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ADVANCING AN ETHICS OF EVIDENCE: A CRITICAL APPRAISAL OF EVIDENCE BASED MEDICINE AND FEMINIST THEORIES OF EVIDENCE

By

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ABSTRACT

ADVANCING AN ETHICS OF EVIDENCE:
A CRITICAL APPRAISAL OF EVIDENCE BASED MEDICINE
AND FEMINIST THEORIES OF EVIDENCE

By

Maya J. Goldenberg

Evidence based medicine (EBM), the coveted standard of best practice in most areas of healthcare, holds the promise of systematizing clinical practice and improving patient care by making healthcare more responsive to research evidence. EBM's commitment to highly controlled experimentation and methods of statistical analysis previously used only for population-based research represents not only methodological innovation, but also a novel regard of the reliability of various forms of medical knowledge. The epistemic narrowing that results from the rigid hierarchy of evidence motivates my proposed new direction for critical analysis of EBM: an ethical analysis of the exclusionary and implicit normativity with respect to scientific knowledge in the context of EBM. By being framed as "better science", normative questions of *meaning* are reduced to technical questions of *measure*.

This mode of critique diverges from the familiar tactic among EBM critics of illustrating the untenable positivist construction of evidence underlying EBM. Advancing an "ethics of evidence" broadens the current scope of the ethics of EBM by demonstrating the ethical significance of the epistemological challenge to EBM's objectivist account of evidence and science. I also further the epistemic challenge to EBM by drawing on the work of feminist philosopher of science Sharyn Clough to promote an alternative configuration of evidence that avoids the objectivism-to-relativism

slide common to postpositivist science studies. I argue that while the critics rightly challenge EBM's objectivist account of evidence, they are unable to offer a decisive alternative. Once the fallibility of empirical evidence and the underdetermination of theory are properly recognized, the critics cannot offer guidance for adjudicating between the competing subjective and interpretive filters that inescapably enter into clinical decisionmaking. Clough's critical reading of postpositivist science studies offers an intriguing explanation for this difficulty in her indictment of representationalism, which, she claims, necessarily leads critical epistemologies of science to relativism. I recast the EBM critiques in light of Clough's Davidsonian analysis, and while I reject Clough's prescribed abandonment of epistemic pursuits in favor of critical empirical science, I support her effort to reinvigorate the normativity of evidence found in objectivist epistemology *without* the objectivism while avoiding the relativism of evidence thought to accompany contextualist theories of knowledge.

DEDICATION

This dissertation is dedicated with love to my grandmother.

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KEY TO ABBREVIATIONS

EBE ..... Evidence Based (Bio)Ethics

EBM ..... Evidence Based Medicine

EBWH ..... Evidence Based Women's Health

IRB .....Institutional Review Board

RCT ..... Randomized Controlled Trial

INTRODUCTION

Evidence based medicine (EBM) is a systematic set of practices that aims to allow physicians to make therapeutic recommendations that correspond to the best available evidence of effectiveness. In its short duration, it has come to be widely regarded as offering a significant and promising means for improving patient care and harnessing healthcare spending. While both epistemological and ethical concerns have been raised and examined within the comparatively small but growing critical literature on EBM, they have been treated separately and the connections between the ethical and epistemological issues have not been investigated. Whether cause or effect, these segregated critiques reveal limited insight into EBM's methodological, philosophical, and sociological complexity. The ethics of EBM currently concentrates on how EBM affects patient autonomy and care, but leaves the mounting critiques of the epistemology underlying evidence based claims (especially concerning EBM's configuration of "evidence") to thinkers outside of the ethical forum.[1] In this investigation, I argue that EBM's construction of evidence needs to be placed at the heart of the ethical issues surrounding patient care. For this reason, the *ethics of evidence* in EBM are examined here.

Initiated only a decade and a half ago as a new paradigm in medical education and practice, "evidence-based medicine" has come to be widely regarded as synonymous with "best practices" in medicine. EBM purports to eschew unsystematic and "intuitive" methods of individual clinical experience in favour of a scientifically rigorous and

[1] This will be discussed in chapter two.

methodical approach to clinical decisionmaking that is grounded in the best and most current research evidence. EBM centres around five linked ideas:

1. clinical decisions should be based on the best available scientific evidence;

2. the clinical problem, and not the habits of clinicians or routine clinical protocols, should determine the type of evidence to be sought;

3. identifying the best evidence means using epidemiological[2] and biostatistical ways of thinking;

4. conclusions derived from identifying and critically appraising evidence are useful only if put into action in managing patients or making health care decisions;

5. clinical performance should be constantly evaluated.[3]

EBM has strived to widely implement these goals into clinical practice by enlisting numerous techniques for the management, evaluation, and application of data for use in patient care. Its hallmark is the hierarchy of evidence that consistently places the evidence derived from randomized controlled clinical trials on top.[4] The synthesis of large quantities of clinical trial data into manageable "clinical summaries" and "meta-analyses"[5] by the hardworking volunteers at the Cochrane Collaboration[6] and other institutional affiliates, and the proliferation of this information to clinicians, educators, actuaries, and medical funding bodies via EBM journals and electronic databases are supposed to revolutionize medical practice and offer objective and politically transparent criteria for funding decisions at the policy level. The political and professional capital of

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[2] Epidemiology was once reserved for public health research, but the EBM founders adapted its techniques for use in individual patient care ("clinical epidemiology").

[3] Davidoff *et al* (1995), "Evidence based medicine." BMJ 310(6987), p. 1085.

[4] Sackett *et al* (1996), "Evidence-based medicine: what it is and what it isn't." BMJ 312(7023), p. 72.

[5] A meta-analysis is a systematic statistical analysis of research data from multiple studies that tries to draw conclusions based on pooled data. Its purpose is to elucidate the answer to a single question

[6] Based at Oxford, the collaboration is an international consortium of workers who construct an ever-enlarging evidence database by contributing their own randomized trials, discoveries of unpublished trials, and meta-analyses. The collected information extends through all branches of medicine and is the main source of evidence for evidence based practice.

EBM cannot be overstated, as it is thought to increase professional responsibility and accountability, improve patient care, and make managed care and medical research more cost effective by ensuring that only the most promising technologies are funded.

The critical literature interrogating EBM focuses primarily on the epistemology of EBM, specifically the numerous concerns surrounding the "evidence" of evidence-based medicine.[7] This direction of critique seems fitting, as the proposed practice of EBM calls for the evaluation and use of the best available evidence for clinical use in patient care. EBM offers a definitive interpretation of what counts as "best evidence" and encourages its cultivation and application by a hierarchy of methods, clinical guidelines, and authoritative evidentiary sources. Critics worry that because the data is derived almost exclusively from randomized trials and meta-analyses, they do not include many types of treatments or patients seen in clinical practice. The trial results are also problematic because they show comparative efficacy of treatment for an "average" randomized patient, and not for pertinent subgroups formed by such cogent clinical features as severity of symptoms, illness, and co-morbidity. Thus EBM brings forward evidentiary quandaries that deserve critical attention.

The more philosophically-inclined critics charge EBM's configuration of evidence with being reductionist,[8] positivist,[9] and foundationalist,[10] and share the general conclusion that EBM's "evidence base" is simply inadequate for properly capturing the

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[7] See, for example, the frequently cited paper, Feinstein and Horwitz (1997), "Problems in the 'evidence' of 'evidence-based medicine'." Am J Med 103(6).

[8] Welsby (1999), "Reductionism in medicine: Some thoughts on medical education from the clinical front line." J Eval Clin Prac 5(2); De Simone (2006), "Reductionist inference-based medicine, i.e. EBM." J Eval Clin Prac 12(4).

[9] Goldenberg (2006), "On evidence and evidence-based medicine: Lessons from the philosophy of science." Soc Sci Med 62(11)

[10] Upshur (2002), "If not evidence, then what? Or does medicine really need a base?" J Eval Clin Prac 8(2).

complex nuances of medical decisionmaking in the clinical context.[11] The debate surrounding EBM has had the surprising effect of moving the epistemological question of what is evidence from the confines of academic journals of philosophy and epistemology to surface in the medical and healthcare trade journals. Configurations of evidence are significantly tied to understandings of the structure of knowledge and epistemic justification; in medicine, the EBM debate fosters self-reflection regarding the nature, goals, and scope of health care.

Intertwined within these epistemological concerns, there is a distinctive and inescapable moral dimension to EBM. EBM is predicated on the moral imperative widely held to drive health care: the duty to achieve health and alleviate human suffering.[12] Supporters view EBM as providing these means and so it is vigorously endorsed as an approach to medicine that *ought* to be practiced.[13] Critics are equally concerned with the ethical implications of EBM. They challenge the alleged moral mandate to practice EBM on the grounds that if the biases and judgments ignored by EBM may insidiously influence the evidence upon which clinical decisions are made, the practice of EBM could lead to worse rather than better patient care.[14] Furthermore, EBM may have unwanted effects on access to health services and may deepen the influence of private interests, at the expense of patient interests, in determining what services are

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[11] Miles *et al* (1997), "Evidence-based medicine: Why all the fuss? This is why." J Eval Clin Prac 3(2); Miles *et al* (1999), "Advancing the evidence-based healthcare debate." J Eval Clin Prac 5(2); Miles *et al* (2002), "Critical advances in the evaluation and development of clinical care." J Eval Clin Prac 8(2); Kerridge *et al* (1998), "Ethics and evidence based medicine." BMJ 316(7138).

[12] Ashcroft (2004), "Current epistemological problems in evidence based medicine." J Med Ethics 30(2).

[13] Ashcroft (2004), "Current epistemological problems in evidence based medicine." J Med Ethics 30(2); Kerridge *et al* (1998), "Ethics and evidence based medicine." BMJ 316(7138).

[14] Christiansen and Lou (2001), "Ethical considerations related to evidence-based practice." Am J Occup Ther 55(3).

made available.[15]

Despite there being distinctive ethical features of EBM, however, ethics is typically treated as an afterthought in the growing EBM discourse. The literature on the ethics of EBM is sparse in comparison to the volume of scholarship into the methodological and epistemological issues surrounding EBM. The ethics literature is also narrow in its limited focus on the impact that EBM has on patient care. An examination into the workings of EBM (in chapter one) will demonstrate that neither the epistemic nor the ethical analyses of EBM can go on responsibly without each other. We will see that there are some signs of acknowledgment of the relation of ethics to epistemology in more politicized commentaries on EBM's knowledge producing activities (such as the EBM critiques coming from feminist epistemology and political economy perspectives), however the ethical relevance of epistemology has not yet been advanced.

While bioethics holds patient advocacy and the protection of patient's rights and interests to be a fundamental preoccupation, this project aims to broaden the scope of the ethics of EBM to include the epistemological debates. Given the methodological innovation that EBM will be shown to present to medicine (see chapter one), as well as the power/knowledge relation mentioned above, the ethical analysis of EBM must address the epistemic issues surrounding this significant knowledge technology. In a study examining the relationship between EBM and patient autonomy, Molewijk et al.[16] illustrate how the bridging of ethics and epistemology is called for in the context of EBM.

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[15] Gupta (2003), "A critical appraisal of evidence-based medicine: Some ethical considerations." J Eval Clin Prac 9(2), p. 119.

[16] Molewijk *et al* (2003), "Implicit normativity in evidence-based medicine: a plea for integrated empirical ethics research." Health Care Anal 11(1).

The study investigated how patients with abdominal aortic aneurysm, a life-threatening disease, responded to and incorporated evidence-based facts into their treatment decisionmaking. Initially the researchers planned to begin the investigation only once they had developed an evidence-based decision-support brochure detailing the relevant facts and treatment options for patients, in consultation with their surgeons, to consider for the decision-making process. The development of the brochure was thought to be straightforward. However, during the process of translating the decision model into a brochure, they realized that there are many different ways to produce and present evidence-based facts and that choosing between them was a subjective process that led to different moral consequences.[17] These brochures came to be recognized by the team as anything but an objective presentation of statistical data, as any representation of clinical information requires various selections and choices concerning, for example, what information is clinically relevant, what are the appropriate inputs for the decision making model, and how the information can be made understandable to the patient.[18] The authors concluded that there is "implicit normativity" in EBM, as the study highlighted how both the production and presentation of scientific information in an evidence-based decision-support contains implicit presuppositions and values which prestructure the moral environment of the process of decision-making. As a consequence, "the evidence-based decision support did not only support the clinical decisionmaking process, it also transformed it in a morally significant way."[19] This phenomenon was thought to

[17] Molewijk *et al* (2003), "Implicit normativity in evidence-based medicine: a plea for integrated empirical ethics research." Health Care Anal 11(1), p. 73.
[18] Molewijk *et al* (2003), "Implicit normativity in evidence-based medicine: a plea for integrated empirical ethics research." Health Care Anal 11(1), p. 74.
[19] Molewijk *et al* (2003), "Implicit normativity in evidence-based medicine: a plea for integrated empirical ethics research." Health Care Anal 11(1), p. 87.

undermine the common assumption within much of the literature on patient autonomy that information disclosure is a conditional requirement before patient autonomy even begins. Instead, patient autonomy is already influenced during the production and presentation of information. The authors saw these results as establishing the need for an increased responsibility by those who produce and present evidence-based facts.[20] I see it as also prompting more bioethical focus and analysis into the knowledge-producing activities of biomedicine.

In this dissertation, EBM's allegiance to an objectivist account of evidence and the seeming modesty of its aim of gathering and applying the best evidence to clinical practice will be demonstrated to obscure the normative dimensions of the evidence-based approach by framing EBM as merely a technical fix to the evidentiary deficits in clinical practice and the resulting limits to the effectiveness of patient care. The separation of the technical and the normative in fact relies heavily on its construal of evidence, which ignores the social features (i.e. value judgments and political interests) present in the production and presentation of empirical evidence.

The bridging of ethics and epistemology is supported by some of the operating assumptions of the medical humanities about the nature of medicine and its sociopolitical importance as well as feminist scholarship in the epistemology of science. Medical humanities research typically regards the activity of medicine as a productive cultural force that is not morally neutral, as medicine reveals new meanings and enlarges possibilities with respect to the human condition.[21] The presumed cultural importance of

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[20] Molewijk *et al* (2003), "Implicit normativity in evidence-based medicine: a plea for integrated empirical ethics research." Health Care Anal 11(1), p. 69.

[21] Hill (1994), "The cultural and philosophical foundations of normative medical ethics." Soc Sci Med 39(9). By "human condition", I mean the philosophically complex phenomenon that encompasses the

medicine[22] is technologically driven, as new advances constantly broaden the scope of medicine's role in society and challenges social conventions, including understandings of life, death, human nature, and personal identity.[23] Ethical analysis that focuses strictly on the ends that medicine and medical technology serve is therefore severely limited. The discipline of bioethics serves to help the medical establishment understand its place in a culture and to help that culture measure the meaning of the medical practices going on within it.[24] It is, of course, technological developments that give direction to the biomedical sciences, and so, bioethics must provide thoughtful and searching analyses of the dynamics of significant technologies like evidence-based decisionmaking.

In feminist scholarship, significant attention has been paid to science because of the recognized sociopolitical stakes of knowledge and knowledge production. The exclusions and harms that have been suffered by women in the name of science have made a feminist case for scientific revisioning. As I will argue, feminist epistemologists of science have demonstrated that the experience and knowledge that we bring to bear on scientific theorizing will be influenced by the social relations of gender, race, and class that characterize our society. Stricter methodological controls cannot "filter out" these factors and relationships.[25] The call for more accurate accounts of the connections between knowledge and sociopolitical relations (including our moral codes) broadens the

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existential experience of being human and living human lives. Put simplistically, there are a series of biologically determined events which are common to most human lives, and the ongoing way in which humans react to and/or cope with these events is the human condition.

[22] Medical sociologist George Weisz has made the claim that understanding the scope of medicine's role is fundamental for understanding our culture. Weisz, ed. (1990), Social science perspectives on medical ethics.

[23] Hill (1994), "The cultural and philosophical foundations of normative medical ethics." Soc Sci Med 39(9).

[24] Engelhardt (1986), The foundations of bioethics.

[25] Harding (1986), The science question in feminism; Longino (1990), Science as social knowledge: Values and objectivity in scientific inquiry; Nelson (1993), "Epistemological communities." Feminist epistemologies; Tuana, ed. (1989), Feminism and science; Longino (1989), "Can there be a feminist science?" Feminism and science; Nelson (1990), Who knows: From Quine to feminist empiricism.

factors relevant to our knowledge and undertakings, such as scientific inquiry, to encompass social relations, politics, values, and other factors long regarded as a threat to objectivity, if not the very antithesis to evidence.[26] Thus feminist science studies provide a valuable framework for analyzing the evidentiary quandaries surrounding EBM as well as important conceptual tools for investigating the ethics/epistemology relation in the context of EBM.

Overview of the Project

The overview of EBM in chapter one casts EBM as more than the simple application of research findings to clinical care and improved health outcomes, but rather an umbrella term that harnessed a specific set of pedagogical objectives (some rather radical) under a name that makes it difficult to argue against; for unlike "outcome measurement" or the use of computers by the bedside, who could possibly be against evidence?[27] Attention is also called to the hubris surrounding the EBM movement, which is later demonstrated to allow EBM to be much more than a medical decision making tool, but also a potential political device capable of promoting certain interests in medicine. By this account, knowledge production is not a value-neutral endeavour and "evidence" is not simple concept.

This more nuanced understanding of EBM also reveals the shortcomings in what have now become the standard ethical and epistemological debates surrounding EBM. In chapter two, a review of the published material on the ethical issues surrounding EBM reveals a sparse literature that is narrow in scope. The current parameters of the ethics of EBM are limited to consequentialist analysis of the ends achieved by EBM with respect

[26] Nelson (1993), "A question of evidence." Hypatia 8(2), p. 180.
[27] Carr-Hill (1995), "Welcome? To the brave new world of evidence based medicine." Soc Sci Med 41(11); Lambert (2006), "Accounting for EBM: Notions of evidence in medicine." Soc Sci Med 62(11).

to patient care, namely whether EBM improves health outcomes and enhances patient autonomy within the decisionmaking context. The previous chapter's analysis of EBM exposes further moral dimensions than the current "ethics of EBM" permits, *including* the moral significance of the epistemology of EBM. The subsequent chapters investigate the epistemological challenges to both EBM and its critics, while also incorporating methodological and sociopolitical considerations into this layered critique. We only return to the ethics of EBM in the last chapter for consideration of the moral dimensions of these challenges.

As the name "evidence based medicine" should suggest, the complex picture of health and well-being, medical authority, economics, political interests, and sensationalism that constitutes the EBM discourse all hinge on "the evidence". The EBM critics have therefore focused considerable attention on the construction of evidence underlying the evidence based approach. I will demonstrate in chapter three that in what is largely a "postpositivist" critique of objectivist accounts of science, the critics have significantly destabilized EBM's epistemic base. This line of criticism fails, however, in numerous respects:

1. It fails to distinguish EBM from its biomedical predecessor, thus undermining the critical conclusion that we must abandon EBM in favour of alternative approaches;

2. By missing the important methodological and epistemic novelty that EBM brings to medicine, important areas of critique are neglected;

3. The postpositivist epistemological critique does not, and I will show, *cannot* offer an alternative account of evidence.

