The Silence

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The Silence

Medicine's continued quiet refusal to take quality improvement actions has undermined the moral foundations of medical professionalism.

by Michael L. Millenson

ABSTRACT: Despite several well-crafted Institute of Medicine (IOM) reports, there remains within health care a persistent refusal to confront providers' responsibility for severe quality problems. There is a silence of deed—failing to take corrective actions—and of word—failing to discuss openly the true consequences of that inertia. These silences distort public policy, delay change, and, by leading (albeit inadvertently) to thousands of patient deaths, undermine professionalism. The IOM quality committee, to retain its moral authority, should forgo issuing more reports and instead lead an emergency corrective-action campaign comparable to Flexner's crusade against charlatan medical schools.

> ...To remain silent and indifferent is the greatest sin of all.
> —Elie Wiesel

NINE YEARS AGO, while researching the book that would become *Demanding Medical Excellence: Doctors and Accountability in the Information Age*, I began to catalog the extraordinary number of avoidable patient deaths and injuries attributable to poor-quality medical care. The magnitude of the toll first left me stunned, then depressed, and finally outraged. As I ultimately wrote:

> From ulcers to urinary tract infections, tonsils to organ transplants, back pain to breast cancer, asthma to arteriosclerosis, the evidence is irrefutable. Tens of thousands of patients have died or been injured year after year because readily available information was not used—and is not being used today—to guide their care. If one counts the lives lost to preventable medical mistakes, the toll reaches the hundreds of thousands.[1]

The studies that I found then (and others) have since been well publicized by the Institute of Medicine (IOM). Yet the silence within much of the health care community about the true dimensions of the crisis caused by poor quality has changed only modestly over time. Many continue to avert their eyes. Many others pay lip service to clinical systems improvement before almost reflexively channeling the conversation onto a more comfortable path. To them, the "quality" problem

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is really about underpaid providers or meddling insurers or irresponsible patients.

This persistent refusal to confront even inadvertent clinician and hospital responsibility for severe quality problems has consequences. By whitewashing history, it continually distorts the public policy debate. It also gives individuals and institutions that must undergo difficult changes a license to postpone them. Most seriously of all, it allows tens of thousands of preventable patient deaths and injuries to continue to accumulate while the industry only gradually starts to fix a problem that is both long-standing and urgent.

Two Types Of Silence

When I condemn silence, I do not mean the often-understandable reluctance of individual clinicians to talk openly about personal mistakes. Rather, I am referring to two systemic types of silences. The first involves a silence of deed: the repeated failure of physician and hospital leaders to respond with corrective action to studies documenting severe and preventable quality problems. The second silence is of word: the absence of a thorough discussion of the tragic consequences of that lack of response. This second silence recalls the dark dystopia of George Orwell's *1984*, where awkward facts swallowed up by the "memory hole" become as if they had never existed at all. A prime example is the policy debate about malpractice.

■ **Malpractice in the 1970s.** The current malpractice crisis has regularly prompted comparisons with similar challenges, beginning with the malpractice crisis in the 1970s. Yet these histories typically omit the critical context of widespread physician and hospital irresponsibility. Until the mid-1960s, for example, nonprofit hospitals were virtually immune from lawsuits, claiming that they were, in essence, "the doctor's workshop"; it took a lawsuit involving a crippled teenage boy to change that.[2] Until the late 1960s few physicians were willing to break the guild "code of silence" and testify against incompetent peers.[3] As medical sociologist Eliot Freidson wrote in the early 1970s, "When doctors were asked what they would do about a colleague whose behavior violated technical norms of conduct, the most common response was 'nothing'."[4] This was an era when hospital ethics did not require that patients be informed of the name of their treating physician and when physician ethics did not require the physician to inform patients about even potentially paralyzing side effects of treatment. As Jay Katz has documented, patient lawsuits and public pressure were needed to force changes in those areas.[5]

It was in this atmosphere, with malpractice judgments soaring, that California hospital and physician groups turned to physician-attorney Don Harper Mills to investigate the prevalence of medical errors. While previous researchers had focused on one institution, Mills examined some 21,000 charts from twenty-three California hospitals. His groundbreaking research concluded that the error incidence rate was "remarkably low" when one weighed the benefits of modern medicine against its risks. To Mills, "remarkably low" meant iatrogenic deaths in California of more than 10,000 hospital patients a year.

