

is evidence based psychiatry ethical?

MONA GUPTA



Is Evidence-based Psychiatry Ethical?

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Mona Gupta

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To my patients

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What does evidence have to do with ethics?

‘Pinel did not cut the chains of the mentally ill because he had just read a well-controlled randomized trial on the effect of chains.’

Participant 2-10¹

1.1 Why a Book about Evidence-Based Medicine and Ethics?

Over the last hundred years, medical research has led to a vast expansion in our knowledge about the human body and its diseases. At the same time, there have been significant developments in the treatments for many health conditions. As a result, we believe firmly that medical research is the route to further knowledge, and further knowledge leads to better health. In recent years, this direct connection between research, knowledge, and improved health has been famously articulated in the concept of evidence-based medicine (EBM). Developed in the early 1990s at McMaster University, EBM is defined as ‘... the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients’ (Guyatt et al. 2008: 783).

EBM captures a very simple and compelling principle—that clinical decision-making should be based, as much as possible, on the most up-to-date research findings. In order to determine which research data offer the best evidence concerning health care interventions, EBM relies on a ranking of research methods from those most likely to those least likely to support truthful conclusions about these interventions. This hierarchy determines which studies yield the best evidence, based on whether they have employed the highest-ranked methods.

But why should we think that EBM, a movement devoted to increasing the knowledge behind clinical decision-making, has something to do with ethics?

¹ For a description of the anonymization of participants, see Section 1.3.

Even though EBM's primary claim is an empirical one—that adhering to EBM will lead to improvements in health outcomes—there is no evidence of the kind preferred by EBM that it can achieve this goal, a point which its proponents concede (Haynes 2002; Straus and McAlister 2000). In the absence of evidence that EBM is the best way to practise, EBM is forced to justify itself in another manner, which it does through an implicit, normative claim: that we should practise EBM. EBM assumes that adhering to its principles is the best way to obtain knowledge about which medical interventions are effective and, therefore, is the best path to improving health. To practise anything but EBM would knowingly lead patients to less effective interventions and worse health. Such a state of affairs could not count as good practice. Thus, EBM's implicit justification is also an ethical one: we should practise EBM because it is the best (most accurate) way to help patients achieve improved health.

Increasingly, good practice (both technically and ethically speaking) is becoming synonymous with evidence-based practice². Yet, there are other ethically relevant considerations in clinical decision-making apart from what is likely to lead to the kinds of health outcomes typically evaluated by clinical research studies. This book looks at where such considerations fit, if at all, in the practice of EBM.

1.2 Why a Book about EBM, Ethics, and Psychiatry?

Many of EBM's leading authors trained in internal medicine and originally envisioned several of its principles applied to problems in their field. Some of the leading EBM online resources, such as *UpToDate*³ and *Clinical Evidence*,⁴ started out with many more entries related to topics in internal medicine than, for example, to psychiatry. But EBM's popularity has spread beyond internal medicine to other clinical disciplines, including psychiatry (Geddes and Harrison 1997; Paris 2000).

In fact, evidence-based psychiatry—the straightforward application of the principles of EBM to the practice of psychiatry (Gupta 2007)—has received enthusiastic endorsement from professional societies representing psychiatrists in many countries. Why might this be so? Both popular and scholarly

² At times I use the term 'evidence-based practice', by which I mean simply using the EBM method in clinical practice.

³ *UpToDate*[®] is an online resource that offers a searchable encyclopaedia of reviews of clinical topics. It is provided by Wolters Kluwer Health and is available by paid subscription.

⁴ *Clinical Evidence* is a database of overviews assessing the benefits and harms of treatments. It is provided by BMJ Publishing Group Limited and is available by paid subscription.

depictions of the harms done to patients in the name of psychiatric treatment continue to have a widespread negative influence on public opinion (Kesey 1968; Szasz 1974). And because the pathophysiological basis of mental disorders remains unknown, this further damages psychiatry's claim to being a legitimate medical discipline. If we don't know why people develop mental disorders, then on what basis can psychiatrists distinguish between illness and normalcy? Are these distinctions based on true knowledge or merely the beliefs and values of psychiatrists? By contrast, the ethical value of other medical specialties is rarely in doubt—people do not question society's need to devote vast resources to oncology; lobby groups do not spring up opposing gastroenterology; there has never been an antidermatology movement (as there is an antipsychiatry movement). It is into the context of this ethical debate about psychiatry that EBM enters. Advocates of an evidence-based approach to psychiatry hope that, if practice is driven by hard scientific data rather than the traditions and inferences characteristic of past eras, there will be greater potential to improve patients' health (Szatmari 2003; Goldner et al. 2001). This, in turn, will solidify psychiatry as a scientifically legitimate and ethical medical practice in the minds of the patients, policy-makers, and psychiatrists themselves.