In chapter four, I consider the objection that critical science studies effectively replaces the objectivist and positivist view of evidence underlying EBM with a relativist

account of evidence in the effort to encourage epistemic holism. This charge of relativism has been frequently mounted against postpositivist epistemologies of science; feminist epistemologies have been particularly criticized for introducing subjective content and politics into science. Yet, against the charges of relativism, feminist epistemologists insist that such inclusiveness in constructs of epistemology, science, and even evidence does not undermine knowledge pursuing activities. Lynn Hankinson Nelson, for instance, argues that the inclusiveness of evidence is inescapable, and therefore acknowledging it does nothing to further the case for scepticism or relativism. The alternative of a more supposedly objective or bounded account of evidence is no more than an article of faith.[28] She and others insist that feminist philosophy's emancipatory program demands normative content in its projects, and its commitment to rethinking concepts clears space for investigation rather than stifles it. I, however, follow both Sharyn Clough's insistence that feminist science studies does not overcome the problem of relativism,[29] as well as her attempts to resolve this problem using Donald Davidson's philosophy of language in my analysis of evidence.[30]

The problem of relativism is addressed in chapters four, five, and six of this investigation into the ethics of EBM because relativism and the inescapable uncertainty of our knowledge claims regarding the veracity of our beliefs is not only an epistemic concern in the context of health care, but also a deeply moral problem. Medical uncertainty and incorrect knowledge may inflict suffering, illness, disability, or death on

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[28] Nelson (1993), "A question of evidence." Hypatia 8(2).
[29] Clough (2003), Beyond epistemology: A pragmatist approach to feminist science studies; Clough (2003), "A hasty retreat from evidence: The recalcitrance of relativism in feminist epistemology." Siblings under the skin: Feminism, social justice and analytic philosophy.
[30] For example, Davidson (2003), "A coherence theory of truth." Siblings under the skin: Feminism, social justice and analytic philosophy; Davidson (1974), "On the very idea of a conceptual scheme." Proceedings and addresses of the American Philosophical Association.

those for whom health care professionals have a duty to care. While EBM's quest to manage and minimize medical uncertainty may be misguided due to its shoddy epistemological basis (see chapter three), its *motivation* is certainly rational, admirable and ethically desirable. Both proponents and dissenters noticeably agree that this pursuit is worthwhile; the disagreement lies in its execution. Furthermore, the relativism encountered by the critics' postpositivist frameworks may discourage wary practitioners from seeking alternatives to EBM, as clinicians find themselves, in the end, needing to act and needing to do so with justification.

The ethics of evidence—the incorporation of the methodological (chapter one), epistemological (chapters three to six), and sociopolitical concerns (chapter three) surrounding EBM into an ethical analysis that appreciates EBM's novelty and complexity—is articulated in the last chapter of this dissertation. It does not focus solely on the *impact* of EBM on health outcomes and patient care, but also considers the ethics of knowledge and knowledge production in biomedicine.

Thus EBM, the authoritative standard of best practice in medicine over the past fifteen years, raises significant epistemological and ethical issues. The philosophical literature examining EBM has focused almost exclusively on the epistemology. Despite EBM being the prevailing standard in biomedicine, and therefore indispensable to bioethics, the ethics of EBM receives little attention. The work that *is* done focuses on how EBM's application affects patient choice, autonomy, and care, but does not broach on the epistemological challenge to the objectivist account of evidence operating as the coveted *base* of medicine. I aim to show that the construction of evidence is at the heart

of the ethical issues surrounding patient care, and in this project, the *ethics of evidence* in the context of EBM are investigated.

CHAPTER ONE

Nothing New About Evidence Based Medicine? EBM's Methodological Innovation

Evidence based medicine is most popularly defined as the "conscientious and judicious use of current best evidence in the healthcare of individuals and populations."[31] EBM's influential doctrine first appeared in the *Journal of the American Medical Association* as a brief polemic authored by the Evidence Based Medicine Working Group:

> A new paradigm for medical practice is emerging. Evidence based medicine de-emphasizes intuition, unsystematic clinical experience, and pathophysiologic rationale as sufficient grounds for clinical decision-making and stresses the examination of evidence from clinical research. EBM requires new skills of the physician, including efficient literature searching and the application of the formal rules of evidence.[32]

EBM rose quickly into prominence in medicine, with virtually every area of healthcare now striving to become evidence based. PubMed currently has over 20,000 citations for "evidence-based". This is a considerable feat for a discipline that is described in the EBM manifesto as largely reliant on conventions and habits of thought and practice.

Yet amidst the hubris, there is a certain obviousness to EBM that has prompted critics to charge EBM with offering "nothing new".[33]

> "Evidence based medicine," one chemist said to me, "What other kind of medicine could there possibly be?" and a consultant physician said gruffly: "We have always practiced evidence based medicine".[34]

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[31] Sackett *et al* (1996), "Evidence-based medicine: what it is and what it isn't." BMJ 312(7023).
[32] Evidence Based Medicine Working Group (1992), "Evidence-based medicine." JAMA 268(17), p. 2417.
[33] See, for example, Benitez-Bribiesca (1999), "Evidence-based medicine: A new paradigm?" Arch Med Research 30(2).
[34] Hope (1995), "Evidence based medicine and ethics." J Med Ethics 21(5), p. 259; Hope is a supporter of EBM who maintains that one sign of a movement being important is when its detractors indignantly maintain that it is nothing new.

In this chapter, I offer a detailed examination of EBM, starting with a historical account of its origins in clinical epidemiology, followed by the methodological innovations that the evidence based approach brings to medicine, and its ties to the outcome movement and policy initiatives. The purpose of this exercise is to distinguish EBM from its biomedical predecessor and to determine the innovation that EBM brings to medicine. This nuanced understanding of EBM will then serve to highlight some of the deficiencies in the current ethical (chapter 2) and epistemological (chapter 3) critiques of EBM, as both will be shown to fail to capture the intricate workings of this important decisionmaking technology and therefore fail to properly account for many of the concerns surrounding EBM.

I propose that EBM's original contribution to medicine, or what separates EBM from other approaches, is the priority it gives to certain forms of evidence, specifically the randomized controlled trial. EBM offers a shift in the sort of evidence that is most highly valued for diagnosis, therapy, and prognosis questions, as heavy emphasis is placed on experimental controls and quantified measures, thus diminishing the previous status of clinical experience and observational studies significantly.[35] This commitment represents not only methodological change, but also a novel regard of the reliability of various forms of medical knowledge. While not a paradigm change, EBM denotes an important shift in biomedical thinking and practice that is a significant alternative to its biomedical predecessor. EBM offers a new answer to medicine's fundamental normative question: how ought we to practice medicine?

[35] Sehon and Stanley (2003), "A philosophical analysis of the evidence-based medicine debate." BMC Health Serv Res 3:14, p. 4.

The epistemic narrowing that results from the rigid hierarchical regard of evidence is a crucial consideration for the new direction in EBM critical analysis being proposed in this research project, namely an ethical analysis of the exclusionary and implicit normativity with respect to scientific knowledge in the context of EBM. The evidence based approach and the Cochrane databases that provide that evidence will be argued to demonstrate intolerance towards alternative forms of knowledge. While the EBM texts claim to appreciate qualitative research methods, for example, the databases decree that acceptable research must be based on randomized trial design. Thus all other health science research, which has been estimated to constitute as much as 98% of the literature, is deemed scientifically imperfect.[36] It becomes questionable whether EBM can promote the multiple ways of knowing deemed important within most health disciplines. With this streamlining of the decisionmaking process, EBM may also be deployed to serve a governmental function, where ready-made and convenient "goals-and-targets" can be used to justify cuts to healthcare funding.[37]

The Origins of EBM

The origins of the evidence-based medicine movement are traceable back to a series of lectures given by epidemiologist Archie Cochrane in the early 1970s, where he argued that many popularly used medical practices were of dubious or unknown safety and efficacy. In these lectures, which were later compiled in *Effectiveness and Efficiency: Random Reflections on Health Services*,[38] he detailed the harms that ensued

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[36] Holmes *et al* (2006), "Deconstructing the evidence-based discourse in health sciences: Truth, power and fascism." Int J Evid Based Healthc 4(3).

[37] Holmes *et al* (2006), "Deconstructing the evidence-based discourse in health sciences: Truth, power and facism." Int J Evid Based Healthc 4(3); Traynor (2002), "The oil crisis, risk, and evidence-based practice." Nurs Inq 9(2).

[38] Cochrane (1972), Effectiveness and efficiency. Random reflections on the health service.

from the prevalent use of unestablished medical interventions to both individuals and populations, by way of iatrogenic injury, waste of resources, and failure to take up more effective treatments. He argued that treatments should be evaluated systematically using unbiased methods of evaluation (such as the randomized controlled trial), and that individual practitioners and the medical profession as a whole should continuously review and appraise their own state of knowledge. Aschcroft has noted the strong ethical imperative behind Cochrane's recommendations, as they were rooted in concern to do no harm, to do one's best for one's patients, and to do so justly by eliminating waste.[39]

Cochrane's programmatic outline was revitalized in 1990 by a group calling themselves the "Evidence Based Medicine Working Group", comprised of professors of clinical epidemiology, medical informatics, and biostatistics at McMaster University in Hamilton, Ontario, who introduced the phrase "Evidence Based Medicine" in a ubiquitous 1992 manifesto as a "new paradigm" in medical education and practice.[40] In the document, the ethical promise was made that the virtuous clinician "whose practice is based on an understanding of the underlying evidence will provide superior patient care."[41] While the ethical imperative to improve patient care remained central, the promise to decrease medical uncertainty by systematic evaluation of the efficacy of current practices was particularly appealing to managed care organizations and health policy analysts facing a crisis situation with respect to escalating healthcare costs and spending. Added to the gamut of methodologies for data collection and analysis first recommended by Cochrane was the use of emerging information technologies to

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[39] Ashcroft (2004), "Current epistemological problems in evidence based medicine." J Med Ethics 30(2), p. 131.
[40] Evidence Based Medicine Working Group (1992), "Evidence-based medicine." JAMA 268(17).
[41] Evidence Based Medicine Working Group (1992), "Evidence-based medicine." JAMA 268(17), p. 2421.

synthesize the large quantities of published studies and to proliferate the information and increase accessibility through electronic databases. The combined picture of EBM as ethically driven to improve patient care, fiscally responsible, and technologically up-to-date likely drove the rapid integration of the movement into medicine, where fifteen years after the Evidence Based Medicine Working Group first formed, EBM is now common parlance within health care. As a burgeoning institution, academic centres[42] and journals[43] dedicated to EBM's advancement have been established with much fanfare,

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[42] Founded in 1993, **The Cochrane Collaboration**, whose motto is "The reliable source of evidence in health care", is an international not-for-profit organization that provides up-to-date information about the effects of health care. The Collaboration produces and proliferates systematic reviews of healthcare interventions through the Cochrane Database of Systematic Reviews. The Collaboration also maintains the Cochrane Library, which contains numerous regularly updated evidence-based healthcare databases and is described as "the definitive resource for evidence-based health care" (www.cochrane.org). Other academic centers committed to promoting evidence-based practices in healthcare include The Centre for Evidence-Based Medicine (UK); Oxford Centre for Evidence-Based Medicine; National Institute of Clinical Excellence (UK); American Family Physicians; Centre for Clinical Evidence Synthesis (USA); Centre for Health Evidence (Canada); Joanna Briggs Institute (Australia). While the strongest EBM bases are found in the UK and North America, EBM is still correctly described as an international movement. In China, for example, the EBM network includes The Chinese Cochrane Centre, with both Chinese University of Hong Kong and Si Chuan University branches; The Peking University EBM Centre; The Fudan Centre for Evidence Based Medicine; The Clinical Epidemiology Society of the Chinese Medical Association; China Epidemiology Network (ChinCLEN); and finally, in an interesting meeting of Western and Eastern traditions, the Evidence Based Chinese Medicine Centre for Clinical Research and Evaluation at the Beijing University School of Chinese Medicine. All of these Chinese institutions are part of a larger Asia Pacific EBM Network, whose member countries are Australia, China, India, Japan, New Zealand, Macau, Malaysia, Pakistan, Philippines, Taiwan, and Thailand. The proceedings of the Network's 6th annual meeting, held December 8-10, 2006 in Hong Kong, can be accessed at: Asia Pacific EBM Network (2006), "Asia Pacific EBM Network Conference 2006." http://www.sph.cuhk.edu.hk/hkcochrane/e-tapenet.htm

[43] EBM journals synthesize and comment on existing clinical evidence. Some of the significant titles include: ***ACP Journal Club***, a bimonthly journal and was the original evidence-based secondary publication featuring structured abstracts and commentaries supplied by experts of high quality studies that are relevant to the practice of Internal Medicine. The journal is available in print as part of Annals of Internal Medicine or as part of the Ovid Evidence-Based Medicine Reviews database; ***Evidence-Based Medicine*** is the BMJ Publishing group's bi-monthly journal, surveying a wide range of international journals in family practice, internal medicine, pediatrics, ob/gyn, psychiatry, and surgery. Practicing clinicians assess the clinical relevance of selected studies and the key details of these essential studies are presented in a succinct abstract with an expert commentary on its clinical application (http://ebm.bmjjournals.com); ***Bandolier*** is a monthly journal produced in Oxford for the NHS. Internet access is free (http://www.jr2.ox.ac.uk/bandolier/); ***Evidence-Based Practice*** is from the editors of the *Journal of Family Practice* . Every article starts with a clinical question chosen by practicing family physicians. The answers are explained by members of the Family Practice Inquiries Network (FPIN), a national consortium of academic and practicing family physicians, medical librarians, and others dedicated to translating research into practice. FPIN Clinical Inquiries appear monthly in the *Journal of Family Practice. Evidence-Based Practice* subscribers can access the FPIN database (www.ebponline.net);

and the "evidence-based" movement has stretched beyond the health sciences[44] to social work,[45] education,[46] and other social science disciplines. It is even generating attention as a promising new approach to bioethics ("evidence-based ethics").[47] The term "evidence-based everything" has been used to describe the enthusiasm for this movement.[48]

What's New about EBM?

Despite the fanfare, it is not immediately obvious that EBM offers something new to medical practice. In response to EBM's demand that medical decisions ought to be based on stringent empirical evidence, critics ask, hasn't modern medicine *always* been evidence-based? Quite surely, and almost by definition, biomedicine has always been grounded in the empirical sciences, which bases its claims on observational evidence. At

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POEMS (Patient Oriented Evidence that Matters) is a regular feature of the *Journal of Family Practice.* Editors review 80 primary care journals and identify studies with patient-oriented outcomes that have the greatest potential to change clinical practice. These articles are then critically appraised by expert family physicians, educators, and/or pharmacologists. POEMS is available by subscription at http://www.infopoems.com/ and is also available as a PDA product called InfoRetriever. Other EBM journal titles include: *Effectiveness Matters; Evidence-based Library and Information Practice; Advanced Studies in Medicine; Clinical Evidence;* Evidence-based Complementary and Alternative Medicine; Evidence-based Dentistry; Evidence-based Dental Practice; Evidence-based Healthcare; *Evidence-based Healthcare & Public Health;* Evidence-based Mental Health; Evidence-based Nursing; Evidence-based Obstetrics & Gynecology; Evidence-based Oncology.

[44] For example, Kovner *et al* (2000), "Evidence-based management (and commentaries)." Frontier Health Serv Manag Summer 2000; McGuire (2005), "Evidence-based population health: A critical realist framework." University of Toronto Comparative Program on Health and Society. Reilly *et al* (2004), Evidence based practice in speech pathology; Von Zweck (1999), "The promotion of evidence-based occupational therapy practice in Canada." Can J Occup Ther 66(5).

[45] For example, Cournoyer (2004), The evidence-based social work skills book; Howard *et al* (2003), "Teaching evidence-based practice: Toward a new paradigm for social work education." Research on social work practice 13(2); Torrey *et al* (2001), "Implementing evidence-based practices for persons with severe mental illnesses." Psychiatr Serv 52(1); Webb (2001), "Some considerations of the validity of evidence-based practices in social work." Brit J Social Work 31.

[46] For example, *Exceptional Children*, the official journal of Canada's Council for Exceptional Children, featured a special issue on "Criteria for Evidence-Based Practice in **Special Education"** (vol. 71, 8; Winter 2005). See also Davies (1999), "What is evidence-based education?" Brit J Edu Studies 47(2); Slavin (2002), "Evidence-Based Educational Policies: Transforming Educational Practice and Research." Educational Researcher 31(7).

[47] See, for example, Roberts (2000), "Evidence-based ethics and informed consent in mental illness research." Arch Gen Psych 57(6); evidence-based ethics is analysed in detail in chapter seven of this dissertation.

[48] Mykhalovskiy and Weir (2004), "The problem of evidence-based medicine: Directions for social medicine." Soc Sci Med 59(5).

the heart of empiricism is the widely held assumption that "only a thoroughly observational procedure can exclude fanciful speculation and empty metaphysics as well as the hope that an empiricist attitude is most liable to prevent stagnation and to further the progress of knowledge."[49] Empiricist epistemology, from Hume onward, is guided by the idea that observation provides a maximally certain foundation of empirical knowledge, a foundation that supplies the basic premises of all our reasoning, and without which there would not even be reliable knowledge claims. This foundational picture of factual or a posteriori knowledge relies on a theory of observational evidence playing a central role in observation obtaining objective empirical knowledge.

In its typical formulation, empiricism is predicated on the position that all empirical knowledge is founded upon a set of independently intelligible and credible observational claims. Observations are understood to both stimulate the formation and regulate the testing of theories. In the role as stimulus, observation of perplexing or surprising events prompts questions of why these things happen, and thereby leads to theoretical explanations. Recurring phenomena call for an understanding of the principles of organization and unification—the theories—to make sense of the observations. Observations serve to test hypotheses as the latter are corroborated by their ability to predict what will actually be observed.

Observation is central to scientific practice because of the supposition that it is the mechanism for acquiring knowledge about the world. Because observations are generated *from* the world of objects, it is distinct from theories, which are understood to originate from the minds of scientists. Observation is supposed to be public and

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[49] Feyerabend (1998), "How to be a good empiricist: A plea for tolerance in matters epistemological." Philosophy of science: The central issues, p. 922.

accessible to anyone willing to look, and therefore it is proposed to provide a source of agreement and a common ground of information to arbitrate disagreements between differing theoretical accounts. Because observation serves as our access to "the facts", it is the most promising foundation on which to build the objective basis of science. The standardized understanding of "evidence" repeats this distinction between the internal mind and the external world, as evidence is defined in the *Oxford English Dictionary* as "an observation, fact, organized body of information that supports a belief".[50]

Because biomedicine is grounded in the natural and life sciences, the critics are correct to think that EBM's empirical commitments are not *new* to medicine's ideal practices (regardless of whether or not they are actually practiced). However, when considering the question of whether EBM offers anything new, we must remember that its proponents have explicitly denied the charge that EBM is "old hat",[51] and have even been grandiose in their descriptions of EBM as being a "new paradigm" promising to "revolutionize" medicine;[52] this description suggests the evidence based approach to offer something radically different from previous approaches, and so it is worth investigating this alleged paradigm change.

Is EBM a New Paradigm?

To illustrate the unique workings of EBM, the new paradigm of medicine, the Evidence Based Medicine Working Group presented the following clinical scenario:

> A junior medical resident working in a teaching hospital admits a 43-year old previously well man who experiences a witnessed grand mal seizure. He had never had a seizure before and had not had any recent head trauma...Findings on physical examination are normal. The patient is

[50] The Concise Oxford English Dictionary (2002).
[51] Sackett *et al* (1996), "Evidence-based medicine: what it is and what it isn't." BMJ 312(7023), p. 71.
[52] Evidence Based Medicine Working Group (1992), "Evidence-based medicine." JAMA 268(17); Sackett *et al* (1996), "Evidence-based medicine: what it is and what it isn't." BMJ 312(7023).

> given a loading dose of phenytoin intravenously and the drug is continued orally. A computed tomographic head scan is completely normal, and an electroencephalogram shows only non-specific findings. The patient is very concerned about his risk of seizure recurrence. How might the resident proceed?[53]

The Working Group explain that the resident practicing *"the way of the past"* (pre-EBM) would consult the senior resident, who, supported in his view by the attending physician, informs her that the risk of seizure recurrence is high, although its precise risk factor is unknown to him. He instructs the resident to relay this information and the related precautions to the patient. The resident does as she is told and the patient, still fearful, is discharged.[54] In *"the way of the future"*, however, the EBM-trained resident asks herself whether she knows the prognosis of a first seizure and, realizing that she does not, proceeds to the library and conducts a literature search on the *Grateful Med* search engine. Her search on the medical subject headings "epilepsy", "prognosis", and "recurrence" retrieves twenty-five titles, of which one is deemed by the resident to be directly relevant. Exercising the critical appraisal skills that she learned in medical school, she reviews the paper, deems the study and its conclusions to be valid, and returns to her patient after only thirty minutes. She conveys the risk of recurrence over time post-incident, and recommends follow-up with his family physician. The patient leaves "with a clear idea of his likely prognosis."[55]

In their comparative analysis of EBM and its biomedical predecessor, Sehon and Stanley argue that the EBM programmatic literature's likening of their approach to a

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[53] Evidence Based Medicine Working Group (1992), "Evidence-based medicine." JAMA 268(17), p. 2420.
[54] Evidence Based Medicine Working Group (1992), "Evidence-based medicine." JAMA 268(17), p. 2420.
[55] Evidence Based Medicine Working Group (1992), "Evidence-based medicine." JAMA 268(17), p. 2420.

