Recent Finding that Widespread Use of Stents Appears Non-Efficacious Shows the Importance of Evidence-Based Medicine

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On November 16, 2006, the *New York Times* reported on the growing body of evidence for the proposition that the use of stents and angioplasties as treatment for blocked arteries is actually not efficacious.[1] According to the article, "a major study, presented Tuesday at a medical conference in Chicago, challenged the widespread use of tiny balloons and metal stents in people who had suffered heart attacks days or weeks before."[2]

Several important bioethics and health policy implications present themselves here. The first, of course, is the question of why certain treatments became virtually standard of care for blocked arteries in certain contexts when it appears that they may be at best non-efficacious? From a clinical perspective, the qualifying phrase "at best" is important because of possible side effects that may attend such treatments, all of which are invasive. This first question goes to the nature of clinical practice itself, and is at the core of the current debate over evidence-based medicine ("EBM"). Proponents of EBM assert that clinical practice ought to be based on the best available evidence of outcomes and efficacy.[3] This, of course, is not to suggest that clinical practice is utterly reducible to empirical evidence (which ought to include qualitative as well as quantitative measures).[4] Opponents of EBM typically argue that clinical practice has for generations relied primarily on the experience and practical wisdom of physicians, and that to do otherwise is to practice what is disdainfully referred to as "cookbook medicine."[5]

While there is much to be said for the knowledgeable, experienced physician's intuition and practical wisdom, there are serious risks to a clinical practice that is not based on the best available evidence. This latest article exemplifies these risks, where what physicians believe is best practice turns out, upon exacting scrutiny, to have little to no positive effect, and may well pose more risk than benefit. As the *Times* article suggests, "[m]edical history is strewn with well-intended treatments that rose and fell when someone finally had the backbone to test them, and the scientific method trumped what doctors thought they knew."[6] But the resistance to EBM is deeply embedded in the fabric of medical practice, so much so that the principal investigator on the stents study indicated difficulty in recruiting "other researchers for her study: some refused to participate, saying it was unethical to leave some patients without stents."[7] The conviction that treatments with stents constituted best practice was so strong even in the absence

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[1] *See* Denise Grady, *When Blind Faith in a Medical Fix is Broken*, N.Y. TIMES, Nov. 16, 2006, at A33.
[2] *Id*.
[3] *See* Howard Brody, Franklin Miller, & Elizabeth Bogdan-Lovis, *Evidence-Based Medicine: Watching Out for its Friends*, 48 PERSPECTIVES IN BIOLOGY AND MED. 570, 571 (2005).
[4] *See id*. at 577; *see also* Jason Grossman & Fiona J. MacKenzie, *The Randomized Controlled Trial: Gold Standard or Merely Standard*? 48 PERSPECTIVES IN BIOLOGY AND MED. 516 (2005).
[5] *See* Brody et al., *supra* note 3, at 571.
[6] Grady, *supra* note 1, at A33.
[7] *Id*.

of compelling (scientific) evidence of their efficacy that many researchers deemed it unethical to conduct a placebo-controlled study.

Of course, refusing to subject a treatment to rigorous testing seems ethically problematic insofar as it ensures the accepted treatment will continue to be accepted without scrutiny of outcomes and efficacy. Jay Katz, in his important book, *The Silent World of Doctor & Patient*, surveys a similar debate regarding the best treatments for breast cancer (whether radical mastectomy or lumpectomy plus radiation produces better outcomes), with each side asserting that to opt for the alternative is to behave unethically (and perhaps even to commit malpractice).[8] All of this acrimony exists despite the fact that the best evidence regarding which treatment is superior is absolutely not dispositive.[9]

The problem, writes Katz, is not the existence of this uncertainty, but the fact that the parties to the breast cancer debate are unwilling to acknowledge that the best evidence simply does not establish a consensus on the best course of treatment for certain kinds of breast cancer.[10] Each party is convinced, despite the lack of exhaustive, uncontroverted evidence to support their view, that their preferred treatment is optimal.[11] Thus, Katz concludes that it is an unwillingness to acknowledge the vicissitudes and uncertainties of clinical practice that drive entrenched convictions as to a preferred treatment even in the absence of compelling data on outcomes and efficacy.[12] In turn, to the extent that such convictions result in treatments that pose serious risks and few benefits (as determined by reliable evidence), the convictions themselves, and the attitudes that inform them, may be ethically problematic.

The second question prompted by the stents study is the basic economic problem, namely, that there are scarce health care resources and comparatively large health care wants. Resources expended on a given treatment cannot obviously be allocated for other purposes at the same time. Concerns of justice and access would seem to suggest that thousands, if not millions of dollars ought not be expended on non-efficacious treatments. Thus, even if there may exist sound clinical reasons for resisting the turn to EBM (and I should mention that I am unconvinced of the soundness of the objections), there are significant policy concerns that militate in favor of encouraging greater efforts for providers to assess preferred treatments in light of the best available evidence. Note that this recommendation encompasses several obligations for the provider:

> (1) to inform oneself about the best available scientific evidence (which, again, is not limited to evidence produced via randomized, placebo-controlled, double-blind studies) on a given treatment;
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> (2) to disclose to patients if and when the best evidence is *not* dispositive, i.e., where the best treatment is simply uncertain; and

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[8] JAY KATZ, THE SILENT WORLD OF DOCTOR & PATIENT 182-83 (2d ed. 2002).
[9] *Id*.
[10] *Id*.
[11] *Id*. at 181.
[12] *Id*.

(3) to support well-designed, ethically sound research protocols that are intended to subject current treatments to rigorous analysis to determine efficacy.

With every report that demonstrates that a widely-used treatment is actually non-efficacious (or worse), trust in medical practice is undermined. The *Times* article concludes by quoting Dr. James N. Weinstein, chairman of orthopedic surgery at Dartmouth Medical School and a researcher at the Center for the Evaluative Clinical Sciences: "'As a nation, we're not doing ourselves any favors by going after the next new thing without doing the studies . . .' When established treatments turn out to be useless, or worse, harmful, Dr. Weinstein said, 'everybody's going to lose trust in the system.'"[13]

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[13] Grady, *supra* note 1, at A33.