

## Accreditation and Regulation: Can They Help Improve Patient Safety?

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### Perspective

My grandfather, an eminent Houston internist, never lived to practice in our modern era of managed care and evidence-based medicine. He used to joke that the reason he never had malpractice insurance in the early days of his career was that he wasn't doing any malpractice then. I know that he resented the growing intrusion of lawyers and legislators into medicine over his years of practice. He was zealous in his pursuit of quality care for his patients, but I think he would have resisted efforts by non-medically-trained managers and regulators to enforce any kind of control over physicians.

I'm not sure what my grandfather would have thought of the modern patient safety movement, with its reliance on a systems approach to reducing harm, and use of methods and insights from nonmedical industries. I suspect that he, like many or perhaps most physicians of his generation, would have felt that nothing was needed beyond heeding the admonition to "First, do no harm." He never knew that I would go on to become a health economist, but I feel safe in assuming that he would not have thought there should be such a thing, and certainly would not have believed that his health economist granddaughter had any business working or writing in the field of patient safety. I don't believe he would have thought there was much value or legitimacy to allowing regulators and accreditors to force changes in medical practice.

I'm sure some readers are, at this point, thinking what a wise man my grandfather must have been. I believe he was an excellent physician, and he was, in many ways, very wise. And, it's human nature to prefer not to be told what to do—a sentiment that tends to be stronger among proud, highly trained professionals. It is not surprising, therefore, to find a certain tension between the culture of medicine and the demands of health care accreditation and regulatory bodies. But I hope to convince readers that he would have been wrong to resist a role for accreditation and regulation in improving the quality and safety of health care.

Before discussing how regulation and accreditation can (and cannot) help improve patient safety, some definitions and distinctions.

Regulation and accreditation are not identical. Regulation involves rules that must be followed, while accreditation is a seal of approval (from some independent accrediting body) certifying that an organization or individual has met specific standards. In practice, in health care, accreditation is frequently so essential that many accreditation requirements have the same power as regulations.<sup>(1)</sup> In this paper, regulation and accreditation will be discussed together and contrasted with other strategies for improving quality and safety.

Quality and safety are sometimes used interchangeably in health care, but they too should be distinguished. If we think of quality of care as a distribution, and graph the amount of care delivered at various quality levels, we might get something like [Figure 1](#). We hope the lower (left-hand) tail is small, and we hope quality is pretty good at the high point of the curve. Some care is truly excellent, but how much is unknown.

High-quality care causes fewer errors and less harm than low-quality care. Quality improvement (QI) aims to shift the entire quality curve to the right and increase the height of the right-hand tail (more truly excellent care). Patient safety improvement is quality improvement focused on lowering or truncating the lower tail of the quality distribution. Both kinds of improvement are needed, and both improve safety for patients, but their focus is different.

Does this distinction have any relevance to the role of accreditation, regulation, and other methods of improving patient safety? I say, yes: Regulation and accreditation are particularly legitimate and useful for patient safety improvements, while they are less useful in ensuring more general QI. It is hard to argue that a clearly unsafe practice should be permitted, and it is much more reasonable to assert, as we do in other areas of public safety <sup>(2)</sup>, that minimum standards be met by a hospital or other health care agency or provider if they wish to continue providing care. It is also important that rules be clear, compliance be observable, and performance be fully in control of the hospital or agency being regulated. Prescriptive solutions therefore work best for less complex problems where one-size-fits-all solutions are sensible, such as "sign-your-site" rules for surgery, requiring hospital staff to wash hands before and after touching patients, and banning known high-risk abbreviations.<sup>(1)</sup>

For complex problems, such as the need to improve the user-friendliness and reliability of device alarms, a coordinated approach involving many parties is essential; no simple rule would improve safety.<sup>(3)</sup>

It is also less legitimate, and less practical, to use rule-making to lift care from acceptable to excellent. It is impossible for all care to be above average; there will always be a distribution of quality. What is reasonable is to ensure that the minimum acceptable standard is sufficiently good and safe to protect the public. In practice, a distribution like [Figure 2](#) would be much better than what we have now. The right-hand tail would represent care delivered at a higher-than-required quality level.

Deciding on the minimum level of quality, the best programs and procedures to be used to achieve it, how to monitor success or failure, and how quickly to raise standards as overall quality and safety increase are all easier said than done. Getting those requirements right is the critical work of accreditation agencies.

