has included bedside medication verification and documenta-

tion using bar-coded labels for medications, patients, and caregivers; computerized physician order entry (CPOE); and an IV medication safety system that incorporates medication safety features with dose limits for drugs. Concurrently with technology assessment, SJC has implemented multiple strategies to engage physicians, nursing staff and other caregivers to improve the recognition and reporting of medication errors, so that the design of the medication use process can be improved in ways that reduce the potential for error. Our activities and assessments validate the observation that the medication use process is extremely complex with many steps performed by humans in conjunction with machines. More than 250 steps are involved in the medication administration process from the time of ordering of drugs by the physician to their administration to the patient by a nurse. Errors can occur in any step.

Prioritizing Technology Investment

It is believed by the Institute for Safe Medication Practices that the combination of CPOE, bar coding and safety infusion systems may finally provide a solid defense against the most serious medication errors.¹ However, a dilemma for many institutions is the cost of implementing all of these systems concurrently when fiscal constraints limit the availability of funds for capital investment. SJC selected an IV medication safety system for its initial commitment of funds based on the belief that this could contribute the greatest benefit to patient medication safety in the shortest amount of time. This conclusion was reached in part as a result of statistics that indicate that 25% of all medication doses administered in our hospitals are given by the intravenous (IV) route (Table 1). IV medications have the greatest potential for producing harm.² Therefore, we concluded that an IV medication safety system, which incorporates dosing limits and data logs for process improvement, would have the greatest impact for risk reduction to patients treated in our institutions.

IV Medication Safety System Implementation

In October 2002 SJC implemented the Medley™ System with the Guardrails® Software in all three of its hospitals. This implementation was preceded by several months of work performed by clinical pharmacists, nurses and physicians at SJC to develop the infusion programming limits and other safety software parameters inherent to the system. Additionally, staff training using internet-based educational modules provided by the company was

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TABLE 1.
SJC Medication
Statistics

- 4,014,396 doses administered in FY03 in 2 tertiary-care hospitals
- 62% of doses were injectable
- 40% of injectable doses were IV
- 995,570 of all doses were IV medications

conducted. All three hospitals were simultaneously converted from the existing IV pumps to the new systems in a single 24-hour period without significant difficulties. The unusual success of the implementation process is attributed to the collaboration of multiple groups of people, including nurses, pharmacists, physicians, medical/surgical buyers, and administrators. This collaboration assured a high level of compliance with the use of the technology by nurses after the IV medication safety system was installed. The implementation experience is outlined in Table 2.

Results

In the months since implementation, "event" data have been accumulated in the computer "brain" in each IV medication safety system. An event is defined as any alert given to the nurse/caregiver that requires a reevaluation of their system programming selection. All events are collected by the system until purged at designated times by SJC. These data have been synthesized for analysis for the time period October 2002 through June 2003, which represents nine months of our initial experience with the safety software at St. Joseph's and Candler Hospitals. Key results of these data are summarized in Table 3 and provide information from the 545 systems in use in these two hospitals. The data indicate that most alerts (57%)

TABLE 2.
SJC Implementation
Experience

- Drug library max-min infusion parameters development
- Extensive pre-implementation training
- System implemented in October 2002
- 600+ systems in 3 hospitals
- 98%-100% compliance by nurses with use of Guardrails® Data ("event") collection October 2002 – June 2003
- Data analysis from 525 systems at SJH and CH

given to nurses were warnings of the possibility of drug overdose.

