IS EVIDENCE-BASED PSYCHIATRIC PRACTICE, ETHICAL PRACTICE?:
A CONCEPTUAL AND QUALITATIVE STUDY

by

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Abstract

Since its addition to the medical lexicon in 1992, the concept of ‘evidence-based medicine’ (EBM) has captured the imagination of the medical world, attracting both passionate advocates and ardent opponents. EBM is defined clinically as “the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.” Yet, its boldest claim is an ethical one: that EBM, rather than any other method, is the most effective way to fulfill our moral duty to help patients achieve better health. Academic debate on this point has been deeply polarized, from those who assert that ethical practice is evidence-based practice to those who argue that evidence-based practice impoverishes practice and robs it of ethical substance. Mainstream psychiatrists have endorsed EBM which holds out the promise of greater ethical legitimacy for psychiatric disorders and treatments through improved scientific substantiation. Evidence-based psychiatry arises through the straightforward application of EBM to the practice of psychiatry and thus shares the same ethical goal of EBM, to improve patients’ health. Given the ethical debates that have framed psychiatry since its
inception as a medical specialty, and the particular nature of mental disorders and their treatments, it is unclear if EBM can be applied to psychiatry, and therefore, whether it can deliver on its ethical promises. This thesis project involved two phases. The first, a conceptual phase, included an analysis of EBM’s ethical commitments as they are represented in its two authoritative textbooks (‘literal’ EBM). This provisional analysis was then extended by a qualitative analysis of the views of three groups of participants concerning the ethics of EBM: 1) EBM developers; 2) mental health practitioners; and 3) philosophers or bioethicists. Combining the analyses from both phases, a more complete depiction of the ethics of EBM was developed in order to address the main thesis question. Evidence-based psychiatric practice cannot be ethical practice by itself. Instead, it can play a small ethical role in clinical practice, only if it is situated within the larger value structure of contemporary medicine and psychiatry.
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Introduction

“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, yeah?”

Participant 2-10

1. Background to the thesis question

Over the last hundred years, medical researchers have expanded vastly our knowledge about the human body and its diseases. As a result, we hold deeply the belief that medical research is the route to further knowledge, and increased knowledge leads to better health. This direct connection between research, knowledge, and improved health found its most famous articulation in ‘evidence-based medicine’ (EBM). Developed in the early 1990s at McMaster University, EBM captured 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. EBM’s foundational definition remains, “…the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients” (Guyatt and Rennie 2002, 674). In order to determine which research data will provide the ‘best evidence’ -- that is, which are most likely to support truthful conclusions about interventions -- EBM relies on a ranking of research methods from what it deems to be the most to the least reliable methods. This

\footnote{For a description of the anonymization of participants, see chapter 5, page 153.}
‘evidence hierarchy’ ranks individual research studies in terms of whether they have employed methods that are likely to yield valid data.

EBM is a complex and elastic concept whose principal aims vary from a general desire to enhance patient care and satisfy patients’ preferences to specific goals of improving identified health outcomes and eliminating the use of ineffective interventions. However, several commentators point out that, by EBM’s own standards, there is no evidence that EBM can achieve these goals. The EBM approach to medical practice has been criticized for not substantiating, by evidence-based means, its basic claim that it is more effective in improving health outcomes than what preceded it (Norman 2003, 129-30; Shahar 2003, 134). This lack of substantiation forces EBM to justify itself philosophically, which it does through an implicit ethical mandate – that we should practice EBM. EBM assumes that the evidence hierarchy is the best path to knowledge about which medical interventions are effective. To practice anything but EBM would abrogate the ethical duty of practitioners to provide the most effective treatments (Gupta 2003). At the same time, as the opening quotation illustrates, practitioners have ethical duties which are not necessarily grounded in evidence (empirical data).

EBM’s popularity has spread beyond internal medicine (the medical specialty for which it was originally conceived) to other clinical disciplines, including psychiatry (Geddes and Harrison 1997; Paris 2000). In fact, evidence-based psychiatry - the straightforward application of EBM to the practice of psychiatry - has received enthusiastic endorsement from psychiatrists. Both popular and scholarly depictions of harmful or even abusive
psychiatric treatments in the recent past continue to capture the public imagination and still undermine psychiatry’s claim to legitimacy as a medical discipline (Kesey 1968; Szasz 1974). 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.

What then is the relationship between ethical practice and evidence-based practice in medicine and in psychiatry? As noted, EBM’s authors imply a special relationship between the two. Some of the literature concerning the relationship between ethics and EBM focuses on the ethical consequences of using or not using best evidence in practice. Goldenberg argues that the parameters of this relationship could be expanded considerably by examining the ways that ethical values are relevant to knowledge production (2007, 62-3). This expansion would encourage examination of the contextual values -- values external to the EBM program -- which are part of the social context in which EBM operates. Several scholars have pointed out the values, either implicit or explicit, operating at all phases of research including the generation, dissemination, and interpretation of data (Downie, MacNaughton, and Randall 2000; Eysenck 1994; Gilbody and Song 2000). These values include judgments about which research questions and health outcomes should be studied and/or funded for study; questions about how to present data, which conclusions ought to be presented, published, and emphasized (or not); and how data ought to be situated within the larger body of knowledge, including
such issues as when data are sufficiently plentiful to change practice or insurance
coverage. We can also attempt to discern internal ethical values, those that are part and
parcel of determinations of what counts as evidence, how choices about research methods
are relevant to what kinds of suffering are deemed worthy of knowledge, and the level of
uncertainty that is tolerable in deeming an intervention effective or not. These
examinations of EBM’s ethics have the potential to modify significantly proponents’
view of EBM as a value-free approach to clinical decision-making. A critical analysis of
EBM suggests a more complex picture of EBM as reflecting certain values as well as
being constituted by certain values (Borgerson 2008, 40-41).

Evidence-based psychiatry is equally implicated in this general analysis of the
relationship between ethical practice and evidence-based practice. However, there are
also specific reasons to be concerned about evidence-based psychiatry. Emerging as it
did with internal medicine (and its emphasis on large-scale clinical trials of
pharmaceutical agents), EBM makes certain assumptions that may not be applicable to
psychiatric disorders or their treatments. To the extent that psychiatry does not conform
to these assumptions, the application of EBM to psychiatry is more likely to be fraught
with epistemological and ethical problems as compared to other branches of medicine.
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 an
ethical mandate to practice evidence-based psychiatry may itself be ethically suspect.
The aim of this thesis is to address the question of whether evidence-based psychiatric practice is ethical practice. As such, I will 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, but in this thesis I wish to focus attention on the very context for which EBM was originally conceived, the individual doctor-patient encounter. Many of the ethical concerns I will discuss are common to all health disciplines where EBM has been utilized. However, my primary concern will be with psychiatry, where persistent and charged ethical debates about the uses and misuses of power remain a fundamental backdrop to contemporary practice.

This thesis project adopts a mixed methods (conceptual and qualitative) approach, and consists of three primary sections followed by my conclusions and future directions. In the first section, chapters one through three provide the exploration and analysis that serve as the conceptual arm of the study. The objectives of these chapters are to define terms and examine concepts as depicted in EBM’s two authoritative texts, the *Users’ Guides to the Medical Literature*\(^2\) and *Evidence-Based Medicine: How to Practice and Teach EBM*. I will supplement my examination of these texts through critical engagement with the existing literature on ethics and EBM. As such, these chapters represent my own analysis of the ethics of ‘literal’ EBM and evidence-based psychiatry. EBM is an approach that continues to evolve and many of its originators remain involved with its ongoing development. As a result, a conceptual analysis of the ethics of ‘literal’

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\(^2\) The *Users’ Guides* is now in its second edition (2008) under the same name but with two additional editors. In this thesis I mainly reference the first edition (2002), particularly for specific quotations. The substantive concepts remain unchanged between editions.
EBM can be usefully extended by a qualitative analysis of the views of EBM developers and EBM critics.

Chapter four begins the second section. Here I will describe the methods used to obtain interview data about the ‘ethics of EBM’ in thirty-three individual interviews with three groups of participants: group one who are EBM developers (nine participants); group two who are scholars engaged in the development, implementation or critique of evidence-based psychiatry (eleven participants); and group three who are philosophers or bioethicists involved in the scholarly debate about EBM (thirteen participants). Chapters five and six offer a description and analysis of participants’ views of the ethics of EBM. Chapters five and six will explore and analyze participants’ beliefs about the ethical assumptions, commitments and implications of EBM. In the third section, chapter seven will provide an enriched analysis of the ethics of EBM using both the textual and human sources of the previous chapters. In this chapter, I will discuss this analysis in light existing literature on EBM and ethics. I will present a framework of the ethics of EBM that takes into consideration the issues emerging from the analysis of ‘literal’ EBM along with the views of those who have witnessed or been involved with the implementation of EBM in practice. Chapter eight offers conclusions and future directions for research.

The main question of this thesis invites the consideration of several component concepts: evidence, medical knowledge, 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. I am aware that
these debates lie in the background of this thesis question, and that each of these concepts and questions merits a thorough analysis on its own. But, a detailed philosophical examination of each is beyond the scope of this project. 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. Given that these component concepts themselves have generated vast philosophical consideration, it will be unsurprising that ‘evidence-based medicine’ proves to be a contested construct itself, both in the literature, and amongst those most expert in its meaning and use. Nevertheless, this lack of clarity surrounding the concept of EBM exposes some of what is assumed about these basic concepts when evidence-based medicine is applied to clinical psychiatric practice. Awareness of these assumptions in turn helps to address the thesis question, whether evidence-based psychiatric practice is ethical practice.

2. The argument ahead

Chapter One – What is Evidence-Based Medicine?

This chapter will attempt to define some key terms of the debate into which I will be entering. The most important of these terms are ‘evidence-based medicine’ and ‘evidence’. In defining these terms, and in representing EBM in general, I will remain as close to the programmatic descriptions as possible by drawing almost exclusively upon the original texts as source material. I will then examine the five steps that comprise the practice of EBM. I will review the debate that has emerged in the scholarly literature,
particularly as it concerns EBM’s basic concepts and its practice. In this review, I will focus most of my attention on the clinical literature while drawing upon some works from other academic disciplines. It is this chapter that points out how some of the most urgent concerns in the debate about EBM are in fact ethical ones.

**Chapter Two – Psychiatry and Evidence**

In chapter two I will continue to examine concepts central to this thesis including psychiatry, mental disorder, and treatment. The first section of this chapter will discuss 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 will argue that the intellectual context of psychiatry 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 in its diagnostic and treatment practices. The second section of this chapter will explore how 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. I will argue that adopting EBM, which seems to put psychiatry on firmer scientific and ethical ground, actually 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. This discussion leads directly to the question of the next chapter, whether the adoption of EBM helps psychiatry to resolve its ethical problems, whether it leads psychiatry to ignore its ethical problems, or whether it actually creates new ones.
Chapter Three – Ethics and Evidence in Psychiatric Practice

Putting together the analyses developed in chapters one and two (which cover EBM, evidence, and psychiatry), I am ready to impose one further layer of investigation, that being an ethical analysis of EBM. The first part of this chapter will explore the values that are embedded in EBM and the ethical theory reflected by those values. Following a discussion of some of the major ethical issues involved in psychiatric practice, I will investigate whether EBM’s ethical stance helps or hurts psychiatry in its attempt to resolve these ethical issues. I will argue that EBM’s ethics are insufficient to be of much help to psychiatry and thus, evidence-based practice cannot be definitive of ethical practice in psychiatry. This chapter will offer a provisional ethical analysis of ‘literal’ EBM which will be compared to the emerging analysis of participants’ views in chapters five and six.

Chapter Four – A Qualitative Investigation of the Ethics of EBM: Research

Approach and Methodology

In this chapter I will provide a rationale for the empirical, qualitative component of this project, along with a detailed description of the overall methodological approach and its techniques, and a discussion of the interpretive framework that will be brought to bear upon the data. I will review the ethical considerations for this part of the research, including informed consent, confidentiality, anonymity, and post-participation engagement with participants. Examples of my information letter, consent form,
Chapter Five – Interpretation and Analysis: What is EBM? Conceptual Clarification

A somewhat surprising and noteworthy outcome of the interviews is the amount of data generated by participants about how to define EBM and evidence. This proved to be so extensive, that I chose to devote an entire chapter to reviewing these concepts again and analyzing participants’ understanding of these concepts. Here, however, we are free from the original texts and are able to examine the definitions provided by participants. Striking convergence about the definition of EBM tended to occur between proponents of EBM, regardless of the group to which they belonged, whereas critics offered a variety of different definitions. The major battleground over what EBM actually is emerged over two main issues: 1) Is evidence simply one consideration among equals (with patients’ values and clinical expertise being the others) in clinical decision-making or does it trump these considerations?; and 2) Does EBM, as currently defined, foster or erode critical thinking? Both proponents and critics want to claim critical thinking (as distinct from critical appraisal, steps 3 and 4 of evidence-based practice) as their own.

Chapter Six – Interpretation and Analysis: The Relationship Between Ethics and EBM

In this chapter, I explore the various ways in which participants described the ethical commitments and implications of EBM. I adopted a ‘centripetal’ approach in which I
examined the values from those most external to EBM (those which are part of the social, professional or institutional contexts in which EBM must operate) to those that are central or internal to the generation of evidence, particularly as understood within the EBM framework. Ethical values enter into this discussion in very particular ways for psychiatry in light of its controversial history and the contested nature of psychiatric disorders themselves. At the end of the chapter I will compare the emerging model of the ‘ethics of EBM’ with the model I argued is implied by ‘literal’ EBM, described in chapter three.

Chapter Seven – Discussion

Although chapters five and six raise the main analytic themes emerging from the data, chapter seven affords me the opportunity to try to integrate the analysis of the first three chapters (‘literal’ EBM) with the analysis of the interviews (chapters five and six). Having integrated the two sources (textual and human), my aim here is to provide a modified and enriched depiction of the relationship between ethics and EBM in order to address the main thesis question: Is evidence-based psychiatric practice, ethical practice? Following chapter seven, I will offer conclusions, limitations and future directions.
References


Chapter One

What is Evidence-based medicine?

1. Definition of EBM

Evidence-based medicine (EBM) is a concept that has come to dominate the medical literature in the last fifteen years. Coined in 1990 by Gordon Guyatt, then the director of residency training for internal medicine at McMaster University, the phrase first appeared in an information document for prospective applicants to the residency program (Guyatt and Rennie 2002, xiv). A 1992 article in *JAMA* introduced EBM to the medical world at large (EBM Working Group, 1992). From these origins, the concept has become widely influential in medical education, clinical practice, research, and health policy (Grossman and McKenzie 2005, 6; Ghali et al. 1999, 133-34; Noseworthy and Watanabe 1999, 230). EBM has been taken up throughout the medical specialties and the allied health disciplines. In 2007, the *British Medical Journal* included EBM among a list of 14 other medical breakthroughs as the most important discoveries in medicine since 1840 (Morrison 2007). It has even received attention in the popular press: in 2001, the *New York Times Magazine* voted EBM one of the best ideas of the year (Hitt 2001).

EBM is still a relatively young idea and some of its originators remain actively involved in its development. The original authors have, with additional collaborators, produced two authoritative textbooks of EBM. The first, the *Users' Guides to the Medical Literature*³, is an edited collection, penned by the fifty-member EBM Working Group, of

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³ Hereafter, *Users' Guides*
a series of articles under the same title which appeared in the *Journal of the American Medical Association (JAMA)* between 1992 and 2000. It is now in its second edition. The second, *Evidence-Based Medicine: How to Practice and Teach EBM*[^4] (2005), is now in its third edition. This edition is written by four authors, not all of whom were involved in previous editions. Yet, they all contributed to the original articles upon which the *Users’ Guides* is based.

In *Evidence-Based Medicine*, practicing EBM is described as a five-step process. By contrast, the *Users’ Guides* focuses on steps 2 and 3 of EBM, the component called ‘critical appraisal’ of the medical literature. Given the authorial overlap, there is consistency in content between the texts. In fact, *Evidence-Based Medicine* references the *Users’ Guides* as a more detailed account of the whole program. Nevertheless, one text may contain information lacking in the other. As a consequence, for the remainder of this thesis, I will refer to both the *Users’ Guides* and *Evidence-Based Medicine* as the two primary sources of the details of EBM concepts and practice.[^5]

Straus and others write that evidence-based medicine requires, “…the integration of the best research evidence with our clinical expertise[^6] and our patient’s unique values[^7] and

[^4]: Hereafter *EBM*
[^5]: Sackett, the lead author on the first two editions of *EBM*, is considered by many to have been the original and leading proponent of EBM in its current form.
[^6]: Straus et al. (2005, 1) define clinical expertise as, ‘…the ability to use our clinical skills and past experience to rapidly identify each patient’s unique health state and diagnosis, their individual risks and benefits of potential interventions, and their personal values and expectations.’
[^7]: Patient values are defined as, ‘…the unique preferences, concerns and expectations each patient brings to a clinical encounter and which must be integrated into clinical decisions if they are to serve the patient’ (Straus et al. 2005, 1).
circumstances
d
" (Straus et al. 2005, 1). This statement exists in parallel to the original definition (Guyatt and Rennie 2002, 674): “Evidence-based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research.” In describing EBM’s origins, the *Users’ Guides* endorses a description of EBM as:

…an attitude of “enlightened scepticism” toward the application of diagnostic, therapeutics, and prognostic technologies in [the] day-to-day management of patients…The goal is to be aware of the evidence on which one’s practice is based, the soundness of the evidence, and the strength of inference the evidence permits. The strategy employed requires a clear delineation of the relevant question(s); a thorough search of the literature relating to the questions; a critical appraisal of the evidence and its applicability to the clinical situation; and a balanced application of the conclusions to the clinical problem.

(Guyatt and Rennie 2002, xiv)

Sehon and Stanley (2003) argue that some EBM proponents interpret these definitions to include all that counts as good medical practice, allowing them an inclusive but empty response to the question of what EBM is exactly. On the other hand, the sizeable and varied critical responses to EBM suggest that it is not merely a vacuous definition but includes substantive elements which opponents have challenged.

The conceptual centrepiece of all of these definitions is the term ‘evidence,’ since it is upon evidence that medicine is to be based. The *Users’ Guides* provides this definition of “potential evidence”: “any empirical observation about the apparent relation between

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8 Patient circumstances are defined as ‘…their individual clinical state and the clinical setting’ (Straus et al. 2005).
events” (Guyatt et al. 2002, 6). *Evidence-Based Medicine* does not define evidence but does provide the following description of “best research evidence”: “…valid and clinically relevant research, often from the basic science of medicine, but especially from patient-centred clinical research into the accuracy and precision of diagnostic tests (including the clinical examination), the power of prognostic markers, and the efficacy and safety of therapeutic, rehabilitative, and preventive regimens. New evidence from clinical research both invalidates previously accepted diagnostic tests and treatments and replaces them with new ones that are more powerful, more accurate, more efficacious, and safer” (Straus et al. 2005). Both sentences are included as part of the description of EBM although the second sentence goes beyond clarifying what is meant by best research evidence to explaining what the authors hope evidence will be used to do.

The phrase ‘clinically relevant research’ (as part of the explanation of ‘best research evidence’) is specified further by the evidence hierarchy. The hierarchy is a ranking of research methods from those that are most to least likely to yield truthful conclusions about the subject of research. The *Users’ Guides* provides the following ranking of research methods that an evidence-based practitioner should use in order to evaluate articles about new treatments⁹:
N-of-1 randomized controlled trial
Systematic reviews of randomized trials
Single randomized trial
Systematic review of observational studies addressing patient-important outcomes
Single observational study addressing patient-important outcomes
Physiologic studies
Unsystematic clinical observations\textsuperscript{10}

(Guyatt and Rennie 2002, 7)

Research data, generated by higher ranked methods supplants data generated by lower ranked methods. How or if unlisted research methods fit into the hierarchy is not explained.

\textit{Evidence-Based Medicine} does not replicate the hierarchy; however, the text describes the research methods against which published studies should be judged. For example, according to the manual, an individual study of a new treatment that was double-blind, randomized and controlled would be of the highest standard; trials that included some but not all of these criteria would fall somewhat below the standard and so forth. Other sources list hierarchies that differ somewhat from this one demonstrating the evolution in some of the basic concepts and understanding of EBM (Upshur 2003). Evolution is neither surprising nor problematic, but does raise the issue of how practitioners should determine which versions of EBM, and its core concepts, to use in practice.

One significant omission in the definition of EBM emerges from the fact that in the phrase evidence-based medicine, ‘evidence-based’ is used as an adjective, implying that there is another term, ‘medicine’ which represents something distinct from EBM. The

\textsuperscript{10} There are new versions of the hierarchy being developed. For example, see: http://www.cebm.net/index.aspx?o=1025
Users’ Guides does contrast EBM with “the traditional paradigm of medical practice…” and states that, “intuition, unsystematic clinical experience, and pathophysiologic rationale are insufficient grounds for clinical decision-making…” (Guyatt et al 2002, 4). This statement implies that prior to EBM, medicine was dominated by the use of these three sources of information in clinical decision-making. Likewise, Evidence-Based Medicine does not formally define ‘medicine,’ but in its preface the book describes how each author became acquainted with the ideas behind EBM and contrasts these ideas with their previous experiences of medicine. For one author, being challenged to “provide evidence to support her management plans for each patient” is contrasted with situations where “the management plan was learned by rote and was based on whatever the current consultant favored” (Straus et al. 2005, xii). For another author, when asking a lecturer for the evidence in support of theories he was presenting, the speaker replied that, “…there wasn’t any good evidence, and that he didn’t believe the theories, but he had been asked by the head of the department ‘to give the talk.’” (Straus et al. 2005, xiii).

Evidence-Based Medicine also contrasts authoritative advice (evidence-based) with authoritarian advice (opinion-based) (Straus et al. 2005, 5). These characterizations of non-EBM or pre-EBM medicine imply something additional to what was suggested in the Users’ Guides notion of traditional medical practice: that medicine involves an uncritical acceptance of information, determined primarily by power relations and cultural predispositions.

The principal accounts of EBM provide little further explanation of EBM’s core concepts. There are allusions to key philosophical commitments such as positivism and
Positivism, a philosophical position popular in the early 20\textsuperscript{th} century, posited that only empirically-verifiable statements could have meaning. This position was eventually discredited in the philosophy of science because of its failure to demonstrate that there was a single logic for all of science. However, it remains a philosophical root of EBM from its quest for ‘truth’ through evidence: “…any \textit{empirical} observation about the relation between two events,” (Guyatt and Rennie 2002, xxi; 50) and its negation of other sources of knowledge, especially non-empirical ones, as potentially evidentiary.

Consequentialism is the ethical theory stating that the moral value of an action is found in its consequences. Utilitarianism is a form of consequentialism in which moral value is located in the amount of utility (often defined as happiness or pleasure) or disutility, resulting from an action. These theories form the ethical backbone of EBM and its commitment to them is evident in its emphasis on doing more good than harm, and in its specific use of the language of utility and disutility (Guyatt and Rennie 2002, 57; Straus et al. 2005, 38). In fact, EBM links these two theories by associating a failure to use what is known empirically to be ‘true’ (about medical interventions) with a failure to offer patients the best means of achieving health (and therefore, utility).

Haynes, a leading EBM originator, has pointed out that some central conceptual and ethical questions remain unaddressed by EBM and require attention (Haynes 2002). Some of these philosophical commitments and conceptual questions will be discussed more fully in subsequent chapters. This chapter will go on to summarize how EBM is applied to actual clinical practice, as described in \textit{Evidence-Based Medicine} and the \textit{Users’ Guides}. 

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2. The practice of EBM

EBM is a complex concept, proposing multiple things at once. It promotes a method for formulating and finding answers to certain types of clinical questions arising in patient care. More specifically, it provides criteria by which to judge the capacity of research studies to yield truthful answers to these questions (a process called critical appraisal). It also suggests a method of making clinical decisions, particularly those involving the use of diagnostic tests and treatments. Through the evidence hierarchy, which ranks research methods according to validity, EBM can act as a powerful force in shaping if not determining, which research questions are investigated and how they should be investigated.

The practice of EBM involves a five-step strategy:

Step 1 - converting the need for information (about prevention, diagnosis, prognosis, therapy, causation etc) into an answerable question

Step 2 - tracking down the best evidence with which to answer that question

Step 3 - critically appraising that evidence for its validity (closeness to the truth), impact (size of the effect), and applicability (usefulness in our clinical practice)

Step 4 - Integrating the critical appraisal with our clinical expertise and with our patient’s unique biology, values and circumstances

Step 5 - evaluating our effectiveness and efficiency in executing steps 1 – 4 and seeking ways to improve both for the next time

(Straus et al. 2005, 3-4).
The text of the *Users’ Guides* covers similar material although does not lay out these five steps. It focuses primarily on step 3 (critical appraisal), devoting a small portion of text to steps 1 and 2. Inter-author agreement between the two texts is apparent in the frequent references made in *Evidence-Based Medicine* to the *Users’ Guides* and to articles written by members of the EBM Working Group. The description below will provide an overview of the five steps of evidence-based practice and will draw on both texts.

2.1. Step 1 – Asking answerable questions

Asking answerable questions refers to constructing content-driven questions about specific medical topics. This step groups most questions into two types: “background” and “foreground.” Background questions concern themselves with disease entities and take the following form: 1) a question root with a verb, and 2) some aspect of the disorder itself. For example: ‘what causes panic disorder?’ Foreground questions have four components: 1) the patient and/or problem of interest, 2) the main interventions, 3) comparison intervention (if relevant), and 4) the clinical outcome of interest (Straus et al. 2005, 16). For example: In adults with major depression, is an antidepressant more likely to relieve symptoms as compared to cognitive-behaviour therapy? *Evidence-Based Medicine* acknowledges that questions about patients’ experiences may also be of importance. Apart from claiming that these questions are best studied by qualitative research and that integrating qualitative research “remains a challenge” for EBM, there is no further discussion of any other types of questions.
The *Users’ Guides* provides a very similar discussion of question formulation in the chapter entitled, “Finding the Evidence,” including the use of the same terminology (‘background’ and ‘foreground’ questions), and the same structures for these types of questions. In addition, this text states that, “There are four fundamental types of clinical questions. They involve: therapy, harm, diagnosis and prognosis.” (McKibbon et al. 2002, 20) The *Users’ Guides* points out that background questions are likely to be best answered by medical textbooks whereas *Evidence-Based Medicine* advises the reader to, “burn your traditional textbooks” (Straus et al. 2005, 32).

*Evidence-Based Medicine* implies that the main advantage of these formulae is that they conform, to the greatest extent, to the ways that research questions in medical studies are asked and indexed by standard medical databases. It is in this sense that the notion of asking “answerable” questions is so important. The questions must be ones for which answers, at least potentially, can be found in the medical research literature. *Evidence-Based Medicine* reports that our “mental and emotional responses to realizing that our patient’s illness call for knowledge we don’t posses” can be alleviated by “…well-built clinical questions and learning how to find the answers” (Straus et al. 2005, 18-9). According to *Evidence-Based Medicine* the benefits of this strategy are clear: “When our questions get answered, our knowledge grows, our curiosity is reinforced, our cognitive resonance is restored, and we can become better, faster, and happier clinicians” (Straus et al. 2005, 23). There is no discussion of questions that are difficult to answer, unanswerable, or not well-formulated using these two templates.
2.2. Step 2 – Finding evidence

Finding evidence, according to Evidence-Based Medicine, should be done in accordance with the “4S” hierarchy, which ranks sources of information. These sources, from highest to lowest include: systems (computerized decision support systems), synopses (evidence-based journal abstracts), syntheses (Cochrane reviews), and studies (original published articles in journal). Systems are computer programs that summarize the data about a clinical problem, and ideally, link to electronic medical records, prompting the clinician about data relevant to that patient’s diagnosis and/or treatment. Properly designed, these programs should be automatically updated when new data regarding problems are available. Evidence-Based Medicine authors believe that no ideal system is yet available; we must rely on computer programs that function as regularly-updated databases of ‘graded’ research data on a variety of clinical topics. Synopses refer to publications that select and summarize high-quality studies, where quality is defined according to how closely the study adheres to EBM criteria such as the evidence hierarchy. Syntheses are databases of systematic reviews exemplified by the Cochrane library, selected by the authors and judged according to explicit criteria. Studies refer to original studies as published in academic journals. The Users’ Guides also mentions the 4S strategy but in an introductory chapter rather than the chapter concerned with searching for evidence. Instead, this text specifically recommends the use of a variety of ‘pre-filtered’ sources of evidence -- that is, sources that summarize studies that conform to the same criteria recommended by Evidence-Based Medicine. Two sources highly recommended by both texts – the ACP Journal Club and the journal Evidence-Based
Medicine – have, as their editor, an individual who is also author of (the book) Evidence-Based Medicine and a contributor to the Users’ Guides.

If pre-filtered sources do not provide the information that readers are seeking, both texts suggest that the reader conduct his/her own ‘unfiltered’ search of MEDLINE. However, Evidence-Based Medicine rates original studies as the least useful form of information in the practice of EBM.

2.3. Steps 3 and 4 - Critical appraisal and integration

In Evidence-Based Medicine, Steps 3 (critical appraisal) and 4 (integration) are combined, while in the Users’ Guides the steps are not described as such. The latter book does, however, outline the same content as found in the descriptions of steps 3 and 4 in Evidence-Based Medicine. For studies concerning diagnosis, prognosis, therapy, and harm, both texts lay out criteria for assessing the quality of a given study. There are also specific criteria depending on whether a study is evaluating a diagnostic test, the prognosis of a condition, or the effectiveness or harmfulness of an intervention. However, for any type of study, readers are directed to ask three fundamental questions: 1) are the results valid?; 2) what are the results (what is the size of the effect)? (Guyatt and Rennie 2002, 51); and 3) how can I apply these results to patient care (or to a specific patient)? (Straus et al. 2005, 4). For the authors of Evidence-Based Medicine, this last question -- determining applicability-- is connected to integration. “To apply evidence, we need to integrate the evidence with our patient’s values and preferences.” (Straus et al. 2005, 132) The Users’ Guides does not describe ‘integration’ as a term, but does
discuss how to apply results to patient care. It also introduces a new term, ‘incorporation,’ of patients’ values which will be described in more detail below.

The process of critical appraisal does not begin with an analysis of original data produced by a given study’s authors. Instead, readers are supposed to begin by using certain criteria to determine what conclusions, if any, can be derived from these data. Even the more detailed *Users’ Guides* does not require readers to determine whether the data analytic techniques, most commonly statistical methods, were appropriately chosen or correctly employed. The practice of EBM is based solely on following the procedure discussed below. “Although Part 1 of this book is concise, after you have mastered its concepts you will be able to ensure that your practice is evidence-based” (Guyatt 2002, xii).

Each type of study (diagnosis, prognosis, therapy and harm) has specific rules or criteria which determine the validity and importance of their results. I will not discuss each set of rules in detail. Instead, I will focus on the rules that are applicable to all types of studies. At times, I will examine specifically the rules governing therapy as these are the rules most applicable to psychiatry where most of the existing evidence is generated through studies of treatments.

To determine a study’s validity is to assess how “close is it to the truth” (Straus et al. 2005, 4). In order to make this determination, the reader must assess a study’s design. According to both texts, certain designs are associated, inherently, with greater validity
because they minimize bias. Bias is a “systematic tendency to produce an outcome that differs from the underlying truth.” (Guyatt and Rennie 2002, 666) For studies of treatment, randomized controlled trials, preferably those that are double-blinded, are considered to be the most likely to yield truthful results. In addition, the study groups have to be prognostically similar and their follow-up has to be sufficiently long. Apart from receiving different experimental treatments, groups should be treated equally. The rules for assessing validity also include aspects of data analysis: participants should be analyzed as belonging to the groups in which they started, regardless of what actually happened in the course of the study (intention-to-treat analysis).

The size of a study’s effect refers to the magnitude of difference made by an intervention and is to be determined by the absolute change attributable to the intervention under study. Readers are encouraged to seek out translations of the reported data into clinically meaningful numbers such as the “number needed to treat – NNT” (the inverse of the absolute risk reduction). Precision of effect is also critical to assessing importance. The texts recommend the use of confidence intervals - the statistically plausible ranges for specific values to fall within - to determine precision.

There are multiple meanings to sub-step 3, “how to apply the results?” The first issue under applicability is whether one’s patients are sufficiently biologically and psychosocially similar to those who participated in the study under review that the results

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11 ‘The number of patients who would need to be treated over a specific period of time to prevent one bad outcome,’ (Guyatt and Rennie 2002, 680).
can be generalized to them. The second question concerns feasibility, which is specifically discussed in terms of affordability or availability (Straus et al. 2005, 79, 133). The third issue under applicability is whether patients are willing to accept the proposed interventions -- that is, whether these interventions are consistent with their values. Application and integration are achieved by answering the questions laid out above. These questions are somewhat different than those under validity and importance in that they cannot be answered by following specific rules but require reasoning skills and/or knowledge of local conditions. The last aspect of applicability – compatibility of patients’ values with proposed interventions – requires communication with patients and the ability to discern values from clinical conversation. Both texts lay out quantitative methods (decision analysis) of eliciting and ranking patient preferences for certain health outcomes as a way of applying, integrating or incorporating patients’ values. These rankings are then combined with some of the figures above such as NNT to compute “likelihood of being helped to harmed” (LHH) ratios. This aspect of applicability involves identifying patients’ preferences and then determining whether these preferences do or do not match the probable outcomes of various interventions. Ultimately, patients’ preferences guide decision-making – both texts imply that these preferences trump any other (unnamed) considerations with the possible exception of cost.

2.4. Step 5 - Self-evaluation

Self-evaluation of EBM practice involves determining how well one is adhering to the directions given in performing the first four steps and can be broken down by asking oneself whether and how well one is performing each component of each step.
Evaluation questions based on what each step entails are listed in tabular form\(^\text{12}\) (Straus et al. 2005, 248-51). Unlike the other steps, the evaluation questions for step 4 do not map fully onto the actual content of this step. Recall that step 4 was to integrate one’s critical appraisal with our clinical expertise and with our patient’s unique biology, values and circumstances. However, the header for this group of self-evaluation questions reads: “A self-evaluation in integrating the critical appraisal with clinical expertise and applying the result in clinical practice.” In other words, between the text and the table, patients’ values are dropped. The questions themselves reflect this discrepancy: 1. Am I integrating my critical appraisals into my practice at all?; 2. Am I becoming more accurate and efficient in adjusting some of the critical appraisal measures to fit my individual patients (pre-test probabilities, NNT/f etc)?; and 3. Can I explain (and resolve) disagreements about management decisions in terms of this integration? In the *Evidence-Based Medicine* text, the techniques mentioned in question 2 (pre-test probabilities, NNT/f etc) are described as a means to apply study data to specific patients rather than to achieve the final aspect of applicability, i.e. integrating patients’ values.

\(^{12}\) ‘A self-evaluation in asking answerable questions
1. Am I asking any clinical questions at all? 2. Am I asking well-formulated questions: two-part questions about ‘background’ knowledge, four or three part questions about ‘foreground’ diagnosis, management etc
3. Am I using a ‘map’ to locate my knowledge gaps and articulate questions? 4. Can I get myself ‘unstuck’ when asking questions? 5. Do I have a working method to save my questions for later answering?’

‘A self-evaluation in finding the best external evidence
1. Am I searching at all? 2. Do I know the best sources of current evidence for my clinical discipline?

‘A self-evaluation in critically appraising the evidence for its validity and potential usefulness
1. Am I critically appraising external evidence at all? 2. Are the critical appraisal guides becoming easier for me to apply? 3. Am I becoming more accurate and efficient in applying some of the critical appraisal measures (such as likelihood ratios, NNTs and the like)? 4. Am I creating any appraisal summaries?’
While this section cannot do justice to the detail provided in these texts about the correct methods of EBM practice, it is noteworthy that the remaining detail is largely technical and invites the reader to master the concepts through examples and practical exercises. The practice of EBM is no more than these five steps, at least according to these recent and authoritative discussions. And it is these five steps, rather than their technical execution, that have provoked a significant response and counter-response from the medical profession and the allied health disciplines. In the next section, I will review this debate and identify some of the major conceptual limitations of EBM that have been raised.

