

cohort studies, were well under way in Northern Europe. Ethical regulations have become stricter throughout the world—fortunately so!—but this has not significantly hindered large-scale studies. Also fortunately, legal action does not seem to constitute a major threat to research outside the USA.

In particular, epidemiological studies have markedly increased in Latin America and Asia, firstly with important contributions of researchers from North America and Europe, but in the last couple of decades with a steadily growing participation of local scientists. For example, our last national epidemiological conference in Brazil attracted over 4000 participants. Many studies on infectious and nutritional epidemiology are under way in Africa, mainly on AIDS and malaria; although these investigations are still mostly led by expatriates, African scientists are building up their own research centres and networks.

I am not sufficiently familiar with the situation in the USA to gauge whether Rothman's article had a major impact. It received a modest 36 citations in the Web of Science since its publication, and the only letter that appeared in the following issues of the *New England Journal of Medicine* was from Alvan Feinstein, who challenged the contribution of William Farr to epidemiology because of his backing of the miasma theory.¹⁰ Hardly a topic of current interest!

Futurology is a high-risk occupation. Again with the benefit of hindsight, looking at Rothman's paper after a quarter century shows that ethical guidelines helped improve epidemiology, and that our discipline evolved much beyond the

study of proximate exposures and of hospital-based studies. Long live epidemiology!

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Commentary: The rise and rise of corporate epidemiology and the narrowing of epidemiology's vision

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Reports of the impending death of epidemiology¹ have proven premature. The year 2000 dawned, and our computer systems, and our system of epidemiological research, both continued to function. When judged by the numbers of epidemiology journals, publications and academic positions, the field is clearly thriving.

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Nevertheless, to have survived is not necessarily enough, and more is not necessarily better. The Rolling Stones have also survived since the 1960s, and sell more albums and concert tickets than ever, even though their ages passed their IQs in the 1990s and Keith Richards was lost to follow-up back in about 1975. When the current state of epidemiology is assessed in terms of quality rather than quantity, it is arguable that Ken Rothman's pessimistic vision of decline¹ has partly been realized. The 'golden age' of risk factor epidemiology seems to have passed. The major discoveries (e.g. tobacco smoking and

lung cancer, asbestos and lung cancer, diet and cardiovascular disease) occurred in 1950–80, and those of us who were born too late have been left with studying the crumbs (or, worse still, studying EMFs).² Moreover, the legacy of risk factor epidemiology is not, as Rothman predicted, ‘the demise of major 20th-century epidemics attributable to tobacco, dietary fats and some carcinogens in the workplace’. In fact, dietary fat is with us in even greater quantities than before,³ and global tobacco⁴ and asbestos production⁵ have hardly changed since 1980—we have merely succeeded in moving their consumption to developing countries.

Rothman identified two main ‘external’ culprits for the predicted decline of epidemiology as a scientific field: (i) problems with obtaining ethical approval; and (ii) interference by government bureaucracy in epidemiologic research. The latter phenomenon is clearly country specific and has both positive and negative features depending on the local context. However, the problems with obtaining ethical approval for epidemiologic research have been a global phenomenon, at least in industrialized countries, and have seriously restricted the field—and seriously jeopardized the public’s health. But these ‘external’ culprits are easy targets, and cannot be blamed for all of the problems currently facing epidemiology. In this commentary, I will focus on two ‘internal’ culprits, in both of which Rothman has played a key role as a participant rather than as an observer: (i) the narrowing of the scope of epidemiology; and (ii) the increasing role of corporate influences.