Of the total 8,294 recorded events, 7,317 (88%) were associated with the administration of two drugs: propofol and oxytocin. In the ICU propofol is administered for ventilator-related sedation, and in the pregnant female oxytocin is administered during the induction and postpartum delivery period. Propofol is a medication frequently given as a bolus in addition to a constant rate infusion to maintain sedation in the ventilated patient. Our data include these bolus propofol doses and provide insight into the amount of this medication per unit of time administered to patients in the ICU. The data indicate that the bolus dose mode for system setting by nurses was not used appropriately during this time period. Additionally, there may be need for further evaluation of clinical outcomes associated with the current process and dosing methodologies of propofol for these patients. The oxytocin data correspond to the current practice of high infusion rates of the drug in the postpartum patient to expel afterbirth; these high infusion rates exceeded those programmed into the system for constant rate infusions during the induction period

TABLE 3.
Event Rates for 525 IV
Medication Safety Systems

- 8,294 "events" resulted in warnings to nurses
- 4,746 (57%) dose greater than maximum
- 2,571 (31%) associated with propofol & oxytocin
- 598 (7.2%) reprogrammed or cancelled processes—presumed to be averted medication errors

and therefore, resulted in system alerts (events).

The data also indicate that 598 events (7.2%) resulted in the nurse canceling the administration process or resetting the system. These warnings involved multiple medications including some of those identified by the USP MEDMARXSM as being associated with the highest liability for harm.² As indicated in Table 4, 76 potential overdoses of heparin and six potential overdoses of insulin were averted. In 30 instances for multiple drugs, doses greater than 10-fold the maximum drug-library limit were cancelled. We believe these 598 events were potentially serious medication errors that were prevented by the MedleyTM System and that can be characterized as "near misses." Given that there were 995,570 IV doses of drugs administered at SJC in our fiscal year 2003, a 7.2% rate of system reprogramming suggests a significant potential for harm is being averted through use of an IV medication safety system.

In addition to averting harm, the system allowed us to discover that nursing staff would be able to program the system more easily and deliver the correct dose of medications, if IV drug labels were reformulated to include the total volume and amount of drug. The technology also allowed us to redesign our heparin proto-

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col. Our former heparin protocol required the nurse to send an order form to the pharmacy to calculate a rate of infusion based on milliliters per hour. With the IV medication safety system, nurses can now program the system by units per kilogram per hour. This one change eliminated at least three steps in the medication process, multiple calculations, and multiple opportunities for error.

Increased efficiency also resulted from another unexpected use for the system that involves our neonatal and pediatric patients. Previously, when orders were written for infrequently used drugs, pharmacists spent time researching and compiling information to determine the correct concentration for a pediatric patient. Now, they are able to quickly reference the dose-checking drug database, knowing that the information is adequately backed by the current literature.

Conclusion

Our preliminary data suggest that in the past, prior to the implementation of an IV medication safety system, events may have been occurring that were obscured by "routine" clinical occurrences in patients that may have been misinterpreted as part of the course of their disease process *versus* iatrogenic in nature. The Medley™ System with Guardrails® Software is providing not only *interdiction* of untoward events but also *information* through its data storage and retrieval characteristics that is useful to continuous quality improvement (CQI) of medication use at St. Joseph's/Candler Health System.

References

1. Institute for Safe Medication Practices Newsletter, February 7, 2002.
2. USP MEDMARXSM, Analysis of Participating Hospital Data, 2001.

TABLE 4.
Selected Data from SJC

Item	SJH	CH	Total	Comment
Reprogrammed	264	257	521	6.2% of events
Cancelled	32	45	77	1.0% of events
Overdoses Prevented				
Heparin	34	42	76	
Insulin	2	4	6	
10-fold	13	10	23	multiple drugs
50-fold	2	5	7	heparin, dopamine, propofol

A Medical Center's Experience Using Smart Infusion Pumps to Manage Medication Administration

Glenn Billman, MD, Medical Safety Officer, Children's Hospital and Health Center, San Diego, CA

Key Points:

- *Intravenous (IV) medications are involved in a high percentage of potential adverse drug events, and prevention of IV medication errors needs to be a priority when considering investments in patient safety technology.*
- *At Children's Hospital and Health Center, enormous value has been derived from the use of smart pumps, which have intercepted significant IV medication errors and have identified the most common types of intercepted errors, the most common times and the most common locations at which they occurred.*
- *Successful conversion to smart pumps was the result of bedside nurses having ownership of the selection and implementation process and data detailing intercepted errors.*

