

Unreliable Research on Error-Related Hospital Deaths in America

Gerard J. Gianoli, M.D.

John Dale Dunn, M.D., J.D.

On May 3, 2016, the online *BMJ* (formerly the *British Medical Journal*) published an article titled, “Medical Error—the Third Leading Cause of Death in the U.S.” by Martin Makary and Michael Daniel.¹ In it, the authors reviewed four prior studies on medical errors^{2,3,4,5} and from these studies extrapolated and projected the incidence of in-hospital deaths due to medical errors in the U.S. for the year 2013 to an astounding 251,454.

Media published the highlights of the Makary/Daniel paper as if it were new groundbreaking research showing a rising rate or epidemic of medical error deaths and a growing problem with hospital patient safety. Simple reading of the article proves otherwise. There was no new research. In fact, there was no research at all. The authors simply referenced old studies published between 8 and 16 years ago. There was no analysis of “rate” of negligent deaths or events, and no demonstration of a change in the incidence of medical errors or medical error deaths.^{2,3,4,5}

Death due to medical errors is an important and serious topic. It deserves careful consideration. However, exaggerating the severity of the problem of in-hospital medical errors supposedly leading to death does no service to the cause of improving patient safety. We do not hold the authors accountable for being misrepresented by the mainstream media. However, we do hold them accountable for unsubstantiated claims and exaggerations that are the problem with their paper. There are five major flaws with the Makary/Daniel paper:

1. Improper definition,
2. Data inconsistency and tabulation of “medical errors,”
3. Extrapolation error,
4. Misinformation regarding death certificates, and
5. Inappropriate recommendations for further research.

Definition of “Error”

Makary and Daniel use an overly broad definition of the word “error” that would not conform to the definition most commonly used by the average reasonable physician, or a definition found in a dictionary. This leads to confusion of the media and subsequently the lay public. It adds to an exaggerated claim in the number of “preventable medical error deaths.” From *Wikipedia* we find the generally accepted definition: “An error is an action which is inaccurate or incorrect.”⁶

Compare this with the *BMJ* article:

Medical error has been defined as an unintended act (either of omission or commission) **or one that does not achieve its intended outcome**, the failure of a planned action to be completed as intended (an error of execution), the use of a wrong plan to achieve an aim (an error of planning), or a deviation from the process of care that may or may not cause harm to the patient [emphasis added].¹

Note that the definition in the *BMJ* article (as well as in the several other referenced studies looking at medical “errors”) includes actions that are correct and not negligent, but do not result in successful outcomes. Consequently, any clinical outcome that is less than was desired can be considered a “medical error” in this distorted and outcome-biased view.

Consider the following clinical scenario: A patient is offered surgery for a condition that has a projected mortality of 100% without surgery. The surgery has an estimated 30% chance for death. The patient chooses to undergo the surgery and dies. There was no medical error here, but simply an unfortunate adverse outcome in a high-risk procedure. The Makary/Daniel study would have listed this patient’s death as an adverse event, medical error death.

In medical care, sometimes even when everything is done correctly, even by the best in the world, the patient dies or has a less-than-desired outcome. The expansive definition of the word “error” used by Makary and Daniel is not error at all, but greatly exaggerates the concept of “medical error deaths” in the minds of the public at large. We argue that their definition of the word “medical error” renders the term meaningless. This distorted version of the definition is the equivalent of the concept condemned as a fallacy in scientific inquiry—outcome bias.⁷ This issue alone would have warranted rejection by the peer reviewers, but there are even more significant deficiencies with the Makary/Daniel paper.

Data Inconsistency

The basis for the claims made by Makary and Daniel are four studies published between 2000 and 2008. Other studies were available to analyze, but the authors give no reason for excluding them. Keep in mind that this was not a meta-analysis with exhaustive screening of the medical literature. No rationale is given for choosing these cherry-

picked studies. One study quoted in their article could have been used for their extrapolation but would have given a much lower number of medical error deaths: 35,000.⁸ This makes one wonder whether other studies not cited by the authors were excluded because they would not support the authors' hypothesis.

The authors claim to have reviewed the four studies for "preventable medical error deaths." Among the four papers cited, only three of the studies actually reviewed individual patient charts. The total number of "preventable medical error deaths" Makary and Daniel found was 35 in the period of nearly a decade during which the studies were completed. To be sure, this is a small number to extrapolate to 251,454 patients per year. However, upon reviewing the cited papers, we are only able to find 14 "preventable medical error deaths." Obviously, this discrepancy would have a profound impact on their extrapolation calculations, bringing their total to 96,000 at most. This discrepancy should prompt the authors to revise their paper or explain their methodology.