The scope and vision of epidemiology

The world that epidemiologists study is rapidly changing. As noted above, many of the major hazards discovered by epidemiologists, such as tobacco and asbestos, have not been eliminated and, for the most part, have merely moved to the developing world. We are seeing the effects of economic globalization,⁶ structural adjustment,⁵ and climate change,⁷ and the last few decades have seen the occurrence of the ‘informational revolution’ which is having effects as great as the previous agricultural and industrial revolutions. The benefits have been mixed, particularly in developing countries,⁶ while the countries of Eastern Europe have experienced the largest sudden drop in life expectancy that has been observed in peacetime in recorded history.⁸

These trends are disturbing, but they should at least keep epidemiologists employed for many decades to come. So why do some modern epidemiologists apparently think that there is nothing interesting or important left to study in population terms and that epidemiologists should essentially become data collectors for molecular biologists? (I should stress that I am not ascribing these views directly to Ken Rothman, but rather I am suggesting that they are typical of ‘modern epidemiologists’ in general). The main reason is that the scope, and vision, of the field have markedly narrowed in recent decades. This is not entirely the fault of epidemiologists, and factors such as the human genome project and the recent strong emphasis on genetic research have also played a (both positive and negative) role.⁹ However, the damage has also in part been self-inflicted. As noted by Rothman,¹ the period 1950–80 saw a remarkable

growth in epidemiology as a discipline, with a ‘rapid succession of theoretical advances in study design and analysis to overcome the inherent handicaps of non-experimental research.’ Rothman himself played a leading role in these developments, including the publication of an elegant and brilliant textbook, which has been strongly influential.¹⁰ The problem is that these theoretical developments, positive as they were, also carried a great deal of theoretical and ideological baggage.¹¹ Traditional approaches to epidemiology started from the standpoint of populations, which involved messy considerations such as context, culture, history and socioeconomic status, all of which strongly influenced health.¹² ‘Modern epidemiology’ strips away all of that ‘noise’ and follows a randomized clinical trial paradigm in which risk factors and disease outcomes are considered in isolation, and the aim of an epidemiologic study is to obtain the same findings that would have been obtained with a randomized controlled trial.

As a result, epidemiologists have been taught that some study designs, particularly cohort and case-control studies, are better than others. No respectable epidemiologist would do an ecologic study, even though, despite their obvious shortcomings, they continue to play a major role in new epidemiologic discoveries,¹³ e.g. in the ‘fetal programming’ field¹⁴ and in asthma epidemiology.¹⁵ Epidemiology has become a set of methods, and epidemiologists attempt to answer the types of questions that can be answered with these methods. This works fine for issues like smoking and lung cancer, but not so well for other risk factors such as beta carotene and cardiovascular disease, hormone replacement therapy, vitamin E and vitamin C intake in relation to cardiovascular disease, or fibre intake in relation to colon cancer.⁹ Other issues, like climate change or poverty, do not fit the paradigm at all (you need at least two planets!), and are therefore ‘someone else’s problem.’

It is as if the house is burning down, but we are focussing on developing better theories on how to change the light bulb—while complaining that the ethics committee is putting obstacles in our way and the government is trying to impose guidelines as to how we should do it. Perhaps the nadir of this purist approach came when those who were trying to restore the population perspective to epidemiology, and to broaden its vision, were condemned as social activists by Rothman and colleagues in an influential paper in the *Lancet*.¹⁶ In fact, the issue is not whether epidemiologists should be activists about the population determinants of disease, such as poverty, but whether they should study them.¹² To let the methods determine the questions that are asked, and to ignore other important public health problems because they do not fit the paradigm, is not only bad public health practice but is also bad science.

Corporate epidemiology

This brings me to the second ‘internal culprit’ in the recent ‘decline’ in epidemiology: the increasing role of corporate influences. As Sander Greenland has noted with regard to the same issue,¹⁷ in a paper, published by Rothman in his journal *Epidemiology*, this involves ‘some unpleasant extra-scientific

issues...that some of our colleagues may prefer to avoid'. Greenland was referring to the role of corporate funding in the criticisms of epidemiology raised by the late Alvan Feinstein. Before his death in 2001, Feinstein disputed most of the major epidemiological findings in recent decades, including the established causal associations between smoking and lung cancer, between oral contraceptives and thrombo-embolism, between diethylstilbestrol and vaginal cancer, between aspirin and Reye's syndrome, between tampon use and toxic shock syndrome, and between estrogens and endometrial cancer.¹⁸ In each instance, these controversies were eventually resolved with the vindication of the original studies, but the debates often lasted for many years, and the necessary safety warnings and regulatory procedures were therefore delayed.¹⁷

