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Risk Factors for Adverse Drug Events Among Older Adults in the Ambulatory Setting

In a recent article in the *Journal of the American Geriatrics Society*, Field et al reported the results of a case control study designed to identify patient level factors associated with the risk of adverse drug events (ADEs) in older adults. As the authors point out, older adults are particularly vulnerable to the risk of experiencing an ADE because of the amount of prescribed medications they take. In this study, investigators sought to identify patients at particular risk for an ADE and to develop prevention strategies to reduce this risk in the older population.

Investigators studied patients from a large multispecialty group practice with a patient base of over 30,000 patients over the age of 65. Ninety percent of these patients were enrolled in a Medicare + Choice Plan. The remaining ten percent of patients was comprised of fee for service Medicare enrollees. All persons over the age of 65 receiving ambulatory care

were eligible for inclusion in the study. Residents of long-term healthcare facilities were excluded. The enrollment period extended from July 1, 1999 to June 30, 2000.

The study's authors used definitions from previously published ADE research. These previous studies define an ADE as an injury resulting from the use of a medication. An ADE may result from a medication error or from an adverse drug reaction in which case, no error is involved. Detection methods for identifying possible drug related incidents included: reports from health care providers, review of hospital discharges summaries, review of emergency room visit notes, computer-generated alerts, review of

automated free-text clinic notes and a review of incident reports. A clinical pharmacist employed these detection strategies when performing medical record review. Information derived from this process was then presented to two physician reviewers who classified each event independently to determine if an ADE had occurred. Potential risk factors such as age, sex, comorbidities, and medication usage at the time of the ADE were also assessed by the reviewing clinicians. If an event was classified as an ADE, the physician reviewers also determined the preventability of the ADE. Interrater reliability among the physician reviewers was calculated using the kappa statistic. The kappa value for

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the judgment related to the presence of an ADE was 0.81. (A kappa value of 0.6 to 0.8 reflects substantial agreement and a value of 0.8 to 1.0 is considered nearly perfect) (Field et al, 1350)

The study identified 1,523 ADEs in 1,299 individuals. Subjects who experienced a preventable ADE had a higher score using the Charlson Comorbidity Index and were noted to take more medications particularly in the following categories: nonopoid analgesics, anticoagulants, antidepressants, antineoplastics, cardiovascular drugs, diuretics, antiseizure medications, gastrointestinal drugs, gout treatment, hematological drugs, hypoglycemics, opioids, respiratory drugs, and corticosteroids. Investigators also suggest that being female and over the age of 80, adds to the risk of experiencing an ADE.

Analyzing preventable ADEs separately investigators determined that of the 1,200 subjects that experienced an ADE, 383 patients suffered from at least one ADE that was preventable. Medications associated with preventable ADEs in this study, included nonopioid analgesics, anticonvulsants, diuretics and antiseizure medications.

Anticoagulants and diuretics were associated with all ADEs and as well as those

classified as preventable. Nonopoid analgesic and antiseizure medications were most often associated with preventable ADEs.

By identifying individual factors most likely associated with an increased risk of adverse drug events in the older population, researchers hope to support interventions designed to prevent the occurrence of ADEs as well as improve the response to those individuals who may have suffered an adverse drug event so as to ameliorate the effects.

The studies' authors advocate periodic review of older person's medication regimens and the indications for usage. Preventative efforts should be focused on patients with multiple medical conditions as well as those on multiple medication regimens that include nonopioid analgesics, anticoagulants and anti-seizure medications.

Study investigators propose one way to combat the incidence of ADEs is through the use of computerized prescribing (CPOE) and monitoring. Since these patients are often seen in the ambulatory setting, developing a connection between CPOE and computerized patient files is needed so that this target population can be identified as a higher risk group.

