

Medication Errors: a Growing Problem?

(3/25/08)- According to The Wall Street Journal (March 5, 2008): "Hospitals in the U.S. are stepping up measures to monitor high-alert medicines -- including sedatives, pain relievers, and treatments for diabetes and blood clots -- to reduce misuse. Aside from investing in bar coding and other systems to verify medication orders, hospitals are also collaborating with drugmakers to improve drug packaging. Some health facilities have created "behavioral accountability" standards to address human error in medication mishaps."

According to Allen T. Shaugnessy, PharmD, Tufts University Family Medicine Residency at Cambridge Health Alliance, Malden, MA, the Beers criteria have become the de facto standard for evaluating drug prescribing in older patients. The Beers criteria is based more on expert criteria rather than firm outcome data. The original Beers criteria study was reported in 1991 and updated in 1997. A later updated study was completed in 2003 by Fick et al. (including Beers). The latter study "identified 48 individual medications or classes of medications to avoid in older adults and their potential concerns and 20 diseases/conditions and medications to be avoided in older adults with these conditions. Of these potentially inappropriate drugs, 66 were considered by the panel to have adverse outcomes of high severity."

The 1991 Beers study "used a two-round survey, based on Delphi methods, with 13 nationally recognized experts to reach consensus on explicit criteria defining the inappropriate use of medications in a nursing home population. The criteria were designed to use pharmacy data with minimal additional clinical data so that they could be applied to chart review or computerized data sets. The 30 factors agreed on by this method identify inappropriate use of such commonly used categories of medications as sedative-hypnotics, antidepressants, antipsychotics, antihypertensives, nonsteroidal anti-inflammatory agents, oral hypoglycemics, analgesics, dementia treatments, platelet inhibitors, histamine2 blockers, antibiotics, decongestants, iron supplements, muscle relaxants, gastrointestinal antispasmodics, and antiemetics."

This original article has been cited in 46 other studies of prescribing inappropriate medicines (PIMs) that this author was able to find in a quick search using Google.

Recent studies including Gallagher et al. conclude that "IP (PIMs) is highly prevalent in acutely ill older patients and is associated with polypharmacy and hospitalisation (sic). However, Beers' Criteria cannot be used as a gold standard as they do not comprehensively address all aspects of IP in older people." Jano & Aparasu concluded: "There is evidence that Beers' criteria of inappropriate medication use is associated with adverse healthcare impact in the community-dwelling elderly. With increasing use of Beers' criteria as quality-of-care measures, there is a need to strengthen the predictive validity of these criteria in all healthcare setting." Under the heading "Data Synthesis" they state: "Most of the 18 studies [they] evaluated were retrospective cohort studies involving patients 65 years of age or older from diverse healthcare settings.

In community settings, there was no evidence of association with respect to mortality and other healthcare use, and evidence regarding quality of life and costs were inconclusive. However, inappropriate medication use was associated with hospitalization measures in community elderly. In nursing homes, there was no evidence of association with mortality and the association with hospitalization measures was inconclusive. In hospitals, there was inconclusive evidence to make any generalizations. Across healthcare settings, inappropriate medication use was associated with adverse drug reactions and costs but not with other outcome measures." The health care setting appears to be an independent variable that effects appropriateness of the physician prescriptions. Physicians may not be fully cognizant of the potential interactive effects of the prescribed medications

Individuals over 65 years of age are the heaviest users of prescription drugs. Adverse drug events (ADEs) occur in older adults. ADEs occur in up to 6.5% of all hospitalized patients and outpatients, and about 28% of these events are preventable. The proportion of outpatients with an ADE ranges from 5% to 35%, depending on the exact definition used. There is a critical need to examine the risk factors associated with having an ADE to increase awareness about medication safety among older adults (See: Oladimeji et al).

It would seem essential that the Beers criteria be subject to a wide ranged evidence-based outcome study that would give greater predictive power to the criteria than its present consensus validation. Of equal importance, the medical profession must use the information tools available to enhance their knowledge of drug interactions, especially in such a vulnerable group as the elderly.