However, although Feinstein has generally been cast as an 'outlier' by other epidemiologists,¹⁸ his activities on behalf of industry were merely part of a continuum in which he was one of the more extreme cases. Many prominent epidemiologists regularly accept funding from industry either to conduct research, or more commonly to criticize research conducted by their colleagues. In some cases, this has gone so far as assisting industry attempts to block the publication of important findings.¹⁹ In addition to the examples cited above, others include 'the episodes of industry cover-up or denial of deadly hazards, as in the Johns-Manville asbestos episode,²⁰ the attempts to suppress the occupational hazards of brown lung disease,²¹ the protracted defence and promotion of cigarettes by the tobacco industry',¹⁷ and many other examples from the fields of pharmacoepidemiology and occupational and environmental epidemiology.²²⁻²⁹ Sadly, in recent years, the threats to the integrity of science have come from government as much as from industry.³⁰ Rothman himself hints at this when he predicts that by the year 2000 'epidemiologists were more often representing vested interests on one side or another of the ever-controversial issues', and he is certainly correct that there are vested interests (and extremists) on both sides of many of these controversial issues. However, in most cases only one side has the funding to hire 'independent experts' to criticize new findings on the safety of a chemical or drug.

It should be stressed that criticism plays an important role in science, and even very biased critics may make important points. However, as Paul Stolley³¹ writes:

'A...distressing development has been the attitude of some self-proclaimed pharmacoepidemiologists that their job is to attack competent studies as consultants to drug companies, who pay them handsomely and even award grants to their research unit as a form of reward. Often the sponsorship of these "disinterested reviews" is not clearly stated. The most pernicious of these articles are characterized by an unwillingness to focus on the totality of the evidence and a concentration on real and imagined flaws that could not possibly account for strong associations'.

Many leading epidemiologists will undoubtedly object to me raising these issues, and will respond that their opinions are not influenced by accepting corporate funding. Rather, they

study the evidence objectively, and then make their opinions known for the benefit of society, and if they receive some funding along the way, then that is entirely appropriate. This is naïve at best. In fact, although deliberate corruption is relatively rare, a company which intends to attack new research showing that a particular chemical or drug is hazardous, merely has to seek out academics who (usually because of sincerely held beliefs) have been very critical of similar studies in the past. Thus, the shaping of the 'case for the defence' usually involves 'selection' rather than 'coercion' of experts. The selection by the company of a few scientists who are hypercritical of others' work can result in massive pressure on public health decision makers. This pressure is particularly effective because it seems to come from independent scientists—it would not be taken so seriously if it came directly from the company. In this sense, hired consultants have the privilege of acting as 'lawyers for the defence' while maintaining the image of being an 'independent jury'.

A second line of defence of their activities that is often offered by 'modern epidemiologists' involves a relatively crude (and convenient!) interpretation of the (already crude) Popperian philosophy of science.³² It is argued that 'science is about criticism' and that by being critical of colleagues' work modern epidemiologists are simply doing their duty as scientists—who pays them for it is irrelevant. In particular, an over-emphasis on requiring the declaration of conflicts of interest is 'the new McCarthyism in science',³³ and the requirement that at least one investigator who is independent of any commercial funder should take responsibility for the integrity of the data and the accuracy of the data analysis is 'unfair—and absurd'.³⁴ In fact, there is plenty of evidence that the source of funding strongly influences the conclusions that are reached, e.g. in the cases of tobacco³⁵ and calcium-channel antagonists.³⁶

Thus, for every epidemiologist trying to change a light bulb, there are now several critics hired by industry to argue that they are doing it the wrong way, or that it is not broken and does not need changing at all, or that they have changed it the wrong way and should do it again. There may even be an industry-funded researcher studying the same light bulb and obtaining different findings, with no requirement that their source of funding is declared, or that anyone independent of the industry has ultimate responsibility for the data. Battling such industry-funded critics in order to get your work published, or to save it from being discredited, often takes even more time, and is more frustrating, than battling with ethics committees to be allowed to do the work in the first place. Both activities are major threats to the integrity of the field, and its survival as a scientific discipline.