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Field T, Gurwitz JH, Harrold L, Rothschild J, Debellis KR, Seger AC, Auger JC, Garber LA, Cadoret C, Fish LS, Garber LD, Kelleher, M, Bates DW. "[Risk Factors for Adverse Drug Events Among Older Adults in the Ambulatory Setting.](#)" J Am Geriatr Soc. 2004;52(8):1349-1354.

Lucian Leape. M.D. Recipient of 2004 John M. Eisenberg Patient Safety Award for Individual Lifetime Achievement

The National Quality Forum (NQF) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) announced the 2004 recipients of the annual John M. Eisenberg Patient Safety Awards. **Dr. Lucian Leape** of the Harvard School of Public Health and Director of the Content and Dissemination Core for the Center of Excellence for Patient Safety Research and Practice received this award in the category of Individual Lifetime Achievement.

According to statements by the JCAHO, Dr. Leape was honored for his "fundamental conceptual contributions to contemporary understanding of the nature of medical errors and the extent of the patient safety problem, and for his tireless efforts to improve the safety of care for all patients."

Reference: Schyve P. "[An Interview with Lucian Leape.](#)" Jt Comm J Qual Saf. 2004;30(12):653-8.

Improving Patient Safety Across a Large Integrated Health Care Delivery System

Allan Frankel, Tejal Gandhi and David Bates discuss creating a patient safety strategy for a large integrated healthcare system in an article published in the *International Journal for Quality in Health Care*.

In this article, three dimensions for improving patient safety are discussed. These include *culture change*, *process change*, and *process measurement*.

The authors point out that one of the main objectives in creating change within an organization is to create a level of transparency where providers and patients can confer openly about how care is rendered. Developing such dialogue helps to identify and mitigate system flaws when they occur. The hospitals leadership's ability to grasp and understand the elements of patient safety are key components in helping create culture change and thus establishing a culture of safety. There has been much discussion in the literature as to what is the most effective way to create change within an institution's existing culture and once established, how to determine when this change is effective.

Process change involves the standardization and consolidation of medical processes and protocols. Standardization helps to reduce variations in clinical care thus reducing the opportunity for errors to occur. Often times, process change involves implementation of a new technology to help regulate an approach to how care is administered.

As institutional leaders at Partners Healthcare moved forward with efforts to create a patient safety program they first established the position of the Partners Patient Safety Officer. The Patient Safety Officer's primary responsibilities are to educate healthcare providers, identify process liabilities, and outline procedures to solve patient safety problems. The hospital then formed The Patient Safety Advisory Group and the Partners Safety Officer Leaders Group to complement and help provide guidance to the Patient Safety Officer role. The Partners Patient Safety Officer Leaders Group is comprised of individuals charged with monitoring patient safety in their own individual institutions. Each of these groups convene regularly to share patient safety strategies and to develop further methods to prevent medical errors, both within the realm of culture change and process change.

The authors point out that one of the main challenges in creating a patient safety program in a large integrated healthcare system is the ability to integrate change at a number of hospitals. In order for changes to be made across the entire healthcare system, each new strategy is first introduced in one hospital, and if the results prove beneficial, the program is systematically introduced to other facilities.

Various methods were used to promote *culture change*. The primary method involved Executive WalkRounds. First devised by the Institute of Healthcare Improvement, Executive WalkRounds effectively involves senior leadership in patient safety. The program consists of getting key hospital figures, including the Chief Executive Officer, to make rounds with the Patient Safety Manager. Together, these key individuals tour different areas of the hospitals to get a first hand view of how care is delivered while eliciting information from those on the front-line responsible for providing care to patients on a daily basis. This group not only talks with healthcare personnel about their individual work with patients, but also uses the WalkRounds opportunity to educate staff on the various elements of patient safety. After touring the individual clinical area, the Walk Round executives then meet to develop a prioritized list of

problems requiring immediate attention. Appropriate personnel are assigned ownership of these issues to help achieve resolution. Feedback is then given to staff that raised the concerns during the WalkRounds process.

