policy and politics

Candor about Adverse Events: Physicians versus the Data Bank

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The idea that health care providers should disclose to patients and families a harm that could have been avoided is no longer novel. Although it is not quite mainstream, many major medical institutions have now embraced the idea that doing the right thing-being honest about errors with those who have been harmed-is also the smart thing to do. It improves patient safety and quality of care; enhances satisfaction for patients, families, and providers; and reduces malpractice litigation costs.1 The University of Michigan has perhaps the best-known program. Since 2001, that institution has seen more than a 55 percent drop in the number of new malpractice claims filed, a comparable reduction in lawsuits, and a dramatic drop in both defense costs and malpractice payouts-money then redirected toward quality improvement.²

A few states have also embraced this approach, sometimes known as "Candor" (for "communication and optimal resolution"). In 2012, Massachusetts enacted a law creating a six-month cooling-off period for potential litigants of a medical malpractice case.³ Potential claimants must tell providers specifically what they believe happened, why it appears to violate the standard of care, what should have happened instead, and how the deviation from care caused the injury. The provider must promptly respond with comparably rich information. Such detailed disclosures permit both sides to undertake at an early point the kind of realistic analysis that,

in more traditional settings, can sometimes drag discovery out for years. The legislation also strengthened protections for apologies and led to the Massachusetts Alliance for Communication and Resolution following Medical Injury (MACRMI),⁴ in which six pilot hospitals are implementing and refining the Candor approach.

One year later, Oregon enacted even broader Candor legislation that requires providers to notify the state of an unanticipated adverse outcome and encourages them to confer confidentially with patients and their representatives.⁵ If those early discussions do not yield a resolution, parties then have the option of confidential, nonbinding mediation. Litigation is still an option thereafter but, it is hoped, is less likely to be used. Information filed with the state about how errors occur is then used to improve care.

All of these efforts face a major challenge. Although many physicians would like very much to achieve insight, reconciliation, and quality improvement in just this way, many fear that money paid to resolve an incident in which they were involved can result in a lifelong black mark in the National Practitioner Data Bank (NPDB). Per the Health Care Quality Improvement Act of 1986 (HCQIA),⁶ Data Bank reports must be made any time an entity such as a malpractice insurer makes a payment, regardless of amount, on behalf of a health care provider pursuant to a patient's "written claim or demand for payment"-regardless of whether there was any deviation from the standard of care or any finding of fault.⁷ If physicians stay away from the table because they fear that monetary payment will translate into professional damage, then it becomes much more difficult to figure out what really happened, improve quality, and convey adequate apologies to patients and families.

Oregon's legislation attempted to avoid Data Bank reports by stipulating that neither the written notices of health care incidents nor the subsequent communications under the statute, nor payments made pursuant to those processes, would count as "written claim[s] or demand[s] for payment"-thereby averting the trigger for a Data Bank report. In response, Public Citizen urged the Department of Health and Human Services to overrule such provisions.8 On May 20, 2014, DHHS responded with a memo regarding its standards for Data Bank reports,9 and in April 2015 it issued a clarification in its updated NPDB Guidebook, for which systematic updates were already under way.¹⁰

Pursuant to HCQIA, DHHS has long recognized a number of avenues by which NPDB reports can lawfully be avoided: the demand is oral rather than written; the practitioner offers to refund the patient's payment; the practitioner pays out of pocket even in response to a written demand for payment. Most importantly, the so-called corporate shield obviates reports where the provider's name is dropped from the suit and a larger entity, such as a hospital or clinic, pays the malpractice damages.¹¹ The University of Michigan, for instance, has long used the corporate shield in its early resolution program, since most of its physicians are employees.¹²

DHHS's latest guidance continues to follow the statute: per HCQIA, a pivotal question is whether a "written claim or demand for payment" was made. Specifically addressing the Massachusetts and Oregon scenarios, the Guidebook provides this question and answer:

Q8: Following an unsuccessful course of treatment, a patient and a practitioner enter into a State-sponsored voluntary series of discussions in an attempt to settle their disagreement before resorting to litigation. The discussions lead to the practitioner's insurance company making a money payment to the patient to settle the dispute. Should this money payment be reported to the NPDB?

