**The Patient Safety Crisis: propaganda and politics in American Medicine**

By John Dale Dunn, MD, JD

Dr Dunn practices emergency medicine in Brownwood, Tex.. He is an inactive member of the Texas, Lousisiana and Nebraska Bars. He is a Research Fellow of the Texas Public Policy Foundation, a policy think tank in San Antonio, Texas.

The Institute of Medicine (IOM) report on patient safety in late 1999, *To Err is Human*, attracted great national attention when it announced that 44,000 to 98,000 patients die each year in American hospitals because of errors. The report relied heavily on a Harvard Medical School group's study of hospital care in New York in 1984 and that same group's study of hospital care in Utah and Colorado in 1992.

Much was made of these two studies and they are the backbone of a patient safety movement that defined itself in 2000 culminating in the IOM report, followed by much fanfare, a White Conference, and much hand wringing in Congress. Like many crises declared by the press and the academy in the past 50 years the foundational research science should be considered carefully before the rhetorical tsunami.

Here I compare American hospital inpatient safety research and corresponding Texas hospital patient safety research with a focus on the major patient safety research of the last two decades that led to the IOM report. The two Harvard patient safety studies that received great national attention are compared here with a stronger, broader, and more robust database from the Texas Medical Foundation (TMF), the peer review organization for Texas. The TMF studies of 300,000 patient admissions during 3 years in more than 400 hospitals are compared with the Harvard studies of 30,000 charts in 51 hospitals in New York in 1984 and 15,000 charts in 28 hospitals in Utah and Colorado in 1992. The comparison shows a positive American patient safety picture that has been ignored too often in the current debate, with low rates of significant injury and death caused by any medical care or hospital care safety or negligence problems.

**The IOM report**

In late 1999, a report by the Institute of Medicine (IOM), *To Err is Human*, published on the Internet and in prepublication form, proposed that patient safety in America was at a crisis, with between 44,000 and 98,000 annual deaths in America caused by hospital and inpatient care negligence. The report breifly reviewed

in its text the research that justified its hyperbolic assertions, and proceeded to promote an IOM outline of a new safety solution for American Healthcare.(1). There is no doubt that the IOM, a branch of the National Academy of Science and considered authoritative, and its report were very influential nationally. The problem is that the IOM can be, and in this case, was the agent of a propaganda program and the report declared a crisis that was, at best, based on weak research.

The IOM report relied heavily in its text and its public relations releases on the findings of the 1984 Harvard study of New York Hospitals, reported in 1991 (2-4). That study was similar in methodology to one other study conducted by Dr. Don Harper Mills for the California Medical Association and reported in 1978 (5). Both studies asserted an approximately 4% rate of bad outcome or "adverse" events and a slightly less than 1% rate of malpractice related events in American hospital inpatient care.

The IOM also reported on the results of another, newer Harvard group study on negligence in Utah and Colorado for hospital care in 1992, which was published in late 1999 and early 2000 (6-10). It asserted a rate of adverse events of 3.1% (1999 report) or 3.9% (2000 report), and a 1.7% rate of preventable adverse events (1999 report) with a 1.1% rate of negligence events (2000 report).

The Harvard studies were the source of the hospital-patient negligence death projections of between 44,000 and 98,000 annually, which attracted much attention and were contrasted to the fewer than 50,000 deaths on the highways annually. The negligence death rate was announced in *USA Today* as the eighth top killer with the lead sentence, "Medical errors kill more Americans than traffic accidents, breast cancer, or AIDS, Institute of Medicine officials said Monday as they called for a sweeping 'systems' approach to make medicine safer" (11).

My first exhibit in the case against the safety crusade is Troyen Brennan, MD, a senior researcher with the Harvard group on the New York and Utah/Colorado studies, stated his concern about misuse of the data from the two Harvard safety studies in the IOM monograph in an essay April 13, 2000, in *The New England Journal of Medicine* (12), which was reprinted in June 2000 *Texas Medicine*, pp 13-15. Dr Brennan wrote:

> I have cautioned against drawing conclusions about the numbers of deaths in these studies.
>
> The reliability of identifying errors is methodologically suspect.
>
> In both studies (New York and Utah/Colorado) we

> agreed among ourselves about whether events should be classified as preventable . . . these decisions do not necessarily reflect the views of the average physician, and certainly don't mean that all preventable adverse events were blunders (12).

Imagine, after 10 years of promoting the safety studies of 1991, a lead researcher in both studies relied on by the IOM would declare as a Harvard researcher in his home town world famous medical journal that the emperor of patient safety research was naked. Maybe we should look further into this crisis.