Context

Children's Hospital and Health Center, San Diego (CHSD) is an independent, nonprofit healthcare organization that offers comprehensive pediatric medical care through secondary and tertiary specialty outpatient clinics and inpatient care. Children are at high risk for medication errors and adverse drug events (ADEs) for a number of interrelated reasons. First, drug absorption, transport, metabolism, and excretion vary by age. Second, the weights of children vary dramatically. For these reasons, dosages must be carefully calculated with most medications being prescribed on a weight basis. Mathematical errors, including misplaced decimal points, can result in 10-fold dosing errors. Third, most drugs come in only a limited number of dosages, so custom dosage preparation is generally necessary for children. This extra work also creates the possibility for errors. Fourth, children lack the physical reserves to withstand the adverse consequences of errors that do occur. For these reasons, the ADE rate in pediatrics is three times

higher than in adults. Intravenous (IV) medications are involved in 54% of potential ADEs in pediatric inpatients. Prevention of IV medication errors needs to be a priority when considering investments in patient safety technology (Figure 1).

Until recently, CHSD used four types of infusion devices, each with their own user interface. Limited dosing information was available at the point of care, and pumps were permissive (i.e., any dosage could be programmed; there were no dosages that the pumps could not deliver within pump's operating limits, e.g., 999 mL/hr). A single caregiver set up a device and programmed it for use with a given patient. There was no double check. To compound these limitations, there was no easy way to accurately discover medication administration errors that were occurring, which ones were intercepted and which were not.

Change

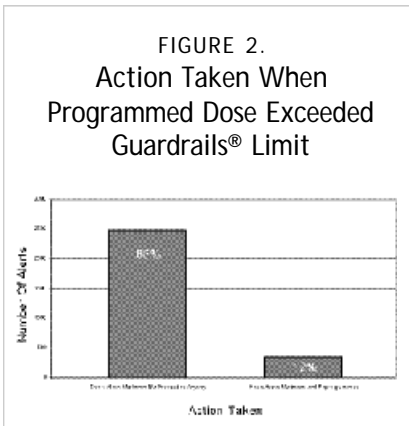
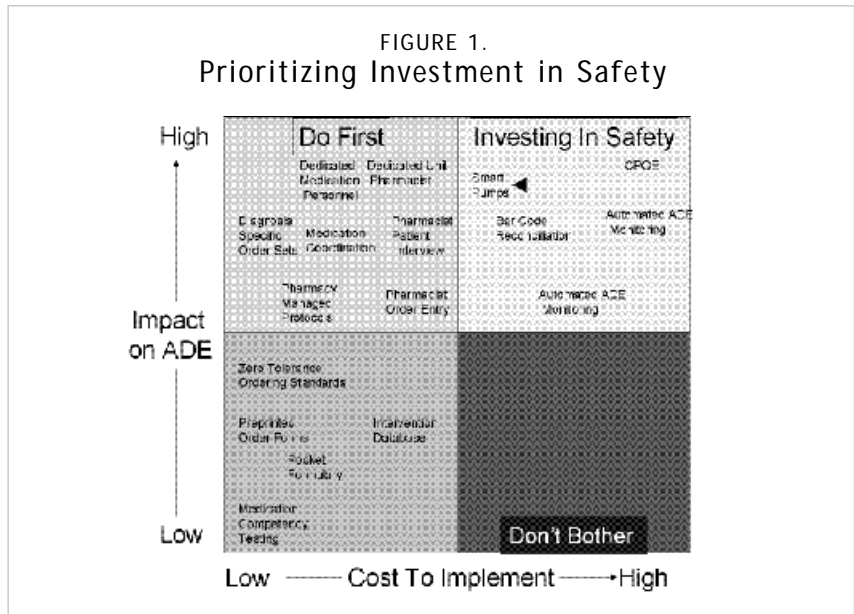
In January 2002, in order to address these limitations, CHSD decided 1) to

reduce the number of devices available (standardize) and 2) to invest in smart pumps. Smart pumps are programmable pumps that have comprehensive, user-determined drug libraries. These libraries are programmed with both so-called "hard" (impassable) and "soft" (passable) dosing limits for each drug. Alerts are signaled whenever these limits have been exceeded. Smart pumps have continuous displays of the selected drug's name and dose, and of doses being infused outside of soft limits (if any). Smart pumps also have a comprehensive log that records dosing limit alerts and subsequent actions (such as bypassing a soft-limit alert, or reprogramming after a hard-limit alert).

