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A Standard-Setting Body for US Health Care Quality Measurement

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Despite widespread efforts to improve the quality and safety of the US health care system, too many patients still suffer preventable harm and experience poor outcomes.[1,2] The measurement and reporting of health care quality is important both for internal quality improvement and for driving competition on quality between providers.[3] Health care stakeholders have a vested interest in the quality of quality measures.[4] Patients, insurers and other payers, and health care purchasers seek quality measures that facilitate selecting and rewarding high-quality providers. For example, payers' efforts to move from paying for volume to paying for value are built on the premise that they can measure provider quality. Physicians, hospitals, and other providers also seek measures that accurately reflect their performance and that can help them identify opportunities for improvement.

There has been an explosion in the number and variety of health care quality measures in recent years, which now number well into the hundreds.[5] Multiple organizations develop quality measures, measure provider performance, or both, including the Centers for Medicare & Medicaid Services (CMS), state Medicaid programs, commercial health plans, individual states, regional collaboratives, nonprofit entities (including Consumer Reports and The Leapfrog Group), and for-profit entities (including *US News and World Report*, and Healthgrades). The National Quality Forum (NQF) endorses selected quality measures developed and submitted to it by others. Yet the quality of many quality measures is suspect.[6-8] Almost none of the measures reported by providers are audited. Different measures, which seek to measure the same construct, often conflict,[9] and some highly publicized measures are seen by many providers as deeply flawed.[10] Incentives generated by pay-for-performance and public reporting can distort reporting. Meanwhile, providers face a growing measurement burden.

Potential Harms With the Current Approach

Flawed measures, especially ones that are developed with limited transparency, can generate significant resistance, dividing the health care community rather than aligning it around an improvement goal. For example, CMS developed its Overall Hospital Quality Star Rating measure through a sole source contract to a contractor who is well qualified, yet has strong methodological views that seem to differ from the broader research community.[11] The result was a highly problematic measure (see Supplemental Table S1, available with the article online), against which the health care community rebelled, with publications highlighting the flaws in the measures.[12] Concerns with measure quality deepen when payers rely on these measures to financially reward supposedly good performance or punish supposedly poor performance.[13,14] Often, more effort is spent on repealing or revising the measures than on improving performance.

The proliferation of quality measures, many of suspect quality, harms health care purchasers and consumers by leading them to incorrectly choose lower-quality providers, harms health care providers by diverting resources from genuine quality improvement toward responding to the measures that exist and imparting financial and reputational risks, and increases overall health care costs. Misinformed or inappropriately incentivized providers might fail to make necessary improvements or might avoid patients who pose higher risks of generating negative reports. Today, despite a plethora of measures, some stakeholders believe that the available measures are rarely helpful for wise decision making.[15] Despite numerous studies, from *To Err Is Human* in 1999 on, that identify medical error as a leading cause of death in the United States,[16] the sad truth is that we do not know how many people die needlessly from medical error in the United States, because we lack scientifically sound performance measures to capture all possible harms.

There is a better way. In this commentary, we discuss the process for and problems with quality measurement and propose a process-based response—a new standard-setting body for US health care performance auditing and measurement.

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Key Steps to Measuring and Reporting Performance

There are 5 key steps in measuring and reporting on health care performance, each with opportunities for error.[4] The first step is specifying the performance measure, including the methodology for defining the measure and the procedures used for assessing validity, reliability, and comparability across providers, including risk adjustment to account for differing patient characteristics. The second step is obtaining and validating the underlying data needed to populate the measure. At present, very little of the data used for health care measurement are audited. Self-reported measures, especially when unaudited, can leave substantial room for gaming.[17] The third step is applying the collected data to the specified measure. Many measures are complex and leave substantial room for discretion, with some measure implementers making minor, or even major, adjustments to the specified measure. When researchers study the reproducibility of quality measurement, the results are often distressing.[18] The fourth and fifth steps are reporting performance in a manner that is useful for the intended audience, such as categorizing providers into performance groups, and communicating those results to a variety of audiences—from consumers to providers and payers—with very different levels of sophistication and medical knowledge, who will use the measures for a variety of purposes. Although there are important issues involving the fourth and fifth steps, we focus here on the first 3 steps.