The IOM report of 1999 projected 44,000 to 98,000 annual national patient deaths. In 1993 after reanalyzing its 1991 research, the Harvard group projected 1.3 million annual patient care injuries and 198,000 annual patient deaths based on its New York data (13). These extraordinary numbers were touted long ago, in fact there was much plaintiff attorney and media attention in 1991 and 92 about the first report, but it didn't catch on. Politics and healthcare are an unpredictable business, but the political left has great patience, particularly in an effort to bring down such an important business and social welfare as health care. So, you ask, what happened to finally catch the attention of the public and the media?

The Harvard Utah/Colorado study data of care in 1992 was used early in 2000 by allies of the Harvard group within the IOM, particularly since the research projected 24,979 annual national negligence event deaths (9, p 268). The dramatic improvement in the number of national deaths projected in sequence by the two Harvard studies just 8 years apart has never been included in the national public relations campaign, since positive trends do not attract the politcally ambitious.

An analysis of the patient safety research requires a close look at terminology and definitions. What are "adverse event deaths" in the Harvard methodology? What are negligence deaths or events?

The Harvard authors say in their report:

> We defined an adverse event as an injury that was caused by medical management (rather than the underlying disease) and that prolonged the hospitalization, produced a disability at the time of discharge, or both. We defined negligence as care that fell below the standard expected of the physicians in their community (2, p 370).
>
> Many patients who died after an adverse event had

> very serious underlying disease, and several surely had shortened life expectancies independent of their iatrogenic injury. Physicians could not, and were not, asked to estimate the number of days of life lost as a result of the adverse event. This is a critical issue, particularly in the case of a terminally ill person (2, p 375).

So the Harvard group defined the following, and those definitions are now used by the safety movement:

- Adverse event: injury caused by medical management as opposed to natural events.
- Negligence event: patient injury caused by care that falls below the standard of care.
- Preventable event: "an AE [adverse event] was classified as preventable if it resulted from an error . . .both negligent and non-negligent" (13, p 144), as well as any event commonly recognized to be caused by failure to follow accepted practices.

.

**California and Harvard medical practice studies**

Three comprehensive studies of negligence or patient safety in American hospital inpatient care have been conducted:

- A study by Don Harper Mills, MD, JD, a pathologist/attorney, for the California Medical Association, looked at care in California hospitals in 1974. It was published in 1978 (5).
- The second study examined care in New York hospitals in 1984. Conducted by a group from Harvard that included Dr Brennan and Lucien Leape, MD, it was published in *The New England Journal of Medicine* in 1991 (2-4).
- The third study reported on patient care in Utah and Colorado hospitals in 1992. It was the Harvard group's second study, led by Dr Brennan, and was published in late 1999 and 2000 (6-10).

**California Medical Association inpatient care study**

The California Medical Association asked Dr Mills to provide a feasibility study of no-fault medical professional liability insurance. David Rubsamen, MD, LLB, of Berkeley, Calif, and John S. Boyden, Jr, MD, LLB, of Salt Lake City, assisted in the study. The charge to Dr Mills' group was to determine the underlying rate of compensable negligence or medical malpractice.

The group selected a representative sample of 20,864 hospital inpatient charts from 23 California hospitals in 1974. A

nurse screening process, using 20 sentinel events similar to those in the Harvard list (Table 1), produced 10,000 adverse event charts for physician review. A total of 970 (4.65% of the total sample) PCEs were found.

After analyzing the PCEs, Dr Mills' group found that 0.79% of the total sample studied were compensable (negligence) care events. The top four levels of injury severity, including all disabling injuries and deaths, comprised 13.4% of the 970 PCEs, or 130 (0.62% of the total sample). PCE deaths numbered 94 (0.4% of the total); the authors noted that 25% of those deaths occurred in terminally ill patients. There were 36 (0.17% of the total sample) disabling injuries.

The Mills group estimated that the PCE cases had a 17% chance of winning a lawsuit for malpractice, with chance of success estimated as high as 44% in a "few" of the cases of the severely injured and dead. This estimate appears to be derived from that fact that 165 (17%) of the 970 PCEs were judged to be negligence events, not an assessment of chance of lawsuit success based on individual case reviews.

**Harvard study of New York hospitals**

David Axelrod, MD, director of the New York State Department of Health, commissioned a study by the Harvard group, led by Drs Brennan and Leape, to analyze the rate of inpatient negligence events in New York hospitals. It was intended, like the California study, to evaluate feasibility of no-fault professional liability insurance.

After its completion, the Harvard study was reported to the New York State Legislature (21) and published in three separate articles in *The New England Journal of Medicine* (2-4). Review and discussion of the study in the mainstream press at the time announced 80,000, 100,000, and 180,000 patient deaths and as many as 3 million inpatient injuries per year across the United States.

In the Harvard group's research protocol, charts for review by physicians were identified from screenings by nurses of 30,195 inpatient records, using the 18 screening criteria listed in Table 1. The 7,743 cases that were identified from the screenings underwent two physician reviews for adverse events, negligence, and injury (Table 2). A third physician review and tiebreaker vote was cast on 1,808 cases on which the first two physicians disagreed. In the end, 1,133 (3.7% of the total sample) adverse events were identified; 972 (3.2% of the total sample) of the adverse events did not involve negligence, and 280 (0.9% of the total sample) were judged to be due to negligence.

