

Cochrane reviews and the behavioural turn in evidence-based medicine

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Abstract

Evidence-based medicine (EBM) has been one of the most important movements in clinical medicine and public health in recent years. At the heart of the EBM movement lies the Cochrane Collaboration, an influential organisation that produces systematic assessments of health care interventions known as Cochrane reviews. Although Cochrane methods were initially designed to test the efficacy of medical therapies, the desire for 'evidence-based' practice has pushed the movement far beyond its initial scope into the assessment of complex social phenomena. Through an examination of one particular Cochrane review, *Physician advice for smoking cessation*, this paper highlights the limitations of EBM and some of the more problematic conceptions of human nature that underwrite Cochrane principles and methodologies.

Keywords: evidence-based medicine; Cochrane reviews; smoking; tobacco use; sociology; critique

Introduction

Evidence-based medicine (EBM) has been one of the most important social movements in clinical medicine and public health in recent years (Traynor 2000; Pope 2003). A term first coined by a group of clinical epidemiologists from McMaster University in Canada in 1992, EBM was announced with considerable fanfare as a new paradigm for medical practice (Mykalovskiy and Weir 2004). According to its supporters, EBM provided an approach to clinical activity that would save the practice of medicine from many of its major ills, moving beyond individualised and irrational decision making towards a careful review of the best available research evidence (Cronje and Fullan 2003; Cohen *et al* 2004; Mykalovskiy and Weir 2004).

At the heart of the EBM movement lies the Cochrane Collaboration (Traynor 2000; Cohen *et al* 2004), an organisation named after Archie Cochrane, a "maverick" British epidemiologist who advocated the use of randomised controlled trials (RCTs) as a means of informing healthcare practice (Greenhalgh 2004). According to its website, the Cochrane Collaboration is:

[D]edicated to making up-to-date, accurate information about the effects of health care readily available worldwide. We are world leaders in evidence-based health care. Our contributors work together to produce systematic assessments of

healthcare interventions, known as Cochrane Reviews... [which] are intended to help providers, practitioners and patients make informed decisions about health care, and are the most comprehensive, reliable and relevant source of evidence on which to base these decisions (Cochrane Collaboration 2010).

As their website states, Cochrane reviews are the central activity of the Cochrane Collaboration. Using a prescribed process and methodology, reviewers scrutinise the published literature to determine its quality and summarise (and where possible conduct meta-analyses of) the evidence of efficacy of a variety of healthcare interventions.

Despite the widespread embrace of EBM, trenchant attacks of the movement and its underlying tenets have been launched within medicine and beyond it. I do not intend to retread the critiques here, which are by now well known, except to say the movement has been attacked on a wide variety of fronts, from its philosophical underpinnings, methodological flaws and anti-humanist 'one size fits all' orientation, to the ways EBM principles align with the neoliberal restructuring of the welfare state and the rationalisation of healthcare services it has engendered (Tonelli 1998; Rodwin 2001; Webb 2001; Upshur 2002; Little 2003; Cohen *et al* 2004; Mykhalovskiy and Weir 2004; Goldenberg 2006; Holmes *et al* 2006; Lambert 2006). However, with some notable exceptions, the critiques have tended to be primarily abstract and philosophical (Mykhalovskiy and Weir 2004).

This paper takes up Mykhalovskiy and Weir's (2004) call for social scientists to conduct empirically grounded examinations of EBM's use through an in-depth examination of one particular Cochrane review. As Mykhalovskiy (2003: 332) notes: "The texts of evidence-based medicine offer important points of entry for an inquiry of the social practices through which EBM is organized as a governing project, yet they have been scarcely researched".

EBM 'creep'

Despite the numerous critiques of EBM, they have not had a noticeable impact on its status amongst government agencies and healthcare organisations. As Goldenberg (2006) notes, evidence-based medicine has a ring of obviousness to it. As an instrument of accountability, in principle EBM is almost impossible to challenge. In the words of Little (2003: 177), "the argument for EBM is strong; irrefutable, in fact. It would be both immoral and irrational to use treatments that were not strongly supported by the best evidence". This self-evident value has therefore enabled the creep of 'evidence-based practice' (as the movement has become more broadly known) into domains outside of clinical medicine.

