

A scientific discipline that developed slowly and flourished briefly for several decades is now nearly gone, leaving behind some knowledge of disease prevention, a few controversial alarms, and a collection of techniques for assessing the health consequences of people's actions. Among the legacies is the demise of major 20th-century epidemics attributable to tobacco, dietary fats and some carcinogens in the workplace and environment.

For many, however, epidemiology was an unpleasant science, providing frequent reminders that we are born into a dangerous world where no action is without some risk. Most of us have been persuaded to discard the belief that our modern world is a safe harbour, but now we shall have to muddle along with little specific knowledge of the risks we face. It is a small comfort, at least, that the methods devised by epidemiologists during the latter part of the 20th century will endure to serve some future generation with sufficient curiosity to apply them.

## References

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- <sup>5</sup> Smith AZ. *Memoirs of an Epidemiologist*. New York: Augur Press, 2002.
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# Commentary: Epidemiology still ascendant

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Though published in 1981, the footnote on the first page of 'The Rise and Fall of Epidemiology'<sup>1</sup> indicates that it was a preprint of a talk 'to be presented December 10, 2004, at the annual meeting of the John Graunt Literary Society, Harvard School of Public Health, Boston.' Back in the 1970s, the facetiously named John Graunt Literary Society, or JGLS, met each Friday in the late afternoon at the Harvard epidemiology department to celebrate Graunt's legacy with brewed beverages. Although the December date 23 years in the future at the time of publication was in fact a Friday, the 'preprint' implied that the JGLS was destined to evolve from a weekly beerfest into a yearly gathering of sober, serious speeches. In an essay that many readers took to be a cynical rant laden with gloomy predictions, this forecast for the JGLS was the gloomiest of all.

In fact the essay was not intended to predict the future of epidemiology, which I have always held to be bright. It was meant to be a warning about the growth of research bureaucracy and its effect on epidemiologic research. By 1980 administrative hurdles for epidemiologic research were growing at a worrisome pace. The essay mentions the travails of 'Dr A. Z. Smith,' who spent a full year trying to get

permissions from 66 Boston-area hospitals to conduct a single study. The pseudonymous Dr Smith was actually my colleague Alan S. Morrison, who did spend that frustrating year getting permissions for a population-based case-control study of saccharin consumption and bladder cancer.<sup>2</sup> The mounting burden was more than just administrative. Institutional Review Boards began telling epidemiologists that the specific objectives of their studies must be spelled out to participants in excruciating detail, making it impossible to avert recall bias in some interview-based studies. The government also introduced new roadblocks. At the time of writing, I was principal investigator for a peer-reviewed government funded contract to study hormonal exposure and birth defects. After approval, I waited 9 months while a clerk in the Office of Management and Budget (OMB) in Washington, who had no training or interest in epidemiology, made time in his schedule to review my questionnaire. Under a new regulation at that time, all approved government-sponsored research contracts had to have their questionnaires approved by the OMB. Approval came only after lengthy delay and in my case was conditional on numerous senseless changes that compromised the value of the information. All this transpired without the benefit of any dialogue.

From today's perspective, the intrusion of review boards and government agencies into the research process may seem routine, and the complaints may seem to betray a naive

innocence. At that time, it was unclear how high the barriers to research would rise. Even so, no one seriously questioned the need to impose ethical review. The research community had been shocked by a series of revelations that made it clear to everyone concerned that a sweeping reform in ethical oversight was warranted. The Tuskegee syphilis study had come to light in 1972, after 40 years of research conducted with a ghastly indifference to ethics.<sup>3</sup> Other studies also had surfaced that severely embarrassed the biomedical research community—studies that involved injecting hepatitis virus into mentally handicapped children,<sup>4</sup> injecting cancer cells into demented elderly patients,<sup>5</sup> and using prisoners for risky research.<sup>6</sup> These studies, particularly Tuskegee, motivated the 1979 Belmont report<sup>7</sup> and the formal establishment of Institutional Review Boards. By 1981 it was clear that ethical and administrative review would be a permanent part of the research landscape. These processes were introduced mainly as a response to callously conducted human experimental research. The concern was that, in an attempt to curtail abuse in human experimentation, the pendulum would swing too far in the other direction. Would non-experimental epidemiologic studies, which were often viewed by lawmakers and many clinicians as peripheral to laboratory or clinical research, begin to face insuperable administrative barriers? Although non-experimental research did not prompt the same ethical unease as human experimentation, neither was it free of ethical concerns, which included deception, intrusion and breaches of confidentiality. Most researchers, however, believed that these issues were more readily addressable and less serious than the experimental maltreatments that made the headlines.

I also worried about some other developments, including the certification of epidemiologists, which was tried briefly by the American College of Epidemiology, but later abandoned, and the growing influence of tort cases as a driving force in epidemiologic research. The dismal scenarios in the essay were extrapolations of developments already occurring in 1981. Sure, concerns were exaggerated to get epidemiologists thinking about the direction that the discipline was headed. On the other hand, it was no exaggeration to imply that new obstacles would confront epidemiologists and demand attention. In the US, the Health Insurance Portability and Accountability Act (HIPAA) arrived in the 1990s. The American College of Epidemiology, portrayed in the essay as becoming our professional union, became instrumental in getting research exemptions written into that law. In the mid-nineties, I was forced to shut down a study of cellular telephones and brain cancer because a tort lawyer fishing for plaintiffs

filed a class action suit without any substance. Again the American College of Epidemiology was helpful in opposing this grim development, though in the end it was impossible to continue the study. In the UK, IRB requirements had grown so onerous by 2000 that researchers conducting a multi-centre study had to submit 60 000 sheets of paper to get IRB approval.<sup>8</sup>

Despite these and other obstacles, epidemiology today appears to be thriving. Graduates from epidemiology training programs, always increasing in number, seem to have little problem finding productive jobs. Epidemiology research, even when controversial, has gained respect in many quarters. Today our challenges seem more centred on methodology or biology, as we focus on coping with intractable biases or explaining conflicting results. Bureaucratic elements still hound us, but they do not seem to be incapacitating, and they have been offset to some extent by new study designs, new analytic methods and data sources that were not available in 1981. These resilient developments, coupled with an unending flow of new research problems to address, make this a time of great opportunity in epidemiology.

## References

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