The Harvard New York data do not identify the number of deaths in the sample that were excluded by physician review as expected, but the authors emphasized that many of the deaths that were counted as caused by negligence were inevitable in critically ill patients. The nurse screening criteria included death, so all deaths were reviewed. Of the 154 adverse event deaths (0.51% of the total sample), 70 (0.23% of the total sample) were judged by the authors to be due to negligence.

A total of 210 negligence injury events were found, of which only 26 (0.09% of the total sample) involved serious disability. All other negligence injuries, 184 (0.6% of the total sample), caused temporary or minor injuries.

The national multiplier or weighting factor of approximately 1,200 was used by the Harvard authors in 1993 to project the New York study data to the nation (13), resulting in their projections of 1,347,000 adverse events and 198,000 adverse deaths. Using this same process results in projections of 84,000 annual negligence deaths and 31,000 annual significant injury events from the New York data.

**Harvard study of Colorado and Utah hospitals**

Although an initial report on surgery events from the Utah/Colorado study was published in the July 1999 issue of *Surgery*, the first comprehensive report of the Harvard group on the Utah/Colorado study appeared at about the same time as the IOM report in the fall 1999 in the journal *Inquiry*, published by the Institute for Critical Thinking at Montclair State University.

The Harvard School of Public Health Study Group successors, with Dr Brennan as the senior researcher and holdover from the New York study, stated that they had confirmed their previous study in New York with this new study of care in Utah and Colorado in 1992 (7). *Medical Care*, the official journal of the Medical Care Section of the United States Public Health Service, published the major report from the Utah/Colorado project in its March 2000 issue (9). Much of the data referenced in the 1999 IOM report did not appear until March 2000 and was referenced as "to be published," which included the authors' estimate of 24,979 annual national negligence deaths.

The Utah/Colorado report on events in the elderly population of Utah and Colorado was published in the *British Medical Journal* on March 18, 2000. Surgical data and economic analysis were the focus of the articles in 1999 (6-7).

**Utah/Colorado study methods**

With the help of the Utah Health Data Commission and the

Colorado Hospital Association, the Harvard group reviewed 15,000 hospital admissions in 1992 -- 5,000 from 13 Utah hospitals and 10,000 from 15 Colorado hospitals that were selected to represent different classes of hospitals. In the March article, the actual number of charts reviewed was 14,700.

The hospitals were chosen from size and activity categories and invited to participate. None of the invited hospitals refused. Nurses screened a representative 14,700 chart samples with a screening event list slightly modified from the New York study to add events from outpatient surgery. Nurse screening produced 842 physician reviews from Utah and 1,978 reviews from Colorado. Twenty-two family practitioners and internists did the physician reviews -- 16 for Colorado charts and 6 for Utah charts. They identified 418 adverse events from Colorado and 169 from Utah, a total of 587 (3.9%) reported in March; 459 adverse events were reported in *Inquiry* in fall 1999.

All physician-determined adverse events were then reviewed by Drs Brennan and Thomas to judge "preventable" adverse events. Preventable adverse events numbered 265 (1.9% of the total), and negligence events totaled 169 (1.1% of the total).

**Surgical events**

The Utah/Colorado surgical study reported in July 1999 counted all surgical problems, such as postoperative infection or other complications, as preventable (6). The surgical-events study also showed that preventable complications were most common, and considered preventable, in the vascular surgery cases of the aorta and lower extremity, coronary artery bypass graft, colon resection, cholecystectomy, prostatectomy, and transurethral resection of the prostate, lowering the rate of adverse events from 19% of the total down to 5.5% (6). The authors didn't comment on the well-known high rate of expected complications in these surgeries because infections, wound complications, or any postoperative complications were considered preventable.

**Specialty and location analysis**

The Utah/Colorado study provided a breakdown of specialty-specific and location-specific adverse and negligence events, eg, 59 surgeon negligence events, 60 internist negligence events, 13 obstetrician and midwife negligence events, 9 gynecologist negligence events, 15 family practitioner negligence events, 7 nurse negligence events, and 8 emergency physician negligence events (9). No analysis is offered on these data, eg, what the internal rate of negligence is for the specialties or how many total cases in the sample were the responsibility of each specialty.

The Utah/Colorado study showed 38 adverse event deaths and 18 cases of significant to grave injuries from adverse events, projecting to 64,809 deaths and 29,934 significant-to-grave injuries nationally. Fifteen deaths and 11 significant-to-grave injuries were judged due to negligence, projected to 24,979 deaths and approximately 18,300 significant-to-grave injuries nationally. The Harvard Utah/Colorado authors used 1,663 as the multiplier to project data from the Utah/Colorado study to the nation. That assumes that age and other demographics of the two states match the nation. Recall that the national weighting multiplier used by the authors for the New York study for national projections for 1984 was approximately 1,200.

