



# Center of Excellence for Patient Safety Research and Practice



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## Center of Excellence for Patient Safety Research and Practice established at Brigham and Women's Hospital.

In 2001, Brigham and Women's Hospital (BWH), was awarded support from the Agency for Healthcare Research and Quality (AHRQ) to establish a Center of Excellence for Patient Safety Research and Practice.

One of three institutions to receive a project grant, Brigham and Women's hopes to build upon other hospital initiatives to improve patient safety. The Centers' main goal is to improve medication safety across a variety of clinical settings and various patient populations through six research projects. The Center will also widely disseminate its tools and ongoing results of this research at both the local and national level.

The Center of Excellence (CoE) is headquartered at Brigham and Women's Hospital and is directed by Dr. David W. Bates, Chief, Division of General Medicine. The CoE includes collaborative projects with faculty and staff from a number of area institutions including: Massachusetts General Hospital, Harvard School of Public Health, Newton-

Wellesley Hospital, Children's Hospital, McLean Hospital and UMass Medical Center. AHRQ has committed \$5 million of their 2001 patient safety directed funding to support this Center over a 5-year period.



The research projects within the Center include:

*Evaluating Tools that Facilitate Reporting, Surveillance and the Analysis of Medical Errors/Adverse Events;*

*Ambulatory Medication Errors and Adverse Drug Events in Pediatrics;*

*Epidemiology and Prevention of Medication Errors in Psychiatric Inpatients;*

*Safe Intravenous Infusion Systems;*

*Improving Safety with Anticoagulation in the Nursing Home; and*

*The Role of Organizational Culture in Promoting Patient Safety.*

## David W. Bates, MD, MSc. receives John M. Eisenberg Award for Research

Dr. Bates was recently honored with the John M. Eisenberg Award for Research for his extensive efforts in evaluating the incidence and preventability of adverse drug events. Dr. Bates' research continues to be at the forefront of national initiatives to improve medication safety.

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## House passes bill to establish voluntary reporting system

The House of Representatives passed a bill on March 12, 2003 to create a voluntary reporting system for tracking medical errors. According to the Washington Post, the Health and Human Services Secretary would certify a number of public and private organizations as patient safety organizations. These organizations would collect and analyze data on medical errors. Information gleaned from this analysis would then be conveyed back to providers in an effort to implement changes that will improve patient safety.

This new bill promises confidentiality to doctors and hospitals reporting medical errors and provides assurance that this information will not be available for litigation purposes. The Senate has yet to act on a similar measure.<sup>1</sup>

This recent measure is synonymous with a need identified by many involved in the field of medical error reduction. In November of 2002, Dr. Lucian Leape, co-investigator and leader of the Center of Excellence Content and Dissemination Core, examined the role of voluntary reporting of adverse events in a Health Policy Report for the New England Journal of Medicine, Patient Safety Series.<sup>2</sup> In this article Dr. Leape closely examines the role of reporting of adverse events in improving safety and assesses the extent to which current

mandatory and voluntary systems accomplish their goals.

"The primary purpose of reporting is to learn from experience. Many other methods are also used to identify threats to safety, but a good internal reporting system ensures that all responsible parties are aware of major hazards. Reporting is also important for monitoring progress in the prevention of errors. Thus, the reporting of close calls, as well as adverse events, is valuable. External reporting allows lessons to be shared so that others can avoid the same mishaps."

As Dr. Leape notes, external reporting can improve patient safety in the following ways:

- Alerts about new hazards can be generated from even a few reports
- Information about the experience of individual hospitals in using new methods to prevent errors can be disseminated
- Central analysis of many reports can reveal trends and hazards that require attention
- Central analysis can lead to "best practices" for all to follow.

"Current reporting practices fall short of these objectives at every stage. In hospitals, staff members often fail to report incidents primarily because of time pressure, fear of punishment, and lack of perceived benefit. Among physicians, shame and fear of liability, loss of reputation, and

peer disapproval are particularly strong disincentives "

Seven characteristics have been identified as critical features of successful reporting systems. They must be non-punitive, confidential, independent, timely, systems-oriented, responsive, and include expert analysis.

Dr. Leape calls for the development of specialty-based and system wide reporting programs and concludes that "federal legislation to protect shared information from discovery would enhance reporting in all systems and accelerate expansion"

Charles Vincent, Ph.D., examines the issue further in a NEJM, Patient Safety Series Health Policy Report, March 13, 2003 article in which he discusses how clinical incidents should be investigated, how to learn from these incidences and how best to support all those involved; patient, families and staff members. In his article, Dr. Vincent advocates the approach called "systems analysis" over "root cause analysis" when investigating clinical incidences.<sup>3</sup> Dr. Vincent's theory is based on James Reason's organizational - accident model and identifies the various frameworks and contributing factors that often influence clinical practices and contribute to adverse events.