What is the relationship between ethical practice and evidence-based practice in medicine and in psychiatry, exactly? The literature on the relationship between ethics and EBM tends to focus on the ethical consequences of using or not using best evidence in practice. Goldenberg argues that interrogating the relationship between ethics and EBM should reach beyond the consequences of using EBM in practice and investigate the ways that ethical values are relevant to the generation of evidence (knowledge production) (2007: 62–3). Such an expansion would encourage examination of the contextual values that are part of the social context in which EBM operates. Several scholars have pointed out that ethical values, either implicit or explicit, operate at all phases of research—not only the generation but also the dissemination and interpretation of data (Downie et al. 2000; Eysenck 1994; Gilbody and Song 2000). These values include judgements about which research questions and health outcomes should be studied and/or funded for study; how to study and represent certain outcomes (e.g. how one should represent a change in depression); which conclusions ought to be presented, published, and emphasized; and how data ought to be situated within the larger body of clinical knowledge (e.g. when there are enough data to change practice or insurance coverage).

Because any approach to clinical knowledge orientates us towards what we ought to know about health, and because health is tied to human flourishing, the very notion of what counts as evidence is not only a matter of fact but

also one of ethics. Therefore, in addition to contextual or external values, an exploration of the ethics of EBM must also consider internal values. Such considerations would include, for example, how choices about research methods influence what we can know and, therefore, value about health; and how we determine what counts as evidence about health. In other words, there are ethical implications of EBM, but it may also be constituted by certain ethical values (Borgerson 2008: 40–1).

Evidence-based psychiatry is equally implicated in this general analysis of the relationship between ethical practice and evidence-based practice. However, there are specific reasons to be concerned about the ethics of evidence-based psychiatry. Emerging as it did with internal medicine in mind (and the large-scale clinical trials of pharmaceutical agents), EBM makes certain assumptions about the nature of disease that may not be applicable to psychiatric disorders, or their treatments. To the extent that psychiatric disorders do not conform to these assumptions, the application of EBM to psychiatry is more likely to be fraught with epistemological and ethical problems than its application to other branches of medicine.

Does making psychiatry evidence-based strengthen its scientific, and therefore its ethical credibility? Whether the application of EBM to psychiatry really does offer improved scientific substantiation to psychiatric knowledge remains controversial. Given the longstanding debates about the use and abuse of power in psychiatry (Foucault 1973; Szasz 1974), using dubious knowledge claims under the guise of doing what's best for patients may be ethically suspect.

Is evidence-based psychiatric practice, ethical? This book aims to answer this question. Therefore, it does not focus on the ways that EBM dovetails with other clinically related spheres such as health policy or medical education. These are important areas in their own right, requiring their own analyses. In this book I wish to focus attention on the very context for which EBM was originally conceived: the individual doctor–patient encounter. Some of the ethical concerns discussed are common to all health disciplines where EBM has been utilized. Others are particular to psychiatry, given the unique subject matter of that field and the persistent debates about its ethical legitimacy as a specialty of medicine.

1.3 The Argument Ahead

In exploring and defining the relationship between ethics and evidence-based psychiatry, the book draws upon two primary sources. The first is the two authoritative texts that lay out the principles and methods of EBM—namely, Guyatt et al.'s *Users' guides to the medical literature: a manual for evidence-based*

