The Case for a Medical Safety Reporting System

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The Institute of Medicine (IOM) report[1] in 1999 set off a firestorm of controversy. Based on 1984 and 1992 data in three states, the authors stated that between 44,000 and 98,000 Americans died annually because of medical errors. The latter figure, rounded to 100,000, is frequently used.

Clearly, in the past decade we do not have even an estimate of the number of patient deaths due to medical errors, by any definition, in any state. Nor do we know the number of patients harmed, but not killed, by medical errors, and we certainly do not know the number of close calls or near misses.

Ironically, a good estimate of the number of error-related deaths would not be difficult to obtain. Physicians care for individual patients. A medical staff could determine, one at a time, whether any death in their institution was error-related. This information could be sent to a neutral body, de-identified, and publicized. While the information might not be welcome, it would be far closer to the true value and would show an openness to flaws that is uncommon in medical care today.

While we may learn from our own mistakes, we seldom learn from those of others. Few medical workers desire to risk censure, malpractice, or ridicule by open discussion of an error.

Legislation to deal with medical errors exists. Since 1987 Massachusetts has had a Patient Care Assessment program that receives a few hundred reports a year and runs with six staff, three of them volunteers.

Last year the American Academy of Neurology developed a web-based system for reporting errors, although the menu of choices doesn't allow for entry of details.

Since the IOM report, half the states now require mandatory reporting of errors–perhaps a good idea, perhaps not, for mandatory reporting may lead to hiding flaws and is one more bureaucratic function that medical professionals have to endure.

The Aviation Safety Reporting Program (ASRP)

It is worth studying how aviation has dealt with errors, for pilots and physicians are similar: both have ultimate responsibility for people's lives, both are respected, well paid, influential, have strong opinions and egos, and take their responsibilities seriously. Aviation used to be far less safe than it is today. What can we in medicine learn from the aviation reporting system? When and why did the two fields diverge when it came to mistakes?

On Dec. 1, 1974, a TWA Boeing 727, in bad weather on approach to Dulles International Airport outside Washington DC, crashed on Mt. Weather, Virginia, killing all 92 aboard.[2] Investigation revealed that six weeks earlier in clear weather, a similar misinterpretation of the approach chart by a United plane's pilot led to a premature descent. The misinterpretation was reported within United, but not disseminated to other airlines for fear of punishment.

Following the Mt. Weather incident, the FAA developed the Aviation Safety Reporting Program (ASRP), providing limited immunity from certain types of enforcement action. Because pilots were uncomfortable reporting to a regulatory agency that could punish, the FAA established the Aviation Safety Reporting System (ASRS), run by an NASA as an objective, non-regulatory agency, to collect, de-identify, and summarize reports.

The ASRS receives more than 34,000 reports a year, more than half a million since its inception in 1976. It has earned the trust of pilots and other workers in the aviation industry. Both programs are far from perfect, however. More than a month may elapse between a report and action. The system is relatively inflexible, has poor inferential and sampling characteristics, and only a small portion of the reports have ever been reviewed. The system does not have the ability to test hypotheses (Blazy ME, personal communication, March 2002).

Still, the results in aviation safety have been nothing short of spectacular, with no deaths occurring in civil aviation in four of the past 20 years, most recently in 2002. Reports have led to improved cockpit communication and fixing of serious mechanical failures before an incident occurred.

How a Medical Safety Reporting System (MSRS) Might Work

Based on aviation's experience, I propose a Medical Safety Reporting System (MSRS) that would have three goals:

The first is to begin to change the medical culture so that reporting mistakes is considered important and not a personal failing. This goal addresses those who feel that the first step is to have physicians change their behavior. Errors are not all due to physicians. Too often, errors lead to punishment without changing a faulty system. My hypothesis is that a safe way to report mistakes has a better likelihood of working than the past system of peer review and punishment. In any case, the hypothesis is testable.

The second goal is to understand the nature, types, and causes of both errors and near-errors. This goal has been criticized for having an unknown denominator. Since even infinite denominators are easily handled (Gaussian, F-, Chi Square, and Poisson distribution, to name a few), perhaps a better criticism would be an inadequate numerator. In any case, the MSRS is about learning about any errors or near-errors workers report, not a specific number.

The third goal is that, armed with aggregate information, organizations will change processes and improve patient safety. This goal, too, is testable.