3. The debate concerning the practice of EBM

EBM has provoked a response as widespread as its influence. Endorsements, analyses, and critiques have emerged from a variety of disciplines ranging from the clinical and statistical, to the philosophical and sociological. Much of the debate focuses on one or more elements of the first four steps of EBM. This section will provide an overview of some of the key debates that have arisen concerning these various components of EBM.

3.1. What’s new about EBM?

The debate begins with a challenge to EBM’s claims of radicalism and novelty. Originators of EBM have declared that it is nothing short of a paradigm shift (EBM working group 1992, 2420-21). This claim borrows directly from the language of the philosopher of science, Thomas Kuhn. By “paradigm” Kuhn meant an “entire framework
of concepts, results and procedures” within which science is conducted (Blackburn 1996, 276). A period of “revolutionary science” could lead to the abandonment of the prevailing paradigm and the acceptance of a new paradigm or framework. Given this characterization of “paradigm,” some commentators wonder whether EBM actually constitutes any real change from its alternative. First, they claim that EBM is not a new development because modern clinical practice has always relied upon scientific evidence (Benitez-Bribiesca 1999). Second, the fundamental tenets of modern medicine, such as the pathophysiological basis of disease, remain unchanged under EBM. To them, EBM is nothing more than an updated way of classifying and seeking out research data, facilitated by the widespread availability of information technologies. This has led some critics to state that EBM’s proponents are “arrogant and seductive” (Polychronis et al. 1996). In response, EBM advocates argue that the rapid availability of higher quality research data and the standardization of methods to appraise this data constitute a major change from pre-EBM practice, in which evidence included any kind of information physicians invoked to support their practices (Davidoff, Case, and Fried 1995; Sackett et al. 1996), and in which unsubstantiated practice strategies were transmitted and accepted uncritically.

The notion that proposed medical interventions should be supported by some form of scientific evidence of their effectiveness, is relatively uncontroversial, at least to those who practice within Western biomedicine (Worrall 2002). What is at stake is how evidence shall be defined and by whom? The critiques of EBM’s first and second steps
(deciding what questions are worth asking and how to find the answers to them) highlight the fact that what counts as evidence can be shaped by social forces.

3.2. Which data count as evidence?

Both steps one and two of evidence-based practice require that the search for evidence takes a particular form. EBM practitioners must ask answerable questions – that is, they must be phrased and researched in accordance with the practices of medical researchers, particularly those researchers who employ the research methods advocated by EBM. What is to be done with questions that are unanswerable or difficult to answer is a point not addressed by proponents of EBM. Steps one and two mean that the evidentiary pool from which research data are drawn for consideration is pre-determined and circumscribed by EBM strategies.

Several authors offer social constructionist critiques of EBM which argue that, rather than freeing us from biases, research data is created and shaped, at least in part, as a result of various social factors. These factors, such as source of funding bias and publication bias, can distort the kinds of research data that are produced, disseminated and available to be ‘tracked down’ using EBM strategies.

Sources of research funding have the potential to narrow the pool of data which is available to be considered as evidence. Studies of interventions with commercial value (e.g. pharmaceuticals or devices) are more likely to receive funding from the businesses which stand to profit, as compared to those interventions which have no such commercial
value (patient-implemented strategies including diet and exercise). As a result, there tends to be more evidence about commercially valuable interventions. Furthermore, techniques used by commercial funders such as ghost-writing\textsuperscript{13} further accelerate the dissemination and influence of industry-sponsored research data within the evidence base. Since EBM is about using the medical literature to determine which interventions are evidence-based, source of funding bias creates the potential for the medical literature to be skewed towards data favouring commercially valuable interventions, while data concerning non-commercially valuable data are less likely to be found (De Vries and Lemmens 2006).

Publication bias refers to the differential publication in medical journals of positive\textsuperscript{14} and/or statistically significant results (Black 1998; Blau 1997; Gilbody and Song 2000). As a result, the total body of available data to be considered as evidence is narrowed because only certain data are disseminated to practitioners through the medical literature. For example, in 2008, Turner and others determined that the majority of negative trials concerning an array of antidepressants had never been published (252-60). There are various ways that the published literature may reflect only certain kinds of results. First, journals themselves having an interest in selling more subscriptions, may wish to make their content more interesting to practitioners by publishing studies where the interventions under investigation are shown to be effective. Second, private companies

\textsuperscript{13} Ghost-writing is a technique used by research sponsors or contract research organizations. Results and analysis are written up into nearly-finished scientific manuscripts and the co-authorship is offered to established academic medical researchers at that stage. The academic authors may offer some or no input in the final manuscript. Some ghost-written manuscripts do not acknowledge authorship by the non-academic writers.

\textsuperscript{14} Positive results are results which show that there is a statistically significant difference in the effect of the study intervention as compared to the control intervention. Negative results are results which show that there is no such difference.
may choose not to submit for publication data they do not wish to see enter the public domain. Lexchin and colleagues (2003) have argued that data generated by commercial funders are more likely to demonstrate the effectiveness of the sponsored intervention than data generated by non-commercial funders. Through publication bias, clinicians may be exposed to a group of studies that misleadingly suggest the superiority of new interventions. Furthermore, publication bias can ultimately lead to the neglect of certain types of phenomena. Because publications count significantly towards researchers’ career advancement (Miettinen 1998), they may choose to study a restricted group of topics which are most likely to yield publishable results, that is, topics that do not fall in the ‘grey zones’ of clinical practice (i.e. practices whose usefulness is uncertain or for which older research data have been equivocal) (Naylor 1995).

Some authors have pointed to a clinical trial register as a possible solution to the problem of publication bias (Moher 1993; Chalmers et al. 1992). A register of all clinical trials intended or underway could ensure that it would not be possible to hold back any trial data from the public domain. For example, under this scheme, when preparing systematic reviews, authors would demonstrate that they examined data emerging from all relevant registered trials, rather than merely those that were published. To date, several national and corporate registers exist and the World Health Organization has developed a uniform set of standards for trial registration that apply to other trial registries (national or corporate). However, the extent to which this will decrease the impact of publication bias remains to be seen.
Technical bias is a greater limitation to EBM-preferred research data as it is an internal part of the structure of EBM rather than being driven by the needs of external parties such as journal editors, researchers or companies. Technical bias favours research that we know how to do and, thus, towards phenomena that we know how to investigate. Culpepper and Gilbert point out that the evidence hierarchy privileges certain types of data and certain types of research methodologies. As a result, phenomena not easily amenable to investigation by these privileged methods may be neglected or presumed unworthy of inquiry compared to those interventions best suited to the preferred methods (1999). For example, “practical evidence” (interpretation of experience) and clinical information derived from intuition and judgment in the clinical encounter are examples of knowledge which have, to date, been poorly integrated into EBM’s evidence (Buetow and Kenealy 2000; Knottnerus and Dinant 1997; Malterud 1995; Tanenbaum 1993). These phenomena could perhaps be more richly understood through a variety of research strategies including qualitative methods which are given only peripheral consideration by EBM proponents.15 As a result, such phenomena receive little research attention.

Alternatively, some phenomena may be inappropriately researched by EBM-preferred methods because these methods cannot adequately investigate them (Kerridge, Lowe, and Henry 1998). Psychodynamic psychotherapy, a mainstay of psychiatric practice for decades, has suffered in the EBM era because of the difficulties in demonstrating its effectiveness using EBM-preferred research methods such as randomized controlled

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15 Numerous scholars have suggested the inclusion of other research methods into the evidence hierarchy, whether they are qualitative (Barbour 2000; Dixon-Woods et al. 2001; Green and Britten 1998; Upshur 2001) or conceptual (Berkwits 1998). The JAMA Users’ Guide does contain a chapter on critically appraising qualitative research which suggests EBM’s nascent openness to these concerns.
trials. Where phenomena are a poor fit for EBM preferred methods, the interventions under investigation seem doomed to be inadequately evidence-based in perpetuity. For example, an RCT of psychodynamic psychotherapy would either have to distort the intervention so much in order to adhere to the methodological demands of EBM, that it may lack ecological validity, that is, it may no longer be a study of what practitioners actually do when they practice this type of therapy. If, on the other hand, this type of therapy could be studied using some alternate research design less favoured by EBM, according to EBM logic, the evidence in support of this intervention would always be considered tentative because an RCT had not been performed.

Numerous authors have acknowledged that, by the rules of EBM itself, there is no evidence that EBM is a more effective means of pursuing health than medicine-as-usual (Norman 1999). They point out that it might be methodologically difficult to support this claim using EBM-preferred strategies such as randomized double-blind controlled trials because of the difficulties in adhering to these requirements in conducting such a study. In other words, technical bias is so powerful, it prevents EBM from justifying itself. Technical bias, then, can skew the total pool of evidence in favour of interventions that are easy to investigate or amenable to quantification, and away from interventions or practices that do not easily fit into the EBM conception of research and evidence. This bias is an inescapable part of EBM as the evidence hierarchy is fundamental to EBM’s epistemological position.
The first two steps of evidence-based practice -- asking answerable questions and tracking down the best evidence to answer a question -- are constrained by what is available to be found. If the total pool of data is narrowed by a variety of distortions, our evidentiary base is lacking.

3.3. What can EBM’s evidence actually tell us?

EBM rests on a bold epistemological claim: if we pursue EBM we will arrive at the most effective means of achieving health. This claim rests on two assumptions: 1) if we pursue the truth we will arrive at the most effective means of achieving health; and 2) if we adhere to EBM’s rules we will maximize the likelihood of arriving at the truth. Discussion of the first assumption has not figured prominently within the debate about EBM. Within Western biomedicine there is a general acceptance that a more scientific (truthful) understanding of disease and human bodies has increased our ability to develop successful medical interventions that have improved health and has replaced previous unsuccessful interventions. Rather, it is the second assumption -- that EBM is our best hope to achieving further truths about disease and medicine -- that has come under fire, and in a variety of ways. In other words, within medicine we accept that a scientific realist’s perspective will improve our knowledge of disease which in turn can be used to develop more effective medical interventions to improve health. What is in doubt is whether EBM is the best way to get us there.

Some scholars focus on the methodological and statistical problems which plague RCT’s and meta-analyses of RCT's (Eysenck 1991; Feinstein and Horwitz 1997; Grossman and
McKenzie 2005; Horwitz 1996; Lau, Ioannidis, and Schmid 1998). According to these authors, poor study design and faulty execution yield flawed data which cannot be considered valid and from which accurate inferences cannot be drawn. Proponents of EBM acknowledge that poor quality research limits validity of data and have called for better-designed studies (Miké 1999). For these authors, EBM’s rules are not flawed, rather some researchers design flawed studies. If researchers improve their study designs, the second assumption behind EBM’s epistemological claim would be correct.

Technical bias, discussed above, may also render research data invalid. By requiring every medical phenomenon in the domains of diagnosis, prognosis, treatment and harm to be investigated using EBM-preferred research methods, it is quite likely that some of these phenomena are not being very well investigated at all. As a result, data produced by such studies may be invalid. However, EBM does not suggest any rules to assist in evaluating the goodness of fit between a specific phenomenon (such as the clinical impact of psychodynamic psychotherapy) and a study design. Instead, EBM contends that there is one design appropriate for all interventions in a given class (e.g. highest quality studies about treatment should be double-blind RCTs). If a study about a given phenomenon does not meet the criteria, then EBM’s solution is to consider the emergent data tentative until a study is conducted according to the preferred design. The possibility that one might have to use non-EBM preferred methods to generate better quality data is never considered within EBM. In this way, adhering to EBM preferred-methods can lead to data that are less likely to be accurate than if one followed other methods.
A major challenge to the idea that following EBM’s rules will bring us closer to the truth about healthcare interventions has been launched by scholars who highlight the philosophically contested nature of probability and the disputes over the meaning of the statistical calculations of probability. Probability is the mathematical foundation upon which quantitative medical research rests. Empirical research is necessarily inductive since it aims to broaden our knowledge and create generalizations beyond the specific objects of inquiry. As such, it is not capable of generating ‘truth.’ Instead, its conclusions must be understood in probabilistic terms. However, there are multiple interpretations of what probability means and how it should be applied to real calculations (Goodman 1999). In medical research, this dispute plays out most sharply in disputes between Bayesian and frequentist thinking about statistics. Bayesian probability, based on the 18th century work of the Reverend Thomas Bayes, is a measure of one’s subjective belief. For frequentists, probability is objective and reflects a true state of nature, independent of what any observer believes. Supporters of EBM aspire to generate data that reflect the state of nature: Does this treatment work (or, is it likely to work) in reality? Thus, the frequentist strategy of hypothesis testing is a prevalent and recommended form of data analysis with EBM-preferred research methods. What neither EBM text tells readers is that this technique is intended to be objective but only permits long-run inferences, inferences based on the assumption of infinite replication of an experiment rather than on one experiment such as a single RCT (Goodman 1999, 998). Hypothesis testing cannot be used to measure the strength of the evidence in an experiment as it does not reflect the underlying data in the experiment. These deficiencies run directly contrary to one of EBM’s goals -- enabling the reader to identify
practice-changing research studies. How can an RCT ever be practice-changing when the mathematical techniques used to generate its data do not permit conclusions from a single experiment?

Another example of a challenge to the assumption of EBM rules being more likely to yield valid data lies in the ongoing debate about randomization. Recall that data from randomized controlled trials (or meta-analyses of such trials) rank as the highest form of evidence according to the evidence hierarchy. Does randomization improve the validity of research? Randomization allegedly balances both known and unknown confounding variables; as a consequence, randomization is advocated by EBM proponents as an essential aspect of high quality research. Whether it actually does lead to less bias in clinical trials is a subject of some debate (Urbach 1993; Worrall 2002; Worrall 2004). Worrall (2004) argues that randomization can only lead to balanced groups (balanced in the sense of one group not systematically including a confounding variable) with infinite replications and that in any one experiment there will likely be confounding variables that are distributed in an unbalanced way between groups. Since some confounders are acknowledged to be unknown, there is no way of knowing if this has happened in a specific experiment. In this case, a randomized design bears no clear advantage over a well-conducted observational design and may even have certain disadvantages. On this argument, the contention that data from a randomized study should be automatically privileged over an observational study may actually lead to less accurate data.
Extending Worrall’s analysis, several scholars have challenged recently the evidence hierarchy, the concept most clearly associated with EBM. Indeed, EBM proponents remind us that the existence of the hierarchy of evidence is the first “fundamental principle” of EBM (Guyatt, Haynes et al 2008, 10). Bluhm (2009) has challenged the automatic privileging of RCTs over other study designs arguing that nonrandomized studies can also achieve the goals of balance between treatment and control groups and may be more useful in many cases because of practical advantages such as longer duration of follow-up. Furthermore, randomization itself is not what circumvents the biases of greatest concern to EBM developers: selection bias and ascertainment bias. She argues that blinding is able to accomplish both tasks, with or without randomization. Thus, the ranking of randomized above non-randomized study designs is not justifiable. Tonelli (2009) has argued that a rigid hierarchy cannot be determined a priori; rather, the most heavily weighted warrant for a given clinical decision depends on the circumstances of the individual patient. Borgerson (2009) has pointed out that bias is pervasive in research, and that there are many types of bias, not only the ones that EBM proponents are particularly concerned about. She argues that the RCT does not uniquely remove biases, including selection and ascertainment bias; thus, RCTs do not have a special claim to causal knowledge.

3.4. How does data become evidence?

A significant body of literature highlights the idea that EBM’s epistemological claim and assumptions obscure the interpretive, and thus subjective, aspect of knowledge generation. EBM’s very definition of evidence suggests that data alone will tell us which
interventions are, or are not, effective. EBM’s definition equates evidence with clinically relevant research, or any empirical observation about the apparent relation between event. How is evidence the same thing as research or an observation? Consider this quotation: “The perfect synopsis of a review or original study would provide only, and exactly enough information to support a clinical action” (Straus et al. 2005, 38). Both EBM’s definitions and this description obscure the interpretive process by which data becomes evidence. Data do not support clinical actions by themselves – they must first be interpreted. Interpretation is a process in which human judgment is used to evaluate the relevance and weight of data including such questions as how to resolve conflicts (or not) between data and how one knows when one has enough evidence to support a conclusion. It is through this process that data are thought to support certain conclusions. EBM’s jump from research, to research data or observations, to evidence obscures the transformative, subjective process through which data becomes evidence in support of particular hypotheses.

Downie and MacNaughton argue that in order for something (e.g. data) to be construed as evidence, it must be judged relevant and weighty with respect to some conclusion (2000). In other words, evidence does not exist on its own; it must be evidence for something, such as some hypothesis or theory. Judgments of whether some datum constitutes ‘evidence for’ require subjective interpretation which may differ between individuals (Oakley-Browne 2001; Upshur 1999). Further, Upshur states that evidence itself does not constitute truth; rather, evidence plays a role in determining what is believed to be true (2001, pers. comm.). He points to the legal notion of evidence as a comparison. In a
court case, evidence is used to support various theories of what actually happened during a crime. One of these theories is ‘discovered,’; on the basis of the available evidence, to be most likely to be true. The selection of evidence to support conclusions is negotiated and debated and is affected by social forces such as power, coercion, and self-interest of one negotiator, or group of negotiators, vis à vis another. It is also affected by psychological forces such as faith or psychic comfort with certain interpretations. These forces may have an impact on which conclusions or theories are ultimately selected to be true.

Thus, evidence is a status that reflects, at least in part, a subjective judgment that a fact increases the likelihood of a given conclusion being true. For any given set of phenomena, there may be many available facts which could count as evidence for a conclusion or theory. But only some facts will be deemed as evidence for that conclusion or theory, which itself is chosen from among several options. Harari (2001) argues that not only medicine but science itself is characterized by, “…intellectual flexibility, tolerance of ambiguous and discordant information obtained by different methods from differing viewpoints and at different conceptual levels, the judicious yet knowingly fallible, theory-derived construction, selection and interpretation of observations and empathically derived experiences …”. Thus, evidence is not, as EBM implies, simply research data or facts applied to a scenario but a series of interpretations which serve and take into account a variety of social, philosophical, and scientific agendas.
3.5. What is integration?

Integration is the aspect of EBM practice that has been least discussed by EBM. To date, what is meant by integration remains implicit. As noted above, the texts tend to use three terms interconnectedly: ‘integration’, ‘application’ and ‘incorporation.’ On their face, these terms try to capture, holistically, the clinical encounter in which research data, expert advice and assessment, and the values of all parties, interact in decision-making. However, the texts of EBM suggest a rather different process, not holistic and narrative, but quantitative through such methods as decision analysis. In essence, integration is the process by which research data are presented to patients whose preferences are matched to the available interventions.

Several authors have pointed out that results from large-scale trials cannot be directly applied to individual patients (Norman 1999, 141; Tonelli 1998, 1238). Evidence-based Medicine advises readers that whether research data apply to any given patient can be estimated by how similar one’s patient is to the trial participants and whether one’s patient could have been included as a trial participant. If not, one is to judge whether the differences would affect the intervention effectiveness. These judgments require pathophysiological reasoning of the type generally eschewed by EBM -- but in this context, it is encouraged. Both Evidence-based Medicine and the Users’ Guides further respond to the issue of application to individual patients by indicating the primacy of N of 1 trials but note that these can only be conducted under specific circumstances (Straus et al. 2005, 172-74).
Critics have charged that this kind of process is not integration at all, but amounts to cookbook medicine and the above description of the clinical encounter does not capture the ‘art’ of medicine (Horwitz 1996). EBM proponents deny this claim by stating that, “evidence is never enough” (Guyatt et al. 2008, 12) and by reiterating that integration with patients’ values is important. Upshur and Colak (2003) point out that the search for research data and its use in justifying clinical recommendations is only one process relevant to medical practice. When interacting with patients who may be seeking information or advice, trying to make decisions, or some combination of these, warrants for action may not be data-based, but may be normative or opinion-based and that these warrants may be entirely appropriate for the type of encounter at hand. These authors suggest that clinical encounters are not all identical. Different evidentiary standards are required in different circumstances and the interplay between clinical expertise, values (and/or preferences), and research data are contextually determined. Thus, there may not be a single formula for how to integrate.

Tonelli (2006) strives to develop the concept of integration by advancing a casuistic model that would lead to the consideration of all type of warrants: 1) empirical evidence; 2) experiential evidence; 3) pathophysiologic rationale; 4) patient goals and values; and 5) system features. Tonelli argues that no one type of warrant can automatically be given priority over the others in all cases, and that warrants must be reasoned about and weighed. For Tonelli, integration is exactly the skill of medical practice and it includes the capacity to engage in this process explicitly, rigourously and knowledgeably.
4. From EBM to evidence-based psychiatry

The preceding discussion did not aim to provide exhaustive coverage of all aspects of the scholarly debate about EBM. However, it did strive to cover the major issues that have arisen in response to EBM’s description of itself, as a comprehensive guide to clinical decision-making. I have also tried to identify the most contentious areas within the scholarly literature about EBM.

By claiming a privileged position as an approach to clinical practice, EBM has captured the imagination of the medical world. It has attracted apostles and adherents while simultaneously being viciously attacked. Its wholesale uptake amongst the healthcare disciplines speaks to the remarkable effectiveness of its spokespeople. Some authors argue that its impact disguises its intentions as a bid for power by health researchers and academic physicians over frontline practitioners, patients, and research participants (Denny 1999; Ray 1999; Traynor 1999). The discipline of psychiatry has, in the last generation, been particularly sensitive to questions of its use and abuse of power. Interestingly, it is within psychiatry that the hopes for EBM have been highest: to quell the persistent public perception of psychiatric interventions as baseless and illegitimate. It is to the field of psychiatry that the next chapter will turn.
References


Chapter Two

Psychiatry and Evidence

In the previous chapter, I explored the textbook descriptions of EBM. As noted, the notion of evidence-based medicine is dependent on the concept of medicine. What is meant by medicine is never discussed in detail by EBM texts. Instead, EBM rests on certain assumptions about medical disorders and their treatments that may not be applicable to mental disorders and their treatments, rendering the importation of EBM principles in psychiatric practice problematic.

In this chapter, I will explore this issue, giving particular attention to some of psychiatry’s theoretical commitments and assumptions about the nature of mental disorders and their treatments. The previous chapter reviewed some of the literature criticizing the principles and practice of EBM itself. In this chapter, I want to examine how evidence-based practice – with its various identified strengths and weaknesses -- does or does not map on to psychiatric practice. Both the last chapter and this one are necessary for the development of an analysis of the ethics of evidence-based psychiatry. An examination of the issues involved in applying evidence-based medicine to psychiatry exposes some of the fault lines where ethical problems may emerge.

The first section of this chapter will discuss 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 will argue that the intellectual context of
psychiatry 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 in its diagnostic and treatment practices. The second section of this chapter will explore how adopting EBM leads psychiatry to take on EBM’s assumptions, thereby cementing a commitment to a particular theory of mind and mental experience. I will argue that adopting EBM, which seems to put psychiatry on firmer scientific and ethical ground, actually leads the field to commit itself to a particular version of mental disorder and treatment, one that is narrower than the current theoretically plural version. This discussion leads directly to the question of the next chapter, whether the adoption of EBM helps psychiatry to resolve certain ethical problems or whether it actually creates new ones.

1. What is psychiatry?

1.1 Conceptual commitments

In this section, I will discuss the essential tasks and some of the core philosophical commitments of psychiatry. The nature of mental disorder is perhaps the debate which frames the entire field, from its inception to the present. I will argue that EBM plays a significant conceptual role in this debate. However, before beginning this discussion, it is important to acknowledge that psychiatry, even as a distinct medical sub-discipline, is a vast enterprise encompassing many transcultural and transtemporal histories. Whether there is some essence of psychiatry that transcends space and time is a subject beyond the scope of this thesis. When I speak of psychiatry, I will be speaking of contemporary, conventional, North American psychiatric practice.
The standard textbook in North American psychiatry, Kaplan and Sadock’s two volume Comprehensive Textbook of Psychiatry (Sadock and Sadock 2005), does not index a single definition of psychiatry in all of its 4,064 pages of text. The previous edition does provide a definition, well into the second volume, in a chapter entitled, “Special Areas of Interest” under subsection 1, “Primary care and psychiatry.” The author of this section writes, “Formally, it [psychiatry] is the branch of medicine concerned with diagnosis and treatment of mental disorders and related conditions,” (Lipkin 2000, 1924). In reality, this seemingly simple definition is preceded by a rich history of how psychiatry became a branch of medicine and of the emergence of the concept of mental disorder, with its accompanying diagnoses and treatments. While this section of the thesis cannot hope to review this material in detail, I will discuss briefly the rise of what we now call the medical specialty of psychiatry.

In his succinct volume Madness, the eminent historian of medicine Roy Porter writes that the distinct concept of the mental, in Western thought, emerged in the mid-18th century. With it came the idea that insanity was actually a mental disorder rather than a physical/bodily one. However, even in this model, the pathophysiology of mental disorders was grounded in bodily function, specifically neurophysiological dysfunction. As such, the investigation, classification, and amelioration of mental disorders lay in the hands of the medical profession in general, since there was no distinct specialty of psychiatry (Porter 2002, 123-155).
In Western Europe, the next hundred years brought refinements in theorizing about the causality, classification, and treatment of mental disorders. The success of neuropathological researchers in identifying specific anatomical changes associated with particular symptoms clusters (e.g. general paresis of the insane) held promise for the eventual elucidation of the biological causes of all mental disorders. Developments in the classification of mental disorders proceeded in tandem. Through careful clinical observation, disorders became distinguished from one another, particularly disorders later classified as neurological, such as Parkinson’s disease. Although new ideas about treatment also emerged -- such as moral treatment (essentially, social rehabilitation) -- there was little success in curing insanity. This failure was particularly evident to the alienists, the doctors who supervised the growing network of public and private insane asylums. In spite of discouraging therapeutic results, there remained a commitment to this emerging discipline. By the middle of the 19th century, alienists and researchers in several countries consolidated their professional authority by organizing themselves into specialist professional organizations with their own academic journals and by securing state recognition of their expertise through medico-legal acts such as certification and involuntary hospitalization. This was the beginning of the contemporary discipline of psychiatry (Porter 2002, 123-155).

As a branch of medicine, psychiatry implicitly adheres to the theoretical commitments upheld by other branches of medicine (Reznek 1991, 13). Broadly, this theory is materialist in that it views the world as containing only one kind of material -- physical material. Human beings are part of the material world. In addition, medicine is
physicalist, assuming that human bodies, like all physical matter, are governed by the laws of nature. Thus, bodies are like complex machines, devoid of meaning and operating deterministically according to physical laws. According to this view, if we knew every law and every variable concerning a particular disease state, it would be possible to predict all specific bodily functions.

Kaplan and Sadock’s book (Sadock and Sadock 2005) confirms that psychiatry adheres to these philosophical commitments. For example, the first five hundred pages of the book are occupied by two large chapters: 1. Neural Sciences and 2. Neuropsychiatry and Behavioral Neurology. Endorsing its materialist foundation early, on page 1, Grebb writes, “It is the human brain after all, that is the biological substrate for emotions, cognitive abilities, and behaviours - that is, everything that humans, feel, think and do” (Grebb 2005, 1). Further, he writes, “…a general trend in neuroanatomy is to describe how networks of brain regions interact to produce what is eventually experienced or observed as feelings, thoughts, or behaviours.” Implied in these statements is the notion that minds, or at least what we call mental functions, must be or arise from physical entities, because there are only physical entities. Everything that we regard as mental or psychological must arise from our physical brains. Thus, psychiatry, like the rest of medicine, is also reductionist (i.e. what is mental is explicable in physical terms, terms that are privileged over mental ones).

As Burwood and others have argued (1999, 7), much of the ongoing debate in the philosophy of mind reflects this particular (materialist, physicalist) conception of body,
one that is upheld by medicine. If this conception is accurate, and bodies are physical entities, then two basic questions about minds emerge: 1) what kinds of things are minds, physical or non-physical? (ontological questions about what exists) and, 2) how do minds cause physical things to happen? (explanatory questions about how minds can make things in the physical world happen). If minds are physical entities, how do physical entities give rise to psychological states? If minds are not physical entities, what are they and how can there be some other substance in the world apart from physical matter?

Burwood et al. point out that the materialist conception of body may be wrong, and that there should be equally troublesome questions to be asked about bodies. However, the assumptions of the mechanistic body are accepted in medicine (and psychiatry) as unproblematic.

Psychiatry has largely embraced the unquestioned physicalism of the rest of medicine and conformed to it. According to the current editor of the Canadian Journal of Psychiatry, “Psychiatry, in Canada and in the world, has truly come of age. Our discipline can now claim the same epistemological status as any other specialty” (Paris 2000, 36). A more detailed discussion of ‘mind,’ from a psychiatric point of view is found in Kaplan and Sadock’s book.

A generally accepted view of the mind is that it emanates from a portion of the activity of the brain. What is this activity of the brain and how does it give rise to such mental processes as perception and cognition? How do the human experiences of sensation, thought, emotion, attention, self-reflection and memory emerge from neural processes? The brain is composed of approximately 10-20 billion neurons. An average neuron is connected to 10,000 other neurons at synaptic junctions. With hundreds of trillion of connections within and among thousands of web-like neural networks, there are countless combinations of
possible activation profiles. The term neural net profile is used to describe a
certain pattern of activation of the complex layers of neural circuits. The neural
net profile is the fundamental way in which mental processes are created. These
activations can lead to further neural processes in a cascade of dynamic
interactions that produce a range of internal events and external behaviors. The
essential components of the mind come directly from how these neural events
create the flow of energy and information. (Cozolino and Siegel 2005, 514)

This explanation suggests that the psychiatric view of mind involves some kind of
correspondence between neural net profiles and feelings or experiences. If the brain is in
a certain state of activation, neural networks interact in complex ways that produce
subjective experience. Yet, this explanation leaves unanswered the question of how
neurotransmitters circulating in synaptic junctions, and ions crossing membranes, are
somehow equal to the joy I feel when my child says something very cute.

Philosophers have offered a variety of solutions to the question of how physical states,
such as neuronal activation, can give rise to mental states. However, the psychiatric
description of ‘mind’ (as given above) does not recognize this conceptual problem. In
spite of the fact that psychiatry’s purpose is the diagnosis and treatment of mental
disorders, understanding the nature of what is mental is not an issue taken up by
psychiatry directly. As a medical discipline, psychiatry’s ultimate aim is effective
healing. The pragmatic impulses of medicine steer psychiatry away from an unresolved
philosophical debate about minds and towards practical concerns of how to intervene
when someone experiences troublesome mental states. It is here that EBM has provided
an ideal companion to psychiatry: an opportunity to strengthen scientifically its claims
about effective healing without having to resolve basic philosophical problems about the
very nature of its subject matter. In fact, in this respect, psychiatry is well-suited to the
adoption of EBM because psychiatrists are not as tied to, and therefore not as reluctant to give up, the pathophysiological reasoning well-established in other medical disciplines. This theme will be developed later in this chapter.

In the meantime, let us examine further psychiatry’s implied conceptual commitments. The earlier definition of psychiatry pointed to the field’s two distinct but related tasks determining: 1) what counts as a mental disorder, and, by implication, how different disorders should be distinguished from each other (diagnosis and classification) and 2) how to intervene when we encounter someone who has a mental disorder (treatment). These tasks are tied necessarily to certain philosophical assumptions, which I will examine in the next section.

1.2. Diagnosis and treatment

In North America, psychiatric disorders are defined and distinguished from each other according to the Diagnostic and Statistical Manual of Mental Disorders (DSM)\textsuperscript{16}, currently in its fourth revision. The DSM is the accepted classification scheme by the mainstream of mental health professionals and is used widely in healthcare settings, within the legal system and by insurance companies. From its third revision onwards, the DSM has, “…attempted to be neutral with respect to theories of etiology,” (Task Force on DSM-IV 1994, xviii). Further, DSM contends that “a diagnosis does not carry any necessary implications regarding the causes of the individual’s mental disorder…” (Task Force on DSM-IV 1994, xxiii). The DSM aims to avoid the connection between

\begin{footnote}
\textsuperscript{16} The International Classification of Diseases (ICD) produced by the World Health Organization, is also a widely accepted classificatory scheme but is not commonly used within North America.
\end{footnote}
diagnosis and causality. In part because, “…it must be applicable in a wide diversity of contexts…by clinicians and researchers of many different orientations (e.g., biological, psychodynamic, cognitive, behavioral, interpersonal, family/systems)” (Task Force on DSM-IV 1994, xv). The word ‘orientations’, however, hides the fact that these are theories -- some independent of each other, some working in concert. This plethora of theoretical orientations reflects the absence of an explicitly agreed upon theory of mind both within and beyond psychiatry, even in the face of the general acceptance of physicalist theories of body and brain.

While disease categories do not represent natural kinds in the philosophical and scientific sense, (Reznek 1987, 63-79) classification schemes should allow clinicians to distinguish between different conditions. Pathogenesis can help to make these distinctions. Usually, a disease will be classified according to its most basic, known cause. In the case of infection, the most basic causal factor is the invading microorganism, hence, these conditions are classified as infectious diseases. In ischemic heart disease, ischemia is caused proximally, by narrowing of the coronary arteries, hence the term coronary heart disease. Since the cause of the narrowed coronary arteries is complex, multifactorial, and not completely known, the disease state is classified by its most basic known cause, the narrow coronary arteries.

Causal theory also underlies treatment. Ideally, medical treatment aims to intervene at the most basic level of causality that is known, which of course is determined by what the causal theory is in the first place. Again, to return to the example of infection, antibiotics
are designed to kill the causal agent – the invading bacteria. It would be insufficient to only treat an infection at a symptomatic level (e.g. treat a vaginal yeast infection with an anti-itching cream), since we know what the causal agent is and have the capacity to intervene at a more basic causal level than symptomatic control. Lung cancer is hypothesized to be caused (in part) by cigarette smoking. However, it is difficult to interrupt the causal process once a tumour has been discovered because the exposure to smoking has already taken place. Furthermore, the causal processes at the lung tissue level are complex, multifactorial and incompletely known (smoking is not the only relevant factor since some smokers do not develop cancer and some people who develop lung cancer have never smoked). Thus, we intervene at the most basic level of causality we do know, the level of tumour cells dividing. We aim to stop the cancerous tissue from propagating itself, growing larger, and causing more pulmonary dysfunction. The conceptual relationship between disease causality and treatment is perhaps best exemplified by fortuitous findings of successful treatment. The discovery that lithium successfully reduces manic symptoms led researchers and psychiatrists to hypothesize the causality of mania based on lithium’s action in the brain.

Through theories of causality, diagnosis and treatment become linked together. If X causes disease Y, and treatment Z interferes with X, X may be eliminated and Y may be successfully interrupted using Z. For conditions in which causal theories are insufficiently developed to intervene at basic levels (e.g. irritable bowel syndrome) or when our technologies are not sufficiently developed to intervene at basic causal levels (e.g. common cold), treatments focus upon symptomatic relief. The DSM states that the
term ‘mental disorder’ “…should not be taken to imply that there is any fundamental
distinction between mental disorders and general medical conditions…” (Task Force on
DSM-IV 1994, xxv). If this is the case, then the link between diagnosis, treatment and
causal theory in psychiatry should be similar to that for other medical disorders.

The DSM states that a mental disorder is,

…a clinically significant psychological or behavioural syndrome or pattern that
occurs in an individual and that is associated with present distress or with a
significantly increased risk of suffering death, pain, disability or an important loss
of freedom.’ In addition, this syndrome or pattern must not be merely an
expectable and culturally sanctioned response to a particular event, for example,
the death of a loved one. Whatever its original cause (emphasis added), it must
currently be considered a manifestation of a behavioral, psychological, or
biological dysfunction in the individual.