Kuhnian paradigm shift is a gross exaggeration.[56] The authors contend that EBM is not a new paradigm because Kuhn described such a large-scale scientific revolution as involving dramatic changes of worldview and even a different world in which scientists must operate.[57] A Kuhnian paradigm is an "entire constellation of beliefs, values, techniques, and so on shared by the members of a given community."[58] The new paradigm will be *incommensurable*, to some extent, with the previous paradigm, a condition that is not met with the evidence based approach in comparison to biomedicine's "basic science approach", which involves "studying the physiological mechanisms of the body and the biochemical properties of drugs."[59]

When EBM is suggested to be a new paradigm, this fosters the impression that an entire set of beliefs, values, and techniques is to be left behind, "and that the whole world of medical research and clinical practice is completely different than it was in the days before EBM."[60] This impression is certainly false. Furthermore, the language of paradigms suggests that health care practitioners must make a "stark choice" between EBM and "traditional" biomedicine, where one can "accept the new regime and completely reject the old, or defensively hold onto the old and dismiss EBM entirely."[61] Aside from not being a productive atmosphere in which to hold a critical debate about EBM, this polarization exaggerates the merits, demerits, and differences between EBM and its biomedical "predecessor".

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[56] Sehon and Stanley (2003), "A philosophical analysis of the evidence-based medicine debate." BMC Health Serv Res 3:14.
[57] Kuhn (1996), The structure of scientific revolutions, p. 210.
[58] Kuhn (1996), The structure of scientific revolutions, p. 210.
[59] Sehon and Stanley (2003), "A philosophical analysis of the evidence-based medicine debate." BMC Health Serv Res 3:14, p. 3.
[60] Sehon and Stanley (2003), "A philosophical analysis of the evidence-based medicine debate." BMC Health Serv Res 3:14, p. 4.
[61] Sehon and Stanley (2003), "A philosophical analysis of the evidence-based medicine debate." BMC Health Serv Res 3:14.

Numerous commentators have characterized the EBM debate as dredging up the hoary "art versus science" dispute regarding the nature of modern clinical medicine. The critics worry that EBM overemphasizes the latter at the expense of the former. Sullivan and MacNaughton, for example, comment that

> the doctor does not deal with illnesses alone but with people who are ill, and for each individual the illness is unique in terms of his or her experience of it and in its presentation to the doctor.[62]

Understanding the unique circumstances of the individual case is thought to involve a form of practical knowledge or judgment quite different from the *technical* knowledge offered by EBM. The "grey zones" of practice,[63] that is, areas where the evidence from randomized trials about risk-benefit ratios of competing clinical options is incomplete, inconclusive, or contradictory and so clinical judgment must be relied on,[64] are repeatedly argued to be missing from EBM's formulaic knowledge base.[65] Indeed, EBM struggles to account for the interpretive dimensions of clinical care, as evidence-based decisionmaking is largely an effort to standardize and rationalize the application of evidence to clinical care. It is no wonder that critics fail to be persuaded by EBM's conciliatory efforts, such as making the first principle of EBM "evidence is never enough". It is also worth asking: if evidence is not the fundamental base of medicine, are we still practicing evidence *based* medicine?

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[62] Sullivan and MacNaughton (1996), "Evidence in consultations: Interpreted and individualized." Lancet 348(9032), p. 941.
[63] Naylor (1995), "Grey zones of clinical practice: Some limits to evidence-based medicine." Lancet 345(8953).
[64] Among the procedures cited by Naylor to be in the "grey zone" are: carotid endarterectomy, upper gastrointestinal (GI) endoscopy, hysterectomy, and percutaneous transluminal coronary angioplasty. RCTs have been done in these areas, but the results have not produced unequivocal conclusions.
[65] Tanenbaum (1993), "What physicians know." N Engl J Med 329(17).

In light of these grey zones, EBM is charged with creating and sustaining the idea that *evidence* and *practice* are opposing concepts.[66] Other dualisms reinforced in the EBM literature include technical vs. experiential/intuitive knowledge, empirical vs. theoretical knowledge, evidence based vs. patient-centred care, and, of course, EBM vs. its biomedical predecessor, which is inappropriately referred to as "traditional medicine".[67] Adherence to these artificial bifurcations seems to misdirect the EBM debate, as they promote undue polarization between EBM and its biomedical alternatives. For instance, the references to pre-EBM as "traditional medicine" in some of the early EBM programmatic literature[68] is an obvious misnomer, as the term typically refers to folk and alternative healing practices. The selection of this inappropriate term was presumably deliberate, as it permitted the EBM originators to emphasize what they alleged to be the widespread tendency of clinical medicine to operate without sufficient evidentiary support to establish the efficacy of their practices. Pre-EBM biomedicine was therefore "traditional" insofar as it is unscientific or at least insufficiently scientific. Some support for this claim has been found in the phenomenon of small area variations of healthcare practice among different geographical regions.[69] However invoking

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[66] Wood *et al* (1998), "Achieving Clinical Behaviour Change: A Case of Becoming Indeterminate." Soc Sci Med 47(11); Pope (2003), "Resisting evidence: The study of evidence-based medicine as a contemporary social movement." Health 7(3).

[67] Accompanying these imposed bifurcations are, of course, efforts at integration, such as "evidence-based patient centred care" (see Aggerty (2005), "Patient focused care in asthma." Practice Nurse 29(2)) or "evidence-based patient choice" (see Hope (1996), Evidence based patient choice.; Parker (2001), "The ethics of evidence-based patient choice." Health Expect 4). An effort to overcome (or possibly deny) the evidence/judgment divide is found in Downie *et al* (2000), Clinical judgment: Evidence in practice.

[68] See Evidence Based Medicine Working Group (1992), "Evidence-based medicine." JAMA 268(17); Sackett *et al* (1996), "Evidence-based medicine: what it is and what it isn't." BMJ 312(7023).

[69] Small area variation analysis is a research tool used by health services researchers to describe how rates of health care use and events vary over well-defined geographic areas. Significant variation has been found to exist, for example, in the rates of hospitalization for chronic obstructive lung disease, pneumonia, hypertension, and in surgical procedures, such as hysterectomy, cholecystectomy, and tonsillectomy. Potential sources of variation include differences in underlying morbidity, access to care, physician judgment, quality of care delivered, patient demand for services, and random variation. Small area variation

"traditional medicine" is polemical (and distracting) in its misrepresentation of biomedicine, as it cannot account for biomedicine's modern scientific framework, its significant technological advances and achievements, and, of course, EBM's ties to the biomedical tradition.

Despite not invoking revolution (or comparable large-scale upheaval) in medical practice, it will now be demonstrated that EBM certainly does bring something new to medicine. The critics who deny this claim likely do so because they misunderstand EBM as asking for no more than rigorous empirical research in medicine. Indeed, "evidence based" will be shown not to be tantamount to "empirical"; the term "evidence based" amounts to much more. While the evidence based approach certainly does call for rigorous empirical research in medicine, this call is accompanied by novel accounts of what counts as valid evidence and what qualifies as the most rigorous methods of empirical research. Rather than a revolution or paradigm change, EBM represents an important *shift* in biomedical thinking and practice that is a significant alternative to its biomedical predecessor. I propose that EBM offers a shift in the sort of evidence that is most highly valued for diagnostics, prognostics, and therapeutics, in its emphasis on experimental controls and quantitative research, which undermines previous regard of clinical experience and observational studies[70] significantly.[71] EBM's hierarchy of

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studies have been used to determine if significant variation exists across geographic areas and to describe relationships between the observed variation and potential causal factors. There are methodological concerns within this area of study, such as the definition of small areas, defining the at-risk population within each small area, sample size, case mix adjustments, and stability of rates over time. For more on small area variation studies, see Parchman (1995), "Small area variation analysis: A tool for primary care research." Fam Med 272(4).

[70] In research about diseases or treatments, this refers to a study in which "nature" is allowed to take its course. Changes or differences in one characteristic, for example, whether or not people received a specific treatment or intervention, are studied in relation to changes or differences in other(s), e.g. whether or not they died, without the intervention of the investigator. There is a greater risk of selection bias than in experimental studies.

evidence is at the service of outcomes research, which uses a cluster of statistical and epidemiological methods for analyzing the therapeutic effectiveness of clinical interventions.[72] This commitment to highly controlled data and methods of statistical analysis that were previously used only for population-based research (such as public health) represents not only methodological change, but also a novel regard of the reliability of various forms of medical knowledge.

The Novel Contents of EBM

Despite the revolutionary promises of eager EBM proponents, the unique content offered to medicine by EBM remains difficult for many to grasp. Hardly anyone can disagree with the goal of getting clinicians to make "conscientious, explicit, and judicious use of current best evidence" for decisions in patient care. Any expressions of doubt about the EBM activities are usually greeted with vigorous accusations of disregarding "today's harsh realities", or ignoring "what happens in clinical medicine".[73] Furthermore, critics are frequently denounced for erroneous beliefs that EBM only uses evidence from RCTs, that it involves "merely the mindless application of the results of megatrials", and that "other forms of evidence are heavily discounted".[74] Feinstein and Horwitz have wisely suggested that the much of the confusion surrounding what EBM actually stands for lies in the distinction between the contents of EBM itself and its application in clinical practice. Furthermore, it is only when this distinction is blurred

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[71] Sehon and Stanley (2003), "A philosophical analysis of the evidence-based medicine debate." BMC Health Serv Res 3:14, p. 4.
[72] Gifford (1996), "Outcomes research: Upstream issues for downstream users." Hastings Cent Rep 26(2).
[73] Sackett *et al* (1996), "Evidence based medicine. Authors' reply." BMJ 313(7049).
[74] Rosenberg, William M. C. and Donald (1995), "Evidence based medicine: An approach to clinical problem-solving." BMJ 310(6987).

that many clinicians claim EBM to offer "nothing new".[75] Most practitioners see little novelty in EBM because they regularly assemble evidence, develop clinical judgment, read medical literature, attend medical meetings, and have discussions with one another. These activities seem entirely compatible with the statement that the practice of EBM consists of "integrating individual clinical expertise with the best available external clinical evidence from systematic research."[76] The activities surrounding the practice of EBM also seems fairly standard, as the data informing evidence-based practice "is not restricted to randomized trials and meta-analyses."[77] It contains "clinically relevant research, often from the basic sciences of medicine" and it includes studies of diagnostic tests, prognostic markers, and "the efficacy and safety of the therapeutic, rehabilitative and preventive regimes."[78] With this description of what is done when EBM is *practiced* and with the overt acknowledgement by the EBM originators that EBM's "philosophical origins extend back to mid-19th century Paris and earlier,"[79] clinicians can easily conclude that EBM is not particularly novel, and may wonder why it has stirred so much fuss and controversy.[80]

The novelty lies, however, in the contents of what is assembled for use. Despite the broad range of information permitted when EBM is practiced, the evidence collected for EBM itself is confined almost exclusively to randomized controlled trials (RCTs) and the meta-analyses of those trials. Furthermore, the hierarchy of evidence confirms this privileging of the RCT. Because meta-analyses only aggregate and evaluate, but do not

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[75] Feinstein and Horwitz (1997), "Problems in the 'evidence' of 'evidence-based medicine'." Am J Med 103(6), p. 530.
[76] Sackett *et al* (1996), "Evidence-based medicine: what it is and what it isn't." BMJ 312(7023).
[77] Sackett *et al* (1996), "Evidence-based medicine: what it is and what it isn't." BMJ 312(7023).
[78] Sackett *et al* (1996), "Evidence-based medicine: what it is and what it isn't." BMJ 312(7023).
[79] Sackett *et al* (1996), "Evidence-based medicine: what it is and what it isn't." BMJ 312(7023).
[80] Feinstein and Horwitz (1997), "Problems in the 'evidence' of 'evidence-based medicine'." Am J Med 103(6), p. 530.

change the basic information, the RCTs themselves become the fundamental source to be considered both for quality and scope of data, and for the range of topics contained in the EBM collection.[81] For "questions of therapy", for instance, Sackett et al. write that

> we should try to avoid the nonexperimental approaches, since they routinely lead to false-positive conclusions about efficacy...The randomized trial, and especially the systematic review of several randomized trials...has become the "gold standard".[82]

The analysis in the next three sections will further examine the novel contents of EBM captured in its methodological privileging of (1) the hierarchy of evidence, (2) the randomized controlled trial, and (3) outcomes measures.

The Hierarchy of Evidence

EBM originated with the pedagogical objective of familiarizing physicians with basic critical skills derived from clinical epidemiology. The hierarchy of evidence is a useful educational tool because it captures EBM's basic methodological and epistemic commitments in a fairly straightforward ranking of methods. EBM proponents strongly hold that the trustworthiness or validity of evidence is a function of the design of the study from which the evidence is obtained,[83] and so the desire to use only the "best evidence from clinical research" in the management of individual patients[84] has resulted in elaborate classificatory schemes for ranking the value of different types of studies.

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[81] Feinstein and Horwitz (1997), "Problems in the 'evidence' of 'evidence-based medicine'." Am J Med 103(6), p. 530.

[82] Sackett *et al* (1996), "Evidence-based medicine: what it is and what it isn't." BMJ 312(7023).

[83] Sackett (1997), "A science for the art of consensus." J Natl Cancer Inst 89; Canadian Medical Association (1994), "Canadian task force on the periodic health examination." Can Med Assoc J 150(12); Sackett (1989), "Rules of evidence and clinical recommendations on the use of antithrombotic agents." Chest 95 (2 Suppl.)Sackett *et al* (1991), Clinical epidemiology: A basic science for clinical medicine; Sackett *et al* (1997), Evidence-based medicine: How to practice and teach EBM.

[84] Sackett and Haynes (1995), "On the need for evidence-based medicine." Evidence-Based Medicine 1; Sackett *et al* (1997), Evidence-based medicine: How to practice and teach EBM; Sackett *et al* (1996), "Evidence-based medicine: what it is and what it isn't." BMJ 312(7023).

Among the numerous published formulations,[85] there is a consistent placement of randomized controlled trials or the systematic review of these trials at the top, retrospective studies well down the list, and clinical anecdotes are seen as providing little if any evidence for the value of intervention.

A Hierarchy of Strength of Evidence for Treatment Decisions

- N of 1 randomized controlled trial[86]
- Systematic reviews of randomized controlled trials
- Single randomized trial
- Systematic review of observational studies addressing patient-important outcomes
- Single observational study addressing patient-important outcomes
- Physiologic studies (studies addressing blood pressure, cardiac output, exercise capacity, bone density, and so forth)
- Unsystematic clinical observations

Figure 1. *Users' Guide to Medical Literature* hierarchy of evidence[87]

While EBM has advanced considerably from its early polemics of "a new paradigm" of medicine to a more tempered self-regard as a technique for clinicians to manage the explosion of medical research available for use in making clinical judgments,[88] the core belief that evidence can be ranked hierarchically with pride of place belonging to systematic reviews of randomized trials remains undisturbed. In the evaluation of treatment effects, for example, a large, well-designed, randomized controlled trial is considered more reliable than those findings from non-randomized prospective or

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[85] See, for example, Centre for Evidence-Based Medicine (2006), "Levels of Evidence and Grades of Recommendation." http://www.cebm.net/levels_of_evidence.asp; Canadian Medical Association (1994), "Canadian task force on the periodic health examination." Can Med Assoc J 150(12).

[86] While a randomized controlled trial is performed on a group, the N of 1 randomized controlled trial is performed on an individual.

[87] Guyatt and Rennie, eds. (2002). Users' guides to the medical literature: A manual for evidence-based clinical practice, p. 7.

[88] See, for example, Haynes (2002), "What kind of evidence is it that evidence-based medicine advocates want health care providers and consumers to pay attention to?" BMC Health Serv Res 2(3).

retrospective studies.[89] Similar schemes have been developed for the ranking of evidence in other clinical categories such as prognosis, aetiology or diagnosis.[90] At the bottom of each of these clinical scales is evidence obtained from case reports and personal experience.

Given the assumption that better evidence will lead to better health outcomes, the logic behind the ranking of evidence is simple: the best way to distinguish between the effects of active treatment from the effects of known and unknown potentially biasing influences is via random assignment of subjects to intervention and control groups.[91] If the chance that we will erroneously recommend ineffective or even dangerous therapy is reduced when it is based on the results of randomized trials, it follows that we should make every effort to identify and catalogue these studies. And this is exactly what is happening. EBM proponents initially endorsed the teaching of critical analysis skills in medical schools so that physicians can properly assess the quality of a study.[92] The hierarchy of evidence is one of the tools used in this task. It was quickly realized, however, that more advanced informatics was needed in order for clinicians to manage the massive amount of research data available. The Cochrane Collaboration has undertaken the monumental task of identifying and evaluating more than a million randomized trials.[93] Systematic reviews and meta-analyses of the randomized trials in particular areas of medicine are now widely available on EBM databases and in journals. This emphasis on randomized trials and their systematic reviews underscores EBM's

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[89] Sackett (1997), "A science for the art of consensus." J Natl Cancer Inst 89(2322).
[90] Centre for Evidence-Based Medicine (2006), "Levels of Evidence and Grades of Recommendation." http://www.cebm.net/levels_of_evidence.asp.; Sackett *et al* (1997), Evidence-based medicine: How to practice and teach EBM.
[91] Peto and Baigent (1988), "Trials: The next 50 years." BMJ 317(7167).
[92] Evidence Based Medicine Working Group (1992), "Evidence-based medicine." JAMA 268(17).
[93] U.S. Cochrane Center (2002), "Training manual for handsearchers."

questioning of the efficacy of treatments based on evidence gathered from non-randomized trials and the extrapolation of data from physiologic and pharmacologic studies.

The privileging of "hard" evidence—the quantified data that is generated by RCTs—over knowledge generated from clinical experience[94] and qualitative measures[95] speaks to an epistemic distrust of subjective or personal experience, which can never establish the truth of a claim beyond a reasonable doubt. Certainty is thought to be achievable by abstracting from the possible sources of cognitive deceit, and so such methodological features as blinding, randomization, placebo, the use of large subject populations, and the replicability of results increase epistemic certainty by guarding against the confounding factors and bias that can enter one's belief system. These methods serve the purpose of abstracting from values to reveal empirical facts. Of the types of trials available, clinical trials offer the strongest and clearest support for any claim that a treatment is effective because they allow scientists to control extraneous variables and test one factor at a time.[96] The hierarchy of evidence is, by the founders' own admission, based on levels of certainty, where the quantified and the scientific forms of evidence are understood to be most resistant to sceptical refutation.[97]

Randomized Controlled Trials: The "Gold Standard" of Medical Research

Cochrane was regarded as something of a maverick among his peers for his controversial theses, among them the view that the randomized control trial should be used to test the effects of medical interventions and thereby correct the ineffectiveness

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[94] Evidence Based Medicine Working Group (1992), "Evidence-based medicine." JAMA 268(17).
[95] Gray (1997), Evidence-based health care.
[96] Schick and Vaughn (2002), How to think about weird things: Critical thinking for a new age, p. 180.
[97] Sackett *et al* (1991), Clinical epidemiology: A basic science for clinical medicine.

and even the harmfulness of contemporary medical practice (this was yet another heretical position at the time). RCTs allow the effects of an intervention to be tested by randomly allocating research subjects to either an intervention group, where they receive the experimental treatment, or a control group, where the conventional treatment or a placebo is administered. Ideally the trial is "double blinded", where both the research subjects and the researchers do not know which group receives the intervention or the control. Cochrane argued that research evidence from such trials could be used to ensure that only effective treatments were administered, thereby allowing national health systems to be more efficient in their spending.[98] A decade later, support for use of the RCT in health care research was growing among North American public health researchers, epidemiologists, and health services researchers.[99] The considerable research effort that was directed toward the synthesis and proliferation of trial evidence into not only public healthcare, but also clinical practice (by the newly energized discipline of "clinical epidemiology"), allowed for the RCT to become a "yardstick by which other sources of information were judged and ranked within a hierarchy of evidence."[100]

The methodological debates that make up the bulk of the EBM literature revolve around the general question whether the refined focus on clinical evidence (as prioritized in the EBM hierarchy of knowledge), or the search for secure knowledge in general, improves our ability to decipher best practices and therefore prescribe the most effective treatments or whether the methods leave out too many important features of clinical care

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[98] Cochrane (1972), Effectiveness and efficiency. Random reflections on the health service.
[99] Pope (2003), "Resisting evidence: The study of evidence-based medicine as a contemporary social movement." Health 7(3), p. 271.
[100] Pope (2003), "Resisting evidence: The study of evidence-based medicine as a contemporary social movement." Health 7(3), p. 270.

that are not readily measurable through evidence-based approaches. This leads to the important further question of whether the RCT rightfully deserves the title of "gold standard".

