Deaths Due to Medical Errors Are Exaggerated in Institute of Medicine Report

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THE RECENT INSTITUTE OF MEDICINE (IOM) REPORT about medical errors[1] contains 2 different messages. One is cool and measured, a call for understanding the cause of errors in the health care system and for developing an approach using computerized and other "mechanical" support systems to decrease error rates. We like that message—indeed, we and our many colleagues at the Regenstrief Institute have been implementing it for the last 25 years.[2-4]

Furthermore, we agree that studying and understanding the causes of adverse events, preventable and otherwise, and developing mechanisms for reducing them are laudable goals that should be pursued. The other message in the IOM report is hot and shrill. It shouts about death and disability in US hospitals: "Preventable adverse events are a leading cause of death" and "at least 44,000, and perhaps as many as 98,000, Americans die in hospitals each year as a result of medical errors." The unstated corollary—reinforced by the death rate from motor vehicle collisions juxtaposed with the death rate from adverse events—is that eliminating preventable adverse events also will eliminate the deaths.

Motor vehicle occupants do survive their ride if collisions are avoided. Unlike most people who step into motor vehicles, most patients admitted to hospitals have high disease burdens and high death risks even before they enter the hospital. Although some hospital deaths are preventable, most will occur no matter how many "accidents" we avoid. Of course, medical errors are never excusable, but the baseline death risk has to be known and factored out before drawing conclusions about the real effect of adverse reactions on death rates, preventable or otherwise.

The headline number of 98000 deaths due to medical errors derives from the data reported in the Harvard Medical Practice Study, a groundbreaking study about adverse events, preventable and otherwise.[5] This and subsequent articles[6,7] by the same group shed light on a subject that had never been systematically studied. These articles impressed us in 1991 and still do. The lower IOM figure (44000) is derived from a 1992 study of Colorado and Utah data using the same methods as the Harvard Medical Practice Study.[8] Both were observational studies and were not designed to describe causal relationships. The Harvard study authors included caveats, such as "lead to death" and "died at least in part as a result of adverse event." The authors of the Colorado-Utah study reported a proportion of patients who died in the adverse reaction group, but said nothing about the cause of these deaths. The IOM did not mention any of these limitations in its report.

In the Harvard study,[5] investigators started with a sample of 31429 patient admissions from the 1984 New York hospital admissions database. They applied screening criteria to find a subgroup of 7743 cases with a high likelihood of having experienced an adverse event. This group included all patients from the original sample who died, returned to intensive care, had excessive length of stay, or met other criteria. Because these selection criteria identify severely ill patients, we refer to it as the *high-severity* group. The Harvard authors targeted this high-severity subgroup for a detailed physician review in search of adverse events. The physicians discovered adverse events in 1278 of these 7743 cases. Of the 1278 high-severity patients for whom an adverse event was identified, the investigators reported that 173 patients (13.6%) died, at least in part because of an adverse event.

The Harvard study includes no information about the baseline risk of death in these patients or information about deaths in any comparison group. Therefore, it cannot be determined whether adverse events are correlated with, let alone whether they cause, death. Indeed, an assertion that adverse events caused death in 13.6% of the patients who experienced adverse events is tantamount to the assertion that there would be no deaths in a group with similar baseline risks who avoided all adverse events. Clinical experience tells us that this is not true.

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How the 13.6% figure was obtained deserves careful consideration. Charts of all patients in the population of 31 429 who met 1 of the screening criteria (which included death) were reviewed for evidence of an adverse event. This approach is a logical way to obtain a high proportion of patients with adverse events. Among the subgroup of high-severity patients who had an adverse event, 13.6% died. What proportion of all patients in the high-severity group died? Using original data from the New York State Public Health Department, we learned that the New York State in-hospital acute care death rate was 3.4% in 1984. This should be a good approximation of the proportion of deaths in the Harvard initial sample of 31 429. By multiplying this figure times the sample size, we estimate that 1069 deaths occurred in the initial sample. Because death was a screening criterion for including a patient in the study sample,[9] these 1069 deaths must have occurred in the high-severity group (n=7743), meaning that 13.8% of the patients in the high-severity group died overall. This figure is very similar to the 13.6% who died in the subset of this population with adverse events. This also means that the proportion of death in the group without adverse events must be very similar, unless many deaths occurred in the group with adverse events that were not attributed to adverse events. While the number of deaths in the adverse event group not attributed to adverse events is not known from the published data, the number is unlikely to be large since it was never referred to in any of the publications from this study.

However, neither the 13.8% of deaths for the overall group nor the 13.6% in the adverse event subset is a death rate in the usual sense of the word because of the sampling procedures used in the Harvard study (ie, death was a criterion for inclusion in the high-severity group). These figures are simply proportions of deaths calculated from the particular study sample; thus, one should not infer that they apply to any prespecified group of patients.

Furthermore, it is invalid for us to compare directly the proportion of deaths in the patients in the high-severity group who experienced or did not experience an adverse event because of many confounding factors, inherent selection bias in the death sample, and the possibility of initial differences in the baseline death risks of the 2 groups. However, it is also invalid for the IOM to assert that the observed deaths were caused by adverse events without presenting or defining the appropriateness of any comparison group whatsoever. Also, the sampling used in the study ensured identification of all deaths but not necessarily all adverse events, since the charts evaluated included all charts of patients who died but not all charts of patients who potentially experienced adverse events. This sampling method inflates the proportion of adverse events that lead to death.