(Task Force on DSM-IV 1994, xxi-xxii)

In spite of the disclaimer, some of the criteria sets that define mental disorders, contain
embedded theories about original causes. For example, the diagnosis of conversion
disorder applies when a person has, “…one or more symptoms or deficits affecting
voluntary or sensory function,” and “psychological factors are judged to be associated
with the symptom or deficit….“ (Task Force on DSM-IV). However, this same criterion
specifies that psychological factors must precede the onset of the deficit, suggesting that
in some way, they bring about the deficit. The next criterion excludes the possibility that
conscious factors, such as knowingly disabling oneself or feigning symptoms, are at play.
Thus, the psychological factors must be unconscious. The causal importance of
unconscious psychological factors in this disorder, and thus the role of causal theories
that hypothesize the existence and function of an unconscious mind, are evident.
Many of the criteria sets contain behaviours as possible signs of the disorder. This suggests the importance of behaviourist theories of mind. Including observable behaviours in definitions of mental disorders is desirable because it includes an objective perspective of the dysfunction involved in the disorder. In the same way that I can discern a heart murmur with my stethoscope, if I can observe an abnormal behaviour, the condition is more believable or valid because it can be confirmed by an outside party who is not the patient. This perspective itself contains important philosophical assumptions, but this is not main point of this example. Consider a comparison to a medical disorder usually diagnosed on the basis of self-reported symptoms such as a migraine headache. The criteria for the diagnosis of migraine headache do not include behaviours which might accompany having a headache such as ‘clutching one’s head’ or saying “ow.” Why is this the case? Because these behaviours are not part of the causal theory of the headache, and are merely associated with the effects of the disorder rather than an integral part of its meaning. Whereas, in a condition such as attention-deficit, hyperactivity disorder (ADHD), we include specific behaviours as markers of the disorder because the theory of mind operating in this case identifies mind function with behaviour.

Thus, the DSM is not atheoretical with respect to etiology, but rather theoretically plural. Reznek has argued that psychiatry incorporates a variety of theories of mental disorder -- psychodynamic, biological, cognitive, behavioural, sociological, and intentional (Reznek 1991, 145-156) -- which can operate singly or in combination in identifying the cause of a mental disorder. In his view, this theoretical pluralism is entirely compatible with the model of disease operating in the rest of medicine.
Theoretical pluralism is also evident in the treatments that psychiatry offers. These treatments can broadly be grouped as psychological (psychotherapy - with individuals, couples, families, or groups) and biological (medications, electroconvulsive therapy – ECT, transcranial magnetic stimulation – TMS, and psychosurgery). Psychotherapies all adopt the viewpoint that talking about one’s experiences can lead to changes in mental states. Such therapies operate entirely at the experiential and intersubjective levels. How these therapies bring about change is a matter of debate that replicates those within the philosophy of mind. One view is that psychotherapies work as medications do: by altering the brain physically through its neurochemical processes (Gabbard 1994, 16). A contrary view is that one cannot think about psychological change in biochemical terms as it is resistant to being described this way. Standard physicalist theory informs the use of biological treatments, that is, that treatments induce biochemical changes in the brain and bring about changes in mental states. As in psychiatry in general, it remains unclear how biochemical changes bring about changes in subjective experience. But because pharmaceutical and other biological treatments do seem to change subjective experience, the physicalist viewpoint is empowered.

Ultimately, if a specific treatment is successful in treating a mental disorder, the etiological pathway of the disorder is inferred from the treatment’s mechanism of action. Because several different interventions seem to be effective in changing mental states, psychiatry’s capacity to resolve questions of etiology remains as limited as that of philosophy. Ashcroft has argued that EBM provides a methodological solution to these
problems of epistemology in that EBM can be used and useful, even in the absence of an uniform theory of causation and explanation (Ashcroft 2004, 134). Here EBM has proved an important tool for psychiatry. Even if psychiatry cannot resolve philosophical debates about its own subject matter, EBM will allow it to progress in pragmatic directions. Yet, in spite of its commitment to pragmatism, EBM does quietly push psychiatry in certain epistemological directions, making this an important marriage of convenience. The next section will explore this relationship between evidence-based medicine and psychiatry.

2. What is evidence-based psychiatry?

2.1. Defining evidence-based psychiatry

Since its original description in 1990, EBM has gained prominence within psychiatry. However, compared to EBM, there is no official text that describes evidence-based psychiatry. This raises the question of who is entitled to speak for evidence-based psychiatry and define its terms. There are, for example, psychiatrists who work in evidence-based psychiatry units (Gray and Pinson 2003), edit evidence-based mental health journals\(^\text{17}\), and teach EBM to psychiatry trainees\(^\text{18}\); however, it is unknown to what extent these individuals share a common understanding of evidence-based psychiatry. In the absence of an agreed-upon definitive source for evidence-based psychiatry, it is likely that it constitutes simply the straightforward application of the definition and rules of EBM to psychiatric practice (Geddes and Harrison 1997; Goldner and Bilsker 1995; Goldner et al. 2001; Gray and Pinson 2003). Thus, any attempt to understand evidence-

\(^{17}\) See, for example, the journal *Evidence-Based Mental Health*

\(^{18}\) The educational curriculum in our psychiatry training scheme (the largest in Canada) includes several lectures devoted to evidence-based psychiatry.
based psychiatry is really an attempt to understand EBM and how well it applies to psychiatry.

As in EBM, in evidence-based psychiatry the concept of evidence is central. There is no definition of evidence that is specific to psychiatry, but its meaning can be inferred through the ‘evidence hierarchy.’ Geddes and Harrison lay out an evidence hierarchy specifically for studies of psychiatric treatments since therapeutics is the area in which the majority of psychiatric clinical research studies are focused. This hierarchy is very similar to the hierarchy described by EBM in chapter one. The similarity between these two hierarchies further demonstrates that evidence-based psychiatry results from the direct application of EBM to psychiatry.

Evidence from a meta-analysis of RCTs
Evidence from at least one RCT
Evidence from at least one controlled study without randomization
Evidence from at least one other type of quasi-experimental study
Evidence from non-experimental descriptive studies, such as comparative studies, correlation studies and case-control studies
Evidence from expert committee reports or opinions and/or clinical experience of respected authorities

(Geddes & Harrison, 1997)

From the evidence hierarchy, we can infer that psychiatric evidence is conceived of as quantitative data drawn from experimental studies, preferably randomized controlled trials or meta-analyses of such trials. These authors provide no further specification of evidence. Furthermore, there is little discussion in the clinical psychiatric literature of what constitutes adequate psychiatric evidence.
Evidence-based psychiatry’s emphasis on empirical quantitative data stands in contrast to actual patient encounters in clinical psychiatry. Unlike some medical specialties in which data obtained in the clinical encounter mostly comprises measurements of various types (whether through physical examination techniques or the results of laboratory or imaging investigations), the standard patient assessment in psychiatry resembles a qualitative research interview -- oral, in-depth, exploratory, and individualized. While the interview is structured by the psychiatrist’s diagnostic aims, sophisticated interviewers are able to weave together the information that their patients provide, whether diagnostically informative or not, into an evolving picture of the whole person. Thus, the skilled psychiatrist has both quantitative and qualitative aims. Quantitatively, s/he enumerates patients’ symptoms and evaluates their severity, using them to classify each patient as an example of a larger, more general diagnostic category. Qualitatively, s/he elucidates the patient’s personal narrative and contributes to its evolution and meaningfulness. The evidence hierarchy aims to substantiate beliefs and decisions regarding the quantitative aspect of clinical psychiatry -- namely, the treatment of the patient as a member of a more generic category but is silent about the qualitative dimension of the psychiatrist’s work. In light of this and other concerns, some authors have questioned whether EBM, and its concept of evidence, can be unproblematically applied to evidence-based psychiatry. These arguments will be discussed below.
2.2. The critical literature concerning evidence-based psychiatry

As discussed in chapter one, there are criticisms of the five steps of EBM practice that are applicable to all specialties of medicine. In a damning statement about the pernicious distortions embedded in what constitutes EBM’s evidence, especially psychiatric evidence, Marcia Angell, former editor of the *New England Journal of Medicine* wrote,

> The problems I've discussed [publication bias, source-of-funding bias, manipulation of diagnostic categories] are not limited to psychiatry, although they reach their most florid form there. Similar conflicts of interest and biases exist in virtually every field of medicine, particularly those that rely heavily on drugs or devices. It is simply no longer possible to believe much of the clinical research that is published, or to rely on the judgment of trusted physicians or authoritative medical guidelines.

(2009)

In the following section, I will focus on the arguments specifically challenging EBM’s applicability to psychiatry. The first, a weaker claim, accepts the theory of EBM but questions its execution in practice. According to this line of thinking, research studies do not reflect actual psychiatric problems and patients sufficiently for the results to be clinically useful (Seeman 2001). For example, patients usually enrolled in RCTs in psychiatry usually have one specific problem (depression), unlike patients in real practice who often have several problems (e.g. depression comorbid with anxiety symptoms and substance abuse). Thus, it is unclear to what extent RCT data obtained by studying patients with a single problem can be applied to patients with multiple problems. Another example is that follow-up in research studies, particularly RCTs of pharmaceutical agents, is often short-term (weeks); however, the actual treatment of mental disorders is usually long-term (years) as these disorders are in most cases, chronic
or relapsing and remitting (Oakley-Browne 2001). According to Healy (2001), this mismatch between clinical trials and the realities of actual patients results from the fact that the majority of clinical trials are designed for a business purpose – to achieve regulatory approval, and thus market access – rather than a scientific or clinical one. Nevertheless, for some authors, EBM can be applied to psychiatry provided EBM-endorsed research studies matched psychiatric patients and problems more closely. Once this is achieved, evidence-based psychiatry will be relatively unproblematic. Countering this claim, Welsby (1999) argues that for many patients, the interactions between multiple medical conditions and multiple interventions over time involve a state of complexity that EBM methods can never capture.

The second kind of argument, a stronger claim than the first, states that the narrative structure and meaningfulness of personal experience are essential components of living with a mental disorder and the psychotherapeutic treatment of mental disorders. These aspects of mental disorder are resistant to measurement, at least in the manner envisioned by EBM (Holmes 2000). In other words, mental states are more than neurochemical processes – they are also lived experiences which cannot necessarily be described and explained in biological or quantitative terms. Thus, methods devised to capture such processes, cannot necessarily capture what patients experience in their disorder and during therapy. Perhaps pharmacological treatments can be adequately evaluated in EBM terms, but psychotherapeutic and social ones cannot. For Holmes, this is not a call to abandon research for non-psychopharmacological interventions, but rather a call to refine alternative research methods. It is also a demand that evidence-based psychiatry
construe research and evidence more broadly, in order to include alternative methods and
to include difficult to research phenomena such as the ‘precox feeling’ and ‘transference.’
Faulkner and Thomas (2002) add to this demand by challenging evidence-based
psychiatry to encourage research in which mental health system users lead in the
development and execution of research studies. They believe that user-led studies are
more likely to focus upon questions and outcomes important to users, which are not
necessarily the same as those considered important by psychiatric researchers adhering to
the demands of evidence-based psychiatry.

Without broadening the concepts of evidence and research beyond their current
specification within EBM, many aspects of psychiatric practice are a poor fit for the
demands of EBM. The challenges involved in evaluating psychotherapy provide an
example of the potential problems of applying EBM to research of non-pharmaceutical
interventions. If researchers choose an RCT design they will be faced with a variety of
methodological problems. A basic one is that some fundamental requirements of EBM,
such as double-blinding, cannot be met. In testing psychological treatments, it is unlikely
that patients will be unaware whether they are receiving an actual therapy or a control
condition, particularly if the consent process has been properly undertaken. In EBM
terms, this immediately creates a major source of bias as the patients who are receiving a
therapy may try harder to get better, or report that they are better compared to those
receiving the control condition.
Another common methodological issue involves the choice of how the therapy under investigation should be delivered. If the therapy is of the same duration it would be in actual practice (ignoring for the moment the common clinical practice of using a variety of psychotherapeutic techniques within the same course of treatment rather than a pure form of any one therapy), it will likely be so long that there will be a large number of dropouts from the study, and treatment effects will be confounded by patients’ use of other interventions (e.g. a patient who meets with his/her religious adviser while s/he also participates in the study). Offering a relatively shorter, purer course of treatment might avoid these methodological problems – and is the approach currently adopted by much psychotherapy research held up as evidence-based - but whether studying an intervention delivered this way will provide results that are generalizable to longer term clinical practice is questionable. The pure manual-based, standardized intervention offered in such trials is not typical of what the vast majority of patients are able to access through local health services. Thus, there is a question of whether these trial data are very useful in actual clinical practice.

A pragmatic trial, a strategy which aims to emulate clinical practice (in terms of eligible patients, duration and type of treatment) in trial design (Roland and Torgerson 1998), may start out with an experiment more closely reflecting actual practice. But will the results of such a trial be given as much credence as results of explanatory trials? McMahon (2002) has argued that potential features of pragmatic design such as less rigid controls, should be considered poor rather than pragmatic design, and that pragmatic designs should be reserved for complex interventions and non-therapeutics. While
psychotherapy certainly fits into the category of a complex intervention, it remains unclear how data from such trials will fare in terms of their credibility and acceptability in EBM terms compared to data from standard RCTs. Two examples of Cochrane Systematic Reviews\textsuperscript{19} of psychotherapy demonstrate that the standard aspects of research design in explanatory trials (such as randomization) are considered so important as to influence the decision about whether to include a study in a review at all (Hay, Bacaltchuk, and Stefano 2004; Price and Couper, 1998). Would pragmatic trials be excused from these requirements because they are trying to emulate clinical practice? This remains to be seen.

Using either pragmatic design strategies or EBM-preferred ones, psychotherapy research will likely produce either less valid data (in EBM terms), or less applicable data, unable to compete with the claims of effectiveness of interventions for which EBM was originally conceived – namely, pharmaceutical agents. Thus, EBM may have the effect of marginalizing whole classes of interventions. In their review of psychotherapy research, Roth and Fonagy (1996) address this problem when they write, “…while we can see that the absence of evidence of efficacy cannot and must not be equated with absence of evidence of effectiveness, this scientific review can only draw conclusions from the evidence available. It cannot use different evidential criteria for different orientations.”

To what extent does this marginalization actually occur in evidence-based psychiatric practice? The journal \textit{Evidence-Based Mental Health}, which adheres to EBM principles,

\textsuperscript{19} The Cochrane Database of Systematic Reviews is an electronically accessible database of articles prepared by interested groups of researchers across medical specialties who compile the original research on clinical topics and subject them to meta-analytic statistical techniques where possible. The purpose of each review is to provide an overall picture of the best research on that topic. The selection of research studies for each review adheres to the dictates of EBM.
summarizes “the highest quality original and review articles” (Evidence-Based Mental Health 2006, 30). In the year 2006, all of the original psychotherapy articles chosen for inclusion in the journal, of which there was a considerably smaller number than studies of pharmaceutical agents, used an RCT design. In other words, to be considered ‘of the highest quality’ psychotherapy researchers must adhere to EBM. Whether adherence to EBM in research will translate into equal acceptability of psychotherapy compared to pharmaceuticals in clinical practice is unknown.

If, on the other hand, researchers employ an alternative research method, such as a qualitative approach, it is not clear how results from such a study will be evaluated according to the rules of EBM, or if they will be counted at all. The Users’ Guide includes a chapter on critically appraising qualitative research (Giacomini, Cook, and Guyatt 2002) but qualitative research is not included on the evidence hierarchy for studies of treatment. This suggests that treatments cannot or should not be studied in this manner, even if quantification of the subject in question is not the most appropriate way of measuring the item of interest.

These debates about evidence-based psychiatry accept that, at a minimum, the effectiveness of pharmacological treatments for psychiatric disorders can and perhaps should be studied, using standard EBM techniques. To some extent, this viewpoint reflects a notion that there can be sophisticated and unsophisticated versions of EBM. An unsophisticated version might remain ignorant of the technical bias that fosters research of pharmaceutical agents at the expense of more complex interventions. A more
sophisticated version might try to take such things into consideration in an attempt to bolster EBM’s claim to be the preeminent model for securing medical knowledge. However, there are certain assumptions and values integral to EBM’s structure which render it inapplicable to psychiatry and its treatments, pharmaceutical or otherwise. In the remainder of this chapter and the next, I will argue that EBM cannot simply be rewritten to take account of the criticisms against it and therefore transform itself into sophisticated EBM. If it were to do so, it would lose the core features of EBM.

2.3 Does EBM apply to psychiatric disorders and their treatments?

Emerging as it did with internal medicine in mind, particularly large-scale clinical trials of new pharmaceutical agents, EBM makes certain assumptions about disease and treatment. EBM’s critical appraisal techniques of research depend on two key strategies in doing clinical research. First, EBM requires researchers to assemble prognostically homogeneous patient groups – a critical first step in launching a research study. Only after this is achieved can other methodological requirements such as randomization be addressed. Without prognostically homogenous groups, one cannot conclude anything about interventions under investigation since it will always be plausible that the results were influenced by the prognostic mix in the study groups. Second, EBM prefers that the outcomes of interventions be measured quantitatively. This section will explore how well these criteria can be met in researching psychiatric disorders.
2.3.1. Prognostic homogeneity

The first key research strategy required by EBM is that researchers assemble prognostically homogeneous patient groups. In Straus et al.’s book, one of the basic critical appraisal criterion by which to evaluate studies of treatments is, “…if the groups were similar in all prognostically important ways at the start of the trial,” (2005, 120). Homogeneity of this type involves having similarities in diagnoses, severity of disease, and any demographic factors that are presumed to be relevant to outcome, including any unknown factors.

Maier (2006) raises the question of whether prognostic homogeneity can be achieved for psychiatric disorders. In psychiatric practice, sets of diagnostic criteria create descriptions of clinical syndromes that enable psychiatrists to diagnose mental disorders and distinguish among them. The Diagnostic and Statistical Manual used by North American psychiatrists is a compendium of these criteria sets for various diagnostic categories. Each category is defined by a list of criteria, a minimum number of which must be met for a patient to be classified as belonging in a particular diagnostic category (e.g. there are nine possible criteria for major depression, and a patient must have at least five of them, including one that is specific to mood to be diagnosed as depressed). Inherent to the way that psychiatric diagnoses are made is the heterogeneity in clinical presentations of patients. One patient may have five of nine criteria for major depression, while the next patient may also have five criteria but only three of these might overlap with the first person’s criteria. In fact, there are 70 possible combinations of four symptoms that someone with major depression might possess (assuming each
combination must include the mood disturbance as the fifth symptom). Then there are also patients who have six, seven, eight or all nine symptoms. There are 93 possible combinations of these numbers of symptoms (again assuming each combination always includes the mood symptom). Furthermore, within each uniform symptom group, each symptom or combination of symptoms may vary in severity from another person with that same combination. Are all of these different combinations of number and severity of symptoms prognostically similar?

The current division of major depression into melancholic and atypical subtypes is a real example of symptom differences leading to within-category prognostic variability. Persons with the atypical subtype of major depression experience some symptom reversal as compared to patients with the melancholic subtype (i.e. weight increase instead of loss, hypersomnia rather than insomnia). Atypically depressed patients respond better to different types of treatments than melancholic patients (Kennedy et al. 2001). However, if the two groups were assumed to be prognostically similar because all patients shared several symptoms of major depression, and were mixed together in a clinical trial of a treatment, the results might not be helpful in guiding practice for either group. This example seems to prove that it is possible to answer empirically, whether specific combinations of symptoms, with specific degrees of severity, are prognostically similar or different from other combinations. One could assemble groups with certain combinations of symptoms at particular degrees of severity, and then follow them over time in order to evaluate whether they are prognostically similar to groups with other combinations of symptoms or with differing degrees of severity. The feasibility of this
approach is questionable, but prior to this practical issue, we encounter another conceptual problem.

A person might have all or almost all the criteria needed to be diagnosed with a disorder yet, also have a unique or unusual symptom that is not included on the list. How much flexibility should there be in interpreting whether an idiosyncratic symptom conforms to one described in the DSM? For example, a patient attends a psychiatric consultation and when asked to describe her mood says, “I feel dead.” The psychiatrist asks what the feeling state ‘dead’ represents, and offers various mood descriptors (sadness, despair, hopelessness) but for the patient, the best way she can describe her state is to say she feels ‘dead.’ Assume that this patient has four of the remaining eight criteria of major depression. In order to make a diagnosis of major depression, the psychiatrist or interviewer must decide whether ‘feeling dead’ can be reasonably interpreted as the equivalent to feeling depressed (or some other symptom, since there is no diagnostic category for which feeling dead is a criterion). Some assessors in this situation might conclude that feeling dead is the equivalent of feeling depressed, others might not. Including such people in a patient group of major depressives in a clinical trial may mean including patients who actually have a different disorder altogether that shares some features with major depression. Alternatively, excluding such patients might mean losing important clinical information about a distinct subtype of major depressives -- those who feel dead. Differences among patients unaccounted for by existing diagnostic criteria have the potential to lead to substantial heterogeneity within apparently uniform
diagnostic groups. For research, these differences could have a major impact on data concerning prognosis, comorbidity, and treatment.

These interpretive difficulties are compounded by the further problem of between-patient differences in interpretation of symptoms. As the word depression becomes increasingly common in lay discourse, it may take on diverse meanings. What one person means by depression or depressed mood, may not be what another person means. Thus, both patient and assessor must engage in a considerable degree of interpretation, even when making a diagnosis using explicit criteria. The variability in clinical presentation, along with these interpretive differences, mean that it is not possible to ensure prognostic homogeneity even within a single diagnostic group.

Can randomization solve this problem? Randomization is a process intended to achieve prognostic homogeneity by evenly distributing unknown confounding variables across otherwise similar trial groups. Worrall (2002) has argued that randomization can only evenly distribute unknown confounders with indefinite replications of a clinical trial. However, he points out that clinical trials are not repeated indefinitely, but rather are conducted only once. Thus, it is quite likely that in any given trial, at least one unknown confounder is distributed unevenly between trial groups, even for those medical conditions more specifically defined than psychiatric disorders can be. Furthermore, even if randomization could distribute unknown confounders evenly in a given trial, for psychiatric disorders in which different patients may have different combinations of symptoms, one is not starting with a uniform group to randomize. The combination of
the tenuous logical connection between randomization and prognostic homogeneity and 
the inherent diagnostic variability of psychiatric trial groups renders randomization 
unable to meet EBM’s basic requirement of prognostic homogeneity for psychiatry trials.

2.3.2. Quantification of outcomes

A second important requirement of EBM-preferred research is that the outcomes of 
medical interventions be measured quantitatively. The evidence hierarchy for treatment 
makes clear that quantitative data resulting from randomized controlled trials or meta-
analyses of these trials achieves the highest rating of validity of research designs. In 
evidence-based psychiatry, psychiatric outcomes, specifically changes in symptoms in 
response to a given treatment, are usually quantified using rating scales. Can symptom 
rating scales reveal changes in the psychological states of people with mental disorders? 
If so, do these scores tell us what we want to know about the interventions under study? 
Do rating scale scores reflect those aspects of disorders that are most important and 
useful to patients? This section will address these questions.

Specific symptoms may have more or less importance for a given patient. For example, 
in measuring changes in depressive symptoms, someone might report that her appetite 
has improved, yet she might still feel terribly depressed. Assume that this person finds 
depressed mood a more troubling symptom than disruption in appetite. Should her 
change in appetite weigh less heavily into her final score on a symptom rating scale than 
the persistence of her depressed mood? Schaffer et al. (2002) have demonstrated that 
patients suffer more from some symptoms relative to others. In response, rating scales
can be designed to weigh certain symptoms more heavily than others. However, any weighting system may not be applicable to a given patient, who rates the burden of suffering differently than the way in which the scale is designed. Thus, a final score will not necessarily reveal the burden of suffering relevant to any individual person.

Defenders of quantification may respond that the point of such measurements, and of trials in general, is not to determine individual suffering but rather the average suffering or improvement in the study population. However, in order for the average result to be useful, its component parts -- the individual scores of individual study participants -- must accurately reflect their experiences.

Quantitative outcome measures also raise the more basic questions of whether numerical representations of experience can convey meaning. For example, a patient describes having experienced two episodes of depression and using a rating scale of 0-10 (0 representing severe depression while 10 represents no depression), he rates his mood for both episodes as 1. However, he describes these episodes as being completely different experiences, unequal in any way apart from the rating. Over the course of treatment, this patient is again asked to rate his mood on a 0-10 scale; he says that his mood has increased from five out of ten to seven out of ten. What does this tell us? We know his mood has changed and that he is feeling better, but it is unclear if the change of two units tells us anything further than the qualitative description ‘better’ would. Is the difference between five and six equal to, or different from, the difference between six and seven? Defining change in numerical terms may falsely impose the logic of numbers onto subjective experience and create a false sense of knowledge about the extent, value, and
importance of the experiential change to the patient. In fact, Goldenberg (after Toombs 1993) has argued that a scientific account of disease may be of limited relevance to patients whose experience of illness has little to do with objective change and more to do with changes in the relationship between oneself, one’s embodiment, and the world. Williams and Garner (2002) also point out that the doctor-patient relationship, not just change in symptoms, is both personally meaningful to patients and has therapeutic potential. Psychiatric practice, and psychotherapy in particular, depending on how they are implemented, take these experiential aspects of illness into consideration, but Goldenberg (2006) argues that research should also reflect this perspective.

To some extent, everyone’s illness experiences is unique, however much one shares in common with another sufferer. This is as true in coronary artery disease as it is in panic disorder or schizophrenia. Where psychiatric disorders differ from most other disorders is that according to our current state of knowledge, the experience of the disorder is the disorder. Most other disorders have both this experiential component as well as a biological component, which is understood in greater or less detail depending on the disorder. In most cases, treatment is aimed at modifying the subjective experience through modification of the biological variables. In spite of whatever knowledge we have about the biological basis of psychiatry, at this point we cannot definitively draw specific pathophysiological or psychopathological conclusions about mental disorders. Patients and providers are left to diagnose and treat mental disorders at the level of experience rather than by intervening with biological variables. Another example from major depressive disorder illustrates this point. A patient reports that he has interrupted
sleep as part of his depression. Poor sleep is a vegetative symptom (Akiskal 2005) and is considered to be a biologically mediated symptom as compared to his psychological symptoms such as sadness and guilt. Treatment would not be considered successful unless these psychological symptoms of depression improved. If these symptoms improved but his sleep never returned to normal, this would be unfortunate but would not lead to the conclusion that his treatment had been a failure. Psychiatric treatments aim to target subjective experiences, not merely biological symptoms; in general, the subjective experience of wellness is more important clinically than changes in biological indices. This example points to the importance of experience and also the need for research studies to accurately capture changes in experience, not merely to quantify symptoms.

3. Conclusions

Evidence-based psychiatry has arisen from the direct application of EBM to psychiatry. However, as I have argued, there are aspects of psychiatric disorders and their treatments that do not conform to the requirements of EBM. As a result, the evidence endorsed by EBM may downplay the complexity of the experience of mental disorders, and potentially, create a distorted picture of mental disorders. In turn, this evidence may not lead to accurate conclusions about psychiatric interventions. Evidence-based psychiatry may place psychiatrists in a situation whereby they believe they have knowledge about interventions they cannot justifiably claim to possess. If EBM does not improve our knowledge, then it cannot claim to be an improvement over pre-EBM. This would undermine the imperative to practice, teach, and learn EBM. If on the other hand EBM were to revise itself to incorporate these considerations: by placing non-randomized or
diverse prognostic and diagnostic groups in research on an equal footing with randomized uniform ones, the evidence hierarchy would be seriously compromised. And in the absence of the hierarchy, EBM is back to putting different sources of knowledge on an equal footing with each other, the very problem it was designed to eliminate.

These problems in applying EBM to psychiatry would not be eliminated if EBM were abandoned. Indeed the difficulties of achieving prognostic homogeneity and in quantifying outcomes existed prior to EBM. However, the lack of attention paid to these issues by evidence-based psychiatry suggests that these difficulties are inconsequential to our understanding of mental disorders. By failing to examine whether the demands of EBM fit well with the clinical dimensions of psychiatric disorders, evidence-based psychiatry promotes a particular view of mental disorders -- namely, that their basic features can be understood in exactly the same way as any other kind of disease. According to this view, mental disorders are understood fundamentally as biological disorders rather than psychological or experiential ones. This change in orientation moves psychiatry away from its theoretically plural stance to one that is theoretically monolithic.

Evidence-based psychiatry’s conceptualization of evidence is influencing our very understanding of the nature of mental disorders; rather than our understanding of mental disorders, determining what counts and does not count as evidence. This revision of psychiatry’s subject matter may or may not be welcomed by the psychiatric community, but it has arrived on the coat-tails of EBM. Its arrival points to the enormous influence of
EBM: from shaping the conduct of research, to determining which interventions are deemed acceptable to consider in clinical decision-making, and even to redefining our object of enquiry. EBM is not only changing our approach to studying psychiatry, it is changing psychiatry itself.

At the same time, psychiatry is more than an academic or clinical enterprise. Like the rest of medicine it is also an ethical one, whose basic ethical imperative is to improve health. To what extent does evidence-based psychiatry reflect and promote this or other values? The next chapter will focus on the ethics of psychiatry, EBM, and evidence-based psychiatry.
References


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Chapter Three
Ethics and Evidence in Psychiatric Practice

1. Introduction

The link between ethics, evidence-based medicine (EBM) and psychiatry has been established by claims that ethical psychiatry must be evidence-based. Writing in the Canadian Journal of Psychiatry in 2000, editor-in-chief and then Chair of Psychiatry at McGill University Joel Paris asserted, “Today, no therapeutic method will be fully accepted unless supported by randomized controlled trials. In other words, understanding disease and treating patients increasingly are dominated by an evidence-based approach.” Paris makes it clear that EBM is a required as the basis for any legitimate practice within psychiatry. He also suggests that it is not only the evaluation of efficacy of interventions that must employ EBM, but our understanding of mental disease itself (2000, 34). In 2003, Peter Szatmari, Professor of Child Psychiatry at McMaster University argued that “…the only ethical practice in [child] psychiatry is one that uses the principles of evidence-based medicine” (2003, 1). Here, even more strongly that Paris, Szatmari links EBM with ethics. Furthermore, he sees EBM as not only being a better scientific approach to psychiatric practice, but also a more ethical approach, one that can potentially improve psychiatry’s ethical standing.

While there is a small literature concerning ethics and EBM (Culpepper and Gilbert 1999; Goodman 2003; Leeder and Rychetnik 2001), the exploration of EBM’s basic ethical commitments has been limited. Most of this work focuses on the ethical impact or
consequences of EBM. Some authors imply that EBM itself is an ethically neutral approach but has the potential to be manipulated for unethical purposes. For example, Charlton worries that policymakers might use EBM as a justification for denying insurance coverage for medical interventions that do not carry official EBM approval (1999, 257-58). Gerber and Lauterbach do not view EBM as value-neutral, but argue that the ethical critiques of EBM are not unique to it and are really critiques of medicine as a whole (2005). Other authors suggest that the concept of EBM contains an embedded normative structure. These scholars believe that EBM can convey the message that it is the only or best route to medical knowledge (Culpepper and Gilbert 1999, 830-831). As such, those who draw upon other sources of knowledge to inform their practice may be practicing unethically. Additionally, some proponents of EBM have argued that failing to make use of EBM’s ever-expanding corpus of scientific knowledge is unethical (Davidoff 1999, 82-3). Few authors have considered the question of whether there are particular ethical issues involved in applying EBM to psychiatry. This chapter will seek to explore more fully the ethics of EBM and EBP. Is EBM committed to certain ethical values? What theory of ethics is reflected in these values? Can these values and theories respond adequately to existing ethical issues in psychiatry? A discussion of these questions will help us to understand whether EBM can provide psychiatry the ethical substantiation claimed by Paris (2000) and Szatmari (2003).

In this chapter, I will address these questions drawing upon Evidence-based Medicine, the Users’ Guides, and the published literature on ethics and EBM as sources. My analysis therefore, is of ‘literal’ EBM -- that which appears in textbooks and published sources.
My attempt to address these ethical questions should be considered provisional, awaiting deepening and expansion by the interview data that will be presented in subsequent chapters. Keeping in mind that EBM is a living practice, and that the interviewees are extensively involved in developing, implementing and critiquing EBM on an ongoing basis, drawing upon their knowledge may help to fill in gaps left by ‘literal’ EBM.

The ethical commitments of EBM are not described directly in either Evidence-based Medicine or the Users’ Guides. At best, implicit references allow the reader to infer some answers. This lack of attention to ethical content is particularly surprising given that, as I will argue, EBM justifies itself using an ethical argument. The first part of this chapter will explore the values that are embedded in EBM and the ethical theory reflected by those values. Following a discussion of some of the major ethical issues involved in psychiatric practice, I will investigate whether EBM’s ethical stance helps or hurts psychiatry in its attempt to resolve these ethical issues. I will argue that EBM’s ethics are insufficient to be of much help to psychiatry. EBM, therefore, cannot provide the ethical basis for psychiatric practice.

2. Is EBM committed to certain ethical values?

2.1 What values are embedded within evidence-based practice?

EBM defines itself as the integration of best clinical evidence with clinical expertise, and patients’ values and circumstances. The model of practice proposed by EBM is as follows:
Best evidence + clinical expertise + patients’ values and circumstances = evidence-based practice

Figure 1 - EBM’s model of clinical decision-making

This model suggests that the values relevant to EBM are patients’ values, and that these lie outside both evidence and clinical expertise. Is this accurate? Let us start with the question of whether values are at play in critically appraising the medical literature and determining whether a piece of research can be considered ‘best evidence.’ Evidence-based Medicine and the Users’ Guides devote a considerable proportion of their total text explaining how to engage in critical appraisal (step 3 of EBM) of the medical literature. The process of critical appraisal, regardless of the type of research study being considered, involves following a structured and quantitative approach to answering three questions: 1) Are the results of the study valid?; 2) What are the results?; and 3) How can I apply these results to patient care? (Guyatt 2002, 51). Neither text invites readers to consider whether these three questions themselves contain embedded values. Nor do the texts consider other ‘critical’ questions such as: 1) Who chooses the research questions and why?; 2) Does this investigation make a meaningful contribution to its field and is this a relevant criterion upon which to judge a study’s quality?; 3) What version of health do we value when we emphasize these methods and these outcomes?; Is this the right version?; 4) What interests are served by these types of results?; and 5) On what bases did the journal accept this article while rejecting others of equal methodological quality (i.e. why does the journal want to publish this material at this time)? A values-free view
of critical appraisal is highlighted in the following quotation: “Linking treatment options with outcomes is largely a question of fact and a matter of science. Assigning preference to outcomes, by contrast, is a matter of values” (Guyatt, Hayward, et al. 2002, 188).

Each of the three critical appraisal questions brings to mind potential associated ethical questions. For example, consider the question “Are the results valid?” In quantitative health research, validity is often determined probabilistically, by establishing that certain results were unlikely to appear through chance alone and are therefore likely attributable to a true effect. However, the degree of statistical uncertainty one is willing to tolerate is a matter of values rather than of science. For example, if one is trying to develop a treatment for a uniformly fatal condition with no current treatment, one might accept a lower degree of probability that positive results of effectiveness represent true effects. A clinician’s moral duty to try to help patients who are destined to succumb to their illness might guide the decision to allow greater uncertainty about effectiveness, when much higher degrees of probability of effectiveness are required for treatments of conditions with less associated mortality. Indeed such was the case in the early stages of AZT trials in which some AIDS activists pushed hard for AZT to be approved quickly, even with a great deal of uncertainty about its effects (both positive and negative) because of the universal and rapid fatality of AIDS at that time (Epstein 1996, 243).

Let us now consider question two: “What are the results?” This question is meant to direction the reader’s attention to determining the size and precision of an effect. Even though the size of an effect seems like a relatively descriptive feature, it can contain
implicit value judgments. For example, the particular ratios or values used to express results can convey different meanings depending on their interpretation and these interpretations might reflect value judgments. Some investigators criticize the use of ratios of relative risk, because these might mask a very small change in absolute risk. A small change in the risk of death from 0.01% to 0.005% will still be a relative risk reduction of 50%. This might not be ‘clinically meaningful’ from a physician’s or investigator’s point of view. By contrast, a woman who is in remission from breast cancer and who might have a relatively low risk of dying from a tumour in the unaffected breast might wish to take any steps to reduce her risk of recurrence and opt for a preventive mastectomy even if the absolute risk reduction is small. Results are not facts, but interpretations of quantitative estimates of facts. Interpretation necessarily includes an infusion of an interpreter’s values, which are likely to differ between individuals.

