

THE ALARIS® CENTER
FOR MEDICATION SAFETY
AND CLINICAL IMPROVEMENT

**Critical
Medications:
Using
Technology
to Address
Administration
Errors**

EXECUTIVE SUMMARY

Conference Report
November 7, 2002
San Diego, CA

AGENDA

- 8:00-8:30 Opening Remarks
Critical Medication Administration Errors-
Framing the Problem
David Bates, MD
- 8:30-9:00 Observational Techniques and Findings
What We Know about Critical Drug Administration
Kenneth Barker, PhD
- 9:00-9:30 FMEA and IV Medication Delivery-Identifying the Gaps
in Drug Administration
Philip J. Schneider, MS
- 9:30-9:45 BREAK
- 9:45-10:15 Practice Reality-Nursing Issues in Critical Care
Bernice Coleman, RN, PhD
- 10:15-10:45 Patient Safety Issues in Drug Administration
Kathryn G. Rapala, RN, JD
- 10:45-11:15 Impact of Current Technology
Richard Kremsdorf, MD
- 11:15-11:45 Bedside Safety Software-IV Medication Use
Error Discovery
Mark Sullivan, PharmD
- 11:45-12:15 Return on Investment
John Parker
- 12:15-1:00 LUNCH
- 1:00-1:30 Performance Sourcing
Charles Denham, MD
- 1:30-4:00 Roundtable
- 4:00 Adjourn
- 4:00-7:00 The ALARIS® Center for Medication Safety Grand Opening

SPEAKERS

David Bates, MD
Medical Director of Clinical and Quality Analysis
Brigham and Women's Hospital
Boston, MA

Kenneth N. Barker, PhD
Director, Center for Pharmacy Operations and Designs
Auburn University
Auburn, AL

Bernice Coleman Ph.D RN ACNP-C, CNS/NP
Cardiac Assist Device Program and Cardiac Surgery
Cedars Sinai Medical Center
Los Angeles, CA

Charles R. Denham, MD, CEO
Health Care Concepts, Inc.
Austin, TX

Richard Kremsdorf, MD
Five Rights Consulting
San Diego, CA

John Parker
Executive Vice President
Protocare Sciences
Chicago, IL

Kathryn G. Rapala, RN, JD
Director, Risk Management and Patient Safety
Clarian Health Partners
Indianapolis, IN

Philip J. Schneider, MS, FASHP
Director of Latiolais Leadership Program
Clinical Professor, The Ohio State University
Columbus, OH

Mark Sullivan, PharmD
Clinical Pharmacy Manager
Vanderbilt University Medical Center
Nashville, TN

Inter-Professional Conference Provides Forum for Thought-Leaders to Focus on Critical Errors and Potential Solutions

A conference held on November 7, 2002, at the newly opened ALARIS® Center for Medication Safety and Clinical Improvement in San Diego brought together a distinguished faculty from clinical practice, academia, organizations and government. David Bates, MD, Medical Director of Clinical and Quality Analysis at Brigham and Women's Hospital, chaired the conference. Philip J. Schneider, MS, FASHP, Director of the Latiolais Leadership Program and Clinical Professor at the Ohio State University, moderated the roundtable discussion.

Nationally recognized experts from multiple disciplines focused on critical medication administration errors and potential solutions. In his opening remarks, Dr. Bates said, "If we want to achieve the dream described in the Institute of Medicine report, *Crossing the Quality Chasm*, we're going to need industry to take leadership in ways like this."

PRESENTATION HIGHLIGHTS

Bates Frames Problem of Critical Medication Administration Errors

Noting that safety is a systems property, Dr. Bates began by emphasizing that healthcare systems need to be substantially safer. His 1997 study showed that administration was the stage most vulnerable to error and that serious and life-threatening potential ADEs were most often related to intravenous (IV) therapy. The cost per PADE was approximately \$5,000 per PADE (1993 dollars), and projected annual costs for a 700-bed hospital were \$2.8 million. He noted, "These are the kinds of data that I think we can use to justify investing in prevention efforts."

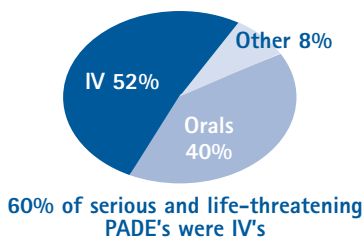
Critical Medication Administration Errors: Case Scenarios

Case 1. A resident physician misplaces a decimal point and orders a 10-fold overdose of morphine in a drip for a premature infant. The nurse administers the medication as ordered; the patient has a respiratory arrest and dies.

