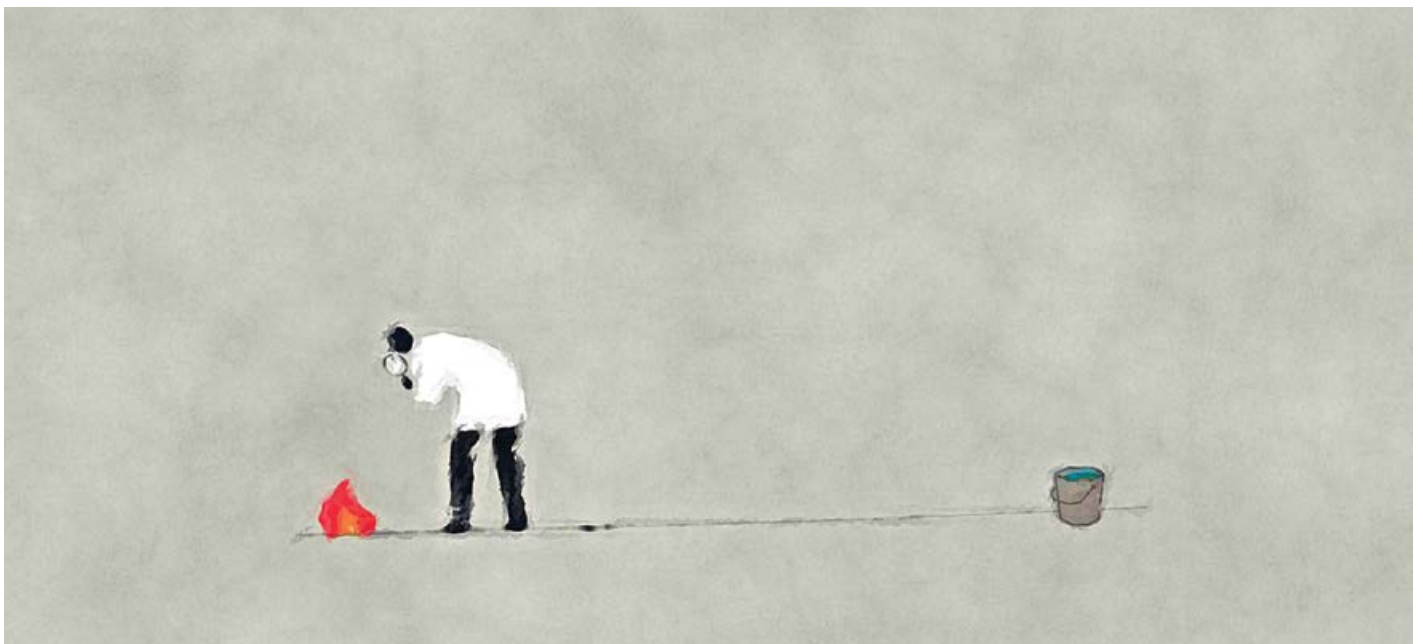




Bringing 'consequentialism' back to epidemiology

In a challenging funding environment,
epidemiologists urge more action

BY ELAINE MEYER



The large and long-enduring Framingham Heart Study is known as one of the success stories of epidemiology. The Washington Post in 2000 named it a top ten medical accomplishment of the 20th century. Data the study has gathered through its regular and detailed physical examinations of over 15,000 participants since 1948 have led to a number of breakthroughs that are credited with dramatically reducing deaths from heart disease.

But in July the Framingham website announced a 40 percent cut to the \$9 million budget contract with the National Institutes of Health's National Heart, Lung and Blood Institute (NHLBI), which supports the study's core operations. The cuts are not only a blow for Framingham but indicative of a more worrying trend, according to some observers.

"[NHLBI] is dramatically reducing its support for the large cohort studies that are ongoing because they are very expensive," says Dr. Lewis Kuller, a cardiovascular epidemiologist at the University of Pittsburgh Graduate School of Public Health. "However they generate a huge amount of valuable data, so you might say on a value basis they are not expensive, and they're certainly not more expensive than the amount of funding that goes into what you might say is basic research."

A field that is devoted to scientifically studying the distribution, cause, and effects of disease and injuries, epidemiologic discovery has motivated public health campaigns and policy changes that have led to longer life spans across the globe, such as anti-smoking regulations, seatbelt laws and speed limits, water treatment, vaccines against infectious diseases, sex education, and folate supplementation in water to prevent birth defects.