Accreditation has been observed to be more effective in promoting good safety practices than state-required error reporting or public awareness (4), and in most hospitals, accreditation requirements are the primary driver of safety efforts.(5) In others, however, particularly those that are more oriented to safety improvement and excellence in general, accreditation requirements are viewed as a floor; staff at the Veterans Health Administration explicitly set safety goals that exceed accreditation requirements, and many hospitals have voluntarily implemented rapid response teams and other optional enhancements to care.(6)

In other words, accreditation and regulation are likely to be quite effective in causing a shift in the quality distribution from [Figure 1](#) to [Figure 2](#), but their main effect will likely be in truncating the lower tail of the distribution.

Increasing the amount of excellent care (right tail) requires organizations to exceed required quality levels. That is likely to happen through a combination of other policy tools, such as pay-for-performance and voluntary improvement work (such as the Institute for Healthcare Improvement campaigns). Boards can play an important role if they begin to hold managers and clinicians accountable for achieving quality targets and continually improving quality and safety goals (7), but board leadership works best by recruiting clinical leaders from all disciplines for bottom-up change.(8)

Two points still seem underappreciated in the literature and by accreditors and regulators. First is the need to consider both costs and effects of potential safety and QI interventions. The reason is simple: no agency can adopt all potential improvements, and if cost-effectiveness is ignored, then less quality/safety improvement will be obtained for the resources dedicated to improvement.(9) Accreditors and regulators need to be sure that they require the most cost-effective changes first, for the same reason.

Second, changes must be evaluated for effectiveness, ideally both before (ex ante evaluation) and after implementation. As required by its own regulations, the U.S. Food and Drug Administration (FDA) carefully studied the evidence on likely costs and effects before announcing its bar code rule of 2004 (10), but it is one of the few agencies with such a mandate.

In ex post evaluation, it is particularly important to detect and assess unforeseen consequences. When the Joint Commission issued its 1998 Sentinel Alert about keeping concentrated potassium chloride only in hospital pharmacies and specialized units such as intensive care units (ICUs), the details of implementation were left to hospitals, and variations in practice occurred. At least one hospital (11) found that delays in receiving dilute solutions from the pharmacy turned ICUs into de facto pharmacies and led general-ward staff to create illicit stashes of the concentrate—potentially creating higher risks than before the change. The Joint Commission had to follow up the initial recommendation with examples of safe and unsafe practices.(12) Absent ongoing monitoring, though, it is impossible to know whether this change was actually beneficial. Similarly, the 2002 attempt to improve care for hospital patients with community-acquired pneumonia (through creating a performance measure monitoring how quickly they were given antibiotics) was shown to have encouraged unnecessary use of antibiotics and not to have reduced mortality, as had been hoped, primarily because of the difficulty of definitive diagnosis in actual clinical settings. The rule was amended in 2006 and again in 2007, but it remains far from clear that it is creating net benefits for patients.(13)

The modern evidence-based medicine movement was started by doctors (14), but even its strongest proponents would not claim to have had the success they hoped for in getting all physicians to adopt their methods. Even when standards for care are clear, they are often not followed; a 2003 study found that patients received only 55% of recommended care, with wide variation between rates for different medical conditions.(15) Evidence of differences in medical practice that do not reflect patient characteristics or preferences, and that worsen patient outcomes, abounds in all countries with advanced health care systems. Evidence of harm caused by care is equally widespread (16), yet growing awareness has not automatically or instantaneously ended the problem. If "first, do no harm" were sufficient, there would be no need for a patient safety movement.

Wider adoption of evidence-based medicine by clinicians may actually be the most promising route for retaining professional autonomy and avoiding having the quality/safety agenda driven by nonclinicians. Interestingly, an ethnographic study at a UK hospital provides some evidence that clinicians facing external pressures to improve performance have become adept at developing their own, clinician-driven safety and quality improvement procedures.(17) This is consistent with the pattern in other safe industries; outside pressure can help promote the cultural and behavioral change needed to create safer systems.

I'll conclude with some evidence-based recommendations to improve the quality and safety benefits from regulation and accreditation. First, regulators and accreditors need to become more aware of the costs and effects of their actions. Changes need to produce net benefits, and the most cost-effective changes should be adopted first. Second, they need to improve their use of monitoring and evaluation of both intended and unintended consequences, so that mistakes can be swiftly corrected. Third, they need to do a better job of meaningfully involving the actual clinicians who will be affected by new rules, guidelines, and measures in their development; this would provide a double benefit, both generating better standards and increasing practitioners' appreciation of the beneficial role of accreditation and regulation. Fourth, they should consider piloting changes (and fine-tuning them based on pilot results) before making them mandatory system-wide. Health care is a very complex system, and it is difficult and dangerous to assume that well-intentioned changes will always have the predicted real-world effects.

