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No Method, Thus Madness?

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Abstract

If you ask most medical school deans if they have a course, program, or center doing bioethics, they will enthusiastically assure you that they do. And their enthusiasm for bioethics grows exponentially in proportion to their interest in showing that they are doing something about managing research ethics issues at their institutions. The same can be said about the entire biomedical research establishment - from private companies to independent research centers to professional organizations - bioethics is on the masthead, the organizational chart, and the agenda of the annual meeting. Not to worry - medicine's got ethics.

Comments

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policy & politics

No Method, Thus Madness?

by Arthur L. Caplan

If you ask most medical school deans if they have a course, program, or center doing bioethics, they will enthusiastically assure you that they do. And their enthusiasm for bioethics grows exponentially in proportion to their interest in showing that they are doing something about managing research ethics issues at their institutions. The same can be said about the entire biomedical research establishment—from private companies to independent research centers to professional organizations—bioethics is on the masthead, the organizational chart, and the agenda of the annual meeting. Not to worry—medicine's got ethics.

It is certainly fine to feature bioethics as a topic area. But there is mounting evidence that perhaps bioethics is not all or even primarily what the doctor should be ordering just now. Some of the problems now ailing medicine require admitting that what has befallen medicine and the health sciences is an epistemological crisis as much as a moral one.

Now this may seem an odd claim since it is hard, or rather, completely impossible, to avoid the phrase “evidence-based medicine” in the august halls of academic medical centers in the United States, Europe, Australia, and New Zealand these days. There are journals, resource centers, toolkits, web sites, and more publications than anyone interested in evidence-based medicine could possibly ever read.

So how could it be that a field that is embracing evidence at every turn, teaching about outcomes, drilling the need for verifiable data into the heads of the next generation, and extolling the virtue of evidence at every conference, meeting, seminar, and water-cooler, possibly be in the midst of an epistemological crisis? Where is the evidence?

♦ ♦ ♦

Contemporary medicine is sailing on very rocky seas these days. It is being buffeted by ever-rising costs, doubts about its efficacy, and intrusions on its turf from competitors that range from optometrists, psychologists, chiropractors, midwives, and nurse-anesthetists to the friendly folks at the herb and vitamin store. Recently, there seems to be real uncertainty on the part of medicine's leaders about what to say in the face of a continuing stream of fraud and misconduct. The editors of the *Lancet*, *Science*, *Nature*, and the *New England Journal of Medicine*—the key guardians of the evidence gates—face a stream of questions about how they plan to secure the gates following the shenanigans of the South Korean researcher who lied about producing stem cells from cloned human embryos and a Norwegian cancer researcher who fabricated findings about ways smokers could reduce their risk of acquiring oral cancer, and their tortured agonizing is painful to watch. Far from having an answer to the question of what distinguish-

es medicine as a mode of healing and a field capable of minimizing fraud, the leaders of the medical professional cling to the phrase “evidence-based medicine” as if intoning the word “evidence” will act as a talisman to keep all the troubles at bay.

But the fervency of the embrace of evidence-based medicine reflects a deeper and much more serious problem among the stewards of medical knowledge—a crisis of faith in the methods, processes, and checks and balances that have, at least since the nineteenth century, been the infrastructure that has permitted medicine to make the transition from an art to a science. Consider the response to the recent battle over what to do about fetal pain.

In the August 24, 2005, *Journal of the American Medical Association*, an article claimed that a review of all the available published medical evidence showed that fetuses do not feel pain until they are at least seven months old. The *JAMA* article appeared at a time when efforts are underway in Congress and state legislatures to use the topic of fetal pain as a way to discourage women from seeking elective abortions. The *JAMA* article contended that there is no medical evidence showing that fetuses can feel pain at twenty weeks. Moreover, it argued that the provision of fetal anesthesia would carry risks to the mother without providing benefit of any sort either to the fetus or the mother.