The concept of 'creep' has acquired sociological purchase in recent years as a means of characterising the processes whereby systems are unintentionally expanded and transformed (Haggerty 2004). An examination of EBM's roots demonstrates the radical expansion of the scope of the movement over time. In one of EBM's core sacred texts, *Effectiveness and Efficiency: Random Reflections on Health Services* (1972/1999), Archie Cochrane advocated the use of RCTs primarily in determining the most effective therapies for medical conditions such as tuberculosis, ischaemic heart disease, etc. In his

words, “the general scientific problem with which we are primarily concerned is that of testing a hypothesis that a certain treatment alters the natural history of a disease for the better” (p. 20). It is clear that Cochrane thought RCTs could be usefully applied to social phenomena as well as physiological interventions; for example, in *Effectiveness and Efficiency* he discusses his attempts to convince a school principal to randomise boys caught smoking to either caning or detention in order to determine the efficacy of these ‘interventions’. However, these ideas remain nascent in his work.

Similarly, in its initial formulation, the focus of the EBM movement was limited to clinical epidemiology and academic medicine. Thus, the first publication about EBM in the medical literature advocated the approach exclusively in the context of improving clinical decision-making around patient treatment (Evidence-Based Medicine Working Group 1992). However, early proponents of EBM clearly saw few issues with the application of EBM principles to fields such as public health, nursing, etc. (e.g., Sackett *et al* 1996) and subsequent iterations of evidence-based medicine soon expanded its gaze to other aspects of health-related activity, including multilevel and complex behavioural interventions targeting whole communities (Carter *et al* 2011). This shift was reflected in the work of the Cochrane Collaboration, whereby reviews on the efficacy of surgical and pharmacological interventions were joined by reviews of behavioural interventions to modify ‘risk’ behaviours such as smoking, drug and alcohol use, dietary practices, physical inactivity, etc. Importantly, the methods for reviewing behavioural interventions were indistinguishable from those promulgated for physiological interventions and assumed a seamless transposition of principles and processes.

EBM ‘creep’ has also seen the movement’s central tenets taken up in fields far removed from health and medicine, such as social work (see Webb 2001) and education (see Oakley 2002). As Oakley (2002) has noted:

The example of the Cochrane Collaboration has made professionals and policymakers in other disciplines think hard about the parallels and differences between health care and other forms of professional intervention in people’s lives (p. 278).

This growing appetite for ‘evidence-based practice’ is epitomised in the work of the Campbell Collaboration, a “sibling” organisation to the Cochrane Collaboration founded in 2000 to disseminate systematic reviews of “social interventions” in the areas of education, crime and justice, and social welfare (Campbell Collaboration 2010; Cochrane Collaboration 2011). Clearly, the desire for evidence-based practice has pushed the movement far beyond its initial scope.

In light of the extraordinary array of topics covered by the Cochrane Collaboration (over 6000 reviews and counting) and the elevated status of Cochrane reviews in promulgating ‘evidence-based’ healthcare, they provide an important instrument through which to critically examine the underlying tenets of EBM. Yet, although several prior critiques of specific Cochrane reviews have been mounted, these critiques tend to be framed from within the paradigm of EBM rather than outside of it (e.g., Sugarman and Kral 2005; Truswell 2005; Fahy and Tracy 2007; Rosén 2009). What follows will entail an examination and critique of one particular Cochrane review. My goal is to use this

specific case to highlight some of the limitations of EBM in the context of complex ‘behaviours’, adding flesh to the bones of the abstract critiques of the movement marshalled to date.