Based on his sampling, Mills calculated that there were 140,000 treatment-caused injuries in California in 1974, including 13,600 hospital-caused fatalities. Subtracting the number of patients Mills thought would have died anyway within a year still left 10,200 deaths. If you take the ratio of those deaths to total hospital admissions in California and apply it to the entire United States (my calculation, but similar to Mills's methodology), you come up with about 120,000 patients who would have lived if their hospital care had not killed them. Mills, in addition to finding the numbers low, noted that from a legal viewpoint, few of the deaths resulted in malpractice suits and even fewer in successful ones.[6]

■ **Malpractice again, in the 1980s.** Small wonder that no hospital industry uproar accompanied Mills's findings. Indeed, the next major study of medical errors did not occur until malpractice premiums soared again about a decade later. Once again, a doctor-lawyer research team—this time, a Harvard group led by physician-attorney Troyen Brennan and this time funded by New York State and the Robert Wood Johnson Foundation—went out to examine errors. The results, this time from a chart examination of hospitals in New York State, equaled about 180,000 treatment-caused deaths and 1.3 million injuries each year when extrapolated nationally. (The researchers did not calculate how many patients would have been expected to die anyway within a year.)[7]

To recap: Two well-designed, well-publicized studies—both, by their own admission, precipitated by economic concerns—uncovered similarly large numbers of treatment-caused deaths. Yet the overwhelming reaction from hospitals and physicians' offices was a deafening silence.

Given that context, it is no surprise that medical historian James Mohr concluded that the malpractice litigation was in many ways a direct consequence of doctors' own clinical laxity. Patients, wrote Mohr in the *Journal of the American Medical Association* in early 2000, had no alternative but to "try to hold individual practitioners, one at a time, to whatever standards they or their [malpractice] lawyers, one at a time, wanted to impose."[8] Put differently, it is the doctors, not the lawyers, who have turned patients into plaintiffs.

Even more troubling than the distortion of the malpractice debate, however, are other consequences of silence. Among the most important of these has been the cumulative cost in patient lives and the undermining of the moral foundations of medical professionalism.

The Toll Of Inaction

There are none so blind as those that will not see.
—Matthew Henry, c. 1710

In 1994 a frustrated Lucian Leape, a physician and one of the Harvard Medical Practice Study researchers, wrote in *JAMA* that the profession largely continued to ignore the preventability of errors.[9] Let us pause for a moment to calculate the cu-

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mulative toll taken by that inaction.

The breadth and depth of Mills's work makes 1978 a fair starting point. Recall that his methodology translated to about 120,000 preventable hospital deaths a year, a number roughly supported by the Harvard research. If you multiply 120,000 by the sixteen years between the Mills study and Leape's professional "*j'accuse*," in 1994, you get 1.9 million preventable patient deaths about which there was near total provider silence. By silence, I mean that there was no substantial effort either to disprove the disturbingly high iatrogenic death estimate or to reduce the number of those deaths.

In late 1999 the IOM's *To Err Is Human* appeared, electrifying the public and prompting a strong political reaction with its estimate that "at least 44,000 Americans die each year as a result of medical errors, ...[and] the number may be as high as 98,000." The report added: "Silence surrounds this issue. For the most part, consumers believe they are protected."[10] Within a year the first legislation to require medical-error reporting was introduced in Congress, and state legislatures began passing error-reporting laws.