The populations of Utah and Colorado were about 5 million in 1990. New York's population was 18 million and the population of the United States was 258 million, so the population ratios were proportionate to the weighting numbers, but no demographic analysis is available on age, ethnic, or other state-versus-nation factors.

Preventable deaths are estimated in this paper for the Utah/Colorado study at 18, based on the information in the study on the elderly in the *British Medical Journal* in March (8). Thus, the preventable deaths projection is 29,934 annual preventable deaths nationally. The preventable deaths and negligence deaths are to be counted with caution, however, because negligence deaths are a subset of preventable deaths and any death may be premature; not all patients were healthy with good prognoses.

**Tort system analysis**

Both Harvard studies evaluated the legal system by matching lawsuits filed to the chart analysis and data. The studies found that many lawsuits were unsupported, and many injured patients didn't sue.

**Texas Medical Foundation studies of quality**

The patient care review work of the Texas Medical Foundation (TMF) was analyzed and compared with the California and Harvard studies. Organized in 1972, TMF is a peer review organization that has been under contract with the Health Care Financing Administration (HCFA) since 1975 to conduct Medicare medical care quality studies for inpatient care in Texas. HCFA supervises and monitors the Medicare and Medicaid programs for financial integrity and patient care quality.

Between 1984 and 1994, TMF reviewed approximately 1 million inpatient medical records selected randomly from more than 400 urban, suburban, and rural Medicare contract hospitals in

Texas. TMF protocol for review was driven by Medicare quality criteria and checklists at all review levels for a 100% review of charts (Table 3).

This paper reviews and summarizes TMF results from 1989 to 1992, as reported in the TMF journal Q*uantum.* TMF analysis of inpatient care review of 317,000 charts over 3 years showed a significantly lower rate of negligence than was found in the California, New York, and Utah/Colorado studies. When compared with matched elderly patient populations, the TMF studies showed a dramatically lower rate of negligence than did the Harvard or California studies -- one-tenth the rate of the other studies (Tables 4,5) (22-24).

TMF reviews of quality are comparable to the California and two Harvard studies, based on the following premises:

- TMF is assigned the duty of finding negligence or quality-of-care problems created by medical care providers -- hospitals, hospital staffs, and physicians.
- A TMF finding of a confirmed quality problem means that inpatient care negligence was evident.
- Level III confirmed quality problems in the TMF reviews are those acts of negligence or omissions that resulted in patient injury (any injury), so Level III compares to the Harvard and California cases with any (not necessarily significant) patient injury.

**Comparison of methodology and data**

The Utah/Colorado authors discuss some methodology changes in their study that address problems with physician judgment reliability noted in the New York study. They reduced the number of training sessions for reviewers to one session by one instructor for each state's physicians and nurses, reduced negligence reviews to one physician rather than two with a tiebreaker, and made two principle researchers in the study the only judges of "preventable" events. They noted the low kappa interobserver reliability problem that occurred in New York but improved to marginal in Utah/Colorado (New York kappa was 0.24; Utah/Colorado, 0.4).

Ambiguities are quantified by measures of agreement, such as kappa, and by the interclass correlation coefficient. The former looks at the percentage of agreement above chance by two observers who are classifying cases into two or more categories (25). The latter measure allows calculation of agreement between several observers (26).

The Harvard New York study authors duplicated the review process on 1% of their charts to test for reliability and validity,

using a criterion of greater than 50% confidence that negligence was present. Harvard New York researchers found the two review processes agreed only 24% greater than chance (14, p 374). (Less than 40% agreement greater than chance is not acceptable.) Evaluation of the Utah/Colorado data on negligence analysis was judged by Dr Brennan to be unacceptable although they reached the marginally acceptable kappa of 0.4 (9). Dr Brennan, in his April essay in *The New England Journal of Medicine*, speaks candidly to that imprecision and the problem of subjective, implicit judgments of negligence (12). Studies of implicit evaluations of patient care show that evaluations are plagued by very low kappa values, as are the Harvard studies. Of 12 studies, kappa values were below 0.4 for all criteria in 7 studies, mixed above and below 0.4 in 3 studies, and above 0.4 in only 2 studies (27).

On the basis of the analysis of interobserver lack of reliability explained above, increased reviews are required to achieve reasonable reliability, not reducing the number of reviews as was done in Utah and Colorado. However, the use of multiple physician reviews is also impaired by the tendency to find fault. For example, if the legal standard of care is that exercised by a prudent physician, would not one judgment of acceptable care be adequate to meet the legal measure?

Based on the low interobserver reliability, multiple and repeated -- not tiebreaker -- reviews as done in the New York study would be a better way to increase reliability. Reliability usually is methodologically assured by repetition. In the Harvard New York study, to achieve an acceptable reliability of 0.51 would require 10 reviews.