Case 2. A physician orders 40 mcg furosemide IV push. The nurse draws up 40 mEq of KCl and gives it push. The patient dies.

Discussing current solutions, Dr. Bates reported that both computerized prescriber order entry (CPOE) and pharmacist participation on physician rounds in the ICU have been shown to reduce errors. Relatively few data are available on bar coding; nonetheless, he felt that there is reason for optimism that this technology also can improve safety.

Distribution of Administration Potential ADEs



ATTENDEES

Roger W. Anderson, DrPH
Head, Division of Pharmacy
M.D. Anderson Cancer Center
Houston, TX

Paul R. Barach, MD
Univ. of Chicago
Anesthesia and Critical Care Medicine
Chicago, IL

Tony Bower, PhD
Project Leader
Rand Corporation
Los Angeles, CA

Dennis Coda, PharmD, FASHP, FASCP
Editor-in-Chief, Hospital Pharmacy
Executive Editor, The Formulary
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Tess Cammack
Associate Vice President, Technology &
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Advanced Medical Technology Association
Libertyville, IL

Cathy Denning, RN, MSN
Senior Clinical Manager-Safety
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Susan Donatelli, RN
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Ray R. Maddox, PharmD
Director of Clinical Pharmacy, Research
and Respiratory Care
St. Joseph's Chandler Health System
Savannah, GA

Roxanne Perucca, MS, CRNI
President, Infusion Nurses Society
Overland Park, KS

Gina Pugliese, RN, MS
Vice President, Premier Safety Institute
Oak Brook, IL

Victoria Rich, RN, PhD
Chief Nursing Officer
Hospital of the University of Pennsylvania
Philadelphia, PA

Peggy Wallace, RN, MSN
Project Manager
Rand Corporation
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Mathew Weinger, MD
Department of Anesthesia
Veterans' Administration Hospital
San Diego, CA

In particular, Dr. Bates noted that intravenous delivery is "a very vulnerable spot. It's hard to detect IV errors, and the true rate, I think, is almost certainly higher than that which we currently know about. These errors have a very high severity level, and it's hard to intercept them if you don't change systems. Just telling nurses to be more careful, does not work. What we need to do is build approaches that help clinicians do what they intend to do and don't rely on training."

His research on safe IV infusion systems focuses on the impact of a smart infusion device with activated Guardrails® Software on error rates, length of stay, and costs for critically ill patients. "Data from continuous quality improvement (CQI) logs from smart pumps and other devices represent an extraordinary resource, a 'treasure trove' that we can mine in our efforts to improve medication administration safety," he said. Dr. Bates has also worked with ALARIS Medical Systems to put together a national consensus group to create standards for dose limits.

Barker Reports Observational Techniques and Findings on Critical Medication Safety

Kenneth N. Barker, PhD, a pharmacy re-engineering pioneer, who introduced the unit-dose medication distribution concept, reported on his studies over many years using direct observation of clinicians to investigate medication errors. He noted that when he began his studies in the 1960s, "We had some promising interventions at hand, such as the new unit-dose concept. So we decided to focus on developing a method of measuring medication error rates so we could move ahead to hypothesis testing, trying out promising solutions and measuring the error rates before and after each solution was implemented during the test period."

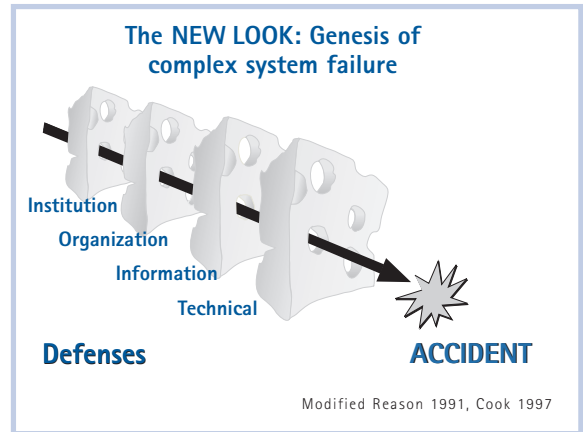
Those studies showed that the overall error rate was 15%, including critical medications. The introduction of a unit-dose system reduced the overall error rate from 18.3% down to 3.3%, which was wonderful, but it proved too expensive prior to the advent of modern computer systems and automation. His 2002 study by observation in 36 health care facilities detected an error rate of 19%, "which might suggest a lack of progress," he said. "But the range was 0-67%, which is encouraging in suggesting that some facilities are learning to do things correctly." A recent study also showed that the IV route of administration had a lower error rate, pointing to the increased attention being given to critical medications.

