



# Center of Excellence for Patient Safety Research and Practice



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## **A Controlled Trial of Smart Infusion Pumps to Improve Medication Safety in Critically Ill Patients**

“Smart intravenous infusion pumps” are instruments designed to reduce the number of errors associated with the administration of intravenous drugs<sup>1</sup>. Through the use of drug libraries and point-of-care decision support feedback is given to the clinician regarding overly high or low intravenous infusion rates and doses. In a recent article published in *Critical Care Medicine*, Jeffrey Rothschild, et al, sought to assess the impact of smart pumps on the incidence and nature of medication errors and adverse drug events in critically ill patients.

The study was conducted at Brigham and Women’s Hospital between February of 2002 and December 2002 in two cardiac surgery (CS) intensive care units (ICUs) and two CS step-down monitored units. The new infusion pumps were implemented on these units prior to data collection. The unit staff was trained on the use of the new pumps through computer-based

modules and hands-on practices. The study design was a non-blinded, prospective time series spanning four 8-wk data collection periods. The first and third weeks were control/off periods and the second and fourth weeks were intervention/on periods.

The study’s authors used definitions from previously published ADE research<sup>2</sup>. Medication errors can occur during any stage of the medication use process including ordering, transcribing, dispensing, administering, or monitoring. Adverse drug events (ADEs) are injuries due to a medication. A potential adverse drug event (PADE) or near miss is a medication error that has the potential to cause harm but does not, either due to chance or

because someone intercepts the error. Serious medication errors have the capacity to cause injury and reach the patient.

Smart infusion pumps record all transactions made when using the device. The information can then be downloaded into a computerized log report for quality assurance purposes. Investigators reviewed transactions generated from these log reports to elicit information about possible adverse drug events. Other methods used in identifying events included chart review, solicited staff reports, hospital incident reports, and a computerized ADE surveillance monitor<sup>3</sup>. Data abstraction revealed several unanticipated nursing practice patterns including bypassing of the drug library,

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overrides of warning alerts when judged inappropriate, and undocumented verbal orders for administered medications. The unit of analysis in this study was the patient-pump-day because log reports did not permit capture of the total number of pump medications per patient per day.

The study analyzed a total of 744 admissions (735 patients). Within this cohort, there were 4,276 and 3,869 patient-pump days in the control and intervention periods, respectively. There were also a total of 5,364 and 5,295 intravenous medications ordered in the control and intervention periods, respectively. In the intervention period, the study found 22 ADEs, of which 11 were preventable, and 82 non-intercepted PADEs. In the control period, the comparable numbers were 28 ADEs, and 14 preventable ADEs. Overall, the study found 219 intravenous medication errors. There was no difference in event severity between the control and intervention groups.

As previously mentioned the study found two problematic intravenous administration practices which occurred frequently. One involved the bypassing of the drug library. Here the authors found that 573 infusions (24%) bypassed the library and of those, three were associated with preventable ADEs and 44 with non-intercepted potential ADEs. The second

was the overriding of alerts including the use of inappropriate boluses. This violation resulted in one preventable ADE and 24 non-intercepted potential ADEs. After the study corrected for these violations, the rates of preventable ADEs and non-intercepted ADEs during the intervention would have decreased from 0.28 to 0.18 and from 2.12 to 0.36 per 100 patient-pump days, respectively.

Investigators were unable to conclude from the studies' findings that smart pumps reduce the rate of serious medication errors. The authors theorize that one of the main reasons for the studies inability to render this conclusion may have been attributed to the design of the pump setup during the study period. The original design made it easy for nurses to bypass the drug library. Overrides of pump warnings were also frequent. During the intervention period of the study, consistent use of the smart pumps' new technological safety advances was not achieved. This study revealed important information about correctable unsafe practices. Subsequently, vendors have made multiple advances to the smart pump design and function so that current infusion pumps now provide additional improvements, more safety advances and programming options. A surprising unintended consequence found in this study was the infrequent use

of the drug library. The extra programming for nurses to use the drug library proved to be an important barrier to library use compliance. Most of the reported infusion pump-related events were associated with human error rather than device failure. In order to alleviate this problem, successful adoption and correct use of the pump's safety features is critical.