References;

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(2/23/08)- Prescription drug abuse-using medication for non-medical reasons- is on the rise in the U.S. across all age groups. In 2006 more than 16 million Americans aged 12 or over reported non-medical use of prescription pain relievers, tranquilizers, stimulants or sedatives, up from 14 million in 2004, according to

the Substance Abuse and Mental Health Services Administration (SAMHSA).

There were nearly 600,000 emergency room visits in 2005 that involved non-medical use of prescription or over-the-counter medicines or supplements, according to SAMHSA, and the majority of them involved patients taking more than one medication.

The most commonly abused groups of medications are the opiod or narcotic painkillers, such as OxyContin or Vicodin, stimulant medications such as Adderall and Concerta, and sedatives for sleep or anxiety, such as Xanax.

Fatal poisonings resulting from high concentrations of prescription medications are also increasing. From 1999-2002 poisonings by opiod painkillers rose more than 90% to 5,592 deaths,, and in 2002 there were more deaths form painkiller poisoning than from heroin or cocaine use, according to a study released in 2006 by the Centers for Disease Control and Prevention.

New findings from the Joint Commission on Hospital accredidation show that using abbreviations when writing prescriptions led to a 4.7% error rate between 2004 and 2006 and that hospital compliance with the commission's "do not use" abbreviations list fell from 75% to 64% over the same period. (*Modern Health Care*, August 2007)

(3/08/07)- Young children are the most likely victims of surgery-related medication errors according to a recently released study, from of the U.S. Pharmacopeia, , the Uniformed Services University of the Health Sciences in Bethesda, Md., and two nurses' associations. Diane Cousins, a health care specialist at USP was the lead author of the study.

To find out more about the U.S. Phamacopeia, please see our article, "The U.S. Phamacopeia (USP) and Medication Errors", and "Seals of Approval".

This study analyzed 11,000 mistakes that had been voluntarily and anonymously reported to the phamacopeia by hundreds of hospitals since 1998. The study was confined to errors made on patients undergoing surgery, and the rate of harm, 5% was much higher than is typical for medication errors. Among children it was 12%.

Most of the errors involved painkillers and antibiotics. Typical dangerous mistakes were failures to administer antibiotics before surgery, failures to note allergies, errors in setting pumps that dispense blood thinners or painkillers, and giving overdoses to infants.

The report made 42 recommendations, among them that hospitals improve communication and designate a pharmacist to be consulted for each patient.

(1/8/07)- On January 2nd, 2007 Jane Brody had a very interesting article in her Personal Health column entitled, "To Protect Against Drug Errors, Ask Questions".

"Medication errors are among the most common medical mistakes, injuring or killing at least 1.5 million people a year and incurring at least \$3.5 billion a year in extra hospital costs alone, according to a report issued in July by the Institute of Medicine of the National Academy of Sciences. This was the institute's second report on the subject, and the committee that compiled it stated that insufficient progress had been made since its first report, "To Err is Human," was issued in 1999."

The column went on to quote Linda R. Cronenwett, dean of the School of Nursing at the University of North Carolina in Chapel Hill, and co-chairwoman of the institute committee: "We need a comprehensive approach to reducing these errors that involves not just health care organizations and federal agencies, but the industry and the consumer as well."

How many times have you received a prescription from your doctor, looked at it, could not make it out, and then just given it to the pharmacists? You may know for example that it is cholesterol-lowering medication, but you can't make out the doctor's handwriting, so you blindly pass it along not knowing if the medication is going to be properly read by the pharmacist. Ask your physician to write the name of the prescription drug on a separate piece of paper from the one on which the prescription is written, so that once you pick up the drug, you can be sure it is the same thing.

Tell your doctor all the drugs and supplements that you are taking so that he/she can be sure that there will not be any adverse reaction to the drug being prescribed.

(11/28/06)- Elderly patients who are prescribed several prescription drugs are more likely to take them if pharmacists provide them in daily packets rather than individual bottles according to a study that was done at the Walter Reed Army Medical Center in Washington. The results of the study were presented at the annual scientific meeting of the American Heart Association held in Chicago this year.

The study found that medication compliance increased sharply among patients who stayed on a program that involved education and regular meetings with a pharmacist as well as having monthly supplies of pills dispensed in a so-called blister pack. Each day's medications were contained in an individual packet, labeled according to day and time.

