



# Can health equity survive epidemiology? Standards of proof and social determinants of health

Ted Schrecker \*

School of Medicine, Pharmacy and Health, Durham University, UK  
Department of Epidemiology and Community Medicine, University of Ottawa, Canada

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## ABSTRACT

**Objective.** This article examines how epidemiological evidence is and should be used in the context of increasing concern for health equity and for social determinants of health.

**Method.** A research literature on use of scientific evidence of “environmental risks” is outlined, and key issues compared with those that arise with respect to social determinants of health.

**Results.** The issue sets are very similar. Both involve the choice of a standard of proof, and the corollary need to make value judgments about how to address uncertainty in the context of “the inevitability of being wrong,” at least some of the time, and to consider evidence from multiple kinds of research design. The nature of such value judgments and the need for methodological pluralism are incompletely understood.

**Conclusion.** Responsible policy analysis and interpretation of scientific evidence require explicit consideration of the ethical issues involved in choosing a standard of proof. Because of the stakes involved, such choices often become contested political terrain. Comparative research on how those choices are made will be valuable.

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## Prologue

Most readers of a certain age will be familiar with the murder of Nicole Brown Simpson and Ronald Goldman, and the events that followed. Ms Simpson's ex-husband, former professional athlete O.J. Simpson, was acquitted of the murders in a controversial trial, but later found liable for civil damages in a lawsuit brought by the family of the victims. Although superficially unrelated to epidemiology, this case serves to illustrate the applicability of the legal concept of a standard of proof to the use of epidemiology in public policy. In common law countries conviction in a criminal trial requires the prosecution to meet a higher standard of proof, proof beyond a reasonable doubt, than in a civil proceeding where a claim for damages can be sustained on a preponderance of the evidence or on the balance of probabilities. The difference reflects an underlying principle: it is ethically more objectionable to reach a false positive conclusion (i.e. to convict an innocent person) in a criminal trial than to award damages against a non-blameworthy defendant in a civil action, because of the presumption that the consequences of the former error are more onerous for the individual affected. In practice, this may or may not be the case, and holding prosecutors to a higher standard of proof in criminal

proceedings requires that defendants be represented by competent counsel, but these *caveats* do not detract from the analytical point.

## Science and values in environmental policy

The analogy with courtroom standards of proof was used to powerful effect in a 1978 article by economist Talbot Page about “environmental risks” like toxic chemicals, which share such characteristics as incomplete knowledge of the mechanism of action, long latency periods between exposure and illness, and irreversibility of effect. He argued that, like criminal proceedings (at least in their idealized form), many forms of scientific inquiry that are relevant to regulating such risks are designed around minimizing Type I errors — false positives or incorrect rejections of the null hypothesis. This organizing principle is exemplified by the 95% threshold ( $p \leq 0.05$ ) below which a finding is routinely considered not to be statistically significant. Page further argued that minimizing Type I errors may be an inappropriate principle when transferred unreflectively to public policy toward environmental risks (see also [Lemons et al., 1997](#)). The possibility of widespread or irreversible damage to public health means that consideration must also be given to the consequences of a Type II error or false negative. “In its extreme,” wrote Page, “the approach of limiting false positives requires positive evidence of ‘dead bodies’ before acting” ([Page, 1978: 237](#)). This is not rhetoric, but rather a precise and literal characterization of how US industries, in particular, resisted regulatory initiatives in the years before and shortly after Page's article appeared ([Jasanoff, 1982; Robinson and Paxman, 1991](#)). More recently, resistance in the US and elsewhere has

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\* F117, Wolfson Building, Queen's Campus, Durham University, University Boulevard, Thornaby, Stockton-on-Tees TS17 6BH UK.

E-mail address: [theodore.schrecker@durham.ac.uk](mailto:theodore.schrecker@durham.ac.uk).

shifted to an emphasis on scientific or science-based regulation — a rhetoric that ignores the central points made by Page, and in this article.

Deferring action pending the availability of more evidence is, in itself, a choice to value some kinds of consequences more highly than others — a point that was made shortly after Page's article appeared by a former senior US official, who noted “the inevitability of being wrong,” at least some of the time, when science is used as the basis for regulation (Jellinek, 1981). The following year Beverley Paigen, a cancer researcher who became involved in a controversy over whether to relocate households living on top of a disused industrial waste dump (the Love Canal), described:

... a conversation [she] had with a Health Department epidemiologist concerning the data on adverse pregnancy outcomes at Love Canal. We both agreed that we should take the conservative approach only to find that in every case we disagreed over what the conservative approach was. To him ‘conservative’ meant that we must be very cautious about concluding that Love Canal was an *unsafe* place to live. The evidence had to be compelling because substantial financial resources were needed to correct the problem. To me ‘conservative’ meant that we must be very cautious about concluding that Love canal was a *safe* place to live. The evidence had to be compelling because the public health consequences of an error were considerable. And so we disagreed on specific detail after specific detail.