Vision of a Medical Quality Standards Board

To help ensure the integrity of quality measurement and reporting, we believe that health care needs a body of carefully developed standards for developing quality measures and auditing the measures as well as the quality measures themselves. A natural place to look for guidance is to prior experience with financial reporting. Others have recognized the potential for health care reporting to draw on financial reporting experience.[19-22] We propose to build on experience with private–public development of accounting standards by the Financial Accounting Standards Board (FASB) and auditing standards by the American Institute of Certified Public Accountants (AICPA). Although imperfect, both organizations are widely seen as successful in their respective domains. FASB has a more than 40-year history of learning, improving, and evolving.

The Board's Charge

Building on that experience, we propose a private, nongovernmental Medical Quality Standards Board (MQSB). We see the MQSB as having 5 principal tasks: (1) develop general principles to guide the development of performance measures ("conceptual principles"); (2) develop measurement standards that specific quality measures would be assessed against, including standards for validity, reliability, and risk adjustment across providers ("measurement standards for quality measures"); (3) develop auditing standards; (4) assess and approve (or not) quality measures developed by other bodies, based on their consistency with the conceptual principles and the measurement and auditing standards; and (5) in the medium to long term, develop its own quality measures, where measures created by other bodies seem insufficient, or participate in joint measure-development efforts.

Especially at first, we expect that the MQSB would concentrate on the first 3 tasks, which currently are often not performed at all or not performed in a rigorous way. Over time, we expect that the board would move to assessing and approving measures, as resources permit, and to developing its own quality measures, where there seems sufficient need. The MQSB members likely would be "generalists"; thus, we would expect that the MQSB would consult extensively with specialists, such as physician groups, especially when assessing specific existing quality measures or developing its own measures.

Principles Guiding the Board's Work

The MQSB would be a self-regulatory organization (SRO). SROs have a long and often successful history in a variety of areas. Financial reporting is one area in which the SRO model has been successful over a sustained period of time.

The MQSB would follow a transparent, inclusive process in developing standards and in reviewing and evaluating measures proposed by others. Seed funding would come from foundations, patient advocacy groups, and private sources. Sustainable ongoing funding would come from hospital and payer support, and perhaps also from health information organizations that need to validate their products in a competitive environment. If the venture succeeds, it might evolve toward mandatory support by payers and providers, similar to FASB's evolution from voluntary to mandatory support by publicly traded companies.

We propose a nongovernmental body because the new entity will need political independence from the competing interests of providers, payers, auditors, and government agencies. Different stakeholders will have different tolerances for measurement error or support different trade-offs among the timeliness, expense, and methodological rigor of a measure. Experience teaches us that some health care providers may prefer that quality not be measured at all, even if assessed with high-quality measures. The MQSB will need to balance these different pressures and tolerances. Having independence from

outside pressures provides the best opportunity for balanced and fair decisions. The MQSB's governance structure, which will be discussed, would be designed to limit political influence on its decisions.

Independence is needed both for those setting the standards and for those verifying their appropriate use. Thus, the MQSB will need to establish standards for auditor independence as well as for how audits should be conducted. We expect that actual data collection will rely heavily on providers' own staff, with oversight by outside auditors. Thus, the MQSB's remit will include standards for both internal and external auditing.

Gaining Buy-In on This Idea

The MQSB would not start from scratch. Instead, it would build on the work done by other organizations to develop and assess measurement and auditing standards, including the NQF, the National Committee for Quality Assurance (NCQA), the Agency for Healthcare Research and Quality, and others. Here too, there is a useful analogy from financial reporting. FASB built on accounting standards developed by a predecessor, the Accounting Principles Board (APB). Initially, the APB statements of accounting standards continued to apply. Over time, the FASB amended and replaced some of these standards; others simply continued in force as authoritative guidance for accountants.