The RCT is promoted by EBM advocates as the only valid way to distinguish treatment effects is to control bias through randomization.[101] The introduction of randomized trials to medical research has been credited by Iain Chalmers, one of the original founders of the Cochrane Collaboration,[102] and others for revolutionizing therapeutic development and increasing the life expectancy of patients from three to seven years over the past half century.[103] When substantial uncertainty exists about treatment effects, it is widely thought to be not only scientifically correct to answer it in a study with the smallest amount of built-in bias, but also most ethical to expose patients to alternative treatment options based on chance only and not upon the biased opinion of a physician.[104]

Many EBM critics point to the "experiential nature" of medical practice for being not only inextricable from but also inappropriately maligned by the evidence based approach.[105] However, supporters of EBM insist that experiential knowledge is worth minimizing because experience allows for the repetition of mistakes. EBM proponents point to the data available suggesting human fallibility and bias in drawing conclusions

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[101] Chalmers (1998), "Unbiased, relevant, and reliable assessments in health care." BMJ 317(7167).
[102] Chalmers was knighted in 2000 for his activism in cumulating evidence in medical research.
[103] Chalmers (1998), "Unbiased, relevant, and reliable assessments in health care." BMJ 317(7167).
[104] Edwards, S. J. L. *et al* (1998), "Ethical issues in the design and conduct of randomized controlled trials." Health Tech Assess 2(15); Frazier and Mosteller (1995), Medicine worth paying for: Assessing medical innovations; Freedman (1987), "Equipoise and the ethics of clinical research." N Engl J Med 317(3); Lilford and Jackson (1995), "Equipoise and the ethics of randomization." J Royal Soc Med 88.
[105] Williams, D. D. R. and Garner (2002), "The case against 'the evidence': A different perspective on evidence-based medicine." Brit J Psych 180(Jan); Tanenbaum (1993), "What physicians know." N Engl J Med 329(17).

based on uncontrolled experience.[106] Others argue that investigators with relationships or experience with a subject form expectations with respect to treatment outcomes that make them less able to produce objective reviews of scientific evidence than non-experts trained in critical appraisal of evidence.[107] A logical deductive framework for interpretation of evidence is therefore argued to be needed if we are to avoid practicing medicine based on uncontrolled experience, which may do more harm than good.[108] The nature of research is meant to reduce uncertainty, even if it cannot be completely eliminated.

The central goal behind the EBM movement is quality of care, and this goal serves as the grounds for encouraging medical practice that utilizes the latest and best evidence. These practices are thought to be the means to enhancing "effective and efficient" clinical decision-making. Critics contend, however, that what constitutes "most effective" can refer not only to clinical effectiveness or cost-effectiveness, but also the extent to which patient-cased outcomes indicate satisfaction with the treatment provided. In light of their concerns regarding incorporating patients' goals and perspectives into healthcare decisionmaking,[109] these critics display a general distrust of guidelines. Guidelines can limit patient choice[110] by leaving patients with a "take it or leave it" option in their treatment decision-making. Evidence-based approaches have been charged with representing a narrow reductionism and epistemic silencing that

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[106] Dawson and Arkes (1987), "Systematic errors in medical decision making: Judgment limitations." J Gen Int Med 2(3); MacCoun (1998), "Biases in the interpretation and use of research results." Ann Rev Psych 49.

[107] Oxman and Guyatt (1993), "The science of reviewing research." Ann NY Acad Sci 703.

[108] Sackett (1989), "Rules of evidence and clinical recommendations on the use of antithrombotic agents." Chest 95(2 Suppl.)

[109] See, for example, Rogers (2002), "Evidence-based medicine and practice: Limiting or facilitating patient choice?" Health Expect 5.

[110] Rogers (2002), "Evidence-based medicine and practice: Limiting or facilitating patient choice?" Health Expect 5.

ignores physicians' clinical judgment and experience[111] as well as patients' voices and perspectives[112] in its overreliance on epidemiological and statistical methodology (particularly the dogmatic adherence to the RCT).[113] EBM, in relying solely on a strict hierarchy of acceptable forms of evidence, prioritizes evidence of clinical effectiveness and necessarily excludes subjective perceptions, including those of the potential or actual recipients of care.[114] Patient narrative and the interpretive features of clinical practice are thought to be crucial features of quality healthcare.[115]

Furthermore, RCT design is better geared for certain kinds of intervention questions. RCTs are ideal for the direct comparison between simple treatments such as two single drugs, and so the pronounced "hegemony of the double-blind randomized controlled trial"[116] can both undermine research into and use of complex interventions and result in a failure to meet the complex needs of individual patients. Regarding the former, the critics worry that because RCTs are increasing in favor, and because the expectation to provide "best evidence" of effectiveness before implementing interventions is growing, complex interventions are by default less likely to be supported

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[111] Tanenbaum (1993), "What physicians know." N Engl J Med 329(17).

[112] Tonelli (2006), "Integrating evidence into clinical practice: An alternative to evidence-based approaches." J Eval Clin Prac 12(3); Edwards and Elwyn, eds. (2001). Evidence based patient choice: Inevitable or impossible?

[113] Miles *et al* (1997), "Evidence-based medicine: Why all the fuss? This is why." J Eval Clin Prac 3(2); Miles *et al* (1999), "Advancing the evidence-based healthcare debate." J Eval Clin Prac 5(2); Miles *et al* (2000), "New perspectives in the evidence-based healthcare debate." J Eval Clin Prac 6(2); Miles *et al* (2001), "Recent developments in the evidence-based healthcare debate." J Eval Clin Prac 7(2); Charlton (1997), "Restoring the balance: Evidence-based medicine in its place." J Eval Clin Prac 3(2); Tonelli (1998), "The philosophical limits of evidence-based medicine." Acad Med 73; Greenhalgh (1999), "Narrative based medicine: Narrative based medicine in an evidence based world." BMJ 318(7179); this point will be further discussed in chapter 3's phenomenological critique of EBM.

[114] Malterud (1995), "The legitimacy of clinical knowledge: Toward a medical epistemology embracing the art of medicine." Theor Med 16; Rogers (2002), "Is there a tension between doctors' duty of care and evidence-based medicine?" Health Care Anal 10(3).

[115] Greenhalgh and Hurwitz, eds. (1998). Narrative based medicine: Dialogue and discourse in clinical practice; Greenhalgh (1999), "Narrative based medicine: Narrative based medicine in an evidence based world." BMJ 318(7179).

[116] Charlton (1991), "Medical practice and the double-blind, randomized controlled trial." Brit J Gen Prac 41(350), p. 335.

over time.[117] As a result, behavioral, psychosocial, community based, and multiple-component interventions lose out in favour of individual patient-based treatments[118] and resultant public health policy-setting increasingly focuses on individuals rather than on groups.[119]

In the arena of individual patient care, critics argue that because EBM guidelines are derived from controlled trials of simplified clinical situations using criteria that often exclude other complicating serious conditions, the evidence may not be applicable to complex clinical situations. The "gold standard" of clinical research is widely thought to have a problem of generalizability of its results to individual patient care.[120] Even Cochrane recognized that while the RCT can measure effectiveness, its results may not be directly replicable in clinical practice,[121] and so Dingwall et al. seem correct in their suggestion that Cochrane's ideas have been used somewhat selectively in EBM.[122] The problem of generalizability begins with the narrow eligibility criteria for randomized trials, which limit conclusions about a treatment's effectiveness to patients who fulfill those criteria.[123] In order to optimize the opportunity to demonstrate efficacy, randomized trials are often conducted in major medical centres using relatively homogenous populations. Patients excluded from such trials can differ substantially from

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[117] De Vries and Lemmens (2006), "The social and cultural shaping of medical evidence: case studies from pharmaceutical research and obstetric science." Soc Sci Med 62(11).
[118] Dieppe (1998), "Evidence-based medicine or medicine-based evidence?" Ann Rheum Dis 57(7); Tallon *et al* (2000), "Relation between agendas of the research community and the research consumer." Lancet 355(9220).
[119] Davey-Smith *et al* (2001), "How policy informs the evidence." BMJ 322(7286).
[120] Culpepper and Gilbert (1999), "Evidence and ethics." Lancet 353(9155); Britton *et al* (1998), "Choosing between randomized and non-randomized studies: A systematic review." Health Technolog Assess 2(13); Feinstein and Horwitz (1997), "Problems in the 'evidence' of 'evidence-based medicine'." Am J Med 103(6).
[121] Cochrane (1972), Effectiveness and efficiency. Random reflections on the health service, p. 2.
[122] Dingwall *et al* (1998), "Catching goldfish: Quality in qualitative research." J Health Serv Research Policy 3.
[123] Feinstein and Horwitz (1997), "Problems in the 'evidence' of 'evidence-based medicine'." Am J Med 103(6).

study patients in a variety of ways that could influence treatment outcomes (i.e. disease severity, comorbid conditions, gender, race).[124] Furthermore, the time periods covered in clinical trials and the measures used to assess outcomes frequently differ from those used to assess the success of a therapy in actual practice. In an effort to be efficient, clinical trials typically use the shortest time possible for determining valid results, employing surrogate endpoints rather than clinically relevant outcomes. Surrogate endpoints are physiological or biochemical markers that can be ascertained quickly and taken to be predictive of clinically meaningful endpoints—such as how a patient feels, functions, or survives—that take much longer to observe. They are "surrogate" insofar as they are outcome measures that are not of direct practical importance but are believed to reflect outcomes that are clinically relevant. For example, cholesterol studies frequently use cholesterol reduction as a surrogate for reduced mortality. Direct demonstration of mortality reduction requires lengthy trials using large subject populations, while cholesterol reduction is known to be strongly associated with mortality benefits, and can be measured easily in smaller numbers of patients. Similarly, blood pressure is not directly important to patients but it is often used as an outcome in clinical trials because it is a risk factor for stroke and heart attacks.[125]

Yet the requirement that surrogate endpoints reliably predict the overall effect of the clinical outcome frequently fails in practice. One explanation for this failure is the possibility that the disease process could affect the clinical outcome through several

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[124] Britton *et al* (1998), "Choosing between randomized and non-randomized studies: A systematic review." Health Technolog Assess 2(13); Tanenbaum (1995), "Getting from there to here: evidentiary quandaries of the US outcomes movement." J Eval Clin Prac 1(2); We already saw this methodological critique in chapter two, where feminist concerns were raised regarding the exclusion of women in clinical trials. In this case, the critique is coming from practitioners, not (necessarily) women's health advocates and/or theorists.

[125] Bandolier Glossary of Terms, "Surrogate endpoints."

causal pathways that are not mediated through the surrogate, with the intervention's effect on these pathways differing from its effect on the surrogate. It is more likely, however, that the intervention affects the clinical outcome by unintended, unanticipated, and unrecognized mechanisms of action that operate independently of the disease process.[126] Fleming and DeMets argue that surrogate endpoints frequently mislead regarding the actual effects that treatments have on the health of patients. For instance, although lipid levels, especially those of total cholesterol or its subfractions and triglycerides, have long been known to be significant predictors of cardiovascular-related mortality, there is debate over the relation between lipid lowering and reduction in overall mortality. The noteworthy Coronary Drug Project (CDP) in the 1970s and numerous trials since then have shown such drugs as clofibrate and niacin to decrease cholesterol levels, however neither agent reduced total mortality.[127]

Taken together, the numerous controls utilized to guard against bias and promote efficiency in medical research limits the relevancy of, and may even distort, the "best evidence from clinical research" in the management of individual patients. While there are differences of opinion regarding the challenges posed in making clinical evidence applicable, EBM fails to engage significantly with this problem. It is notable that EBM's penchant for methodological rigor may be at odds with the ad hoc nature of clinical practice; Tanenbaum has even suggested that the precision of "best evidence" is fundamentally irreconcilable with its clinical relevance, given the particularity of patients

[126] Fleming and DeMets (1996), "Surrogate end points in clinical trials: Are we being misled?" Ann Int Med 125(77).
[127] Fleming and DeMets (1996), "Surrogate end points in clinical trials: Are we being misled?" Ann Int Med 125(77).

and the significant improvisational dimensions of clinical practice.[128] The debate over RCTs highlight that the problem of evidence in EBM does not only concern what knowledge is missing from the evidence based decisionmaking framework, but also the nature of the knowledge that *does* enter into consideration.

Outcomes Measures: Clinical Effectiveness and the Quality Movement in Medicine

EBM was introduced to healthcare in the wake of what has been famously described as the "third revolution" in health care,[129] a turn toward assessment and accountability in light of escalating health care costs creating a "crisis" situation in health care spending throughout the industrialized world. Patients and payers widely subscribed to a "waste theory" that described physicians squandering healthcare dollars on unenlightened diagnostic tests and unproductive medical treatments.[130] The urgency with which the public demanded physicians be apprised of what does and does not work—that is, attention to medical outcomes—led to what soon became known as the "outcomes movement" in health policy. Evaluating clinical effectiveness was seen as a fiscally responsible means of only financing the most promising therapies and research. EBM facilitated the clinical data that outcomes research requires in order to evaluate best practices.

Eliciting EBM's place within the "quality movement"[131] captures a shift in medical rationality/knowledge from previous incarnations of biomedicine by way of

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[128] Tanenbaum (1995), "Getting from there to here: evidentiary quandaries of the US outcomes movement." J Eval Clin Prac 1(2); Shaugnessy et al. refer to this improvisational feature as "clinical jazz" in Shaughnessy *et al* (1998), "Clinical jazz: Harmonizing clinical experience and evidence based medicine." J Fam Pract 47(6).

[129] Relman (1988), "Assessment and accountability: The third revolution in medical care." N Engl J Med 319(18).

[130] Tanenbaum (1994), "Knowing and acting in medical practice: The epistemological politics of outcomes research." J Health Pol Policy Law 19(1), p. 27.

[131] Bodenheimer (1999), "The movement for improved quality of health care." N Engl J Med 340(6).

EBM's insistent epistemological privileging of standardized information over judgment, quantified measurement over experience, epidemiology over bench science, and the fragmenting of the therapeutic relationship. Furthermore, understanding EBM's grounding in clinical epidemiology and outcomes research in health policy has been argued by many critics to situate the movement in a new scientism—economism—which has transferred the dictates of positivism into late-capitalist discourse, thus shifting medical authority from the laboratory to the marketplace.[132] This latter point will be discussed later in the political economy critique of EBM.

Paul Ellwood, the progenitor of managed care, first coined the term "outcomes management" in a 1988 publication in the *New England Journal of Medicine*, where he defined it as "a technology of patient experience designed to help patients, payers, and providers make rational medical care-related choices based on better insight into the effects of these choices on patient life."[133] Outcomes research uses statistical analysis of clinical data to determine if particular therapeutics are associated with particular results.[134] By subsuming efficacy and effectiveness research, including clinical trials, it is a variety of clinical epidemiology, which seeks the broadest determination of what health care dollars are buying. EBM is considered the course of clinical medicine presented by such research.[135]

The outcomes movement argues for the primacy of probabilistic knowledge derived from statistical studies for medical practice and the vigorous adoption of this

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[132] See, for example, Frankford (1994), "Scientism and economism: regulating health care." J Health Pol Policy Law 19(4).
[133] Ellwood (1988), "Outcomes management: A technology of patient experience." N Engl J Med 318(23).
[134] Tanenbaum (1994), "Knowing and acting in medical practice: The epistemological politics of outcomes research." J Health Pol Policy Law 19(1) p. 28.
[135] Tanenbaum (1995), "Getting from there to here: evidentiary quandaries of the US outcomes movement." J Eval Clin Prac 1(2), p. 97.

position within health care indicates a radical shift in medical rationality. Polychronis et al., for example, regard the ascendancy of EBM as the triumph of statistics over clinical common sense based on deterministic reasoning.[136] Clinical epidemiology is now held by some to be a *basic* medical science.[137] Along with privileging aggregate measure, EBM is charged with encouraging a "fragmented" picture of medical knowledge in its support for "the separability of expertise from expert and of knowledge from knower, and the distillation of medical truth outside the clinical encounter."[138] By giving credibility to the belief that better knowledge of what is efficacious or appropriate medical action is obtained outside the clinical encounter by individuals who have no direct familiarity with the patient,[139] the evidence-based approach to health care takes authority away from the practitioner and silences any epistemic legitimacy that patients may claim to have pertaining to their illness and treatment.[140]

Epidemiology was, of course, a segment of public health research, as it focused on population rather than individual or clinical aspects of medicine. The term "clinical epidemiology" first appeared in the 1930s to signal attempts by some epidemiologists to

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[136] Polychronis *et al* (1996), "Evidence-based medicine: Reference? Dogma? Neologism? New orthodoxy?" J Eval Clin Prac 2(2).
[137] Upshur (1999), "Priors and prejudice." Theor Med Bioeth 20(4), p. 321.
[138] Tanenbaum (1995), "Getting from there to here: evidentiary quandaries of the US outcomes movement." J Eval Clin Prac 1(2), p. 102.
[139] Others are thought to be able to know better by having access to selective summary data about the patient and the ability to compare such summary data for an individual to that of a population as a way of determining the proper action for a given individual. This is proper course in epidemiology.
[140] In Cochrane's *Effectiveness and Efficiency*, Cochrane reflects on his years imprisoned in a German POW camp, where he was forced to serve as the only camp physician for 20,000 undernourished men. Upon a denied request for more medical staff, where a German officer proclaimed that doctors are "superfluous", Cochrane wrote, "I was furious and even wrote a poem about it; later I wondered if he was wise or cruel; he was certainly right." See also "Superfluous Doctors" in Cochrane (1974), Poems from prison.

move their expertise closer to the bedside. The discipline[141] came to prominence in the 1980s when a group of physicians who shared a conviction that the scientific base of clinical practice should be strengthened, published the first edition of the key textbook *Clinical Epidemiology*,[142] which was the precursor to "evidence based medicine".