This suggests that reliable determination of negligence would require a jury of experts, and even then it would be biased in this study because of screening for sentinel events, with the prejudice of retrospective analysis of bad outcomes (28). It also suggests that physicians will always be available on both sides of the negligence question. Sometimes, the safety study data are less reliable. The Harvard New York group compared its methodology with other similar studies in negligence research (2, p 374). The problems it had with validity and reliability were candidly discussed in their original publication and in Dr Brennan's essay of April 2000 (12).

The California Mills group sampled carefully and reviewed internally, but did not publish any measures of internal reliability. The group of reviewers -- 3 physicians -- also was very small, and interactive evaluations were the norm.

To conduct interobserver reliability analysis in the TMF studies is not possible because the final ruling requires a consensus

of individuals and committees interacting with the hospital or the physician at various levels -- first, the nurse reviewer; then, the physician reviewer; and then, higher levels of reviewers, including single reviewers and committee reviewers. No internal duplication of review is available for testing of reliability. Letters of inquiry, phone interviews, and in-person interviews all are tools used in the TMF review process, which was in place in the referenced time frame. The TMF nurse review should not be considered a Harvard type screening for adverse events, since the TMF nurse reviewers do a protocol and content review beyond the criteria of the TMF generic screens (Table 1) and the Harvey study screens (Table 2), and there was a low threshold for physician review.

The use of 1,200 and 1,600 as multipliers of the Harvard study data to project national deaths or negligence events assumes sampling and analysis methodology that are extremely representative of the American population. Can such a claim be made, given 1-year studies in 51 and 28 hospitals that use 1/1200 and 1/1600 sample sizes?

Negligence events data are presented in Table 5 for all the patient care studies reviewed here and in Table 4 for Medicare-age patients; the same data are presented from TMF for both, since TMF does only Medicare reviews. Older patients usually have a more complicated and fragile medical status that increases the frequency of adverse events, so the California and Harvard rates are higher for the elderly group. The more dramatic contrast in negligence rates is seen in the elderly patient group, but TMF negligence rates are still lower for a non-age-matched negligence.

When the rates of significant injury and death in the Harvard studies are compared with all the other studies, the rate of negligence causing disabling injury and death is less than 0.5%. Significant injuries are the measure of real malpractice cases, and the rates of significant negligence injuries are very small in all the studies (Tables 4, 5).

The trend in adverse events, negligence events, and negligence deaths over the 25-year period is shown in Table 6. Negligence deaths are on the decline in the studies, and some decline in adverse events is evident, but the changes in rates are changes in underlying small rates of negligence. Using weighting multipliers makes fractions of a percent into large numbers, since there are more than 20 million admissions to American hospitals every year -- many for complicated and increasingly complex and critical illnesses and injuries.

**Adverse drug event studies**

Other than the two Harvard studies and the California study, no

other major multiple-hospital inpatient safety studies have been conducted. However, other studies of hospital safety have been reported on a smaller scale, particularly studies of adverse drug events (ADEs) (14,15). The ADE research was considered prominently in the IOM report. In many cases these small and imperfect studies were referred to as conclusory on the question of the dangerous nature of American Healthcare, but are they?

The ADE studies are small and focused and deal with a universe of drug reactions and effects -- expected and unexpected, preventable and unpreventable (16). Consider two editorials discussing problems of ADE research by two experts, Jerry Avorn, MD, and David Bates, MD, of Brigham and Women's Hospital in Boston, published in *The Journal of the American Medical Association*. Dr Avorn says the following about two ADE reports: "These two studies push hard at the boundaries of clinical epidemiology and health services research, and a skeptic might wonder whether the envelopes of these disciplines might not have gotten a bit nicked in the process" (17). Dr Bates, in an editorial commenting on another drug event study, says problems exist in studies of ADEs -- whether they are properly identified and evaluated, and whether ADEs are really avoidable in a practical sense, particularly in severely ill patients (18).

Undoubtedly, the millions of daily drug administrations in hospitals present a potential for error. The measure of the magnitude and consequences should not be lost in data dredging and statistical manipulations invited by such an imposing denominator. Hundreds of drug events occur daily on every floor of every hospital in America. The solution to the problems with drug administration and drug interactions is being developed across the country with fail-safe pharmacy computer programs tailored for individual patients.

Moreover, the ADE research is like the safety research in general that reminds one of the saying "for a man with a hammer every problem is a nail." In an anxious effort to prove that their research is important and addresses a major crisis, every caveat is in the small print, every weak conclusion that proves a crisis is a headline. The ADE research counted events that were not events and the general safety research did the same thing. No wonder we have the confessions of a Harvard Physician-Attorney on the pages of the world renowned *New England Journal of Medicine*

**THE MOVEMENT-2000 AND 2001**

The number of seminars and the symposia on patient safety have increased along with the political activity directed to safety.