The new entity will need to be seen as valuable by a variety of stakeholders. Measure developers must come to view participating in the MQSB's standard-setting process, and adhering to the resulting standards, as more advantageous than not doing so. Given the political and practical challenges of mandating adherence to the standards, establishing an entity with unimpeachable integrity, lack of bias, and willingness to receive input from a variety of stakeholders would be a primary goal.

Proposed Structure of a MQSB

We propose to model the MQSB governance structure after FASB, which has a need for independence from its managers: Congress (which is influenced by company managers) and accounting firms. FASB uses a 2-tier structure—an expert, "lower-level" standard-setting body, with members selected by a larger, more inclusive upper-level board. This structure serves several goals: it enhances the political independence of the lower-level standard-setting board; it ensures the selection of high-quality board members; and it separates fundraising, which is done by the upper-level board, from standard setting, which is done by the lower-level board. We propose a similar 2-level structure—a small, expert standard-setting board to write and approve standards and a larger, more inclusive, upper-level foundation board (Figure 1). The foundation board—similar to the Financial Accounting Foundation, which appoints the lower-level FASB—will appoint members of the standard-writing board, will help insulate the standard-writing board from political pressures, and will conduct fundraising and outreach to stakeholder groups.

Foundation Board

- 15-20 members
- Members from organizations interested in health care performance reporting (multistakeholder)
- Appoints members of Standard-Setting Board
- Responsible for fundraising

Standard-Setting Board

- 5-7 members
- Experts in health care performance measurement and data auditing
- Serve full time for a substantial term
- Sever all outside business ties
- Subject to conflict of interest rules
- Work supported by professional staff

Figure 1. The proposed 2-level governance structure of a Medical Quality Standards Board.

The smaller expert board would comprise 5 to 7 full-time, well-paid board members. Similar to FASB, it is intended to be prestigious enough—and well paid enough—to attract members of the highest caliber. Standard-setting board members will serve for a substantial term (perhaps 5 years, renewable once, or 7 years, renewable for additional 3 years); they will sever all outside business ties and be subject to strict conflict of interest rules, including limits on outside compensation, adapted from the rules that apply to FASB members and to federal judges.[23] At least 1 member should be a consumer representative without ties to the medical community/industry.

Although not required, we expect that over time, the MQSB will develop a committee structure, with committees composed of MQSB members and perhaps additional persons with specific expertise, ex officio, who would not have voting rights. Three natural committees would be (1) a committee focused on measurement standards, (2) a committee focused on auditing standards, and (3) an emerging issues committee that could provide a rapid response to proposed new quality measures and other emerging issues more quickly than the full MQSB could, given its open and inclusive process. The emerging issues committee might be patterned on the FASB's Emerging Issues Task Force, which provides preliminary guidance on new issues that may later be decided by the full FASB. At the same time, we expect that the MQSB's main output—including conceptual principles, measurement standards, auditing standards, review and approval

of quality measures developed by others, and development of its own measures—would be decided on by the full board.

Key Tensions to Balance

The creation of an MQSB comes with a number of tensions that would need to be resolved over time. How will the new body build on prior standard-setting work and interface with other private and public bodies such as NQF, CMS, and NCQA? Initially, we expect that the MQSB will have plenty to do in developing conceptual principles and measurement/auditing standards, reviewing the hundreds of existing quality measures against those standards (which could lead to full endorsement, qualified endorsement, proposals to modify the standards so that they could earn endorsement, or rejection). Over time, the MQSB might develop its own measures or collaborate with others in producing performance measures.

We expect that the MQSB will find it useful to issue a limited number of "concept releases," patterned on the FASB's Statements of Financial Accounting Concepts. These releases would address general issues that cut across many specific measurement, auditing, and quality standards. For example, currently, a wide variety of public and private organizations develop quality measures, often largely in isolation from each other; indeed, sometimes in competition with each other. One role for the MQSB could be to develop cost–benefit concepts, under which measure developers would be expected to assess, at least roughly, the expected benefits of an additional measure and to compare those benefits to the measurement and auditing burden on providers.

Another area for a concept release is assessing measure validity, reliability, suitability for auditing, and comparability across providers, including any necessary risk adjustment. These assessments often are not undertaken in a systematic way today. In our view, they should be a central part of measure development.