Allen J. Taylor, chief of cardiology at Walter Reed was the author and principal investigator for the study.

(11/8/06)- A coalition of health-care purchasers, quality groups and governmental agencies working with the National Quality Forum (NQF), have agreed to endorse a single set of 30 "safe practices" that all hospitals should use to prevent death and injury to patients. The agreement resulted from the landmark Institute of Medicine report in 2000 entitled "To Err is Human," which found that as may as 100,000 patients die each year as a result of medical mistakes.

The public has until November 14th to comment on the practices that are discussed in the proposal. When the NQF issues the final safe practices guidelines, it will include examples of programs hospitals can use to train staff to convey difficult information to patients, discuss end-of-life care and disclose bad outcomes.

Among the groups that advised the committee to create the new measures are the Leapfrog Group, a coalition of large employers that surveys hospitals on safety and quality measures; the hospitals on safety and quality measures; the federal Centers for Medicare and Medicaid Services; the Joint Commission on Accreditation of Health Care Organizations, the leading hospital accrediting body, and the Institute for Healthcare Improvement, a nonnprofit group which leads hospitals in safety collaborative programs. Provides such as Kaiser Permanente also participated in the effort.

Medicare and private insurers are expected to use the safety program in "pay-for-performance" programs that provide incentives for compliance. Hospitals that fail to comply risk losing credentials they need from the Joint Commission to be reimbursed by Medicare and Medicaid, and also from the private insurers.

(10/28/06)- The results of an ongoing governmental study shows that harmful reactions to medications send more than 700,000 Americans to emergency rooms each year. People 65 and older faced more than double the risk of requiring emergency room treatment, and were nearly seven times as likely to be admitted to the hospital than younger patients.

The study's database included 63 nationally representative hospitals that reported 21,298 bad drug reactions among adults and children treated in emergency rooms during the period from 2004 through 2005.

The project was developed by the federal Centers for Disease Control and Prevention, the Food and Drug Administration and the U.S. Consumer Product Safety Commission.

The medicines most commonly associated with the adverse reactions included insulin for diabetes; warfarin, and anticoagulant and amoxiicillin, and antibiotic used for many infections.

(7/25/06)- Medication error continue to plague our medical system according to the latest report released by the Institute of Medicine of the National Academies (IOM). The report, "Preventing Medication Errors" found that medication errors harm 1.5 million Americans each year at a cost of at least \$3.5 billion annually. Several thousand deaths each year are due to medication errors.

The report is the fourth in a series done by the institute, with the first report having been released in 1999 entitled "To Err is Human". That report estimated that medical errors of all sorts led to as many as 98,000 deaths each year, which is more than was caused by highway accidents and breast cancer combined.

Charles B. Inlander, president of the People's Medical Society, a consumer advocacy group, and an author of the most recent report stated that only about 6% of the nation's hospitals have medication computer-entry systems.

The report urged that all prescriptions be written electronically by the year 2010. Just 3% of hospitals have electronic patient records, according to Henri Manasse, chief executive of the American Society of Health-System Pharmacists. The report went on to call for tighter restrictions in connection with the free samples that are given to doctors by the pharmaceutical companies.

The report criticized the drug companies for failing to reveal all the results of the clinical trials of their drugs. The report also stated that every week four out of five adults in this country take at least one medication. A third take at least five different medications.

The report also called for the government to spend about \$100 million in research to determine the best and most cost-effective measures to eliminate this problem. It found that confusing drug labels and packaging are responsible for one-quarter to one-third of medication errors, including 30% of all medication-error deaths.

(2/8/06)- The Food and Drug Administration has promulgated new label rules that will apply to all new drug approvals, to drugs approved within the last 5 years, and to any drug for which a major label revision is requested. Older drugs will avoid the new rule. The new rules phase in over 7 years for drugs that have been approved in the past 5 years. The changes are voluntary for drugs that were approved more than 5 years ago.

About 300,000 people are injured and almost 100,000 are killed each year because of medication errors according to some recent studies. Studies have also shown that only one in ten doctors routinely read drug

labels. Drug agency officials estimate that the nation spends \$4 billion to \$4.8 billion on medical errors that could be avoided "through measures that provide better information to doctors, such as prescription drug labeling."

