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# Approaches for a Policy for Science

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Dr. Lauer (1), writing from his current position in the Office of the Director, Division of Cardiovascular Sciences, National Heart, Lung, and Blood Institute, and from his former positions as Director of Cardiac Clinical Research at the Cleveland Clinic Foundation, as well as a contributing editor of the *Journal of the American Medical Association,* explores the nexus of science and policy or policy and science, both of which are and should be closely aligned. He raises many excellent points and issues to be considered, some of which I believe his readers could agree on, whereas other issues, both conceptual and technical, might generate considerable discussion and perhaps even controversy.

## Areas of Agreement

Dr. Lauer concludes with a call to action to work together to "ensure that our patients benefit from the incredible power of the scientific method." Certainly that is a goal that can be shared by all.

He raises the issue of computed tomography coronary angiography (CTCA) to frame his article. CTCA has been quite controversial in terms of its optimal use: the rapid progression from one generation of the technology to the next (e.g., 60- vs. 120-slice scans) and which is the most useful version from a clinical standpoint. There is a paucity of comparative effectiveness studies, and there are no randomized clinical trials in this area.

There are data from outcomes-based randomized trials of diagnostic tests outside the cardiovascular arena (e.g., fecal occult blood test), in which the finding of an abnormal test result leads in some cases to life-saving procedures, such as surgery for asymptomatic malignancies.

Difficulty in enrolling patients in randomized clinical trials is a real, but a multifaceted, problem. The paperwork associated with such trials is complex, clinicians are busy and strapped for resources, funding for research coordinators is often very problematic, institutional review boards sometimes raise questions that are hard to answer, and insurance companies may not pay for some of the ancillary tests and follow-up required by randomized clinical trials.

## Concerns/Disagreement

Against this background of agreement, there are areas of concern/disagreement.

1. From a technical standpoint, in Dr. Lauer's paper (1), the first reference (which sets the tone for subsequent discussion) in this scientific paper is written by a "health industry reporter for *USA Today*." That seems to be a rather inauspicious beginning to a very important article about policy and science, particularly because Dr. Lauer calls for recommendations of care based on scientific study, not based on reports from the *lay press.*

Dr. Lauer questions the scientific database on which the "vast majority of guideline recommendations are based," labeling them as "inferior evidence." It is true that there is a dearth of randomized clinical trials on many important diagnostic and therapeutic approaches used in cardiovascular disease. In such a setting, expert opinion or expert guidance documents are used. In the real world, when there are difficult decisions to be made and challenging cases to be managed, a team-based approach of experts focused on the specific patient at hand has great value. Accordingly, expert consensus guidelines form a very important part of medical care. (An interesting, somewhat parallel liberal-arts comment would be that the writers of the United States Constitution did not have all that much evidence on which to base the Constitution, and yet it has been a very good expert consensus document that has stood the test of time.) Importantly, some areas of clinical care may not be able to be tested in randomized clinical trials. In the recent past, the National Institutes of Health has not been in a position to generously fund such randomized trials, and industry has declined to do so. This issue is of central importance.

It also must be kept in mind that trials have their own biases. Limitations related to selection bias for entry into a trial may negate general conclusions or the ability to extrapolate the results to the broad range of clinical practice seen in day-to-day patient care.

Trials are also affected by the fact that technology changes rapidly, and the results obtained may differ from one generation of the technology to the next. For example, the specific technology used in the recently approved transcatheter aortic valve replacement procedure for high-risk patients with aortic stenosis is based on iterations of the device that will never be seen in the rest of the world because they

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are now obsolete. Accordingly, the results obtained with more recent second- and third-generation devices may make the procedure more effective and safer.

2. The concept of working closely with government agencies should be straightforward, but the reality is somewhat different, as witnessed by the multitude of forms that patients must fill out to fulfill Medicare/Medicaid requirements or the challenges facing people who would like to participate in a randomized clinical trial but are unable to do so because their insurance carriers will not fund ancillary tests.
3. Finally, it is important to remember that some issues can be well addressed by nonrandomized studies or registries. For example, the concept of door-to-balloon time, which has revolutionized the care of patients with acute myocardial infarction, is based on observational experience and expert consensus and not, as Dr. Lauer suggests, based on "inferior evidence."

## Summary

The most important message from Dr. Lauer is that we need to move toward the goal of basing policy on science. In working together, professional societies, clinicians, scientists, and regulatory agencies can accomplish much.

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### REFERENCE

1. Lauer M. A policy for science. J Am Coll Cardiol 2012;59:2154–6.

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