Schneider Focuses on Identifying Gaps in IV Medication Administration

Professor Schneider discussed how the limits of human performance affect the medication use system and pointed out that new patient safety standards from the Joint

Commission on Accreditation of Healthcare Organizations (JCAHO) emphasize taking a more proactive approach. He noted that a complex-system failure occurs when latent conditions (look-alike drugs, task redundancy, the nursing shortage) and active failures (pick wrong drug, administer drug at wrong dose) align such that an accident occurs.

The challenge is to build defenses into the system to reduce latent conditions and to take human factors into account in designing processes and technology to prevent error. He described failure mode, effects, and criticality analysis (FMECA) as a systematic approach that can identify ways that a process can fail, why it might fail, and how it can be made safer.



"With conventional infusion systems, there is no 'test of reasonableness' at the point of care to validate whether an infusion has been programmed correctly before medication is delivered to the patient," Professor Schneider remarked. "Providing a nurse with an alert if a programming mistake could result in delivery of a fatal dose is one way to acknowledge the limits of human performance and to address one of the latent failures that contributes to patients being harmed."

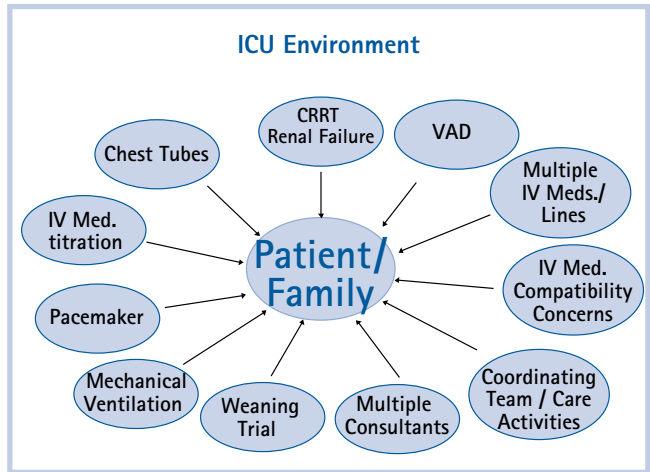
Coleman Emphasizes ICU Nurses' Practice Reality in Critical Care

The impact of the intensive care unit (ICU) environment on IV medication administration was presented by Bernice Coleman, PhD RN ACNP-C, CNS/NP, a clinical nurse specialist with over 25 years of ICU experience. Emphasizing that the patient and family are at the center, Coleman pointed out that ICU complexity includes multiple IV medications, both continuous and intermittent; not enough lines for drug administration; and the need to balance changing care priorities with the needs of the patient, family, physician and ancillary team. The ICU nurse's responsibilities and interventions on patient problems within this dynamic environment have the potential to increase distraction and lead to medication error.

"Nurses in critical care may be the brightest and best," Coleman said, "but ever-increasing technology and patient acuity provide an impressive challenge for the practice of critical care nursing. Our current practice arena requires that nurses manage technology and patient acuity on a minute-to-minute and day-to-day basis, which makes our work

extraordinarily intense. The ICU nursing environment on a given day must have the right number of nurses with the right expertise and skills, ancillary support and amount of time to deliver expert care that meets the needs of our critically ill patients'."

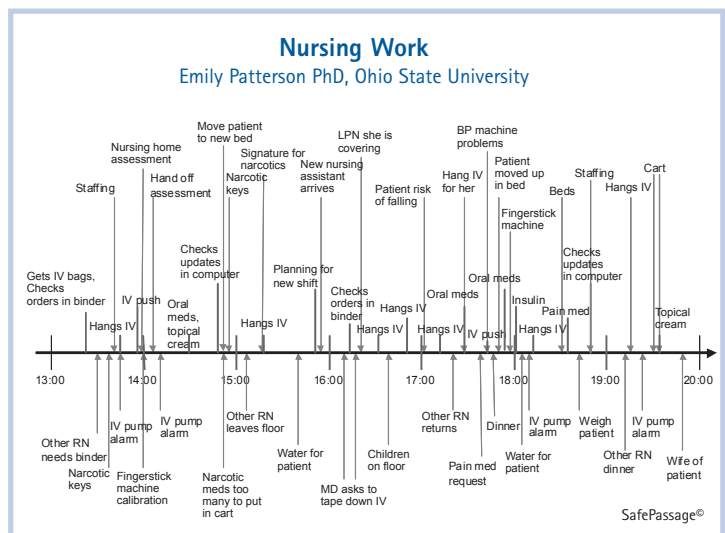
Coleman recommended 1) point of care computerization that provides a double checking system prior to IV medication administration and allows all technology attached to the patient to be interactive and responsive to patient care changes, and 2) an ICU nursing workforce that is adept at managing the technology while protecting the caring environment.