Furthermore, Makary and Daniel used the "I" category from the NCC MERP Index for Categorizing Medication Errors in extrapolating errors from these four studies. An "I" category event is defined as "error occurred that *may have* contributed to or resulted in patient death" [emphasis added].⁹ The authors made no effort to clarify the "may have" attribute in the assertions of medical errors. Simple reading of this definition implies that even though there is suspicion of a medical error causing death in these cases, it is also possible that a medical error did not cause death in these cases. Consequently, of the 14 preventable medical error deaths or "I" level events found in these studies, it is certainly possible that none of the errors caused the deaths in these cases. The words "may have" give no estimate of the probability, and there was no serious effort to apply a standard of care for judgments of negligence. Thus, a fair-minded researcher should include "zero" at the bottom of the range of possible deaths due to medical errors, which is called the confidence interval in observational studies. A confidence interval including no effect (i.e. "zero") over a huge range with an "average" of 251,454 deaths is a mathematical way of stating that the calculations are meaningless. Makary and Daniel gave no details on how they arrived at this number.

Using our number of 14 instead of 35 preventable medical error deaths would give a range of 0 to 96,000.

Extrapolation Error

Whenever extrapolating from a study group to a larger group, one must make sure that the study group is a representative sample of the larger group. If the sample is not representative, the result of the extrapolation is meaningless. None of the studies are representative samples. For example, two of the studies included only Medicare patients. Given that 75% of all deaths in hospitals are in the 65-year-old and

older category, this would create a huge distortion in the outcome when extrapolating.

For example, this would be like calculating the pass completion rate for Drew Brees, the undisputed National Football League record holder, by extrapolating from "Hail Mary" passes only. That would give the erroneous result that he completes less than 5% of his passes, rather than his record rate of 70%.

It is unreasonable to extrapolate from the medical "Hail Marys" (in a patient population that is less healthy by definition and prone to treatment complications) to the general medical population. This is why the authors of the studies cited by Makary and Daniel did not do so. A representative sample would have to include low-risk patients as well.

Makary and Daniel write:

Of note, none of the studies captured deaths outside inpatient care—those resulting from errors in care at home or in nursing homes and in outpatient care such as ambulatory surgery centers.... We believe this understates the true incidence of death due to medical error because the studies cited rely on errors extractable in documented health records and include only inpatient deaths.¹

This comment is erroneous since adding in a lower-risk pool would lower their extrapolation of negligence or preventable deaths to a general population, not raise it. The comment would only possibly be true if they were actually tabulating the total number of deaths rather than extrapolating from a sample group. High-risk populations distort the rate of bad outcomes and increase the rate of potential complications of treatment. Correcting the extrapolation error would more than likely adjust the Makary/Daniel estimates in the downward direction. Unfortunately, since the samples are not representative, a recalculation cannot be performed.

Misinformation Regarding Death Certificates

Makary and Daniel, in their conclusions, recommend having a section on death certificates for the attending physician to state whether the patient died of a medical error. They claim this would "heighten awareness and guide both collaborations and capital investments in research and prevention." However, death certificates already have two sections—one for cause of death and one for manner of death.¹⁰ The cause of death is the physiologic reason the patient died as well as the cascade of events that led to the demise. The manner of death to be checked off by the attending physician includes homicide, suicide, natural causes, accident, pending investigation, or could not be determined. If a medical error is believed to have occurred, then the appropriate manner of death to check would be "accident," and the sequence of events can be listed on the

“cause of death” cascade. For many years there has been ample means for the physician to express his judgment about a medical error. Furthermore, an autopsy should be ordered or recommended to confirm these suspicions.