EBM distinguishes itself from pre-evidence based biomedicine by its orientation toward outcomes research, while biomedicine is more dependent on bench science. While biomedical research entails laboratory science that aims to reveal the mechanisms of medical cause and effect in order to determine what ought to be effective, EBM seeks to generate probabilistic knowledge regarding what is likely to work, for whatever reason.[143] John Wennberg, director of the Centre for Evaluative Clinical Science at Dartmouth Medical School and well known in the field for developing a strategy for studying the population-based rates of health resource allocation and utilization, regards biomedical science to be at the service of evaluative science in treatment decisionmaking. The role of the former is to generate ideas and technologies, while evaluative science provides the necessary clinical information linking treatments to outcomes.[144]

The consistent placement of the RCT at the top of the EBM hierarchy of evidence is better understood in light of the biomedical versus evidence-based distinction, as this research method serves the objectives of outcomes research by appearing bracket out a whole range of scientifically and epistemologically difficult questions about why

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[141] Clinical epidemiology is described as an "apparent oxymoron" by Mykhalovskiy and Weir (*op cit.* 48) for breeching what were well-established oppositional distinctions between public health and curative medicine, epidemiological and clinical knowledge, and population vs. patient care (p. 1065).
[142] Sackett *et al* (1985), Clinical epidemiology: A basic science for clinical medicine.
[143] Tanenbaum (1994), "Knowing and Acting in Medical Practice: The Epistemological Politics of Outcomes Research." J Health Pol Policy Law 19(1), p. 28.
[144] Wennberg (1992), "AHCP and the strategy for health care reform." Health Affairs 11(1).

treatments work or do not work.[145] Rather than determining the properties that make an intervention work, for example, RCTs establish efficacy by comparing the outcomes found in a similar subject population receiving a comparator intervention. The practical and professional advantages of this pragmatic approach to health care decision making are significant. For starters, definitive evidence from a trial or meta-analysis of the results of a set of trials appear to settle the question of whether a treatment works or not without need for appeal to any deeper biological theory to explain *why* the treatment works or not (as required in deterministic or bench medical science).[146] Furthermore, definitive biological explanation has not always led to safe or beneficial treatment of actual patients. The RCT "acts as a practical filter permitting the calibration of scientific good ideas against clinical reality (however that is constructed)."[147] Because RCTs entail the comparative study of two or more competing courses of treatment (including placebo when indicated), the RCT "offers a technique for dispute resolution within medicine: where there is discord, let a trial be."[148]

Because EBM and outcomes research are closely allied, the concerns regarding the latter are similar to those launched against the former. The task of outcomes research, to solve the problems of quality and cost that beset the healthcare system and to do so by scientific rather than political means raises the expected postpositivist concerns about the tenability of value-free measures. Furthermore, Tanenbaum's account of the

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[145] Ashcroft (2002), "What is clinical effectiveness?" Stud Hist Phil Biol & Biomed Sci 33(2), p. 220.
[146] Of course there are several ways in which "does it work?" can be construed. See Ashcroft *et al* (1997), "Implications of socio-cultural contexts for the ethics of clinical trials." Health Technol Assess 1(9); Ashcroft (2002), "What is clinical effectiveness?" Stud Hist Phil Biol & Biomed Sci 33(2).
[147] Ashcroft (2002), "What is clinical effectiveness?" Stud Hist Phil Biol & Biomed Sci 33(2), p. 220-221.
[148] Ashcroft (2002), "What is clinical effectiveness?" Stud Hist Phil Biol & Biomed Sci 33(2), p. 220.

"epistemological politics" of the US outcomes movement[149] brings into question whether this research can ever be so benign that it merely "informs decision makers...and helps them make better decisions."[150] The championing of probabilistic knowledge to improve clinical practice is argued to replace subjective professional judgment with micromanagement by insurance companies and government.[151]

While Tanenbaum is accused of pandering to the fears of physicians and other professionals who perceive outcomes research to be a threat to autonomous practice,[152] her criticisms are not against outcomes research *per se*, as she recognizes the usefulness of statistical analysis in evaluating medical care. Her target is rather the outcomes *movement*, the organized effort of one research community and its champions to gain special privilege for statistical evidence, to consider it the only true evidence of medical effectiveness, and to predicate an accountable health care system on physicians' adherence to norms of practice derived from outcomes studies. Similar to EBM, the critics find utility in outcomes research for improving patient care, but they question its near-hegemonic status in influential health policy and administrative circles.

In Conclusion

While the so-called "new paradigm" in healthcare hardly proves to be revolutionary, EBM represents a *shift* in clinical methodology away from bench science toward epistemology. The evidence based approach is marked by the flourishing relationship that the evaluative sciences and informatics, once solely the domain of

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[149] Tanenbaum (1994), "Knowing and acting in medical practice: The epistemological politics of Outcomes Research." J Health Pol Policy Law 19(1).
[150] Sage (1994), "Outcomes research [letter]." N Engl J Med 330(6).
[151] Tanenbaum (1995), "Getting from there to here: Evidentiary quandaries of the US outcomes movement." J Eval Clin Prac 1(2); Tanenbaum (1993), "What physicians know." N Engl J Med 329(17).
[152] Cangialose (1994), "Outcomes research [letter]." N Engl J Med 330(6).

business and managerial studies, now have with medicine, in EBM's valuing of standardized measures, aggregate behaviour, and radically fragmented medical knowledge. The novelty that EBM brings healthcare will be shown in the next two chapters to have considerable ethical and epistemological significance.

The standard ethical (chapter two) and epistemological (chapter three) arguments launched against EBM will be demonstrated, however, to be deficient in light of the detailed discussion of EBM undertaken in this chapter. Both will be seen to capture only part of the evidence based approach and therefore the analyses prove to be narrow. Specifically, the ethical analysis focuses only on the *impact* of EBM on patient care in its consequentialist considerations, and misses the ethical issues that arise in its operating assumptions and intricate workings. The epistemological critique is also narrow in its critique of the problematic objectivism underscoring EBM's understanding of "evidence". We will see that this concern faults not only in narrowing the range of epistemic considerations and concerns, but also in failing to distinguish EBM from its biomedical predecessor, which has been similarly charged with a naïve epistemology of science.

CHAPTER TWO

Introducing an Ethics of Evidence to the Ethics of EBM

Along with presenting complex ethical challenges to patient care, evidence based medicine introduces a new area of consideration for healthcare ethics—the ethics of evidence—that brings the epistemological questions of what constitutes evidence and how medical knowledge is justified into ethical consideration. Valerie Miké first coined the term "ethics of evidence" to denote the moral implications of developing and applying evidence.[153] I similarly want to forge connections between the ethical and epistemological challenges that the evidence-based approach brings to medicine. Specifically, I want to broaden the ethics of EBM beyond its current focus on how individual patient care will be affected by EBM with respect to quality of care and the incorporation of patient values, priorities, and cultural needs into the healthcare encounter to include how ethical and other action-guiding norms shape what counts as evidentiary considerations. I aim to show in this dissertation that the current broad/abstract epistemological challenges to EBM concerning the neutrality of science and EBM's objectivist account of evidence are ethically relevant.

A good place to begin is with EBM's underlying philosophical commitments. The Evidence Based Medicine Working Group offers a very limited accounting of the philosophy of EBM in a brief essay entitled "The Philosophy of Evidence-Based Medicine" that appears in their authoritative manual for evidence-based clinical practice, the *Users' Guides to the Medical Literature*.[154] In the brief (7 pages) introductory essay, the authors offer two fundamental principles of EBM. The first is "evidence is never

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[153] Miké (1999), "Outcomes research and the quality of health care: The beacon of an ethics of evidence." Eval Health Prof 22(1).

[154] Guyatt *et al* (2002), "Introduction: The philosophy of evidence-based medicine." Users' guide to the medical literature: A manual for evidence-based clinical practice.

enough" for clinical decisionmaking. Arguably in response to the common criticism that EBM offers a "cookbook" approach to medical decisionmaking that relies too heavily on evidence of treatment efficacy,[155] the authors state that "decision makers must always trade the benefits and risk, inconvenience, and costs associated with alternative [patient] management strategies, and in doing so, consider the patient's values."[156] They admit, however, to have made limited progress in incorporating such factors into the evidence-based approach, and conclude that "addressing these issues constitutes an enormously challenging frontier for EBM."[157]

The second fundamental principle of EBM is its subscription to a hierarchy of evidence for use in evidence-based treatment decisionmaking that privileges the data derived from randomized controlled trials over unsystematic (i.e. observational and uncontrolled) methodologies. The *Users' Guides'* brief description fails to acknowledge and explicate the implicit epistemological commitments regarding what constitutes reliable knowledge built into this methodological hierarchy.[158] The remaining four pages of the essay are dedicated to EBM's remaining commitments: "Clinical Skills, Humanism, and Social Responsibility". EBM originated as an innovative medical curriculum at McMaster University,[159] and was quickly proliferated beyond the confines of the medical school and its student body through a "How to Read Clinical Journals" series published in several consecutive editions of the *Canadian Medical Association*

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[155] The Evidence Based Medicine Working Group object to the charges of "cookbook medicine" in Sackett *et al* (1996), "Evidence-based medicine: what it is and what it isn't." BMJ 312(7023).
[156] Guyatt *et al* (2002), "Introduction: The philosophy of evidence-based medicine." Users' guide to the medical literature: A manual for evidence-based clinical practice, p. 5.
[157] Guyatt *et al* (2002), "Introduction: The philosophy of evidence-based medicine." Users' guide to the medical literature: A manual for evidence-based clinical practice, p. 6.
[158] The hierarchy of evidence and the epistemological commitments underscoring the ranking of methodologies it will be discussed in the next two chapters.
[159] Evidence Based Medicine Working Group (1992), "Evidence-based medicine." JAMA 268(17).

Journal in 1981[160] and the "Users' Guides to the Medical Literature" series in the *Journal of the American Medical Association* from 1993-2000 (the JAMA series later became the contents of the manual currently under discussion).[161] The clinical skills so strongly promoted as a precursor to delivering the highest quality of patient care contain further epistemological as well as methodological commitments underscoring the evidence based approach that, once again, are not accounted for in the brief essay on the philosophy of EBM. Lastly, the commitment to humane clinical practice—"compassion, sensitive listening skills, and broad perspectives from the humanities and social sciences"[162]—and the suggestion that physicians should be concerned with the health system in which they work and in broader policy issues[163] suggests broad ethical and socio-political concerns and commitments to be tied into the founders' vision of evidence-based healthcare. Thus the philosophy of EBM deserves more investigation than what is offered in the *Users' Guides to the Medical Literature*'s brief exposition. Interestingly, the name of the manual in which the philosophy of EBM essay was published—*Users' Guides to the*

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[160] Sackett (1981), "How to read clinical journals: I. why to read them and how to start reading them critically." CMAJ 124(5); Haynes (1981), "How to read clinical journals: II. To learn about a diagnostic test " CMAJ 124(6); Tugwell (1981), "How to read clinical journals: III. To learn the clinical course and prognosis of disease." CMAJ 124(7); Trout (1981), "How to read clinical journals: IV. To determine etiology or causation." CMAJ 124(8); Sackett (1981), "How to read clinical journals: V: To distinguish useful from useless or even harmful therapy." CMAJ 124(9).

[161] See, for example, Oxman *et al* (1993), "Users' guides to the Medical Literature, I: How to get started." JAMA 270(17); Richardson and Detsky (1995), "Users' guides to the medical literature, VII: How to use a clinical decision analysis. A. Are the results of the study valid?" JAMA 273(16); Richardson and Detsky (1995), "Users' guides to the medical literature, VII: How to use a clinical decision analysis. B. What are the results and will they help me in caring for my patients? Evidence Based Medicine Working Group." JAMA 273(20); Dans *et al* (1998), "Users' guides to the medical literature, XIV: How to decide on the applicability of clinical trials results to your patient." JAMA 279(7); Hunt *et al* (2000), "Users' guides to the medical literature, XXI: Using electronic health information resources in evidence-based practice." JAMA 283(14).

[162] Guyatt *et al* (2002), "Introduction: The philosophy of evidence-based medicine." Users' guide to the medical literature: A manual for evidence-based clinical practice, p. 9.

[163] Guyatt *et al* (2002), "Introduction: The philosophy of evidence-based medicine." Users' guide to the medical literature: A manual for evidence-based clinical practice, p. 9. This brief mention is presumably what the authors meant by "Social Responsibility".

Medical Literature—did not register with the authors as being fundamentally normative and therefore filled with numerous philosophical commitments.

The more recent descriptions of EBM offered by its founders, the Evidence Based Medicine Working Group, avoid the early polemics of "new paradigms"[164] and instead promote it as a clinical tool for managing medical knowledge and improving clinical practice.[165] This current pragmatic presentation of EBM should not be allowed to obscure its substantial methodological, epistemological, and ethical assumptions. Unpacking EBM's concepts, methods, and philosophical commitments is an important area of medical humanities research given the enormous uptake of the evidence based approach throughout the health sciences. The future of biomedicine appears to be evidence-based. This chapter will begin with EBM's ethical assumptions and overview the current scope of the "ethics of EBM" literature.

To begin, EBM starts with the ethical promise that it can improve patient care by methodologically and accurately identifying the best, the useless, and the harmful practices in healthcare. Much of the advocacy literature on EBM carries a moral tone to it. One supporter, for instance, strongly states that "if evidence based practice can reduce uncertainty and therefore better inform clinical decisions, then it becomes blameworthy not to bend one's knee at this altar."[166] Even members of the Evidence Based Medicine Working Group, who did not identify any ethical principles among its fundamental principles of EBM, used moralizing language in a 1995 promotional editorial for the new journal *Evidence Based Medicine*:

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[164] Evidence Based Medicine Working Group (1992), "Evidence-based medicine." JAMA 268(17).
[165] Haynes (2002), "What kind of evidence is it that evidence-based medicine advocates want health care providers and consumers to pay attention to?" BMC Health Serv Res 2(3).
[166] Goodman (2003), Ethics and evidence-based medicine: Fallibility and responsibility in clinical science, p. 49.

> *ACP Journal Club* and *Evidence Based Medicine* will publish the gold that intellectually intense processes will mine from the ore of about 100 of the world's top journals. Doctors owe it to themselves and their patients to make sure that they keep up with what is new and important.[167]

Both moral tone and religious connotation are found in many EBM endorsements despite the difficulty that there is currently no empirical support for EBM's claims to improve health outcomes.[168]

While this "paradox of EBM"[169]—no evidence for evidence-based medicine—has been conceded by supporters of evidence based practices, they refuse to recognize this impediment as the philosophical trump card that some critics suggest it to be. Some insistent EBM supporters have engaged in crude, if not zealous, avowals of EBM's methodological superiority, leading Brian Haynes, one of EBM's founders, to caution that without concrete empirical evidence, it is too early to conclude that EBM is morally required.[170] Due to these instances of "decerebrate genuflection at the altar of the randomized controlled trial,"[171] EBM proponents are criticized for failing in the end to *critically* engage in the philosophical dimensions—particularly the epistemic justification—of EBM.[172] Buetow charges EBM with being *unable* to justify its faulty

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[167] Davidoff *et al* (1995), "Evidence based medicine." BMJ 310(6987), p. 1086.

[168] EBM is unable to draw conclusions about its own effectiveness because there are so many confounding variables, some of which cannot be eliminated. The originators of EBM recognized this impediment to proving their own claims regarding improving patient outcomes early on, but maintained that "this proof is no more achievable for the new paradigm than it is for the old, for no long-term randomized trials [comparing the two] are likely to be carried out" (Evidence Based Medicine Working Group (1992), "Evidence-based medicine." JAMA 268(17), p. 2424).

[169] Norman (1999), "Examining the assumptions of evidence-based medicine." J Eval Clin Prac 5(4).

[170] Haynes (2002), "What kind of evidence is it that evidence-based medicine advocates want health care providers and consumers to pay attention to?" BMC Health Serv Res 2(3).

[171] Brody *et al* (2005), "Evidence-based medicine: Watching out for its friends." Persp Biol Med 48(4), p. 577.

[172] Tonelli (2006), "Integrating evidence into clinical practice: An alternative to evidence-based approaches." J Eval Clin Prac 12(3); Buetow (2002), "Beyond evidence-based medicine: Bridge-building a medicine of meaning." J Eval Clin Prac 8(2); Upshur (2005), "Looking for rules in a world of exceptions: Reflections on evidence-based practice." Persp Biol Med 48(4)

epistemic basis,[173] while Upshur encourages philosophical engagement by EBM advocates in order to enable critical debate and discourage the current polemics.[174] Haynes tries to minimize EBM's philosophical weaknesses by pointing out that the evidence based movement is more pragmatic than epistemological,[175] but this admission hardly justifies EBM's theoretical deficiency. The entirety of this dissertation demonstrates the significant fallout from a flawed philosophy of medicine.

In an innovative use of evidence-based methods, Mona Gupta, a critic of EBM, has offered a critical appraisal of EBM's philosophical commitments.[176] She proposes that EBM carries a built-in moral mandate to engage in evidence-based approaches to medicine that relies on the ethical premise that we ought to improve patient care and the epistemological premise that EBM will lead us to this improvement:

Premise 1 (ethical): We ought to pursue the most effective means of achieving health
Premise 2 (epistemological): Only if we pursue EBM do we arrive at the most effective means of achieving health

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Conclusion: Therefore, we ought to pursue EBM

Figure 2. Gupta's characterization of the implicit values of EBM[177]

Gupta suggests that if one accepts the basic value that the best care ought to be pursued and the epistemic assumption that optimal patient care is best pursued via the evidence based approach, one arrives at the moral conclusion that all clinicians ought to practice

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[173] Buetow (2002), "Beyond evidence-based medicine: Bridge-building a medicine of meaning." J Eval Clin Prac 8(2).
[174] Upshur (2005), "Looking for rules in a world of exceptions: Reflections on evidence-based practice." Persp Biol Med 48(4).
[175] Haynes (2002), "What kind of evidence is it that evidence-based medicine advocates want health care providers and consumers to pay attention to?" BMC Health Serv Res 2(3).
[176] Gupta (2003), "A critical appraisal of evidence-based medicine: Some ethical considerations." J Eval Clin Prac 9(2).
[177] Gupta (2003), "A critical appraisal of evidence-based medicine: Some ethical considerations." J Eval Clin Prac 9(2), p. 114.

EBM. The first/ethical premise, by Gupta's account, is fairly uncontroversial, as most of us would agree that the best patient care ought to be pursued. The trouble for EBM arises, according to Gupta, within the second/epistemological premise. The justification of EBM rests entirely on establishing the epistemological premise that EBM provides the means for reducing uncertainty and improving health outcomes. EBM's moral claim therefore hinges on consideration of what constitutes clinical reasoning, knowledge, authority, expertise, and of course, evidence. [178] It is therefore not surprising that the bulk of the critical literature on EBM is on methodological and epistemological issues and the ethics of EBM literature is sparse in comparison. EBM is understood to present an epistemological challenge to biomedicine, with ethical issues regarded as a secondary concern.

Biomedicine's methodological dominance in the western world is grounded in its claims of effectiveness in achieving health relative to other alternative medical systems. EBM challenged biomedicine's status on the grounds of its having a superior means of pursuing health (the epistemological premise). In order to defend this contention, EBM assumes the veracity of two further claims. First, EBM assumes that only if we improve the ratio of true to false beliefs about how medical interventions operate will we discover the most effective means of achieving health. This is a fairly uncontroversial claim among medical researchers and practitioners, as better health is thought to arise from more truthful understanding of human physiology and pathology. Secondly, and more controversially, EBM assumes that *only if we pursue EBM*[179] *do we maximize the*

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[178] Goodman (2003), Ethics and evidence-based medicine: Fallibility and responsibility in clinical science, p. 14.

[179] Of course, we do not all agree on what "pursuing EBM" means. Brody et al. distinguish between a "crude" EBM endorsed and practiced by many genuflecting EBM enthusiasts which involves uncritically

likelihood of arriving at the truth about the effectiveness of medical interventions. It is only with these two premises that we arrive at the initial epistemic claim in support of the moral mandate to practice EBM, namely that EBM offers the most effective means of achieving health.[180]

A review of the epistemological challenges to EBM in the next chapter will illustrate, however, that the assumption that EBM is the method most likely to bring us closer to medical truth is highly contentious. To presume this claim requires the further assumption that research data generated by EBM-preferred methods is unlikely to reflect biases and that the inferences culled from these data will similarly be unbiased. Critics have challenged both EBM's methodological ability to limit bias and the very epistemic tenability of scientific objectivity (as it is popularly understood).