Adherence by measure developers to the ideas outlined in the "concept releases" could discourage issuance of at least some—hopefully many—of the measures that divide the health care community. Today, there is often a tension among those who develop a new measure, payers and patients who seek information about quality, and those being measured, which often results in providers feeling that the measure is unfair, inaccurate, or simply burdensome for limited marginal benefit. Recent publicized examples of measures that have divided the health care community include CMS's Overall Hospital Quality Star Ratings, which systemically gave higher ratings to smaller community hospitals and much lower ratings to major academic medical centers,[24] and ProPublica's surgeon quality ratings, which were criticized for methodology choices that included failure to adjust for hospital-level performance, failing to include complications occurring during the index hospitalization, and nonstandard practices in measuring surgical complications.[8] (See online Supplementary Table S1 for a more in-depth discussion of these measures.) Both these measures diverted providers' attention away from quality improvement work and toward attacking the fairness of the measures. These measures, developed through nontransparent processes and without broad input, broke the trust of those being measured.

Another tension involves the interaction between the MQSB and public bodies, such as CMS, state health departments, and other regulators. If the MQSB achieves its potential, it can provide a neutral source that outside bodies can rely on to evaluate quality measures and recommend revisions or repeal of existing measures and to provide independent advice on measures that the outside bodies are considering.

How should the MQSB balance the speed, cost, and accuracy of gathering and reporting performance? Here, we envision a structure in which the same underlying quality measure might be subject to different variations, with different trade-offs. For example, rapid, lower accuracy measures might provide valuable information that hospitals and other providers can use in self-analysis and improvement; these may be measures that the provider does not plan to make public. In contrast, slower, higher accuracy measures might be appropriate for public reporting. The rapid, nonpublic measures also might cover shorter time periods, whereas public measures would use longer periods, for which the accumulation of data over time will enhance the precision of estimates.

Other tensions to resolve include, when is it appropriate to use narrow measures of performance and when is it appropriate to use composite measures? Should central line-associated bloodstream infection rates be combined with, for example, surgical site infection rates into a broader measure of hospital success at limiting infections? The answers might depend on the audience.

How should we balance the cost of auditing against the incremental quality assurance provided by more extensive audits? How should quality measures be designed, so that they are auditable, reproducible across providers, and implementable in the real world, given turnover among frontline staff charged with implementing them?

How do we ensure that the organizational structure of the MQSB, and its proposed upper-level board, represents all key stakeholder groups? How will it develop measures that meet the needs of different stakeholders? How do we avoid stifling innovation in measurement? And how do we address consumer values and preferences of consumers in selecting measures? These and many other important questions will need to be addressed—many of them by the MQSB itself.

Conclusion

The current health care performance measurement enterprise has fallen short of its full potential to deliver high-quality, low-cost care. Despite an ever-growing number of performance measures, and substantial and growing resources devoted to measurement, there is much evidence that the current cacophony of often conflicting measures is not meeting the needs of providers, payers, or consumers. Some current measures are so ill designed that they have generated resistance to the quality measurement enterprise as a whole.

The process by which many measures are developed, collected, and reported can help explain these results. In most cases, the underlying data are not audited. Often, methodologies are not rigorously reviewed against established criteria. Measures are sometimes simply rolled out, without prior public scrutiny and assessment of the proposed methodology. Many measures leave substantial room for reporting discretion or are so complex that reporting error is inevitable. And measure validity and reliability are rarely measured or reported.

Health care needs a professional, independent organization to set standards for collecting and auditing health care quality data and specifying performance measures. Such an approach can accelerate the development of valid and reliable quality measures and mitigate the division stimulated by measures such as CMS's Overall Hospital Quality Star Rating.

Creating a new standards body will not be easy. The body we propose will need to bring together diverse stakeholders and navigate sometimes conflicting goals. But keeping the status quo is worse. The effort, though large, is an essential step if we are to realize the full potential of health care quality measurement. The past success of FASB and AICPA in developing accounting and auditing standards provides reason for optimism that the task is achievable.

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