In the Spotlight

Clinical Guidelines: Straight Talk or Strait Jacket?

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Consistency may be the hobgoblin of small minds, as Emerson famously put it, but consistency is also a hallmark of valid science. If an apple indeed fell on the head of Sir Isaac Newton, we can be sure it accelerated to earth at $9.8 \text{ m/sec}^2$, the same rate at which an apple would fall today. An absence of consistency implies a lack of scientific truth.

The absence of consistency in the U.S. health care system (how doctors treat patients) has given rise to criticism that American health care is not scientifically based—and that we may be wasting billions of dollars on ineffective or even harmful treatments. This criticism rests on the work of John Wennberg and his colleagues at Dartmouth, who have shown there is great geographic variation—that is, inconsistency—in the rates of many surgical procedures across the country. They found, for instance, that the rate of back surgery among Medicare patients in Santa Barbara, CA, is five times as great as the rate in the Bronx. Because the prevalence of disease in these populations does not differ by that much, it's clear the California doctors have a lower threshold for performing surgery.

Accordingly, the argument goes, there exists a potential patient for whom the doctors in California would recommend surgery and for whom the Bronx doctors would not. If that's the case, either the California doctors or the Bronx doctors could be practicing scientifically correct medicine—but not both.

In response to this variation, there are increasing calls for the imposition of national practice guidelines. These guidelines would denote which tests should be ordered in response to specific symptoms, and which treatments are to be chosen on the basis of the test results. Creators of guidelines propose using the methods of Evidence Based Medicine: consult the medical literature and determine what treatments or approaches are truly supported by the evidence. There will then be one "best" standard promulgated for all physicians who treat the subject disease.

In the case of back surgery, a guideline might dictate that a patient 55 years of age or younger with severe back and leg pain for 6 weeks or more, with moderate muscular weakness and a positive MRI, should have lumbar surgery.

As a practicing orthopedic surgeon, I have not seen that specific guideline, but it's a close approximation of what one may look like. Yet this particular guideline, however clear it may be, is not apt to reduce the variation Wennberg discovered. Forget for a moment that some 56 year olds would rightly bristle at arbitrary, age-based treatment denials; forget that some patients are not known for their patience, and won't wait 6 weeks; forget even that "severe" back and leg pain and "moderate" weakness are subjective criteria.
This guideline will fail in actual practice because it does not represent a genuine consensus of the medical community regarding the "right" approach to lumbar disc disease. That is, if surgeons in Santa Barbara operate on 65 year old patients with pain for 4 weeks duration and the Bronx threshold is 45 years of age and 8 weeks of pain, the wisdom of Solomon does not produce a correct answer of 55 and 6. The correct answer is indeed unknown and the variation we see reflects that uncertainty.

Simply put: guidelines won't help reduce practice variation when that variation is based on divergent opinions within the medical community. Doctors in Santa Barbara have a tacit but fundamental disagreement with their colleagues in New York on the so-called indications for surgery. This disagreement flourishes because of the dearth of good outcomes study data and the absence of good techniques for assessing patient preferences. Add to that differences in medical cultures and varying incentives for action, and one might say we are lucky that the surgical rates differ only by a factor of five.

To be sure, guidelines can be useful. They can remind the distracted physician to administer antibiotics before surgery or beta-blockers after a heart attack, for example. They further can serve as benchmarks for quality performance: the Centers for Medicare and Medicaid Services can measure (and reward) hospitals with a higher rate of peri-operative antibiotics—and by so doing, increase compliance.

Guidelines are particularly helpful when the problem at hand is one of erratic implementation of consensus medical expertise. For instance, doctors agree that central venous catheters should be inserted only after washing one's hands and cleaning and draping the patient's skin—yet they don't always do it. Peter Pronovost and his colleagues at Johns Hopkins and Michigan, reporting in the New England Journal of Medicine, showed that implementing a simple guideline encoding these and a few other rather conventional suggestions reduced the rate of catheter-related bloodstream infections by two-thirds.

But there are limits on the power of guidelines. A valid guideline does not create consensus; consensus creates a valid guideline. If there is no general concurrence in the medical community on the correct therapeutic approach, a guideline won't dampen variation in practice. In particular, a tight guideline will be shunned by all who disagree with its underlying theory; and a guideline lax enough to generate broad support will—by its very laxity—fail to reduce practice variation.

A guideline in the setting of controversy or uncertainty at the minimum misleads: it articulates resolution when there is no resolution at hand. Doctors will reject it not because we are stubborn (though we can be) and not because we are nostalgic for the days of physician autonomy (though we should be); doctors will reject guidelines of Procrustean rigidity simply because it is the right thing to do. As noted by the 14th century French surgeon, Henri De Mondeville, "Anyone who believes that the same thing can be suited to everyone is a great fool, since medicine is practiced not on mankind in general, but on every individual in particular."

Practice variation may be bad; but foolish consistency, the true object of Emerson's scorn, would be worse.

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