This is not a scientific issue, nor can it be resolved by scientific methods. The issue is ethical, for it is a value judgment to decide whether to make errors on the side of protecting human health or on the side of conserving state resources (Paigen, 1982: 32).

Jellinek's point that “postponing action ... is a decision” in the same way as taking regulatory action was reiterated by Grandjean (2004); the larger issue of the need to set standards of proof based on explicit normative consideration of the potential consequences of Type I and Type II errors in policy was comprehensively revisited in the academic literature by Cranor (1993: 3–48) and subsequently by Shrader-Frechette (1996: 20–23), Lemons et al. (1997) and Parascandola (2010), among others.

Contrasting orientations characterize recent approaches to regulating environmental and consumer product risks in the United States and the European Union. In the latter, the precautionary principle is written into a variety of legal instruments, often resulting in stricter regulatory standards (i.e., less emphasis on avoiding Type I errors) than in the United States (Vogel, 2012). This has not always been the case, and critically, neither approach is more scientific or ‘science-based’, and neither is ‘correct’. Rather, the approaches reflect application of different sets of values to dealing with scientific uncertainty. This point remains inadequately understood, as shown for example by Löfstedt's (2013) effort to contrast “evidence based” regulation (based on quantitative risk assessment) with what he sees as the “unscientific” application of the precautionary principle.

### Social determinants of health: looking “upstream”

Such lack of understanding arguably continues to compromise the quality of public policy toward environmental risks such as hormonally active agents or “endocrine disruptors” (Kortenkamp et al., 2012; van Vliet and Jensen, 2012). Strong parallels exist with issues that arise in the context of heightened concern for health equity — “the absence of systematic disparities in health (or in the major social determinants of health) between social groups who have different levels of underlying social advantage/disadvantage — that is, different positions in a social hierarchy” (Braveman and Gruskin, 2003: 254) — and the emerging body of evidence on social determinants of health (Commission on Social Determinants of Health, 2008). The pathways that lead from conditions of life and work to health disparities, by way of multiple

exposures and vulnerabilities (Diderichsen et al., 2001), are if anything more complex and less predictable than those involved with the operation of environmental risks. As in the case of environmental risks, both researchers and those seeking to use their findings for policy and advocacy must therefore make or understand multiple “methodological value judgments” (Shrader-Frechette and McCoy, 1993: 84–101).

These begin with the choice of outcomes for study. Over a time frame that permits effective policy response or intervention design, changes in mortality rates and causes of death may be too crude an indicator of the consequences of social and economic inequalities except in the case of catastrophic disruptions like the collapse of the former Soviet economy and the parallel collapse of social supports and health systems (Frank and Haw, 2011). In less extreme situations, changes in mortality data or the prevalence of other adverse outcomes may, given the accumulation of effects of disadvantage over the life course (Blane, 2006), take decades to become evident. This effect has been described as “epidemiological inertia” (Frank and Haw, 2011: 676) and raises problems similar to those associated with the long latency associated with many health outcomes attributable to environmental risks. Against this background of uncertainty, how long is too long to wait to see whether “dead bodies” appear?

Assuming that the choice has been made not to wait for the epidemiological Godot of data on mortality or other health outcomes, should evidence of (for instance) changes in risk factors like obesity, which contributes to a broad range of adverse health outcomes, or allostatic load, which is a basic concept in the physiology of chronic stress (McEwen and Gianaros, 2010; Seeman et al., 2010), be sufficient to justify initiating an intervention or to consider it successful? Or should the net be cast wider still? Support for this latter position comes from an important literature review on overweight and obesity: “Many strategies aimed at obesity prevention may not be expected to have a direct impact on BMI, but rather on pathways that will alter the context in which eating, physical activity and weight control occur. Any restriction on the concept of a successful outcome, to either weight-maintenance or BMI measures alone, is therefore likely to overlook many possible intervention measures that could contribute to obesity prevention” (Mooney et al., 2011: 22). No algorithm will provide a correct answer, and the choice of how much evidence is enough should be addressed as an issue of public health ethics.

Use of the randomized controlled trial (RCT) as the gold standard for intervention research, sitting atop a hierarchy of evidence, likewise incorporates a set of methodological value judgments that merit reconsideration. Although examples exist of sound RCTs of large-scale policy initiatives such as conditional cash transfers to low-income households (Lagarde et al., 2007) and housing vouchers to enable the poor to move to less distressed neighborhoods (Ludwig et al., 2011), many kinds of interventions and policies cannot be assessed using RCTs, for reasons of ethics, costs, logistics, or all of these. Even when an RCT is conceptually possible, insisting on evidence from RCTs may build into intervention research a bias against larger-scale, contextual interventions that are difficult to evaluate in this manner (Schrecker et al., 2001: 1679–1682; National Research Council and Institute of Medicine 2013: 164, 262–263). And the problem of fallacious inferences of lack of effect remains (cf. Greenland, 2011). Again illustrating inadequate understanding of the issues, the authors of a recent commentary on social epidemiology implicitly concede many of the points made here, while nevertheless urging researchers to focus on questions that can be addressed using experimental or quasi-experimental methods, and “identifying causal relationships that can be of the most use to policymakers,” without addressing the values or politics driving policymakers' choices about usefulness (Harper and Strumpf, 2012).