Question three – “How can I apply these results to patient care?” -- is the critical appraisal step that is most obviously value-laden because it involves formulating the information and/or recommendations that physicians will give to patients. In discussing how to answer this question, the Users’ Guides asks readers to consider whether “… the investigators measured all outcomes of importance to patients” (Guyatt 2002, 51). A clinician might wonder whether a given study tried to investigate outcomes that are meaningful to patients. The ethical dimension is clear -- if the outcome of interest is not at all important to patients, then no matter how well a study has been designed and executed, it cannot be applied to patient care.
Molewijk and colleagues take this analysis a step further (2003). Their attempt to summarize clinical facts for presentation in a decision aid demonstrates the implied normativity of the facts themselves. They conclude that it is not possible to present neutral facts as part of a decision-making process. Instead, the facts themselves contain a normative dimension that not only informs the decision-making process but transforms it.

Apart from this diversion, no other values are explicitly mentioned. The following passage from *Evidence-based Medicine* makes the point that the critical appraisal step and evidence generation in general are viewed in a value-neutral way:

> So in deciding whether a valid guideline is applicable…we need to identify the 4 B’s (burden, beliefs, bargain, barriers) that pertain to the guideline and decide whether they can be reconciled with its applications…Note that none of these B’s has any effect on the validity of the evidence component of the guideline. (Straus et al. 2005, 172)

Instead, values (such as cost-effectiveness, perception of usefulness, etc.) are part of evidence-based decision-making but for EBM, they lie outside of evidence generation and the critical appraisal of evidence.

The preceding discussion points out that ethical values might be an important and unacknowledged component of critical appraisal. Recently, EBM proponents have been emphasizing the importance of patients’ values in clinical decision-making (Montori and Guyatt, 2008, 1815; Guyatt, Haynes, et al. 2008, 12-13) which is laudable although banal. There is nothing within EBM that suggests that evidence-based recommendations ought to be forced on patients; therefore, the recognition that patients have the right to informed
consent is not novel. At the same time, the absence of attention to any other values apart from patients’ values ignores the fact that parties other than patients might have values relevant to the practice of EBM. In the course of ordinary clinical decision-making there are at least two parties involved: patients and clinicians. Other parties might also be involved directly or indirectly: society (through the services or interventions that are covered through either public insurance plans), private companies (through the services or interventions they are willing to cover), institutions (who might choose to develop certain programs or clinics and not others), and family members (who might be involved in decision-making or expected to respond to the consequences of decisions made by patients). EBM is silent on whether or how these values operate within its practice.

It is easy to see how clinicians’ values might be a part of clinical practice. Overt expressions of clinician values such as “I don’t believe in prescribing this medication,” or, “I think you should try to tolerate that side effect,” might be less common than clinician values being manifest through ‘clinical expertise.’ The nature of clinical expertise (or judgment) is a subject that goes beyond the scope of this thesis; however, for the purpose of this discussion, we can note that clinical expertise, like any form of expertise, involves a considered weighing of various options or factors at play in a clinical scenario. Further, it contributes to a decision about what intervention(s) or course(s) of action to recommend to patients. Given that there is no formula for the exercise of clinical expertise in every circumstance, the weighing process itself is subjective in the sense that different clinicians will assign different weight to the various options or aspects of the decision under consideration. When it comes to clinical
expertise about diagnosis, some clinicians might weigh the appearance of certain symptoms more heavily than other symptoms. With respect to treatment, some clinicians might weigh the possibility of symptomatic improvement more heavily than the side effect burden than other clinicians. These values might be explicitly expressed in the course of decision-making, or might instead subtly play a role in clinicians’ expertise and inform what they discuss with patient in the process of deciding about a clinical plan. EBM may remove these values from our view by implying that adherence to an evidence-based recommendation (e.g. to take a certain treatment) is ethically the right thing to do.

While patients’ values are explicitly described as part of evidence-based decision-making, the preceding discussion reveals that other ethical values might also be relevant to, and operational within, this process. These values can be obscured because EBM contains a basic ethical platform upon which its practice is based. The next section will discuss this ethical basis of EBM.

2.2. The ethical basis of EBM
Let us start with the question, ‘Why should we practice EBM?’ There is no empirical answer to this question. In other words, there is no evidence of the sort that is recognized by EBM that EBM is more likely to lead to improved health than other forms of practice (Norman 1999, 129-30; Shahar 2003, 134). Furthermore, leading proponents of EBM acknowledge that there cannot be such evidence because conducting RCTs of EBM practice would be difficult and possibly unethical (Haynes 2002, 6). EBM’s scientific superiority, and therefore greater effectiveness in improving patients’ health compared to
pre-EBM practice, are simply assumed to be true. Therefore, by its own standards, EBM is not evidence-based. Some EBM proponents point to specific examples of how in recent years, well-designed RCTs have demonstrated that standard treatments were doing harm, findings which led to significant practice change. However compelling these individual case examples appear, they cannot provide support for the general contention that EBM is the most effective means of achieving health. Thus, it is obliged to defend its assumptions philosophically, which its advocates do only implicitly through the values and assumptions described below.

EBM contain an implicit mandate – that we should practice EBM. Thus, the basic conceptual structure of EBM is a normative one. According to the inherent rationale of EBM, it is the most likely path to greater knowledge about which medical interventions are effective. The following diagram illustrates this path

![Diagram]

**Figure 2 – Conceptual structure of EBM**

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20 If EBM cannot demonstrate its superiority empirically, then it should argue in its favour using philosophical arguments demonstrating why the particular empirical methods it espouses are the most likely basis for drawing truthful conclusions.
EBM acknowledges that there can be disagreements between clinician and patient as to what ‘health’ means. Furthermore, EBM posits that in settling these disagreements, priority should be assigned to patients’ values. At the same time, where practitioners and patients can agree on what constitutes health, EBM assumes it can arrive at improved health. Thus, to practice anything but EBM would abrogate the ethical duty of practitioners to provide the most effective means of achieving health. Indeed, some proponents of EBM have argued that failing to make use of EBM’s scientific knowledge is unethical (Davidoff 1999, 82-3). On this view, EBM claims by its very nature to be the most ethical thing to do (Gupta 2003).

EBM, like medicine, does not simply arrive at a moral position; it also proceeds from a moral position. EBM takes certain values for granted. These values (see Table 1) represent the same moral starting point from which medicine as a whole proceeds. Embedded within the concept of EBM is the first basic value -- that we should pursue health. If not, there would be no need for EBM at all, since its ultimate purpose is the improved health of patients. The basic value in favour of the pursuit of health is a relatively uncontroversial one, particularly within the professional health care community. Obviously, the pursuit of health is the raison d’être of the health care professions; therefore, little time is spent questioning it. Controversies about the pursuit of health are more likely to focus on what constitutes health, how to achieve health, or how to allocate resources fairly in order to achieve health. From this initial premise, EBM holds that if we should pursue health, then we should pursue the most effective means of
achieving that goal. Thus, EBM is able to defend the moral conclusion that we should pursue the most effective means of achieving health.

We ought to pursue health.
If we ought to pursue health, then we ought to pursue the most effective means of achieving health.
Therefore, we ought to pursue the most effective means of achieving health.

Table 1 - Implicit values of EBM

It is worth noting that a determination of the best definition of health is a vast subject which lies beyond the scope of this thesis. This terrain is even more contested within psychiatry where notions of healthy or normal mental experience are highly diverse, and where passionate debates about personal freedom play out. What is most important for this discussion is that ‘health’, in an EBM context, is exactly what the researchers who chose particular outcomes to study determine it to be. If the specified research outcome for a drug treatment for major depression is a 50% reduction in depression rating scale scores, as it has been for a generation of RCTs on antidepressants, then that is what ‘health’ is.

In chapter one, I argued that EBM asserts itself through an epistemological claim -- that EBM, rather than medicine-as-usual, is the most effective means of securing knowledge about health (and thereby pursuing health). EBM, rather than medicine-as-usual, should
be the dominant method of pursuing health. In order to defend its assertion of being the most effective route to health, EBM makes two assumptions. First, EBM assumes that only if we pursue the truth (true conclusions about medical interventions) will we discover the most effective means of achieving health. This is a premise that most medical practitioners and researchers would accept as correct. They would point to the numerous successful medical interventions that have replaced previous unsuccessful interventions thanks to a more truthful understanding of human physiology and pathology. Second, and more controversially, EBM assumes that only if we pursue EBM do we maximize the likelihood of arriving at the truth (about the effectiveness of medical interventions). It is with these two premises that we are led to the conclusion that only if we pursue EBM do we arrive at the best means of achieving health.

| Only if we pursue the truth will we arrive at the most effective means of achieving health. |
| Only if we pursue EBM will we maximize the likelihood of arriving at the truth. |
| Therefore, only if we pursue EBM do we arrive at the most effective means of achieving health. |

**Table 2 – Implicit epistemological assumptions of EBM.**

The unstated moral value that we should pursue the most effective means of achieving health, and the epistemological assumption that EBM is the most effective means of achieving health, together lead to an inescapable moral conclusion: that we should practice EBM. This conclusion arises out of the implicit values and assumptions of
If we do not practice EBM, we are not pursuing the best means of achieving health, which contravenes a fundamental ethical duty of practitioners. EBM justifies its practice ethically and asserts a moral obligation for its practice. This moral obligation constitutes the bedrock of EBM’s ethical commitments—improved health through improved knowledge of the effectiveness of interventions, best achieved via EBM.

We ought to pursue the most effective means of achieving health.
Only if we pursue EBM do we arrive at the most effective means of achieving health.
Therefore, we ought to pursue EBM.

Table 3 – The (moral) justification of EBM

This section has argued that EBM contains an ethical rationale (see Figure 3 at end of chapter). Does this rationale reflect a particular ethical theory or orientation? The next section will discuss this question.

2.3. What theory of ethics is reflected in EBM’s values?

EBM, then, is committed to certain moral values and is justified by an ethical argument rather than an empirical/scientific one. Yet the authoritative accounts of EBM do not explicitly identify or elaborate upon its ethical foundation, nor do they tie themselves explicitly to a single theory of ethics. There is but one reference late in the Users’ Guides to EBM’s ethical foundation, in a chapter entitled “Economic Analysis”:

Some would argue—taking an extreme of what can be called a deontological approach to distributive justice—that the clinician’s only
responsibility should be to best meet the needs of the individual under her care. An alternate view—philosophically consequentialist or utilitarian—would contend that even in individual decision-making, the clinician should take a broader social view. In this broader view, the effect on others of allocating resources to a particular patient’s care would bear on the decision. Our own belief is that while individual clinicians should attend primarily to the needs of the patients under their care, they should not neglect the resource implications of the advice they offer their patients. Neglect of resource issues in one patient, after all, may affect resource availability for other patients under their care.

(O’Brien et al. 2002, 625–26)

Despite the claims of these authors, others have argued that EBM has consequentialist, rather than deontological, underpinnings (Kerridge, Lowe, and Henry 1998). The basic principle behind EBM is that interventions that are shown (using EBM-preferred research methods) to have a positive effect on large populations will, if applied to individual patients, lead to improved health outcomes for those patients. This indicates consequentialist commitments – what is important for consequentialists is not the agent, or the action performed by the agent, but the consequence of that agent’s action.\(^{21}\) A consequentialist viewpoint must be able to specify and defend a consequence that is good in itself, and within EBM, health is assumed to be that good. However, not just any definition of health is permitted. EBM’s approach to decision-making gives researchers, first and foremost, the authority to define what constitutes improved health or decreased harm to health. It is researchers who typically choose the outcomes under investigation in medical research, and it is these outcomes that EBM seeks to achieve. This is not to say that deontological and virtue ethics are actively dismissed; however, the central purpose of EBM practice is not to foster clinicians’ virtues or enhance our actions or duties.

\(^{21}\) Consequentialism is the ethical theory that the [moral] ‘value of an action derives entirely from the value of its consequences’ (Blackburn 1996, 77).
towards patients. If EBM pleased patients and/or physicians, but did not improve health outcomes (consequences) any further that what preceded EBM, there would not necessarily be the urgent imperative—as its authors suggest—to teach and learn it.

EBM is not only consequentialist, it also contains a commitment to utilitarianism. For a consequentialist theory to be considered utilitarian, it must emphasize how well specific consequences maximize ‘utility’, or happiness (Blackburn 1996). In addition, utilitarian theories must be impartial and consider everyone equally in the calculation of utilities. These criteria are manifest in the principle of utility specified as “the greatest happiness for the greatest number” (Solomon 1996). EBM does take a broadly utilitarian ethical perspective, in that it focuses on maximizing good by maximizing particular health outcomes. Indeed, Straus et al. (2005) even use the language of utility: “a utility is the measure of a person’s preference for a health state” (156); “decision analysis requires explicit and quantitative specification of values. These values, expressed as utilities, represent measurements of the value to the decision maker of the various outcomes of the decision” (189); and “The winning strategy, and preferred course of action is the one that leads to the highest utility” (156).

EBM assumes that there will be general concordance between what researchers assume to be improved health and the health states that patients prefer. Thus, if patients choose according to their preferences, this will lead to greater good in the form of improved health. But even though utility is defined as the satisfaction of patient preferences, this does not capture what is emphasized as good in EBM. If patient preferences were
satisfied but EBM led to no improvement in health, or to even worse health (according to researchers or clinicians) than pre-EBM practice, the principle of EBM utility would not be satisfied.

The preceding discussion has focused on the greatest good, but what about the greatest number? We can see how EBM concerns itself with this aspect of the principle of utility by several references within the *Users’ Guides* to considerations of cost in the process of medical decision-making. For example: “Before acting, therefore, ascertain the benefits and risks of therapy and seek assurance that the societal resources (usually valued in dollars) consumed in the intervention will not be exorbitant” (Guyatt, Cook, et al. 2002, 57); or “clinicians need not only weigh the benefits and risks, but also consider whether these benefits will be worth the health care resources consumed” (O’Brien et al. 2002, 623). Why should cost be a relevant factor? One could imagine the whole EBM program existing without any consideration of cost at all. Indeed, EBM proponents have claimed that EBM is neutral about cost, supporting only the most effective interventions regardless of cost (Sackett et al. 1996). Yet, cost consideration is explicitly mentioned in the authoritative texts and actually performs a crucial piece of ethical work in cementing EBM’s commitment to utilitarianism. Cost containment means that we have the resources to maximize the number of people who can benefit from (evidence-based) interventions. Thus, the principle of utility—greatest good for the greatest number—is satisfied.

There is an interesting conceptual symmetry between EBM and utilitarianism. Utilitarianism involves a moral accounting in which the amount of utility produced from
one action is counted and compared to the amounts of utility produced by alternative actions. The process EBM puts forward for clinical decision-making that incorporates patients’ values (decision-analysis) is very similar. Using EBM-preferred research data, the clinician estimates the probabilities of the various possible outcomes and then, ideally, the patient expresses his/her preferences for those outcomes in quantitative terms called ‘utilities.’ The clinician uses quantitative expressions to determine what course of clinical action will maximize utility for the patient. The purpose of decision-analysis is to engage in a similar type of moral accounting as in utilitarianism: to determine which action will lead to the greatest moral good (according to the patient). However, whether people’s preferences can be quantified, whether such quantification results in meaningful information, and whether such a procedure would lead to health, happiness or justice – on these matters EBM is silent.

3. Ethical debates in psychiatry

In the previous section, I examined the ethical orientation of EBM. In investigating the ethics of evidence-based psychiatric practice one wonders about the extent to which EBM’s ethics converge with psychiatry’s ethics: to what extent can EBM provide psychiatry with an ethical framework that might assist psychiatry in resolving some of its specific ethical issues? In this section, I will explore the major themes that have arisen in psychiatric ethics in the contemporary era.

Consideration of ethical issues has been an integral part of the development of psychiatry as a professional and scholarly discipline. While some of the specific issues have changed
as psychiatric practice has evolved, the main ethical questions have consistently concerned the two primary tasks of psychiatrists: diagnosis and treatment.

In order to determine who does or does not fall within their professional purview, psychiatrists must determine who can be thought of legitimately as having a psychiatric disorder. This task requires that psychiatrists possess shared and objective standards of what constitutes a psychiatric disorder. Psychiatrists have traditionally faced two major problems in meeting these criteria. First, they rely primarily on self-reporting of symptoms. People can say that they are experiencing things without actually experiencing them, and clinicians have no independent method (such as lab tests) of verifying those statements. Unlike in other areas of medicine, specific anatomical lesions or physiological dysfunction have yet to be identified as the causes or even correlates of psychiatric disorders. Apart from observing patients’ behaviors, there are few objective methods of assessing most psychiatric disorders. Critics of psychiatry charge that the absence of objective verification increases the likelihood that psychiatric diagnoses contain value judgments—rather than scientific judgments—about what is normal and what is abnormal.

The second perennial problem in diagnostics is how to draw the line between ‘normal’ and ‘abnormal’ in domains that exist along a continuum and where the range of normal is wide. Researchers can try to differentiate scientifically between normal and abnormal using prognosis (the development of morbidity over time). People who suffer from a true disorder ought to fare worse over time than people who do not. But apart from definitive
outcomes (such as completed suicide), psychiatrists are faced with the problem of determining which outcomes should be considered morbid, and how to determine whether these outcomes were caused by the symptoms, the social contexts in which people live, or an irreducible combination of both.

These intractable problems in the philosophy and ethics of psychiatry collided with the arrival of new drug treatments in the mid-20th century. Medications such as lithium and chlorpromazine seemed to reduce dramatically certain psychiatric symptoms, and these results strengthened the case that such symptoms had a biological basis. Nevertheless, the persistent absence of a system of objective verification of psychopathology, the limitations of the new drugs (both in terms of effectiveness and side effects), and the obvious failures of, and grave harms done by, much-vaulted therapies such as malaria fever therapy, insulin coma therapy, and frontal lobotomies (Fennell 1996), kept alive ethical questions about psychiatric diagnosis and treatment through what came to be known as the antipsychiatry movement.

The antipsychiatry movement emerged in the late 1950s and took aim at both the content and process of psychiatric diagnostics, at psychiatric treatments and their adverse effects, and at the institutional settings in which treatment was often delivered. Antipsychiatrists argued that psychiatric disorders were not real disorders at all, that mental illness was merely a label for describing violations of social norms, and that psychiatrists couldn’t even differentiate between patients with real and feigned mental disorders (Szasz 1974; Rosenhan 1973; Scheff 1984). These authors picked up on the basic conceptual and
ethical problems of psychiatric diagnosis: if we can’t be sure that psychiatric problems are real diseases, how can we be ethically justified in construing them as abnormal? Critics of psychiatry also highlighted ethical issues concerning treatment, particularly in psychiatric institutions. They worried that much of what we construe as mental illness was actually a response to the internal dynamics and organization of psychiatric institutions (Goffman 1961) and that psychiatric institutions and treatments—such as lobotomies and unmodified ECT—were really expressions of social control rather than of therapeutic intervention (Scull 1979; Scull 1977). Some scholars brought a feminist analysis to this debate by arguing that psychiatry was inherently misogynistic. Both Chesler (1972) and Showalter (1985) argue that, at various times in history, women have been considered more vulnerable to mental illness or more likely to be mentally ill by virtue of innate biological predispositions. As a consequence, they contended, women were more likely to be confined to psychiatric institutions. In this interpretation, psychiatry was complicit in the systemic oppression of women. Both feminist scholars, and their revisionist predecessors, viewed psychiatric hospitalization and treatment as ethically questionable practices that often did more harm than good.

In 1980, there was a major revision, expansion, and dissemination of the Diagnostic and Statistical Manual (DSM) of psychiatric diagnosis, the dominant diagnostic reference book in North America. One of the goals associated with this revised third edition of the DSM was to render diagnoses more objective by making diagnostic criteria less open to psychiatrists’ interpretation (and therefore less subject to their value judgments). The DSM III’s authors accomplished this by developing criteria sets for each diagnostic
category that were anchored primarily in behavioral signs, and attempted as much as possible to avoid diagnostic criteria that were explicitly theoretically derived (for example, symptoms whose presence would be posited by psychoanalytic theory). Contemporaneously, the appearance of Prozac (fluoxetine) on the market in the mid-1980s heralded a new era of ‘biological psychiatry’ (Shorter 1997) and was followed rapidly by several novel additions to the pharmacopoeia. Newer medications with more specific actions and seemingly fewer side effects than their older counterparts promoted a belief that psychiatrists were closer to an objective, neurological understanding of mental disorder. At the same time, a confluence of factors, including an evolving understanding of civil rights for mentally ill persons and social policy that promoted less restrictive outpatient care, responded to some of the ethical concerns about hospitalization raised by the antipsychiatrists.

A new generation of patients—the psychiatric ‘consumer-survivors’—has kept alive some of these conceptual and ethical issues. They argue that mental disorder is brought about and perpetuated, at least in part, by problematic social circumstances such as poverty and poor living conditions. It simply cannot be understood solely as an objective neurobiological process. The second and more radical message is that psychiatric treatments, even if scientifically based and concordant with patients’ values, might do more harm than good (Everett 2000). The side-effect profile of the second generation of antipsychotic medications is sometimes highlighted as an example that psychiatric treatments are still hazardous (Carey 2008). As a result, survivors also question the ethics of psychiatric treatment, especially involuntary treatment, which is legally permissible
throughout North America and many other legal jurisdictions.

This summary does not provide an exhaustive list of all ethical issues relevant to psychiatry. For example, I have omitted consideration of how decisional incapacity can affect psychiatrists’ work with mentally ill persons. There are also major issues at the interface of psychiatry and the criminal justice system. This review does, however, capture some of the major themes from both historical and contemporary ethical debates about psychiatry. Ultimately, many day-to-day clinical ethical issues in psychiatry result from these still unsettled debates concerning the legitimacy of psychiatric diagnoses, the risks versus benefits of psychiatric treatments, and the rights of psychiatric patients in view of psychiatrists’ legal powers to detain and treat them involuntarily. Proponents of EBM hope that grounding psychiatric diagnosis and treatment in scientific evidence will put psychiatry on firm ethical ground. As discussed earlier in this chapter, EBM is certainly motivated by ethical commitments; however, these might or might not address psychiatry’s core ethical issues. The next sections will explore EBM’s ethics and whether they address existing ethical issues within psychiatry.

4. Can the ethical values and theories reflected by EBM respond adequately to existing ethical issues in psychiatry?

The utilitarian commitments of EBM might help psychiatry with ethical concerns that have been raised repeatedly about psychiatric treatments—namely, that psychiatric treatments do not help and might even harm patients. EBM tackles quite directly the question of which treatments are effective, ineffective, or harmful. On the surface, it
appears as though the utilitarian commitments of EBM serve psychiatry quite well by identifying which of its treatments can improve health for the greatest number of patients. But this impression could be misleading. Could EBM lead to the support of interventions that are less effective than they appear? Technical bias (a bias in favor of what we know how to do), publication bias (a bias in favor of publishing positive data, certain topics, or certain methods), and source-of-funding bias (a bias in favor of certain interventions because of greater financial resources for research about them) are all potential sources of systematic bias that affect the total pool of evidence and skew it in favor of experimental, commercially profitable, interventions that might be less effective than claimed, ineffective, or even harmful. These biases might also lead us away from interventions that could be effective.

The case of pharmacotherapy for adolescent depression illustrates the problem of embedded bias within EBM. The development in the 1980s of selective serotonin reuptake inhibitors (SSRIs) as a treatment for depression changed practitioners’ attitudes towards initiating antidepressant treatment. Because of the belief that they had a relatively benign side-effect profile compared to earlier classes of antidepressants, and were at least equally effective, physicians were more apt to prescribe them on a trial basis than previous antidepressants. This was as true for the adolescent population as it was for the adult population. Extrapolating largely from studies of efficacy conducted in adults, and from a small body of research on adolescents, practitioners also prescribed SSRIs to treat adolescent depression. But in 2001, David Healy, a psychiatrist working in Wales, created a maelstrom in Canada when he publicly argued that SSRI use was linked to
suicidality and completed suicide. At the time, Healy was disbelieved, criticized as an alarmist, and his contract for a new position at the Centre for Addiction and Mental Health and the University of Toronto was rescinded by its Department of Psychiatry (Carey 2005; Healy 2002). Three years later, writing in the *Canadian Medical Association Journal*, Jane Garland (2004) discussed the warnings that had been issued in 2003 by several national regulators (including in Canada and the United States) about the potential for SSRI treatment to increase suicidality in children and adolescents. Pointing out the pernicious effect of publication bias, Garland argued that once the psychiatric community considered proprietary data (data in possession of the pharmaceutical companies that had funded the studies of SSRIs but not in the public domain) alongside published data, they could conclude that, with the possible exception of fluoxetine, SSRI treatment in the adolescent population was ineffective and potentially harmful. Several authors have since addressed these questions of effectiveness and risk of suicidality in the adolescent depressed population (Cheung, Emslie, and Mayes 2005; Hall and Lucke, 2006; Hetrick et al. 2007), and this debate has taken on a scholarly, rather than a polemical tone.

Was EBM implicated in the reluctance to take seriously claims of harm caused by SSRIs? It seems quite possible that because claims of harm were initially brought forward on the basis of anecdote, a lower form of evidence, and were not supported by the publicly available RCT data, they were not given serious consideration. This example illustrates how EBM can lead us towards interventions that might be ineffective or even harmful, and thus might not satisfy the utility principle. Technical bias, exemplified by the EBM
approach, keeps us suspicious of claims that are not justified on the basis of the highest form of evidence -- RCT data -- while publication bias removes from our view certain data. Source of funding bias keeps the research literature focused on interventions that are commercially profitable while giving private funders (such as pharmaceutical companies) power to determine which data are even released into the public domain. Even though EBM’s utilitarian ethics appear to serve psychiatry quite well by attempting to determine which treatments improve health for the greatest number, and which are useless or even cause harm, it might fail in these aims because it contains its own embedded biases that prevent us from accurately assessing whether good can be achieved. While these biases are common in the medical literature across specialties, they generate greater ethical concern for psychiatric research because of the harm caused by interventions within the recent history of psychiatry. For critics, the case of SSRIs and suicidality only strengthens the view that current psychiatric ‘evidence’ continues a long tradition of psychiatrists claiming scientific justification even while doing harm to patients.

If psychiatrists know that their sources of information are potentially distorted in particular directions, adopting EBP -- which does not take these distortions into consideration -- undermines their claim of having more accurate knowledge compared to others. Moreover, if psychiatrists cannot rely on research data, then they cannot be confident in the effectiveness claims of EBM-researched interventions. This might lead to recommending interventions that are not effective, or bypassing interventions that are effective. Thus, EBP might lead to worse rather than better patient care. This is contrary to the basic ethical duty of medical practitioners, a problem that is compounded if
psychiatrists are aware of the negative patient care consequences of EBP but continue to endorse it.

While EBM directly tackles ethical questions related to the efficacy of psychiatric treatments (even if it does so problematically), it largely ignores other major ethical debates in psychiatry, such as the debate concerning the validity of diagnosis. Instead, EBP assumes that psychiatric diagnoses are valid and focuses attention on which tools do a better or worse job of establishing diagnoses. In so doing, it might distract from the normative questions of whether certain experiences should be diagnosed as medical conditions or not.

For EBM-preferred research methods, diagnosis is an essential starting point, because the validity of results depends upon the research participants being similar—in other words, being from a homogenous diagnostic group. Diagnoses need to be objectively verifiable, otherwise it cannot be determined that two people with the same diagnostic label actually have the same problem. In psychiatry, diagnoses are vulnerable to charges of subjectivity resulting both from the differences between those who do the diagnosing and also between those who are diagnosed. Contemporary psychiatric diagnostics attempt to respond to these demands of research by moving, through each revision of the DSM, towards diagnostic categories in which mental experiences are increasingly behaviorally anchored. Quantification, achieved through numerical scores on symptom rating scales, is another strategy to improve the objectivity of diagnoses. These strategies might yield groups that are homogenous in some sense, but these diagnostic procedures obscure the
substantive question of whether a given diagnostic entity is a disease requiring medical intervention.

Carl Elliott’s article on apotemnophilia, which appeared in *The Atlantic* in 2000, vividly illustrates this point. Exploring the desire experienced by some persons to have one or more limbs amputated, Elliot raises questions about whether this desire constitutes a mental disorder, a fetish, a lifestyle preference, or some other phenomenon. He describes the lengths to which some people have gone to obtain an amputation, including various forms of self-mutilation. I have used Elliot’s article to discuss philosophical and ethical issues in psychiatric diagnosis with several groups of psychiatry residents and their reaction is always the same. We want to believe this is a mental disorder of some sort rather than a lifestyle preference. As a result, we balk at the idea of amputating limbs as requested, because a disorder requires reversal, not collusion.

Not all desires for surgical changes to the body are considered to be abnormal. We do not tend to think of people who want larger breasts, differently shaped noses, or full body tattoos as disordered. We are prepared to allow people to pay for and obtain these bodily alterations. Why the difference with apotemnophiles? Ultimately, it rests in the fact that what they value about living a good life is so radically different from our own conception that we can’t believe it is psychologically normal. As a result, we resist the idea that the medical profession should enable people to fulfill such (pathological) desires.

Can EBM help to resolve these types of disagreements about the validity of diagnosis and
help us ‘understand disease’, as suggested in the earlier quotation from Paris (2000)? An EBM approach to this issue might be as follows. We could design a tool that can reliably determine who is an apotemnophile and who is not. We could conduct an RCT in which some participants received their desired amputation and some did not, and then attempt to measure their satisfaction or degree of suffering. Perhaps the results would be compelling: those who received the amputation might be very satisfied compared to those who did not. Yet these results would bypass an essential piece of moral work, which involves the determination of whether we want to identify apotemnophilia as a mental disorder or not. Should we call such people disordered and refer them to psychiatrists, as we might do with someone who has a delusion about a body part? Or should we call them normal and refer them to cosmetic surgeons, as we would someone who was dissatisfied with his or her appearance? This judgment might be informed by scientific data, but it is ultimately normative in nature.

Even if we can agree that a certain condition -- say schizophrenia -- is a disorder, there is more moral work to be done to figure out how to treat it. EBM obscures these normative aspects of treatment. Some might argue that the right thing to do is eliminate symptoms, while others might claim that a better treatment approach is to assist patients in learning how to live with symptoms. But how do we come to decide which outcome is preferred? All that an EBM approach can conclude is that treatment ‘A’ works better than treatment ‘B’ for a particular symptom. There is no room within the moral framework of EBM to consider these questions of how best to live when one has a disorder. Using EBM, it is researchers who decide what interventions should be evaluated and what outcomes are of
most importance. Through its embedded ethical stance, EBM implies that following the evidence will lead to improved health and/or decrease in harm, without much consideration of what constitutes improved health in the first place and who ought to define it.

A final ethical issue in psychiatry that EBM is unlikely to resolve is the question of whether involuntary psychiatric treatment is legitimate. As long as we believe that EBM is a valid method of determining diagnostic categories and treatment effectiveness, we might conclude that we have an ethical responsibility to see that it gets to the greatest number of patients, to do the greatest good, even if through involuntary means. One must introduce ethical considerations lying outside the utilitarian ethics of EBM, such as notions of human rights, to consider whether involuntary treatment is ethical. One could adopt a utilitarian approach to involuntary treatment by assigning utility to patients’ ability to refuse unwanted treatment alongside whatever utility would be generated by treating patients in involuntary circumstances. It is noteworthy, however, that the current and successful justifications for respect of patients’ refusals of treatment are not grounded in such utilitarian calculations, but rather rely on concepts of inalienable human rights, such as the freedom from bodily interference and the right not be to arbitrarily detained.

5. Conclusions

I have argued that the complex ethical issues in psychiatry are beyond the scope of EBM’s moral framework. These issues extend well beyond questions of treatment effectiveness, or how to achieve the greatest good for the greatest number through
psychiatric treatments, to more fundamental questions of how we define disease, how we understand abnormality, and what constitutes a humane response to both. EBM – at least as it is described in its authoritative texts - can draw attention away from these important ethical questions, focusing on narrower issues of treatment effectiveness in rarefied circumstances. Although advocates of an evidence-based approach to psychiatry hope to quell concerns about the ethically thornier questions through scientifically valid research data produced by replicable methodologies (something along the lines of, “we are not imposing our values, we are just going by the evidence”), they neglect to consider that, at best, EBM’s ethics can only address a limited set of ethical questions. However, as I suggested earlier in this chapter, it is actually questionable whether EBM can accomplish even this more limited goal. As a result, EBM cannot by itself provide the ethical substantiation sought by some psychiatrists.

Thus far in this dissertation, I have examined the ethics of EBM and of evidence-based psychiatry as laid out in the key EBM texts (see Figure 3). My analysis has examined these texts (‘literal’ EBM) and the critical debate that grew up in response to them. However, the ethics of evidence-based psychiatry lie not only in what is contained or implied by the authoritative texts that describe it, but in the views of those who are responsible for its ongoing development, implementation, and critique. Thus, my analysis to this point should be considered provisional. Ultimately, EBM and EBP are ideas that must be put into practice, and in that live context, ethical commitments that were not evident from ‘literal’ EBM might become apparent. In order to elucidate these ethics of EBM in practice, the next three chapters will be devoted to a qualitative investigation
involving the participation of three groups of informants: 1) developers of EBM; 2) mental health professionals involved in the development, implementation and/or criticism of EBM; and 3) scholars who have considered EBM from ethical or philosophical perspectives. The next chapter will discuss the methodological approach and analytic framework in which these interviews were conducted and understood.
Basic Ethical Principle of Medicine and Psychiatry:

\[ \uparrow \text{Help} \quad \text{AND/OR} \quad \downarrow \text{Harm} \]

in order for medical practice to be ethical, it must increase help or decrease harm or both

Pre-EBM sources of information

- often inaccurate and/or biased

EBM-preferred sources of information:

- more likely to be accurate, less likely to be biased

Convention
Authority
Faith
Intuition
Theory
Practitioners’ Medical Education
Research data

\[ \downarrow (= \text{leads to}) \]

? knowledge about health interventions

\[ \downarrow \]

some worse health outcomes

\[ \downarrow \]

No help OR \( \uparrow \) harm

Therefore, pre-EBM practice was not as ethical as EBM is

Patients’ values or preferences are concordant with these outcomes

\[ \uparrow \text{knowledge about health interventions} \]

\[ \downarrow \]

better health outcomes

\[ \downarrow \]

\( \uparrow \) help OR \( \downarrow \) harm

Therefore, EBM is ethical

Figure 3 - Ethics of EBM as implied by ‘literal’ EBM
References


Goffman, E. 1961. *Asylums: Essays of the social situation of mental patients and other*


Chapter Four

A Qualitative Investigation of the Ethics of EBM:
Research Approach and Methodology

1. Introduction

The first three chapters of this thesis have investigated the scholarly literature and primary texts concerning EBM and evidence-based psychiatry. This review drew my attention to some of the key conceptual and ethical issues facing EBM and evidence-based psychiatry, and also to the unanswered questions concerning the ethics of evidence-based psychiatry. This first phase of the project also allowed me to provide a provisional analysis of the ethics of ‘literal’ EBM and evidence-based psychiatry. The first chapter described EBM, discussed the academic debate concerning EBM, and identified some unanswered questions about its meaning and application in practice. The second chapter highlighted the distinct features of psychiatric disorders and treatments, and the potential philosophical and ethical challenges that may arise in the context of applying EBM to psychiatry. Chapter three explored the ethical commitments of EBM and psychiatry and investigated the issue of whether EBM could supply psychiatry with the ethical substantiation it seeks. The content of these chapters have facilitated the development of a provisional analysis of the ethics of EBM and evidence-based psychiatry as well as a framework that depicts the implied ethics of ‘literal’ EBM. The framework is a tentative depiction of the ethics of EBM as elucidated from its key texts. This framework guided this next, empirical stage of research which involved interviews with informants about their understanding of the ethics of evidence-based psychiatry. I interviewed three groups of participants: group one consisted of people who were, and
remain, involved in the development of EBM; group two consisted of practitioners working in mental health, who are involved in the implementation and scholarly debate about the use of EBM in mental health practice; and group three participants were scholars who had investigated philosophical or ethical aspects of EBM. The participants’ viewpoints clarified and extended what is found in the EBM texts (‘literal’ EBM). I was then able to use these two different kinds of sources (texts and people) to re-examine my tentative framework and develop a new version describing the ethical commitments of evidence-based psychiatry. I will bring together my interpretation of participants’ views with my earlier analysis of ‘literal’ EBM in chapter seven and address the question of whether evidence-based psychiatric practice is ethical practice.