From 1994—when providers could have responded to Leape's pleas—to 1999 equals five years and another 600,000 deaths, using the Mills estimate. That yields a total of some 2.5 million men, women, and children who died from treatment in American hospitals between 1978 and 1999. If, for argument's sake, you choose to retroactively apply the lowest 1999 IOM estimate of preventable deaths (44,000) to the entire time period, the total still approaches a million people. Moreover, the number of injured, calculated by using the Harvard findings, would be about seven times as large—from seven million to seventeen million people, depending on your original estimate.

The sheer size of such statistics can render them impersonal. So divide the number of deaths by the average number of acute care hospitals during this period (generously, about 5,500). What you end up with is nine to twenty-two patients unnecessarily dying every year at every community hospital in the country, every year, for twenty-one years. One can argue what percentage of these deaths was preventable; one cannot credibly argue that there was any serious effort by providers to prevent them.

The small numbers at any individual institution may explain why individual doctors overlooked the problem. But if, say, medication errors (only one type of quality failure) were truly a "hidden epidemic," as Leape put it, was it because they were undetectable or because there was no support for detecting them? How can it be that the commonplace nature of medical errors surprised doctors and administrators who work in hospitals daily, yet 42 percent of the public said in a 1997

survey that they personally knew of a situation where a medical error was made?[11] And why was it that the nursing literature called medication errors "the skeleton in the closet of health care providers" in an article that appeared eleven years before *To Err Is Human*?[12]

The IOM Breaks The Silence

To be sure, *To Err Is Human* broke the public silence about medical errors, and the report has prompted widespread promises of change. Respected physician and hospital organizations have for the first time endorsed a variety of specific safety improvements, and large government and private purchasers have for the first time added their voices in strong support. Nonetheless, it remains to be seen whether the anecdotal success stories are truly representative. Like the famous "file drawer" effect, institutions that do nothing say nothing.

Consider the following: A Brooklyn teaching hospital is honored for reducing drug errors and saving lives with computerized physician order entry. Across the river a Manhattan teaching hospital quietly rejects buying computers and tells doctors to improve their handwriting. Not one physician (or nurse or hospital executive) in the Manhattan hospital resigns, organizes a noisy protest, or even quietly leaks the decision to a reporter.

An affluent downtown Chicago hospital touts its large investment in preventing infections; it omits mentioning its belated investment in medication-error prevention. At an equally affluent suburban Chicago hospital, meanwhile, senior administrators remain silent while physicians scoff openly at buying error-reduction technology that is unreimbursed.

At a meeting of academic medical centers' leaders, eminent speakers endorse the necessity of preventing mistakes. Privately, a physician confides that she pried an error-reduction budget out of her hospital by fibbing that they would lose Medicaid funding unless they acted.[13]

This continued quiet refusal to take quality improvement actions exacts a price: the undermining of the moral foundations of professionalism.

Physicians' Resistance And The Failure Of Professionalism

Society relied primarily on the ethical commitment of the provider to the patient for high-quality care...The blame [for the failure of this strategy] largely lies with the professional dominance of medical care.

—Troyen Brennan and Donald Berwick, *New Rules: Regulation, Markets, and the Quality of American Health Care*

The virulent resistance by many in the medical profession to confronting evidence about systemic quality failings is neither new nor an aberration. For example, when John Wennberg first presented his pioneering research on practice variation at medical society meetings in staid New England, other physicians routinely tried to shout him into silence.[14] Twenty years later *JAMA* editor George

Lundberg decided to place Leape's 1994 article on doctors ignoring errors in a Christmastime issue that he hoped reporters would overlook. When, instead, the article was widely publicized, "hate mail began pouring in [from AMA members]," Lundberg wrote well after the fact. "I was accused of being on the side of the lawyers, a damned turncoat and traitor to the cause."[15]

This silencing of talk about errors has been so effective and so little noticed that policymakers and in-the-trenches physicians alike are often lulled into a misplaced faith in professional self-policing. In a not atypical example, a physician writing in the journal *Effective Clinical Practice* described how colleagues "felt betrayed" by *To Err Is Human*—they "felt as if all of their past efforts [to improve care] were discounted as inconsequential." Why, for instance, was there just a "brief mention of the work by anesthesiologists, which has reduced the risk of anesthesia by more than 100-fold"? Or "programs like the American Academy of Orthopedic Surgeons' protocol in which patients and others 'sign their site' to prevent wrong-side surgery"?[16]

