American College of Clinical Pharmacology Response to the

Institute of Medicine Report

"To Err Is Human: Building a Safer Health System"

Prepared by The Public Policy Committee

Background

The public press is laden with articles describing serious errors in medical care and treatment that are associated with increased morbidity and mortality. In fact, a recent Institute of Medicine of the National Academies (IOM) report estimates that as many as 98,000 people in the U.S. die each year from medical errors. This number is greater than the death toll from breast cancer, auto accidents, and AIDs. The total financial impact of these errors on the U.S. economy is estimated to be between $17 billion and $29 billion. This situation has prompted a heightened awareness and proposed actions by the Federal Government to control this epidemic of errors in medical care. The IOM report outlines four key areas of action:

1) Heightened awareness and establishment of a national focus regarding patient safety.

2) Mandatory and immediate reporting of errors to enhance the current voluntary reporting system, facilitate learning, and expedite the implementation of corrective actions.

3) Setting safety standards via oversight organizations, group purchasers, and health professional groups.

4) Creation of safety systems within healthcare organizations to enhance the implementation of safe practices at the level of healthcare delivery.

Response

The IOM study alleged that mistakes ranging from drug errors to surgical errors to missed diagnoses had been responsible for the deaths of 44,000 to 98,000 patients per year. The IOM Study was based on two reports in three states – New York in 1984 and Utah and Colorado in 1992. The New York study sampled 30,000 charts from 51 state hospitals and apparently found that 3.7% of the patients suffered injury from their treatment, severe enough to disable them or prolong their hospitalization. Fifty eight percent (58%) of these injuries were attributed to error and 13.6% were said to be fatal. These numbers were then extrapolated to the number of people hospitalized in 1997, leading to the 98,000 estimate. In Utah and Colorado, the study was carried out in 1992

with a sampling of 15,000 charts. Utilizing the same methods as the New York study, the investigators arrived at the 44,000 number. Although very little has been said for fear of being politically incorrect, one must wonder how accurate studies such as these can be, given the retrospective aspects of the investigation, the large span of years, the extrapolations to populations so different across the country and across the vast array of hospitals caring for such a wide variety of patients. One must wonder whether generalizations really can be made and how accurate these estimates are relative to the true incidence of medical errors across the country.

One of the investigators, Troyen A. Brennan, M.D., J.D., M.P.H., at the Brigham and Women's Hospital in Boston, Massachusetts wrote an extremely important editorial in the New England Journal of Medicine on April 13, 2000. Some critical insights can be gleaned from this editorial. Dr. Brennan states:

"The combination of the strikingly large number of errors cited by the report and the connotations of the word 'error' create an impression that is not warranted by the scientific work underlying the IOM Report."

"In both studies we agreed among ourselves about whether events should be classified as preventable or not preventable. But these decisions do not necessarily reflect the view of the average physician and certainly do not mean that all preventable adverse events were blunders. For instance, surgeons know that post-operative hemorrhage occurs in a certain number of cases, but with proper surgical technique, the rate decreases. Even with the best surgical technique and proper precautions, however, a hemorrhage can occur. We classified most post-operative hemorrhage resulting in the transfer of patients back to the operating room after simple procedures (such as hysterectomy or appendectomy) as preventable, even though in most cases there was no apparent blunder or slip-up by the surgeon. The IOM Report refers to these cases as medical errors, which to some observers may seem inappropriate."

"Perhaps more to the point, neither study cited by the IOM as the source of data on the incidence of injuries due to medical care involved judgments by the physicians reviewing medical records about whether the injuries were caused by errors. Indeed, there is no evidence that such judgments can be made reliably."

"The report and the accounts of it in the media give the impression that doctors and hospitals are doing very little about the problem of injuries caused by medical care. Yet the data that the report cites give a different impression. In the three studies cited, the rate of injury due to medical care was 4.6% in California in 1976, 3.7% in New York in 1984, and 2.9% in Colorado and Utah in 1992. Moreover, if one extrapolates from our studies in New York and Colorado and Utah, in order to calculate the number of deaths nationwide due to substandard care, the total decreases

from 92,000 deaths in 1984 on the basis of the data in New York to 25,000 in 1992 on the basis of the data in Colorado and Utah. Although no statistician would be convinced by data extrapolated from three different settings, and although my colleagues and I cautioned against drawing conclusions about the number of deaths in these studies, the evidence suggests that safety has improved not deteriorated."

"Is there reason to believe that hospital care has become safer? The answer is yes. At least over particular periods for particular procedures. The reduction in mortality rates is due, in large part, to technological advances. But it is also due to simple attention to surgical practice. Surgical training has always emphasized commitment to details, systematic thinking, and intolerance of failure – the hallmarks of approaches to the prevention of errors. This is anything but the 'cycle of inaction' that the IOM notes. An important part of the medical ethic is the improvement of care which most physicians and hospitals take very seriously. I do not mean to imply that all hospitals perform at optimal levels or that we should not be scrutinizing the effects of new management techniques on the quality of care. Indeed, the profession should welcome a renewed emphasis on safety, but it is inaccurate to suggest that safety has been overlooked."

In this editorial, Dr. Brennan goes on to say that the computerization which as been suggested by the IOM Report is a fine idea, but that it is extremely expensive and that no health insurers or employers purchasing health insurance have been willing to pay for the extra expense. Given the current financial status in which most hospitals find themselves, investing in computerized hardware and software is unlikely. He also notes that identifying errors is "methodologically suspect" and that unless the so-called science of error detection improves greatly, any effort to prevent errors may deteriorate into a marketing ploy after easy solutions have been undertaken.