Why is an empirical investigation of this kind necessary? Typically, what is ethical has been the domain of philosophically-oriented bioethical analysis, while a description of what people believe to be ethical falls within the scope of sociology or anthropology. Shouldn’t an ethics investigation aim to unravel the ethical aspects (theories, principles, values) at play at the conceptual level, independent of what any informant thinks they might be? After all, an informant’s description of the ethics of EBM is just that - a description – which does not mean that those are the ethical commitments of EBM. I believe that the ethics of EBM and evidence-based psychiatry cannot be adequately investigated without an empirical phase for two reasons. First, EBM is more than a concept or theory – it is also a model of practice. This means that it cannot be fully understood unless it is examined as it manifests in practice by those who attempt to implement and use it. Writing about the Russian context, Geltzer’s qualitative analysis of
thirty-five interviews concerning the uptake of EBM in that country aptly demonstrated how the application of EBM theory is practice context specific (2009). Second, as I have previously argued, the theory of EBM is underdeveloped and aspects such as its ethics are mostly implied rather than stated. Thus, its ethical commitments are more completely understood by asking those individuals who have been most closely involved in its development, implementation and critique to clarify and extend what is found in the texts -- including what they assume and interpret from what is written and not written. It is the iterative process between what is contained in the written sources about EBM and evidence-based psychiatry, how users understand those sources, and how they practice EBM and evidence-based psychiatry that ultimately determines its ethics. As a result, both textual and human sources are needed to identify the ethics of EBM and evidence-based psychiatry, and to develop an analysis of whether evidence-based psychiatric practice is ethical practice.

While EBM is itself an approach to how to conduct and evaluate research, one has to step entirely outside its epistemological framework in order to research it. This is because the research strategies endorsed by EBM as being the most valid (such as meta-analyses and RCTs) would not allow one to investigate the questions which form the focus of this thesis, questions which are descriptive and analytical rather than experimental. Thus, I will turn to qualitative approaches that offer systematic methods of gathering and analyzing non-quantitative data. Qualitative research approaches are well-suited to investigate areas not easily amenable to quantification, or which require understanding personal perspectives in depth -- in this case, experts’ views of the ethics of EBM.
The qualitative research tradition falls within a constructivist, epistemological framework. This framework assumes that reality is subjective and plural (Crabtree & Miller 1999, 10) and recognizes that there is no objective place from which to conduct research. Thus, values and perspectives, including those of both participants and researchers, are relevant and contributory to the research enterprise. As a result, all knowledge is contingent and, for some scholars, relative. By contrast, quantitative research methods (including those valued by EBM itself) fall within positivist or post-positivist epistemological frameworks. According to these views, reality has an independent, true standing, and knowledge can be objectively determined. Post-positivism emphasizes the probabilistic nature of knowledge, as opposed to the positivist outlook which aims to achieve knowledge in absolute terms. Post-positivism recognizes the role that values can play in influencing the research process and what ultimately counts as knowledge. At the same time, however, it views good science as separate from values and seeks to separate values from the scientific process as much as possible.

While research traditions tend to be classified as belonging to one or the other epistemological camp, individual researchers do not necessarily commit themselves to one framework and often employ a mix of methods, even while investigating the same subject. For example, researchers interested in postpartum depression might use quantitative techniques to examine symptom prevalence in large populations while employing phenomenological techniques to investigate women’s experiences of depression.
2. Research tradition

This research project will use the qualitative approach of ‘case study’ (Stake 1995, Yin 2003). Such an approach has been employed by a variety of scholars across disciplines (Yin 2003, 1) and there are several texts which describe how to conduct case study research. Of these, two authors are acknowledged as being leading experts in the use of this method, Robert E Stake and Robert K. Yin (Lohfeld 2004, pers. comm.).

Yin’s definition of the case study is “an empirical enquiry that investigates a contemporary phenomenon within its real-life context, especially when the boundaries between phenomenon and context are not clearly evident” (Yin 2003, 13). This is certainly true when considering the question of how practitioners describe the ethics of evidence-based psychiatry. The specific principles, rules and values they might identify are likely to be embedded within the larger scheme of clinical practice and even more broadly, within the professional, cultural and ethical norms of the medical community. Stake defines a case study as a research strategy intended to investigate ‘objects’ (people, institutions, events) ‘bounded’ in place and time (Stake 1995, 2). It is less apparent that the ethics of evidence-based psychiatry are bounded in this manner as they are not defined by discrete temporal or geographical parameters. For the purpose of this phase of the thesis project, the time period of the case study will be bounded by the period of data collection.

Both Stake (1995) and Yin (2003) emphasize the singular importance of clear research questions in case study research, pointing out that not any interesting question constitutes
an appropriate question. Yin (2003) argues that cases are best structured around ‘how’ or ‘why’ questions which create opportunities for exploratory, descriptive and/or explanatory research. Stake (1995) advocates for the development of ‘issues’ to serve as focal points of a case. He argues that conflictual fault lines allow for deeper work than questions which are informational or evaluative. Further, Yin (2003) and Stake (1995) agree that the use of multiple data sources (documents, interviews, observation, and the review of artifacts) and triangulation of these sources are common features of case study research.

Yin’s method of case study research is highly structured. He offers a format for the entire research process including approaches for: 1) preparing for data collection (developing a research protocol, doing a pilot study); 2) collecting data (using multiple sources, maintaining a case study database and chain of evidence); and 3) specific data analytic techniques (pattern matching, explanation building, time series, and logic models). Yin’s approach emphasizes objective observation in the service of confirming or disconfirming specific study propositions. He advocates for high standards of rigour in case study research and views the specificity of his approach as an attempt to meet that demand. Indeed his concerns about validity (both internal and external) and reliability in research methods, along with his interest in propositional confirmation, imply a post-positivist rather than a constructivist epistemology. At the same time, Yin does emphasize the interpretive aspect of all phases of case study research, from the choice of case and unit of analysis, to the actual data analysis, to the drawing of conclusions.
Stake’s approach to case study research is considerably more interpretive and organic than Yin’s. Stake acknowledges that his method is informed by his long history of using case study methods for one purpose in a single discipline -- that is, program evaluation in education. While he favours the use of rich description and interpretation made directly from observations, he is also careful to point out the ways that specific data collection techniques (such as tallies of happenings), or analytic strategies (such as line by line coding) are most appropriate for certain types of research questions.

While case study research emerged from the social sciences, it has been more recently adopted by the field of bioethics. The advent of ‘empirical bioethics’ -- the attempt to describe the moral world rather than philosophize about it -- has sent bioethicists searching for appropriate strategies to investigate their topics. Qualitative approaches, particularly the case study method, have been welcomed by bioethicists wanting to draw upon empirical data that preserves the complexity and meaningfulness of ethical problems (Bell et al. 2004; Martin, Hollenberg, et al. 2003; Martin, Singer, et al. 2003). Thus, the choice of the case study method for a bioethics research project is particularly fitting.

At the same time, there can be concerns about using this type of method for the purpose that I intend. A major issue in any qualitative research is how one can generalize (transfer) findings from one group of sources, such as a group of interviewees, to others. For example, what one group of participants report in one study is not representative -- nor is it intended to be -- of what a larger group of people believe, including those with
similar characteristics to the participants. Thus, both the philosophy and the design logic of any qualitative approach limit the possibility of drawing conclusions applicable to a larger universe.\textsuperscript{22} This could be an important concern for this study, which is trying to investigate the ethics of evidence-based psychiatry in general, not just according to one group of respondents.

The documentary review phase of this project addresses, to some extent, the limitation about transferability. While the participants in this study are only speaking for themselves, they are doing so in reference to \textit{Evidence-Based Medicine} and the \textit{Users’ Guides}, which are the original descriptions of EBM and are accepted as authoritative within medical communities. By referring back to these sources, this group of participants (and thus, others within the larger medical and research communities) have an anchor point for their views which makes transferability possible.

3. Methods

In this project, I was guided by methodological precepts articulated by Stake and Yin, at times drawing from Stake, at others from Yin. The overall ethos of this project is more in line with Stake’s approach rather than Yin’s. While Stake’s approach may be viewed as constructivist and Yin’s as post-positivist, the two authors maintain some views (definitions of case study research; the importance of guiding research questions) and

\textsuperscript{22} This concern is of particular importance within the quantitative, experimental traditions (now dominant within the health sciences) where the overall purpose of research is to obtain generalizable conclusions. Qualitative researchers have a somewhat different concern about ‘transferability,’ the ability of one’s project’s data to be applicable to other participants or groups of interest (rather than population in general). From here on, I will use the term ‘transferability’ rather than ‘generalizability’ as it is more appropriate for the aims of this project.
endorse specific techniques (the importance of obtaining multiple sources of data) that are philosophically compatible in combination. Why the need for combining methods? Case study methods are in evolution with leading exponents often covering different areas or aspects of enquiry. Drawing valuable lessons from more than one leading author when applying the methods to new areas or topics is necessary in order to develop a comprehensive research plan. For example, Stake does not develop a detailed notion of rigour while Yin does address this topic through his recommendation for specific techniques designed to enhance rigour (such as the chain of evidence). There is nothing within Stake’s approach, or within a constructivist epistemology more generally, that would eschew this technique. A chain of evidence makes transparent the researcher’s analytic choice points and the reasoning behind her choices. This transparency can invite productive scholarly debate of the researcher’s choices and interpretations regardless of the epistemological framework that lies in the background.

Stake describes two main types of case study: intrinsic and instrumental. In intrinsic case study research the case itself is of primary interest; in instrumental case study research, the case’s purpose is to illustrate certain important issues of concern to the researcher, the participant or both (Stake 1995, 3). This project was conducted as an instrumental case study, in which the case (three groups of participants plus EBM texts) was used to investigate the issue of interest -- ethical commitments of evidence-based psychiatry.

Stake (1995) argues that case study research begins with the development of issues that evolve as the project evolves. The notion of ‘issues’ stands in contrast to Yin’s
propositions (2003) which are more akin to the hypotheses common in quantitative research. Issues are used to guide and shape the research as opposed to propositions which are designed to be confirmed or disconfirmed. For this project, I have developed two related issues: 1) is evidence-based psychiatric practice, ethical practice compared to pre-evidenced-based practice?; and 2) on what ethical basis is evidence-based practice justified?

As both authors point out, because there are usually more variables of interest than data points, the case study is generally characterized by the use of multiple data sources, “with data needing to converge in a triangulating fashion…” (Yin 2003, 14). In this thesis, I drew upon three distinct groups of respondents who constituted three separate data sources (even while they yielded the same data type – interview data). In addition, the two primary EBM texts reviewed in the earlier chapters served as an additional data source. Yin specifically recommends the maintenance of a case study database and a chain of evidence in order to enhance the rigour, specifically the auditability of case studies. I did both and have discussed further below in sections d) Data collection procedures and g) Rigour.

3.1. Setting, sources and participants

This phase of the project comprised interviews with participants about EBM, evidence-based psychiatry, and ethics. Most informants lived and worked in Canada, the United States, and the United Kingdom while the project was underway. There were three groups of participants: group one consisted of EBM developers; group two consisted of
mental health practitioners involved in the implementation and scholarly debate about the use of EBM in mental health practice; and group three participants were scholars who had investigated philosophical or ethical aspects of EBM. I interviewed these participants in a private venue of their choice. Because of the geographical distance between me (at the University of Toronto) and some of the participants, some interviews were conducted by telephone.

3.2. Sampling and recruitment

I selected the interviewees through a combination of several sampling strategies.

Politically important case sampling, which selects persons considered to be important or highly knowledgeable about the topic (Creswell 1998, 119), was used to identify several potential key informants from each of the three groups. Chain sampling, in which current participants identified other knowledgeable people, was also used to identify other potential respondents. These two sampling techniques were used until informational saturation had been achieved --that is, the point at which there is no new data exemplifying analytic categories (Creswell 1998, 243). This stands in contrast to ‘theoretical saturation’ in which the researcher returns to the field in order to gather further data from purposefully selected sources in order to test the emerging theory. Although I did not know a priori how many informants would be required to achieve saturation (Sandelowski 1995), qualitative case studies often have approximately thirty to forty-five respondents (Creswell 1998, 122). In this case, I anticipated having ten to fifteen respondents per group. By the study’s end, I had interviewed 33 participants: 9 in group one, 11 in group two, and 13 in group three.
I compiled a list of names and addresses of potential recruits. I was aware of most potential participants through their written contributions to the scholarly literature in which case, their contact information was usually available in the public domain, either accompanying their writings or on the websites of the institutions to which they were affiliated. I searched for the contact information of potential informants identified through chain sampling in the same way, although in some cases it was provided to me by the participant. I emailed each potential participant an information letter (see Appendix A). There were a few potential recruits whose email addresses I could not find but whose institutional mailing addresses were available in the public domain; therefore, I sent these individuals hard copies of the information letter. The letter described the purpose and sponsor of the project, what the participant was being asked to do, and potential risks and benefits. The letter provided contact information so the participant could contact me if s/he was willing to participate or had any questions. When participants emailed me, I responded by email and assisted them in scheduling interview times, dates and places where applicable. I sent a second round of emails to any potential participants who did not respond. I did not initiate any further contact if I did not receive a response to the second email. Some people initially agreed to participate but then did not respond to follow-up emails of which I sent two before discontinuing contact.
3.3. Data collection procedures

Yin identifies three principles of data collection (2003, 97) including: 1) the use of multiple sources of data in order to achieve evidentiary convergence;\textsuperscript{23} 2) creating a case study database (compiling collected data in a retrievable, reviewable form so that it is accessible to outside scrutiny); and 3) maintaining a chain of evidence documenting methodological choice points and the rationales behind them. In this project, I adhered to these principles. First, I used multiple sources of data in the form of three distinct interview groups and documentary evidence in order to develop a multi-perspectival understanding of the ethics of evidence-based psychiatry. The project’s database consists of all interview transcripts and the coding scheme with definitions of each code along with corresponding excerpts from the text for each code. I have also compiled a methodological decision trail as well as my reflexive memos into an electronic file. This document reveals some of my own attitudes, values and reasoning which inevitably contribute to and shape the research process and findings.

In terms of the formal collection of data during interviews, I adopted the following procedures. At the start of each interview, participants signed a form acknowledging that they have given informed consent to participate and to have their interviews recorded (see Appendix B). I told participants that they could take a break at any time. All interviews took approximately one hour. Because some interviewees lived at great distance from me, I conducted their interviews by telephone. Following each interview, I completed a ‘postmortem form’ (see Appendix D) which allowed me to reflect on content and process of the interview, including my own reactions to it. In keeping with

\textsuperscript{23} Stake also endorses this principle.
the iterative aspect of qualitative data collection and analysis, the postmortem reflections enabled me to modify the interview guide (see Appendix C for first version) in light of previous participants’ answers and suggestions.

The audiotapes of the interviews were couriered to an independent, professional transcriptionist who transcribed each recording verbatim to a word processing file on her own computer. Once typed, the tapes and electronic files (on USB devices) were couriered back to me. The transcriptionist deleted all interviews from her computer once she received confirmation that the electronic file was successfully opened on my computer. I compared the audiotaped and typed versions of each interview to correct any transcription errors. I also ensured each transcript was stripped of any potentially identifying data, unless it was information that was available in the public domain or information that the participant was comfortable including. On a few occasions, in reviewing the transcripts, there were points I did not understand. I contacted those participants by their preferred means (always email) and asked for clarification.

3.4. Interpretive framework

In addition to the specific techniques I have used to examine the data which are described below, an interpreter uses an analytic perspective which informs her understanding of the data as a whole. In this project, I draw upon the ‘internal critique’ of science to organize and analyze the data (Tiles 1996, 220). This group of critiques argues that even if one sets aside the contextual values that frame science (and medical research), there remain values that are constitutive of those endeavours. Whatever (objective) standard is used
to determine whether results, laws, or theories are true or false, this same standard must also be tied to a normative notion of how this should be achieved. This view does not require that the results of scientific study ought to be rejected as false, but recognizes that any standard that favours one set of results, or interpretation of results must yield results that are partial and are “conditioned by interests and values” (Tiles 1996, 224). These values are tied to the goals of science through both specific methods and specific desired outcomes.

I borrow from this internal critique of science to inform my examination of the interview data about the ethics of EBM and evidence-based psychiatry in three specific ways. First, my investigation of the ethical commitments of EBM is underscored by the point that medical research about a particular intervention or health outcome is only ever a partial view of it. Some of the gap is filled in by our views of what constitutes health -- which is ultimately an ethical view about how health contributes to living a good life. For me, this is particularly clear in the case of psychiatry: how are our notions of mental health dependent on ethical values of what we think are ‘good’ subjective experiences? In my analysis, I am interested in what versions of mental health might be promoted by EBM and what versions might be neglected. Second, the recourse to methodology via the evidence hierarchy is a way of establishing an objective standard for identifying valid versus invalid data. This standard can be tied to certain ethical values about the worthiness of disorders, treatments, effects, and suffering. What are those values and what kind of suffering should be valued? Third, internal values of EBM in particular may converge, diverge or operate in parallel with values that already animate medicine
and psychiatry. I am, therefore, interested to know whether participants view this potentially transformative intersection of values as occurring.

When I read the data presented in chapters five and six, I do so with these questions and this perspective in mind. As such, I recognize that this view is also only a partial view of EBM and evidence-based psychiatry.

3.5. Analytic procedures

I subjected each interview transcript to analysis appropriate for case study research. Drawing upon the ‘editing’ style of data organization (Crabtree & Miller 1999, 21-22), I began by examining the transcripts without a set of predefined codes. Using the qualitative data management software package HyperResearch, I developed codes (words or phrases) as I read the text, codes which were attached to text segments (phrases, statements or paragraphs) in the transcripts. The codes were listed and defined in a modifiable (electronic) codebook. The codebook evolved by comparing prior and current applications of codes. Therefore, codes were added, dropped and merged depending on the review of later transcripts. The emerging codebook served an additional iterative function, informing me about the need for modifications to the interview guides and propositions.

Once the codebook was complete, I grouped many codes into smaller numbers of supra-codes which captured themes in the interviews. These ‘supra-codes’ facilitated pattern
recognition of themes within and between participant groups. I was also able to identify themes exclusive to one or two groups versus all three groups. The purpose of this procedure was to identify the key themes emerging from a specific interview group(s), along with the interrelationships among themes and between groups. In my reporting of the data (chapter 5 and 6) and interpretation of the data (chapter 7), I focused on areas of convergence and divergence between groups along the lines of the themes identified in the earlier analysis steps. Using the data, I was able to refine the earlier framework describing the ethics of evidence-based psychiatry. The emerging interpretation was also emailed to agreeable participants with a request for feedback about any errors, omissions or further considerations. The feedback I received did not require changes to the analysis.

3.6. Rigour

In this project, rigour was established according to how well the research meets credibility, fittingness, and auditability, the three criteria of rigour described in the literature concerning qualitative research (Sandelowski 1986, 29-33). Yin recommends similar criteria for rigour used in quantitative research, including internal validity, external validity, construct validity, and reliability (Yin 2003, 34). Although Yin argues that these criteria are applicable to any kind of social research, I have chosen to use Sandelowski’s criteria. Yin’s criteria have very particular meanings within quantitative approaches, and in using the same terms, there is a danger that qualitative techniques will be expected to fulfill these criteria in the same manner. Using altogether different
terminology emphasizes the need to judge qualitative research on its own terms, bearing in mind its specific capabilities and limitations.

Credibility refers to the ability of a research project to present “faithful descriptions or interpretations” of experience (Sandelowski 1986, 30). Developing credibility has been built into the methods of the project by sending summaries of the emerging interpretations for each group, to all participants (all participants wished to receive these summaries). I also sent a copy of the individual transcript to any participant who wished to receive it (about half of the participants wanted their transcripts). I asked them to send me feedback about any errors or omissions on my part, a process known as member-checking. Member-checking contributes to credibility by allowing participants to ensure that the data and interpretation accurately reflect their views. Fittingness refers to the match between the data and the themes and categories developed in the study. I strove to achieve this by ensuring that each finding is linked to the raw data, and that higher level abstractions are supported by actual quotes or excerpts from transcripts. Auditability refers to the transparency of the research decision-making process. Because this project adopts an interdisciplinary approach (bioethics, qualitative methods) without a well-known, specified set of research procedures, auditability was a central dimension of rigour. I justified overall methodological choices as well as specific data analytic issues in a chain of evidence so that these may be examined and replicated by others if warranted. As is customary in qualitative research, I have made explicit my values and perspectives (particularly in the last chapter) so that the reader of the research report may be able to judge the impact of these personal factors upon the findings. I have
documented some of my attitudes in research memos and interview post-mortem forms contained within my case study database.

4. Ethical issues

The major ethical considerations in this thesis project occurred during the interview phase of the study. These considerations are those that are traditionally identified in human subjects research specifically, obtaining informed consent, providing confidentiality in gathering and storing data, ensuring anonymity in reporting data, and providing participants with feedback concerning the conclusions of the research. I have described the procedures to achieve these goals below.

4.1. Informed consent

The consent process began when the participants received the information letter (see Appendix A) from me which detailed what they were being asked to do, and potential risks and benefits. The information letter contained my telephone and email contact information in case participants had any questions about the study. This procedure gave participants whatever amount of time they need to think about whether they wished to participate and the opportunity to have any questions answered.

At the start of each interview, I gave each participant the opportunity to ask any further questions. I clarified the interview and recording procedures, reviewed the procedures for maintaining confidentiality and anonymity, and reminded participants that they can decline to answer any questions they wish, but continue to participate by answering
subsequent questions. In particular, I advised them that, at any time, they may speak off the record and I would turn the recorder off and make notes or not depending on their preferences. I also reminded them that they could withdraw from the study at any time during or after the interview and withdraw any or all of the data they have provided. Following this discussion, each participant was asked to acknowledge his/her consent by signing and informed consent form (see Appendix B), which I witnessed. Participants were given a copy of the form to keep for their own records. I read the consent form aloud to the telephone participants and I filled it in according to the responses they give me. I mailed an electronic copy of the form to each telephone participant immediately following the interview. I kept copies of all consent forms.

4.2. Confidentiality and anonymity

In order to secure the data, audiotapes of the interviews were couriered (with a requirement for a signature by the recipient) to an independent, professional transcriptionist. Once typed, all tapes and electronic files (on USB devices) were couriered back to me. The transcriptionist deleted all interviews from her computer once she received confirmation that the electronic file was successfully opened on my computer. To preserve anonymity, I ensured each transcript was stripped of any potentially identifying data. Actual names were replaced by letters such as A or B. Locations names were removed if the actual name could compromise personal identity. When the findings of the study are being written, either in this thesis or in articles, I will ensure that no quotations or excerpts can be traced to any participant. The names of participants or their institutions have not been used at any stage of the research. Instead,
each participant has been identified by a number code to ensure privacy. No information has been mentioned in any writing that would disclose any personal identity, apart from information that is already in the public domain. For example, if a participant made reference to a book about evidence-based medicine written by Dr Joe Smith, I did not delete Dr Smith’s name from the transcript since the fact of his authorship is in the public domain.

I have stored recordings, anonymized hard copies of interview transcripts, and consent forms in a locked cabinet to which only I have access. I have stored anonymized, electronic versions of interview transcripts on my computer. Access to the computer has been secured by use of a specific password known only to me. On completion of the project, the recordings will be erased. I will store the anonymized computer files of the transcripts for ten years following the completion of the study in accordance with best practice in qualitative research. Keeping the transcripts, which form a major part of the case study database, ensure that the researcher’s work can be reviewed and challenged by fellow researchers if necessary. Signed consent forms (or verbally agreed to consent forms in the case of telephone interviews) will also be stored for the same period in order to demonstrate that appropriate steps were taken in recruiting and working with participants. After ten years, the hard copies of consent forms and transcripts will be destroyed.
4.3. Feedback to participants

I asked all participants at the time of their interviews if they were interested in receiving summaries of the emerging interpretations from their own group. I instructed them to send me comments or feedback if they wished by phone or email. Participants also had the option of receiving a copy of their own transcripts. Finally, participants were told they could contact me to ask about the study’s progress at any time. I will also be available to give presentations about this study and its findings at their place of work if they wish.

4.4. Withdrawal

The information letter that was mailed to participants stated clearly that participants could withdraw from the study at any time, even after they signed the consent form (or verbally agreed to participate by telephone), with no consequence to themselves. The letter also informed participants that they could choose to withdraw parts of all of their interviews, even after they are complete, up until the point where I completed the data analysis. I committed to destroying any withdrawn data but to keep the signed consent form and indicate on it that the participant withdrew. Keeping these forms is a quality assurance mechanism for the study ensuring that I maintained an accurate record of how many people agreed to participate and how many withdrew. Remaining aware of these facts would alert me to potential problems in the study that required amelioration. For example, if several people had withdrawn from the study after agreeing to participate, there may have been aspects of data collection that required revision. Before each
interview began, I reminded each participant of this information. However, no participant chose to withdraw from the study, or to withdraw any data.

4.5. Research Ethics Board review

This project was reviewed by the University of Toronto Research Ethics Board (Health Sciences). I adhered to the basic requirements of ethical research in accordance with the Tri-Council Policy on Research Involving Human Subjects and also any additional requirements imposed by the Research Ethics Board. I also submitted a study renewal form when the first period of approval (one year) had passed.
References


Chapter Five
Interpretation and Analysis: What is EBM? Conceptual Clarification

1. Introduction

For this project, I interviewed three groups of participants: group one consisted of people who were, and remain, involved in the development of EBM; group two consisted of practitioners working in mental health, who are involved in the implementation and scholarly debate about the use of EBM in mental health practice; and group three participants were scholars who had investigated philosophical or ethical aspects of EBM. 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. There were nine participants in group one, eleven in group two, and thirteen in group three yielding a total of thirty-three participants. In the next two chapters, I will discuss the data obtained during the interview phase of this research project (providing ample excerpts from the interviews) and will offer my analyses and interpretations of these data in between excerpts. In both chapters, I will be exploring what participants believe EBM is and what its ethical commitments are. In other words, I give primary attention to what participants think EBM means, what it implies, and what it is trying to convey. This chapter will provide an introduction to the participant groups and will aim to clarify the central concepts relevant to the thesis question: evidence, evidence-based medicine, and evidence-based psychiatry.

There are several reasons why I have chosen to devote a chapter to conceptual clarification and why I will draw heavily upon the raw data for this purpose. First, upon
reviewing the interview transcripts, it is clear that trying to define the concepts needed to address the overall question of this thesis generated an enormous amount of data, which itself is a finding of crucial importance. Participants spoke at length about the challenges of trying to define and understand EBM, and related concepts such as evidence. Any scholarly examination of EBM must grapple with this challenge. Second, since the participants were themselves expert in understanding and applying these concepts, and were invited to participate in this study because of this expertise, it seemed appropriate to allow their own responses to dominate the discussion in this chapter. This was particularly relevant because this thesis project’s aim is to elucidate the ethical commitments of evidence-based psychiatry as found in key EBM texts as compared to beliefs held by these same EBM experts. The first three chapters represent my own review and analysis of the ethical commitments as found in the texts (‘literal’ EBM) while chapters five and six describe and discuss participants’ understanding of EBM’s ethical commitments. Finally, my professional identification as a psychiatrist played no small role in my attachment to the raw data and my decision to extract lengthy passages for review by the reader. As a psychiatrist, I place a premium on understanding people in depth and emphasize people’s own voices in describing and making sense of experiences or, in this case, ideas. Upon reviewing the data, I believed that it was important for me to try to convey to the reader, the insightfulness and intellectual creativity of the participants and I believed their own words accomplished this task better than what would have been achieved through paraphrasing or summarizing.
Nevertheless, it is the case that I structured this chapter in a particular manner and gave attention to certain themes. What I have attempted to do is to highlight those concepts that are most crucial to understand in order to address my overall thesis question concerning the ethics of evidence-based psychiatry. In trying to explore the nature of evidence-based medicine and evidence-based psychiatry, I selected quotations that were in direct response to questions posed about these basic concepts. I did not generally ask participants what evidence is, nevertheless, they often addressed this in the context of defining evidence-based medicine.

In general, I observed a striking convergence of views between group one participants. This was unsurprising, perhaps because of the fact that many of the developers are in close contact with each other and regularly collaborate. Group two participants largely fell into two subgroups: those who were proponents of using EBM and those who were critical or at least cautious about its application to psychiatry. Those who advocated for the EBM model shared many views with group one participants. Those who were critical of EBM tended to cite reasons that exposed the difficulty of applying EBM to psychiatric disorders and their treatments. Group three participants, whether they were proponents, critics or neither, tended to identify similar themes as their fellow group members which I believe is attributable to their shared disciplinary perspective. There was convergence in this group around the notion that EBM comprised a narrower set of principles than what participants in the other two groups believed.
A major area of divergence fell under the theme of ‘limitations of EBM.’ Group one participants were largely silent on this point, raising only pragmatic barriers to evidence-based practice on the few occasions where limitations were discussed at all. By contrast, many group two and three participants raised points related to this theme. Both groups identified epistemological issues, such as the limitations of RCT data and the problem of applicability of data when moving from populations to individuals. Group three participants also worried that EBM offered a false, or at least incomplete, picture of practice that did not given adequate attention to a variety of essential clinical tasks such as the cognitive process of ruling in or out diagnoses, or the process of weighing conflicting warrants for action.

The process of clarifying concepts allowed me to discuss first-order themes -- that is, themes that were addressed directly by participants. This chapter ends with a section exploring second-order themes, that is, themes that I have developed as a result of close engagement with the data and in particular, the first order themes.
2. The participants and their reasons for interest in EBM

Participants became interested in EBM for a variety of reasons. In group one (EBM developers), participants commented on their own desire to understand how and why medical decisions are made, and to have the tools to be able to challenge people’s thinking and decision-making in a rational way.

1-2: …up until then it was very much more of a traditional kind of educational approach in [the city where 1-2 trained], and that it was whatever your staff physician told you that this is what you did, and so this is kind of really I found very empowering, that they were actually talking to us about getting skills so that we could actually be better consumers of the literature and understand what it was.

1-6: …that's how I would say what was appealing to me to be a little bit more in depth and being able to assess the evidence by myself so I can resist and I can have arguments in my hands...

Like group one participants, some group two participants (mental health practitioners) were interested, even concerned, about how clinical decisions are made.

2-6: …as a resident sitting in grand rounds in child psychiatry when they were talking... somebody was presenting a case about eating disorder. And the person presenting the case was very much into family therapy and made the comment that really the driving motivation in this girl's psychopathology was the fact that she had a distant father and an over-involved mother. I said to myself, 'Shit, that's what they say about everybody regardless of what the problem is.' So I thought to myself, ‘what I'm being taught in terms of etiologic factors is not very discriminatory. It doesn't discriminate among different sorts of problems.’ So that was [what] really made me as a resident begin to think about what are, how do we think about etiologic factors in psychopathology? And then I did a degree in clinical epidemiology so I have a Masters degree in clinical epidemiology where I learned about critical appraisal and I've always been a strong proponent of trying to introduce more critical appraisal into practice.

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24 In the subsequent two chapters, when I quote a participant, I will quote them by study code. The codes have been assigned as follows: the first number reflects the group to which the participant belongs while the second number reflects the order in which they were interviewed (1 means first participant). Thus, ‘3-2’ means group three, second participant.
Many participants encountered EBM directly through their work as researchers where it was particularly important to understand concepts like evidence.

2-10: I didn't become interested in EBM as such, but in research and science and concepts of psychiatry and I did research and doing research means coming across the term as a concept and the idea and the objectivity of evidence...

Group three participants (philosophers/bioethicists) became interested in EBM for a wide variety of reasons. For some, an academic focus on ethics was an entrée to this topic.

3-2: …that's why I became more and more interested in evidence-based medicine or cost effective analysis because I had a long-term interest in resource allocation, justice issues in health care.

3-11: The practical spin-off to my theoretical work has been an area called ‘values-based practice,’ a deliberate parallel with evidence-based practice because what values-based [practice] gives you, a process for working with complex and conflicting values in health care decision making. That is the parallel of, a straight parallel, complementary rather than similar to, process that evidence-based gives, to working with complex and conflicting evidence.

3-9: And so I became quite interested in decisions under uncertainty. I mean if you were my physician, at what point is it appropriate for you to make a prescribing decision, for example, based on a meta-analysis as opposed to a randomized trial….And that raised the ethical issues related to informed consent…

Others became engaged with conceptual and philosophical issues posed by EBM:

3-5: …it also looked like a very interesting area for me to think about the philosophy of medicine. What's the foundation of medical knowledge? Is there such a thing as a clinical science or is medicine simply applications of biochemistry, pharmacology, physiology and so on that it doesn't have its own science? So I got interested in the idea of evidence-based medicine as an attempt to make a free-standing science of medicine with its own rules, its own laws, its own theory of causation, its own, methodology for securing facts and so.

3-7: … my real connection is from the side of logic and critical thinking.
3-13: …as a philosopher of course hearing the term evidence certainly my ears prick up and I started to get really interested in what kinds of epistemological questions were relevant to EBM and that weren't being considered by the people who had developed it. My interest in the ethical aspects of EBM actually sort of comes through the epistemological aspect so I, rather than taking maybe a more traditional approach in terms of moral theories, I'm interested in the ethical issues that arise when we think about evidence in a certain way or we choose to take certain epistemological approaches to medicine.

Finally, some group three participants had understood EBM broadly, invoking sociological perspectives in addition to philosophical or ethical ones to develop their own understanding of this topic.

3-3: And it was then that I really got to know about the world of evidence, EBM, and the fact [that] this was in managerialist papers, put the word ‘quality’ in front of anything and you improve it. In this area, put ‘evidence-based’ in front of anything and you automatically improve it. And this whole innovation where ‘evidence-based’ gets tagged onto everything you do, and you then invent the analysis later.

This brief introduction to the study’s participants illustrates that they approached the topic of evidence-based medicine from a wide variety of perspectives: clinical, ethical, philosophical, and even sociological.
3. Conceptual clarification: what is EBM?, what is evidence?, what is evidence-based psychiatry?

3.1. What is EBM?  Group One (EBM developers)

There was much agreement amongst group one participants about how to define EBM. Most respondents focused on EBM as the linkage of research knowledge to clinical practice, noting that our knowledge (evidence) can be stronger or weaker. Moreover, it is part of evidence-based practice to be able to tell the difference. Group one participants resisted what they believed was a common perception of EBM as an ‘RCT’s or nothing’ mentality describing this as a misunderstanding of EBM. Instead, these participants focused on EBM as the generation and understanding of all types of research-derived knowledge in combination with an awareness of patients’ values and the role of these values in clinical decision-making.

1-2: …so really about bringing the evidence, the best available evidence and a lot of times people think there is only one type of evidence, but it's really the best available evidence that we have that's out there with our clinical expertise and with our patient values, and it's really to me it's bringing those three pieces together.

1-3: …the whole purpose of evidence-based medicine is to ground our management, our clinical management of patients in evidence. We want to do what's best for our patients and that means understanding research that can inform us about what's best for our patients, or other less systematic observations.

1-6: …what EBM I think says that among other things, you need to know the evidence, and also says that you should be able to assess the validity of this evidence or how to phrase it differently, the hierarchy of this evidence. The difference of different levels of believability and by that I mean how trusting we are in estimates of effects of different interventions. So that is the first pillar of evidence-based medicine. Using the best available evidence, being able to distinguish between different quality of evidence, and recognizing also that evidence doesn't make the decision for you and that you need to know values and preferences of individual patients.
There was divergence amongst group one participants about how one becomes an evidence-based practitioner. Some respondents noted that the majority of practitioners would never learn critical appraisal skills in depth because they lacked either aptitude or interest. Some went on to comment that that level of skill could only be achieved through graduate level training and intensive mentoring while others believed that continuing education courses and practice would be sufficient.

8-1: …before I got into the Masters program I took a 12 session 'how to look at the literature' and taught by ________. I did this as a resident. And at the end I thought, “Oh good, now I'll be able to read the literature.” I started to read the methods and results, couldn't do it. Gave up. It wasn't for 12... even for somebody who was exceptionally, potentially exceptionally skilled at this, 12 sessions of an hour and a half each were not enough to allow me to read the literature. And in fact I remember the way the program was structured then, I did one course during the summer when I got it and then I did a statistics course and how to design an RCT course in the autumn. And I remember it was about October that I started saying “Hey, I can read methods and results now.” That is what it took.

Most participants agreed that someone who consults pre-appraised sources, but never engages in critical appraisal herself could legitimately count herself as an evidence-based practitioner.