To achieve CHSD's objectives, a multidisciplinary group of 15 senior nurses, three physicians (including anesthesiologists and senior care area physicians), two pharmacists, one biomedical engineer, one materials management representative, and CHSD safety personnel was convened to evaluate and select a pump for hospital-wide use. The inclusion of a breadth of nursing input was deliberate, both for nurses' knowledge as content experts and in the belief that nursing buy-in was essential to successful implementation and use of the new devices. The timeline for selection was three months.

When the selection process had narrowed the field to two candidate pumps, these devices were made available to the general nursing staff for their review and input. This step provided additional useful information and served to engage the nursing staff at large in the decision-making process.

After one pump was selected, a group of five senior nurses, five physicians (including anesthesiologists and senior care area physicians), one pharma-



cist, and the medical safety officer met to design the drug library, including hard and soft dosing limits, for nearly 100 drugs. Each of the five nurse/physician pairs was responsible for providing input, review, and approving the profile for their care area. The approval process was felt to be an important reflection of the personal accountability for these critical decisions.

The new pumps and their libraries were evaluated briefly before proceeding to full deployment. An important discovery at this juncture led to the decision to embed the anesthesia drug library within each of the care area profiles rather than as a stand-alone directory. This change was made to ensure that access to emergency medication dosing alerts was unfettered. Once this change was made, the 450 new pumps were rotated into service in October 2002. The time interval from selection of the smart pump manufacturer and model to the go-live date was two months.

Measures

The smart pump collects data that can be used to evaluate patient safety

without labor- and time-intensive (and often practicably infeasible) chart reviews. Pumps collect data on medication dosages; the number of alert events (i.e., when hard or soft limits are exceeded during programming); staff responses to alerts (i.e., canceling drug selection; reprogramming weight, dose, or duration information for the selected drug; overriding the alert); and dates, times, and locations. Data obtained from the pumps are provided as an Excel database.

Results

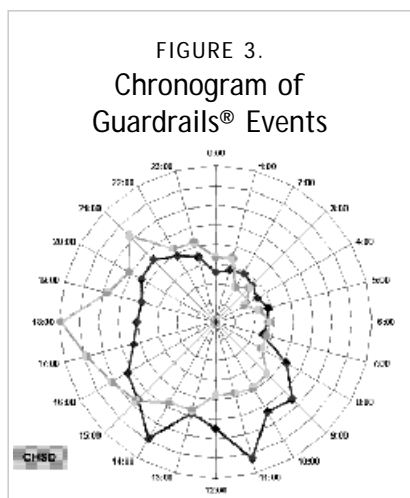
From CHSD's perspective, enormous value has been derived from the use of the smart pumps. First, the pumps have provided an exciting window of investigation into the medication administration process. Before the introduction of the smart pumps, performance monitoring of the medication infusion process relied almost entirely upon completing and submitting occurrence reports. The information provided by the pumps is much more comprehensive and detailed than the information from occurrence reports. Specifically, in six months after the pumps were placed into action, over 4,000 alerts

were recorded by the devices.

Second, the use of these pumps has prevented many significant errors from reaching the patient. While the majority of the 4,000 Guardrails® Alerts were interpreted to reflect the aggressive pharmacologic management of patients within the critical care environment, about 12% of the alerts led to the reprogramming of the infusion device (Figure 2). The instances when a pump was reprogrammed after an alert were interpreted as intercepted and prevented medication errors. The majority of errors that were recorded exceeded the alert limits by a factor of less than 1.5. Some of the intercepted errors involved high-alert medications at increased multiples (> 2.5 times the alert limit), suggesting that some of the errors had a significant potential to cause harm if the dose were actually administered.