The highly detailed pages of print ad in newspapers and magazines will be replaced by clearer statements about a drug's risks. Television ads will also have to change when they discuss a drug's risks. Drug labels will for the first time have a highlights section that summarizes the vital information needed to prescribe a drug safely.

The new section will first list safely warnings and then summarize any recent changes. There will be a new section telling doctors what they have to tell their patients about the drug. Advice as to how to use and dose the medication will be included in the label.

The new rule does not affect the drug information sheets that patients routinely receive when they get the medication in their package for the drug. The new rules have been under review for more than 5 years and is the first major change to drug labels in 25 years. It affects the accordion inserts included with some boxed prescription drugs.

In a preamble to the new rules, it is stated that they pre-empt, or supersede state liability statutes.

(6/10/05)- Illegible handwriting is not the only reason for prescription errors. Sometimes the prescription itself may be an erroneous one. According to a study published in the American Medical Association's Archives of Internal Medicine decision checks for support such as checks for drug allergies and interactions between medications should be available also to insure that the prescription is a correct one.

More sophisticated decisions on drug interactions and dosages should be available in this modern era or technology that we are in today. In a study that was done at the VA Medical Center in Salt Lake City over a 20-week period in 2000, the VA found that more than half fo 937 patients studied experienced significant "adverse drug event," defined as injury resulting from the use of a drug.

So far only 5% to 10% of hospitals have invested in "computerized order entry systems", which can cost from \$8 million to \$12 million

(6/4/05)- One of the most frustrating things that happens to patients and the administrative staff of a medical facility is the need to constantly give and check up on whether or not the patient is covered for the health-care costs that he/she may be incurring. A consortium of different health-care providers is hoping to come up with an electronic solution to this problem.

The consortium named the Council for Affordable Quality Healthcare (CAQH) is attempting to hammer out a set of interoperable rules for exchanging health benefit and eligibility information. The group includes such disparate organizations as the health-insurance company Aetna Inc., the HMO Humana Inc., some of the biggest Blue Cross and Blue Shield plans and the federal Centers for Medicare and Medicaid Services (CMS).

Once information-exchange standards are established medical technology information companies will take over to provide the needed software to make the program work. According to a survey conducted for the Medical Group Management Association, a physicians practice that contains 10 physicians spends about \$39,000 annually to verify coverage eligibility. Very frequently health-care coverage is denied and the staff

has to spend many frustrating hours on the phone or on the computer trying to straighten out the coverage problem.

(11/24/04)- The results of two recently released studies shows that hospitals are making fewer errors, but still fall short on their safety results. The results of the first Hospital Quality and Safety Survey that was done by the Leapfrog Group, a consortium of major U.S. employers, shows that only 21% of the hospitals surveyed were fully compliant with the 27 safety practices developed by the National Quality Forum, a nonprofit group created to develop a national strategy for health-care quality measurement and reporting.

In the other report, which came from the Safe Medication Practices, a nonprofit group that surveyed 1,600 hospitals that responded, it found that "significant headway" in avoiding medication errors. This group conducted its first survey on this topic in 2000, so it is able to compare the progress of lack of progress over the last few years. The survey showed a 20% overall increase in hospital implementation of its safe practice recommendations. But the survey continues to show that drug names and packaging still often lead to mixups, and that the federal government has yet to develop new standards for design and labeling of drugs in order to prevent errors.

Both of these surveys were voluntarily completed by the hospitals involved in the final tallies. The surveys are a direct result of the report from the Institute of Medicine which came out in 1999 showing that an estimated 98,000 people die from medical errors in the U.S. each year, and an estimated 7,000 of those deaths were from medication errors. You can find the Quality Index results of the Leapfrog study at www.leapfroggroup.org. The index shows the results of the hospitals compliance with the 27 procedures used to indicate what the hospital is doing to reduce medication errors.