Another important benefit of the smart pump gleaned from this study was the computerized log recordings of actions associated with the pump. Having these reports available allows for the objective measurement of infusion practices, which can then be used to provide staff feedback. Demonstrable institutional support and behavioral improvements are needed to reduce medication errors. This study provides some examples of how to improve infusion practices. These include nursing and physician education to eliminate undocumented verbal orders, changing the workflow to make it easy to use the library, and including a new pump interface automatically encountering the drug library.

This study was conducted on the cardiac surgical service in a single hospital and may not be generalizable to other critical care settings. Another limitation of the study was that in the absence of direct observation or bar coded medication administration, the study

could not be certain the infused drug matched the medication documented by the nurses. To substantially improve infusion safety, it is necessary to both refine the technologies involved and consider human performance aspects of the new technology.

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## Evaluation of Nationally Mandated Drug Use Reviews to Improve Patient Safety in Nursing Homes: A Natural Experiment

The Centers for Medicare and Medicaid Services (CMS) updated the drug use review protocol of nursing homes in July of 1999. The protocol now includes a list of high-risk medications adapted from the Beers list of potentially inappropriate medications for elderly

adults. Since these inappropriate medications are considered a patient safety concern, Briesacher et al, in a recent article in the *Journal of the American Geriatrics Society*, studied the effectiveness of this policy change in reducing exposure to inappropriate medications in nursing homes (NHs).

The study was conducted over a four-year period between 1997 and 2000 with the guideline expansion implemented in July of 1999. Investigators used Medicare beneficiaries living in NHs (n=2,242) and assisted living facilities (ALFs) (n=664) as the sample population in the study. The new policy was mandatory for NHs, but not for ALFs. Also, based on the 1997 Medicare Current Beneficiary Survey (MCBS) the medication patterns for NHs and ALFs are very similar. Therefore, comparing the incidence and prevalence rates for both allowed the effects of the policy change to be isolated and explored. Using the CMS explicit criteria that were adapted from the 1997 Beers list of inappropriate medications for older adults, the study was able to develop 32 potentially inappropriate medications that were restricted for all NH residents, as well as six for residents with certain conditions. These inappropriate medications were then broken down into various categories by legitimacy. These categories included always avoid, rarely

appropriate, or some acceptable indications.

The results of the study show that for medications considered never or rarely appropriate, the NH rates rose slightly after the policy change, but the overall change was indistinguishable from that of ALFs. Exposure levels for inappropriate medications with some acceptable indications show the rate to be much higher for NHs than for ALFs at the start of the study. The rates steadily decreased over time through the implementation in July 1999 for NHs. However, NH exposure rates rose again towards the end of the study to the same levels as at the beginning. The most inappropriate medication use in this category came from antihistamines.

Exposure rates climbed steadily during the study period for medications restricted for residents with certain diagnoses. The rates rose from 8.1% at the start to 14.7% at the end for NHs and 3.0% to 7.2% for ALFs. The majority of the exposures came from the disease category of seizure disorders/epilepsy. A comparison of prevalence to incidence rates showed that most post-policy Beers criteria use was new use.

This study showed that the expanded drug use review protocol for NHs was ineffective and offered a negligible protection for the

older population from receiving inappropriate medications. The findings also indicated a lack of adherence to the new policy. However, there were factors that may have affected the results such as physicians working in both NHs and ALFs and applying the Beers criteria to both settings, and there are some NHs that do not seek CMS certification. This study reflects the medication exposure of beneficiaries with longer stays because the MCBS does not include all medication use of people who move between residences.

The lack of effectiveness of the new CMS policy showed that difficulties lie in the identification of target medications as well as the determination of consequences for violating the policy. Drug use criteria selection is very challenging because there are many inappropriate drugs that have advocates. Applying the criteria list is also a challenge because it is difficult to find a successful compromise between flexible and mandatory rules. This study provided evidence that CMS drug criteria reviews are ineffective in reducing inappropriate medication exposure to the populations in NHs. Better safeguards must be implemented for safety, financial, and efficiency purposes.