If there ever was a jobs program for doctors who don't practice medicine, this is it. Safety experts move about the country, expounding on safety programs and strategies.

The Agency for Healthcare Policy and Research (AHCPR) that for many years did medical policy development for practice guidelines now has a new life as the Agency for Healthcare Research and Quality, and has new funding, announced in early 2001 as $75 million for safety research with more to come. Of course it took no time at all and a stroke of the pen to create the new AHRQ with many of the prominent medical personalities that pushed the crusade a part of the program. And the IOM goes on, never answering the questions that one might ask?

- If the ADE research is already outdated why did you tell the publid that it was so important?
- If the Harvard research was so unreliable, why did you promote the derivative numbers to fan up a crisis and scare the public?
- Are the key people in your activities about patient safety planning to cash in on their new found prominence as saviors of the American Healthcare System?
- How does diminishing the respect of the public for American doctors, nurses and hospitals work to the advantage of a society with the best healthcare in the world?

**American Healthcare's Response**

From up close this doctor can tell you why this paper would be disliked by American medical leadership and political movers and shakers in the hospital industry. It is the same reason that we should always be wary of risk aversive lawyers and manageers when we are trying to do the right thing. Faced with a hostile leftist media, plaintiff attorneys who are experts in public relations and demagoguery, and without a clue, the medical establishment repeated the mantra "every death is one too many."

Faced with the possibility of a new risk management source of funding, Organized medicine and the hospital industry accepted the idea that resources might be stretched but that the politically wise thing to do would be to acquiesce rather than question lousy research. It has happened before. What could a little effort to make things safer hurt--right?

Well, it could hurt a lot. Complete safety is not possible in complex healthcare environment. We now attempt medical feats unheard of before, on patients that are sicker than ever. There really are medical marvels and miracles now considered

commonplace, but they are risky. Risk managers are ponderous and slow, but also controlling in their work. Imagine the healthcare system run by the post office, or a congressional staffer just graduated from the Kennedy school of government. Does the name Ira Magaziner ring a bell?

Don't count on medical leadership to have a clue--they are courtesans and poseurs in the new game of public relations, damn the science. They are a new generation of professionals who trade their positions for politcal recognition and leave their brains in the fridge The attraction for medical elites is the control and the position, and that creates one more layer of creative paperwork, cheap and pointless talk and a drain on limited medical resources.

The short analysis is that medical care is always intended and designed to prevent mistakes, but that adverse events occur when you take the responsibility for care of sick people. The alternative with better outcames data is to become the careful socialist system, rationing, cutting back, and protecting the reputations of the apparatchiks and the semi-retired medical dons who seem to have found a home in the new safety campaign and aspire to be national patient safety patrolmen.

## AN AFTERTHOUGHT IN RESPECT FOR PRESIDENT REAGAN

President Reagan made a difference because he believed in the American people and the eventual victory of his conservative ideas. Conservatives, or libertarians of the classic tradition understand what is inherently wrong about this safety movement, it presumes the superiority of elites of the IOM and the Medical Academy at the expense of the professionals that have made American Medicine without peer in the world.

It is my belief that the safety crusade that was cooked up for the benefit of a few elites will go away and that medicine and healthcare will continue to measure itself the way that services in a free society should be measured--we will do the best with what we know. Ultimtely people believe in each other, not in some monstrosity concocted by the anointed. The energy expended on this safety program will eventually find its way to better patient care. We can believe what President Reagan and Will Rogers did, that no politician can permanently harm this country because it is built on freedom and personal effort and it measures success the old fashioned way--by how we all work to improve the society.

**Acknowledgment**

The author wishes to thank Brian K. Nelson, MD, professor of emergency medicine at Texas Tech School of Medicine at El Paso, for help on the methodology and statistical analysis.