Of particular interest was the finding that the magnitude of dosing errors that resulted in reprogramming was not random; 10-fold errors were especially prominent. This was interpreted to reflect either a misinterpreted physician order or a misplaced decimal point during infusion rate programming. Review of the data revealed that 10-fold programming errors most commonly involved dopamine. Interventions resulting from this finding are underway.

At CHSD, the time-based data provided by the smart pumps also revealed



that alerts occurred much more frequently at 18:00 hours (Figure 3). A variety of factors were felt to have contributed to this finding. Specifically, 18:00 hours is the last hour of a 12-hour shift. It is also the peak trauma care period, and the time when most of the next day's elective admissions occur. Concurrently, 18:00 hours has also been one of the pharmacy's scheduled medication delivery times. In light of the data provided from the pumps, these competing conditions, tasks and responsibilities are now felt to have predisposed to errors occurring at this time of day. Discussions about methods to redistribute some of these tasks are under review. Smart pump data will be used to measure the effectiveness of selected interventions.

Lessons learned

Analysis of smart pump data identified the most common types of intercepted errors, the most common times and the most common locations at which they occurred. These data have confirmed that harm is not random and have helped identify opportunities for improvement. By focusing on errors that were caught (reprogrammed events), the pumps were cast in a non-threatening light—the kind of light most likely to sustain gains.

Modern medical management relies heavily upon infusion therapy. Nursing staff depends upon their ability to use infusion devices. Nurses can therefore be highly resistant to changes involving the infusion systems to which they are accustomed. In retrospect, two central factors were felt to be most responsible for the success of our conversion. First, the bedside nurses had ownership of the selection and implementation process. Second, the ability of the pumps to detail errors that were intercepted and prevented has dramatically underscored the significant personal value that the use of the pumps has provided to the nursing staff.

In the future, more real-time data evaluation is planned. It is now recognized that data would be more useful if pumps recorded the total number of infusions, so that error rates can be calculated. Data regarding patient identity and staff identity also will be helpful so that

additional information can be collected (via chart review) when alerts were overridden. The smart pump vendor is currently evaluating all three of these requests.

While the work described here 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 are not concerns unique to 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 pumps are used.

References

1. Kaushal R, DW Bates, C Landrigan, et al. Medication errors and adverse drug events in pediatric inpatients. *JAMA*. 2001;285:2114-20.

Roundtable Discussion Summary

Does intravenous (IV) therapy need to be a higher priority patient safety issue?

Participants agreed that IV therapy is a high-risk method for administering medications and needs to be a higher priority as a patient safety issue.

- Most medication error studies have been done with drugs being administered through a non-intravenous route, so error rates with IV therapy have not been well documented.
- Early experiences with the continuous quality improvement (CQI) logs from smart pumps have shown that IV medication administration errors detected and prevented are actually quite common.
- There are more variations in drug concentrations and base solutions with IV therapy compared with other routes of administration, making standardization difficult.
- The doses of medication administered by the IV route often vary, change, and are determined by the weight of the patient, making errors more common.
- Because of these variations and the acuity of patients who receive their drug treatment by this route, it is harder to build standardization into the system of IV medication administration, compared to other routes of administration.
- Harm is more likely to result from errors in administering medications through the IV route than through other routes of administration.

"I think the reason it's not high on the priority list is we don't have our hands around the data, which are still being ascertained." *Christopher Shaffer, PharmD, BCPS*

"There may well be thousands of patients who die every year, and we attribute their deaths to the underlying illness, when they are actually dying of errors. Without IV medication safety systems, we just don't know about it." *David Bates, MD*

"A 'near miss' may be a dose that was programmed in units that were different from what was intended. A thousand times difference between a microgram and milligram—those are huge multipliers." *Tim Vanderveen, PharmD, MS*

"We've learned so much about IV therapy in the last couple of years based on the smart pump CQI data; before we had those data, we really did not know this enormous variability in best practices, in concentrations, drug names, etc., exists." *Rick Crass, PharmD*

Are smart pumps an effective way to improve and measure IV drug administration safety?