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of Nationally Mandated Drug Use Reviews to Improve Patient Safety in Nursing Homes: A Natural Experiment." *Journal of the American Geriatrics Society*. 2005 Jun;53(6): 991-6.

## **Five Years After *To Err Is Human*: What Have We Learned?**

The Institute of Medicine (IOM) report *To Err Is Human* stimulated a major shift in focus toward patient safety because it reported that as many as 98,000 people die annually as a result of medical errors<sup>1</sup>. Patient safety is now an important concern for many people from health care providers to patients. This article summarizes what has happened, analyzes the reasons why improvement has not been greater, and makes recommendations for what needs to be accomplished to realize the IOM's vision.

This article showed that the effects of the IOM report are evident in three important areas: viewing the task of error prevention, enlisting the support of stakeholders, and changing practices. In viewing the task of error prevention, the IOM report dramatically changed the way that health care professionals and managers think and talk about medical errors and injury. There are very few individuals who now doubt that preventable medical injuries are a serious problem. Also, the concept that bad systems, not bad

people, lead to the majority of errors and injuries has become widely accepted in health care. Interest in patient safety technologies, such as the computer-assisted physician order-entry systems, has increased. Another reason for the increase in attention to patient safety is that active harm, or misuse (errors and defects in treatment), causes the most public interest and emotional reaction than overuse (receiving treatment of no value) or underuse (failing to receive needed treatment).

The second major effect of the IOM report according to this article was to enlist a broad array of stakeholders in order to advance patient safety. The first stakeholder was the federal government, which in 2001 appropriated \$50 million annually for patient safety research. Congress also put the Agency for Healthcare Research and Quality (AHRQ) as the lead federal agency for patient safety. AHRQ has been an important voice for safety through its support for evaluating best practices, demonstrations to enhance reporting of errors, and its development of patient safety indicators and evidence-based test practices. The Veteran's Health Administration has emerged as an important part of patient safety for their safety, research, and training programs.

The article points out a number of nongovernmental organizations that have joined the patient safety revolution. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the National Quality Forum (NQF) are working together to develop and approve measures of quality care, as well as implementing these practices in various hospitals. The Centers for Medicare & Medicaid Services and the Centers for Disease Control and Prevention have worked to reduce surgical complications. The National Patient Safety Foundation has become a major force in increasing awareness, while the Accreditation Council on Graduate Medical Education and the American Board of Medical Specialties are engaged in an effort to define competencies and measures in each specialty. The Institute for Healthcare Improvement has helped hospitals redesign their systems for safety.

Contributions toward patient safety have also come from regional coalitions, which facilitate stakeholders to work together to set goals, collect data, disseminate information, and provide education and training. Purchasers and payers have entered the patient safety arena, particularly the Leapfrog Group. This group has encouraged the adoption of a number of safer practices in hospitals. However, the

most important stakeholders are the thousands of devoted physicians, nurses, therapists, and pharmacists in the hospitals and clinics who have become much more alert to safety hazards.

The third effect of the IOM report according to this article was to accelerate the changes in practice to make health care safe. In 2002, the NQF published a list of 30 evidence-based safe practices ready for implementation. Then in 2003, the JCAHO required hospitals to implement 11 of these practices. A few examples of these practices include improving patient identification, communication, and surgical-site verification. Results of a few large controlled studies of these changes have been done and are encouraging. Another major practice change occurred in teaching hospitals in 2003 when all residency training programs implemented new residency training work hour limitations. These changes were made due to the Accreditation Council on Graduate Medical Education and also knowledge of the direct relationship between fatigue and errors. Significant changes are being made in patient safety, but these changes are local and do not impact national statistics.