Rapala Compares Legal, Regulatory, and Patient Safety Concerns

Many external factors affect patient safety efforts. Kathryn G. Rapala, RN, JD, a fellow in the American Hospital Association and the National Patient Safety Foundation patient management leadership program, pointed out that the legal system in the United States focuses on identifying who can be held accountable for an error, which discourages open information. Laws vary by state and can encourage or discourage open information.

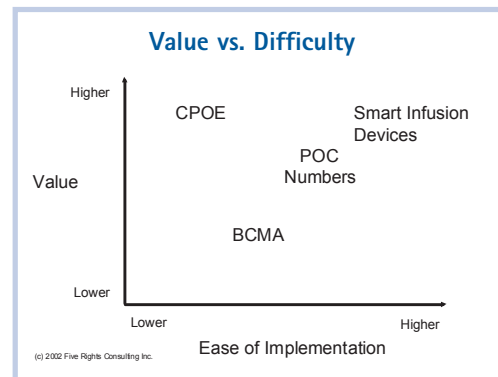
In terms of the regulatory environment, Rapala noted that JCAHO has recognized that errors are not the result of one person and has worked to engage organizations in systems analysis. Increasing demands for the disclosure of any error has proved problematic for many institutions, increasing workload and creating confusion about which approach is best. The complexity of care, including interruptions to a nurse's work, also affects medication safety. Key to preventing medication errors is to focus on the people



who are administering medications or providing care. "Organizations need to create a culture of safety, understand the complexity of the work being performed, and recognize that healthcare is an extremely complex environment," she said. Most of all, organizations have to shift from reacting to errors to being proactive in preventing errors. "Technology and evidence-based practice provide useful tools for improving error prevention," Rapala said. "But it is important to understand the work, so that the technology solution fits the problem."

Kremsdorf Assesses Impact of Current Technology

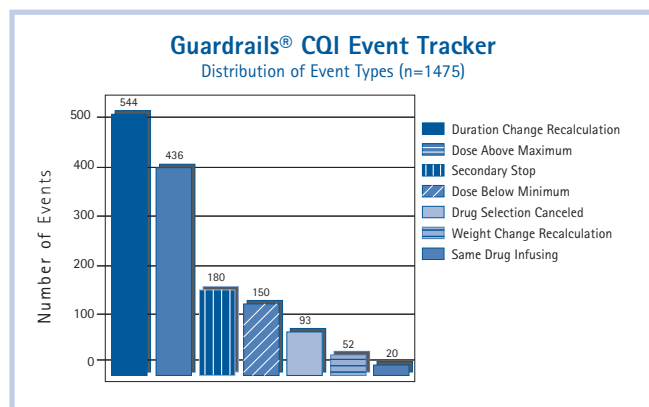
Drawing on his extensive experience in working with large healthcare systems to prioritize their technology investments, Richard Kremsdorf, MD, emphasized the importance of recognizing clinicians' hierarchies of needs. "They want technology that provides them with data such as basic laboratory results, point-of-care (POC) numbers, and the medication administration record, before the more complicated technology such as CPOE," Dr. Kremsdorf said. "Resistance occurs when tools don't match needs, do not make clinicians more efficient, or are missing functionalities."



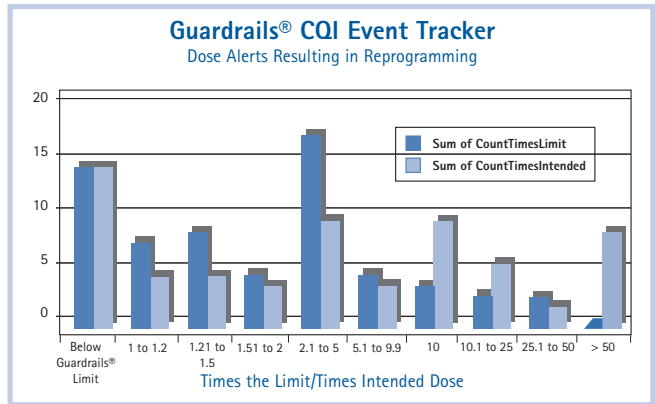
Noting that CPOE and bar coded medication administration offer numerous benefits, Dr. Kremsdorf also pointed out that systems' deficiencies can make implementation difficult. "A technology such as a smart infusion device, which has a high level of value and low difficulty of implementation, has a greater likelihood of being accepted by clinicians and having a positive impact on medication safety, compared with systems such as CPOE which can offer great value but where implementation is complex and challenging."