Dr. Vincent states that "systems analyses and support for patients and staff should be absolute priorities in any risk-management and safety strategy."

References:

1 Retrieved from the World Wide Web, <http://www.washingtonpost.com/wp-dyn/articles/A16911-2003Mar12.html>. Retrieved March 14, 2003

2 Leape, LL. Reporting of Adverse Events [Health Policy Report], NEJM 2002;347:1633-1638.

3 Vincent, C. Understanding and Responding to Adverse Events [Health Policy Report], NEJM 2003; 348: 1051-1056.

## **JCAHO Patient Safety Standards – implemented: January 2003**

The Joint Commission of Accreditation of Hospitals recently adopted patient safety measures which all hospitals scheduled for accreditation surveys after January 1, 2003 must comply. The JCAHO patient safety goals were developed based on an Advisory panel comprised of experienced physicians, nurses, pharmacists and other national patient safety experts. In identifying these goals this Advisory group was asked to evaluate the evidence and validity of the Sentinel Event Alert recommendations and to examine the practicality of institutions implementing these recommendations.<sup>1</sup>

The following is a list of the first set of six JCAHO National Patient Safety Goals. Included with this list are the Sentinel Event Alerts examined in providing the basis for each of these recommendations.<sup>2</sup>

### **1. Improve the accuracy of patient identification.**

a) Use at least two patient identifiers (neither to be the patient's room number) whenever taking blood samples or administering medications or

blood products. (Sentinel Event Alert #10 -August 1999 - "Blood transfusion errors- Preventing future occurrences")

b) Prior to the start of any surgical or invasive procedure, conduct a final verification process, such as a "time out," to confirm the correct patient, procedure and site, using active—not passive—communication techniques. (Sentinel Event Alert #24- Jan 2002 Perspectives "A follow-up review of wrong -site surgery")

### **2. Improve the effectiveness of communication among caregivers.**

a) Implement a process for taking verbal or telephone orders that require a verification "read-back" of the complete order by the person receiving the order. Sentinel Event Alert # 19 "Look -alike, sound -alike drug names"- Jul 2001 Perspectives)

b) Standardize the abbreviations, acronyms and symbols used throughout the organization, including a list of abbreviations, acronyms and symbols not to use. (Sentinel Event Alert #23- Medication errors related to potentially dangerous abbreviations- Nov 2001 Perspectives)

### **3. Improve the safety of using high-alert medications.**

a) Remove concentrated electrolytes (including, but not limited to, potassium chloride, potassium phosphate, sodium chloride >0.9%) from patient care units. (Sentinel Event Alert #11- "High -Alert Medications

and Patent Safety"- See JCAHO website)

b) Standardize and limit the number of drug concentrations available in the organization. (Sentinel Event Alert #11- "High -Alert Medications and Patent Safety"- See JCAHO website)

### **4. Eliminate wrong-site, wrong-patient, wrong-procedure surgery.**

a) Create and use a preoperative verification process, such as a checklist, to confirm that appropriate documents (e.g., medical records, imaging studies) are available. (Sentinel Event Alert #24-" A follow-up review of wrong site surgery"- Jan 2002 Perspectives)

b) Implement a process to mark the surgical site and involve the patient in the marking process. (Sentinel Event Alert #24-" A follow-up review of wrong site surgery"- Jan 2002 Perspectives)

### **5. Improve the safety of using infusion pumps.**

a) Ensure free-flow protection on all general-use and PCA (patient controlled analgesia) intravenous infusion pumps used in the organization. (Sentinel Event Alert #15, Infusion Pumps: Preventing Future Adverse Events- See JCAHO web site)

### **6. Improve the effectiveness of clinical alarm systems.**

a) Implement regular preventive maintenance and testing of alarm systems. (Sentinel Event Alert #25, "Preventing ventilator -related death and

injuries"- Apr 2002 Perspectives)

b) Assure that alarms are activated with appropriate settings and are sufficiently audible with respect to distances and competing noise within the unit.<sup>2</sup> (Sentinel Event Alert #25, Preventing ventilator -related death and injuries"- Apr 2002 Perspectives)

References:

1 JCAHO 2003 National Patient Safety Goals  
[www.jcaho.org/accruited+organizations/patient+safety/npsg/npsg\\_03.htm](http://www.jcaho.org/accruited+organizations/patient+safety/npsg/npsg_03.htm) Retrieved Jan 1, 2003

2 NCPS: National Center for Patient Safety: Special Edition: JCAHO Patient Safety Goals 2003;  
<http://www.patientsafety.gov/tips.html>: (Accessed April 10, 2003)  
JCAHO Approves National Patient Safety Goals for 2003; Joint Commission Perspectives. 22 (9), 2002 Sep.