**References**


1. Kohn LT, Corrigan JM, Donaldson MS, eds. *To Err is Human -- Building a Safer Health System.* Washington, DC: National Academy of Science Press; prepublication, November 1999; final publication, 2000.
2. Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients: results of the Harvard Medical Practice Study I. *N Engl J Med*. 1991;324:370-376.
3. Leape LL, Brennan TA, Laird NM, et al. The nature of adverse events in hospitalized patients: results of the Harvard Medical Practice Study II. *N Engl J Med*. 1991;324:377-384.
4. Localio AR, Lawthers AG, Brennan TA, et al. Relation between malpractice claims and adverse events due to negligence: results of the Harvard Medical Practice Study III. *N Engl J Med*. 1991;325:245-251.
5. Mills DH. Medical insurance feasibility study. *West J Med*. 1978;128:360-365.
6. Gawande AA, Thomas EJ, Zinner MJ, Brennan TA. The incidence and nature of surgical adverse events in Colorado and Utah in 1992. *Surgery*. 1999;126:66-75.
7. Thomas EJ, Studdert DM, Newhouse JP, et al. Costs of medical injuries in Utah and Colorado. *Inquiry*. 1999;36:255-264.
8. Thomas EJ, Brennan TA. Incidence and types of preventable adverse events in elderly patients: population based review of medical records. *BMJ*. 2000;320:741-744.
9. Thomas EJ, Studdert DM, Burstin HR, et al. Incidence and types of adverse events and negligent care in Utah and Colorado. *Med Care*. 2000;38:261-271.
10. Studdert DM, Thomas EJ, Burstin HR, Zbar BI, Orav EJ, Brennan TA. Negligent care and malpractice claiming behavior in Utah and Colorado. *Med Care*. 2000;38:250-260.
11. Davis B, Appleby J. Medical mistakes 8th top killer. *USA Today*. November 30, 1999:1.
12. Brennan TA. The Institute of Medicine report on medical errors -- could it do harm? *N Engl J Med.* 2000;342:1123-1125.
13. Leape LL, Lawthers AG, Brennan TA, Johnson WG. Preventing medical injury. *QRB*. 1993;19:144-149.
14. Lesar TS, Briceland L, Stein DS. Factors related to errors in medication prescribing. *JAMA*. 1997;277:312-317.
15. Bates DW, Spell N, Cullen DJ, et al. The costs of adverse drug events in hospitalized patients. *JAMA*. 1997;277:307-311.
16. Classen DC, Pestotnik SL, Evans RS, Lloyd JF, Burke JP. Adverse drug events in hospitalized patients: excess length of

stay, extra costs, and attributable mortality. *JAMA*. 1997;277:301-306.
17. Avorn J. Putting adverse drug events into perspective [editorial]. *JAMA*. 1997;277:341-342.
18. Bates DW. Drugs and adverse drug reactions: how worried should we be? [editorial] *JAMA*. 1998;279:1216-1217.
19. Brennan TA, Localio AR, Laird NM. Reliability and validity of judgments concerning adverse events suffered by hospitalized patients. *Med Care*. 1989;27:1148-1158.
20. Brennan TA, Localio AR, Leape LL, et al. Identification of adverse events occurring during hospitalization: a cross-sectional study of litigation, quality assurance, and medical records at two teaching hospitals. *Ann Intern Med.* 1990;112:221-226.
21. *Patients, Doctors, and Lawyers: Medical Injury, Malpractice Litigation, and Patient Compensation in New York.* Report of the Harvard Medical Malpractice Study to the State of New York; 1990. (Contact the New York State Department of Health, General Counsel's Office.)
22. *Quantum*. Annual report to the provider: April 1, 1989-March 31, 1990. Austin, Tex: Texas Medical Foundation; 1990:6, fig 10.
23. *Quantum.* Annual report to the provider. April 1, 1990-March 31, 1991. Austin, Tex: Texas Medical Foundation; 1991:7, fig 10.
24. *Quantum*. Annual report to the provider: April 1, 1991-March 31, 1992. Austin, Tex: Texas Medical Foundation; 1992:7.
25. Fleiss JL. The measure of interrater agreement. In: *Statistical Methods for Rates and Proportions.* New York, NY: John Wiley and Sons; 1981:chap 13.
26. Fleiss JL. Reliability of measurement. In: *The Design and Analysis of Clinical Experiments.* New York, NY: John Wiley and Sons; 1986:chap 1.
27. Goldman RL. The reliability of peer assessments of quality of care. *JAMA*. 1992;267:958-960.
28. Caplan RA, Posner KL, Cheney FW. Effect of ouctome on physician judgments of appropriateness of care. *JAMA*. 1991;265:1957-1960.

**Table 1. Adverse event screening criteria for the Harvard medical practice study (19,20).**

1. Hospitalization within the previous year for patients under age 65 years and within the previous 6 months for older patients
2. Admission to any hospital after this discharge period
3. Previous failure of medical management or unfavorable results
4. Trauma incurred in hospital
5. Unfavorable drug reaction in hospital
6. Transfer from general care to special care unit
7. Transfer to acute care hospital
8. Return to operating room during this period of hospitalization
9. Treatment for organ damage after an invasive procedure
10. Acute myocardial infarction, cerebrovascular accident, or pulmonary embolism during or after an invasive procedure
11. Neurologic deficit at discharge
12. Death
13. Temperature higher than 28.3° C on day before or day of discharge
14. Cardiac or respiratory arrest
15. Five-minute Apgar score less than 6 or complications of abortion or labor or delivery
16. Other undesirable outcomes
17. Indication of litigation in medical record
18. Length of hospital stay above 90th percentile for diagnosis-related group in patients under age 70, and 95th percentile in those 70 or older*

* For the Harvard Utah/Colorado study, No. 18 was changed to: Unplanned open procedure or admission after outpatient surgery (9).