It was agreed that IV medication safety is likely to become a bigger issue because of improvements in ways to avert errors and detect near misses using CQI logs from smart infusion pumps.

- Medication error detection systems currently in use are either not quantitative (voluntary event reports), or too time consuming (chart review).
- Using information from these logs not only identifies the problems or

medications that are most commonly associated with errors, but also the analysis of this information can facilitate the identification of latent conditions that need to be corrected.

- Data logs can also be used to measure improvements in IV medication safety.

"We're going to fix a lot of errors that have never been reported, by using these pumps. It's a real-time surveillance tool. It's a real-time tool to discover the mistakes that are going on out there as well as mitigate against them." *Nancy Pratt, MSN*

"We had spent three and a half months standardizing concentrations of solutions, but we still had at least 82 critical errors that could have resulted in harm, had the IV medication safety system not been in place." *Ray Maddox, PharmD*

"When we've taken these 'near miss' data back out to the nurses, they perceive enormous value to the data, and the data have been very compelling to them, both to extend the change and to continue the process." *Glenn Billman, MD*

"So, we've got to get this information out to them (nurses) as soon as possible, because, if you incentivize them, they you won't get the bypasses. They're not going to do the work-arounds if they understand what the importance of it is to them and for their patients." *Elizabeth Plant, Dip ClinPharm*

"I have never had difficulty getting a nurse involved in trying to understand or wanting to deal with the data at hand." *Norma Barr, RN, MN*

"What's not yet recognized in pharmacy is the bigger piece of this IV medication safety system, and that is its value in terms of the CQI data as it relates to reduction of medication errors."

Ray Maddox, PharmD

How important is improving the safety culture in an organization as an antecedent to adopting new technology, such as smart pumps?

It was agreed that a culture of safety is critical to making any change in an organization, especially a change that involves a new technology. This is true for several reasons.

- First, a capital investment is required; this requires diverting money from revenue generating programs to those that improve patient safety.
- Second, the changes required to introduce new technology affects the work of staff, often increasing the amount of time required to do it.
- Third, the information generated by a technology like smart pumps can only be used to make improvements if a culture of safety exists.

"A moment of insight is worth a lifetime of experience." *Oliver Wendell Holmes* (Note: Did NOT attend the conference!)

"The biggest driver of cultural change is actually the senior people in the organization." *Dave Schlotterbeck, CEO*

"One of the ways to get things to progress more rapidly is when there is a broader understanding of what the issues are and where there's value. One of the things I believe is that hands-on caregivers don't actually have the tools they need to do a good job. Given the tools, they will be way more effective, and they actually want to use the tools." *Richard Kremsdorf, MD*

"Compliance related to the use of the pumps is greater than 90% in our organization, and it is that way because noncompliance is addressed very quickly and straightforwardly by nursing leadership—not only at the highest level, but also down to the manager level in the clinical areas. Another reason is that the selection process and purchase process was driven clinically—the clinical decision was given to and made by nurses at our institution."

Ray Maddox, PharmD

"The front-line staff really are the important voices we need to hear." *Kathy Rapala, RN, JD*

"One way to find out about the culture of safety is to ask 'Hey, what's it like around here?' If people are not talking about a culture of safety, then you don't have one." *Dave Schlotterbeck, CEO*

"Until we can make the rationale for using new technologies such as smart pumps meaningful and compelling from a value perspective for that front line practitioner, we're going to see people that don't understand, so they'll work around it." *Kathy Rapala, RN, JD*

"Did the pump help you? Did it catch you doing something wrong?" 'Well, yes.' As nurse executives and nurse leaders, we have to talk to nurses in that kind of a manner, so that they understand how important and how powerful a tool like an IV medication safety system is." *Victoria Rich, RN, PhD*

What is the best organizational infrastructure to improve safety in organizations and what strategies are needed to improve medication use safety?

Many approaches to improving safety with different infrastructures were dis-

cussed, each of which can be successful. It was concluded that:

- No one infrastructure or strategy can be recommended for improving medication use safety—it is institution-specific.
- Senior leadership and support are needed.
- Nurses, physicians, pharmacists, information technology, and finance all need to be involved.