Despite those "big wins" of the past, some epidemiologists are concerned that because their field hasn't achieved comparable public health improvements in the last decade, it will have difficulty weathering the current financial climate. "Implicit in pressures [from large funders] is a growing dissatisfaction outside the field of epidemiology with epidemiologic description and correlation and a sense that our current approaches are not leading to 'wins,' to practical solutions to diseases and challenges to health, or to science that is more saliently useful to decision makers with a responsibility to the health of the public," says Dr. Sandro Galea, chair of the department of epidemiology at Columbia University's Mailman School of Public Health.

On top of this, a few critics have argued that the observational cohort studies commonly used in epidemiology are "lead[ing] the public astray," as Drs Paul Sorlie and Gina S. Wei put it in a 2011 article that itself is sympathetic to the use of such studies.

The critics compare observational research of risk factors unfavorably to the methods of randomized controlled trials that are commonly used in drug studies. "While the tools of epidemiology—comparisons of populations with and without a disease—have proved effective over the centuries in establishing that a disease like cholera is caused by contaminated water, as the British physician John Snow demonstrated in the 1850s, it's a much more complicated endeavor when those same tools are employed to elucidate the more subtle causes of chronic disease," writes one of the most vocal critics, science journalist Gary Taubes, in the New York Times in 2007.

While this is a controversial view among epidemiologists, some still believe their field needs to re-assert its relevance. "I think over time, a lot of epidemiology has become data analysis and data dredging and highly sophisticated statistical modeling but without any emphasis on the application of epidemiology on public health and preventive medicine," says Dr. Kuller.

'Consequentialist epidemiology'

In June, Dr. Galea stood before a hotel ballroom filled with his peers to give the annual outgoing president's speech at the Society for Epidemiologic Research (SER) meeting in Boston.

"We are seeing a gross failure in our improving the health of populations," he said. Epidemiology risks being shunted aside if its practitioners do not use it for "consequentialist" purposes. "Academic epidemiology now spends most of its time concerned with identifying the causes and distributions of disease in human population, and far less of its time and imagination asking how we might improve health," Dr. Galea wrote in a follow-up article published in September in the American Journal of Epidemiology.

Reviewing articles in the four leading epidemiology journals, Dr. Galea and his colleagues found that over 85 percent focused on causality or etiology of a disease "with little particular attention to how that etiology may be relevant to intervention." The 14 leading epidemiology textbooks "devote[d] the overwhelming majority of their content to educating the reader about how we may identify causes and distribution of disease."



“Our focus on causal thinking at the expense of pragmatic thinking is not cost free, and runs the risk of marginalizing us as a discipline,” he says, citing as examples journal articles that focus on “illicit drug use and cognitive function in the mid-adult years” and “the relationship between premature birth and age at onset of puberty.” Epidemiology needs “a demanding, rigorous approach that focuses us ruthlessly on our outcomes—rather than our approaches and methods,” he continues.

One example of where epidemiology could be more focused on outcomes is on the issue of gun violence. Although epidemiologists have found evidence that gun availability leads to an increase in homicide and suicide, the field could make a more meaningful contribution if it studied the consequences of different regulatory approaches to gun control.

“This approach would have epidemiology leading the way on both implementation science and on translation of population health science, when, in actuality, we are at best involved in these emerging movements on the margins.”

Dr. Galea is not the first to express

these concerns. In 1967, the president of the American Public Health Association (APHA), Dr. Milton Terris told attendees at the organization’s annual meeting that: “Public health problems, whether new or old, are essentially social in character and can only be solved in terms of social policy.

“The task of public health workers is to convince society to undertake the specific social measures, governmental or other, which are required to solve specific health problems, and to participate in the implementation of these policies,” said Dr. Terris, who was known as an outspoken advocate for a progressive public health policy.

At another APHA annual meeting, in 1983, Dr. William Foege made his own call for a consequential epidemiology. In his talk, he said that epidemiologists should not shy away from political involvement. “[Epidemiology] is a tool to change the world, not merely to study the world,” said Dr. Foege, whose own consequentialist resume included working on the 1970s campaign that eradicated small pox and directing the U.S. Centers for Disease Control and Prevention (CDC).