Patient safety leaders also attempt to foster *culture change* by using accountability principles to improve reporting of medical error among health care providers. A new incident reporting system was designed to insure confidentiality for those who report an error but at the same time does not impede other processes for monitoring providers by the institutions.

Implementing “Safety Briefings,” (brief conversations between doctors during common “transitions in care.”) attitudinal surveys, new orientation strategies that emphasize patient safety during new and current employee training, and new education processes for health care providers are other measures currently being considered to promote culture change in an attempt to reduce medical error.

The Partners Patient Safety program chose to focus on three clinical areas in an effort to standardize care through the use of *process change*. These efforts included anticoagulation

management, placement of central venous catheters, and computerized physician order entry (CPOE).

A multidisciplinary group including physicians, nurses and information technology specialists convened to discuss how best to centralize information about patients and their anticoagulation status and how to streamline the steps required in managing patients anticoagulation needs thus decreasing the opportunity for error. The group is working to develop a new software program that will consolidate information about patients to improve the efficiency of managing anticoagulation and make this information available in all areas of the healthcare delivery system. This information would help support clinicians who care for patients in large warfarin clinics as well as clinicians who see patients in traditional office practice settings.

The use of point-of-care blood testing devices to measure the international normalized ratio (INR) is also being tested as an alternative to the standard method of sending a blood sample to the laboratory. Point of care testing aims to also help reduce the steps required in the anticoagulation management process. Partners Healthcare is also working with regional visiting nurses associations (VNA) to develop

ambulatory clinic- based models to manage anticoagulation using point of care testing.

Experts at Partners Healthcare have also launched efforts to educate practitioners about best practice guidelines for central venous catheter insertions. (CVC). This effort is aimed at reducing the incidence of blood stream infections resulting from this process.

The Partners organization has promoted the use of CPOE, which has already been shown to reduce the amount of serious medication errors. This technology currently exists in two of the large teaching hospitals Within the Partners system. Citing the substantial safety benefits of CPOE, the Partners Safety Advisory Group has recommended to Partners leadership the adoption of this technology in other institutions. The Partners leadership has made a commitment to implement CPOE in all Partners institutions over the next few years.

Additional ongoing projects aimed at implementing process change involve training doctors with simulators and providing other methods of computerized data entry.

One example of process *measurement* includes utilizing a universal reporting

method, which would be secure, fast, and easy to use. The issue of improving patient safety continues to incorporate new ideas and help fund new research.

These authors along with other members of the Partners Patient Safety program and members of the Center of Excellence for Patient Safety Research and Practice continue to work alongside the staff and leadership of Partners Healthcare to study and advance new ideas in patient safety.

Reference:

Frankel A, Gandhi TK, Bates DW. ["Improving patient safety across a large integrated health care delivery system."](#) International Journal for Quality in Health Care Vol 15; Supplement 1:i31-40.

Patient Safety Imperative: First Annual Harvard CME Course on Patient Safety

The first annual Harvard CME course focusing on Patient Safety was held on October 25th at the Boston Marriot Hotel. The course provided a comprehensive update and review of medical error and patient safety and featured internationally renowned experts in the field of patient safety. David Bates, MD and Saul Weingart, MD co-chaired the event that was sponsored by Brigham and Women's Hospital and Beth Israel Deaconess Medical Center in

Boston. The course was comprised of various lecture topics related to this study and breakout sessions that allowed for more interactive learning. The goal of the program was to provide clinicians with the information and tools needed to improve care provided to patients and to help individuals serve as patient safety leaders within their own communities and institutions.



(Mr. Soshnick talking with Dr. David Bates. Excerpt from *Patient Safety* a special that previously aired on PBS. Courtesy of the Healthy Body, Healthy Mind Network)

In Memory of Julian Soshnick, Patient Safety Advocate and Center of Excellence Benefactor

It is with great sadness that we convey the loss of Mr. Julian Soshnick. Mr. Soshnick was director and former long-term officer at Analogic Corporation. He passed away Sunday, August 8, at his home in Rockport, Mass. He is survived by his wife Martha, his children JoAnne and Jeffrey, and his granddaughter Ella.

