Clinical Guidelines, the Politics of Value, and the Practice of Medicine: Physicians at the Crossroads

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Introduction

Guidelines have been important adjuncts to clinical decision making. However, guidelines have also been used in regulatory processes, including the Patient Protection and Affordable Care Act (ACA), in ways that stretch them well beyond their intended use. Guidelines are not standards. They are guides. They are provisional. Their application as standards in the regulatory framework is cause for concern.

Standards are quite different from guidelines. They deal with clinical circumstances that can be defined with precision. The first standards were developed in the early 1900s to deal with matters such as tuberculosis prevention and radiation safety.¹ Over time, standards have been applied to many discrete therapeutic interventions and procedures,² and in recent years they have come to include checklists for defined processes.³

Although guidelines have existed for millennia in authoritative texts, the form in which we know them today is comparatively recent. Starting with only a handful in the late 1950s, their numbers increased sufficiently to prompt the establishment of a clearing house in the early 1990s.¹ Some conditions now have multiple guidelines, whereas others have none. Their use by physicians in the course of treatment decisions has proved to be invaluable. But even with the aid of guidelines, quality care depends on the judgment of competent physicians who are trained to cope with complexity and uncertainty and who understand the nuanced characteristics of their patients' particular circumstances.

Regulators were quick to use guidelines, starting as early as 1980, when utilization review was introduced. In subsequent years, guidelines were incorporated into pay-for-performance (P4P) measures,⁴ the Physician Quality Reporting System (PQRS),⁵ and other, similar instruments. And they are essential elements in the value-based purchasing systems and accountable care organizations (ACOs) established by the ACA.

The Value Culture

Placed in a broader context, the use of guidelines in regulatory processes can be seen as part of the struggle between physicians, who value their professional autonomy, and government and industry, who have sought to wrest control from a profession that they have seen as too powerful.¹ Concern that just such a struggle might ensue is reflected in the original Medicare Act of 1965, which declared that "nothing in this title shall be construed to authorize any Federal officer or employee to exercise

any supervision or control over the practice of medicine."⁶ In fact, considerable control has been exercised, although not specifically over the practice of medicine. The lever of control is "value," a paradigm that links quality and cost. Indeed, it is through the politics of value that clinical decision making has been progressively wrested from physicians' control,⁴ and it is the regulatory application of guidelines that has become an instrument in this process.

The value culture builds from a belief that costs are high because quality is low. One oft-cited example is the many thousands of deaths that have been attributed to physicians' errors,⁷ although the numbers claimed may be exaggerated.⁸ Another is the broadly refuted⁹ claim that 30% of health care spending is due to unexplained geographic variation in physician practices,^{10,11} although most such variation is explained by geographic differences in poverty and its high toll on health care resources.^{9,12} Yet, these beliefs are rooted in a simple truth. Physicians' practices are imperfect. And they are powerful beliefs. They have fueled the conclusion that someone is doing something wrong and something must be remedied.¹

Part of the remedy has been found in the reimbursement system, where excessive spending has been attributed to misaligned incentives that lead physicians to choose volume instead of value. The favored solution is to cease paying for service and start paying for the "right care."¹³ Moreover, because it is physicians who have traditionally defined the right care, that responsibility must now be placed elsewhere. As framed in statements by former Center for Medicare & Medicaid Services (CMS) Administrator Donald Berwick, "In the past, physicians' commitment to the patient ensured the provision of appropriate care."^{14(p168)} However, "no longer is the physician, paternalistically committed to the patient, the driving force in medical care. Health care is being rationalized through critical pathways, guidelines and integrated business structures."^{14(p24)} Regulating for improved medical care involves designing appropriate rules invested with authority."^{14(p9)} Achieving these goals demands "restriction of the autonomy of health care professionals."^{15(p759)} This shift in the locus of control from physicians to regulators has been fostered by thought leaders within and beyond the profession, and too often, guidelines are tools to that end.

The Tyranny of Guidelines

Guidelines are expressions of the optimal pathway for the average patient, but, of course, most patients are not average. An example of how the doctrinaire application of guidelines to all

patients can be harmful was provided in a recent study which showed that the inflexible use of the most widely accepted hypertension guidelines would lead to inferior outcomes.¹⁶ Moreover, although many of the most clinically useful guidelines deal with important issues, it is through their exercise of judgment in myriad small decisions that physicians display their competence. The following two cases illustrate how the inflexible use of guidelines can adversely affect such decisions

Case Report 1

Patient No. 1 is a morbidly obese 37-year-old man who, 16 years previously, was treated for stage IIBX Hodgkin's lymphoma, nodular sclerosis type with standard chemotherapy followed by radiation therapy to the neck and mediastinum. Reviews of patients with Hodgkin's lymphoma treated at Memorial Sloan-Kettering Cancer Center (MSKCC)¹⁷ and elsewhere¹⁸⁻²⁰ have found striking increases in carotid and coronary atherosclerosis 10 years and more after radiation to these ports. As a result, follow-up at MSKCC includes screening for early coronary artery disease. Although the current National Comprehensive Cancer Network (NCCN) guidelines for Hodgkin's lymphoma note that cardiovascular symptoms may occur at a young age, they make no specific recommendations for screening.²¹ Lacking such a guideline, this patient's insurance carrier denied payment.