1-6: I would say the evidence-based practitioner is a person who know which place, which textbook, which other practitioner, which clinical teacher behaves himself or herself according to those principles and I do not think this person would necessarily need to go into details behind the final statements.

There were varying accounts of how EBM works in practice. In *EBM*, Straus and others write that, “Evidence-based medicine requires the integration of the best research evidence with our clinical expertise and our patient’s unique values and circumstances” (2005, 1). By what process exactly does the practitioner ‘integrate’ evidence with
clinical judgment and patient values? Some participants believed it was a clear process, involving weighing up the three components of evidence, judgment and patients’ values.

1-2: Integration means being able to consider all those three components that I talked about, so not just relying on one aspect, so not just saying, based on my clinical experience this is what we're going to do; So it's being able to think about all three of those pieces and sometimes one of those pieces weighs more heavily that the others.

At least one participant believed that ‘integration’ was distinct from decision-making.

Another participant stated that the integration process was unknown and that EBM did not have much to say about it.

1-4: Well that's where the mystery begins. We don't know in that decision making process how to put that together. That's why... it's a black box that includes patients' wishes, clinical judgment, the circumstances the patient and what we know about the treatments. And evidence-based medicine doesn't have much to say about that. Now the people who are involved in evidence-based medicine are trying to figure that out but I don't think anybody can honestly say they understand all those dimensions and that's where I guess professionalism takes over, whatever that is, the art of medicine and so on. But if you're trying to describe that or trying to look to evidence-based medicine to tell you what's going on I don't think that's conceivable. We don't know how to do that. All we can do is hope that what the medical profession has to offer is a reasonable way or the best way we know of to do that.

How patients’ values in particular are ‘integrated’ in the practice of evidence-based medicine is an area where there was divergence amongst group one participants. Is the practitioner’s responsibility simply to lay out all possible treatment options along with the evidence for and against and then allow a patient’s values to determine which options will be chosen? Or should the practitioner use her knowledge of a patient’s values to pre-determine what options and/or what evidence to present? Participants themselves were
not certain about whether using knowledge of patients’ values to circumscribe the
discussion of options was consistent with evidence-based practice.

Interviewer (I): I want to just go back and follow up on an example that you gave
earlier, the MS example and the physician who gives out evidence without
thinking about whether the patient can actually afford it and then puts the patient
into a dilemma. Let’s say that physician was aware that there was good evidence
to support a treatment that was very expensive and was aware that the patient
couldn’t afford it and furthermore, based on their relationship with the patient,
was aware that sharing that information with them would put them into a
dilemma. Is it evidence-based practice for that practitioner to say, ‘I think I’m not
going to tell...I’m aware of the evidence. I’m aware that it’s a well-supported
treatment but I think I’m not going to share that information ‘cause I don’t want
to stress this patient or this family or their financial resources beyond their
capacity.

1-4: It’s clearly an ethical decision how you’re going to present this to the
patient. And I’m not saying how you should handle that particular decision. I’m
saying the evidence can’t handle it for you. It has to be incorporated into that
process. For example some of the considerations that might allow you to phrase it
one way to one patient and another way to another patient include taking into
account adverse effects or the difference between that new treatment that’s very,
very expensive and the next best treatment which is pretty much as good, not
quite, but doesn’t have all the baggage of adverse effects or the uncertainty since
we haven’t seen the new one around for a while or long enough to know what its
adverse effects are. So there’s easy ways to maybe rationalize or whatever, in
both the good and bad sense of presenting different stories to different patients.

Group Two (mental health practitioners)
In contrast to group one participants, who viewed ‘evidence’ as only one piece of the
tripartite structure (evidence plus clinical expertise, and patients’ values) of EBM, group
two participants focused on ‘evidence’ as EBM’s defining concept and believed that the
evidence hierarchy laid out what counted as evidence. Those who advocated for the use
of EBM in psychiatry believed the hierarchy was a reasonable ranking of research
methods. Others believed that the evidence hierarchy portrayed a narrow understanding
of evidence and potentially even a misleading one as it suggested that RCT data allows one to obtain, or at least approximate, truth.

The practice of EBM involves a set of skills that have to be taught and fostered in training. Some participants believed that one might also require a basic temperament or attitude in order to want to learn and use these skills in practice.

2-8: I suppose in educational terms it would be the knowledge, skills, competencies and attitudes. I think the key thing here, inevitably, has to be the attitudes.

Furthermore, some participants believed that trust or faith in EBM was required as the validity of the evidence hierarchy had never been proven, nor had it ever been shown that evidence-based practice led to improved patient care.

2-6: Nobody has ever done a randomized trial... this is a great irony of EBM... nobody has ever done a randomized trial to randomly assign people to have practitioners in an EBM way and a non-EBM way so that would be the only way to be... so this is the great irony. So I have to take it on faith.

Supporters believed that these skills fostered a greater awareness of uncertainty and the limitations of medical knowledge while critics believed that adherence to EBM limited one’s capacity for critical thinking. For them, critical thinking is what allowed one to see through EBM to its own limitations.
One participant viewed EBM primarily as a means of negotiating diverse interests in healthcare. Whether it had any ability to generate meaningful knowledge about interventions was unknown.

2-10: I think the current central position stems from its role as a currency in negotiating on a society level the interest, the different interests of people in the health care profession or in the health care provision.

**Group Three (philosophers/bioethicists)**

Compared to the other groups, participants in this group repeatedly raised the idea that EBM had many meanings and it was difficult to choose one because there were various accounts and it depended who one asked and which sources one privileged.

3-10: …I keep finding myself thinking of Humpty Dumpty when he says, ‘A word means whatever I want it to mean, no more and no less,’ and that’s what evidence-based medicine often is.

Participants argued that this variability in definition might reflect an evolution in the concept of EBM, whether as a result of a natural process of improvement or as a way of deflecting criticisms of the original formulation. One participant offered a more radical interpretation positing EBM as a catch-phrase whose substantive meaning was intentionally unclear so as to give power to those who controlled it.

3-3: The emotive concept is in fact primary and the descriptive concept we can then decide that later. So what's happening is you've got a group of people who are taking control of a professional area, claiming ownership of it by claiming ownership of the key persuasive terminology in that area. You make the term evidence yours then you can decide at a later date what counts as evidence. You've claimed the authority to determine what's good and bad in that area, what ought to happen and what ought not to happen, what people have a warrant to do and what they don't have a warrant to do. So it struck me that evidence-based
medicine really was a movement that... it got going... its power was based on the seductiveness of the terminology.

Another participant (3-1) went further likening EBM to a “religious movement” that was “objectively wrong.”

Many participants in this group saw ‘critical appraisal’ as the core function of EBM and as engendering a potentially positive development in physicians’ learning and practice behaviour. However, they believed that EBM has evolved away from the idea of the individual practitioner engaging in critical appraisal herself and towards the use of pre-appraised sources. Most participants agreed that reliance on pre-appraised evidence sources was good enough evidence-based practice from a clinical point of view, and perhaps even necessary as individually conducted critical appraisal was likely too onerous a task for most clinicians. At the same time, some participants viewed the use of pre-appraised sources as an unfortunate compromise that diluted EBM’s most powerful, positive, and novel contribution.

3-12: …I think that in the early days evidence-based medicine had at its core this idea that people were going to be critically engaged with research, so individual physicians were going to be seeking out the research evidence and they were going to critically analyze it themselves and they were going to bring that into their practice. And I think that most of that is gone now. I think that the expectation on physicians is that they look up the best available evidence-based guideline on whatever it is that they're worried about and that they follow that.

3-5: …the ethos is not to take these things on trust just because they've been digested for you but actually to do critical appraisal for yourself because after all those things fall out of date even more quickly than the scientific journals and they don't get updated as often as you'd like. And they may not answer the question you need to know the answer to and so it might, for the really purist EBM theorist, be rather like taking your final English literature exam on the basis of the Cliff's Notes. You've got to go back to the sources and check them for yourself. So I think what is good enough and what is really the sort of ideal and
the ethos driving evidence-based medicine as a social movement are actually quite far apart.

Some group three participants also discussed the question of how one becomes an evidence-based practitioner. There seemed to be two potential paths to evidence-based practice. The first was advanced methodological and statistical knowledge:

3-10: I mean to me it seems to carry with it a specific set of, a specific skill set that really, I don't know that you necessarily need an MPH or a Master of Science of Epi to do it but more and more it seems like you do. As the analyses get more and more complex in a lot of this clinical research it takes somebody with a fairly developed skill set to interpret…

However as this same participant pointed out, in the absence of this specific skill set, perhaps best or only obtained through graduate training, it is difficult to determine who else is an evidence-based practitioner. These concerns were related to this group’s close exploration of the term “integration.” Again this participant pointed out that EBM had not sufficiently defined integration which made it impossible to determine what did and did not count as evidence-based practice.

3-10: The patient has ARDS and low tidal volume ventilation we’ll all agree, clinical research shows that that’s better for outcomes. But every time I put him on low tidal volume ventilation he goes into a malignant arrhythmia and he drops his blood pressure and he looks like we’re going to have to code him but if I put him on higher tidal volume he does okay in terms of his heart. So now my pathophysiologic, my understanding of that circumstance, pathophysiologic rationale, that is malignant arrhythmia is bad for outcome in this individual case is going to take priority and I’m not going to use the proven therapy of low tidal volume ventilation and is that okay? Does that make me an evidence-based medicine practitioner or not?
3.2. What is evidence?

The questions of how to define evidence, and how EBM defines evidence were of varying degrees of importance to each group. Group one participants (EBM developers) largely endorsed the evidence hierarchy as both valid and as a sufficiently broad enumeration of sources of evidence. Some participants expressed a concern that EBM is often misunderstood as only taking RCT data into consideration, when in fact the hierarchy is quite specific that there are many possible sources of evidence to bring to bear upon clinical decisions and that one must use the best available source. This clarification makes clear the theoretical and practical importance of the hierarchy.

1-3: …it's really providing the best care we can for our patients based on what we know through systematic research rather than just our own anecdotal observations or things that people have told us that we haven't really confirmed to be true about management of patients and, you know, understanding that there are all sorts of sources of evidence. It's not just randomized clinical trials. It's all sorts.

By contrast, many participants in both groups two (mental health practitioners) and three (philosophers/bioethicists) found that EBM’s notion of ‘evidence’ was too narrow a concept and focused on the problems of ranking sources of evidence in a hierarchical form with randomized controlled trials at the top. Some group two participants expressed the concern that EBM’s concept of evidence was not only narrow but had the potential to portray a false notion of evidence.

2-1: There’s a notion that, as the X-Files would put it ‘the truth is out there’, a truth to be uncovered, and experimental observation and deduction of hypotheses is the method of uncovering reasoning, that reason is very important and this is whole enlightenment value that permeates through scientific inquiry to the current day.
Not only did group three participants find the concepts of EBM and integration to be unclear, but they had a great deal to say about the conceptual building blocks of EBM, such as ‘evidence’ and the ‘evidence hierarchy.’ This is unsurprising given that most of these participants were either professional philosophers, or were scholars whose primary academic focus was philosophy or ethics.

Like group two participants, respondents in this group viewed ‘evidence’ as the central concept of EBM and did not view EBM as a tripartite structure that placed clinical expertise and patients’ values on an equal footing. In fact, some argued that for EBM to be a substantive concept, it had to prioritize evidence and the evidence hierarchy over other considerations.

3-10: …under that definition I could know all of the medical literature, right?, and I go in to practice and I base every one of my decisions based on sort of my clinical gut instinct. I know all the literature, right? I just don't weight it very heavily. I'm integrating it but I'm just, I'm bringing it in with a very low weighting and I'm emphasizing, I'm weighting heavily my clinical expertise. I could still claim under that definition to be an evidence-based medicine practitioner. But I'm not sure that anybody else would see you as that and if they would then I'm not sure what the difference is.

3-6: I think an evidence-based medicine does point in both directions, research and clinical. So this ‘best available evidence’ is only really relevant to the clinical. I suppose most people are very much aware of it on the research side as well where RCTs are put out as the highest form of evidence. So I guess that’s one, uh, reason. And I think from the point of view of evidence-based practitioners, if they go too far down all they’re asking is for the best available evidence, you start saying, ‘well in what way is that different from what people were saying 20 years earlier?’ And those clinicians who got very angry by the evidence-based physicians and evidence-based medicine people who felt the evidence-based medicine people were saying, ‘You’ve always practiced on the basis of poor evidence and you’ve been practicing lousily and now we’re coming along and telling you how you practice.’ And those people who felt upset by that might reasonably challenge the evidence-based medicine person and say, ‘Tell us how we haven’t been practicing on the base of evidence. We’ve had all sorts of
At the same time, some group three participants found the evidence hierarchy to be a philosophically indefensible concept as it suggested that there was a correct route to knowledge in all similar situations. To these participants, a correct route to knowledge could not logically be predetermined. One participant ventured that the hierarchy was necessarily implicitly dependent on a foundation of theoretical knowledge.

3-12: I just find it really interesting that there's this sort of hypocrisy in terms of the amount of critical attention that that [a trial of a complementary or alternative medical intervention] will receive, and a pharmaceutical trial won't receive that same amount of attention and I think that betrays the commitment that people intuitively have or naturally have to some sort of theoretical explanation for things. And if EBM takes that seriously then they have to look more closely at what they count as evidence and I don't think they've done that yet.

One participant pointed out that the evidence hierarchy could not provide a logical basis to EBM and was doing little more than serving a social and career purpose for its proponents.

3-3: If you said what we should all... well of course responsible practitioners should think about evidence and should have good evidence for their conclusions. It’s bloody obvious isn’t it? We’re not making you a professor on the basis of that. If you wrote a paper that just said that, I’m sorry, there’s nothing terribly exciting here. You know. So you need something exciting. ‘Oh no. We’ve got this new view of what evidence really is.’ Then you’ve got something exciting to say. Then you’ve got a vested interest in claiming that you have something new and interesting and exciting and definitive about what evidence really means for everyone here.
Ultimately some participants in this group believed that EBM was misguided in trying to be too inclusive. The relatively smaller role of parsing out methodological problems in research and teaching that to clinicians seemed to be a philosophically defensible set of ideas. It was only when EBM proponents began adding notions of integration and trying to include patients’ values alongside evidence that its actual application in practice became unclear and thus, difficult to defend.

3.3. What is evidence-based psychiatry? Group 1 (EBM developers)

EBM developers believed that the basic principles of EBM could be and are being applied to research and practice in psychiatry. However, they noted that psychiatric interventions did not have as much evidence behind them as interventions in some specialties.

1-1: In principle it shouldn't be [different]. Psychiatry falls into a group of specialties that don't have a lot of evidence behind what they do…

Some participants also noted that even with evidence at their disposal, psychiatrists have to pay more attention to patient- and context-specific factors in clinical decision-making.

1-9: So a lot of the management plans in psychiatry seem to be heavily influenced by plausible options for the patient determined by life circumstances, emotional psychological reserve, social supports, the environment in which the person lives. And that makes perfect sense. I know very little about the evidentiary basis for different drug choices so, you know I couldn't critique or think ‘oh why that drug and not that drug?’ but the general approach about the follow-up, where the person goes to when they're ready to go home, who goes with them, what the... all the things around their discharge after they've tried to take their life. That's the exposure that I have to psychiatry and in the context of what we've been talking about, it does seem, it's not for me to judge, but highly
appropriately context- and patient- and setting- specific how the person is managed. So it has to do, just like cost is an issue of circumstances, the care plan seems to be context-specific.

Some participants wondered whether the special problem of patient incapacity would make it harder to have the kind of shared decision-making process that EBM practitioners viewed as fundamental to their work.

**Group 2 (mental health practitioners)**

Unsurprisingly, group two participants contributed more than the other two groups on the subject of how EBM might or might not apply to psychiatry. There was a clear bifurcation in this group into two sub-groups: those participants who were supporters of EBM and its application to psychiatry and those who were critics of EBM or at least were cautious about its application to psychiatry. Supporters tended to view evidence-based psychiatry as a reasonably straightforward application of the principles of EBM to psychiatry. They were mainly concerned about the amount and quality of research data that psychiatrists had to draw upon.

2-6: …so in mental health there's less evidence, particularly in my field, in ______, there's less empirical evidence out there so there's still a role for my judgment and experience and whatever to play in the context of making a clinical decision. The principles are the same. The dataset is smaller.

Some critics accepted EBM as it is currently configured, but saw it as capable of only playing a small role within the complexities of clinical practice while others saw a more significant role for EBM within psychiatric practice if it could encompass broader notions of evidence and of evidence-based practice. For example, some believed that a more
inclusive version of the evidence hierarchy would improve the model while others went further, encouraging practitioners to be aware of the published research literature but to be highly skeptical of its findings, except for the broadest of principles.

2-3 ...you can be consistent with the evidence without being strictly evidence-based. So for example I’m publishing a book this year on the treatment of _____. It is not one method, ____ and here’s the evidence, you know, stuff like that. It’s sort of like look, this is how you could practice in the office using some of the principles that have been developed in research without following it to the letter.

Even supporters of EBM acknowledged potential barriers to implementation in psychiatric practice. For example, when an intervention was found to be effective but was complex and required a considerable time investment to learn (like a psychotherapy) it might be difficult for practitioners practice it.

2-5: if you as a psychiatrist were trained primarily in pharmacology and you read that the best treatment for depression is CBT but you haven’t had any training in CBT what are you going to do? Your choices are either, ‘well, let me shut down my practice for three months and go off somewhere and get training in CBT or not see these patients which is a lucrative part of my income, or continue doing what I have been doing.’ Guess what the average practitioner is going to do? So I think the impact is limited to interventions that are easy to implement. If the literature says intervene with a diastolic of 85 rather than 90, that doesn’t require a new set of skills on your part. If the review literature says you have to learn a new intervention and that intervention is going to take time to learn, then I think evidence-based practice is going to have a small impact in that area.

Those who were cautious about the capacity of EBM to be applied directly to psychiatry and its treatments drew upon two main types of arguments. First, there were externalist arguments that pointed out challenges lying outside EBM. In particular, several participants noted that pharmaceutical industry funding of clinical trials had the potential to distort research data to the point where it might not be able to be taken seriously.
Others argued that there were features of psychiatric disorders and treatments themselves that made the application of EBM problematic. Several participants suggested that complex interventions such as psychotherapy or social interventions are difficult to evaluate using EBM-preferred research methods. Furthermore, the outcomes that these interventions are trying to effect may themselves be more difficult to measure than ‘hard’ endpoints (such as death) in medicine or surgery. Most particular to psychiatry’s case, some participants observed that the nature of psychiatric diagnosis itself made it difficult to ensure stable diagnostic groups to study.

2-4: People just have a sense that there’s a tremendous amount of mistrust over the syndromes. Because not only can we select the outcomes. You know, if you want to pull the rabbit out of the hat you’ve got to put the rabbit in. So we can uniquely manufacture outcomes. We could also manufacture scales custom to the application. So I think psychiatry is more prone to the abuse of evidence-based medicine.

These participants also believed that these same measurement demands of EBM pulled psychiatric researchers away from therapeutic factors that were non-specific (such as empathy in psychotherapy) towards specific ones (such as specific therapy modalities) and away from general indicators of well-being (finding a job) and towards illness-specific ones (symptom rating scales). Participants offered two explanations for the appeal of evidence-based psychiatry. Supporters pointed out that the history of psychiatry was littered with many failed and harmful interventions. And, because contemporary psychiatry remains more vulnerable to moral judgments in both diagnosis and treatment than other medical disciplines, EBM served as an important antidote.

2-9: But of course in psychiatry particularly hearing these terrible stories from the past from giving malaria to patients and all sorts of horrible things which had been done in the word of treatment in the past which I suppose makes it particularly important I think.
Those participants who were more suspect of EBM’s role in clinical practice, saw its actual purpose in sociological terms.

2-10: There is a specific problem for mental health care because psychiatry throughout its history, modern psychiatry since the Enlightenment has always been characterized by huge struggles and one of them was a desperate struggle to be part of medicine. We want to be there as well. That’s still there. And to share the income, the status, and all that of the rest of medicine. And maybe our patients have benefited from that to some extent. I’m not saying that’s good or bad but that’s very much one of the hard problems of psychiatry. By all means let’s be part of this great… and not the social science rubbish and teachers and all those other professions. And for that evidence-based medicine was sent from heaven because now we’ve got something. We can produce trials as well, and yes, we can do that just like you, we are also good medics and proper medics more importantly.

Group 3 (philosophers/bioethicists)

The main issue identified by group three participants on the question of whether EBM could be applied to psychiatry was that EBM made certain assumptions about disease and about treatment. Where those assumptions held for psychiatry, EBM could be applied, where they did not, there would be difficulty both in interpreting and using data generated.

3-11: …an example of an area where an evidence-based approach was appropriate is in the treatment of depression because severe depression, major depression is a condition where I at least guess some of the complexities, major depression I’m talking about, is lost. It’s a bit more like having appendicitis than say, a personality disorder. So it’s a condition where the effect of different approaches to treatment could be and of course is looked at in a traditional evidence-based way to good effect.

3-5: On the face of it, it should be a simple deductive inference that if medicine and psychiatry are continuous then evidence-based medicine and evidence-based psychiatry should be continuous, conceptually. But there is the question of whether evidence-based psychiatry and psychiatry are continuous because people
will say that what is evidence-based psychiatry does not map onto psychiatrists’ account of what they’re doing or patients’ account of what they’re doing in the following sense, that the kinds of things that you can test using sorts of methodology favoured by EBM are actually not typical of the majority of things that psychiatrists do or want to do for their patients. And the sort of outcomes that you can measure in such tests are not the sort of outcomes that psychiatrists want to influence on their patients want to have influenced.

At least one participant did not think that there was any particular about psychiatry that made the application of EBM problematic, but rather believed that the application of EBM in any field had problems because its basic principles were flawed.

3-12: I’ve yet to find someone who really claims, a group that claims this as their own really ‘cause even the people in clinical practice who you’d think would be the ones that they’d say well EBM was for us don’t think it’s for them. They think it was an epidemiological thing foisted on them and now they’re stuck trying to figure out how to apply this to an individual patient which was, which is this whole difficult thing that they have to do that doesn’t seem like it falls straightforwardly for any of the EBM principles at all. So nobody is really taking ownership of the original movement because it doesn’t really fit with anybody. It’s got these epidemiological sort of underpinnings but at the same time it really was geared toward clinical practice but in an inappropriate way because it really doesn’t help physicians to figure out how to balance all these different sources of evidence and values and everything else and make that clinical decision. So evidence-based psychiatry I’m sure is running into the same problems that people in research in alternative medicine are running into and in all the other areas, in public health where they’re saying the basic principles in the most charitable definition seem reasonable and we want to incorporate those but there’s a whole bunch of baggage that seems to be tied up with EBM and do we want to adopt all of that? I’m sure that advocates of EBM would be, would think that you could just transfer it right across. I’d say no, you can’t just take the principles of EBM and apply them to evidence-based psych, and just use them in psychiatry but that’s not because there’s something unique in psychiatry so much as that the principles themselves were already problematic in the first place.

One EBM supporter in this group also wondered, like group one participants, if the special problem of decisional capacity would make it harder to use an evidence-based approach in psychiatry.
4. Analytic themes

In the previous section, I provided an overview of some of the basic concepts relevant to this thesis project, from the point of view of the study’s participants. Examining these concepts provided rich and varied data. In addition, these data highlighted three major analytic themes which I will discuss in greater depth below: 1) whether supporters or critics of EBM, study participants view the ideal practitioner as a critical thinker; 2) there are varying and even contradictory accounts of what EBM is; and 3) the idealized psychological position of the EBM practitioner may be in conflict with the real, relational and therapeutic needs presented in individual clinical encounters.

4.1. Critical thinking versus critical appraisal

Both supporters and critics of EBM wanted medical practice to stake claim on the notion of critical thinking. Supporters viewed the practice of EBM as fostering critical thinking while critics viewed adherence to EBM as eroding critical thinking. Even critics who did see a role for EBM believed that one needed critical thinking skills to evaluate how EBM could and could not be useful in practice. In other words, having critical appraisal skills did not equip one to think critically more generally.

The ability to understand the uncertainty of medical knowledge exemplified these different approaches to critical thinking. ‘Uncertainty’ was a concept discussed by some participants in all three groups. In the passage below, participant 1-8 described a scenario in which there was inherent uncertainty in applying evidence.
1-8: There was a patient with stroke and should they give Heparin or should they not give Heparin to this patient with stroke. And they called this consultant and that consultant and they were looking for somebody who would tell them the right thing to do and their image was, ‘If only I find the right person, they will tell me the right thing to do.’ And it was a huge, this was like a revelation to them and I think that this was my most dramatic individual experience of this, that people, that the clinicians realize that there isn’t a right thing to do and that it may well be that we don’t know whether we should give Heparin or not give Heparin. So people would ask questions, they sometimes ask questions for which you can’t even imagine the experiment that would answer the question, right? It’s not possible. It’s a question that will never be answered. But so there’s this, it’s almost to an extent a child’s view of the thing that all questions are answerable and somebody has the answer. I think that’s whether consciously or unconsciously within traditional medical training I think that’s something that people pick up or it gets inculcated or I don’t know how it gets there exactly but that’s pretty... I’m perhaps putting it in an extreme way, but I think that really is an underlying way of looking at it. So now we [EBM developers] say something quite the opposite. You never know the right thing to do. It just becomes more and more and more likely that X is the right thing to do. And the expert there may be potentially no better at telling you than you yourself could be so there’s one thing of this underlying, everything is fallible and everything is uncertain as opposed to there’s a certainty out there if I could just find somebody that could tell me what it is.

In this passage, 1-8 argues that while you cannot have certainty in medical knowledge, one can have probability and that it is through practicing EBM that one develops a more accurate understanding of probability and what clinical knowledge is more generally.

EBM, rather than traditional medical training, will provide practitioners with an approach to thinking about knowledge that enables them to make decisions themselves. Participant 1-6 points out that uncertainty also resides in the differing interpretations that people bring to bear on research data. Even more strongly than above, participant 1-6 invokes expertise in EBM or critical appraisal as a way of determining what the correct interpretation is.

1-6: Looking at the same evidence, and I could quote you a number of examples, looking at the same evidence different groups of people make different recommendations. And I am talking about opposite recommendations. When they
do an opposite recommendation almost certainly make it what we call weak and that is a crucial maybe, that may be a crucial point which is, sometimes we are sure about what we are recommending and sometimes we are less secure. And I think this is the most recent development in this field of EBM where we are really trying to distinguish between those two. So you may easily say a weak recommendation in favour of something, and Up To Date went this route now, which also says that other people may well behave opposite. And we still believe that's the right thing to do but we will not hold anybody responsible or to the point if they decide to do the alternative. Now the problem obviously will be when people are adamant about their choices and I tell you that most often one of them unfortunately is wrong and I don't know how to resolve it other than go to somebody who is able to judge the evidence.

By contrast, participant 3-3 emphasizes that being able to understand and handle uncertainty is part of being a thoughtful practitioner and that EBM may actually obscure the need to engage in critical thinking because it implies there is a ‘right’ way of approaching uncertainty.

3-3 …we are de facto in a situation where reasonable people can disagree over the appropriate framework to bring to bear on the evidence in all sorts of practical cases. And where they do there isn't a book. This is the problem of life. This is where the existentialists have got something to say. There isn't a book that you can look to and go, 'Oh yes, there's the right answer.' That's where each person as a practitioner or whatever has to think 'Okay, I've got a decision to make here. There's two different views of what I'm doing here and they give me different conclusions in this instance. Which should I adopt? Which should I be guided by?' There's no way out of that by appealing to some spurious, objective hierarchy in that sense. No. It's... that's our situation. We have to decide sometimes.

4.2. Challenges in defining EBM

As was clear from the preceding section, there was a spectrum of views on what actually constitutes EBM. This spectrum ranged from a very tightly cited definition involving the integration of best available evidence with clinical expertise and patients’ values to a movement that emphasize research data in clinical care, particularly data generated by randomized clinical trials and meta analyses, to an unsubstantive or emotive term whose
Critics highlighted this lack of clarity and pointed out the conundrum that EBM developers find themselves in with respect to the definition of EBM. If EBM, as the current definition reads, attempts to include a variety of factors in clinical decision-making such as clinical expertise and patients’ values, it is very difficult to be able to determine what does and does not constitute EBM in practice. Couldn’t anyone who says that they integrated (as discussed above, ‘integration’ is also an unclear term) these factors argue that they were engaged in evidence-based practice, regardless of what decision was made? How can this be meaningfully distinguished from the kind of practice that existed prior to the emergence of EBM? In fact, when participants were queried on this point, across groups they pointed to the application of research data from properly conducted clinical empirical research in accordance with the evidence hierarchy as the important distinguishing feature between pre-EBM and evidence-based practice. Thus, some participants argued that EBM, despite protestations, really is just about evidence; furthermore, if it wants to say something meaningful, it ought to be about evidence and about better quality (i.e. RCT) evidence in particular. However, others argued that the notion of an evidence hierarchy may be philosophically untenable. If there is going to be a priority placed on research data, which many participants believed could be defensible, the justification of the evidence hierarchy needed to be developed further. These conceptual problems may provide an explanation, or at least a partial response, to the point made by some group one participants that EBM is frequently
misunderstood as being exclusively focused on RCT data. It might be that those who interpret EBM as being RCT-centred are implying that the focus on clinical research data, particularly in accordance with the evidence hierarchy, is the most innovative and substantial contribution of EBM. To these participants, conceiving of EBM as a tripartite structure (evidence, patients’ values, and clinical expertise) in which these three different inputs are ‘integrated’ according to some unspecified process may not seem to be novel or different as compared to pre-EBM practice. As a result, they focus on what is novel: the prioritization of RCT data by the evidence hierarchy.

4.3. Does the psychology of EBM map onto the psychology of clinical practice?

This theme did not emerge frequently, but was developed primarily by participants in group two (all mental health practitioners). Furthermore, it was a novel theme, one that I have not seen explored in any detail in the extant literature on EBM. These participants wondered whether there was not only something about clinical training, but about clinical practice, that required practitioners to learn how to be certain or at least behave and decide as though there was certainty.

2-9: …doctors feel quite, even though intellectually they accept the argument of randomization when it comes to making a decision about an individual patient often they think, ‘Oh this is the thing which I should do. This is what’s best even though’...

I: And where does that come from, where does the confidence come from…?

2-9: Well, I think the other thing which happens is that in medical school people are forced to be decisive. Medicine is a very practical specialty. And I certainly remember a bit of bedside teaching with a surgeon who said, ‘Are you going to operate on this person who has appendicitis, yes or no? You’ve got to make your mind up.’ And I think there is this sort of push to make doctors decide what to do, because you have to.
Particularly in psychiatric practice, patients come to physicians distressed and suffering, often invisibly. One of the primary tasks of psychiatry is to instill hope that practitioners can assist patients to change their situations in positive ways. EBM demands that we only believe we can do this to the extent that the probabilistic nature of clinical research allows.

2-3: [to become an EBM practitioner] You have to train yourself to think more like a PhD than like an MD. The scientist has to always start with doubt and all scientific discussions are ‘How do you know that?’ Doctors are faced with sick, desperate people who want certainty and we often slip into certainty unjustifiably as a way of coping with that situation.

Here participant 2-3 speculates that the doubt needed for the conduct of good research may not be compatible with the relational demands of clinical practice.

5. Conclusions

Earlier in this chapter, participant 1-4 described evidence, clinical expertise, and patients’ values and circumstances as coming together in a “black box.” When asked whether EBM is what happens before the black box or does it include the black box, this participant answered:

1-4: It has to include the black box but if you think about what effects...whatever evidence you have is bound to be or its independent effect is bound to be less than you would find in the trial because it’s got to go through this decision-making process that has to include other elements. So it’s not going to be a straight line equation between evidence and outcomes in practice. But if it only sits outside that black box it doesn’t do anything. It’s totally irrelevant to what its purpose is. Its purpose is to try to help.... so it’s an extra tool that’s available to practitioners to try to come up with a recommendation that’s to the patient’s advantage.
This participant makes clear that EBM has an overall ethical purpose: to improve patient care (and health) by offering patients better-substantiated interventions. This chapter has introduced some of the conceptual and practical issues that surround the use of EBM in practice, particularly in psychiatric practice, as identified by the study’s participants. In what ways do the participants believe these issues intersect with the ethical commitments, goals, and implications of EBM? The next chapter will explore these questions and will develop a framework of participants’ beliefs concerning the ethics of evidence-based practice combined with my own earlier analysis. This framework will be compared with the ethics of ‘literal’ EBM presented in chapter three.
Table 4 - Key interpretive findings regarding central concepts: evidence, evidence-based medicine, evidence-based psychiatry

<table>
<thead>
<tr>
<th>PARTICIPANT GROUPS</th>
<th>THEMATIC AREAS</th>
<th>Group One (EBM developers)</th>
<th>Group Two (Mental health practitioners and scholars)</th>
<th>Group Three (Philosophers and bioethicists)</th>
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</thead>
<tbody>
<tr>
<td>EBM</td>
<td>EBM involves the consideration and weighing of: best evidence, patients’ values and circumstances, and clinical expertise in clinical decision-making. How this weighing is done is unclear.</td>
<td>EBM is about using evidence, as defined by the evidence hierarchy, in clinical practice.</td>
<td>EBM has many meanings. This reflects the fact that EBM tries to include many concepts within its definition, most of which are poorly defined (e.g. integration). In the absence of greater conceptual clarity, it is difficult to say what counts as evidence-based practice and what does not.</td>
<td></td>
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<tr>
<td>Critical thinking versus critical appraisal</td>
<td>EBM promotes critical thinking, in addition to the specifics of critical appraisal.</td>
<td>This group was largely silent on this matter.</td>
<td>Critical appraisal is not the same thing as critical thinking, however, critical appraisal is an important component of good clinical practice. Critical thinking is essential for good clinical practice. EBM may obscure the need for critical thinking or even discourage critical thinking.</td>
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<tr>
<td><strong>Evidence</strong></td>
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<tr>
<td>Evidence includes knowledge derived from research data and can be of high or low quality. The evidence hierarchy defines evidence and helps one to distinguish between high and low quality evidence.</td>
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<tr>
<td>EBM’s evidence is defined by the evidence hierarchy.</td>
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<tr>
<td>Evidence is a warrant for beliefs about something. It is a broader notion that what is captured by the evidence hierarchy. A hierarchy of evidence cannot be logically justified.</td>
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<th><strong>Evidence-based psychiatry</strong></th>
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<tr>
<td>Evidence-based psychiatry is EBM applied to psychiatry.</td>
</tr>
<tr>
<td>Evidence-based psychiatry is intended to be EBM applied to psychiatry. However, a straightforward application is not possible due to the particular nature of mental disorders and their treatments.</td>
</tr>
<tr>
<td>Evidence-based psychiatry is EBM applied to psychiatry. Where the assumptions of medicine and psychiatry converge, this application is straightforward. Where they do not, the application is not straightforward.</td>
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References

Chapter Six

Interpretation and Analysis: The Relationship Between Ethics and EBM

In this chapter, I explore the various ways in which participants understood the ethical commitments and implications of EBM and evidence-based psychiatry. Because ‘ethics’ is a term of central importance in this investigation, it was essential to determine whether there was a shared meaning of ethics amongst participants. I asked all participants how they defined ethics, and what they understood it to be. Participants consistently identified ethics in the healthcare environment in its normative form, whose purpose was to determine what kinds of actions are right and wrong, and why. Some participants commented that ethics in this form intersected with professional and legal standards of what is right and wrong.

In reporting on the data, I adopt a ‘centripetal’ approach in which I examine the values from those most external to EBM (those which are part of the social, professional or institutional contexts in which EBM must operate) to those that are internal to the theory of evidence-based medicine and the generation of evidence. Once again, I place emphasis on raw data; however, in this chapter, my structuring of the segments reflects the interpretive lens (internal critique of science) I discussed in chapter four. I show the ways in which ethical values are not only part of the external or contextual conditions in which EBM operates, but are also necessarily part of the structure of EBM itself. In other words, ethical values are intrinsic to the knowledge-producing and knowledge-translating activities of EBM. They are not merely a reflection of distortions or misuses of EBM or
of the social context of healthcare in which EBM operates. EBM’s activities, both its goals and methods, are bound up with the pursuit of health, including the moral dimension of that concept.