Mr. Soshnick was actively involved in the establishment of Analogic Corporation, a leading developer and manufacturer of advanced medical and security imaging equipment. He was appointed Vice President of the company in 1982. Even while battling cancer, Mr. Soshnick lent his time and talent in assisting the Center of Excellence's efforts towards educating the public about the importance of improving patient safety. Mr. Soshnick participated in a televised special on patient safety directed by the Healthy Body, Healthy Mind network. This program aired on several Public Broadcasting Stations nationally in 2004. Through the generosity of Mr. Soshnick and his wife, the Center continues to research and develop interventions aimed at improving patient safety in various clinical settings.

Researchers Investigate Barriers to CPOE Adoption

In a recent article published in *Health Affairs*, Eric Poon, David Blumenthal, Tonushree Jaggi, Melissa M. Honour, David Bates, and Rainu Kaushal identified the most common barriers to hospital implementation of computerized physician order entry (CPOE).¹ Furthermore, they proposed strategies for overcoming these barriers.

Previous articles had established the need to improve patient safety and the effectiveness of CPOE at meeting this need.² The Institute of Medicine's report "To Err is Human" estimated that, medical errors account for approximately 98,000 deaths per year.³

Computerized order entry has proven to be effective in reducing medication errors by 55 percent. (Poon et al. 184) However, despite these results, only a small percentage of hospitals currently have this system in place. If CPOE reduces errors, why have only 10-15 percent of hospitals adopted this technology? To answer this question, Dr. Poon and his colleagues conducted interviews with high-ranking officials from various hospitals that were in different stages of implementation of CPOE to address the challenges many institutions face in adopting CPOE and ways to overcome these. They classified hospitals into five categories ranging from full implementation to no implementation, and called hospitals at random from within these groups. Interviews with up to three hospital managers lasted one half-hour each.

From their data, the researchers identified the three most important barriers to CPOE implementation: "physician and organization

resistance," "high CPOE cost and lack of capital," and "product/vendor immaturity" (Poon et al, 185, 187,188). They also asked the executives to comment on strategies to overcome these barriers.

First, the executives reported resistance to CPOE by physicians who are hesitant to abandon traditional paper-based systems and worried that CPOE will limit their workflow. To overcome this barrier, the article suggests strong leadership and modeling of CPOE use by management to demonstrate the hospital's commitment to the system. Furthermore, strong support staff can ease the transition and address workflow problems. After the transition period, the article argues, workflow will improve over traditional paper-based systems.

The second barrier raised by the executives was the cost of CPOE systems. Since there is no viable business argument for CPOE, cash-strapped hospitals have difficulty justifying the considerable cost. The article claims that CPOE is a worthwhile investment for hospitals whose top priority is patient safety. Furthermore, the authors speculate that external funding sources such as the government and insurance companies could provide financial incentives for CPOE implementation.

The final barrier identified by the authors from their interview data was the immaturity of software products. Hospitals are wary of investing in a software product that lacks a proven record of success. The authors propose the development of a "standardized toolkit to evaluate products functionality and reports on vendors' track records" to help hospital officials select reliable products. (Poon et al, 189)

In their discussion, the authors were surprised to find that physician resistance was often of greater concern to hospital administrators than the cost of CPOE implementation. They encouraged hospitals to "mitigate the cost barrier by refocusing their priorities on patient safety" (Poon et al, 189). Finally, the authors called on external policymakers to introduce political and financial incentives for CPOE adoption: public pressure to improve patient safety could convince hospitals to invest in CPOE.

The authors express hope that their research will inform hospital administrators and external policy makers about CPOE implementation and propel this effective patient safety instrument into more hospitals.

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