Eleven years later, as president of SER,



Dr. John Snow’s map of cholera cases in London. The map has been colorized to enhance the mapping of deaths depicted by bars running perpendicular to streets. After mapping the area’s 13 public wells, Dr. Snow noted the spatial clustering of cases around one particular water pump on the southwest corner of the intersection of Broad (now Broadwick) Street and Cambridge (now Lexington) Street.

“The bulk of our research efforts identified risk factors but rarely affected public health actions,” says Dr. Cates.

Dr. Willard Cates reinvigorated the call for a consequential epidemiology, telling his peers to “seize the day of impending healthcare reform.”

He saw in the field the same problems as Dr. Galea describes today. “The bulk of our research efforts identified risk factors but rarely affected public health actions. We were told that epidemiologists tended to ‘torture’ our data until some—frequently obscured—associations were found,” recalls Dr. Cates, who is currently president of Family Health International and an adjunct professor at University of North Carolina-Chapel Hill, Emory University, and University of Michigan School of Public Health, in a response to Dr. Galea’s article.

Those who talk about a consequential epidemiology don’t see it as a departure but rather as a return to the field’s roots. These roots are embodied by the story of Dr. John Snow. An anesthesiologist living in nineteenth century London, Dr. Snow began monitoring cases of a deadly cholera outbreak in 1854. He found that nearly everyone who had died lived near a water pump on Broad Street in the city’s Soho neighborhood.

Based on the deaths and a water sample from the Broad Street source, he became convinced that cholera was transmitted not through the atmosphere—the popular theory of the time—but through contaminated water. He took this theory to the local government parish, prevailing on authorities to remove the Broad Street pump handle so it could no longer be used as a water source. Although Dr. Snow did not have complete information to prove his theory, cholera stopped spreading soon after. (It would take many more years for health authorities to embrace water and sewage treatment).

Dr. Snow’s decision to act for the public good based on the imperfect information he had is what epidemiology of the best kind looks like, say consequentialists. “It is unlikely that John Snow would be revered in public health if he had merely studied cholera,” says senior vice president of the Robert Wood Johnson Foundation Dr. James S. Marks in a 2009 article in the journal *Preventing Chronic Disease*. “Our heroes have been tied to action.”

Worries in a time of austerity

Epidemiologists admit that whether or not the field can adapt, the funding climate is one of the worst in recent memory.

The 2013 budget sequester forced the CDC to slash 5 percent of its \$285 billion budget for 2013, which will reduce global efforts to eliminate malaria, polio, and other infectious diseases and cuts to prevention programs for HIV, cancer, heart attack, and stroke.

The sequester also cut 5 percent or about \$1.6 billion of the \$30 billion budget for the NIH, which is now funding only 15 percent of grant applications, a decline from about 30 percent from nearly a decade go. Going forward, the NIH’s

budget is slated to shrink by 8.2 percent annually.

“I’m very worried about the effect of cuts. I think it will change the nature of epidemiologic research. Epidemiology has been able to build itself up as its own discipline because we have been able to get large grants to fund our work,” says Dr. Galea.

Dr. Michael Lauer, director of the division of cardiovascular science at NHLBI, is more optimistic. “Look at [the budget cuts] as an opportunity to do things in ways that are bigger and better and more effective than what we’ve ever done before,” he says. “When resources become scarce, people become resourceful. There are a lot of exciting developments that are happening that should make it possible for epidemiology to not only stay relevant but to actually grow to much higher levels than we’ve ever seen.”

In fact, some epidemiologists have been concerned about the future of the NHLBI, which funds many notable epidemiology cohort studies. NHLBI last year suspended Framingham’s regular exams, which its principal investigator has called “the lifeblood of the study,” and future exams in the Multi-Ethnic Study of Atherosclerosis cohort (MESA), a medical research study involving more than 6,800 men and women from six communities in the United States. Patient health information will, however, be collected by phone or mail.

“We cut exams to allow us time to engage in longer term strategic planning in the setting of ever decreasing budgets,” says Dr. Lauer, adding that the NHLBI’s buying power is 30 percent lower than it was ten years ago because of flat or decreasing budgets and inflation.