Case study

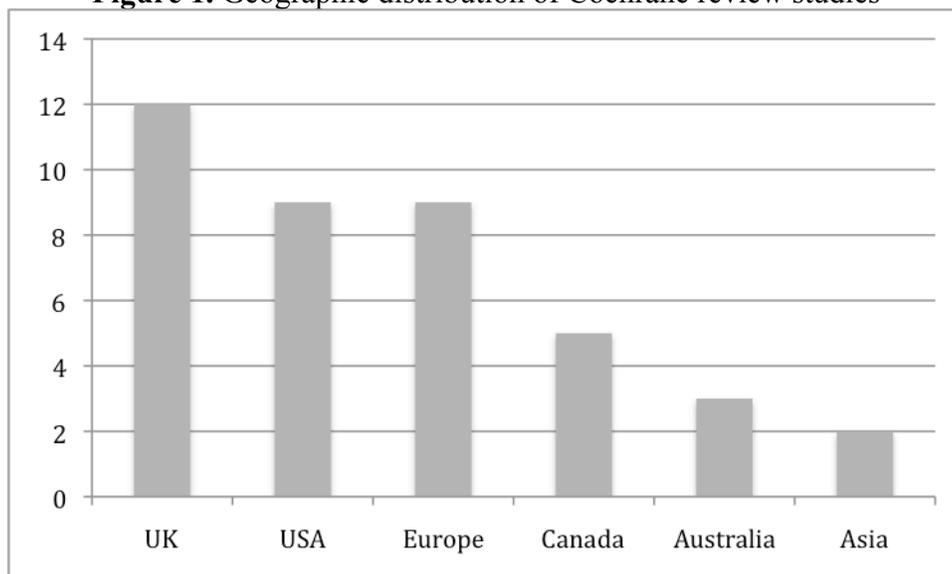
The Cochrane review I would like to turn your attention to is *Physician advice for smoking cessation* (Stead, Bergson and Lancaster 2009). I have chosen this review because it is highly influential in a field I am familiar with, and because it provides an example *par excellence* of a review where the focus of intervention is a ‘behaviour’ rather than a medical condition. It is also located at the interstices between primary care and public health, dealing as it does with a patient-level intervention that is expected to have a population-level effect.

The aims of this review are fourfold: 1) to assess the effectiveness of physician advice in promoting smoking cessation; 2) to compare the efficacy of brief with more intensive interventions; 3) to assess the efficacy of various aids to advice (e.g., pamphlets); and 4) to determine the effect of such advice on mortality. Drawing on the results of 41 RCTs it concludes the following:

Simple advice has a small effect on cessation rates. Assuming an unassisted quit rate of 2 to 3%, a brief advice intervention can increase quitting by a further 1 to 3%. Additional components appear to have only a small effect, though there is a small additional benefit of more intensive interventions compared to very brief interventions (Stead, Bergson and Lancaster 2009: 2).

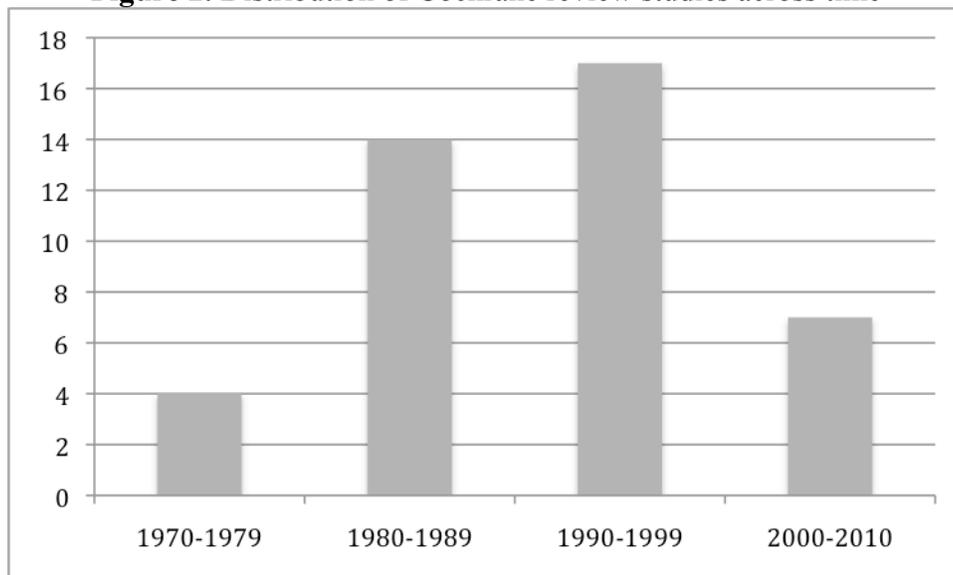
In light of these findings, organisations such as the National Institute for Health and Clinical Excellence in the United Kingdom, the Office of the Surgeon General in the USA, Australia’s Department of Health and Ageing and Health Canada have formally recommended such interventions as standard ‘good practice’ for physicians and encouraged them to intervene systematically with all smokers they interact with (Bell *et al* 2011a).