Case Report 2

Patient No. 2 is a 46-year-old man with diffuse large B-cell lymphoma who is being treated on a protocol that includes combination chemotherapy with rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone (*R-CHOP*) with growth factor support every 2 weeks. Because this regimen is emetogenic, MSKCC supportive care policy includes prophylactic treatment with aprepitant. Although NCCN guidelines include an option of *R-CHOP* treatment every 2 weeks rather than every 3 weeks,²² treatment at this interval was not within the guidelines followed by the patient's insurance carrier, and coverage for aprepitant was denied.

The two circumstances described above do not represent major decisions, but they were important decisions, and the inflexible application of guidelines influenced them adversely. Such actions are not unique to oncology practice. In a recent example, patient care was harmed by the denial of payment for medication in two psychiatric patients with mood disorders, one because the dose was considered too low and the other because it was considered too high, although symptom control was good in both patients.²³

From PQRS to P4P to ACOs and Comparative Effectiveness

The broad application of guidelines as regulatory tools is illustrated by the PQRS program, which uses more than 250 measures. Most are quite narrow, and many deal with processes of care or patient satisfaction, neither of which correlate with clinical outcomes.^{2,24} In England, adherence to specific perfor-

mance standards by Primary Care Trusts simply led to the decreased use of other elements of care of equal or greater importance.^{25,26} Nonetheless, such standards are being incorporated into P4P programs, even though P4P has generally failed to reduce expenditures,^{2,27,28} even in Massachusetts, whose health care reform was used as the model for the ACA.²⁹

Despite these experiences, guidelines will soon be applied to value-based purchasing and ACOs, through both rewards for providers who meet the stated standards and penalties for those who do not. In announcing its proposed rules for ACOs, the Centers for Medicare & Medicaid Services noted that "we could provide a detailed description of evidence-based guidelines for various conditions and diseases for which we would hold ACOs accountable. However, we have concerns that a prescriptive approach would be premature and potentially impede the goals of this program."^{30(p77)} But without a doubt, the goal is to use rules invested with authority.

To fairly assess the use of guidelines and standards, risk adjustment will be essential. Comorbidities are one important element, but income is even more important. Costs are highest and outcomes are worst among patients who are poorest and most disadvantaged.^{9,12} Unfortunately, the administrative data commonly used to assess value lack sufficient information to properly adjust for poverty. It is not surprising, therefore, that concerns have been raised that incentive payments might harm providers who disproportionately care for the poor,^{2,31} as has occurred in California already²⁹; that the financial goals of ACOs could create incentives to avoid low-income patients,³² as has occurred in medical homes already, both in the United States and Canada^{33,34}; and that the application of value-based quality standards could harm providers who disproportionately care for the poor.³⁵

Finally, although most guidelines have been the product of work by expert physicians, they soon will be the product of the comparative effectiveness panels mandated by the ACA. Although the federal government is currently constrained from applying the results of such panels in a regulatory manner, the *New York Times* has editorialized that they should,³⁶ and others have noted that value can only be achieved by requiring adherence to clinical guidelines.³⁷ Yet, concern about the validity of even the highest quality guidelines currently in use has prompted the Institute of Medicine to issue a set of rigorous standards for trustworthy guidelines.³⁸

Conclusion

Best practice guidelines are being used to an increasing degree, not only by physicians to improve the level of care, but also by bureaucrats to constrain reimbursement and guide the pathways of care. Physicians recognize that most guidelines simply reflect the provisional opinions of so-called experts about care under modal circumstances, and they know that all are subject to change in accordance with the constant flow of new information.^{38,39} In the hands of a knowledgeable physician, the integration of guidelines into decision making can aid in reducing expenditures and raising quality. However, their inflexible application can be an impediment to both, and the pervasive

expansion of their use by regulators should be greeted with deep alarm. In the last analysis, high-quality care depends on the autonomous exercise of sound clinical judgment by competent and caring physicians.⁴⁰⁻⁴² Preserving that elusive and endangered professional characteristic should be a matter of utmost concern.

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