**Table 2. Harvard study negligence scale.**

1. Little or no evidence of management causation or negligence
2. Slight evidence
3. Not quite likely (less than 50/50 odds, but a close call)
4. More likely than not (greater than 50/50 odds, but a close call)
5. Strong evidence
6. Virtually certain evidence

**Table 3. Generic quality screens used for Texas Medical Foundation study, 1988-1992.**

Screen 1. Adequacy of discharge planning
Screen 2. Medical stability of the patient
Screen 3. Deaths
Screen 4. Nosocomial infections/bacteremia
Screen 5. Unscheduled return to surgery
Screen 6. Trauma suffered in the hospital

**Table 4. Negligence rates for Medicare age patients.***

| | | | |
|---|---|---|---|
| **Texas Medical Foundation** (1989-1992) | 317,333 charts reviewed | 2,582 (0.8%) confirmed quality problems | 475 (0.14%) Level III confirmed quality problemsH |
| **California** (1974) | 3,826 charts reviewed | 275 (7.22%) failed quality screens | 30 (0.79%) liability cases (estimate)I |
| **Harvard New York** (1984) | 4,980 charts reviewed | 283 (5.7%) adverse events | 94 (1.9%) negligence eventsə |
| **Harvard Utah/Colorado** (1992) | 3,966 charts reviewed | 448 (11.2%) adverse events | 249 (6.2%) preventable adverse events&<br><br>22 (0.5%) significant injury and death cases |

* The Texas Medical Foundation reviewed charts for Medicare patients only, so the numbers for the Texas Medical Foundation must be compared with the numbers for Medicare patients in the California and Harvard studies.

H References 26-28.

I The California study group estimated a 17% chance of successful litigation for all preventable compensable events (PCEs), with up to 44% chance of success for a few of the severe injuries. Although the group reported higher rates for PCEs in the elderly, the rate of negligence was the same across the age groups at approximately 0.79% (5).

ə References 2-4.

& The Utah/Colorado study report on elderly patient care in the March 2000 issue of the *British Medical Journal* did not analyze or report for negligence.

**Table 5. Inpatient medical quality review.**

| | Year | No. of Charts Reviewed | No. of Confirmed Quality Problems | No. of Level III Confirmed Quality Problems (patient injury) |
|---|---|---|---|---|
| Texas Medical Foundation | 1989-1990 | 94,408 | 1,172 | 223 |
| | 1990-1991 | 118,442 | 806 | 163 |
| | 1991-1992 | 104,483 | 604 | 89 |
| Total | 1989-1992 | 317,333 charts | 2,582 (0.8%) failed screens | 475 (0.14%) negligence events with any patient injury* |
| Harvard New York | 1984 | 30,195 charts reviewed; 7,817 failed generic screens | 280 (0.9%) confirmed quality problems | 89 (0.28%) negligence injury severity level 4-6<br>70 (0.23%) negligence deaths |
| Harvard Utah/Colorado | 1992 | 15,000 charts reviewed; 2,868 failed general screens | 459 (3.1%) or 587 (4%) adverse eventsH | 265 (1.8%) preventable events<br>169 (1.1%) negligence events (subset of preventable events)<br>10 (0.07%) significant injury negligence events<br>18 (0.12%) preventable deaths<br>15 (0.1%) negligence deaths (subset of preventable deaths) |
| California | 1974 | 20,864 charts reviewed | 970 potentially compensable events | 165 (0.79%) negligence events<br>36 (0.17%) negligence injury severity 3.4-3.6<br>40 (0.19%) negligence deaths |

The California and Harvard study findings are on all groups and areas of care. California used the term "potentially compensable event," the equivalent of "adverse event" in the Harvard studies.

* References 26-28.

H The difference in adverse event counts from Utah/Colorado is not explained but was reported as 459 in the 1999 *Inquiry* report (7) and as 587 in the *Medical Care* report of March 2000 (9). The negligence numbers are from the 2000 report; the preventable event numbers, from the 1999 data. Rates and calculations were kept consistent with the differences between 1999 and 2000 adverse event reports.

**Table 6. Trends in patient safety.**

| | 1974 California | 1984 Harvard New York | 1992 Harvard Utah/Colorado | 1989-1992 Texas Medical Foundation |
|---|---|---|---|---|
| Adverse event rate, % | 4.6 | 3.8 | 3.1 or 4.0 | 0.8 |
| Negligence event rate, % | 0.79 | 0.9 | 1.1 | 0.14 |
| Negligence death rate, % | 0.2 | 0.2 | 0.1 | -- |
| Projected number of national negligence deaths* | 52,000H | 84,000 | 24,979 | -- |

* Some death numbers reported elsewhere are adverse events deaths.

H This number is a rough estimate based on the state figure multiplied by the California-to-national population ratio. The number is the product of the same process used by the authors of the Harvard studies in New York and Utah/Colorado.