## Patient Safety: Adverse Drug Events in Ambulatory Care

It has become increasingly evident over the past few years that adverse drug-related events occur frequently among inpatients. One study found that 6.5 percent of hospitalized patients had an adverse drug event, and twenty-eight percent of these were preventable. However, little is known about rates in the outpatient setting.

A recent New England Journal of Medicine article, Adverse Drug Events in Ambulatory Care by Gandhi, et al., studied four adult primary care practices in Boston, all of which were affiliated with medical centers.<sup>1</sup>

Two of the practices were hospital-based and two were community-based. One of each type of practice used a computerized system for prescribing drugs and one of each type used a manual system. The computerized system contained required fields (drug, dose, quantity, and duration) and provided printed prescriptions. It did not however offer default doses and did not perform automatic checks for allergies or drug interactions.

Patients were eligible for inclusion in the study if they received a prescription from a participating provider at a clinic visit during the study period. Patients were excluded if their physicians determined they were too ill to participate or if they were unable to speak English or Russian. Patients meeting criteria for eligibility were sent letters describing the study's aim towards helping to improve medication prescribing practices. Patients were asked to participate in a telephone survey at 10-14 days. Patients could actively opt-out of the study either by returning the postcard included with the informational letter sent describing the study or, by declining at the time the survey was initiated by the interviewer. A follow-up interview was conducted three months after the index visit and at which time questions were asked about the patient's symptoms and their overall general health. At the three months interval, a research nurse closely examined the medical records of each study participant. All adverse drug events identified were independently reviewed by two physicians at which time the reviewers determined the

likelihood that the event was related to a medication. The event was classified according to severity and preventability. Severity classification categories included "fatal or life threatening", "serious", or "significant". Events were also classified as "nonpreventable", "preventable", or "ameliorable."

The results of this study showed that "of the 661 patients who responded to the survey (a response rate of 55 percent), 162 had adverse drug events (25 percent; 95 percent confidence interval, 20 to 29 percent), with a total of 181 events (27 per 100patient). Twenty-four of the events (13 percent) were serious, 51 (28 percent) were ameliorable, and 20 (11 percent) were preventable. Of the 51 ameliorable events, 32 (63 percent) were attributed to physicians failure to respond to medication -related symptoms and 19 (37 percent) to the patients failure to inform the physicians of the symptoms."

This study is important because it showed that adverse drug events were found in 25 percent of ambulatory patients, a rate five times as high as that found in another recent study of community living elderly. The reported rate of adverse drug events was felt to be this high because the study involved calling patients directly and asking them about problems with their medications - many of these problems were not recorded in the charts.

Thirteen percent of the adverse events were serious. About one in ten of these adverse drug events could have been completely prevented, and another third could have been ameliorated or made less serious

if they had been addressed more quickly.

The issues around the ameliorable events relate mainly to patient-doctor communication and monitoring for side effects. In two thirds of these ameliorable cases, the physician was informed about the problem but didn't make an appropriate response and in the remaining one third, the patient didn't inform the doctor they were having a problem.

Patient characteristics were not associated with a higher frequency of adverse events but some drug classes carried more high risk, specifically medications to treat depression and high blood pressure.

The prevention strategies that appear most likely to be successful were improving education about side effects, enhancing patient-doctor communication, and implementing computerized prescribing.

The Investigators of this study tried to identify and understand how these events might best be prevented. Their focus was on the systems involved rather than the particular individuals. This study clearly shows that current systems associated with outpatient prescribing could be substantially improved.

<sup>1</sup> **Gandhi TK.** , Adverse drug events in ambulatory care.[comment]. [Journal Article] *New England Journal of Medicine*. 348(16):1556-64, 2003 Apr 17.

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

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**Bates,** David MD, is quoted in the Philadelphia Inquirer, February 4, 2003 and in the Washington Post, February 18, 2003 regarding recent findings from the Annals of Internal Medicine article, The Incidence and Severity of Adverse Events Affecting Patients after Discharge from the Hospital.

**Bates,** David MD is quoted in a recent Wall Street Journal article entitled "The Informed Patient: Intravenous Pumps Can Dispense Deadly Errors." (March 27, 2003). Forster AJ. Murff HJ. Peterson JF.

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**Landrigan,** Christopher recently received a career development award (K08) from AHRQ entitled "Effects of Sleep Loss and Night Work on Patient Safety."

Dr. Landrigan is also serving as Principal Investigator on a grant funded by Medimmune, to study adverse events and medical errors in infants admitted with bronchilitis.

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