“As part of being careful stewards of public monies, we see a need to carefully review all long-term, higher-cost projects,” he adds, noting this is not the first time



PHOTO: HYPERSAPINES / FLOKRI

Although epidemiologists have found evidence that gun availability leads to an increase in homicide and suicide, the field could make a more meaningful contribution if it studied the consequences of different regulatory approaches to gun control.

in its history that NHLBI has suspended exams. “In this era of big data and small budgets, we need to think about how we realign our strategies in order to maximize what we get out of the dollars we receive.”

Yet some experts believe that the data from contemporary cohort studies still provide the most thorough and up-to-date picture of the changing risk factors and prevalence of chronic diseases in the U.S. Cohorts have shifted focus to study not just cardiovascular events—which have been on the decline for several decades—but contemporary problems like rising rates of diabetes, obesity, and lung disease using state-of-the-art technologies, says Dr. R. Graham Barr, an associate professor of epidemiology and medicine at Columbia University’s College of Physicians and Surgeons who studies respiratory illness using MESA data.

“The ability to use novel imaging

approaches in these cohorts allows us to start to re-define the disease for clinical purposes,” he adds. “MESA, for example, has the longest longitudinal follow-up of measures of emphysema on computed tomography of any study.”

The infrastructure of the cohorts has also allowed rapid responses to new public health concerns, such as acquiring data on e-cigarette use, says Dr. Barr.

Even before the cuts, some observers believed that epidemiology was already losing influence at the NIH to biological sciences like genetic and molecular biology and neurology.

“I don’t think it gets the same kind of respect as some of the most basic sciences, and there are some reasons for that. It seems to many a little bit more subjective. Rarely are there randomized trials,” says Dr. Marks.

“Because epidemiology is ultimately

population level findings, it has been devalued in the eyes of NIH, and it has devalued the extent to which epidemiologic findings are useful, particularly as NIH has become more interested in translation of its findings to clinical cures,” says Dr. Galea.

Epidemiologists point out that such clinical cures can be expensive and can take years or decades to become available to the general public, while preventive approaches that often come about because of epidemiologic research—such as awareness campaigns, regulations, and improving access to health care—can be implemented sooner. “Epidemiology is a crucial part of the way that case is made for the public and policy makers. We can’t afford to treat ourselves out of our health crisis. We can’t continue to pay for more and more treatment for more and more disease,” says Dr. Marks.

“What’s happened over the last couple

of decades has been the growing awareness of the implications of social factors for health, whether that's education, poverty, transportation, parks, etc.—the social environment. Epidemiology or its techniques are one of the few ways that those factors can be assessed."

Should epidemiologists be more like economists?

Despite this sense of urgency, epidemiologists as a culture are hesitant to over-state the meaning of their data and rarely use their research to take strong policy positions. They commonly offer the disclaimer that a study they've done does not show that an exposure caused a disease, simply that there is a link between the two.

"The challenge for us as epidemiologists is we can get committed to an issue and sometimes over-interpret or over-value the science that we've done and push the policy decision that is premature," says Dr. Marks. "On the other hand, science that is immature or incomplete may be better than no knowledge. If a body of work, even if relatively modest, points in a single direction it probably indicates a higher likelihood that that direction is causal than another—not a certainty, but a higher likelihood. When you're in a policy discourse sometimes you have to speak with greater confidence than your data warrant in order to be heard," he adds.

He acknowledges that "the most important issues" are "among those that are the hardest to measure: connectedness, support for each other. And many things that are outside of medical care: quality of a diet, the access to fresh food, safe places to play."

According to Dr. Galea, by not getting involved in policy discourses, epidemiologists are ceding an important policy role to another discipline: economics.


"Epidemiology is very conservative about its causal thinking. In some respects that's a good thing and sort of refreshing. But what it has done is it has allowed the insertion of economics into the health arena. Economists have positioned themselves as people who ask big questions that are of societal interest. They have the self-confidence as a discipline to say that their findings shed light," he says.

He points to the theory that attributes lowering crime rates in the U.S. to the

legalization of abortion, which was put forward by two economists. "The methods used in that kind of assertion are the same type as used in epidemiology. But epidemiology would never have the boldness to make that assertion," he says. "[Economics] gets bashed around for its shortcomings. That's where the saying 'dismal science' comes from. It is a dismal science but at the same time, it is a science that has an impact on day to day public discourse."

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