clinical practice (2nd edition, 2008, hereafter *Users' guides*) and Straus et al.'s *Evidence-based medicine: how to practice and teach it* (4th edition, 2011, hereafter *Evidence-based medicine*). The second set of sources is made up of interviews that I conducted with three groups of respondents: group 1 consisted of nine people who were, and remain, involved in the development of EBM (referred to as 'EBM developers'); group 2 consisted of 11 practitioners working in mental health, who are involved in the implementation and scholarly debate about the use of EBM in mental health practice (referred to as 'mental health experts'); and group 3 included 13 scholars who have investigated philosophical or ethical aspects of EBM (referred to as 'philosophers/bioethicists' or simply 'philosophers'). All group one and two participants were or have been engaged in clinical practice, while only three group three participants had ever worked as clinicians.⁵ The EBM texts offer a (sometimes incomplete) picture of EBM. However, because EBM is an approach that continues to evolve, it is necessary to supplement the texts with the ideas expressed by its originators and those engaged in its ongoing development or critique. Other voices in the debate about the ethics of EBM are included in my review of the existing literature in this area.

1.3.1 Contentious Issues

The main question of the book invites the consideration of several basic concepts such as evidence, medicine, health, and mental disorder. Indeed, these concepts relate to even more basic philosophical debates concerning the nature of minds, the justification of knowledge, and the relationship between ethics and epistemology. These important debates form the necessary background, but a philosophical examination of each is beyond the scope of this book. What I have tried to do is illustrate some of the contentious issues that arise in the philosophical debates about these concepts, particularly as they relate to the field of psychiatry and EBM. Given that these component concepts have themselves generated vast philosophical analyses, it will be unsurprising that EBM proves to be a contested idea, both in the literature and among those most expert in its meaning and use. Nevertheless, this lack of clarity surrounding

⁵ In this book I quote many participants directly, using a numerical code to denote each participant. The first number refers to a participant's disciplinary group (1, 2 or 3). The second number distinguishes each participant from the others within the group. Thus, P1-8 is the eighth participant from group 1. I had to include my question in some quotations in order to contextualize the participant's answer. In these cases, I denote my speech with I (for interviewer) and then quote myself directly. Occasionally I insert text in square brackets; this is usually to clarify an indefinite pronoun.

the concept of EBM exposes some of what is assumed about these more basic concepts when EBM is applied to psychiatric practice.

1.3.2 Defining Terms

The objective of Chapter 2 is to define terms and examine the basic concepts of EBM as depicted in EBM's two authoritative texts: *Users' guides* and *Evidence-based medicine*. The most important of these terms are 'evidence-based medicine' and 'evidence'. I also examine the five steps that comprise the practice of EBM, which its authors describe as a framework for clinical decision-making.

In defining these terms and describing the five steps, the book remains as close to the programmatic descriptions as possible by drawing almost exclusively upon the original texts as source material. I then make use of my interviews with EBM experts to try to further delineate the concept of EBM—what it implies and what it is trying to convey—in order to fill in details missing in the texts. I provide excerpts from the interviews interspersed with my own interpretations of these segments. I also highlight areas of convergence, divergence, and ambiguity between the respondents and the texts, and between respondents themselves. Near the end of the chapter I return to steps 3 and 4, critical appraisal and integration, in an attempt to clarify how EBM works in practice.

1.3.3 Debating EBM

Chapter 3 reviews the debate that has emerged in the scholarly literature, particularly as it concerns EBM's basic concepts and its practice. This review draws attention to several contentious areas relating to EBM's five steps, including the social context of medical research; what kinds of data do, and should, count as evidence; the process by which data become evidence (and evidence for what exactly?); and how evidence becomes meaningfully integrated with clinicians' expertise and patients' values, as EBM instructs that it should. The issues highlighted in this debate, along with the conceptual clarifications of Chapter 2, show how some of the most urgent concerns in the debate about EBM involve the role of ethical values in both its theory and practice.

1.3.4 Applying EBM to Psychiatry

In Chapter 4 I examine concepts that are relevant to applying EBM to psychiatry, including psychiatry, mental disorder, and treatment. The first section of Chapter 4 discusses the evolution of the modern discipline of psychiatry and the assumptions about the nature of mind, disease and treatment that are embedded within its practice. This section argues that current psychiatric practice is framed by the unresolved philosophical debate about the nature of mind.

Psychiatry, as a practical discipline, does not attempt to resolve this debate, even though various theoretical commitments are implied through its diagnostic and treatment practices.