Inappropriate Recommendations

The recommendation to use death certificates in medical error death research presumes that death certificates contain reliable information and represent good judgment about whether medical errors occurred. However, death certificates are notoriously inaccurate. Multiple studies have shown a 25%–60% inaccuracy rate in the cause of death on the death certificate compared with autopsy.^{11–14} Thus, if Makary and Daniel want “heightened awareness” and “capital investment” allocated to the best use, they should be advocating more frequent autopsies. The autopsy rate was approximately 50% in the 1970s, but has dropped to less than 5% currently.¹⁵

When some deviation from the standard of care occurs and the patient dies, there is a strong tendency to blame the deviation. However, this is not always justified. An autopsy—the gold standard for determining cause of death—is required to be sure. The four studies Makary and Daniel relied on for their paper did not include autopsies. The death diagnoses in the 14 cases thus had a likely inaccuracy rate of 25%–60%. Extrapolating from this rate is meaningless. The lay press nonetheless used it to claim that patient safety events, negligence events, and adverse events are more lethal than automobile accidents. A petition generated by members of the Pennsylvania Medical Society asks that the article be retracted.¹⁶

History of Patient Safety Studies

The Institute of Medicine (IOM) report on patient safety in late 1999, *To Err is Human*,¹⁷ attracted great national attention when it announced that 44,000 to 98,000 patients die each year in American hospitals because of patient safety problems and that a patient safety crisis exists in American health care and American hospitals. The report relied heavily on a Harvard group’s study of hospital care in New York in 1984, published in 1991,^{18–20} and another Harvard group’s study of hospital care in Utah and Colorado in 1992, published in 2000.^{21–23}

In 2000, John D. Dunn reviewed and compared American hospital inpatient safety research from the previous three decades,²⁴ and compared the major patient safety research cited by the IOM report with the work of the Texas Medical Foundation (TMF), the Medicare quality of care review contractor for more than 400 Texas hospitals. TMF reviewed 318,000 medical admissions of Medicare patients in a 3-year period and reported their findings of negligence-caused injuries.^{25–27}

In 2005, in response to an appeal in the *New England Journal of Medicine* to expand and strengthen the patient safety crusade, Dunn wrote another comprehensive review of the patient safety crusade and politics.²⁸ He compared the Harvard patient-safety studies that received great national attention with the more robust TMF database that did 100% review. The other three studies screened for adverse events, a method that encourages outcome bias. Only 4% of all the Harvard^{18–23} and California²⁹ inpatient charts were reviewed after they dropped out on generic screens. The methods used by Texas Medical Foundation involve 100% review by quality criteria, not adverse event screens.

TMF studied 300,000 patient admissions during 3 years (1989–1992) in more than 400 hospitals. The Harvard studies reviewed 30,000 charts in 51 hospitals in New York in 1984, and 15,000 charts in 28 hospitals in Utah and Colorado in 1992. TMF interviewed and interacted with the persons who cared for the patients, whereas the researchers in the other three studies did not. Multiple-level reviews by individuals, and then panels with provider interactions were performed by TMF, but not in the other three studies.

Dunn’s detailed analysis and comparison of the adverse events data of all the studies (Tables 1 and 2) showed a positive patient safety picture, with a low rate of negligence events causing injury or death, stable for three decades in the other three studies, and a lower negligent injury rate in the TMF study. Note that the TMF studied high-risk Medicare patients. The analysis showed low rates of significant injury or death caused by negligence.

Another consideration in comparing the two Harvard studies was the modification of the definition of “events” from negligent in the Harvard 1984 New York Study to include “preventable” (could have been prevented) events in the Utah/Colorado study that inflated the rate of events counted from less than 1% to 1.8% in the Utah/Colorado study of care in 1992.

In a candid essay after the release of the IOM paper, Dr. Troyen Brennan, the senior researcher for the Harvard group, also warned that the IOM was misusing the research of the patient-safety studies and failing to warn of methodological problems. Dr. Brennan stated his concern about misuse of the data from the two Harvard safety studies in the IOM monograph in a *New England Journal of Medicine* essay.³⁰

Dr. Brennan writes:

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.... [T]hese decisions do not necessarily reflect the views of the average physician, and certainly don’t mean that all preventable adverse events were blunders.¹⁸

Table 1. Comparisons of the Patient Safety Studies

Study	Year	No. of Charts Reviewed	No. of Confirmed Quality Problems	No. of Level III Confirmed Quality Problems (patient injury)
Texas Medical Foundation ²⁴⁻²⁸	1989-1990	94,408	1,172	223
	1990-1991	118,442	806	63
	1991-1992	104,483	604	89
Total	1989-1992	317,333	2,582 (0.8%) failed generic screens*	475 (0.14%) negligence events with any patient injury ²⁴⁻²⁸
Harvard New York ¹⁸⁻²⁰	1984	30,195 charts reviewed; 7,817 failed generic screens*	80 (0.9%) confirmed quality problems	89 (0.28%) negligence injury severity level 4-6 70 (0.23%) negligence deaths
Harvard Utah/Colorado ²¹⁻²³	1992	15,000 charts reviewed; 2,868 failed generic screens*	459 (3.1%) or 587 (4%) adverse events	265 (1.8%) preventable events 169 (1.1%) negligence events (subset of preventable events) 10 (0.07%) significant injury negligence events 18 (0.12%) preventable deaths 15 (0.1%) negligence deaths (subset of preventable deaths)
California ²⁹	1974	20,864 charts reviewed	970 potentially compensable events*	165 (0.79%) negligence events 36 (0.17%) negligence injury severity 3.4-3.6 40 (0.19%) negligence deaths