This article also highlights barriers to the progress of the patient safety movement. One of the biggest barriers to

progress is the culture of medicine, which can be characterized as a focus on high standards of autonomous individual performance and a commitment to progress through research. This culture has brought profound advances in biomedical science and has delivered cures to millions of Americans. These improvements have created challenges to safety. The first challenge is complexity. This new modern health care requires much more complex and advanced technology than in the past. The second challenge is medicine's commitment to individual, professional autonomy. In order to increase patient safety, medical professionals must change their behavior. Health care providers must adapt to this new non-blaming systems-oriented approach to errors and establishing new lines of accountability. Fear is a third challenge. Many physicians thought that the IOM report would undermine public trust, which would in turn lead to malpractice liability. This fear inhibits doctors' willingness to discuss and admit errors.

Another key impediment to progress depicted in this publication is a lack of leadership at the hospital or health plan level. Despite requirements by the JCAHO and the NQF, few of the chief executive officers and boards of hospitals and health plans have made safety a top

priority. Another barrier is a lack of measures to identify problems, measure progress, and demonstrate improvement. The current reimbursement structure provides another example of an obstacle to improving safety. The current system actually rewards less safe care in many instances. Oftentimes, payers subsidize unsafe care without knowing it. In these situations, physicians and hospitals can bill additional services that are needed when patients are injured by their mistakes.

This article provides information on what needs to be done within the next 5 years to improve and accelerate patient safety. Advances are likely in four areas: implementation of electronic health records, wide diffusion of proven and safe practices, spread of training on teamwork and safety, and full disclosure to patients following injury. Barriers to electronic health records, such as the lack of standards and ensuring interoperability, are being overcome. Now major payers and health care systems realize that this area of patient safety is a financially worthwhile investment. The acceleration of the adoption of safe practices is almost certain now because the JCAHO and several payers have indicated interest in furthering the adoption of the NQF proven safe practices. Since hospitals have become more experienced in making

changes, their capacity to do so will increase. The interest in team training has grown rapidly over the past several years, aided by the adoption of simulation techniques. Finally, the debate over disclosure of injuries to patients is drawing to a close because evidence is being presented that full disclosure does not increase the risk of being sued and few health care organizations question honest disclosure following an injury.

In order to achieve success with these advances, this article comments, a national commitment is needed. More sustained and powerful pressure on hospital boards and leaders from outside the health industry is needed. Public concern, regulation, and reimbursement do provide pressure to change, but fail in the ability to mobilize a large change. A better approach might be to favor in-payment hospitals and physicians who actually achieve levels of safety. It also might be worthwhile to create negative financial consequences, or disincentives rather than financial rewards. The most important single step that should be taken by the United States to align the forces of change would be to set and adhere to strict, ambitious, quantitative, and well-tracked national goals. The article calls upon AHRQ to team up with all of the national groups, as well as all of the major payers to set up goals for patient safety to be

reached by 2010. A couple of starting places proposed by the article include abiding by the list provided by the Commonwealth Fund-IOM and the incorporation of rapid response teams to prevent failures to rescue in hospitals. The United States will not become safe until we choose to become safe.

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### **David Bates, MD, MSc. elected to serve as member of the Institute of Medicine of the National Academies**

**I**n October 2005, Dr. David Bates was one of 64 individuals given the distinguished honor of being elected to serve as a member of the Institute of Medicine of the National Academies. Members of the Institute of Medicine lend their expertise to a wide range of issues in medical science, health services, public health, and health policy.

### **Michael Cohen, M.S. recipient of MacArthur Fellows award**

**M**ichael Cohen, President of the Institute for Safe Medication Practice (ISMP) and CoE Steering Committee member was recently

selected as one of 25 individuals to receive the MacArthur fellowship award. This award is based on the following criteria: exceptional creativity, promise for important future advances based on a track record of significant accomplishment, and potential for the fellowship to facilitate subsequent creative work.

Mr. Cohen has been a leader in the patient safety arena and a champion towards the prevention of medication error and adverse drug events. Mr. Cohen is co-founder of the voluntary, and confidential Medication Error Reporting Program (now administered by U.S. Pharmacopoeia), for medical professionals to learn about and understand the causes of errors.

## Frontline: Patient Safety Publications, Research Projects, and Presentations

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