If my grandfather were still practicing medicine today, I know that he would support efforts to improve quality and safety, because he always wanted to do what was best for his patients. I am equally sure that he would believe physicians and other practitioners should be the leaders. He would probably be skeptical of the role of accreditation and regulation to do anything beyond setting minimum standards, and no doubt he would have preferred payment-for-performance and other voluntary improvement strategies. I hope readers will be convinced, though, that regulation and accreditation are an important part of the solution to our quality and safety problems.

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References

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1. Wachter RM. Understanding Patient Safety. New York, NY: McGraw-Hill; 2007. ISBN: 978-0071482776.

- [2.](#) Leape LL, Berwick DM. Safe health care: are we up to it? *BMJ*. 2000;320:725-726. [\[go to PubMed\]](#)
- [3.](#) Clinical Alarms Task Force. Impact of clinical alarms on patient safety: a report from the American College of Clinical Engineering Healthcare Technology Foundation. *J Clin Engineering*. 2007;32:22-33. [\[Available at\]](#)
- [4.](#) Hosford SB. Hospital progress in reducing error: the impact of external interventions. *Hosp Top*. 2008;86:9-19. [\[go to PubMed\]](#)
- [5.](#) Devers KJ, Pham HH, Liu G. What is driving hospitals' patient-safety efforts? *Health Aff (Millwood)*. 2004;23:103-115. [\[go to PubMed\]](#)
- [6.](#) McCarthy D, Blumenthal D. Stories from the sharp end: case studies in safety improvement. *Milbank Q*. 2006;84:165-200. [\[go to PubMed\]](#)
- [7.](#) Haughom JL. The PeaceHealth governance journey in support of quality and safety [Perspective]. *AHRQ WebM&M [serial online]*. July 2007. [\[Available at\]](#)
- [8.](#) Larson L. Physician autonomy vs. accountability: making quality standards and medical style mesh. *Trustee*. 2007;60:14-16, 21, 1. [\[go to PubMed\]](#)
- [9.](#) Warburton RN. Patient safety--how much is enough? *Health Policy*. 2005;71:223-232. [\[go to PubMed\]](#)
- [10.](#) Bar code label requirement for human drug products and blood; proposed rule. *Federal Register*. March 14, 2003; 68:12499-12534. [\[Available at\]](#)
- [11.](#) Shojania KG, Duncan BW, McDonald KM, Wachter RM. Making Health Care Safer: A Critical Analysis of Patient Safety Practices; Evidence Report/Technology Assessment No. 43. Rockville, MD: Agency for Healthcare Research and Quality; 2001. AHRQ Publication No. 01-E058. [\[Available at\]](#)
- [12.](#) Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Samples of alternative approaches to the recommendations. Oakbrook Terrace, IL; 2003.
- [13.](#) Wachter RM, Flanders SA, Fee C, Pronovost PJ. Public reporting of antibiotic timing in patients with pneumonia: lessons from a flawed performance measure. *Ann Intern Med*. 2008;149:29-32. [\[go to PubMed\]](#)
- [14.](#) Sackett DL, Richardson WS, Rosenberg WMC, Haynes RB. Evidence-based Medicine: How to Practice and Teach EBM. New York, NY: Churchill Livingstone; 1997. ISBN: 978-0443062407.
- [15.](#) McGlynn EA, Asch SM, Adams J, Keesey J, Hicks J, DeCristofaro A, Kerr EA. The quality of health care delivered to adults in the United States. *N Engl J Med*. 2003;348:2635-2645. [\[go to PubMed\]](#)
- [16.](#) Kohn LT, Corrigan JM, Donaldson MS, eds. To Err is Human: Building a Safer Health System. Washington, DC: National Academy Press; 2000. ISBN: 0585212732.
- [17.](#) Waring J. Adaptive regulation or governmentality: patient safety and the changing regulation of medicine. *Sociol Health Illn*. 2007;29:163-179. [\[go to PubMed\]](#)

Figures

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**Figure 1. Model of current distribution of quality of care.**[\(Go to figure citation in commentary\)](#)



**Figure 2. Model of potential distribution of quality of care.**[\(Go to figure citation in commentary\)](#)

