

Practice Guidelines and Outcomes Research, Part I: Insights from the Clinton Health Care Task Force

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Reasons for the Outcomes Revolution in Medicine

Government-developed practice guidelines were described as "nothing less than the beginning of a peaceful revolution in American medicine" by James O. Mason, MD, HHS Assistant Secretary of Health.¹ Arnold Relman, former editor-in-chief of *The New England Journal of Medicine*, called the "outcomes movement" with its associated guidelines "the third revolution in medical care."² Articles in prestigious medical journals assume that practice guidelines are "a new reality."³ The AMA already offers the *Directory of Practice Parameters*, complete with three updates, for sale (\$99 for members, \$149 for non-members).⁴

The "revolution," if it occurs, is unlikely to involve voluntary adoption of the guidelines by clinicians. Only 20% of medical organizations surveyed by HHS reported using clinical practice guidelines produced by the federal government, and 63% of the users had difficulty with them, most commonly because of resistance by clinicians.⁵

Reasons given for the implementation of guidelines by the Agency for Health Care Policy and Research (AHCPR) are:

"1. Doctors, nurses, and other health care providers will make practice decisions that rely more on science-based knowledge and respected professional judgment than is currently the case.

"2. Patients will become better informed health care consumers who can work as partners with their health care providers.

"3. Unnecessary health care practices will be eliminated or greatly reduced.

"4. The quality of health care will improve.

"5. The overall costs of health care will decrease."⁶

Future articles will examine the likelihood that practice guidelines and outcomes research can achieve these stated objectives. This article will examine the most likely motivations for the outcomes movement. Clearly, of the five reasons listed above, the last should be placed first.

The Function of Guidelines

In managed care systems based on capitation, physicians are "no longer independent actors." This situation "spawns a need for new systems designs and navigation-

al tools to guide patients through the care process."⁷

A necessary part of the system, as envisioned by the Clinton Task Force on Health Care Reform, would be the Computerized Patient Record (CPR), maintained by Accountable Health Plans (AHPs): "Electronic patient records would be available to any authorized user in the managed competition system. The CPR package assumes that decision support, clinical practice guidelines, and medical information will be available on-line during patient encounters. The government role would be extensive, including the definition of data collection and reporting requirement for each entity...."⁸

Discussions of practice guidelines soon comes to the issue of cost: "the result of patient outcomes research and the development of clinical practice guidelines is integral to the health care reform objective of

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cost containment."⁹

One way to contain costs is to exclude treatments from insurance coverage; practice guidelines were envisioned as one method of determining exclusions.¹⁰ "There are lots of treatments whose benefits vary continuously depending on some patient characteristic...But as you move down the range, the amount of benefit gets smaller and smaller, and somewhere you need to stop using the treatment. We will have to use guidelines to draw the line, and the line will be drawn based in large part on costs."¹¹

Some cost-containment strategies, such as price controls, create incentives to increase the volume of services. Practice guidelines could serve as a check on that tendency, especially when used in profiling practice patterns to "identify deviants."¹²

Enforcement of Guidelines

Although the term "guidelines" sounds reassuringly benign, advocates of the revolution do not intend to make mere suggestions. It is one thing to limit coverage through the terms of a voluntary insurance contract. The next step is to limit the types of insurance that may be offered. "Include no treatment in approved (for tax-advantaged status) guidelines beyond the best guess of the experts."¹³

A further step is to limit the treatments that patients are allowed to purchase on their own:

*Should we allow consumers to decide that they want to pay...for the procedure anyway? Isn't this the heart of the question for controlling the percentage of GDP that health care represents? ...I think it is preferable to change FDA rules or public law such that no such treatments could be offered at any price.... To offer such treatments but not include them in the benchmark benefits plan would sound like discrimination based on income, since the rich could buy the treatment, even though its comparative effectiveness and efficiency had not been shown to be better than the approved approach.*¹³

Another Task Force consultant was concerned that the variability that we see in medicine today might be allowed to survive in a reformed system: "If the entire universe of care is permitted, we will not have advanced the state of the art with regard to a minimal benefit package."¹⁴

Reformers recognize the need for physician cooperation: "By definition and necessity, any participating provider will have to adhere to clinical practice guidelines if their [sic] outcomes are to be effectively measured and not found to be significantly out-of-line with the expected norms."¹⁵ To gain cooperation, varying degrees of coercion are suggested. For example, compliance with guidelines might serve as an affirmative defense in a malpractice action.¹⁶

One Task Force consultant asked: "Should we require that patients sign some type of informed consent sheet that describes the standard treatment (Federal guideline) for the patient's condition? Should the provider be required to explain and justify to the patient any deviations from the Federal guideline for the patient's condition?"¹⁷

Potential sanctions for not following guidelines include exclusion from a managed care plan or even delicensure.

Task Force participants recognized the difficulties in imposing Federal guidelines, such as the requirements of the Administrative

Procedure Act. (The APA requires that persons affected by a federal regulation at least have the opportunity to give input, even though the agency is free to disregard the input after reading it.) "Notice and comment procedures have become a nightmare for many agencies; it is now generally agreed that the federal regulatory process in many agencies has...become unacceptably sluggish and indeed may have 'ossified'...because of the complexity of the notice and comment..."¹⁸

Suggested bypass mechanisms included invoking exceptions for cases involving government grants, contracts, or benefits, or making the legislation specific enough to be "self-executing so that agencies could take action directly under it without having to issue an intermediate layer of regulations."¹⁸

The Status of the Revolution

Immediate federal implementation of national guidelines was stalled by the defeat of the Health Security Act. However, many participants in the Task Force came from and have returned to the private sector. The data management and managed care corporations they represent could still implement the basic ideas. If the federal government does not pass a law to deprive people of their rights, then physicians and patients may still be induced to "voluntarily" relinquish those rights, as through economic coercion.

The rationale for practice guidelines and their actual effect in practice need close examination. Both efficacy and safety are far from established, even if one were to be in total agreement with their purpose.

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