Ethical values enter into this discussion in very particular ways for psychiatry in light of the controversial history over how to define mental illness and what constitutes an appropriate response to it. At the end of the chapter I will compare the emerging model of the ‘ethics of EBM’ with the model implied by ‘literal’ EBM, as described in chapter 3.

1. The social context of EBM

A discussion of the relationship between ethical values and evidence profitably begins with a consideration of the social context in which EBM has emerged, thrived and been used.

The discussion of social context was dominated by groups 2 (mental health practitioners) and 3 (philosophers/bioethicists) participants. When group one participants contributed to this discussion, they did so along two lines: they identified antagonism to EBM within the medical community, and they identified the important role EBM has played in advancing the professional and/or public understanding of medical research. Group 2 and 3 participants viewed EBM as emerging in the context of certain social values such as accountability, transparency, standardization, risk management, the commodification of health care, and the political importance of social order. In these cases participants were not claiming that EBM was purposefully devised to accord with those values, but
that it could be understood as one of several programs or movements that exemplified those values.

2-1: …the notion that we can automate the process and mechanize it to the point where it's a kind of McDonald's production line, that you know everyone gets their dose of pharmacotherapy or CBT or whatever the thing might be and you know we know exactly how much it costs, and we know what it looks and we know how long it takes to eat. You know I think these are kind of flawed notions and to some extent, I mean they tap into social and cultural pressures at a much higher level in mental health or even medicine.

3-8: I think of evidence-based medicine as couched in all kind of other movements out there. I mentioned the accountability movement already so I think EBM arose kind of as that sort of idea in health care we need to reduce waste, we need to increase transparency. These are all democratic and cost-saving values. EBM came in as a great way to sort of facilitate those ends. So it creates a different ethical context where you need to justify democratically and transparently every move you have and the evidence provided by evidence-based medicine provides a way to do that. I don't think EBM changed that. I think it facilitated that kind of a shift in thinking that we needed to make everything transparent and accountable.

At the same time, EBM can be intentionally co-opted by political and legal considerations such as the need to set controls on medical practice, or the need for an arbiter of standard of care.

2-10: But evidence-based medicine is certainly something that determines that these rules... again if we go to this neuroleptics example... very often of course it's much better to tell a patient, “Okay, you don't want to take your medication. Let's make that experience together and see whether you're fine off,” you know. If he's then re-hospitalized... we learn from it together and maybe then you changed your attitude or you will not have changed your attitude. I think medics would agree that there's with many patients much more successful strategies than saying, “Look, you have to take this. I prescribed it.”...However, if something goes wrong...I've gotten all the age and stature that I can live with that, but a young doctor would be in trouble cause the first question was, “Why did you not prescribe antidepressants or neuroleptics? Here it is in NICE guidelines based on evidence.” And they would automatically be in a defensive position.
3-1: And the other people that were very interested in it were essentially managers, health service managers and politicians. And my interpretation of the reason why evidence-based medicine was picked up and pushed so hard in Britain was that it was a way of controlling medical practice. It had been very difficult for politicians and managers to control clinical practitioners because the clinicians were acknowledged to have the most important form of expertise. When evidence-based medicine came in and asserted that the real expertise was actually an analysis of other people's research this put statisticians into control but statisticians were funded and employed by the managers of the National Health Service and the politicians controlled the managers. It enabled politicians to control at a very fine level of detail, the activities of clinicians.

Even without the apparatus of the state or the threat of litigation behind it, some participants worried that EBM was an authoritarian approach between doctor and patient, and between government or health care system and doctor.

3-6: …so if you're not careful, and this again comes to the sort of arrogance and the paternalism worry, if you're not careful it all comes down to say a patient with these clinical situations, this is the right thing to do. And then we're right back to the paternalistic medicine of...all the patient has to do is inform the doctor of their clinical evidence on which the clinician can make the diagnosis and then the physician knows how to treat them and that's what we've been getting away from in ethics for the last 30, 40 years.

The “arrogance” referred to in the preceding passage was noted by several participants who viewed EBM proponents of exaggerating the benefits of EBM while not responding to the criticisms of it. Arrogance, authoritarianism, and silence are what these participants believe fosters the antagonism towards EBM identified by group one participants.

3-1: I regard it as something of a disgrace that these people [proponents of EBM] are not made to reply because the traditional thing with medical research was that if somebody made a criticism in a recognized journal in a recognized academic forum then that criticism was assumed to be valid unless it was refuted. And what happened with evidence-based medicine if people made very substantive and argued criticism in recognized journals with some authority and in public and they were never refuted and in fact people refuse to engage with them but instead of
that being taken to be evidence that they could not refute the accusations, the failure to engage was just allowed to go by. And so the evidence-based medicine group and Cochrane Collaboration and people in the *British Medical Journal* who were supporting it would have this ability to make statements without having to engage in debate or to answer any substantive comment. The paper that most, the most cited paper that's supposed to be critical of evidence-based medicine was written in the *Canadian Medical Journal* and it cited ________. Their idea of engaging in something was just to mention that a criticism had been made so then they said that these are not true and that was it. And this was regarded as a triumphant refutation to actually simply list them and say that they weren't true.

2. **EBM must be situated within values**

In the previous section, participants discussed the social context that frames EBM and the values that permeate that context. In the next two sections, I will describe how participants understood the relationship between EBM and ethical values.

The formal definition of EBM includes patients’ values as something that needs to be integrated with research evidence and clinical expertise. Group one participants (EBM developers) tended to view values as coming together with evidence likes pieces of a puzzle. Some participants in groups two (mental health practitioners) and three (philosophers/bioethicists) took a different perspective, viewing EBM as only having meaning within a larger structure of values that frames all of practice.

2-1: …what is the purpose of mental health care? Why are we there? What are we actually trying to achieve? And what's the relative balance between what we think is in the person's best interest and what they think is in their best interest? And these kind of discussions just don't have invariant solutions, they're not amenable to automated problem-solving, they're not sensible things to try and address through manuailized means, they're values, and unless we're able to articulate our values and negotiate with individuals, it's a slightly flawed endeavour…
Some participants, such as this group two participant quoted above, implied that these values are contested and require examination. I believe the social and political contexts of psychiatric practice, compared to other forms of medical practice, lead clinicians in the field to view values, including patients’ values, to be the backdrop of all practice. EBM enters into this ‘values-saturated’ context as one component of the clinical encounter. Adopting a somewhat different perspective on this same theme, others believed that the goals and values of medicine were well-established, provided an accepted moral framework for the profession, and that the values of EBM were simply the values of medicine as a whole. No group one participants raised this theme.

3. Values that inform EBM

Group 1 (EBM developers)

The notion that certain ethical values inform, animate, or underscore EBM was a theme raised by all three groups, although there were various points of divergence about how this was discussed. Group one participants believed that research funders’ or service payers’ values might inform the creation and interpretation of research data, that societal values can inform what health care services are available, and that practitioners’ values inform how data are presented to patients. Yet, these beliefs seemed to be in tension with this group’s portrayal of evidence as neutral, with only patients’ values entering into the equation to determine which interventions will be chosen or eliminated. Some group one participants were uncertain as to how or if values other than patients’ values fit into the EBM model, while other respondents were certain that non-patient values did not play a legitimate role in EBM and that their influence represented a distortion of EBM.
1-9: The physician’s values might determine what even is on the table for discussion, and there may be censoring of options because the physician doesn’t feel that these are suitable or potentially valuable or not plausible that the patient would actually consider this option. And they may be understood by the physician, or the physician may be unaware of that sort of censoring that is going into what is offered.…

I: So let’s say we’re in a case scenario where the physician’s values have led to a narrowing of the options that are on the table for discussion. Is that still EBM?...

1-9: Well I don’t know if the concept of EBM is defined by what information the physician offers up as an option. I don’t know, is that still EBM? It’s a hard question to answer, but that would certainly be a situation where the physician would not be proposing one option in a discussion that is based on his or her values, so it could be seen as a, like you said a narrowing or more of a circumscribed set of choices because of the suppression of one of them. So probably that would not be the fullest description of laying out all the options….I mean it’s naïve to think that they [physicians’ values] have nothing to do with it. But in that situation it would seem like the physician would be, obviously modifying or manipulating those things that are under consideration, presuming that there’s some rationale for doing whatever is being suppressed. That’s not the fullest discussion of all of the options.

Group 2 (mental health practitioners)

Group two participants shared group one participants’ beliefs about external values having the potential to inform what kinds of research data are created, and how they are interpreted and disseminated. However, the major preoccupation of group two participants under this theme was that the intersection of societal, research funder, practitioner and patient values with EBM affect what one can offer to patients as treatment. Some participants, particularly those in the UK, viewed societal values manifest in nationally-mandated treatment pathways which make use of EBM to constrain patient choice, either appropriately or inappropriately. Others viewed EBM as appropriately curtailing the widespread uptake of bogus or ineffective interventions.
2-10: But, the psychoanalyst…who 25 years ago would have indulged in his theories and at the same time pumped his patients full of neuroleptics up to the eyeballs. And how grateful we all are that there’s evidence-based medicine challenging that and possibly, possibly changing it…

Many group two participants observed that research funders’ values can constrain patients’ options in a manner that is hidden from view, by harnessing EBM to promote pharmaceutical interventions without there being opportunities for research of psychosocial interventions or even watchful waiting.

2-7: This is well-known that industry with the financial means is able to bias the medical debates also in order to promote their therapies and a particular problem in my opinion is also that in terms of EBM it’s always the therapy that is in favour towards the possibility of ‘wait and see’ or ‘do nothing.’ So ‘do nothing’ is always under-researched in comparison to ‘do something’…

At the same time, some participants noted that EBM allowed them to uphold the basic ethical principles of the medical profession including beneficence and non-maleficence by empowering them to refuse to prescribe useless, harmful or fad interventions. In such cases, EBM supported practitioners’ values in the treatment decision-making context. A few participants focused attention on the role of EBM in strengthening informed consent. I believe these latter two points are emphasized by group two participants as a result of how mainstream psychiatry views its own history.

2-6: I’m embarrassed by our history. I’m embarrassed by the psychoanalytic tradition, right? It was like a fascist tradition.

By and large, psychiatrists are taught that the history of our field is littered with examples of useless treatments, harm to patients, and disrespect of mentally ill persons – and that contemporary psychiatry aims for a more scientific and patient-centred practice.
Evidence-based psychiatry proponents believe that EBM may fulfill a special role within psychiatry as a tool to rectifying these negative aspects in the history of psychiatric practice.

**Group 3 (philosophers/bioethicists)**

While group three participants also identified the role of research funders’ values in determining what research is conducted, and the role of societal values in determining what services are offered, these participants emphasized that EBM itself can contain hidden values and/or assumptions. No participants in groups one or two pointed out this issue. Group three participants rejected the idea that the only values relevant to EBM were patients’ values and noted that a limited focus on patients’ values could divert attention away from other values operating as part of the framework. Furthermore, one participant believed that EBM’s attempt to incorporate even patients’ values through technical methods such as decision analysis was flawed.

3-10: I mean the whole idea of patient utilities I find kind of laughable the idea that you can take a patient's goals and values and quantify them in some sort of way or label them and say, “Oh well, yeah, you're a risk averse patient,” okay?, “…based on you filled out this questionnaire and you're a risk averse patient’ and so risk averse patients shouldn't get this chemotherapeutic regimen and should instead go to palliative care. And the patient says “Well you know what? I want the chemotherapy.” So far when evidence-based medicine attempts to sort of measure, quantify and incorporate, goals, values, patient preferences in somehow a more objective way I think is problematic and not ideal and so I would say yeah, you know, I appreciate that they're acknowledging those things are important, um, but how they're going about it, I think is not ideal.

A few participants worried that EBM contained its own conflicts of interest. A focus on teaching and disseminating EBM can be used as a vehicle for career progress, but more specifically, the generation of research data, an essential component of EBM often
involves relationships between investigators and industry. These relationships could distort experts’ opinions about what data to count or discount as evidence.

Some group three participants pointed out that the theory of EBM does not acknowledge its embedded values, and that EBM proponents believe that individual practitioners could be neutral in their application of the model. These respondents thought this view of evidence-based practice was wrong and that EBM by itself could not identify and be critical of hidden values within its own model or within the research literature.

3-8: My criticism is that they [EBM] claim to be value-neutral and many of their methods attest to that. For example that idea of the critical appraiser, that somehow if they have the right methods and they know how to use them, that they're somehow going to be able to get past all that. It's just not true. Not to say that all judgments are the same. There are better clinical judgments than others but it's not about who has values and who doesn't. It's about which values are playing in.

4. Connection between evidence and values

For most participants, the consideration of ethical values and their relationship to EBM focused on the idea that ethical values external to the practice of science or research might play a role in evidence-based practice. However some participants, almost all from group three (philosophers/bioethicists), went further and explored the idea that the generation and interpretation of evidence itself could not be separated from ethical values.

Participants identified ethical values embedded within EBM’s concept of evidence. For example, EBM prioritizes the methodology of randomized control trials. Consequently,
this method is ideally used to settle questions of uncertainty. The level of uncertainty required about the likely effectiveness of an intervention (equipoise) before one decides to undertake an RCT reflects a value about which interventions should be considered treatment (and thus available to suffering people) versus experimental. Put another way, equipoise is partly related to moral judgments about suffering and when we should intervene in another’s suffering with medical interventions. Other participants suggested that the prioritization of RCT data meant that large numbers of individuals (including their time, goodwill, and health) and enormous financial resources had to be expended in trying to obtain this type of data. These cases carry ethical judgments about the importance of resolving uncertainty about interventions versus expending resources in other ways.

One participant explicitly raised the idea that evidence-based practice is rational and rational practice is ethically good. But many others, proponents and critics alike, alluded to a similar idea (without naming it as such) in their praise for EBM’s capacity to challenge ineffective practices and erroneous ideas. Without EBM, participants believed it has been difficult, historically, to challenge personal beliefs or fads as there seemed no basis to undermine them. EBM ties ethical practice to rationales and to rationality more generally. Western medicine takes as fundamental the idea that a rational scientific approach to understanding bodies and their treatments is valid and is the best route to improving health. Some participants made this connection by pointing out that EBM was simply a manifestation of the basic goals and methods of medicine itself.
3-12: I think that it [EBM] has had a positive impact or at least partly did or started to and stopped, I'm not sure, but at least started to have a positive impact in that it forced people to justify their knowledge claims. And I do think there is a moral dimension to that act. So if we want to characterize pre-EBM medicine as one where people deferred to authority without questioning where that authority came from or why that authority was the authority, then the fact that EBM at the very least forced people to have to answer the question, ‘Well, what's your evidence for that?’ ‘Why are you making that decision the way you are?’ ‘What are the grounds for that?’ I think that that's actually a powerfully positive ethical outcome of evidence-based medicine.

One participant wondered whether ethical values might be involved in the justification of knowledge claims, questioning the separation of ethics and epistemology. If knowledge is a true, justified, belief then the notion of justification could contain ethical values.

3-12: ... in epistemology you have this, the true, justified belief is knowledge. And so when we’re concerned about, justification of knowledge, so not the belief bit, not the truth bit, but the justification of knowledge…I think that there’s something to this idea that the justification of a knowledge claim is also a moral claim and this has to do with the fact that we assign sort of moral status to certain actions that we take and the act of justifying or the act of claiming that you know something is an action in the same way that helping an old lady across the street is an action. So these are actions that we take and when I claim to know something... I think it’s entirely possible that there’s a moral dimension to that sort of claiming of knowledge…

This section has illustrated that there are potentially, many ways in which ethical values can inform and influence the generation of evidence. This particular theme may point to a need to rectify what one group three participant called the absence of an “ethical platform” for EBM.

5. Relationship between ethical practice and evidence-based practice

At a broad level, some participants, especially those who were proponents of EBM, believed that EBM itself had played an active role in highlighting ethical issues,
particularly those relating to the generation and interpretation of research data. For example, the critical appraisal skills one needed to practice EBM were the same ones that help clinicians to identify the (sometimes intentional) distortions and biases in research methods and misinterpretations or poor interpretations of research data. As mentioned above, among critics of EBM, a major worry was that diluting critical appraisal so that it was less concerned with primary interpretation of the research literature and more oriented towards the use of pre-appraised sources would render it a less effective tool for critical engagement with the medical research literature.

A complicated picture emerges from the study data about how to understand the relationship between ethical practice and evidence-based practice. Some participants viewed EBM as a minimal ethical standard:

2-7: Well, I think EBM gives you some kind of a guideline that maybe prevents you from doing completely stupid things. If you follow the guidelines of EBM you cannot go completely wrong.

Others viewed EBM as ethically obligatory and even definitive of ethical practice. In such cases, participants emphasized awareness of ‘best evidence’ or ‘keeping up with the literature,’ as being the essence of EBM. Whether EBM was ethically required versus being ethically desirable seemed closely tied to the kinds of results it generated. Some participants hoped that EBM would successfully identify the most effective interventions, in which case, evidence-based practice would be ethically desirable although patients still had the option of refusing the most effective, evidence-based interventions. Others saw EBM as being oriented towards identifying useless or even harmful interventions. Where it was able to achieve this goal, EBM was considered to be ethically obligatory.
Many participants understand adherence to EBM as a somewhat interpretive exercise. Several respondents believed that ‘rigid’ or ‘blind’ adherence to EBM could impede rather than promote ethical practice. The kinds of considerations that were supposed to lead to a more flexible evidence-based practice were not specifically identified but two examples pointed out the kinds of deliberations that might be required to demonstrate flexible rather than rigid EBM. One participant discussed the idea that non-evidence-based practice could do good:

1-6: I remember one day going to a country where everybody who comes to a physician and is a little weaker and complains of tiredness gets intramuscular injection of vitamins. And I’m saying ‘Why the hell are you doing this? I mean you know, you have these studies showing you it has no effect?’ And they say ‘We are not doing any harm and they expect it and they feel better.’ It was a dilemma for me. I didn’t argue with it. I didn’t argue with what they said.

I: Do you think that’s an ethical practice?

1-6: According to them it was. According to them they were doing what’s right. And who am I to judge it?...

I: Well, I’m asking you to judge it.

1-6: If you are asking me to judge it I would say ‘yes’.

Another participant pointed out that at times one must allow patients to choose a treatment option, even in the face of evidence it would not be effective.

2-5: …and one of the health economists developed what’s called a decision board. So it’s a piece of cardboard covered with velvet and you start off with just a circle. Okay. You’ve been diagnosed as having breast cancer so you put that on the board. You have two options. Option one, option two. For option one these are the possible benefits, side effects, probabilities of each. So the physician walks the patient through every decision….And then in essence s/he gives the board or a small copy of the board to the patient and says, ‘Go home. Don’t make
a decision now. Talk to your doctor. Talk to your husband. Come back and decide.’ Okay. So what this student wanted to look at was radiation following lumpectomy. The evidence is I think 100% in one direction. Radiation does nothing. In terms of longevity. Women do not live any longer following lumpectomy whether or not they have radio- whether it’s due to the fact that by the time they get to radio- it’s too late or whatever positive effects radio- has is counteracted by the negative cardiotoxic effect, whatever. The evidence is clear. [The researcher] went through the board with many, many women. Every single one of them wanted radio-.’

In essence, what these participants identified above was that evidence-based practice could be ethical practice, but sometimes non-evidence-based practice could also be ethical. In these examples, what seemed to make non-evidence-based practice ethical, was both respect for individual patients’ beliefs and an endorsement for broadly shared ethical values such as respect for cultural values about what should happen in a healthcare encounter (in the first example) and the moral duty to offer treatment options for potentially life-threatening illnesses (in the second example).

Participants expressed a related worry that evidence-based practice could be unethical. There were two major sub-themes that emerged under this idea. First, there was a tension between believing that EBM appropriately defined treatment options and a fear that it inappropriately restricted patient choice. A second and related point was that EBM dehumanized practice, both because it was a highly technical mode of working and because it necessarily required the privileging of population-derived data in application to individuals whose needs and circumstances might be very different from population averages.

3-10: I think those who are relying like in our last example relying solely or predominantly on published evidence may actually impede ethical practice and
for a couple of reasons. I mean one is I think ethical practice is best practice and 
I'm not convinced that they're practicing optimal medicine. And from an ethical 
standpoint, if you agree that the practice of medicine is focused on doing best for 
the individual patient at hand as opposed to public health, right?...... where we're 
more interested in effecting benefit across a population, if you really believe that a 
physician's duty is focused on the individual patient at hand then I think often 
times evidence-based medicine practice as we defined in the latter cases can do 
the patient a disservice. You're not treating them as an individual, right? You're 
treating them as... if you're just trying to apply the results of population-based 
clinical research to individuals, you're in some ways devaluing their 
individualism... by saying what distinguishes them from other patients is not 
important enough to influence that decision. To me that has an ethical 
implication.

Ultimately, most participants believed that ethical practice and evidence-based practice 
are not identical. They implied that ethical practice was determined by its own criteria, 
not just by the criteria that define evidence-based practice. Furthermore, practitioners 
could discern what is ethical practice, and this determination could be independent of 
what is evidence-based.
Table 5 - Key interpretive findings regarding the relationship between evidence-based practice and ethical practice

<table>
<thead>
<tr>
<th>PARTICIPANT GROUPS</th>
<th>GROUP 1 (EBM developers)</th>
<th>GROUP 2 (Mental health practitioners and scholars)</th>
<th>GROUP 3 (Philosophers and bioethicists)</th>
</tr>
</thead>
<tbody>
<tr>
<td>INTERPRETATION OF KEY THEMATIC AREAS</td>
<td>Evidence-based practice includes consideration of patients’ values alongside evidence and clinical expertise. Social, professional, and practitioner values exist – what role they do play or should play in evidence-based practice is unclear.</td>
<td>Evidence-based practice happens within the larger context of health care which includes many ethical values (including social, professional and practitioner values). Whether EBM acknowledges these values or not, they play a role in any attempt to practice EBM. Attention to all parties’ values (patients, practitioners, society’s etc) in mental health care, is particularly important because of the diversity of values about mental illness and treatment.</td>
<td>Evidence-based practice happens within the larger context of health care which includes many ethical values (including social, professional and practitioner values). In addition to the contextual values of medical practice and the social context of medical practice, evidence-based practice reflects certain constitutive values. (e.g. prioritization of a particular research method reflects a value – both epistemological and ethical - placed on the kind of knowledge obtained by that method).</td>
</tr>
<tr>
<td>Relationship between ethical values and EBM- general</td>
<td></td>
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<tr>
<td>Relationship between evidence-based practice and ethical practice.</td>
<td><strong>Group 1</strong> (EBM developers)</td>
<td><strong>Group 2</strong> (Mental health practitioners and scholars)</td>
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<tr>
<td><strong>Evidence-based practice can be ethical</strong></td>
<td>Implementing evidence-based recommendations about effectiveness is ethically desirable as long as they are congruent with patients’ values.</td>
<td>Evidence-based practice represents a minimal ethical standard, but there is more to ethical practice than evidence-based practice.</td>
<td>Evidence-based practice is ethical when it encourages clinicians to engage critically with the medical literature including being aware of the many ethical values and social interests at play in clinical practice and research.</td>
</tr>
<tr>
<td>Evidence-based practice is rational practice. This gives it ethical force.</td>
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<tr>
<td><strong>Evidence-based practice can be unethical</strong></td>
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<tr>
<td><strong>Non-evidence-based practice can be ethical</strong></td>
<td>Non-evidence-based practice can be ethical when it upholds established ethical principles (e.g. informed consent/patient autonomy)</td>
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<td></td>
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<tr>
<td><strong>Non-evidence-based practice can be unethical</strong></td>
<td>Evidence-based practice is ethically obligatory for those interventions which evidence shows are harmful and not helpful.</td>
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</tbody>
</table>

Non-ethical practice can be unethical (e.g. restricts patient choice inappropriately, can be dehumanizing, can be authoritarian).
6. Comparing frameworks

Here again is figure 3, initially presented in chapter 3

Basic Ethical Principle of Medicine and Psychiatry:

\[ \uparrow \text{Help} \quad \text{AND/OR} \quad \downarrow \text{Harm} \]

(in order for medical practice to be ethical, it must increase help or decrease harm or both)

Pre-EBM sources of information
- often inaccurate and/or biased

EBM-preferred sources of information:
- more likely to be accurate, less likely to be biased

- Convention
- Authority
- Faith
- Intuition
- Theory
- Practitioners’ Medical Education
- Research data

\[ \downarrow (= \text{leads to}) \]

? knowledge about health interventions
\[ \downarrow \]

some worse health outcomes
\[ \downarrow \]

No help OR ↑ harm

Therefore, pre-EBM practice was not as ethical as EBM is

Quantitative Research Data
(prioritized by the evidence hierarchy)

\[ \uparrow \text{knowledge about health interventions} \]
\[ \downarrow \]

better health outcomes
\[ \downarrow \]

↑ help OR ↓ harm

Therefore, EBM is ethical

Patients’ values or preferences are concordant with these outcomes

I argued that EBM, as it was laid out, was utilitarian in its orientation and its primary ethical aim was to maximize improvement to patients’ health through changes to specific health outcomes.

Figure 3 - Ethics of EBM as implied by ‘literal’ EBM
Basic Ethical Principles of Medicine and Psychiatry:

Act in individual patient’s interests, do no harm, respect individual autonomy, respect cultural and ethical diversity

Individual practitioners must have accurate knowledge in order to fulfill these principles

Pre-EBM sources of knowledge
- Convention
- Authority
- Intuition
- Theory
- Practitioners’ Medical Education
- Research data

EBM-preferred sources of knowledge
- Quantitative Research Data

EBM’s methods help to identify values in data production

-socio production of research data is influenced by contextual values e.g. $S$, conflict of interest
-evidence hierarchy represents epistemological and ethical values

interpretation of research data and justification of knowledge claims can be influenced by values

application of data to practice reflects social, professional and ethical values

Values abundant in pre-EBM sources

? knowledge about health interventions

some worse health outcomes

No help OR ↑ harm

Therefore, pre-EBM practice was not ethical (or less ethical than EBM practice)

?↑ knowledge about health interventions

clinical practice

better health OR ↑ autonomy

worse health OR ↓ autonomy

promotes ethical practice

impedes ethical practice

ethical practice co-determined by non-evidentiary considerations
Figure 4 - Revised framework of the ethics of EBM
Chapter Seven
Discussion

In the previous two chapters, I laid out some of the central analytic themes that arose during this qualitative section of this project. The aim of this chapter is to integrate those themes with the main ethical issues explored in chapters one through three in response to the central question of this thesis project: is evidence-based psychiatric practice, ethical practice?

1. The ethics of EBM

1.1 The ethical values and principles exemplified by EBM

In chapter three I argued that EBM was committed ethically to utilitarianism. While some authors have concurred with this perspective (Kerridge, Lowe, and Henry 1998), others are non-committal or simply do not comment about the ethical basis of EBM (Leeder and Rychetnik 2001; Culpepper and Gilbert 1999). I have argued that EBM’s overall purpose is to achieve the greatest good for the greatest number, where good is understood to be improved health, as defined by EBM. However, the picture of the ethics of EBM painted by participants was rather different. In fact, only three participants in this study explicitly and spontaneously described EBM as inherently utilitarian. Many more participants recognized that EBM is oriented towards maximizing good for the largest number of people but noted that the ethics of medical practice requires consideration of individual good and that sometimes, the good of the many must indeed be sacrificed for the good of one. Because EBM is implemented within the larger ethical arena of clinical practice it too must wrestle with these competing imperatives. In fact, whatever EBM is
in theory, it is ultimately a living practice whose nature can only be exposed fully when viewed in the context of actual clinical care. At that point, the ethics of EBM are contiguous with the ethics of clinical practice which will necessarily include the ethical issues relevant to the specific context in which care is practiced (e.g. the type of healthcare system, the health and social needs of the population at hand, the social and political values at play etc). In other words, there can be no ‘ethics of EBM’ independent of the myriad ethical considerations that frame and colour the local context of practice. Participants identified several practice-guiding ethical principles which are applicable to my own context, an urbanized part of Canada, including such considerations as:

- do no harm
- the primacy of individual choice as manifest through informed consent
- the importance of offering treatment options in terminal or serious illness
- respect for cultural diversity
- equity of access to healthcare services
- just stewardship of healthcare resources

The first four of these principles in particular, illustrate the ways that the good of the many must be balanced with the good of the one, particular one’s own patient.

1.2. The ethical goals of EBM

While ethical, evidence-based practice involves the weighing of several potentially competing ethical principles, it also strives to accomplish certain ethical goals. What
remains unclear from the key EBM texts, and even from interviews with EBM developers is what EBM’s intended outcome(s) is supposed to be. There appears to be a divide reflected both in the literature surrounding EBM and in the data of this project concerning whether EBM’s primary role is to improve patient care through a strengthened (through better evidence) informed consent process, by improving health outcomes, or both. However, in a recent article, Djulbegovic, Guyatt (a leading EBM developer) and Ashcroft describe EBM as, “…a practical approach to improving the quality of medical care by eliminating dangerous or ineffective treatments, promoting the use of well-tested treatments, and stimulating the evaluation of treatments where there is reasonable uncertainty about their merits” (2009, 159). In other words, improving health outcomes seems to be the most important goal of EBM.

Nevertheless, along with some scholars (Hope 1995; Parker 2001) many participants in groups one and two believed there was a special relationship between EBM and informed consent. For some, the notion of a ‘shared decision-making model’ (the manner in which participants used this phrase was evocative of informed consent) was an essential component of EBM. Evidence-based practice was ethical practice because patients’ values were examined in the process of shared decision-making and were given primary consideration in making treatment decisions. Envisioned this way, shared decision-making could have existed before EBM, but what improves it now, is the supposed availability of improved research data. Therefore, evidence allows the practitioner to strengthen shared decision-making. What is implied by EBM is that improved decision-making leads to improved health outcomes – if patients are informed with high quality
research data about the interventions likely to improve health, they will choose those. But what if on the whole, they do not? What if EBM led to improved informed consent practices and satisfied patients’ preferences, but did not improve health? There is certainly room within the ethics of pre-EBM clinical practice to describe such a state of affairs as ethical practice, but the question for this thesis is whether EBM would be judged an ethical success on these terms.

My interpretation of the data generated by this project is that strengthening informed consent and improving health outcomes are both ethical goals of EBM. That is, EBM can be considered ethical as long as patients are provided with the best evidence about their treatment options, regardless of which options they choose and regardless of how good or poor their outcome is. At the same time, improving health outcomes (as defined by researchers and practitioners) is also a core ethical goal of EBM. But if these outcomes are not concordant with patient-preferred outcomes, then they can be subordinate to patients’ wishes in many circumstances.

In what circumstances are health outcomes more important than patients’ preferences and vice versa? The data point to the idea that EBM has the potential to tell us two different kinds of things about interventions: whether they are effective and whether they are useless or even harmful. When practitioners use research data to advise patients about the relative effectiveness about interventions, they are using evidence in a way that conforms to the original definition of EBM, that is the use of evidence ‘…in making decisions about the care of individual patients’ (Guyatt and Rennie 2002, 674). Whether
or not the health outcome is optimal, EBM’s original aim has been satisfied because it
has strengthened shared decision-making.

At the same time, some participants pointed to another purpose of EBM, namely, to
identify interventions which are both unhelpful (useless) or harmful. Participant 5-3
captures this sentiment:

‘…if you talk to the sort of first generation EBM people…you find that they’re
principally interested in patient safety, removing dangerous treatment. They’re
very concerned with the inadequate publication of clinical trial data from the
pharmaceutical sector. They’re very concerned with clinicians continuing to use
treatment when there’s well established evidence that it doesn’t work. They’re
very concerned about the inadequacies of medical education and the way in which
students come out of medical school not knowing how to appraise evidence, and
postgraduate, post graduation and that there’s no way in which people are
encouraged to update their knowledge and skills and so on. So it’s about
worrying about the bottom end.’

Inasmuch as awareness of the medical research literature enables practitioners to avoid
offering these types of interventions to patients, EBM has fulfilled another ethical goal:
improving health outcomes. In such cases, EBM is judged an ethical success because it
has convinced practitioners not to offer useless or harmful interventions for patients to
consider. Participant 1-1 argues:

‘I think that those physicians who are clinging to practices that have been
discredited… that is not ethical. I think when we know something doesn’t work,
or when we know it causes harm, or when we know that something doesn’t work
as well as an alternative, to continue to cling to it, to continue to treat patients
with it is a failure of ethics…’

Under these circumstances, health outcomes are more important that patients’ values.

Even if a patient requested an intervention that that was thought to be harmful, it would
be ethical (perhaps obligatory) for the practitioner to refuse to offer it. The following exchange between participant 9-2 and I illustrates this idea:

I: What if somebody wants something that’s not evidence-based? What do you do about that situation?

P: Well as a doctor I’d say, ‘Well, there’s no evidence for that. It’s up to you.’

I: So if they say, ‘No I really do want that thing.’

P: Oh I see, I’m supposed to give it to them...say, ‘I really want some... benzodiazepines.’ I would say ‘No, I can’t do that because I’m very sure that it is a bad idea to give you long-term benzodiazepines. So I feel that would be against my ethical principle directing your interests.’

I: So that’s one of the values. I mean that’s one way of framing it, that evidence does trump patient values sometimes. If a patient wants something and it’s not evidence-based, you will not give it.

P: No.

Although these types of situations are cast as ones in which evidence trumps patient preferences because of the potential for harm, the evidence of harm in these cases is determined in part by researcher or practitioner values about what kinds of outcomes are appropriate or not. The benzodiazepine example is apt and germane to psychiatry. Many patients use benzodiazepines to help them fall or stay asleep. And while practitioners can marshal many good health-related reasons why this is not the best way of facilitating healthy sleep patterns in patients with insomnia, some patients will prefer to take benzodiazepines, including on a long-term basis, risking the harms that practitioners fear. When a practitioner refuses to prescribe this way, s/he does so in accordance with his/her own values about what a good health outcome is. Calling this ‘evidence’ obscures the ethical dimension of this clinical decision to withhold prescription.
EBM strives to be a complete model of clinical decision-making in practice. It acknowledges that patients’ values are relevant to clinical decisions. It even proposes a technique (decision analysis) to try to capture and quantify these values. At the same time, EBM is silent about other values that are also part of clinical decision-making, whether they are practitioners’ values, system values or institutional values. While group one participants (EBM developers) agreed that such values exist and frame clinical encounters, there has been no sustained exploration, either in their interviews or by EBM texts about how to give these values appropriate consideration. By ignoring them, EBM clings to its vision of being a value-neutral technique (apart from the recognition of patients’ values). Clinical decision-making is ultimately a normative exercise involving questions of how to achieve health, and what states of health are consistent with living a good life. Such an exercise cannot be value-neutral and renders EBM’s claim to being value-neutral incoherent.

1.3. Can EBM accomplish its ethical goals?

Whether EBM is primarily about strengthening informed consent or improving health outcomes or both, a major issue that is raised in the scholarly literature over and over again is whether EBM actually can accomplish its goals. Making a strong ethical case for EBM, Goodman frames the question this way: ‘how should one make an empirical decision under uncertainty when an error might harm someone?’ (2005, 552). Goodman argues that medical research has already proven itself as a better route to achieving knowledge about disease and treatment than any other route. By his logic, it is unethical not to be aware of and practice according to evidence-based practice guidelines.
Recognizing that individual variation exists, Goodman allows that sometimes such guidelines are not applicable to a specific patient but that it is incumbent on the practitioner to make the case that deviation from guidelines is necessary. Shahar counters by pointing out that it is not merely in cases of potential deviation that doctors ought to be engaging in argument and interpretive judgement (1997). He poses the same question as Goodman, ‘one may ask how doctors are to make medical decisions in the presence of permanent uncertainty. The answer is very simple: on the basis of some interpretation of empirical experience – a subjective exercise with no universally accepted logical rules (Shahar 1997, 115). Shahar’s point is that medical research data might be quite essential to good clinical practice, but to insist as Goodman does, on a codified interpretation of these data via the evidence hierarchy or by practice guidelines moves practice away from the very ethical goals EBM is trying to achieve. By contrast, many critics of EBM from a variety of positions: sociological, philosophical and statistical, argue that the data generated by EBM’s preferred methods are subject to such major distortions, misinterpretations and/or biases themselves, that our knowledge may not improve. What is implied by these critiques is that making decisions under uncertainty using ‘best evidence’ may not be ethical at all.