*Generic Screens were introduced in the California study and used with some modifications for outpatient surgery in the Harvard studies. Charts that failed generic screens have adverse outcome, unanticipated complications, or potentially compensable events that triggered close physician review.

Table 2. Trends in Patient Safety¹⁸⁻²⁹

	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*	52,000†	84,000	24,979	--

* Some death numbers reported elsewhere are adverse events deaths.

† 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.

Political Ramifications of the Patient Safety Movement

The development of the cottage industry of patient-safety advocates, and in particular the politics of patient safety as a way to denigrate the medical profession, could help make way for government-financed and controlled "healthcare" with the formerly independent professionals morphed into servants of apparatchiks and "mandarins," who not only control financing, but also provide orders and guidelines asserted to be necessary because of claimed negligent and greedy medical professionals.

The patient safety "experts" now dominating the professional medical environment, providing guidelines and precautions

and protocols and determining use of resources and priorities for care, could not have been put in place without media and political classes whose members constantly campaign to diminish the medical profession.

Those from the medical profession who provided the junk research, with its loud warnings of an epidemic of doctor- and nurse-caused deaths, were part of the scheme, and the leaders of organized medicine joined the crusade to diminish the status of their colleagues because they assumed they would end up being on the control boards and committees telling physicians and nurses what is best for them, and what they can or cannot do. These controllers insist on vast amounts of electronic data

to feed the maw of the new, ever-more bloated government healthcare bureaucracy, with its insatiable need for reports and studies.

These safety doyens first claim to quantify the problem of nurse and physician incompetence and negligence, and then offer to save the public from the dangerous hobgoblins they have created.

As H.L. Mencken wrote: "The whole aim of practical politics is to keep the populace alarmed (and hence clamorous to be led to safety) by menacing it with an endless series of hobgoblins, all of them imaginary." And: "The urge to save humanity is almost always a false front for the urge to rule."

Daniel Webster warned us that "Good intentions will always be pleaded for any assumption of power. The Constitution was made to guard the people against the dangers of good intentions. There are men in all ages who mean to govern well, but they mean to govern. They promise to be good masters, but they mean to be masters."

Conclusions

The widely publicized *BMJ* article claiming that medical error is the third-leading cause of death in the U.S. is badly flawed and should be retracted. It will not further the cause of patient safety. Instead of outcome-based judgment on whether an error "may have" caused an adverse event, we need autopsy studies and reliable assessments of negligence to determine the actual cause of death and help reach an informed conclusion, based on rigorous criteria, about the role of error or failure to follow the standard of care in cases of death or adverse events in hospitalized patients.

Gerard Gianoli, M.D., is a neuro-otologist practicing at the Ear and Balance Institute in Covington, LA. Contact: ggianoli@gmail.com. **John Dale Dunn M.D., J.D.**, is a consultant in emergency services/peer review and serves on the civilian faculty for the emergency medicine residency at Carl R. Darnall Army Medical Center, Fort Hood, Texas.