The second section of Chapter 4 defines evidence-based psychiatry. It then returns to the interviewees, who offer their own conceptions of evidence-based psychiatry, compared to what is currently portrayed in mainstream literature. In the third section the interviewees explore the application of EBM to psychiatric diagnosis and treatment. This section argues that adopting EBM leads psychiatry to take on EBM's assumptions about disease and treatment, thereby cementing a commitment to a particular theory of mind and mental experience.

1.3.5 Questioning EBM's Assumptions

In Chapter 5 I examine the ways in which the assumptions about disease and treatment that underlie EBM do and do not apply to mental disorders. Drawing on the academic literature on this point, the first section of this chapter examines the application of EBM to psychiatry, including practical considerations such as the limitations of the way that randomized controlled trials (RCTs) in psychiatry are currently conducted, as well as the difficulties in studying non-pharmacological treatments.

The second and third sections of the chapter discuss several problems that emerge in the clinical research literature in psychiatry, including the placebo effect, the presence of the so-called non-specific therapeutic factors, and the meaning of quantifying mental health outcomes. The chapter concludes by arguing that adopting EBM, which seems to put psychiatry on firmer scientific and ethical ground, leads the field to commit itself to a particular version of mental disorder and treatment, one that is narrower than what is allowed by its current theoretical pluralism.

1.3.6 Ethical Values Embedded in EBM

The first section of Chapter 6 explores the ethical values embedded in EBM's five steps. It goes on to argue that EBM substantiates itself ethically by claiming that it is the best way to achieve health. It then discusses the ethical theory reflected by this stance. This analysis enables me to offer a picture of the ethics of 'literal' EBM—that is, the version of EBM described in its key texts.

In the second section of Chapter 6 I discuss how the ethics of EBM applies to psychiatry. Looking at some clinical examples of diagnosis and treatment, I argue that the ethical values of EBM affect psychiatric practice in distinct ways, given the controversial history of its science and the contested nature of psychiatric disorders themselves.

1.3.7 Important Themes about Ethics and EBM

Chapter 7 returns to the interviewees, discussing four important themes or issues emerging from their views about the relationship of ethics to EBM. The first is that EBM is an exemplar of larger ethical trends in society. The second is whether EBM is value-free or value-laden. The third is how one determines which of EBM's two distinct goals—improved health outcomes versus satisfying patients' preferences—takes priority? The fourth is whether it is or is not ethical that EBM be used as a tool for resource allocation.

Using these themes and example offered by the interviewees, I discuss the relationship between ethical practice and evidence-based practice. Evidence-based practice may or may not be ethical; non-evidence-based practice may or may not be ethical. Whether it is or not depends on certain features of the situation, such as local attitudes to health care, practitioners' values, and patients' psychological needs in the trajectory of their illness. This discussion allows me to use the interviewees' reflections to offer a picture of the enriched ethics of EBM compared to the ethics of literal EBM implied by its foundational texts.

1.3.8 A Last Look at the Ethics of Evidence-based Psychiatry

Chapter 8 addresses the main question of the book: is evidence-based psychiatric practice, ethical? While psychiatrists hoped that EBM could help to solidify its scientific and ethical credentials, in Chapter 5 we saw that this may not be possible. If EBM cannot supply psychiatry with the ethical substantiation it seeks, what will do the job? This chapter contrasts EBM's ethics with those underlying several other approaches to the clinical encounter, including the biopsychosocial model, postpsychiatry, and values-based practice.

I conclude by taking a last look at the ethics of EBM. Does it have something distinct to offer psychiatry? I argue that quite apart from its utilitarian impulses, EBM contains an implicit call to virtue. That is, it asks clinicians to cultivate the intellectual and moral virtues involved in responsible scientific knowing. This may be EBM's most important and innovative contribution to ethical, clinical practice.

1.3.9 Future Directions

Where does a clearer understanding of the ethics of evidence-based psychiatry leave the field, and in what directions does psychiatry need to evolve scientifically and ethically? I offer three conclusions following the arguments made in this book. The first is that EBM could be improved if it were to contract: aim

to do a smaller task that would be at once more modest but also more defensible, epistemologically and ethically. The second conclusion is that psychiatry needs to reject the constraining discourse of EBM and define the questions and methods that are appropriate to the subject material of its discipline—whether these are or are not part of the subject matter of the rest of medicine. The third conclusion is that by identifying how and where ethical values play a role in psychiatric practice, bioethical analysis offers psychiatry a helpful companion. The question is not whether ethical values are at play in psychiatry, but whose values and why?