At the heart of this debate is the issue of whether patients’ interests are better advanced using EBM than pre-EBM. Externalist critiques that focus on industry interests in generating, interpreting and disseminating data implicitly argue that in these cases, patients’ interests are subjugated to commercial interests. Related critiques place

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25 This is not to suggest that other research methods are not subject to distortions or biases, but the evidence hierarchy has been developed precisely on the basis that the highest ranked methods are less subject to distortions that lower or unranked methods.
patients’ interests behind population interests, career interests, institutional interests, and
journal interests. Whether EBM’s main goal is to improve the quality of information that
informs decision-making or to improve patients’ health, these critiques all point out how
either goal is compromised by the ways in which patients’ interests are sidelined in
favour of others. Will the EBM approach prove itself to achieve either goal? This is an
important question whose answer remains to be determined.

1.4. EBM and resource allocation

A major finding of this project, and a theme that I did not investigate in my own analysis,
concerns EBM and its role in resource allocation. There were participants who believed
that EBM had a significant role to play in the just allocation of resources, while there
were others who were ambivalent about this use of EBM and still others who believed
that it was exactly this application of EBM that rendered it suspect and even unethical.
These lines of convergence and divergence fell, quite strikingly, along national lines
(regardless of whether participants were proponents or critics of EBM). Participants
from the UK, where EBM has been adopted explicitly by the National Institute for
Clinical Excellence (NICE) as a tool in resource allocation along nationally mandated
treatment pathways, were deeply concerned about the extent to which this led to
disregard of individual patient values and needs. A related concern was the extent to
which the uptake of EBM for resource allocation forced practitioners to act unethically,
by setting aside their knowledge of individual patients or local circumstances and provide
treatments that were inappropriate in specific circumstances. One reason why UK
participants may have consistently expressed concern may relate to the way in which the
resource allocation projects have played out in that country. Participant 5-3 speculates on another possible reason why even EBM supporters may be ambivalent about emphasizing a potential role for EBM in resource allocation.

I: ‘I wanted to ask you whether you think EBM as it stands includes resource allocation as part of it or whether that’s added on…or even a misapplication?’

P: I think it is part of it and you can’t really, you couldn’t really talk about evidence-based medicine without talking about it, if for no other reason than historical ones that the sort of founding text of the movement is Archie Cochrane’s Effectiveness and Efficiency where effectiveness and efficiency are linked together in the title but also in the analysis throughout the book. And it places that the need to use resources efficiently at the heart of what it is to organize a just and effective health service. That said, one of the reasons why supporters of evidence-based medicine sometimes avoid engaging in debates about cost effectiveness is because the vast majority of treatments have never been subject to, so they say… I have no idea how you could actually demonstrate that fact that the vast majority of treatments have never been tested but so it is said and I think it’s plausible to say that most treatments have never been tested, so simply to say, ‘Well we can’t allocate resources except on the basis of robust clinical evidence,’ would be to say ‘Well we’re not going to do 95% of medicine at all.’

Participants in Canada, while recognizing that resource allocation was an essential aspect of health policy were ambivalent about whether EBM should properly play a role in this task. Participants in the US or participants commenting on the US situation in which EBM can be used by private insurance companies to determine eligible or ineligible treatments, were divided about whether this was an ethical use of EBM or not. On the one hand there was a worry that such determinations applied population-derived information to all holders of a given policy, without taking into account individual variation or needs. On the other hand, some pointed out that EBM allowed such macro level determinations to be made on a more rational basis than any other means.
2. Evidence-based psychiatry in practice

Thus far I have discussed the ethics of evidence-based medicine in general. While these general concerns apply to psychiatry as well as any subspecialty of medicine, I want to turn my attention to the relationship between ethical practice and evidence-based practice in psychiatry.

2.1. Science as a route to ethics

Group two participants, all practitioners in mental health who are closest to the concerns and debates within that field described a connection between the history of psychiatry and the importance of evidence-based psychiatry. In the last generation, the practice of clinical psychiatry has undergone a massive transformation. The advent of DSM-III in 1980 began to tip the balance of power away from psychoanalysts, who had dominated the theory, practice, and administration of psychiatry since the 1930s, towards the exponents of the new biological psychiatry (Shorter 1997, 239). As this latest phase in psychiatry gains momentum, the version of its pre-history most commonly found in the popular imagination characterizes past practitioners and interventions as coercive, even abusive, and portrays the body of psychiatric knowledge as unscientific. The unscientific status of psychiatry is part of what rendered its practices unethical (Ghaemi 2009, 249). If it has an inadequate scientific basis, then on what grounds should psychiatrists be given a professional monopoly in the care of the mentally ill including the legal powers to enforce their treatments? In his book, ‘Ethics and Evidence-Based Medicine: faillibility and responsibility in clinical science,’ Goodman, like some participants, ties ethical practice to rational practice and argues that evidence-based practice is the best model of
rational practice we have (2003, 129-140). EBM helps psychiatrists combat the
historical portrayal of psychiatry as unscientific and therefore, unethical.

As argued in chapter 2, the complex and largely unknown nature of mental disorders
makes their study in accordance with the dictates of EBM more difficult. Proponents of
evidence-based psychiatry would likely challenge this argument, claiming that EBM does
not require a specific or even known theory of pathogenesis to be useful in the evaluation
of treatment effectiveness. However, as Giacomini argues, EBM does (and has to)
contain hidden theoretical commitments, including pathophysiological ones (2009, 241-
242). It is not possible to devise intelligible research questions or studies without having
plausible hypotheses which are necessarily based on a variety of theoretical (including
pathophysiological) assumptions at play. For example, EBM-preferred research
questions and methods are structured so as to investigate certain types of questions
optimally (e.g. the effect of pharmaceutical agents on specific variables in controlled
conditions). This kind of effect assumes that healing occurs through the action of a
biochemical agent upon some physical, bodily entity. In the case of psychiatry, EBM-
preferred questions fit best with a strictly biological model of mental disorders (major
depression occurs because of changes in certain brain neurotransmitters). These kinds of
commitments make EBM’s use in psychiatry scientifically problematic because such
assumptions may not fit with what is currently known about the biopsychosocial nature
of mental disorder. Thus, there is a question of whether practicing evidence-based
psychiatry is really more scientific in the sense of being connected to existing and
established knowledge. It is possible a strictly biological model is correct. If so, it
should be demonstrated rather than be accepted because it fits with a preferred model of research. The social forces that distort evidence-based psychiatry as much or more than evidence-based medicine in general, also raise questions about whether it is more scientific in the sense of being open to scrutiny. These doubts about the scientific status of evidence-based psychiatry lead directly to questions about its ethics. If not more scientific than our previous practices of psychiatry, does EBM place psychiatry on sounder ethical ground than pre-EBM practice?

2.2. Evidence-based practice and patient-centred practice

Some study respondents believed that the ethical practice of psychiatry requires a strong patient-centred orientation that is confident enough to relinquish professional power where appropriate.

‘…the hierarchy of evidence relegates the importance of the experience of the individual user or the patient. And I think that’s an ethical choice, particularly as I said, the history of services shows that there are real dangers of doing that. If the individuals views, values or preferences, are not at the heart of what decisions get made then the history suggests that they’re routinely subjugated and ignored, and I think evidence-based medicine, evidence-based mental health hasn’t yet found the technology to incorporate the individual’s views of the world into the kind of information it generates, and… I think that’s the major ethical challenge of evidence-based mental health and frankly, I think it may not soluble... A conceptual problem is its [EBM’s] unit of currency is groups and the problem is that groups lose key information about individuals necessarily. And I guess my view is that it’s that key information that is lost, that is in fact seen as a problem to factor out through random allocation or RCTs, is what should be the central driver for mental health care. So I guess it reflects my general view clinically that the power to decide about what treatments or interventions are or are not provided is far too far with clinicians and that fits with the evidence-based mental health framework, because only clinicians have privileged access to this knowledge. And it’s a professional kind of passport, that you have systematic review evidence to say what’s best for the patient. But the problem is that that just doesn’t work and it’s toxic and harmful for some people and it results in predictable consequences of major
issues about people wanting nothing to do with mental health services, feeling that they recover *despite rather than because of* the service and having vary big misgivings about mental health, high levels of coercion and compulsion and so forth.’

According to these views, in order for psychiatry to fulfill the ethical goal of patient-centredness, it must realize it exists within a moral superstructure that goes beyond, and is separate from, evidence-based psychiatry (Cox 2008). Furthermore, psychiatrists need to be aware of and committed to this (non-evidence-based) structure. In addition to the basic ethical principles of medicine described above, these include: recognition of the often socially marginalized positions of mentally ill persons, recognition of the power of the psychiatric profession along with a commitment to reducing the power imbalance between clinicians and patients, and a commitment to authentic, personal presence with patients and families. In other words, the practice of ethical psychiatry has room to include evidence-based psychiatry, but it far exceeds it. Indeed it is this moral superstructure that distinguishes it from charlatanism.

There may be a special role for psychiatry in exploring the relationship between ethical practice and evidence-based practice. Psychiatrists have a strong tradition of advocating for models of practice that give voice to our ethical (and intellectual) commitments. Engel’s biopsychosocial model, still a classic work within psychiatry, articulated a comprehensive view of health and disease as multiply-determined that went beyond the standard biomedical perspective (Engel 1979, 161). The model has had a profound influence on practice to the present day. For example, the Royal College of Physicians and Surgeons of Canada identifies the biopsychosocial model as the framework to guide
all instruction in psychiatry and makes clear that teaching faculty are to instruct in accordance with this model (RCPSC 2007, 2).

More recently, in the late 1990s, Bracken and Thomas, both psychiatrists in the UK adopted a more radical position than Engel in developing the notion of ‘postpsychiatry.’ The authors wanted to preserve what was valuable and ethical about the psychiatric encounter while questioning its professionally-driven aspects (2001) including a diagnosis-focused, evidence-based form of practice. By contrast with Engel’s model, they put a premium on social aspects of madness and recovery and de-emphasize biological and psychological ones. They also emphasize the patient’s perspective, even at the expense of the professional or scientific one.

Fulford, also a psychiatrist in the UK, has developed the concept of ‘values-based practice’ (VBP) a direct and intentional parallel to evidence-based practice (2004). His ten principles are meant to work in tandem with evidence-based practice. For Fulford, values-based practice fills a gap left by evidence-based practice, namely, a structure for negotiating the complex values often found in the clinical encounter. Values-based practice stakes out a somewhat less radical position than postpsychiatry does by seeking a collaboration with evidence-based practice rather than by offering a strong rebuttal of it. VBP also provides an alternative to the algorithmic, quantified procedure of EBM’s decision-analysis in viewing communication in the clinical encounter as playing a substantive ethical role, not merely a procedural one.
These three examples illustrate the potential within psychiatry to explore the ethical ground not covered by EBM. Developed as they were after the advent of EBM, these latter two proposals in particular portray a vision of evidence-based practice as at most, a small component of ethical practice.

2.3. Evidence-based psychiatry, ethics, and suffering

Psychiatry as a field exists in contested terrain about the nature of mind and thus, the legitimacy of mental suffering. In need of an arbiter for the complex disputes about mental disorder and the social entitlements it brings, psychiatrists find an ally in EBM which advances the evidence hierarchy as an objective standard to judge validity. However, any methodology contains within it a valuation of what it can study and the procedures it uses. In the case of health research, these values cannot be divorced from ethical values about what kinds of suffering are worth knowing about, worth intervening in, and under what circumstances. Whatever we count as disorder and whatever we are trying to treat (whether DSM criteria or psychoanalytic defense mechanisms) are inextricably linked to what we think matters when it comes to mental experience. And what we think matters is reflected in what we research. As a result, any model of practice, research, or decision-making will tell us something about our relative valuations of suffering. EBM is connected to a specific mode of knowing and is capable of generating specific kinds of medical knowledge. What EBM is able to tell us about mental disorders and their treatments will help to determine what kinds of suffering psychiatrists ought to pay attention to and deem worthy, and will define our role in that suffering. After all, the entire point of EBM is to base our practice on evidence. If we try
to treat entities or use interventions not based on evidence, we run the risk of being
deemed ‘non-EBM’ practitioners. Even though EBM intends to be an objective
standard, it functions as an ethical standard, influencing judgments about to whom and to
what psychiatrists’ duties ought to lie.

3. Is evidence-based psychiatric practice, ethical practice?: summary

It depends. Evidence-based psychiatry has the potential to play a role in ethical practice
provided it conforms to the ethical framework of clinical practice in general, and of the
ethical complexities of psychiatry in particular. Evidence-based practice can steer us
away from continuing to use harmful or useless practices serving as a valuable antidote to
ideology and fads, both of which have infected psychiatric practice at the expense of
patients. EBM can provide useful information to assist patients and practitioners in
selecting amongst more than one potentially effective intervention. However, applying
research data in clinical scenarios without giving attention to the assumptions about
health and suffering that have been made to generate those data can be unethical. The
same is true regarding blindness to the social and ethical context of knowledge
production in the sphere of psychiatric research. In both of these cases, interests and
values are being masked and presented as ‘evidence.’ Instead, ethical practice requires
making these values transparent and negotiating rather than obscuring them. Because
ethical values necessarily play a role in determining how we understand mental disorder
and what we propose to use when we intervene, there must be room for values to direct
practice, including the option of offering and making choices that are non-evidence-
based. This does not mean that we have to accept ideology and fads but it does mean that
we have to reach beyond EBM’s restricted notion of evidence to broader social practices in science including: a commitment to rationality, scrutiny, openness to minority views, and vigorous intellectual debate. Such practices are complemented by the ongoing commitment to the core values of psychiatry: patient-centredness, patient empowerment, and practitioner authenticity. As keepers of these ethical commitments, there is a significant opportunity for psychiatrists to play a leadership role in reconstructing and repositioning EBM.
References


RCPSC. *See* Royal College of Physicians and Surgeons of Canada.


Conclusions

1. Conclusions

The original question posed by this thesis was, ‘Is evidence-based psychiatric practice ethical practice?’ Evidence-based psychiatry, an extension of evidence-based medicine, is underscored by a basic ethical value to pursue health. EBM contains an epistemological assumption that its methods will lead us to interventions that achieve health most effectively. As reviewed in chapter one, most of the critical literature examining EBM accepts its basic values, but takes issue with its epistemology: does the knowledge generated by EBM’s methods really lead us to interventions that are most effective in achieving health? This body of literature argues that there are good reasons to think that EBM’s methods are not the best route to clinical, medical knowledge. As discussed in chapter two, when evidence-based medicine is applied to psychiatry the epistemological pitfalls of EBM are compounded by such issues as they exist within psychiatry (How do we know when someone is experiencing a mental disorder? How do we distinguish between normal and abnormal mental experiences?, etc). Not only do the epistemological issues of EBM create problems for evidence-based psychiatry, but its basic ethical commitments may also be inadequate. In chapter three I argued that EBM’s ethical platform is essentially a utilitarian one and that utilitarianism cannot help psychiatry to resolve the ethical problems faced in its theory and practice in spite of hopes from within the profession that it will.
This line of argument provided a backdrop to the themes emerging from my analysis of participant interviews in the qualitative component of this thesis project discussed in chapters five and six. Participants identified ethical values that were both external and internal to EBM. Awareness of these values is critical to understanding evidence and the practice recommendations that follow from it. Ideally, the existence and role of such values should be made explicit and open for scrutiny.

At the same time, the ethics of EBM cannot be fully understood until EBM is put into clinical practice, at which time it operates within the values that inform practice in a given context. EBM as a theory may be utilitarian, but EBM as a practice is not. EBM allows practice to be more rational which is connected to being more ethical, in the sense that rational practice is viewed as being more likely to assist the pursuit of health and of individual patient needs. However, rationality (in EBM terms) is not the only determinant of ethical practice. Non-EBM practice can also be ethical.

This conclusion is particularly important for psychiatry: evidence-based psychiatry is not going to be able to provide the field of psychiatry with ethical substantiation on its own. Rather a commitment to certain core virtues and duties constitute the ethical framework of psychiatry within which evidence, as defined by EBM, plays a role (other forms of evidence also play a role). In light of the history of harm done by psychiatrists and psychiatric treatments, the contested nature of mental disorder, and the diversity of values about the best ways of responding to disordered mental states, this ethical framework is
particularly important both in terms of establishing trust between psychiatrist and patient, and between psychiatrists and society as a whole.

What are the implications of these findings? The first, and most significant, is that EBM alone is insufficient to constitute a comprehensive framework for ethical psychiatric practice. Furthermore, in view of its epistemological limitations, it is insufficient as a comprehensive framework of psychiatric knowledge. In addition, EBM is a constraining medical discourse, redefining how we ought to understand and intervene in mental disorders which itself has significant ethical implications. While EBM focuses our attention on specific types of research questions, methods, and outcomes, it obscures the values that shape its practice. Practitioners and the public alike are increasingly aware of the impact of external values (such as those of the pharmaceutical industry) on the generation, interpretation and dissemination of research data, but internal values remain obscure and part of the ‘objective’ methods of medical research rather than a product of the [social] practice of medical research and research more generally. In the absence of much fuller participation by practitioners and researchers in the debate about EBM, it has the potential to be as authoritarian a mode of practice as the one is sought to replace. Even worse, EBM could be a model of bad practice – in which practitioners and patients draw premature conclusions about best (meaning both effective and/or ethical) practice where there is legitimate room for debate and difference. This could be more damaging to psychiatry than other medical disciplines, which has been plagued by controversy about the use and abuse of power since its inception.
2. Limitations and interpretive considerations

2.1 Limitations

There are several potential limitations and interpretive considerations that should be mentioned. First, as in all qualitative research, there is a limit to the extent to which the findings can be transferred to individuals in different contexts. In keeping with the parameters of case study research, these findings should be considered to be consistent with the dominant ideas about EBM, evidence-based psychiatry and ethics at the time the data were collected (2008). The ideas and analysis reported here are not intended to be representative of all views about EBM. At the same time, I did interview several leading participants in the growing debate about EBM; therefore, I was able to include many of the key English language viewpoints. Further, I asked all participants if they would suggest others I should interview for the project. I was able to interview several of these suggested participants. However, I did only conduct interviews in English with fluent English speakers. Therefore, any major contributors to the critical debates about EBM who do not publish in English would have been unknown to me. I interviewed a few participants for whom English was not their first language who were also asked to suggest additional participants. They did not suggest additional non-English language speakers.

A second limitation is that these viewpoints could perhaps have been richer had there been more opportunity for interaction between participants. Even without convening groups of participants, I could have brought more content from previous respondents’ interviews into future interviews. Although I did this to some extent, I tended to ask
questions from my existing interview guide which underwent only a few modifications, largely between groups, through the course of the project. I did believe there was an analytic benefit to consistency between individual interviews in that it enabled me to have a larger pool of data within groups, which would allow me greater comparisons between groups. For this project, between group comparisons seemed to be a productive way of thinking about the data, as part of the context of this project was the way in which the debates about EBM had been framed within specific disciplines (medicine, psychiatry, and bioethics).

A third potential limitation concerns the extent to which I was immersed in the literature about EBM prior to conducting the interviews. Within some qualitative approaches (e.g., grounded theory), extensive knowledge of the existing literature is discouraged in part because it positions the researcher within a particular viewpoint rather than facilitating analysis from a relatively naïve stance. This was not a grounded theory project, and within case study practice there are varying viewpoints about the extent to which one should master the existing literature. I do not think I could have undertaken either the conceptual analysis that constituted the first part of this project, nor conducted sufficiently sophisticated interviews without a command of the literature on EBM. Many of the arguments are too complex and intertwined with many other debates to have been able to tease them apart during hour-long interviews.
2.2 Interpretive considerations

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, having already undertaken some academic work examining the ethics of EBM and sympathetic to arguments expressing grave concern about the epistemological underpinnings of EBM. When I began the interview process, I was sympathetic to many of the critical views of EBM. I was aware of this and I worried that it would influence my attitude during the interviews. Nevertheless, I did try to adopt an interviewer’s stance of being open and interested in all viewpoints and exploring them to their fullest extent. A few participants (including those who are proponents of EBM) commented that I ‘didn’t give anything away’ about what I thought myself.

Because I interviewed most group one participants first, many of whom were EBM proponents, my own beliefs about EBM were challenged at an early stage of the project. Attempting to adopt an interviewer’s open-minded stance required me to evaluate the ‘pro-EBM’ arguments more neutrally and reflect more deeply on their meaning. In addition, as I interviewed group two and three participants, I saw how nuanced their critical views were. I recognized that 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. While I have retained the use of these terms at various points in the thesis, I believe the analysis shows that all three study groups share some common concerns about EBM and have also identified its areas of strength.
A significant observation about national context emerged during the course of conducting the interviews. It was evident that the way EBM had been implemented varied greatly in different countries, determined largely by the ways in which their own healthcare systems operated. Participants’ views were influenced to a great extent by how EBM was operating in their own countries given the demands of their own systems and the practitioners’ and patients’ needs within those systems. These differences are so crucial that readers might consider whether my analysis should be or could be differentiated by country. For example, what differences might it make to the conclusions of this thesis to focus only on the UK or to include countries with very different health care systems?

Finally, I should note that the conceptual analysis done in chapters two and three was not guided by a specific theoretical framework but was underscored by the basic approach of Western analytic philosophy which places importance upon defining terms and clarifying concepts. The analysis I have undertaken is limited and each of the concepts I have tried to discuss -- psychiatry, EBM, and ethics of psychiatry -- could be given much more extensive consideration. My more circumscribed treatment was in the service of arguing for a particular vision of the ethical commitments implied by EBM, rather than to provide a detailed philosophical analysis of these terms.

3. Future directions

Given the widespread uptake and impact of EBM among the health disciplines there is an urgent need for engagement between EBM developers, who continue to contribute to its evolution, and EBM critics who have argued in detail the various ways that EBM can fail
to live up to its promise. There are a variety of directions this project could take given that refinements of EBM and evidence-based psychiatry require the efforts of different parties and groups.

There are at least two significant directions forward for the ethics of EBM and evidence-based psychiatry. A challenging area for philosophers would be to examine what, if any, role ethical values play in the justification of knowledge claims. A major thread in the debate about EBM, and in its public and professional impression, is the extent to which evidence can somehow determine moral judgment or even does away with the need for moral judgment – a welcome development for many clinicians vexed by ethically contentious clinical situations where values can be diverse. One of the most important implications of internalist critiques demonstrating the values internal to EBM, to evidence-based psychiatry, to psychiatry and indeed to evidence itself, is that EBM can no longer be viewed as a neutral mediator between competing values but must be seen as contributing and reflecting certain values. This development encourages EBM users to be aware of values at every level, including at the level of the basic information we provide to patients. A second promising area for work in ethics and EBM/evidence-based psychiatry is to investigate qualitatively the interface of evidence and values in clinical practice. The theoretical portrayal of values in evidence-based practice is essentially of patients’ values as a gatekeeper as to which interventions will be undertaken and which will be avoided. This project has identified the roles of social contextual values, practitioners’ values, values of healthcare professions, and of the healthcare system in evidence-based practice. How does a practitioner integrate these values with the
principles of evidence-base practice? Does the particular nature of mental disorders and what is known about them present specific ethical challenges in attempting to apply the principles of EBM? These questions would ideally be addressed by prolonged field observations of practice circumstances and interviews with practitioners and patients.

Another potential direction for future development is the reconstruction of EBM itself. Many participants pointed out that in its attempt to be inclusive of patients’ values, EBM had become an unwieldy and ill-defined concept. Rather, it was the original focus on critical appraisal that was clear, innovative, and an improvement to ethical practice. Could EBM developers take on this criticism and move EBM forward by taking it back to basics? Group two participants made mention of the extensive moral framework which, while contested, already frames psychiatry. Could evidence-based psychiatry actually play a stronger role as a handmaid to ethical practice? Even without the participation of EBM developers, opinion leaders in psychiatry could take up this challenge by redefining EBM to fit the needs of psychiatry. Whether this is possible in a professional context that discourages any distinctions between mental health and the rest of medicine is uncertain (Quirion 2009).

Finally, the question that I find most engaging is that one I am most often faced with when I discuss my work with fellow psychiatrists: ‘What is the alternative to EBM?’ It is this question that I plan to investigate in my future research. This question has both ethical and epistemological dimensions. First, as I have argued, and has been pointed out by participants in this project, EBM cannot serve as an ethical basis for psychiatry,
given its own ethical commitments and in light of the contested state of knowledge about what mental disorders are. Psychiatrists are already leaders within the medical profession in developing a framework for ethical practice. Such a framework must be sensitive to the particular needs of psychiatric patients and psychiatrists’ work but also has the potential to move the rest of medicine, and EBM, towards a more robust understanding of the many values that determine, inform, and limit clinical practice, education, and policy. Second, EBM cannot serve as an epistemological basis for psychiatry, even for psychiatric treatments, as its methods are simply too limited to capture all relevant knowledge about mental disorders, their presentations, and their treatment. A more comprehensive description of psychiatry’s epistemology must reflect the various ways of knowing used by mental health practitioners to understand their patients’ experiences. The development of such a framework holds the promise of advancing psychiatry in a welcome direction. Weary of the relentless bureaucratization of the healthcare encounter, practitioners and patients alike could benefit from a deeper understanding of how one human, by virtue of detailed, personal engagement, comes to help in the healing of another.
February 5, 2008

Dear

RE: a research project entitled, ‘The ethics of evidence-based psychiatry: a conceptual and qualitative study.’ (This project was funded by the Canadian Institutes of Health Research through a fellowship award)

I am a doctoral student at the University of Toronto. I am writing to ask for your help in doing my doctoral research project. Please see the end of this letter for my contact information, and the contact information for my supervisor, Dr Ross Upshur.

1. Why am I doing this project?
I am conducting this study in order to better understand the ethical values, principles, and theories that underlie evidence-based psychiatry (EBP). This project represents the second phase of my doctoral research. The first stage consisted of a conceptual analysis of the ethics of evidence-based medicine (EBM) and EBP and made up the first three chapters of my doctoral thesis. This next phase of the project is empirical and includes individual interviews with the participants mentioned below.
Since its original formulation in the early 1990s, EBM has become highly influential in clinical practice, medical education, research, and health policy. At the same time, there has been considerable debate about EBM. This debate has focused on the scientific quality of much research data, the professional power of those who control what counts as evidence, and the question of whether EBM really does lead to improved knowledge about clinical interventions. There has been less discussion – either in authoritative EBM texts like the *Users Guide to the Medical Literature*, or the academic literature - about the ethical content of EBM.

EBM has received particularly enthusiastic support from psychiatry, to which it offers the promise of greater *ethical* acceptance through improved *scientific* credibility. The memory of harmful, or even abusive, psychiatric interventions continues to undermine psychiatry as a legitimate medical discipline. Advocates of evidence-based psychiatry (EBP) imply that psychiatry’s ethical acceptability can be bolstered by using evidence-based practice because EBP can protect patients from potentially useless, or even harmful interventions.

I am interested to know more about the ethics of EBP. In the academic literature, most work on the ethics of EBM is theoretical. Including people’s actual beliefs in an ethical analysis is a novel way of approaching this topic. In this project, I will seek out the views of three groups: developers of EBM, persons knowledgeable about evidence-based psychiatry, and authors who have written about the philosophy or ethics of EBM/EBP.

### 2. When and where will the study take place?
The interviews will take place in a quiet and private location of your choosing. If you live a great distance from me, we may arrange to do the interview by telephone.

### 3. Who is being asked to take part and what will they do?
The people I am inviting to participate are people with considerable expertise in developing and/or using EBM/EBP or who have expertise in ethics and/or philosophy and EBM/EBP. I am asking participants to take part in a one-time individual interview conducted by me. The interview will last approximately one hour. I believe that approximately 45 participants will be needed to help gather the information I am seeking.

During the interview I will ask you about your views about ethics and evidence-based psychiatry. I will ask you what ethical values are included in evidence-based psychiatry and what ethical impact, if any, you think evidence-based psychiatry has. At any time, you may ask to speak off the record and I will turn the recorder off. I will make notes, or not at that time, depending on your preference.

The interviews will be audiorecorded and transcribed verbatim onto a computer by an independent transcriptionist. If you agree, I might contact you after your individual interview.
interview to clarify anything I have not understood. You may refuse to be contacted for clarification if you wish.

After all the interviews are completed, I would like to email you a summary of the analysis I am developing from these interviews and ask you for any feedback you might have. I will give you a date by which I need to receive your feedback. You can email or telephone me with feedback, according to your preference. You may refuse to receive this summary if you wish, or you may simply disregard it when it arrives.

If you choose to participate, you can refuse to answer some questions but continue to participate by answering the others. You may stop participating at any time, even after signing the consent form or partway through your interview. After your interview, you can withdraw some or all of the interview data you have provided. If you decide to stop participating, I will destroy your recording and transcript and there will be no consequences to you.

If you like, I will email you a copy of your transcript for your records.

4. What are the risks and benefits of the study?
The study has very little risk. Participation is voluntary; participants are not required to answer any questions they do not want to, yet may continue to participate by answering the remaining questions.

It is unlikely that individual participants will experience any specific benefits as a result of participating in this study. Some may find that discussing the ethics of EBM is intellectually stimulating, fostering new ideas.

The findings of this research project could benefit the practice of psychiatry. Increasing awareness of the ethical aspects of EBP could improve the way that psychiatrists use evidence in clinical decision-making and could refine the EBM approach to psychiatric practice.

5. Is the study confidential?
The decision to participate, or not, is voluntary and will be kept confidential. All the information collected will be kept confidential. Once an interview has been transcribed, I will review the transcript and remove any identifying data. The names of participants or their institutions will not be used at any stage of the research, including the reporting of results. Instead, each participant will be identified by a number code (e.g. participant 1) to ensure privacy. No information will be released or printed that would disclose any personal identity, apart from information that is already in the public domain. For example, a participant might make reference to a book about evidence-based medicine written by Dr Joe Smith. In this case, I would not delete Dr Smith’s name from the transcript since the fact of his authorship is in the public domain. When using any
participant’s quotations in disseminating results, I will identify him/her by his/her group name (e.g. developer of EBM) and his/her code number (e.g participant 1).

I will store recordings and anonymized, hard copies of interview transcripts in a locked filing cabinet to which only I have access. I will store anonymized, electronic versions of interview transcripts on a computer. Access to the computer will be secured by a specific password known only to me. The original recordings of individual interviews will be destroyed upon completion of the research project. I will keep the transcripts for ten years following completion of the project to allow for research audit, in keeping with best practices in qualitative research. After ten years, I will destroy the transcripts.

The only time I would have to break confidentiality is if you reveal information about the abuse or neglect of a child (even if it was a long time ago) that was never reported to the appropriate Children’s Aid Society.

6. How will I find out about the study’s results?
Any published materials (e.g. journal articles) that result from this study can be sent to you if you wish. If you want any other information about the study’s progress or its findings, you can contact me directly. If your unit or department would be interested, I can arrange with you to give an oral presentation at your own institution about this study’s results.

7. How do I contact you if I am willing to participate in this study, and/or I have questions about the study?
Feel free to contact me by phone, mail or email, whichever is most convenient for you:

Dr. Mona Gupta
Department of Psychiatry, 9th Floor
Women’s College Hospital
76 Grenville Street
Toronto, ON M5S 1B2
Canada
telephone: 416.323.6037
email: mona.gupta@utoronto.ca

Your ideas are very important to the study. I hope you will agree to take part.

Yours sincerely,

Mona Gupta MD, FRCPC, MA
Doctoral Candidate, University of Toronto
OTHER CONTACT INFORMATION

**Supervisor:**
Dr Ross Upshur  
Director, Joint Centre for Bioethics  
88 College Street  
Toronto, ON M5S 1B2  
television: 416.978.4756  
email: ross.upshur@sunnybrook.ca

**Research Ethics Board Contact:**
This study has been reviewed and approved by the University of Toronto Health Sciences Research Ethics Board. If you have concerns or questions about your rights as a participant or about the way the study is conducted, you may contact:

Ms Jenny Peto  
Ethics Review Coordinator  
Health Sciences Research Ethics Board  
University of Toronto  
Simcoe Hall, Room 10A  
27 King's College Circle  
Toronto, ON, M5S 1A1  
television: 416-946-3273  
email: ethics.review@utoronto.ca
Appendix B

Consent Form

INFORMED CONSENT FORM

RE: a research project entitled, ‘The ethics of evidence-based psychiatry: a conceptual and qualitative study’

I have read the information provided in the information letter about this study being conducted by Dr Mona Gupta, a doctoral student at the University of Toronto, under the supervision of Dr Ross Upshur, also of the University of Toronto.

I have had the opportunity to ask questions about participating in this study, and to receive any additional details I wanted to know about the study.

I understand that I may withdraw from the study at any time and that if I withdraw, any data I have provided will also be withdrawn and destroyed. I understand that my participation is completely voluntary.

I will be given a copy of this consent form for my records.
1. I agree to participate in an individual interview.
   ____ Yes
   ____ No

2. I agree to allow the researcher to audiotape my interview.
   ____ Yes
   ____ No

3. If the researcher wishes to clarify anything I have said in the interview after I have participated, I agree to be contacted by her. I understand that I can participate in the interview without agreeing to this further contact. I also understand that I can agree to be contacted now, but change my mind at a later date.
   ____ Yes
   ____ No

4. I agree to receive a summary of the analysis of all of the interviews by email. If I have feedback on the researcher’s analysis, I will contact her by email or telephone. (She will send me her email address, telephone number, and date by which I must respond with the summary).
   ____ Yes
   ____ No
5. I would like to have the following items emailed to me:

___ a transcript of my interview

___ any publications that result from this project

In addition to your email address (if you requested any items under number 5), please provide any contact information that I may use:

e-mail: _________________________________

telephone: ______________________________

mail: _______________________________________________________________________

________________________________________________________________

__________________________________________

Signature of Participant                          Date

__________________________________________

Signature of Witness                             Date
Appendix C

Interview Guide

First Version, February 2008

The Ethics of Evidence-Based Psychiatry: a conceptual and qualitative study

ID:

Group:  1  2  3

Participant Number ______

Introduction:

➢ Thank person for participating

➢ Briefly describe study and process of the interview

➢ Review consent form

➢ Ask if there are any questions
Section I – General Questions about EBM/EBP

1. Thank you for agreeing to participate in this interview. Can we begin by you telling me a bit about what your professional background is, and how you became involved with EBM?

2. What does the phrase ‘evidence-based medicine’ mean to you?

3. Is evidence-based psychiatry different from evidence-based medicine? If so, how? If not, should it be?

4. How does one become a practitioner of EBM/EBP?

5. What are the qualities of an EBM/EBP practitioner?

Section II – Ethics and EBM/EBP

6. What does the term, ‘ethics’ mean to you?
   Probe: What does it mean to be an ethical practitioner/researcher/collage etc?

7. a) Does evidence-based practice promote or impede ethical practice?
   b) Is this any different for psychiatric practice?

8. Do you think EBM is value-neutral or value-laden? Please elaborate.

9. What has been the ethical impact of EBM/EBP, if any?
   Probes: practice, teaching, research, policy

10. Are there ethical challenges for EBM/EBP? If so, what are they?

11. Is there anything else you would like to say that I haven’t asked about?

➢ Thank you very much for your time.

➢ I will stop the recorder now.

➢ Before we end, could you suggest any other people with expertise in EBM, EBP or bioethics/philosophy whom I should interview?
Appendix D

Post-Interview Memo

Interview date:

Interview format:

Participant:

Date memo completed:

1. How did the interview go? What were the major points?

2. What would I do differently or the same?

3. To what did I have a reaction during the interview?

4. To what did the participant have a reaction during the interview?

5. Should I make any changes to the interview guide?

6. Describe the participant.

7. Other
Copyright Acknowledgements

The author wishes to acknowledge:

Wiley-Blackwell Publishers, and the Journal of Evaluation in Clinical Practice, the copyright holders of Tables 1, 2 and 3 and Figure 2.

The kind permission of Springer Science and Business Media and Springer/Kluwer Academic Publishers, regarding Theoretical Medicine and Bioethics, 2007, 28:103-120, Does Evidence-Based Medicine Apply to Psychiatry? Much of this article appears in the second half of chapter two.