REFERENCES

1. Makary MA, Daniel M. Medical error—the third leading cause of death in the US. *BMJ* 2016; 353: i21369. Available at: <http://dx.doi.org/10.1136/bmj.i2139>. Accessed Aug 20, 2016.
2. HealthGrades Quality Study: Patient Safety in American Hospitals; 2004. Available at: http://www.providersedge.com/ehdocs/ehr_articles/Patient_Safety_in_American_Hospitals-2004.pdf. Accessed Aug 20, 2016.
3. Office of Inspector General. Department of Health and Human Services. Adverse Events in Hospitals: National Incidence among Medicare Beneficiaries; November 2010. Available at: <http://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf>. Accessed Aug 20, 2016.
4. Classen D, Resar R, Griffin F, et al. Global "trigger tool" shows that adverse events in hospitals may be ten times greater than previously measured. *Health Aff* 2011;30:581-589. doi: 10.1377/hlthaff.2011.0190.
5. Landrigan CP, Parry GJ, Bones CB, et al. Temporal trends in rates of patient harm resulting from medical care. *N Engl J Med* 2010;363:2124-2134. doi:10.1056/NEJMs1004404pmid:21105794.
6. Error. *Wikipedia*. Available at: <https://en.wikipedia.org/wiki/Error>. Accessed Jun 20, 2016.
7. Outcome bias. *Wikipedia*. Available at: https://en.wikipedia.org/wiki/Outcome_bias. Accessed Jun 20, 2016.
8. Provenza A, Rohan S, Trevejo E, et al. Evaluating inpatient mortality: a new electronic process that gathers information from front-line providers. *BMJ Qual Saf* 2015; 24:31-7. doi: 10.1136/bmjqs-2014-003120 pmid:25332203.
9. NCC MERP Index for Categorizing Medication Errors. National Coordinating Council for Medication Error Reporting and Prevention; 2001. Available at: <http://www.nccmerp.org/sites/default/files/indexColor2001-06-12.pdf>. Accessed Jun 20, 2016.
10. National Center for Health Statistics, Centers for Disease Control and Prevention, U.S. Dept. of Health and Human Services. Instructions for completing the cause-of-death section of the death certificate. Available at: http://www.cdc.gov/nchs/data/dvs/blue_form.pdf. Accessed Jun 8, 2016.
11. Nashelsky MB, Lawrence CH. Accuracy of cause of death determination without forensic autopsy examination. *Am J Med Pathol* 2003;24:313-319.
12. Mushtaq F, Ritchie D. Do we know what people die of in the emergency department? *Emerg Med J* 2005;22:718-721. doi: 10.1136/emj.2004.018721.
13. Mieno MN, Tanaka N, Arai T, et al. Accuracy of death certificates and assessment of factors for misclassification of the underlying cause of death. *J Epidemiol* 2016;26(4):191-198. doi: 10.2188/jea.JE20150010.
14. Hoff CJB, Ratard R. Louisiana death certificate accuracy: a concern for the public's health. *J La State Med Soc* 2010;162:350-353.
15. Shojania KG, Burton EC. The vanishing nonforensic autopsy. *N Eng J Med* 2008;358:873-875. doi: 10.1056/NEJMp0707996.
16. Whitman E. Blog: *BMJ* medical errors paper fuels growing debate. *Modern Healthcare*, Jul 18, 2016. Available at: <http://www.modernhealthcare.com/article/20160718/BLOG/160719920>. Accessed Aug 20, 2016.
17. Kohn LT, Corrigan JM, Donaldson MS. *To Err Is Human: Building a Safer Health System*. National Academies Press; 1999.
18. 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.
19. 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.
20. 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.
21. 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.
22. 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.
23. Studdert DM, Thomas EJ, Burstin HR, et al. Negligent care and malpractice claiming behavior in Utah and Colorado. *Med Care* 2000;38:250-260.
24. Dunn J. Patient safety in America: comparison and analysis of national and Texas patient safety research. *Texas Medicine* 2000;96(Oct):66-74. Available at: https://www.heartland.org/sites/all/modules/custom/heartland_migration/files/pdfs/23751.pdf. Accessed Aug 20, 2016.
25. Quantum. Annual Report to the Provider: April 1, 1989-March 31, 1990. Austin, Tex: Texas Medical Foundation; 1990:6, fig 10.
26. Quantum. Annual Report to the Provider: April 1, 1990-March 31, 1991. Austin, Tex: Texas Medical Foundation; 1991:7, fig 10.
27. Quantum. Annual Report to the Provider: April 1, 1991-March 31, 1992. Austin, Tex: Texas Medical Foundation; 1992:7.
28. Dunn J. Patient safety research—creating crisis. *News. American Council on Science and Health*, Jan 10, 2005. Available at: <http://acsh.org/news/2005/01/10/patient-safety-research-creating-crisis/>. Accessed Aug 20, 2016.
29. Mills DH. Medical insurance feasibility study. *West J Med* 1978;128:360-365.
30. Brennan TA. The Institute of Medicine report on medical errors—could it do harm? *N Engl J Med* 2000; 342:1123-1125. Available at: <http://www.nejm.org/doi/full/10.1056/NEJM200004133421510>. Accessed Aug 24, 2016.