Conclusions

So what do the next twenty years hold for epidemiology? It would be foolhardy to make a prediction, and there are multiple trends and influences in multiple directions. However, at least there is some light at the end of the tunnel with regards to both the sets of issues that I have discussed.

First, with respect to the scope of epidemiology, things are changing, and some trailblazers such as Tony

McMichael are doing their best to drag epidemiology into the 21st century,^{7,37–41} by studying global issues such as climate change, while incorporating and building on the theoretical developments of ‘risk factor epidemiology’.^{42–44} This will, or at least should, see the survival of epidemiology, even if it involves bad news for humanity. As George Davey Smith has written:

‘Epidemiology will only progress if it combines a detailed understanding of the ways through which the historical, economic and political constitution of how the world is influences the health of populations—and thus, the individuals within these populations—with the appropriate development of methodology and concepts to deal with this complexity.’¹⁴

Unfortunately, as Rothman himself notes,¹ quoting Max Planck,⁴⁵ such new knowledge is likely to only triumph ‘because its opponents eventually die, and a new generation grows up that is familiar with it’. In some instances, epidemiology will become more complicated⁴⁶—a problem perhaps reflected in the quantum leap in complexity between the first¹⁰ and second⁴⁷ editions of Rothman’s textbook. However, it is a fundamental scientific principle that things should be made as simple as possible, but not simpler.⁴⁸ If complexity is the price of being relevant and addressing the major public health problems, then so be it.

Second, with regards to the corporate influences on epidemiology, there is no simple solution. However, for the last two decades there has been substantial discussion on ethics in epidemiology,^{49–52} partly in response to the unethical conduct of many industry-funded consultants. A number of websites (e.g. http://www.ucsusa.org/scientific_integrity/ and <http://www.cspinet.org/integrity/>) are now devoted to fostering integrity in science. Recently there have been renewed calls for scientists to ‘engage in processes to assert positive principles of ... how science should work, and how it should be applied to public policy decisions’ rather than simply having a list of what not to do.³⁰ This will require ‘strong pressure from within the scientific community for codes of ethics conduct and financial conflict of interest’³⁰ with the goal, not of restricting what people can do, but to ensure complete transparency ‘through full declaration of potential sources of conflicts of interest’.¹⁴ Ultimately, perhaps what is needed is to create some sort of licensure in which epidemiologists would ‘sign up’ to not take funding from any vested interests (corporate or otherwise).

Finally, I would like to commend the *International Journal of Epidemiology* for assembling these commentaries (albeit seven years after the millennium!) on what has been an important and influential paper.¹ Although predictions on the future of epidemiology (or any other scientific discipline) are invariably wrong, and hindsight is also invariably biased by what the author wants to happen next, it is nevertheless useful to take stock at regular intervals of ‘who are we, where have we come from, and what has happened to our luggage?’ I look forward to the next round self-reflection and philosophizing, presumably in the year 2020, at which time I will undoubtedly have the opportunity to see the Rolling Stones perform once again.

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Commentary: Epidemiology needs the patients to survive

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According to Pubmed, the pessimistic and rather emotional paper of Ken Rothman on the presumed rise and fall of epidemiology in 1980¹ was his 59th after being in the 'business'

for almost 10 years. He was undoubtedly speaking on behalf of many of his colleagues at the time in expressing the threatened demise of his profession. By 2007, having become an influential teacher, he has been involved in 209 articles on a wide range of subjects, often in the domain of congenital defects, early life exposures, pharmaco-epidemiology and disease aetiology. In 1981, he was still optimistic enough to found the New

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