The blunt answer is that professionalism alone has consistently failed to protect patients. Rather, it has been professionalism pushed into action by pressure from the press, public, politicians, and the pocketbook.[17] For example, anesthesiologists finally acted to improve patient safety only after a television exposé of anesthesia accidents. Rising malpractice premiums—an economic incentive—provided an extra sense of urgency.[18] Similarly, the "sign your site" protocol came in reaction to a nationally publicized incident in which a Florida surgeon amputated the wrong foot of a diabetic man in 1995. The People's Medical Society, a consumer group, had suggested a "sign your site" initiative a decade before, only to be met by indignation and ridicule on the part of surgeons.[19] In mid-2002 the provider-dominated Joint Commission on Accreditation of Healthcare Organizations (JCAHO) finally proposed rules requiring hospitals to reduce wrong-site surgery—seven years after the scandal and seventeen years after the consumer group had suggested such a move. Even with this delay, and even with the utter simplicity of the act of signing one's name, 20–40 percent of surgeons continue to resist efforts to get them to sign voluntarily, a past president of the orthopedic academy admitted to the *Washington Post*.[20]

"Physicians are neither saints nor sinners," says Mike Magee, a physician whose tireless work on behalf of professional pride and dignity has earned him the nickname "the Norman Vincent Peale of medicine." The truth, says Magee, is that doctors are like everyone else. And, like everyone else, physicians do not readily adapt proposed improvements to their customary work habits unless, as Everett Rogers wrote in *Diffusion of Innovations*, specific criteria are met. The first of these hurdles is that an innovation must offer relative advantage over what already exists.[21] Rogers' rubric holds true whether the innovation involves cutting-edge technology or cutting off the wrong foot.

Achieving "relative advantage" can be surprisingly difficult. That is because the

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innovation not only must offer a real advantage, it also must be perceived as offering one. The same requirement for perceived advantage is at least as important in changing basic professional assumptions—for example, that my doctor's unaided clinical judgment is superb. "Paradigm shifts" take hold only when the defenders of the old ways of thought can "no longer evade anomalies that subvert the existing tradition," as Thomas Kuhn put it in *The Structure of Scientific Revolutions*.[22]

It is by creating false perceptions of reality that the widespread silence about the daily impact of medical quality problems, the silence about the extent of the profession's failure to correct those problems, and the silence about the cumulative patient death and injury toll all come together to do grave damage. Episodic IOM reports are hardly an adequate remedy.

To be sure, *To Err Is Human* and the even more comprehensive *Crossing the Quality Chasm*—a March 2001 report about the pervasive overuse, misuse, and underuse of care—have been eloquent. The reports have appealed to reason and to emotion, pointed to a vision, and laid out a blueprint. What the authors have not done—crucially, in my view—is to act as if they really believe their own findings. For if you really believed that a minimum of 120 people every day were dying preventable deaths in hospitals, you would draw a line in the sand. You would insistently demand that doctors and hospitals immediately adopt at least a minimum set of preventive practices (for example, bar-coding drugs). Rather than going on to write your next report, you would—in my view—bluntly warn colleagues that the IOM would publicly censure those who resisted implementing these minimum practices and would call for the same kind of stringent sanctions against them that Abraham Flexner, the American Medical Association (AMA), and the Carnegie Foundation fought to apply to charlatan medical schools at the turn of the last century.

Instead, the IOM has subtly let the profession off the moral hook. *To Err Is Human*, for example, evokes religious forgiveness: "To err is human, to forgive, Divine." (The saying comes from Alexander Pope's *Essay on Criticism*.) I presume that the IOM's point was that doctors are human, should openly acknowledge the inevitability of mistakes, and should plan in advance to mitigate harmful consequences. This line of argument is continued in the broader examination of quality improvement in the IOM's subsequent report, *Crossing the Quality Chasm*: "Trying harder will not work. Changing systems of care will."