Many raised questions about the study's findings. But they did so in a most peculiar way—they “outed” some of the authors of the study as being involved with abortions or the advocacy of abortion rights.

When *JAMA* published the paper, a disclosure was included that the authors had no financial interests in any drugs or devices discussed. Requiring authors to disclose financial conflicts of interest is by now a standard requirement for all major medical journals. But there was no disclosure of the fact that one of the five authors runs an abortion clinic at San Francisco's public hospital while another worked temporarily more than five years ago for an abortion rights advocacy group.

Douglas Johnson, legislative director of the National Right to Life Committee, professed to be shocked by this omission. “These are people with years of professional and ideological investment in the pro-abortion cause, not some neutral team of medical professionals,” he told the *Chicago Tribune*. “We think readers and viewers have a right to know who’s filtering the information they’re being presented with.”

It is hardly surprising that someone active in the movement to criminalize elective abortion would yell foul at the idea that *JAMA* could have run this article without a disclosure of the pro-abortion involvement of some of the authors. What is astounding, and indicative of the sad state of epistemological affairs in medicine, is that two former editors of the *New England Journal of Medicine* agreed with Johnson.

Arnold Relman told the *Chicago Tribune* that the editorial staff at *JAMA* “must have known there would be criticism from the right-to-life people. In a situation as contentious as this, it seems more disclosure should be the rule rather than less.”

Marcia Angell concurred. “Suppose it were the other way. Suppose there were an article that said that (fetuses) do feel pain and it was written by people who were involved in the right-to-life movement. Would I want to know that? I think I would.”



If these claims are right, then medicine is truly and utterly lost. If every potential source of bias is to be revealed alongside every published article, then medical and biomedical journals will consist of nothing but long biographical essays about the authors. There will be no room for science in any journal that seeks to identify and disclose all of its authors’ possible biases.

There is nary an author publishing today in biomedical journals who lacks ambition, enemies, vices, dreams, aspirations, patriotic feelings, pride, or an ego. These are all powerful sources of bias. So are such factors as where one went to school, one’s religious affilia-

tion, political commitments, economic status, social upbringing, cultural outlook, and character. Is all of this to be disclosed by every author? Must we know that an author is pursuing tenure, wants to impress his peers, has hated a key rival at another medical school ever since they were together as undergraduates, is desperate to belong to the local country club, hopes to finally make his parents proud, lusts after a colleague’s spouse, abjures meat, looks at pornography on the Internet, leaves bad tips, is a Scientologist, or is gay? Is all this necessary to assess the author’s claim, based on a review of the literature, that a fetus does not feel pain until twenty-eight weeks?

Medicine needs to both know what its methods are for dealing with bias—and for that matter for detecting fraud—and then believe that it can weather the storms induced by politics, money, ambition, and greed. To put the point another way, talking about evidence without being sure what methods, techniques, and strategies can be relied upon to produce valid evidence is talking through your epistemological hat.

Now as it happens, medicine does have such methods, techniques, and strategies. They consist of the randomized trial, the case-control study, the drive to subject hypotheses to confirmation and falsification, the need to demonstrate a degree of consistency among new theories and old ones, the family history, and the correlation of the pathologist and the postmortem with the diagnostician, among others.

But few physicians or those who work with them have any sophistication about the philosophy of science. Even fewer have ever been taught anything about the philosophy of medicine. And fewer still can give a coherent presentation on what the core infrastructure is that distinguishes the science of medicine from the faith and testimonials of religious healers or the loopy claims of the talk radio nutritionists.

This has got to change. The only way for medicine to weather its current storms is not to adopt the mantra of evidence but to know where evidence

comes from and why it is to be trusted. If our medical schools and academic research centers do not take this need far more seriously than they now do, if they do not make the philosophy of medicine a part of the culture of academic medicine and a key element that is presented when medicine travels in public, then soon enough those who cry bias, greed, conflict of interest, ideology, or misconduct at any claim they do not like will only have to make the charge to make it stick.