The Leapfrog study shows that 80% of the responding hospitals have put procedures in place to avoid operating on the wrong body parts, and 70% now require a pharmacist to review all medication orders before a drug is given. The study goes on to show that 50% of the responding hospitals do not have procedures in place to prevent bed sores, and 70% do not have a protocol for ensuring adequate nursing staff. Four in ten do not have policies requiring workers to disinfect their hands before and after seeing a patient.

For more on this topic please see our article: <u>Drug Resistant Bacteria and the Importance of Cleanliness.</u>

(8/7/04)-In a study done by Health Grades Inc., a health-care-consulting firm in Colorado, it was concluded that medical errors contributed to the deaths of over 600,000 patients over the last 3 years. Health Grades estimated that an average of 195,000 patients a year died from preventable hospital errors.

The Health Grades study was based on data from 37 million Medicare patients over 65 years of age in every state of the union. The study also concluded that many of the solutions now proposed for the problem-such as computerized physician order entry and electronic medical records-won't prevent the majority of such errors.

The majority of patients who died in the study were taken from a medical coding called "failure to rescue", which refers to errors in diagnosing or treating illnesses that occur after an operation, such as pneumonia. This diagnosis makes it impossible to determine if the deaths were due to preventable errors. If hospital errors were counted by the Centers for Disease Control as a cause of death, they would rank sixth, ahead of diabetes, influenza and pneumonia.

The FDA's Office of Drug Safety is reviewing a number of its policies on packaging and labeling of drugs to identify medications where dosing and strength mistakes might cause harm. According to a study coauthored by Kenneth Barker, a professor of pharmacy research at Alabama's Auburn University, a typical pharmacy filling 250 prescriptions a day makes an average of four mistakes. There are about three billion prescriptions dispensed each year in the U.S. This in turn means that there are about 51.5 million errors annually, with 3.3 million of them being potentially serious or deadly according to the study.

The FDA has been holding hearings over the last few months to review the procedures for approving names of new drugs. The new prescription drug law that was passed in 2003 provides for adoption of standards by 2008 for "e-prescribing,", so that doctors can electronically submit prescriptions directly to local drugstores via the Internet. The non-profit Institute for Safe Medication Practices (ISMP.org) monitors medication errors through a voluntary anonymous reporting system. The ISMP issues safety alerts to advise the FDA, doctors and pharmacies of safety issues in connection with different drugs.

The release of the results from the fourth annual database from the **U.S. Pharmacopeia**, a non-profit group of pharmacists and other medical professionals that develops standards for prescription-drug usage and medication errors shows that prescription drug errors continue to be a growing problem.

For 2002, the year of the latest study, the database saw what it called a "large upsurge" in reported errors. Reported errors increased by 82% even though the database grew by only 31%. This increase may have been caused by a change in culture at many of the reporting institutes that are now encouraged to report any medication errors. There were 192,477 reports of medication errors in 2002. According to the study, older patients, meaning those over 65 were twice as likely to be harmed by a medication error. Of the cases reported about 1.7%-required intervention to save patients lives or resulted in permanent harm.

While technology can help reduce the amount of errors, it is very costly to install. Allen Vaida, the executive director of the nonprofit Institute for Safe Medication Use, said that he cost of installing bar-code technology at a 300-bed hospital was about \$1.5 million plus a couple of hundred thousand a year to maintain. The study showed that about 10% of all medication mistakes resulted from computer-entry errors.

According to a study done by a group of researchers at the University of Massachusetts Medical School in Worchester, the non-hospitalized elderly suffer from about half-million preventable drug side effects each year. The side effects ranged from nausea to life-threatening kidney failure. The study was based on examining the Medicare records of about 30,000 Medicare beneficiaries in the New England area.

Many of the errors were the result of errors by the physicians, such as inadequate monitoring or lack of awareness of drug interactions. Jerry Gurwitz, a professor at the university stated: "It's obvious that it's a major issue, a major problem." About 20% of the side effects were caused by patient mistakes. Studies have found similar results for hospitalized patients, but this is one of the first studies that dealt with non-hospitalized patients.

The results of the study suggest that more than 1.9 million-drug side effects-about one-fourth of them preventable-happen each year among non-hospitalized elderly people. Some of the problem arose because of the interaction that occurred among the various prescription drugs that the user was taking. This problem arises most of the time because of failure to tell one doctor what drugs another doctor has prescribed for the patient. Patients must tell their physician about all the medications that they are on. This includes informing your physician of any herbal or over-the counter medications that you may be taking as well as any other prescription drugs that you are on.