Finally, Dr. Brennan identifies an extremely important aspect of the dangers in this report. He asks, "Why, some might ask, should the public not know about blunders made by doctors? The answer is that most injuries from medical care are not due to mistakes. More important, a system of self-reporting relies on careful and confidential investigation by peers. Without confidentiality, I doubt there will be substantial voluntary reporting. In addition, public disclosure would spawn lawsuits which in turn chill any interest in voluntary reporting. Unfortunately, the law is less and less sympathetic to so-called peer review protection which judges increasingly hostile to claims of confidentiality."

He goes on to say that "if the only legislative result of the IOM Report is federally mandated reporting, we will have failed, and once the publicity dies down, the rates of injury due to medical care will remain unchanged." The thrust of his argument is that all efforts will fail unless there is confidentiality and tort reform.

The IOM Report is clearly flawed based on a simple analysis. However, the healthcare system is clearly in need of revision, and "errors" when they do occur, are often the result. As Clinical Pharmacologists and members of the American College of Clinical Pharmacology (ACCP), many of us are either directly or indirectly involved with the interface between pharmaceuticals, the patient, and patient care. As an organization dedicated to the development of safe and effective medications, we are deeply concerned with the number of medical errors that are associated with the use or misuse of prescription medications. The most important key to correcting medication errors does not reside in improving the handwriting of physicians as has been suggested by the IOM report. Rather, the key is the pharmacist and the nurse. There was a time when hospitals were appropriately funded and many institutions had satellite pharmacies on every floor or every other floor. All medication orders were made through the pharmacist, and if there was any question about the drug, the dose, or whether it was being given to the correct patient, the pharmacist would consult the nurse and/or the doctor to assure accuracy. With this process, many errors were detected and avoided. But today, with severe fiscal constraints, satellite pharmacies exist only for one 8-hour shift or, more commonly, do not exist at all. Drugs are dispensed through a central pharmacy usually severely understaffed during at least two shifts and worse on weekends. Pharmacists have been laid off from hospital positions leaving the dispensing of medication open to potential errors.

Although Medicine is a science, it is a labor-intensive science because it deals with biological entities, namely we humans, all so similar yet all so different. The application of science and technology to the bedside is only as good as those who deliver it. In many situations, non-medical staff may be used for clinical observation. These observations are generally incomplete because these individuals have been inadequately trained and lack the necessary clinical experience. However, they are being utilized because they are much less expensive than nurses. Meanwhile, for the nurses that do remain, the patient to nurse ratio has progressively increased reducing the quality of care, and the "harried" nurses are called upon to do everything but nursing – both reasons why nurses are "burning out" and leaving the profession, further exacerbating the problems of caring for hospitalized patients. Thus, important changes in the status of patients go unrecognized or recognized too late, and because medications are often dispensed in a hurried manner, medication errors are increasingly likely to occur.

These errors can take many forms such as:

- Mislabeling of medications
- Transcription errors
- Confusing similar sounding drugs that have completely different therapeutic effects
- Toxic drug interactions

- Overdosing/overmedicating (especially in the elderly)

- Miscalculations of dose based on weight (example: mg/kg vs μg/kg)

These are just a few of the potential types of errors that can occur with medications. Specific to this report, the IOM charges the Food and Drug Administration (FDA) with the responsibility of increased pre- and postmarketing surveillance, standardization of drug packaging and labeling that will increase patient safety, and require pharmaceutical companies to rectify the confusion regarding "sound-alike" and "look-alike" medications. In theory, all of these current practices are in effect and it will require societies like ACCP to increase both awareness and education through its members. We have identified several key areas that will enhance trained clinical staff, safety awareness, training, and accountability, and should provide a platform to meet the objectives of the IOM. These include but are not limited to:

1. Restoring the financial health of the medical care system in this nation through which appropriate nursing staff levels should be restored to provide true bedside nursing, preventing many medical errors; and also restore pharmacists in satellite pharmacies – which will prevent most drug errors.

2. Developing strong clinical pharmacology programs in our medical schools, our nursing schools and our pharmacy schools so that the proper teaching of pharmacology and therapeutics can be developed. Subsequently, our medical, nursing, and pharmacy students would graduate with a firm grounding in the basics of therapeutics. Clinical pharmacologists, whether they be MDs, PhDs or PharmDs, should be made major players in the medical care rendered by house office.

3. Expanding CME programs in pharmacology and therapeutics to keep physicians in practice current in all the complexities of contemporary therapeutics.

4. Expanding the role of the ACCP and other interested societies in the development of a variety of different educational approaches directed toward physicians, nurses, and pharmacists regarding all aspects of therapeutic intervention.

5. Developing "consumer-focused" materials to educate patients regarding common errors and what they can do to protect themselves in inpatient, outpatient, and home healthcare situations.

6. Developing "redundant" systems to ensure that all prescriptions and doses are confirmed and approved by at least two healthcare professionals with the appropriate sign-off and tracking.

7. Developing automated tracking systems and bar coding systems that reduce the potential of prescription and dosage errors.

8. Identifying a clinical pharmacologist that should serve as an ombudsman in all hospitals to track possible medication errors and to educate the medical and nursing staffs on how to mitigate such errors.

As Dr. Brennan indicated in his thoughtful editorial, great strides have been made in medical care and patient safety has improved enormously. While the IOM report may have overstated the issue and failed to present a balanced view, the ACCP feels that the message and objective of enhanced patient safety is critical and we should strive for "zero" medical errors.