A: It depends. If, during the course of discussions, the patient made a written complaint or written claim demanding a monetary payment for damages, the payment must be reported. If the complaint or claim for damages was never put in writing, the payment is not reportable.¹³

In sum, "dodging the data bank" can be accomplished fairly readily: plaintiff-attorneys can pick up the phone, and health care providers can respond, "Thank you for phoning"; providers in Candor programs can initiate the communication and resolution process instead of waiting until patients file written demands; providers can waive fees; hospitals and clinics can invoke the corporate shield and keep employeephysicians out of the NPDB.¹⁴

But is this virtuous or pernicious? Does it let bad doctors continue to practice with impunity? In reality, the medical-malpractice portion of the NPDB does very little to track or improve quality of care, and, in fact, it interferes with the system-level quality improvements fostered by Candor. These are among its limitations:¹⁵

• there is little if any correlation between negligent iatrogenesis and the filing of a lawsuit;

• the NPDB's malpractice report section is based on an antiquated concept of quality improvement, seeing adverse outcomes as primarily the product of incompetent or miscreant individuals;

• physicians with multiple medmal payments almost always show up elsewhere in the NPDB, whether via credentialing or licensure actions;

• med-mal litigation often takes years to resolve, and hence reports at best yield outdated information; • physicians employed by the federal government are governed by different criteria and are rarely reported to the NPDB;

• similarly, physicians whose services are shielded from malpractice liability via charitable or sovereign immunity likewise are unlikely to be reported;

• since in states that forbid consentto-settle clauses in malpractice contracts, the insurer may simply make a business decision that it is cheaper to settle a claim than fight—such a med-mal payment shows nothing about quality of care; and

• NPDB reporting mandates are essentially unenforceable because there is no reliable way to track whether insurers make payments in the first place—a precondition for detecting failures to report such payments.

Far better approaches are now emerging. In value-based purchasing, providers' payments are based not simply on inputs but also on outcomes, satisfaction, cost-efficiency, and other factors important to improving health. Although specific metrics are imperfect and evolving, health care organizations have considerably greater incentive to evaluate and continually enhance providers' qualifications, skills, and services far more closely than ever before. These activities-exemplified by Candor programs' efforts to do the right thing for current and future patients alike-are far more likely to improve care than often-random "black marks" against providers.

1. R. C. Boothman, S. J. Imhoff, and D. A. Campbell, "Nurturing a Culture of Patient Safety and Achieving Lower Malpractice Risk through Disclosure: Lessons Learned and Future Directions," Frontiers of Health Services Management 28, no. 3 (2012): 13-28; D. C. Hetzler, "Superordinate Claims Management: Resolution Focus from Day One," Georgia State University Law Review 21 (2005): 891-908; A. Kachalia et al., "Liability Claims and Costs before and after Implementation of a Medical Error Disclosure Program," Annals of Internal Medicine 153 (2010): 213-21; M. Mello, D. Studdert, and A. Kachalia, "The Medical Liability Climate and Prospects for Reform," Journal of the American Medical Association 312 (2014): 2146-55; S. Bell et al., "Disclosure, Apology and Offer Programs," *The Milbank Quarterly* 90, no. 4 (2012): 682-705; M. Mello et al., "Communication-and-Resolution Programs," *Health Affairs* 33, no. 1 (2014): 20-29.

2. Boothman, Imhoff, and Campbell, "Nurturing a Culture of Patient Safety"; Kachalia et al., "Liability Claims and Costs." Other programs can be found at Stanford, the University of Illinois, University of Washington, and Johns Hopkins, among many others.

3. Mass. Gen. Laws ch. 231 § 60L; Michigan also embraced a 182-day period.

4. See Massachusetts Alliance for Communication and Resolution following Medical Injury, http://www.macrmi.info/#sthash. bLRr481Q.dpbs.

5. Oregon Laws 2013 chapter 5, amending ORS 30.278, 31.250 and 743.056.

6. 42 U.S.C. 11101 et seq.

7. The NPDB tracks two other kinds of data: adverse clinical privilege decisions by hospitals and other entities with peer review and state adverse licensure actions taken by medical and dental boards to address competence or conduct.

8. Public Citizen, letter to Kathleen Sebelius regarding Oregon malpractice-reporting law, September 10, 2013, http://www.citizen.org/ documents/2155.pdf.

9. U.S. Department of Health and Human Services, memorandum regarding appropriate medical malpractice payment reporting to the NPDB in light of recent medical malpractice reforms in Massachusetts and Oregon, May 20, 2014, accessed June 2, 2015, at http:// www.citizen.org/documents/2211%20Enclosure.pdf.

10. National Practitioner Data Bank, *NPDB Guidebook*, April 2015, http://www.npdb.hrsa.gov/resources/NPDBGuidebook.pdf.

11. The corporate shield is an option so long as dropping the physician from the suit is not a condition of settlement. See E. H. Morreim, "Malpractice, Mediation, and Moral Hazard: The Virtues of Dodging the Data Bank," *Ohio State Journal on Dispute Resolution* 27, no. 1 (2012): 109-78.

12. Kachalia et al., "Liability Claims and Costs."

13. NPDB Guidebook, April 2015, E-27 (p. 104).

14. Morreim, "Malpractice, Mediation, and Moral Hazard."

15. Ibid., 156-72.

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