To return to the ethics, Gupta's analysis should not be taken to suggest that the ethics of EBM is somehow uncontroversial or decidedly secure. While slim in quantity, there is ethical debate over the moral correctness of evidence-based practice. While the duty to provide the best patient care is widely accepted within medical ethics, and where EBM advocates and critics disagree is on its execution and not the value in itself, the ethics literature illustrates that there is more to ethical medical practice than both the effort to and the success in achieving health for patients. The considerable ethical significance placed on autonomy and justice, for instance, suggests that the value placed

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accepting RCTs while rejecting all other forms of evidence, and a "sophisticated" EBM, which entails the thoughtful application of the best available evidence, which does not come from the single RCT but rather an "N of 1" RCT (Brody *et al* (2005), "Evidence-based medicine: Watching out for its friends." Persp Biol Med 48(4). p. 577). In the authoritative account of EBM found in the *Users' Guide to Medical Literature*, a ranking of research methods lists the N of 1 trial first and the single RCT as third, following systematic reviews of randomized trials as number two (Guyatt and Rennie, eds. (2002), Users' guides to the medical literature: A manual for evidence-based clinical practice, p. 7).

[180] Gupta (2003), "A critical appraisal of evidence-based medicine: Some ethical considerations." J Eval Clin Prac 9(2), p. 114.

on achieving health does not encompass the entire scope of the ethics of EBM. Furthermore, the duty to deliver the best care possible frequently competes against other prima facie equal duties, such as the duty to uphold patient autonomy. By broadening "best patient care" to constitute more than achieving the best health outcomes and to also incorporate patients values, beliefs, and preferences, the "ethics of EBM" brings into focus the anticipated impact of EBM on individual patient *care* and not just the impact on patient health outcomes.

A criticism of EBM that garners special ethical interest is that EBM's methodology makes it difficult to apply medical evidence to individual patients, thereby undermining the goals of patient choice and shared physician-patient decisionmaking.[181] Clinical data represents an average effect of the intervention on a homogenous trial population that met admission criteria. Trial subjects typically must display few comorbidities in order to meet the requirements of the research protocol and so the results of such trials might not be applicable to patients with confounding variables.[182] Furthermore, when clinicians make decisions for individual patients, the information needed for pertinent clinical subgroups formed by such clinical features as severity of symptoms, illness, and comorbidity, may not be reported or made available. For example, tPA and streptokinase can be expected to have different rates of both beneficial and detrimental effects when acute myocardial infarction is treated in a relatively elderly man who also has congestive heart failure, or in a relatively young man without failure. Clinicians and patients would want to know risk/benefit appraisals for each treatment in

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[181] See, for example, Kerridge *et al* (1998), "Ethics and evidence based medicine." BMJ 316(7138), p. 1153.

[182] Culpepper and Gilbert (1999), "Evidence and ethics." Lancet 353(9155), p. 830. This issue is discussed in more depth later in this dissertation manuscript.

those subgroups, not just for an "average" acute myocardial infarction.[183] Feinstein and Horwitz maintain that the randomized controlled trial, which originated in agricultural research, was never intended to answer questions about the treatment of individual patients.[184]

The point about subgroups can be pushed further—in a sense, aren't we all a subgroup of one? It needs to be asked how the significance of group and individual differentiation can be best taken into account in medical research and clinical practice.[185] The difficulty with EBM is that it appears to prematurely answer this question in its allegiance to epidemiological and public health methods (i.e. population-based research). The critics suggest that pre-EBM approaches to biomedicine demonstrated more variety in its responses to the question of differentiation, as they did not subscribe to a rigid hierarchy of evidence.

The question of applicability ties into the important ethical question whether EBM supports or denies patient autonomy and choice. In "Evidence Based Medicine and Ethics", Hope frames EBM as an important means for upholding patient autonomy:

> Patient choice goes beyond consent and should involve the patient in the whole decision-making process. In order for such autonomous authorization to be genuine, both the patient and the doctor need access to good quality information. For this, if for no other reason, there is an ethical imperative for support of the fundamental tenets of evidence based medicine.[186]

Miké similarly promotes EBM as a necessary precursor to ethical medical practice in her version of "ethics of evidence", as it is only with accurate information that decisions can

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[183] Feinstein and Horwitz (1997), "Problems in the 'evidence' of 'evidence-based medicine'." Am J Med 103(6), p. 532.
[184] Feinstein and Horwitz (1997), "Problems in the 'evidence' of 'evidence-based medicine'." Am J Med 103(6), p. 531.
[185] Private correspondence with James L. Nelson.
[186] Hope (1995), "Evidence based medicine and ethics." J Med Ethics 21(5), p. 259.

be properly informed and consent can be genuine.[187] Yet it has been argued by EBM critics that the full implementation of EBM standards of best practices will lead to limited lists of approved health care services determined by policy elites far removed from the bedside.[188] Bad outcomes in cases in which care deviated from the guidelines could become "a risk management nightmare."[189] Thus, against the claim that EBM's provision of the most up-to-date and relevant evidence helps patients make informed choices, critics have argued that informed consent requires not only current and relevant information, but also an offering of genuine choice.[190] The "fundamental principle of EBM" that "evidence is never enough" is regarded as lip service by critics such as Lambert,[191] who accuses EBM proponents of co-opting the criticisms without genuinely responding to the problem—for example, in empty slogans such as Hope's "evidence-based patient choice".[192] Greenhalgh similarly describes a "sirenic accommodation" by EBM advocates to the interpretive character of medicine in a manner that seductively distracts attention from and de-emphasizes a hierarchy of evidence.[193] She refers specifically to a widely quoted riposte by Sackett and colleagues to critics who accused them of naive empiricism, where the EBM founders claimed that

> the practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence.... By individual clinical expertise we mean the proficiency and judgment

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[187] Miké (1999), "Outcomes research and the quality of health care: The beacon of an ethics of evidence." Eval Health Prof 22(1). Miké's ethics of evidence will be examined in chapter 7 of this dissertation.
[188] See, for example, Brase (2004), "How technocrats are taking over the practice of medicine: A wake-up call to the American people."; we will be returning to this important systemic issue in later chapters.
[189] Goodman (2005), "Ethics, evidence, and public policy." Persp in Biol Med 48(4), p. 550.
[190] This should not be understood to suggest that *all* options must be made available to the self-legislating patient. For instance, the health practitioner is not obliged to, and may even be held culpable for, providing treatment requested by the patient that she has good reason to think is harmful.
[191] Lambert (2006), "Accounting for EBM: Notions of evidence in medicine." Soc Sci Med 62(11).
[192] Hope (1996), Evidence based patient choice.
[193] Greenhalgh (1999), "Narrative based medicine: Narrative based medicine in an evidence based world." BMJ 318(7179).

> that individual clinicians acquire through clinical experience and clinical practice.[194]

Sackett et al. were anxious to acknowledge that there is an art to medicine as well as an objective empirical science but, Greenhalgh laments, they did not attempt to define or categorize the "elusive quality" of clinical competence. She explores the dissonance between the "science" of objective measurement and the "art" of clinical proficiency and judgment,[195] and attempts to integrate these different perspectives on clinical method in her system of "narrative based medicine", which draws on the intuitive and subjective aspects of clinical method as well as rigorous clinical data in order to generate integrated clinical judgment.[196] Rogers[197] and Jones and Sagar[198] express the moral concern that patients might be discouraged from making choices that are regarded as less efficacious and therefore are not endorsed by EBM and its derivative clinical guidelines. When making a decision about medical treatment, patients or substitute decisionmakers have to compare different procedures and techniques and trade off the chances of benefits and of toxicities, and the severities of outcomes. Each patient will do this slightly differently and may even come to prefer a treatment option that EBM and its derivative practice guidelines suggest should be abandoned.[199] Furthermore, ethical patient care can never rely solely on gauges of efficacy. For instance, the use of restraints are effective in preventing falls among institutionalized geriatric patients, but the loss of personal liberty

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[194] Sackett *et al* (1996), "Evidence-based medicine: what it is and what it isn't." BMJ 312(7023), p. 71.
[195] We will return to these themes in the next chapter's analysis of phenomenological critiques of EBM.
[196] Greenhalgh (1999), "Narrative based medicine: Narrative based medicine in an evidence based world." BMJ 318(7179).
[197] Rogers (2002), "Evidence-based medicine and practice: Limiting or facilitating patient choice?" Health Expect 5(1).
[198] Jones and Sagar (1995), "Evidence based medicine. No guidance is provided for situations for which evidence is lacking." BMJ 311(6999).
[199] Jones and Sagar (1995), "Evidence based medicine. No guidance is provided for situations for which evidence is lacking." BMJ 311(6999).

and freedom of movement has prompted most institutions to ban the practice except in rare circumstances.[200]

A common theme among the critics is that, against EBM's highly rationalized and algorithmic decisionmaking schemas, clinical decisionmaking relies on much more than the evidence.[201] In Culpepper and Gilbert's argument that the nature of general practice limits the extent to which EBM can be applied, they explain that

> patients frequently present with problems related to difficulties in coping with symptoms, their fears about their health, or early on in the natural history of an illness when signs and symptoms are nonspecific. The tools most helpful to the general practitioners include knowledge of both the patient and the natural history of the illness.[202]

In such circumstances, the main determinants of the "best" course of action are the physician's judgment guided by clinical experience, limited scientific evidence, and the patient's preference.[203] EBM appears to therefore err in trying to eschew clinical judgment (the know-how that comes from practice and experience) from the healthcare encounter.[204]

In contrast to Hope's general acquiescence to the evidence based approach, Kerridge et al.[205] present a review of ethical concerns associated with EBM that hinge on the fundamental counterclaim to EBM: the reliability of evidence does *not* lead to better decisionmaking. They see the strongest ethical argument in support of EBM to be the contention expressed by Hope (among others) that EBM improves our knowledge base

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[200] Culpepper and Gilbert (1999), "Evidence and ethics." Lancet 353(9155), p. 830.
[201] Kerridge *et al* (1998), "Ethics and evidence based medicine." BMJ 316(7138).
[202] Culpepper and Gilbert (1999), "Evidence and ethics." Lancet 353(9155) p. 829.
[203] Culpepper and Gilbert (1999), "Evidence and ethics." Lancet 353(9155), p. 829.
[204] We will return to the issue of clinical judgment later on. The issue of eliminating alternative sources of knowledge will also prove to be crucial to the meeting of ethics and epistemology in the ethics of evidence (see chapter 7).
[205] Kerridge *et al* (1998), "Ethics and evidence based medicine." BMJ 316(7138).

and therefore can improve health outcomes and engender more informed decisionmaking. Yet EBM's methodical approach can offer no mechanism for resolving such problems as:

(1) *immeasurable outcomes and intangible values*;[206]

EBM claims to provide a simple and logical process for reasoning and decisionmaking: look at the evidence and decide accordingly. But to make balanced decisions, all the relevant consequences of an action must be considered. This proves to be challenging. Current measures of some outcomes of medical treatment, such as pain, are inadequate; other outcomes, such as justice, may not be measurable; other complex outcomes, such as quality of life, may not even be adequately definable.[207]

When comparing competing values in healthcare, the difficulty arises that some values that are easily quantified into economic terms must be balanced against other values that are not quantifiable as such. Bernard Williams has noted that

> Again and again defenders of such values are faced with the dilemma of either refusing to quantify the value in question, in which case it disappears from the sum altogether, or else of trying to attach some quantity to it, in which case they misrepresent what they are about and also usually lose the argument, since the quantified value is not enough to tip the scale.[208]

The problems of immeasurable outcomes and intangible values surface in micro and macro-levels of healthcare decisionmaking when we face the dilemma of providing a costly, risky, yet potentially life-saving treatment to a terminally ill patient. In such cases, how does one measure justice and then balance it against mortality outcomes or cost?[209]

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[206] Kerridge *et al* (1998), "Ethics and evidence based medicine." BMJ 316(7138), p. 1151.
[207] Kerridge *et al* (1998), "Ethics and evidence based medicine." BMJ 316(7138), p. 1151.
[208] Williams (1972), Morality.
[209] Kerridge *et al* (1998), "Ethics and evidence based medicine." BMJ 316(7138), p. 1152.

(2) *competing claims by different interest groups*;[210]

For instance, Ruggeri and Tansella's evaluation of outcome measures in mental healthcare concluded that "studies should be comprehensive, to consider all parameters on which an intervention should be effective, and multiaxial, to consider various views by which the intervention would be considered effective".[211] The authors highlight the need to consider biological, psychological, and social outcomes from everyone's perspectives, but the question arises: what if those perspectives differ? What if a patient's family and physician want to place an elderly patient with dementia in a nursing home, while the specialist and social services do not? What evidence will then count? Different stakeholders may disagree as to what facts are pertinent. And what is pertinent seems like an evaluation: the evidence will not decide the matter.[212]

(3) *systematic bias in the allocation of resources to those treatments for which there is rigorous evidence of effectiveness, or towards those for which there are funds available to show effectiveness.*[213]

While EBM's high standards of evidence are meant to ensure the reliability of healthcare interventions, the time and cost associated with achieving this standard may limit the availability of worthwhile treatment, prophylaxis, and diagnostic programs for which there is limited evidence available. This is, of course, based on a conceptual mistake—the absence of evidence of effectiveness is not the same as evidence of ineffectiveness[214]—however EBM may still bias health policies in favour of industry-funded innovative pharmaceuticals.

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[210] Kerridge *et al* (1998), "Ethics and evidence based medicine." BMJ 316(7138), p. 1152

[211] Ruggeri and Tansella (1995), "Evaluating Outcomes in Mental Health Care." Current Opinion Psychol 8(3).

[212] Hughes (1996), "Evidence-based medicine and ethics." J Med Ethics 22(1).

[213] Kerridge *et al* (1998), "Ethics and evidence based medicine." BMJ 316(7138), p. 1153.

[214] Goodman (2005), "Ethics, evidence, and public policy." Persp in Biol Med 48(4), p. 552.

The ethics of EBM reviewed in this chapter ends with this critical conclusion: since EBM provides a focused approach to the interpretation of research findings and translates them into clinical options, it provides the clinician with a valuable tool for managing the knowledge base of medicine. However, this approach also focuses on average and mean effects and rarely provides guidance to help the physician tailor care and treatment to the individual patient. EBM also fails to provide guidance about how to respond to an individual patient's values, priorities, and socio-cultural needs.[215]

In Conclusion

The ethics of EBM's current preoccupation is with the impact of EBM on patient care. This focus was argued to be narrow in scope, as the complex picture of EBM illustrated in chapter one highlighted many other ethically relevant considerations. A more robust ethical analysis of EBM requires us to "dig into" the workings of EBM. Yet even within the current confines of the ethics of EBM, both the problems of application of research evidence to individual care plans and the incorporation of patients' preferences into evidence-based decisionmaking manage to challenge parts of EBM's epistemological basis on ethical grounds concerning patient care, thus forging initial connections between the ethics and epistemology of EBM. In an effort to draw further connections, the next chapter will turn the investigation toward the epistemological debates surrounding EBM. The "ethics of evidence" was mentioned earlier to offer a new area of investigation for healthcare ethics. Academic bioethics has been criticized for rarely interrogating the nature of medical knowledge in its reasoning; medical knowledge is frequently presumed to be scientific, uncontested, and imparted by the

[215] See, for example, Culpepper and Gilbert (1999), "Evidence and ethics." Lancet 353(9155).

clinician onto the individual patient.[216] In the context of informed consent, for example, medical knowledge is pressed to be made accessible and understandable to lay persons, however its "source"—a pool of clinically-derived and expert-sanctioned knowledge—goes uncontested. In an interesting contrast, clinical ethics, in fact, regularly faces the ethical challenges surrounding clinical uncertainty. I propose that the ethics of EBM must be broadened to consider more than the *impact* EBM has on patient care, and in the final chapter of this dissertation, the moral relevancy of the epistemic and related methodological issues surrounding EBM will be considered in a comprehensive review of the ethics of EBM.

[216] Belkin (2003), "Shifting the focus: the historical meaning of managed care and the search for ethics in mental health." Rationing sanity: Ethical issues in managed mental health care.

CHAPTER THREE

On Evidence in Evidence Based Medicine: An Epistemology Critique[217]

As the term "evidence-based decision-making" should suggest, "evidence" plays a prominent role in this particular configuration of medicine and medical decision-making. Quite surely, the founders of the EBM movement offered what is now the standard definition of EBM: "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients".[218] Yet standing in tension with the movement's fanfare as a new paradigm in medical education and practice is the seeming obviousness of EBM's claims. Modern medicine has, of course, always been understood to rely on empirical evidence in its experimental and justificatory practices. Despite the criticism that it offers nothing new, EBM has generated considerable attention as an innovative decision-making technology and has come to be widely regarded as the hallmark of "best practices" in medicine.[219]

To have evidence is to have some conceptual warrant for belief,[220] and it is the practice of basing all beliefs and practices strictly on (empirical) evidence that allegedly separates science from other activities.[221] The EBM movement promotes a more scientifically rigorous approach to medical practice via methodological clinical decision-making based on examination of evidence derived from the latest clinical research. This evidence is then proliferated using evolving information technologies, and evidence-

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[217] This chapter is based on: Goldenberg (2006), "On evidence and evidence-based medicine: Lessons from the philosophy of science." Soc Sci Med 62(11).
[218] Sackett *et al* (1996), "Evidence-based medicine: what it is and what it isn't." BMJ 312(7023), p. 71.
[219] The *New York Times Magazine* even named EBM as one of the most influential ideas of 2001.
[220] Goodman (2003), Ethics and evidence-based medicine: Fallibility and responsibility in clinical science, p. 2.
[221] Husserl (1982), Ideas pertaining to a pure phenomenology and a phenomenological philosophy: First book: General introduction to a pure phenomenology; Kuhn (1996), The structure of scientific revolutions.

based medicine aficionados, such as those found in the Cochrane Collaboration[222] and on the editorial boards of various evidence-based practice journals, describe the movement as a new paradigm in medical education and practice, a description that carries with it a science enthusiasm that has not been seen since the days of positivism.

The apparent obviousness of basing scientific medicine on the evidence has, of course, not gone unnoticed, but this factor has made EBM difficult to argue against. Few doctors, one suspects, would be willing to assert that they do not attempt to base their clinical decision making on available evidence. However the apparent obviousness of EBM has been challenged on the grounds of how "evidence" has been problematized in the philosophy of science. In this chapter, the positivist understanding of evidence as "facts" about the world maintained in EBM is shown to be untenable, as such a picture of science has been seriously undermined by "postpositive" philosophies of science. EBM's ability to guide healthcare decision making by appealing to "the evidence" as the bottom line is attractive to many because it proposes to rationalize this complex social process. Yet it does so through the positivistic elimination of culture, contexts, and the subjects of knowledge production from consideration, a move that permits the use of evidence as a political instrument where power interests can be obscured by seemingly neutral technical resolve.

Logical positivism is a philosophical system that recognizes only scientifically verifiable propositions as meaningful. This school of thought originated in Vienna in the 1920s by a group of philosophers and scientists concerned with the philosophy of formal and physical science, however it was their attitude toward science and its relationship to

[222] Grimshaw (2004), "So what has the Cochrane Collaboration ever done for us? A report card on the first 10 years." Can Med Assoc J 171(7).

philosophy that defines the "Vienna Circle". Because the Circle rejected the possibility of justifying knowledge claims that were "beyond" the scope of science, they dismissed *meta*physics and many of the claims made in theology and ethics as nonsensical (or unverifiable). Emigration by many of the Circle's members to Britain and the United States during the early war years led to the strong influence of logical positivism on Anglo-American analytic philosophy. The "post-positive" turn in the philosophy of science refers to the critical examinations of scientific thought and practice that originated in the second half of the 20th century by such historically-oriented philosophers as Thomas Kuhn, Norwood Hanson, and Paul Feyerabend. Their historical analyses of scientific change and progress undermined the positivist-empiricist endorsement of the claims of science to provide a value-free understanding of the natural world. Their examination of the relationship between science and values (and the denial of their possible or even preferable separation) has been enriched by the insights of feminist epistemologies of science and phenomenological investigations. Feminist epistemologists have exposed the political stakes in knowledge production by demonstrating the androcentric assumptions underlying conventional understandings of scientific thought and practice, while phenomenologists have questioned the goals and methods of scientific medicine (including what forms of evidence are pursued) through examination of the patient's lived experience of illness and dis-ease. Postpositivist, feminist, and phenomenological epistemologies of science's critiques of the presumed "self-apparentness" of evidence have been deployed in undermining the configuration of evidence underlying the evidence based approach.