The Medical Safety Reporting System (MSRS) would allow:

• Voluntary, optionally anonymous, confidential reporting of errors and near-errors to a neutral agency. Mandatory reporting is onerous, and medical personnel don't need another regulation. Anonymity will protect those who might not speak up if they know they might be sanctioned. Nevertheless, ability to ask a reporting individual more questions would certainly be desirable. People will be more likely to speak up if they know they won't be sanctioned (Blazy ME, personal communication, July 2001). Near-error reports would be encouraged, as they represent system flaws that may cause harm. A neutral agency is needed, because many current regulatory agencies are perceived as punitive.

• Reports from any staff member, not just physicians. Nurses, aides, and others probably see more errors and consequences of faulty systems than do physicians.

• No patient, physician, or facility names in the report. None of this information is relevant; not having it lessens privacy concerns.

• A simple report form stating what the reporter saw and why it may have happened. Requiring root-cause analyses will inject unnecessary complexity and lead to reports not being filed.

• Protection for the report unless the incident was deliberate or criminal. A patient rape, for example, would not be protected.

• Reports to be summarized, investigated, de-identified if not anonymous, and aggregate information sent to the quality committees of participating organizations. Reports would be sent to the MSRS by phone, mail, e-mail, or fax, depending upon how confidential the reporter wished to remain. Reports would not be used as evidence in any punitive action, and current uses for information gathered by other means would not change. The voluntary, confidential report to a neutral body would still be used for learning and would be protected from discovery as it is disseminated through the quality assurance (QA) process to many organizations. The format of the reporting form must be worded carefully, and the information must be an integral part of a quality assurance committee's agenda, not raw data.

• Periodically, participating organizations to be surveyed to study how well the MSRS is known, used, and whether any changes have occurred as a result. We don't know whether medical personnel would use the MSRS. If used, we don't know whether the information would be adequate to be useful to organizations. If it is, we don't know whether provable, measurable changes will occur. In time, we need to know whether the MSRS should be adopted, modified, or discontinued. Too many "feel-good" or "ought-to-work" programs never undergo scrutiny of whether their effort and expense are actually effective.

• No change in use of information obtained by other means. The MSRS would not preempt a patient's right to sue, nor would it prevent investigations by plaintiff's lawyers. The MSRS itself, however, would be protected. Parenthetically, many in the legal profession have castigated the medical profession for a conspiracy of silence and the need to get to the truth. It would be interesting to see whether the MSRS, a far better way to get at truth than we currently have, would be supported by these same lawyers.

A pilot process in a unit or an organization could be done cheaply, with few people. It would require appropriate protection through quality assurance, a safe means of reporting, and quick feedback.

The MSRS is not unique. The Veterans Administration has begun a similar system, but its legal situation is different from that of the rest of the profession. What is somewhat surprising is that the director of the ASRP has not been contacted by any of the major safety organizations nationwide (Blazy ME, personal communication, March 2002)**.**

Many organizations I have contacted about the MSRS have never replied, including the Arizona Trial Lawyers Association. Many others have expressed interest, but few want to take the next step, despite the fact that, as an Arizona Hospital and Healthcare Association executive told me, "We are one medical error on a celebrity away from sweeping federal regulation."

How Could the MSRS Be Brought About?

The MSRS has been sent to Rep. Jim Kolbe (R-AZ) and to Sen. Jon Kyl (R-AZ). Both have expressed "interest" in the proposal, perhaps as part of a tort reform bill rather than a specific medical error bill.

What are other possible next steps?

Legal counsel of an organization could work to develop a form and a feedback system that would meet local peer review statutes while recognizing physician and non-physician reporting. The charge to legal counsel would be to see how the system could occur, not why it shouldn't take place.

An organization could be found to pilot the MSRS. The results of a pilot test would be valuable both in modifying the MSRS and enhancing its credibility with others.

A federal waiver could be obtained to protect all who are involved during the pilot period. Aggregate reports will need more protection than peer review statutes offer.

Waiting for Congress to act has risks. Concerns include: whether a body receiving reports will be neutral; who will keep the database; how quick the feedback will be; and whether reporting will be mandated, not voluntary. Many do not consider the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to be neutral; indeed, the problem with medical errors developed on its watch. We need a database that can be developed quickly and from which information can be sent to participating facilities within a month for most errors, and immediately for major ones. If through the MSRS people see that we can learn from mistakes without punishment, voluntary reporting should become the standard.

A functioning MSRS would show our detractors that we are serious about fixing errors. The MSRS need not be perfect: it only has to be better than what we're doing.

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The author acknowledges the encouragement and support of Mark Blazy, head of the ASRP.

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