Sullivan Looks to Integration of Information Technology to Enhance Patient Safety

Mark Sullivan, PharmD, began by focusing on the patient and sounding a note of caution. "Any time you add information technology and changes can occur more quickly, you have more potential to introduce harm into the system," he



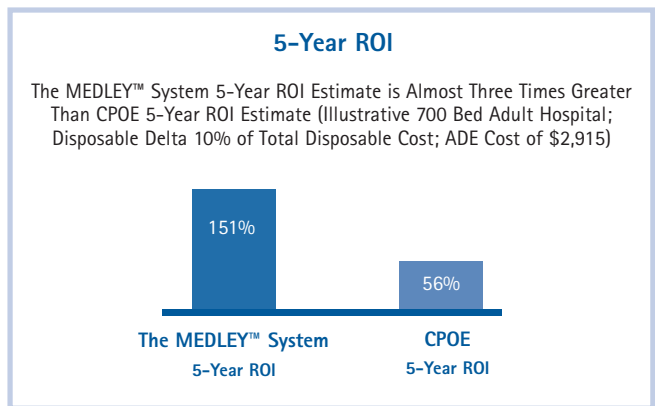
said. "The primary requirement must always be, 'First, do no harm.'" At Vanderbilt University Medical Center, CPOE is integrated with the pharmacy information systems (PIS), so that a certain amount of duplicate function provides greater safety. Computerized tools such as treatment advisories help clinicians evaluate patients and make more informed treatment decisions.



"We wanted to integrate decision support at the bedside, and now we have a tool to do that. We chose the MEDLEY™ System because of the importance of the software in the pumps to prevent medication errors at the bedside," Dr. Sullivan said. "Without any change in practice at the point of care, we now have a whole new trove of data from the pumps to mine for CQI-related issues."

Parker Compares Return on Investment

"With regard to medication safety, clinical issues are obviously paramount, yet economic issues must be considered as well," noted John Parker, Protocare Sciences, in his presentation on the use of science-based analytic software, clinical tools and extensive databases to calculate return on investment (ROI). "Typically, in the mind of a chief financial officer (CFO), the minimally acceptable ROI for capital projects is going to be 20% or 30%—in other words, a fairly high return or even higher, depending on the perceived risk or the certainty of achieving those returns."



"The ROI estimates for CPOE and the MEDLEY™ System are very attractive," he said. "The two technologies are complimentary, not mutually exclusive. The ROI is higher for the smart infusion device, because the upfront costs are lower and you get to the returns almost right away, as opposed to a long implementation period before you start to realize any of the value of CPOE."

"The MEDLEY™ System has the advantage of being highly measurable in capturing actual events that were avoided," Parker said. "For the first time, we can move out of conjecture and into hard data."

Denham Advocates Performance Sourcing

Charles Denham, MD, is founder of the Texas Medical Institute on Technology and the CEO of Health Care Concepts, Inc. He uses performance sourcing, which evaluates cost, impact, and difficulty of adoption, to help healthcare executives invest in safety technology. Dr. Denham cautioned that "Buying technology, by itself, is not enough-as people realize when a huge project, such as a CPOE initiative, fails." Other factors influencing success include best practices, the costs of bringing about cultural changes (training, etc), which typically are one to two times higher than the cost of the technology itself, and system integration. Imaging, lab, CPOE as it applies to medication management, and the smart pump systems all have to work together and have impact on PADEs.

"Then we have to weigh cost, impact, and difficulty of adoption, so that we can generate speed to impact. This is what can persuade CFOs, CEOs, and Boards of Directors, which are investing enormous sums of money into these technologies," he said.

Dr. Denham noted during the discussion, "We haven't found anything like the smart pumps in terms of speed to impact and a well circumscribed area that you can tackle with best practices. If they really do work the way they need to work, we haven't found anything that compares to the impact in terms of lives saved, potential dollars saved, risk management and malpractice."

The ALARIS® Center for Medication Safety and Clinical Improvement

Mission. The mission of the ALARIS® Center for Medication Safety and Clinical Improvement is to raise awareness among health care professionals of the risk of harm associated with critical drug delivery errors and to share clinical best practices to achieve patient and caregiver safety.

Additional Information. Please visit www.alarismed.com or contact:

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ALARIS Medical Systems, Inc. develops practical solutions for medication safety at the point of care. The company's "smart" technology-the MEDLEY™ Medication Safety System with the Guardrails® Safety Software-reduces the risks and costs of medication errors.

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