TUCSON — SCIENTIFIC data from clinical trials provides the foundation of medical decision making, from a doctor’s prescription pad to sweeping public health policies. Public trust that the data is accurate and unbiased is the glue that binds our $3 trillion health care system. I worry that this trust, particularly when it comes to American men and their physicians and screening programs for prostate cancer, is now at risk.

In 1970 I discovered the prostate-specific antigen, or PSA, which is now the most widely used tool in prostate screenings. But there has been a growing concern about whether the use of the PSA test has led to overdiagnosis and overtreatment, with millions of unnecessary surgeries, complications and deaths.
Nevertheless, the medical community has roundly embraced the results of a recent study finding that PSA screening reduced prostate cancer deaths by 20 percent. The study, the European Randomized Study of Screening for Prostate Cancer, joined another survey, the so-called Swedish Goteborg study (the results of which provided a basis for the European Randomized Study), which found an astounding 44 percent reduction.

But there’s a big problem with both of these studies: In March the Goteborg study’s authors announced in the British Medical Journal that their data “are not available to outside investigators.”

That the researchers would block access to government- and charity-supported research is bad enough. Even worse, it calls into question why, if the data was strong, the researchers wouldn’t open it up to independent scrutiny.

As it turns out, there are some major concerns about the methodology and results of the studies, first raised last fall in the Journal of the National Cancer Institute by two Australian researchers.

The European Randomized Study reported results from seven countries, while Goteborg was a single-site study in Sweden. In both, men were divided into two groups: One underwent regular PSA tests, while the other was not screened. The results were published in The New England Journal of Medicine and the journal Lancet Oncology, respectively.

As the Australian researchers, Ian E. Haines and George L. Gabor Miklos, noticed, there was something strange about the data sets: A large amount of the data in the European Randomized Study came from a separately reported Finnish study, which showed no significant lifesaving benefits of PSA screening.

They found further red flags in terms of biased patient treatment. Many of the men who developed prostate cancer received excessive amounts of a treatment called hormonal monotherapy, which some research now indicates can actually accelerate cancer. Depending on which groups — screened and not screened — those men were in, the results of the study could be significantly compromised. And yet that information was missing from the published reports. When Drs. Haines and Miklos requested the European data to undertake independent analyses, researchers in both studies were unwilling to release it.

Even more troubling was that the European Randomized Study investigators transferred an astounding 60 percent of the data from the Swedish Goteborg study into their own data pool. Since the Goteborg study was alone among country-specific studies in showing an almost 50 percent reduction in prostate cancer deaths for screening recipients, such an overweighting of the data obviously tipped the balance in favor of lives saved. This is a bright-line ethical breach: Without this biased transfer, the lifesaving claims of PSA screening vanish.

Further bias was highlighted by Otis Brawley, the chief medical and scientific officer of the American Cancer Society, and by Paul Goldberg, the editor of the Cancer Letter. They pointed out that the nonscreened Swedish men who contributed to the two studies were not even informed that they were in a clinical trial, which introduced an unacceptable variable between them and the PSA-screened men, who were informed.
Finally, several senior authors of the European trials, and their American supporters, have potential conflicts of interest that relate to payments from companies involved in marketing PSA tests, or in holding patents in the PSA and prostate cancer diagnostic space — relationships documented by the International Committee of Medical Journal Editors, in the forms that accompany the PSA-study publications and in disclosures found in CA: A Cancer Journal for Clinicians.

As a result, those physicians who have not examined the data in depth are now treating patients on the basis of deeply flawed data. How flawed? That’s the real issue: Because the authors won’t release their data, we don’t know.

It is imperative that, as part of America’s continuing efforts at health care reform, we develop a declaration of principles about the need for data transparency. Our regulatory bodies must insist that clinical trials, and especially taxpayer-funded ones, be open to scrutiny by independent investigators who have no ties to industry. Hoarding data, especially flawed data, is unacceptable when lives are at stake.

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