Well, yes. But in Judaism and Christianity alike, forgiveness is never granted until a sin is honestly acknowledged. In health care, the far more typical scenario is what has happened with the AMA, to pick just one example, which went from calling errors "isolated" (contradicting its own flagship journal) to plumping for

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"systems change" without missing a beat. What is more worrisome, the IOM's focus on "system" improvement ignores the repeated refusal by individual physicians and hospital leaders to adopt systems—even systems as simple as using a pen to sign a surgical site!

Suppose that an airline's managers and pilots repeatedly resisted installing collision-avoidance systems despite solid evidence of their worth. Suppose, too, that they complained that the radar was not reimbursed adequately, required inconvenient retraining, provided no competitive advantage in attracting passengers at a time when airline profits were low, and (sotto voce) was an insult to pilot judgment. No one would blithely blame "airline culture" for an ensuing disaster, and no one would absolve individual pilots and managers of responsibility for that disaster simply because they never intended for passengers to be harmed.

The Responsibility Of The IOM Committee

The IOM has taken on the leadership mantle in the drive to transform American medicine, and so the question must be asked: Why does its Committee on Quality of Health Care in America preach "revolution" and "transformation" but prescribe gradualism? Is it because declaring that a specific hospital is dangerous would anger powerful interest groups who might stop cooperating on other fronts? Is it because those who work in health care are caring people, so there is something unseemly about giving them an ultimatum? Is it because an ultimatum would impose a difficult financial burden?

All of those factors are true today, were true last year, and will be true next year. Also true is that years of avoidable delay in preventing errors and instituting evidence-based practice have allowed well over one million trusting patients to unnecessarily die and millions more to suffer injuries. That horrifying equation does not make any individual doctor, nurse, or hospital executive evil. The overwhelming majority of those deaths occurred as providers labored mightily to heal the sick. But if the IOM doesn't act as if a minimum of 120 preventable deaths a day is an emergency—and yes, I know we couldn't immediately prevent all or even most of them—then why, to be blunt, should anyone else?

The personal morality of the members of the IOM quality committee and their dedication are both beyond question. I admire, respect, and am inspired by them as individuals. Yet by not declaring certain current practices as beyond the pale of medical respectability as anything Flexner ever encountered, the committee has broken the silence of the word but let the silence of the deed remain mostly intact. They have implicitly undermined their own moral authority by settling for a gradual phase-in of changes that they personally have been demanding for years; that

they personally know from bitter experience have been resisted while patients have died; and that they know—better than anyone—could in many cases be done a lot sooner than they are requesting. They make this compromise, I can only assume, because they believe that "working within the system" through gradualism offers the best opportunity to save lives.

I respectfully, but strongly, disagree. Yes, there are important technical barriers to quick quality improvement, but the most formidable technical barriers are ultimately secondary.[23] I say to those on the quality committee: If you will only act together to demand change, you possess the passion and prestige, eloquence and erudition to shatter the silence of inaction. If you settle for gradualism, the silence will persist for far, far longer. If you will only act together in constant, blunt, and well-informed advocacy, you possess the power to command the attention of legislators, regulators, industry groups, the news media, and the American public. There are time-tested strategies for true transformation that have been embraced by everyone from Martin Luther King Jr. to Mothers Against Drunk Driving. Issuing reports every year or so and engaging in methodological arguments with academic skeptics is not one of those strategies.

There is a world of difference between calling for a revolution and actually leading one. (And, yes, the latter is far riskier to one's professional well-being.) That difference is why the quality improvement movement, it pains me to say, remains essentially a sideshow for most providers and most of the public. Covering the uninsured, paying doctors and hospitals better, giving a drug benefit to Medicare patients—to the public and policymakers, that is "high-quality" care; the phrase "evidence-based medicine" draws a complete blank.