Figure 1. Geographic distribution of Cochrane review studies



The *Physician advice for smoking cessation* review includes trials from 14 countries, including: Australia, Canada, England, France, Germany, Hong Kong, Italy, Japan, the Netherlands, Norway, Scotland, Spain and Sweden (see figure 1). The publication dates of the studies span a 35-year period from 1972 to 2007 and almost half the studies (44%) included in the review were published more than 20 years ago, with 17% published in the past 10 years (see figure 2). In light of the time lag between the conduct of studies and their publication, the actual time frames of the studies likely precede their publication dates by 2-5 years.

Figure 2. Distribution of Cochrane review studies across time



Although little detail is provided in the review regarding the 31,000 odd smokers included in the studies, there is considerable heterogeneity in the study populations. Seventy-three per cent of the included studies were conducted with smokers attending primary care clinics while the remaining studies were conducted with specific categories of smokers, including: mothers, civil servants and other employees, diabetic outpatients, patients with smoking-related diseases (e.g., COPD, myocardial infarction, cancer) or smokers at risk for such, and asbestos-exposed smokers. Despite the heterogeneity of the included study populations, results are pooled in a meta-analysis to quantify the effects of physician smoking cessation advice on the generic or ‘average’ smoker (Kravitz, Duan and Braslow 2004).

Eliding context

For most social scientists, what is obviously lacking in descriptions of research evidence presented within this and other Cochrane reviews is any acknowledgement of “...social structural influences and social, cultural, political and economic dimensions, despite their critically important role in determining health status and outcomes” (Lambert 2006: 2642). As several observers have noted, evidence as synthesised in Cochrane reviews is

gender blind and ignores the social determinants of health (Rogers 2004; McGuire 2005). In consequence, potential differences in the effectiveness of interventions based on factors such as sex, social class, age and ethnicity are elided.

In response to such criticisms, an Equity Methods Group has been formed within the Cochrane Collaboration that aims to:

[E]ncourage authors of Campbell and Cochrane reviews to include explicit descriptions of the effect of the interventions not only on the whole population but to describe their effect upon the disadvantaged and/or their ability to reduce socio-economic inequalities in health and to promote their use to the wider community (Campbell and Cochrane Equity Methods Group 2010).

However, to date the group has not had a substantive impact on the overarching methodologies of the Cochrane or Campbell Collaborations.

Less commented upon is the way in which Cochrane reviews aggregate the results of studies varying widely across time and space. As previously noted, studies included in the *Physician advice for smoking cessation* review span a 35-40-year time span. Yet, the prevalence and social context of tobacco use has undergone marked changes over the past four decades. For example, in 1981 39.5% of the Canadian population smoked (Health Canada 2007), but by 2008 the smoking prevalence had dropped by more than half to 18% (Health Canada 2009). A similar trajectory is evident in other English-speaking countries such as the UK, the USA and Australia, which also witnessed a substantial reduction in smoking prevalence over the same period.

The drop in smoking prevalence is partially due to changing attitudes towards the practice, which has been transformed from a socially acceptable and widespread habit into an increasingly vilified one over the past three decades. The changing social attitudes towards smoking in the English-speaking world have been accompanied by the introduction of comprehensive tobacco control strategies, including taxes on cigarettes, limitations on how tobacco products may be marketed, distributed and sold and widespread bans on smoking in indoor spaces (and a growing number of outdoor spaces as well). The last 10 years have also seen the introduction of explicit policies of tobacco ‘denormalisation’: efforts to utilise the power of social pressure to make smoking “less desirable, less acceptable and less accessible” (California Department of Health Services 1998: 3; see Bell et al. 2010a, 2010b for further discussion).