"We have found in looking at medication safety that a system-wide safe medication practice committee has proved successful. We have a multidisciplinary group at the table including nursing, pharmacy, information technology, physicians. That committee is where we discuss things like technology; we're also looking at our CPOE system and the problems that we are having with lack of interfaces between our pharmacy system and point of care systems." *Elaine Levy, RPh*

"Any interdisciplinary group that's actually figured out how all these pieces are going to work and how we're going to redesign work flow to deal with the technology pieces could be really invaluable to enhancing our ability to take care of patients." *Rita Shane, PharmD, FASHP, FCSHP*

"It takes various incentives, and sometimes mandates (published studies, professional guidelines, and accreditation standards) to help hospitals decide to spend money to buy technology that improves patient safety." *Nat Sims, MD*

"It only took five years, from 1985 to 1990, to go from 5% of the hospitals in this country who utilize oximeters and captographs intraoperatively to

Roundtable Discussion Summary

100% —and that's about as fast as anything can move." *Ellison Pierce, MD*

"The closer you can align your strategy with what the caregivers tell you, the more likely you are to be successful, because the resistance factor goes away." *Richard Kremsdorf, MD*

"One way to herd cats is with tuna." *Charles Denham, MD*

"The fact of the matter is that every hospital in this country is going to be investing in IV pumps sometime in the next 10 years." *Steve Meisel, PharmD*

"The tipping point is that ECRI is now rating any device that doesn't have dose error reduction software as not a recommended device." *Tim Vanderveen, PharmD, MS*

"One of the things that did fuel the fire to get the pumps purchased was the fact that I could point to one of those categories of harmful events, and they were pump failures. So it was an easy sell from a safety perspective." *Nancy Pratt, MSN*

"Nurses want three things: they want to be financially rewarded, they want to be valued, and they want to be heard. So, the more we can involve them in decision-making regarding smart pumps, they'll make that decision because it's intuitive to them." *Joan Vitello, PhD, RN, FAAN, FAHA*

"Feedback is the key. I took our preliminary findings on 'near misses' from the smart pump CQI data, and I fed them right back, even as raw as they were, to the front-line clinicians. When they have the tools they need, they respond." *Jacqueline Sullivan, PhD, RN, CCRN*

"Part of the reason I believe that the compliance is greater than 90% at our institution is that the selection process

and purchase process was driven clinically—the clinical decision was given and made by nurses in our institution." *Ray Maddox, PharmD*

"I think most physicians, if you make them aware of this situation—both the variability and that 7% to 10% of pump input requires reprogramming that may hurt the patient—I think they'd be very amenable to change. I think they wouldn't have any objections relating to that." *Frank Overdyk, MSEE, MD*

Is there a business case for investing in improvements in medication use safety? How important is an evidence base to support the investment?

This generated the most discussion, with general agreement that:

- Innovators and early adopters are making patient safety investments and changes on intuition, rather than a strict business-case or evidence-base analysis.
- There is not currently enough information to make business-case or evidence-based decisions.
- This is needed for widespread adoption of new patient safety technology.

"The level of evidence here so far is pretty modest. I did the evidence review for bar coding, and the last time this was done, there was not even enough evidence to make IV medication safety systems part of the evaluation." *David Bates, MD*

"There are a lot of technologies out there that can make a difference, so three things that I think are necessary to look at are the cost, the ease of adoption, and how long it takes to make a difference." *Dave Schlotterbeck, CEO*

"Purchasing smart pumps was an easy decision. I had budgeted barcode money, and we spent it on the pumps. The bottom line is that the bar code money was safety money, and this was safety technology. We were going to buy new pumps, so I threw the money in to getting the smart pumps, because that was progress and meant we could reduce harm real-time." *Nancy Pratt, MSN*

"The question will be not whether (hospitals) will buy new IV pumps, but whether they will buy IV pumps with this technology built in or not." *Steve Meisel, PharmD*