### Science and contested political terrain

Such issues have historically been of far more than academic importance when the choice of a standard of proof becomes contested political terrain. The economic payoffs from “manufacturing uncertainty”

(Michaels, 2006; Michaels and Monforton, 2005) can be formidable when proposals to regulate environmental, workplace or consumer product risks are involved. The strategy of manufacturing uncertainty was perfected by the tobacco industry starting in the 1950s, and has since been pursued by various industries facing regulation of hazards associated with their products or activities (Davis, 2007: 296–434; Michaels, 2006); a recent journalistic exposé makes this point about the sugar industry's response to escalating concern about rising prevalence of overweight and obesity (Taubes and Couzens, 2012). Indeed, overweight and alcohol abuse have been categorized as “industrial epidemics” in which “the vectors of spread are not biological agents, but transnational corporations” that “implement sophisticated campaigns to undermine public health interventions” (Moodie et al., 2013: 671). Critically, the success of industry protagonists depends on their ability to frame the debate (incorrectly) as one about the strength of scientific evidence, rather than about the values that should be brought to bear on the treatment of scientific uncertainty and protection of public health.

As in the case of environmental risks, adopting what has been called a tobacco industry standard of proof (Crocker, 1984: 66–67) with respect to social determinants of health means the evidence may never be strong enough. Michael Marmot, later to chair the Commission on Social Determinants of Health, has warned that “the best should not be the enemy of the good. While we should not formulate policies in the absence of evidence to support them, we must not be paralyzed into inaction while we wait for the evidence to be absolutely unimpeachable” (Marmot, 2000: 308). Issues of scale, standards of proof and hierarchies of evidence converge in cases where health effects of past policies are being considered as a guide for future action, for example when the potential health consequences of public sector austerity programs are considered, as recommended by a recent review of health equity in WHO's European Region (Marmot et al., 2012). It can be argued that the austerity programs now being adopted in many jurisdictions (although not all) constitute a large-scale social experiment on non-consenting populations (Stuckler and Basu, 2013); whatever the quality of the epidemiological evidence that emerges in a decade or so, when enough data have been accumulated, some of us regard the experiment as ethically problematic and irresponsible.

Obviously, what counts as strong evidence will depend on the objects of study; for understanding how macro-scale social and economic policies influence health by way of its social determinants, anthropology may be as relevant as epidemiology (Pfeiffer and Chapman, 2010). The argument here is not for neglecting rigor, but rather for recognizing that different research designs and disciplines have their own distinctive standards (methodological pluralism), and that some important and policy-relevant questions are answerable using some research designs and disciplines but not others. Arguing (for example) that action on social determinants of health should await evidence from experimental or quasi-experimental studies must be understood as adopting a tobacco industry standard of proof, and as a political and ethical choice rather than a scientific one. As suggested by the example of overweight and obesity, complex population health problems are best addressed using a “portfolio of interventions” (Swinburn et al., 2005) informed by various kinds of evidence, an approach now accepted both in health policy and in development policy (Snijlsteit, 2012; Snijlsteit et al., 2012). A promising research strategy organizes inquiry around contrasts between “epidemiological worlds”: this concept, introduced but not adequately theorized by Rydin et al. (2012), accommodates the reality that social disparities, like many environmental exposures, reflect multiple dimensions of (dis)advantage, potentially cumulative in their effect. Controlling for all but a single variable in the interests of methodological elegance or greater precision about causation simply disregards that reality.

The argument is also not for unreflective adoption of a precautionary or risk-averse approach. Even in the context of environmental risks, especially when resources are limited, what constitutes precaution or risk-aversion is not always self-evident or uncontroversial. Although

the extensive literature cannot be explored here, *The Economist* observed 20 years ago that: “If a developing country has the choice between (a) investing in scrubbers on power stations to prevent acid rain and (b) building hospitals, it will build hospitals first. And it will make more sense to persuade local industry to dump its toxic waste with reasonable safety than to persuade it to treat the stuff to American levels” (Cairncross, 1992: 10). Beyond the environmental risk frame of reference, the examples multiply. The critical point is that intellectually responsible approaches to assessing evidence for action on social determinants of health involve generic questions that cannot be answered by epidemiology, or by any science *qua* science: What kinds of hazards or harms are most important to guard against? And what are the appropriate standards of proof? This article is intended to stimulate both debate on these points in the context of social determinants of health and interest in comparative research on how those questions are answered in policy and law.

#### Conflict of interest statement

The authors declared that there are no conflicts of interests.

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