From "Patient Safety Research: Creating Crisis," by John Dale Dunn, M.D., J.D.:

The annual national total death numbers per year constantly quoted from the IOM and subsequent safety reports are 44,000 to 98,000. But what if the IOM, in its capacity as the de facto think tank arm of the National Academy of Sciences, is using flawed statistics for political ends -- to make the case for greater government intervention in healthcare? The IOM papers and research on patient safety were funded by a federal agency, the Agency for Healthcare Research and Quality (AHRQ), throughout most of the 90s known as the Agency for Healthcare Policy and Research. That organization lost its original job of writing clinical guidelines and was devoid of purpose before the safety movement was energized. It reinvented itself after the 1999 IOM safety report as the guardian of patient safety. The more evidence for a patient safety crisis the safety movement discovers, the stronger the case for AHRQ's existence.

The death numbers pronounced in the IOM monograph of 1999 and repeated since were based on two research projects of a Harvard Medical School group, the first looking at fifty-one New York hospitals in 1984 (published in NEJM in 1991.(3,4) The second study was of hospital care in twenty-eight Utah and Colorado hospitals in 1992, published in 1999 and 2000.(5,6,7,8,9) Although neither of these studies actually asserted 44,000 or 98,000 anywhere in the data, the IOM authors created these numbers, and the media has used them as if they were hard data, despite the range of hypothetical deaths -- 44,000 to 98,000 -- varying by over 100% and despite a serious mistake by the IOM: exaggerating a national projection of 25,000 deaths in the later Utah/Colorado study.

USA Today's November 30, 1999 front-page headline proclaimed "Medical mistakes 8th top killer," and the accompanying article reported: "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."(10)

As a safety expert, I was outraged to read the prepublication release of the 1999 IOM monograph because I had analyzed the 1991 report of the Harvard study in New York that the IOM was relying on and found it to be deeply flawed. Still, when the IOM report came out in 1999, organized medicine had already quietly agreed to play a supportive role in any government-proposed safety program, fearing the alternative of an even more direct regulatory role for government. But the patient safety crusade hadn't counted on an honest Harvard physician/attorney named Brennan.

Voices of Dissent Are Heard

Troyen Brennan M.D., J.D. — a lead Harvard researcher on the two studies that were the backbone of the IOM report and the source of the negligence death numbers that scared so many — asserted in an essay in NEJM that the research of the Harvard group was weak and was being misused by the IOM. Brennan wrote:

1. "I have cautioned against drawing conclusions about the numbers of deaths in these studies."

2. "The ability of identifying errors is methodologically suspect."

3. "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."(11)

Another major segment of patient safety research relied on by the IOM in their 1999 announcement of a crisis was research on adverse drug events (ADEs), meaning undiscovered or uncorrected mistakes in prescribing and administration of medications and fluids. However, that research is frequently weak. It is clear that the ADE research dredges for numbers and exaggerates effects by including "possible" drug events and expected-and-unavoidable drug events.

So say Jerry Avorn, M.D., and David Bates, M.D., of Brigham and Women's Hospital in Boston, writing in the *Journal of the American Medical Association* (JAMA). Dr. Avorn says in an editorial about a couple of 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."(12) Dr. Bates, in an editorial commenting on another drug event study, says problems exist in studies of ADEs, such as whether they are properly identified and evaluated and whether ADEs are really avoidable in a practical sense, particularly in severely ill patients.(13) The millions of drug administrations daily in American hospitals present a potential for error, but also an opportunity for research data dredging and manipulation, including the creation of a "crisis." (my emphasis underline added)

(pertinent endnotes)

10 Davis B, Appleby J. Medical mistakes 8th top killer. USA Today, November 30, 1999:1.

11 Brennan TA. The Institute of Medicine report on medical errors -- could it do harm? NEJM 2000;342:1123-1125.

12 Avorn J. Putting adverse drug events into perspective [editorial]. JAMA 1997;277:341-342.

13 Bates DW. Drugs and adverse drug reactions: how worried should we be? [editorial]. JAMA 1998;279:1216-1217.