Evidence and Evidence Based Medicine

The popular histories of science recount scientific progress as having been motivated by the evidence-based practices of innovative scientists. Rejecting the dogma and superstition that pervaded their historical moment, these innovators let the evidence, gathered through careful and unbiased experimental methods, dictate their beliefs and scientific theories.[223] Thus science purports to be a democratic enterprise insofar as the beliefs of the Church, accomplished colleagues, or department chairs are subject to the same critical inquiry as lay beliefs.

"Evidence-based" is typically read in medicine and other life and social sciences as the empirically adequate standard of reasonable practice and a means for increasing certainty. Evidence-based practices are therefore enormously appealing in the age of moral pluralism; rather than relying explicit values that are likely not shared by all, "the evidence" is proposed to adjudicate between competing claims. However the notion that any claim (including scientific beliefs) can stand or fall in light of the evidence assumes a "givenness" of evidence as "facts" about the world. Positivistic empiricists have regarded evidence in this way: any bias that enters scientific inquiry in the *context of discovery* is eradicated in the purifying process of the *context of justification.* The evidence left standing after scientific inquiry is assumed to be "facts" about the world and therefore warrants the title *scientific* evidence.

EBM promotes such a scientistic conception of evidence in its endorsement of evidence derived from systematic and methodologically rigorous clinical research and maligning the use of intuition, unsystematic clinical experience, patient and professional

[223] Harding (1986), The science question in feminism; Kuhn (1996), The structure of scientific revolutions.

values, and pathophysiologic rationale.[224] This preference has prompted critics to detail other sources of evidence that enter into clinical decision making[225] and to defend the unsystematic intuitions and expertise that arise from clinical experience as epistemically significant and indispensable to clinical decision-making.[226] Yet even before we consider the complex nature of clinical decisionmaking, we can question the very tenability of the conception of evidence being assumed in evidence-based practice. In this chapter, I draw on major lines of thinking in the philosophy of science over the past half century to question the "evidence base" of EBM.

Postpositivist Philosophy of Science

Much of the philosophy of science over the last half century has been preoccupied with challenging the positivist picture of scientific methodology on two grounds. In the first, Hanson,[227] Kuhn,[228] and Feyerabend[229] have claimed that observation is theory-laden, that is, our observations are "coloured" by our background beliefs and assumptions (and therefore can never be, even under the most ideal circumstances or controlled experimental settings, the unmitigated perception of the nature of things). In the second, Pierre Duhem[230] and W.V. Quine[231] have argued that theories are underdetermined by

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[224] Buetow and Keneally (2000), "Evidence-based medicine: Bridge-building a medicine of meaning." J Eval Clin Prac 6(2); Evidence Based Medicine Working Group (1992), "Evidence-based medicine." JAMA 268(17).

[225] Buetow and Keneally (2000), "Evidence-based medicine: Bridge-building a medicine of meaning." J Eval Clin Prac 6(2); Upshur *et al* (2001), "Meaning and measurement: an inclusive model of evidence in health care." J Eval Clin Prac 7(2); Buetow (2002), "Beyond evidence-based medicine: Bridge-building a medicine of meaning." J Eval Clin Prac 8(2).

[226] Tanenbaum (1993), "What physicians know." N Engl J Med 329(17).

[227] Hanson (1958), Patterns of discovery.

[228] Kuhn (1996), The structure of scientific revolutions; Kuhn (1970), "Reflections on my critics." Criticisms and the growth of knowledge.

[229] Feyerabend (1978), Against method.

[230] Duhem (1982), The aim and structure of physical theory.

[231] Quine (1960), Word and object.

data. In other words, our theory choices are never determined exclusively by "the evidence".

The first claim is damaging (if not devastating) to the positivist empiricist picture because the principles of empiricism are tendered against the background presupposition that, at least under carefully controlled and intersubjectively repeatable circumstances, one's perceptions are unaffected by the beliefs one has and by the assumptions one makes about the objects that one is observing. These observations are supposed to provide a maximally certain foundation of empirical knowledge, a foundation that supplies the basic premises of all our reasoning and without which there would not even be any probable knowledge. Empiricist epistemology, from David Hume's[232] 18th century configuration onward, seems to rest on the assumption that there can be an absolutely stable and invariant correspondence between perceptions and the stimuli which produce them. Logical positivists advanced this position through their alternative linguistically-oriented philosophical programme that disavowed metaphysics and promoted the verifiability criterion of meaning. The verifiability principle asserts that a statement is meaningful if and only if you can state what sense observations would determine whether it is true or false (i.e. the statement must be empirically verifiable in order to be meaningful). One intended consequence of the verifiability criterion is that all non-empirical forms of discourse, including ethics and aesthetics, are not "literally" or "cognitively" meaningful, and thus belong to "metaphysics".[233] This basic tenet of logical positivism is attributed to the influence of Ludwig Wittgenstein's[234] *Tractatus*

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[232] Hume (1977), An enquiry concerning human understanding; Hume (2000), A treatise of human nature.
[233] For a classic expression of this view, see Carnap, "The elimination of metaphysics through logical analysis of language." Logical positivism, pp. 60-81.
[234] Wittgenstein was never a member of the Vienna Circle.

Logico-Philosophicus, which proposes a general theory of linguistic representation, according to which propositions are "logical pictures" of possible facts. This implied that a proposition is not meaningful unless it determines a precise range of circumstances in which it is true. A partial exception to this theory of meaning was made for tautologies (such as "Either it is raining or it is not raining") and contradictions (such as "It is raining and it is not raining"), since such propositions say nothing: they are, respectively, true or false in all possible circumstances. They show, however, the workings of the "logical constants": not, or, and, etc. In metaphysics, however, philosophers have often tried to say something about reality as a whole, making *claims so general and fundamental that they are arguably indifferent to the particular facts of the world.* On Wittgenstein's theory of language, such claims are literally nonsensical words without meaning.[235]

A. J. Ayer, the Circle member credited with introducing logical positivism to the English-speaking world, formulated the verifiability criterion of meaning.

> To be literally meaningful, while not analytic, a statement must be such that an observation statement can be deduced from it in conjunction with certain other premises, that could not be deduced from those premises alone.[236]

Statements are only meaningful when they are directly verifiable (i.e. they are observation statements) or they are derivable from observation statements. Because no statement which refers to a "reality" transcending the limits of all possible sense-experience can possibly have any literal significance, he held that "our charge against the metaphysician is not that he attempts to employ the understanding in a field where it

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[235] Wittgenstein (2001), Tractatus logico-philosophicus.
[236] Ayer (1936), Language, truth, and logic, p. 190.

cannot profitably venture, but that he produces sentences which fail to conform to the conditions under which alone a sentence can be literally significant."[237]

The postpositivist critics mentioned above object that observations can never be "givens" or "data", but are always the product of interpretation (in light of our background assumptions). The idea of unambiguous objects of perception is simply a myth, and so the positivist grounding of observational statements as foundational to true knowledge, as well as the maligning of all areas of inquiry that use nonempirical (and nonlinguistic) modes of analysis, creates a problematic epistemic framework.

The charge that theories are underdetermined by data—commonly referred to as the "Duhem-Quine thesis" in the philosophy of science—concerns the claim that any given body of evidence may support numerous, even contradicting, theories. The charge once again undermines empirical science's self-understanding as an objective enterprise that progresses (i.e. accepts, refines, or rejects scientific theories) in light of how theories stand up to empirical evidence. Since scientific theories are deductively underdetermined by the data, scientists must adopt extraempirical criteria for what counts as a good theory when deciding to accept one theory in preference over its empirically adequate rivals. This "extraempirical criteria" can be subject to the whims, preferences, biases, and social agendas of the researching scientists, and not the rigour of evidenced-based adjudication.[238]

While the "theory ladenness" objection challenges the stability of observations themselves, the "underdetermination" thesis undermines the stability of evidential relations. Both accounts have seemed to permit the unrestrained expression of scientists'

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[237] Ayer, Language, truth, and logic, p. 182.
[238] Of course, empiricists hold some extraempirical criteria to be more epistemically justifiable than others, such as "theoretical simplicity" or vulnerability to refutation.

subjective preferences in the content of science. If observation is theory-laden, then it cannot serve as an independent constraint on theories, thus permitting subjective elements to constrain theory choice. Similarly if observations acquire evidential relevance only in the context of a set of assumptions, a relevance that changes with a suitable change in assumptions, then it is not clear what protects theory choice from subjective elements hidden in one's background assumptions. Although empirical adequacy (the ability of a theory to predict empirical events) serves as a constraint on theory acceptance, it is not sufficient to pick out one theory from all contenders as the true theory regarding a domain of the natural world.

Postpositive Implications for EBM

A 1995 publication in *The Lancet* documented the disagreement among members of a research team regarding the interpretation of their trial results for streptokinase treatment for acute ischemic stroke.[239] Upon "agreeing to disagree", the team presented two views.[240] No one position was seen to be wrong at least insofar as both sides appeared to be supported by the clinical data.[241] In the editorial introducing the opposing conclusions, Richard Horton, the journal's editor-in-chief, mused that

> exposure of the sharp intellectual conflicts that developed in MAST-I [Multicentre Acute Stroke Trial – Italy] reveals the interpretive fluidity of science, a state that is commonly unacknowledged in a published scientific text and one that is often neglected when applying uncertain evidence, even from large randomized trials or meta-analyses, in the clinic.[242]

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[239] Horton (1995), "MAST-I: Agreeing to disagree." Lancet 346(8989).
[240] See Candelise *et al* (1995), "Randomized controlled trial of streptokinase, aspirin, and combination of both in treatment of acute ischemic stroke." Lancet 346(8989); Tognoni and Roncaglioni (1995), "Dissent: An alternative interpretation of MASTI-I." Lancet 346(8989).
[241] Horton (1995), "MAST-I: Agreeing to disagree." Lancet 346(8989).
[242] Horton (1995), "MAST-I: Agreeing to disagree." Lancet 346(8989), p. 747.

Horton's editorial recounted that there had been serious dispute among the writing committee of the multi-centre trial about the presentation of MASTI-I regarding the interpretation of the trial results. One camp held a guarded view of the applicability of the findings to treatment while members of the other side were more optimistic about the *same* evidence. A manuscript articulating the majority view was submitted to the *Lancet* without comment on the disagreement. Horton recounts, however, one missed clue: in the covering letter accompanying the submission, Dr. Candelise, the primary investigator, had written that "the present version of the article has been approved by *a majority* of the steering committee."[243] The journal editors only caught wind of the conflict when they asked for commentary by the research group on contradictory reviews of the study by two experts in stroke research that, in fact, mirrored the researchers' dispute. The editorial team proceeded to work up the manuscript for publication, but when the version of MAST-I that was eventually accepted for publication was sent to the group to confirm authorship, two senior researchers, Drs. Tognoni and Roncaglioni, could not sign onto it.

The points of dispute were two-fold: first, disagreement over the emphasis that should be placed on subgroup analyses, and second, regarding the validity of statements about efficacy in a study that ran less than half its course. Horton maintained that the issue of safety was an overriding concern for all investigators, but this priority may have been diluted by including speculative comments about efficacy. What is relevant to the postpositivist claims about the nature of evidence is that the *same* data led to this disagreement. The conflict was over the interpretation of evidence.

Horton closes with the editorial commentary that differences of opinion should

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[243] Horton (1995), "MAST-I: Agreeing to disagree." Lancet 346(8989) (my emphasis).

not be silenced. To encourage their explicit expression in future submissions to the journal, he writes:

> *The Lancet* encourages interpretive dissent between authors, ideally within the confines of the final research report. But if consensus cannot be achieved, authors should be willing to agree to disagree. If an anguished dispute over interpretation cannot be settled, [the editors] will provide authors with the opportunity to publish their legitimate dissent alongside their now orphaned article.[244]

Despite this advocacy of democratic debate within the medical literature, Horton concedes that a worrying question remains about the validity of published trial data: "how often are differences of interpretation about data suppressed in the final published record either by force of majority or personality?"[245]

Before drawing from the MAST-I case negative conclusions about EBM, it is worth asking whether this problem of interpretation is unique to EBM or whether it applies equally to non-evidence-based protocols. EBM, of course, does not use unique methodology compared to its predecessors. However it does convey a clear methodological preferencing. The MAST-I study is "evidence based" insofar as its methodology would rank highly among EBM's hierarchy of evidence: the study was large, the subjects were randomized, and rigorous statistical methods were used for comparative analysis. The MAST-I case is damning to EBM's claims of methodological superiority because here we have an instance of the evidence based approach *failing* to "eschew unsystematic and intuitive methods" from medicine.

Yet even before the interpretation of evidence begins, empirical evidence undergoes numerous subjective interpretations. Even within the confines of strictly *evidence-based* practice, there is room for dispute regarding the design of a study on the

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[244] Horton (1995), "MAST-I: Agreeing to disagree." Lancet 346(8989), p. 747.
[245] Horton (1995), "MAST-I: Agreeing to disagree." Lancet 346(8989).

grounds of measurement error, contaminated solution, malfunctioned equipment, poor design, or bias, and there are no predetermined rules for the statistical interpretation of the results of a test.[246] Once the data is interpreted and the study is published—creating another layer of selection—the highly prized meta-analysis provides a further level of interpretation, one that is notably "high impact" insofar as it carries the institutional brand "evidence-based medicine" and because individual practitioners that rely on these summaries for evidence-based decision-making are no longer critically reading the trial data. Finally, the practitioner must apply one more layer of interpretation in her application of trial results to a specific patient. The formal methods promoted by EBM to replace so-called "traditional" medicine's over-reliance on intuition, habits, and unsystematic clinical experience[247] appear to repeat the misplaced effort to separate science from values.

Even the evidence based approach involves a host of normative judgments regarding what evidence is admissible and how strongly the different forms of admissible evidence should be weighted. Thus judgments must be made at all levels of research, data analysis, and application—Steven Goodman, for example, writes about a U.S. policy dispute over mammograms that faltered on what studies should be included or excluded for evidentiary consideration.[248] EBM offers only guidelines for conducting RCTs, and there is currently no standard way of doing RCTs.[249] Therefore, discord can arise regarding what counts as a "sufficiently valid" RCT that should be included in policy

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[246] Shahar (1997), "A Popperian perspective of the term 'evidence based medicine'." J Eval Clin Prac 3(2).
[247] Evidence Based Medicine Working Group (1992), "Evidence-based medicine." JAMA 268(17).
[248] Goodman (2002), "The mammography dilemma: A crisis for evidence-based medicine?" Ann Int Med 137(5).
[249] Hoey (2006), "Editorial and scientific independence: Misreading the evidence, misleading the public." Ruth Cooperstock Memorial Lectureship.

considerations.[250] Goodman proposes that it is only when there is consensus on these judgments—for instance, in studies where the data confirming or denying a hypothesis is strong—"that an illusion is created that the evidence is speaking for itself and that the methods are objective."[251] Cases such as MAST-I and the "mammography dilemma" should raise awareness that judgment cannot be excised from the process of evidence synthesis.

Feminist Epistemologies of Science

Feminist philosophers endorse the post-positivistic conclusions derived from analyses of the relations between observation, evidence, and theory and have taken the critique of empiricist epistemology further to challenge empiricism's "silent partner": the theory of the unconditioned subject. This unbiased observer is argued in feminist thought to be the necessary companion to empiricist epistemology, and reflection on this subject's unusual and implausible ontology reveals further difficulties with positivist thought. Positivism, therefore, not only errs in holding sensory observation in ideal observation conditions as the privileged source of knowledge, but also inappropriately attaches a dubious theory of epistemic agency in which knowers are detached and neutral spectators separate from the objects of knowledge. Positivist empiricism does not, in fact, yield neutral and universally valid conceptions of knowledge. Instead, knowledge is indelibly shaped by its creators and attests to the specificities of their epistemic locations. Indeed, it is *because* subjects are characterized as irrelevant to knowledge claims in positivist

[250] Goodman (2002), "The mammography dilemma: A crisis for evidence-based medicine?" Ann Int Med 137(5).
[251] Goodman (2002), "The mammography dilemma: A crisis for evidence-based medicine?" Ann Int Med 137(5), p. 364.

epistemologies that knowledge can appear to be verifiable by appeals to the evidence.[252]

Notions of evidence and theories of epistemic agency are, therefore, closely related. Donna Haraway argues that the notion of "matters of fact" depends on many kinds of transparencies in the grand narratives of the experimental way of life.[253] The "modest witness", the protagonist of the dramas of the Scientific Revolution who testifies without prejudice to new facts, had to be constructed in sufficiently detached and abstracted terms to make plausible the unusual situation where *his* experiences could somehow represent everyone's and no-one-in-particular's experiences. Notions of evidence as "self-appearing" similarly rely on such a knower.[254]

Feminist epistemologies of science have demonstrated that the ideals of the autonomous knower—the dislocated, disinterested observer—and the epistemologies they inform are the artefacts of a small, privileged group of educated and prosperous white men. Their material circumstances allow them to believe that they are autonomous individuals without specific locations (i.e. gendered or raced) *even* in their positions of privilege.[255] Haraway's postulation of such a "modest man", whose narratives mirror reality, requires invisibility, such that "such a man must inhabit the space perceived by its inhabitants to be the 'culture of no-culture'."[256]

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[252] Code (1993), "Taking subjectivity into account." Feminist epistemologies, p. 17.
[253] Haraway (1996), "Modest witness: Feminist diffractions in science studies." The disunity of science: Boundaries, contexts, and power.
[254] Nelson (1993), "Epistemological communities." Feminist epistemologies.
[255] Feminist psychologists have argued that affluent white boys are nurtured to embody the psychosocial characteristics needed for detached and objective knowledge seeking, deliberation, and work. For example, see Keller (1985), Reflections on gender and science and Bordo (1987), The flight to objectivity: Essays on Cartesianism and culture. It should therefore be no surprise that they can come to see themselves as disembodied rational beings.
[256] Haraway (1996), "Modest witness: Feminist diffractions in science studies." The disunity of science: Boundaries, contexts, and power, p. 429.

In this culture, the inhabitant's contingencies can be established with all of the authority, but none of the considerable problems, of transcendental truth. His modesty is of a specifically modern, professional, European, masculine and scientific form (and is therefore very different from the virtue typically attributed to women), and it imbues him with a disguised epistemological and social power concealed by modernist ideals of "rationality", "objectivity", and "value-neutrality". His modesty guarantees his legitimacy as an "authorized ventriloquist for the object world, adding nothing from his mere opinions, from his biasing embodiment. And so he is endowed with the remarkable power to establish the facts. He bears witness."[257]

Feminist epistemologists of science charge that underlying the orthodox account of scientific investigation and justification is a presumed universality of experience (or at least the potential for such universality through the refined abilities of the modest witness), which presumes, in turn, both a view of evidence and a view of knowers, where individuals can have unmediated or unfiltered access to a reality that itself admits of only one systematization.[258] In what appears to be an equation of "orthodox empiricism" with naïve realism, Nelson, among others, proposes that it is only by positing this framework of a shared reality experientially accessible to all sentient beings that anybody (or everybody) can discover, observe, or witness truths about the world. While one's faith in such universality might be partly underwritten by similarities in sense organs, it also requires that there is a unique, true theory of nature and that our sense organs are sufficiently refined to discover it and discriminate it from possible alternatives.[259]

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[257] Haraway (1996), "Modest witness: Feminist diffractions in science studies." The disunity of science: Boundaries, contexts, and power, p. 429.
[258] Nelson (1993), "Epistemological communities." Feminist epistemologies, p. 131.
[259] Nelson (1993), "Epistemological communities." Feminist epistemologies, p. 132.