Does psychiatry need to stake out its own ground, scientifically and ethically, compared with other medical specialties, in order to best respond to the particular characteristics of mental disorders and the needs of those who suffer from them? If so, what would that look like? This type of discussion goes beyond the debate about EBM towards the development of psychiatry's own vision of ethical, clinical practice.

1.3.10 Overall Methodological Approach

The appendix offers a detailed description of the overall methodological approach for the interviews and the techniques used, as well as a discussion of the interpretative framework that was brought to bear upon the interviews. I review the ethical considerations for the interviewees, including the process of obtaining informed consent, and protection of confidentiality and anonymity.

1.4 Interpretive Considerations

My goal in writing this book is to examine evidence-based psychiatry using the perspective and methods of bioethics, in the hope that this will deepen the understanding of the issues psychiatrists face in trying to practise EBM. I hope that the content will resonate with clinicians as well as those scholars within bioethics and philosophy who work on subjects related to clinical practice.

I have tried to offer a faithful and honest rendering of the foundational texts that describe EBM. When it comes to ethics, some of the arguments are implied. At times I discuss what is implied in the texts, particularly when it is supported by the interpretations of other authors or EBM authors' other writings. However, much of what we want to know about the ethics of EBM is left unsaid. In this case, I do not try to guess the authors' meaning or read between the lines but simply leave certain ideas in the original wording, pointing out where detail or explanation is lacking.

Meanwhile, the reader should be aware where my personal sympathies, biases, and beliefs as a researcher lie. I came to this project as a critic of EBM

myself, sympathetic to arguments expressing concern about the epistemological underpinnings of EBM.

Because I interviewed most of the EBM developers first, my own beliefs about EBM were challenged at an early stage of the project. Trying to adopt the neutral stance of an interviewer required me to evaluate the 'pro-EBM' arguments more dispassionately and reflect more deeply on their meaning. As I went on to interview mental health practitioners and philosophers/bioethicists, I saw how nuanced their critical views were. The terms 'proponent' and 'critic' did not fully capture the sophistication of their arguments and instead created a black and white frame to the debate. Nevertheless, I have retained the use of these terms at various points to reflect the fact that, despite the nuance, there are experts who believe wholeheartedly in EBM and others who wish to see it abandoned, or at least greatly modified.

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What is evidence-based medicine?

2.1 Definition

In only 20 years the concept of evidence-based medicine (EBM) has captured the imagination of the medical world. Coined in 1990 by Gordon Guyatt, then the director of residency training for internal medicine at McMaster University in Hamilton, Ontario, Canada, the phrase first appeared in an information document for prospective applicants to the residency programme (Guyatt et al. 2008: xxi). Guyatt was searching for a phrase to capture the methods of teaching and practising medicine that he, and several colleagues, had been developing at McMaster over the previous decade.

These methods emerged from the work of David Sackett and colleagues in the Department of Clinical Epidemiology and Biostatistics at McMaster. Sackett, a specialist in internal medicine and founding chair of the department, had written a textbook in 1985 about clinical epidemiology and its applications to clinical research. With colleagues from the department, Sackett wanted to share his knowledge of research methods with the average practitioner. He believed that if practitioners were better equipped to understand medical research, they would be more likely to draw upon recent findings in clinical decision-making. In his view, so they should, as this would improve the care they offered. To that end, he and his colleagues published an influential series of guides to reading the medical literature in the *Canadian Medical Association Journal*; these appeared between 1981 and 1984. Brian Haynes (another specialist in internal medicine in the department) and colleagues published a related series in the *Annals of Internal Medicine* in 1986.

A 1992 article in the *Journal of the American Medical Association (JAMA)* introduced the concept of EBM to the medical world and defined it as ‘. . . the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients’ (Evidence-Based Medicine Working Group, 1992). From these origins, the concept has become enormously influential in medical education, clinical practice, and health policy (Grossman and McKenzie 2005: 6; Ghali et al. 1999: 133–4; Noseworthy

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