The IOM report[1] cited a number of other studies to support the argument that medical errors are a major cause of death. Most of these other studies also depended on physician chart review, qualified their claims with words like "possible cause," and lacked any kind of control or comparison group; however, the IOM did not emphasize these limitations. Furthermore, the IOM cited a study that claimed 7000 deaths were due to medication errors in 1993.[10] However, this study miscounted deaths due to drug abuse as due to medication errors, according to a subsequent letter[11]; thus, in our opinion, the study should not have been cited.

The IOM figures focus on "preventable adverse events" rather than the total set of adverse events, but their estimates of preventable deaths depend on the relationship between adverse events in general and death. The number of preventable adverse events that caused death is calculated as a direct proportion of the total adverse events that cause death; therefore, if the relationship between overall adverse events and death declines, so does the relationship between preventable adverse events and death.

The Harvard study acknowledged that eliminating the adverse event (and even the negligence) would have little effect on the life expectancy of many terminally ill patients, but did not quantify the possible implications of this phenomenon on the death figures in the adverse event group. The 30-day posthospital admission mortality rate of 11.6%[12] and the 30-day death risk up to 40% for some categories of Medicare patients[13] suggest that an important proportion of hospitalized patients are at, or near, the end of their lives. If we are not careful about the mechanisms constructed to detect and reduce errors, end-of-life decisions could be distorted.

Given these facts, using available data and some reasonable assumptions, we believe that the increment in the published death rate due to adverse events above the baseline death rate could be very small. We also assert that the available data do not support IOM's claim of large numbers of deaths caused by adverse events (preventable or otherwise). The first author of the Harvard study recently raised other related concerns about the IOM report.[14] Clearly, more study with careful attention to risk levels is needed to determine the true impact of adverse events on death rates among hospitalized patients. Until those results are available, the design of regulatory solutions is premature.

The IOM uses elaborate controls to ensure a careful balance of interests in the parties on the committees that produce reports and it uses extensive review to avoid errors in its reports. However, the reliance on studies without controls to make headline claims about huge numbers of preventable deaths was one error that it did not catch—perhaps proving the point once again, in an Escherian way, that humans do err.

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Institute of Medicine Medical Error Figures Are Not Exaggerated

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FEW PUBLICATIONS IN RECENT MEMORY HAVE RECEIVED as much notice or stimulated as swift a response among policy makers as the Institute of Medicine (IOM) report on medical errors.[1] Within 2 weeks of the report's release last November, Congress began hearings and the president ordered a government-wide study of the feasibility of implementing the report's recommendations. The IOM called for a broad national effort to include establishment of a Center for Patient Safety within the Agency for Healthcare Research and Quality, expanded reporting of adverse events and errors, development of safety programs in health care organizations, and intensified efforts by regulators, health care purchasers, and professional societies. However, while the objective of the IOM report, and the thrust of its recommendations, was to stimulate a national effort to improve patient safety, what initially grabbed public attention was the declaration that between 44 000 and 98 000 people die in US hospitals annually as a result of medical errors. These estimates represent current national extrapolations from the results of 2 large population-based studies carried out to assess the impact of medical injury.[2,3]

A telling measure of the impact of this publicity has been the sudden emergence of questions about the validity of the mortality estimates, particularly those from the first Medical Practice Study (MPS). These findings have not been seriously challenged since they were published 9 years ago. In this issue of THE JOURNAL, McDonald et al[4] raise new questions about these mortality figures and their implications, noting that the MPS investigators did not calculate "excess" mortality, and may, therefore, have exaggerated the extent of fatal injury.

The first MPS did, in fact, have significant limitations and important methodological weaknesses. It was not designed primarily to study risk factors for injury, for example, but to assess the extent of injury that could lead to malpractice litigation, hence the exclusion of nondisabling injuries and the focus on negligence. The study's most serious limitation is probably that it was a retrospective medical record review study. Many important events in patient care are not recorded in the medical record. Some errors are not even known to clinicians caring for the patient. Studies of autopsy, for example, have found potentially fatal misdiagnoses in 20% to 40% of cases.[5-7] On balance, the reliance on information extracted from medical records most likely led to a substantial underestimate of the prevalence of injury.

Another serious weakness of the MPS is that it relied on implicit judgments by physicians. While extensive efforts were made to strengthen the accuracy and reproducibility of these judgments through training of physician reviewers, use of a highly structured data collection instrument, and duplicate review with rereview and resolution of disagreements, errors undoubtedly occurred. It is possible that these errors "canceled out," ie, overinterpretation of medical error was balanced by underinterpretation, but that is unknown. A serious weakness of any retrospective review is hindsight bias, the tendency to impute causation to an action when the (bad) outcome is known.[8] Hindsight bias would tend to overestimate the number of deaths due to adverse events.

McDonald et al also state that many patients categorized in the MPS as dying as the result of an adverse event would have died anyway, and that the more relevant number is those who died solely because of the adverse event. To estimate this "excess mortality" they determined the mortality among all patients whose records were screened for adverse events in the MPS. They label these patients selected for chart re-

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