These changes have effected a radical transformation in the social composition of smoking, with an inverse relationship between socio-economic status and smoking prevalence now evident throughout the western, industrialised world (Burns and Warner 2003). Thus, 30 years ago GPs, a sizeable proportion of whom were smokers themselves (Adriaanse and Van Reek 1989), dealt with a very different population of smokers to their contemporary counterparts. Indeed, UK research suggests that a significant minority of tobacco users attending GP practices today are ‘hardcore’ smokers highly resistant to quitting (Macintosh and Coleman 2006). How valid is it therefore to assume that the results of studies conducted 20-40 years ago, or even 15, shed light on effective strategies

today? Yet, this a basic assumption of Cochrane review methodologies, including those of the Equity Methods Group.

A related assumption underpinning Cochrane Reviews is that it is possible and desirable to aggregate the results of studies conducted in diverse geographic and cultural contexts. As figure 1 demonstrates, although the majority of the studies (71%) included in the *Physician advice for smoking cessation* review were conducted in English-speaking countries (e.g., the UK, the USA, Canada and Australia) it also assesses studies from Scandinavia, Western Europe and Asia. Incorporating results from studies in Hong Kong and Japan seems particularly problematic, given the strongly gendered composition of smoking in both countries, and differing cultural ideals regarding doctor-patient communication.

Yet, even within broadly similar countries there are significant differences in the cultural and socio-political context of smoking which make direct cross-country comparisons problematic. For example, although variation exists between provinces and territories, Canada has long been seen as a global leader in tobacco control and was an early adopter of tobacco advertising and sponsorship bans, tobacco taxes, mandated warnings on cigarettes, and smoke-free legislation (Cunningham 1996). Australia was also a reasonably early adopter of a variety of similar tobacco control strategies. The UK, in contrast, adopted a number of tobacco control measures more recently, with a tobacco advertising and sponsorship ban initiated in 2005 and indoor smoking bans introduced in Scotland in 2006 and the rest of the UK in 2007. However, unlike the other countries it also provides intensive support for smokers through the National Health Service's Stop Smoking Services. The legislative environment in the US is more difficult to characterise, given the widespread variation in tobacco taxes, smoke-free legislation and tobacco advertising from state to state. Different social attitudes towards smokers and the tobacco industry have also been found in the four countries (Hammond *et al* 2006), with Canadian respondents reporting significantly greater social 'denormalisation' and Australians recounting the highest level of anti-industry beliefs. In sum, assumptions about the universal efficacy of these interventions, regardless of their cultural setting, seem highly suspect (see also Bell *et al* 2011a).

Cochrane reviews and underlying conceptions of 'human nature'

The aggregation of studies across time and space remains a largely unquestioned tenet of Cochrane reviews, whether those examining the efficacy of drug and surgical interventions or those focusing on behaviour modification. It is therefore instructive to consider exactly why this is deemed appropriate practice and what it reveals about conceptions of human nature underlying EBM principles and methodologies.

As critiques of public and population health have long noted, these disciplines generally invoke a mechanistic and deterministic view of human behaviour that segments human actions into discrete, independently alterable phenomena or 'variables' (Coreil and Levin 1985; Coreil *et al* 1985; Bibeau 1997; Labonte 1997; Robertson 1998). Influenced by behaviourism, the underlying framework is positivistic and evokes a "science of behaviour" or "physics of society" modelled on the natural sciences (Coreil and Levin

1985: 107, see also Coreil *et al* 1985). Accordingly, dominant behavioural conceptions operate on the assumption that what ‘causes’ an individual to smoke can be modelled on the causal relationship that connects smoking to lung cancer, and the processes involved are treated as structurally analogous (Mair 2011). A recent article in the *New Zealand Medical Journal* typifies this logic, stating:

When children see or know others are smoking, they are at increased risk of smoking and of continuing to smoke, because of the example and normalisation of smoking. There appears to be a dose-response effect, so the more there is smoking around them, the more youth are at risk of smoking (Tay and Thompson 2008: 16).

Here, smoking is treated as an exposure event, with doses of increasing frequency more likely to cause observers to start smoking. In this framing, the context and meaning of smoking become completely irrelevant (Mair 2011). As Bourgois, Lettiere and Quesada (1997) note, by forcing behaviours into a natural science paradigm, epidemiological approaches elide power relations and disguise the most significant parameters of social processes. Thus, “Research questions become focused around discrete variables that are technocratic at best or completely arbitrary at worst” (p. 166). In this conceptualisation, as critics of behaviourism have long noted, smokers are treated as mindless automatons at the whim of environmental stimuli (Catania and Harnad 1988).