"There is no question in my mind that this needs to be driven as a nursing decision. You've got to have the pharmacy along and you've got to have materials management along, but if you take this, you know, down another path and then try and stuff it to the nurses, it's a non-starter. You let the nurses choose what they want; they're going to go with this pump because it makes sense." *Nancy Pratt, MSN*

"As we examine how we would organize ourselves to do that, we see seven different silos, each of which are involved in only a piece of infusion technology: materials management, pharmacy, IS to a tiny extent, quality and safety, biomedical engineering and patient care services. Each of these has small amounts of capital under their control which, if aggregated, could do the whole project, but it's not centrally coordinated." *Nat Sims, MD*

"It is really important to get that information back out to those front-line people and help them understand why they should use the system and use it appropriately and how by using it appropriately, there is a business case for it." *Kathy Rapala, RN, JD*

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"I now can clearly articulate the number of incidents where I have been able to intercept medication errors from reaching the patient by using smart pump technology. That to me adds value to move this forward... As a member of administration, I am now able to look at my staffing and begin to articulate areas of vulnerability. I can start shifting resources and unload some of those responsibilities that are all happening at a particular time of day. Now I have a very specific indicator that allows me to track that ...There is enormous nursing satisfaction in being able to get to a common platform; this is where they perceive direct personal value to them... Overall, in looking retrospectively I can say without question that this is one of the smartest things that we have done. *Glenn Billman, MD*

"I agree that it cannot be intuitive. It has to show a bottom line. I have been a COO. I know that. And I have been with CEO's that have always said to me, 'You have to show me how much you can add to the bottom line if I buy these things.'" *Victoria Rich, RN, PhD*

"We saw that there was a business case (for the Medley™ System devices) because of cost avoidance. We were able to appeal to intuition (that converting to safe pumps was the right thing to do) on many levels, and all the nurses that had used these pumps refused to go back (to our previous pumps)." *Al Gould, RN, MSN, CCRN*

"The average settlement cost for medication errors is a little over \$143,000 per settlement. If I had 82 critical medication errors that were prevented, it's in excess of \$11 million." *Ray Maddox, PharmD*

"I do believe this will be part of a nursing retention strategy... because those really helped to start to make you safe." *Victoria Rich, RN, PhD*

"I review cases for a legal firm, and there's nothing for getting an administrator's attention like a \$2-3million dollar settlement." *Frank Overdyk, MSEE, MD*

"Our expenses on liability aren't anywhere close to anything we've seen published (but) it almost doesn't matter what the average cost is. You could sell this product based on one case." *Nancy Pratt, MSN*

"On average, malpractice expenses are going up 40% per year, so anything that can stem the tide of that growth can really speak to that issue." *Charles Denham, MD*

"Anesthesia premiums have gone from \$30,000 to \$40,000 per year to \$80,000 or so in 1983 dollars. So, I think you are wise in looking at the malpractice insurance side of all this." *Ellison Pierce, MD*

"I can tell you that we've taken a close look at IV medication safety systems. It just hasn't been articulated in a way that it needs to be articulated. If you really measure a fully loaded, enterprise-wide systems impact, I think it's probably got the best business case out there." *Charles Denham, MD*

"I've played a lot with the model, and there are four key inputs. The savings come from the cost of events, though-put, malpractice, and the number of events. Malpractice ends up a distant third, and the biggest variable is the number of adverse drug events that you prevent. A lot of the

business case depends on what that figure is." *David Bates, MD*

"From what I heard today and in the past, there is evidence—evidence from non-randomized trials and retrospective data. It seems like it had a little bit more of a harder or scientific type of a connotation than intuitive." *Jacqueline Sullivan, PhD, RN, CCRN*

"There will be a lot of competition for these scarce capital resources, and I think the ROI evaluations are important. Smart pumps have a good ROI, and two other main benefits are that the ease of adoption and the time to make a difference with smart pumps are very different as compared to any of the other approaches we mentioned." *David Bates, MD*

"I don't think you make a business case separately from a clinical case; I think it's made together." *Kathy Rapala, RN, JD*

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