A review of the professional medical literature consistently alerts the reader to studies of problems with medication delivery. One such study, by Bruce and Wang, looked at the error rate during administration of parenteral medication by nursing staff in a hospital setting.

During emergencies, parenteral administered medications are preferred because oral medications may be poorly absorbed and not provide as rapid response as needed. This study used a direct, disguised observational method in an admission unit during daylight hours (8:00 AM to 4:30 PM) for 4 weeks. Any error observed that was potentially dangerous to the patient was either stopped or corrected immediately. Ethical considerations were not compromised. It is well reported that poorly prepared and/or administered parenteral therapy can cause thrombus formation, severe hypersensitivity reactions and infections.

In a total of 127 opportunities for error, 27 errors were observed (25% error rate) which included wrong time errors (medication administered one hour over the prescribed time). If one removes these types of errors, the rate of errors was reduced to 10.7%. The researcher's conclusion was that parenteral medication administrations errors are common in the United Kingdom. This does not necessarily mean that the same results would occur in the United States, but it is still disquieting especially when one looks at nursing homes and the demands made on nursing staff.

Apropos to the above, we recently were made aware of a Webcast on medication errors sponsored by the **U.S. Pharmacopeia**, presented by Diane Cousins, vice-president of USP's Center for the Advancement of Patient Safety. She reported that 97.6% of the medication errors occurring in hospitals, which voluntarily reported errors during 2001 to the MedMARx medical error database, were not harmful to patients. Her report contained the following data:

- 37% of the errors occurred at time of medication administration (most common).
- 26% of the errors occurred in documenting the medication administered
- 21% of the errors occurred at time of dispensing the medication
- 29% of all errors involved failure to administer an ordered dose (most common)
- 21% of all errors involved improper dose
- 14% of all errors involved prescribing errors.

Further analysis of the report indicates that 38% of the most common medication errors were caused when a health care provider had the necessary knowledge and experience but did not perform accordingly. This was followed by 20% for failure to follow procedures and 15% because of transcription errors. She pointed out that transcription errors were the fifth most common cause of medication errors.

The top products involved in medication errors were insulin, morphine, heparin, warfarin and potassium chloride.

Staffing issues played an important role in contributing to medication errors. The contributing factors included 46% involving distractions, 24% involving increased workloads. Kerri Wachter, Staff Writer for *Family Practice News* (Jan. 1, 2003), reports that "Staffing issues such as inexperience and insufficiency, among others, accounted for 43% of contributing factors."

One wonders how, in this era of staff shrinkage, and other cut backs, as well as making use of less well-trained individuals, the health industry hopes to reduce the amount of errors. (Parenthetically, we should point out that the figures above are based on hospitals voluntary reporting of errors. How many incidents go unreported?)

Could the old adage "pennywise, pond foolish", while simplistic in such a complex setting as the health care industry hold true? Yes, we all are aware that 14% of our GNP is consumed by the health care industry. But has anyone stopped to consider the long-term effects of the adjustments being made today in hospitals? What are the future expenses based on lowered health quality indexes today, especially in light of the fact that our population is getting older and hospitals are dealing with more complex health issues?

Ref: J. Bruce & I. Wong. Parenteral Drug Administrations Errors by Nursing Staff on an Acute Medical Admission ward during the day. *Drug Safety* 2001; 24(11): 855-862

PS: While the above refers only to medication errors, this writer was made aware of a egregious surgical error that involved leaving a 13-inch retractor inside an individual following an operation. It was only when the individual had to pass through an electronic surveillance machine at the airport that the error was noted. Apocryphal or true, there is no excuse for such an error.

Please see our earlier articles on this topic:

The U.S. Pharmacopeia (USP) and Medication Errors and also Seals of Approval

FOR AN INFORMATIVE AND PERSONAL ARTICLE ON PRACTICAL SUGGESTIONS WHEN SELECTING A NURSING HOME SEE OUR ARTICLE

" How to Select a Nursing Home"

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