DESPITE THE SETBACKS, progress is visible. The transformation of medicine is inevitable, and the encroaching information age will bring accountability. But when? To hasten that day, I commend to the IOM's quality committee, to providers, and to policymakers a famous Talmudic saying. It goes this way: "He who saves one life…is as if he saved the entire world."

NOTES

1. M.L. Millenson, *Demanding Medical Excellence: Doctors and Accountability in the Information Age* (Chicago: University of Chicago Press, 1997), 353.

2. *Darling v. Charleston Hospital*, 33 Ill. 2d 326, 211 N.E.2d 253 (1965).

3. Millenson, *Demanding Medical Excellence*, 59–62, 165–166.

4. E. Freidson, *Profession of Medicine: A Study of the Sociology of Applied Knowledge* (New York: Dodd, Mead, 1970), 347.

5. J. Katz, *The Silent World of Doctor and Patient* (New York: Free Press, 1984), 48–84.

6. D.H. Mills, "Medical Insurance Feasibility Study—A Technical Summary," *Western Journal of Medicine* (April 1978): 360–365. Mills matched the characteristics of the patients in his sample to state data from the California Health Data Corporation.

7. T. A. Brennan et al., "Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study, I," *New England Journal of Medicine* 324, no. 6 (7 February 1991): 370–376. The extrapolation to the United States as a whole comes from L.L. Leape, "Preventability of Medical Injury" (Address to the American Association for the Advancement of Science annual meeting, Chicago, Illinois, 9 February 1992).

8. J.C. Mohr, "American Medical Malpractice Litigation in Historical Perspective," *Journal of the American Medical Association* 283, no. 13 (2000): 1731–1737.

9. L.L. Leape, "Error in Medicine," *Journal of the American Medical Association* 272, no. 23 (1994): 1851–1857.

10. Institute of Medicine, *To Err Is Human: Building a Safer Health System* (Washington: National Academy Press, 1999).

11. C. Chamberlain, "Medical Mistakes Affect Many: Poll Finds Widespread Error," ABC News, 9 October 1997, abcnews.go.com/sections/living/DailyNews/medmistakes1009.html (11 December 2002). The poll was by the AMA-supported National Patient Safety Foundation.

12. Millenson, *Demanding Medical Excellence*, 62.

13. Each of these examples is based on the author's personal experience. To identify those involved by name, however, would have required allotting space for response and is not critical to the points being made.

14. Interviews by the author with John Wennberg, Dartmouth Medical School, 1994.

15. G.D. Lundberg with J. Stacey, *Severed Trust: Why American Medicine Hasn't Been Fixed* (New York: Basic Books, 2000), 169–172.

16. E.B. Larson, "First Do No Harm—To Err Is Human," *Effective Clinical Practice* (Nov/Dec 2000): 294–296.

17. For a fuller treatment of the role of the news media in motivating improvement, see M.L. Millenson, "Pushing the Profession: How the News Media Turned Patient Safety into a Priority," *Quality and Safety in Health Care* (March 2002): 57–63.

18. C. Guadagnino, "Improving Anesthesia Safety," *Physician's News Digest*, February 2000, www.physiciansnews.com/spotlight/200wp.html (11 December 2002).

19. C. Inlander, founder, People's Medical Society, personal communication, October 2002.

20. S.G. Boodman, "No End to Errors: Three Years after a Landmark Report Found Pervasive Medical Mistakes in American Hospitals, Little Has Been Done to Reduce Death and Injury," *Washington Post*, 3 December 2002.

21. E.M. Rogers, *Diffusion of Innovations*, 3d ed. (New York: Free Press, 1983), 1, 14–15.

22. T.S. Kuhn, *The Structure of Scientific Revolutions*, 2d ed. (Chicago: University of Chicago Press, 1970), 6.

23. J.P. Newhouse, "Why Is There a Quality Chasm?" *Health Affairs* (July/Aug 2002): 13–25.