Cochrane reviews of behavioural interventions adopt a similarly positivistic model of human nature derived from the natural sciences (Webb 2001). This framework suggests that human ‘behaviours’ can be isolated, intervened in and modified in much the same way as human physiology. The use of the term ‘intervention’ in both contexts demonstrates the breadth (and depth) of the analogy: attempts to transform individual ‘behaviours’ in the name of rectifying unhealthy lifestyles are treated as equivalent to physical intercessions into the human body to modify the course of disease. Interventions retain their efficacy across time and space because culture, meaning and context are irrelevant. The existence of the placebo effect challenges the idea that human responses to drug or surgical therapies can be isolated from their social, cultural and historical context (Moerman 2002). This assumption – already stretched in the context of clinical medicine – becomes untenable when applied to complex social practices like smoking (or any of the other ‘behaviours’ examined within Cochrane reviews). Yet, there has been surprisingly little critique of this feature of Cochrane methodologies amongst social scientists.

However, models of behavioural change articulated in EBM owe a debt not only to behaviourism but also to the cognitive shift in the human sciences (Bibeau 1997). In this cognitivist view, human beings are shaped primarily by cognitive blueprints that scientists can learn to ‘read’ in order to predict actual behaviours of individuals (Bibeau 1997). According to this framework, unhealthy behaviours are caused by faulty forms of cognition that need to be corrected. As Basu (2004) points out in his critique behavioural interventions to prevent HIV/AIDS, the overarching assumption is that if people just *know* how ill health occurs – and stop being in denial about it – they will change their unhealthy behaviours. The primary ‘treatment’ therefore becomes the health education

message, delivered at an appropriate moment by a healthcare professional (Balslem 1991).

Although rationality and reason are social practices, never established in pure form (Kapferer 2002), this model is premised on an assumption of the universal 'rational' human (Webb 2001). Indeed, the concept of rationality lies at the heart of EBM and is central to its organising logic: 'rational' processes produce 'rational' knowledge and 'rational' humans (Webb 2001; Cronje and Fullan 2003). The "...results of rationality should and will be *universal* – any rational person, if s/he begins with the same information, will arrive at the same conclusions" (Cronje and Fullan 2003: 355, my emphasis). This model presumes both the universal rationality of the knowledge EBM produces and the universal rationality of those it is directed towards: both the targets of intervention and those expected to do the intervening (healthcare professionals). There is little room in this worldview for variations across time and space – rationality, it is assumed, is timeless and universal. In this framework the large numbers of physicians and patients who express concerns about this model can only appear as *irrational* – obstinately refusing to recognise an irrefutable and universal truth.

Conclusion

The rise of EBM has not only dramatically transformed the landscape of clinical medicine, its effects have been felt across a variety of allied health disciplines and well beyond them. However, the 'creep' of EBM into these new domains and the behavioural turn it has taken requires considerably more critical examination than it has received to date. That the efficacy of interventions into complex and embedded social practices like smoking has been determined using methodologies developed to study the efficacy of medical interventions is an extraordinary turn of events, although less surprising, perhaps, in light of the 'death of the social' that scholars such as Rose (1996) and Kapferer (2005) have written about. Here, the assumptions of a universal body and human nature become simply unsustainable.

In light of the status of Cochrane reviews as the 'gold standard' in evidence-based healthcare and public health initiatives, and their extraordinary power to influence national and international policy agendas, there is a very real danger that such reviews will lead to the promotion of sexist, racist and classist interventions that are ineffective or actively harmful for certain segments of the population (McGuire 2005). However, there is also a larger danger that ethnocentric (especially Eurocentric or Americentric) interventions will be universalised as 'best practice' for populations around the globe for which they are ill suited. Given that the assumptions on which these reviews are based are untenable to most social scientists, they would do well to turn their lens to these reviews and to exposing and interrogating the assumptions underwriting them. Such analyses may be harder for the proponents of EBM to ignore than the abstract critiques that have dominated discussions of the movement to date.

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