Experience alone, however, does not warrant the assumption that only one system could organize the world or that the world is of a determinate nature, specifiable in categories that our sense organs will lead us to discover. There is nothing in our experience to rule out the possibility of a future theory that is commensurate with all of our experiences to date but incompatible with the current theory. There is also nothing in our experience or in our current knowledge about our sense organs to warrant the inference that they are able to discriminate a "best" theory of nature (if, indeed, there is such a thing) from multiple candidates.[260]

Feminist epistemologists are particularly resistant to the notion of shared experience that supports orthodox empiricism because feminist investigations into the lives of women reveal great diversity of experiences, many of which are distinctly gendered, raced, classed, or mediated by numerous other social stratifications. For orthodox empiricists (including positivists, who apply radical empiricist epistemology to science), historical, gendered, and locational differences between and among knowers reduce to bias or aberration and should be discounted in formal justification procedures. Feminists object that such reductions exclude and even harm women, as the so-called universals that are thought to underlie the social context (and serve as the foundation of scientific knowledge) are distinctly androcentric. This claim has been illustrated by numerous documentations of gender bias in the natural and biological science.[261] For all

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[260] It should be noticeable, at this point, that empiricists *should* presumably agree with this feminist commentary, as empiricism is a fallibilist theory. Current science, for example, is merely the set of beliefs that are currently the most reasonable to believe. Nelson advocates feminist empiricism, and Feyerabend writes on "How to be a Good Empiricist" to highlight the need to deny the tendency among the "orthodoxy" to subscribe to positivist/objectivist thinking.

[261] For example, see Hubbard and Lowe, eds. (1979). Genes and gender; Fausto-Sterling (1989), "Life in the XY corral." Women's Studies Int Forum 12(3); Fausto-Sterling (1992), Myths of gender: Biological theories about women and men; Keller (1985), Reflections on gender and science; Haraway (1989),

of its alleged experiential grounding, the experience with which empiricism works is an abstraction in which cognitive specificities are homogenized under one dominant conception of what counts as knowledge and of who qualifies as a knower. In practice, those conceptions mirror and replicate the experiences that their (usually white, male, prosperous, and educated) creators are positioned to regard as exemplary.[262]

The inexactness of the term "experience" seems to allow it to resonate in many ways, to function as a universally understood category, and to create a sense of consensus by attributing to it an assumed stable and shared meaning.[263] By assuming it as a foundational concept in empiricist epistemology, experience is protected from different meanings and relativisms, and therefore establishes the possibility for objective knowledge.[264] This move effectively removes subjects from critical scrutiny as active producers of knowledge, and it is this insistence of separation of meaning and experience that is crucial. Epistemology constructs "truth" on the foundation of the speaker's irrelevance.[265]

That speaker is, of course, the modest witness. It has already been discussed how he bears witness in his unbiased accounts of the world. His modesty authorizes him to do so. His subjectivity, therefore, *is* his objectivity. Lorraine Code has argued that "objectivity" is "a generalization from the *subjectivity* of quite a small group."[266] However, this group "has the power, security, and prestige to...generalize its experiences and normative ideals across the social order thus producing a group of like minded

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Primate vision: Gender, race, and nature in the world of modern science; Haraway (1991), Simians, cyborgs, and women: The reinvention of nature.

[262] Code (1991), What can she know? Feminist theory and the construction of knowledge.

[263] Scott (1991), "The evidence of experience." Crit Inquiry 178(3), p. 782.

[264] Scott (1991), "The evidence of experience." Crit Inquiry 178(3), p. 785.

[265] Scott (1991), "The evidence of experience." Crit Inquiry 178(3), p. 785.

[266] Code (1993), "Taking subjectivity into account." Feminist epistemologies, p. 22.

practitioners ('we') and dismissing 'others' as deviant and aberrant ('they')."[267] Within the privileged "culture of no culture", the witness's narratives "lose all trace of their history as stories, as products of partisan projects, as contestable representations, or as constructed documents in their potent capacity to define the facts."[268] The evidence of experience is therefore called into question.

For positivist epistemologies, of which medicine retains its residue, sensory observation and experience in ideal conditions is a privileged source of knowledge offering the best promise of certainty. When experience is taken as the origin of knowledge, the individual subject's perception becomes the bedrock of evidence on which explanation is built at the expense of inquiry into subject formation. Joan Scott argues that reliance on experience precludes critical examination of the workings of the ideological system itself, its categories of representation (such as man, woman, homosexual, heterosexual), its premises about what these categories mean and how they operate, and of its notions of subjects, origins, and cause. Instead "experience" reproduces its terms: it does not allow us to see that it is not the individuals who *have* experience, but subjects who are constituted *through* experience.[269] By taking experience to be a given, and ignoring how discourse and history structure one's experiences, the status quo—the same social order that maintains the privilege of the modest witness—is left unexamined.

Because knowers are understood to be collaborative agents, whose epistemic projects are shaped by, and evaluated within, the communities where their knowledge-

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[267] Code (1993), "Taking subjectivity into account." Feminist epistemologies, p. 22.
[268] Haraway (1996), "Modest witness: Feminist diffractions in science studies." The disunity of science: Boundaries, contexts, and power, p. 429.
[269] Scott (1991), "The evidence of experience." Crit Inquiry 178(3), p. 777.

producing practices occur, standards of evidence are by no means "self announcing", but rather socially and historically relative, dynamic, and of our own making.[270] While experience can remain central to our evidential claims, it must be understood to be inherently social, for we experience the world through the lens of our projects, categories, theories, and standards. Therefore, what constitutes evidence for specific claims or theories includes not only experience, but also the knowledge and standards constructed and adopted by epistemological communities.[271] Against the insistence of radical empiricists, feminists contend that science is not a value-free enterprise. Even the notion of empirical adequacy is conditioned by a set of beliefs which cannot be disentangled into "factual" and "evaluative" categories.[272] The benefit of unmasking the assumptions, norms, and values at play in scientific inquiry is that we can now address the important socio-political question of which values *ought* to enter the scientific arena.

In sum, feminist insights tell us that rather than empirical evidence *increasing* certainty by factoring out the subjective features of everydayness that bias our understanding of things, the constructs of "objectivity", "universality", and "value-free" instead *obscure* the subjective elements that inescapably enter all forms of human inquiry. Since the evidence is by no means objective or neutral, but rather part of a social system of knowledge production, many feminist epistemologists recommend social models of scientific practice. This model entails recognizing our background assumptions as playing a *constitutive* (and not a biasing) role in knowledge acquisition and evaluation.[273] Scientific inquiry cannot be value-free, as traditional empiricists

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[270] Nelson (1993), "Epistemological communities." Feminist epistemologies.
[271] Nelson (1993), "Epistemological communities." Feminist epistemologies, p. 142.
[272] Nelson (1993), "A question of evidence." Hypatia 8(2).
[273] Longino (1990), Science as social knowledge: Values and objectivity in scientific inquiry.

required, for cultural and social values make knowledge possible. These values must, of course, be subject to examination and critique, ideally by those from outside of the community who do not share those cultural assumptions. Thus the evaluation of scientific beliefs becomes more rigorous: in addition to demonstrating empirical adequacy, scientific beliefs must be subject to public scientific inquiry, where the background assumptions motivating the investigation are explicitly recognized and therefore subject to the same critical scrutiny that "good empiricists"[274] subject their knowledge claims. This public activity not only raises the standards of theoretical adequacy, but also better mediates the knowledge/power interplay in scientific investigation. Once we recognize that an uninterrogated conception of empirical adequacy is not sufficient to act as a criterion of theory choice, we can turn to the question of what epistemological virtues we want our theories to additionally display. A feminist philosophy of science is explicitly political—as contrasted with the *implicit* political character of other philosophies of science—as science is recognized to be a vehicle for feminism's emancipatory programme.

Feminist Implications for EBM

Against feminist misgivings about so-called objectivity, rationality, and value-neutrality, EBM proposes to introduce rational order into the deliberative processes of healthcare decision-making. The epistemic concerns of feminist scientists and philosophers are accompanied by a feminist commitment to improving the lives of women.[275] Feminist critiques of science are driven by a deep concern that the

[274] Feyerabend (1998), "How to be a good empiricist: A plea for tolerance in matters epistemological." Philosophy of science: The central issues.

[275] Of course, proponents of evidence based approaches to women's health may similarly hold that desire and testify to the improvements to women's healthcare that can arise from the rigorous evaluation of

abstractions made in the names of scientific objectivity, generalizability, and predictability harm women. These tendencies appear to resurface in the practice of EBM.

EBM promises consistent and impartial evidence about the benefits and harms of treatments due to the transparent use of high quality primary research in systematic reviews and meta-analyses. These results are then applied in equally transparent processes to make clinical decisions.[276] Feminist insight reveals that the practices of EBM are marked by potential or actual gender bias, which has led at least one critic—Rogers[277]—to argue that EBM is bad for women's health. Despite the idealistic suggestion that evidence-based methods can improve women's health by making available more high quality data regarding the efficacy of different treatments, thus leading to more informed treatment choices by and for women, EBM, according to Rogers, is in fact "superimposed upon current medical practice, repeating and reinforcing existing biases against women, both in research and in treatment."[278] The shortcomings of biomedicine for properly addressing women's health needs, as articulated by feminist scholars and allies of the women's health movement over the past few decades, are not corrected by evidence-based medical practice.

Because evidence-based clinical decision-making, policy determinations, and the formulation of clinical guidelines rely upon existing clinical research, the movement reflects any gaps or biases that currently exist in medical research. Women's health research has been marked by a sexist research agenda that over-focuses on women's

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current women's health practices. There is disagreement within the field of women's health regarding the advantages and disadvantages of evidence based women's healthcare.

[276] Rogers (2004), "Does evidence-based medicine offer fair benefits for all?" Ethics J Am Med Assoc 6.

[277] Rogers (2004), "Evidence-based medicine and women: Do the principles and practices of EBM further women's health?" Bioethics 18(1).

[278] Rogers (2004), "Evidence-based medicine and women: Do the principles and practices of EBM further women's health?" Bioethics 18(1), p. 54.

reproductive-related issues (fertility, menstruation, menopause, and breast and gynecological cancers) while failing to properly investigate gender dimensions of other health problems that appear to have sex-differentiated causes, incidences, responses to treatment, and prognoses due to a combination of biological factors, social conditions, and social processes.[279] Some examples include HIV/AIDS, coronary heart disease, depression, and tuberculosis.

Gender bias also arises in the performance of research, where women have been grossly underrepresented as subjects in clinical trials.[280] This exclusion has been justified on the grounds of the need for homogenous subject populations, the fear of harms to pregnant women and offspring, the alleged difficulties accounting for women's hormonal fluctuations in data analysis, and the purported difficulties recruiting women.[281] Critics insist, however, that biological differences between men and women are significant enough that research evidence is often *not* relevant to women and therefore the use of medical technologies on and by female patients is dangerous. Despite robust criticism, the bias towards male participants in research trials remains. In the US, 85% of research participants are male; this rises to 95% in Canada.[282]

The fact that certain areas of women's health are underresearched, others are overresearched, and other areas of health research lack evidence relevant to women suggests that the evidence that serves as the basis for evidence-based medicine may not be helpful for women. EBM is implicated for the past mistakes of medicine because it

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[279] Rogers (2004), "Evidence-based medicine and women: Do the principles and practices of EBM further women's health?" Bioethics 18(1).
[280] Dresser (1992), "Wanted: Single, white male for medical research." Hastings Centr Rep 22(1); Merton (1993), "The exclusion of pregnant, pregnable, and once-pregnable people (AKA women) from biomedical research." Am J Law Med 19(4). *NB*: This is especially the case for women of colour and elderly women.
[281] Dresser (1992), "Wanted: Single, white male for medical research." Hastings Centr Rep 22(1).
[282] Sherr (2000), "Women and clinical trials." Women, Health, and the Mind

presents much of this evidence as authoritative and even arguably reifies much of the thinking and methods that allowed for these egregious gaps in research to occur in the first place. While informed by feminist epistemological insight, this critique is largely methodological rather than epistemological, as it demonstrates EBM to fail on its own terms by not meeting its own standard of best evidence for women's health. Irrespective of the epistemological critiques of what constitutes the "evidence base" of EBM, the evidence is only rigorous by EBM's own standards for the select male populations that are properly represented as research subjects in clinical trials. The internal or methodological critiques of EBM was detailed in chapter one, where the pride of place given to the randomized control trial as the "gold standard" of medical research was challenged.

Feminist researchers have found bias against women not only in the production of the research that informs EBM, but also in the purportedly fair methods used to analyze and synthesize the evidence.[283] A common critique of EBM's pre-graded evidence hierarchies is that they do not acknowledge that research methods must be tailored to the question at hand, and that different questions gather best evidence from different research designs. Leaving aside the gendering of the quantitative vs. qualitative debates in the social sciences—with the former being regarded as "masculine" and the latter as "feminine"[284]—qualitative methods have been favoured by many feminist researchers for allowing the voices of women to be heard in describing problems and in finding solutions. The endorsement of an evidence hierarchy that discounts evidence from qualitative research has implications for women's health insofar as health interventions

[283] Rogers (2004), "Evidence-based medicine and women: Do the principles and practices of EBM further women's health?" Bioethics 18(1).
[284] Oakley (2000), Experiments in knowing: Gender and method in the social sciences.

that recognize the social and political context contributing to women's poor health have consistently proven to be more effective in improving health outcomes. Because judgment cannot be excised from the process of evidence synthesis, qualitative research can be instrumental in deciphering the underlying assumptions that, say, policy makers bring into their formulations of mammogram guidelines. Further research into how those assumptions correspond with the expectations of the women being encouraged to partake in screening regimes can ensure better policies and better rates of compliance. EBM methodology in fact supports a reductionist model of health and disease that is not amenable to the crucial social, political, and experiential determinants of women's health.

Phenomenology of Science and Medicine

Phenomenological approaches to science and medicine further challenge notions of evidence in evidence-based medicine by questioning why relevant evidence is assumed to come primarily from clinical trials and other "objective" measures. They argue instead that the patient's self-understanding and experience of illness[285] also offers a legitimate source of relevant medical knowledge. This theoretical approach is grounded in the philosophy of Edmund Husserl and his followers who questioned the philosophical completeness of natural sciences. They argued that Cartesian dualism, which split the world into minds and bodies, the spiritual and the physical, was erroneous and created a truncated body of science that exhibited impressive technological ability to control nature but could not address questions of human self-understanding. This led to a

[285] The emphasis on the patient's *experience* of illness in medical phenomenology may seem, at first, to be at odds with feminist epistemology, where the evidence of experience is suspect. Feminists speak to supposedly universal sensory experience, which is shared by ideal observers and grounds empiricist knowledge claims, however, while phenomenologists focus on the very subjective experience of illness (or the illness narrative).

"crisis of meaning", which Husserl attributes to the failure of positivist natural science.[286]

The biomedical model is charged with suffering from similar problems, as the technological abilities of modern medicine fail to address the existentiality of illness. Self-proclaimed "medical humanists" like Stanley Reiser,[287] David Reiser and David Rosen,[288] who lament the lost "art" of medicine, regard the well-documented increase in patient dissatisfaction (despite the amazing technological advances) as a similar crisis. The rising popularity of alternative medicine can be understood to be part of that backlash, as patients increasingly seek out unorthodox practices despite the impressive technological success of the orthodoxy. The biomedical model is grounded in the natural sciences, and medical practice consists of the practical application of these sciences to human illness and health.[289] However, with the unity, predictive power, and exactitude of scientific medicine comes the neglect of those components of human distress that elude description in natural scientific nomenclature.[290] It is demonstrated in the illness narratives of Kay Toombs[291] and Oliver Sacks[292] that these nonsomatic components of human life that typically get disregarded as "subjective" features of illness stubbornly remain crucial to the experience of illness and to recovery.

By taking seriously questions about the world as experienced rather than scientifically described, phenomenologists seek to reunite science with life experience and to explore the relationship between the abstract world of the sciences and the

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[286] Husserl (1970), The crisis of European sciences and transcendental phenomenology.
[287] Reiser (1978), Medicine and the reign of technology.
[288] Reiser and Rosen (1984), Medicine as human experience.
[289] Schwartz and Wiggins (1985), "Science, humanism, and the nature of medical practice: A phenomenological view." Persp in Biol Med 28(3), p. 333.
[290] Schwartz and Wiggins (1985), "Science, humanism, and the nature of medical practice: A phenomenological view." Persp in Biol Med 28(3), p. 332.
[291] Toombs (1993), The meaning of illness: A phenomenological account of the different perspectives of physician and patient.
[292] Sacks (1984), A leg to stand on.

concrete world of human consciousness. Toombs argues that as embodied beings, we experience life in and through the body both before and after we develop cognitive and symbolic structures for mapping experience and meaning.[293] Phenomenologists typically speak of "embodiment" instead of "the body" to deemphasize the physical body and the assumed subject-object split that comes with anatomical description. They instead aim to create an understanding of our bodies in their experiential "givenness".

From this emphasis on the "lifeworld" rather than the scientific organization of the world, a different account of illness ensues. When the body is no longer thought of as merely an anatomical entity, but rather as the source of our experiences, illness becomes a way of "being-in-the-world" that is best described as a sense of disorder, a loss of control, of "things not being right in the world". This embodied understanding of illness resists medical classification as these categories lack its existential qualities. In fact, illness may not even be localized to any one place. Elaine Scarry has forcefully described in *The Body in Pain: The Making and Unmaking of the World*[294] that pain obliges a loss of the taken-for-grantedness of our bodies, and illness can be understood as, similarly, the loss of the "at-handedness" or "everydayness"[295] of things. Toombs' philosophical reflections on living with MS lead her to conclude that health is not experienced as the absence of disease, but rather as a state of unselfconscious being that illness shatters. Illness is a problem of embodiment, as the usual effortless and unselfconscious unity of the body and the self is disrupted, making one pay explicit

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[293] Toombs (1993), The meaning of illness: A phenomenological account of the different perspectives of physician and patient.
[294] Scarry (1985), The body in pain: The making and unmaking of the world.
[295] Heidegger (1996), Being and time.

attention to the body as suddenly problematic (and separate or alien from the self).[296]

Toombs examines the different ways that physicians and patients approach and understand illness and encourages physicians to try to understand what illness *means* to the patient.[297] She advises that rather than trying to understand disease as a breakdown of the objectified body-machine, the physician must try to approach illness as a disturbance in the patient's ability to relate to and function in the world, as it is one's embodiment, one's capability of interacting with the world, that is damaged in the event of illness.

Such an approach to medical practice would refigure both the goals of medicine and the practices used to meet those ends. Once the patient and not the disease exemplar becomes the subject of examination and treatment, the personal anecdotes, life circumstances, and other subjective features of the patient's circumstances become crucial parts of the diagnosis.[298] Diagnosis would therefore not be tailored to medical categorization, as the goal of treatment would not be centred so much on the elimination of disease, but rather the reintegration of the patient into the lifeworld. This is not to say that the elimination of disease would not factor in as an important feature of treatment, but it certainly would not be regarded as more important than, say, rehabilitation.[299] This framework requires a different configuration of evidence that does not presume the scientific completeness of reductive categories and aggregate measures.

Phenomenological Implications for Evidence Based Medicine

Reflecting on how the popular idea of "patient-centred care" remains largely

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[296] Toombs (1993), The meaning of illness: A phenomenological account of the different perspectives of physician and patient.
[297] Toombs (1993), The meaning of illness: A phenomenological account of the different perspectives of physician and patient.
[298] Greenhalgh and Hurwitz, eds. (1998), Narrative based medicine: Dialogue and discourse in clinical practice.
[299] To borrow a slightly overused expression, this model emphasizes *care* instead of *cure*.

unrealized in clinical practice, R. G. Evans notes that while physicians are encouraged to make diagnoses in physical, psychological, *and* social terms, "the evidence based medicine that is currently promoted either restricts itself to physical evidence alone, or casts such evidence at the top of a hierarchy that tends to devalue any evidence 'lower down'."[300] The hierarchy of evidence promotes a certain scientistic accounting of the goals of medicine, which, the worry goes, is incommensurable with the proposed reorientation of medical practice toward the patient's search for meaning in the illness experience. The bridging of scientistic "measure" and existential "meaning" has received some attention in the critical EBM literature[301] with the general consensus that we need an "integrated" model of evidence that properly reflects modern health care's constitution by diverse academic traditions—including the humanities, social sciences, and the pure and applied sciences—that rely on equally diverse notions of evidence.[302]

While EBM values evidence that is statistical in nature and general in its application, and therefore places quantitative data derived through the application of recognized study designs at the top of its pre-graded hierarchies of evidence, the phenomenological approaches rooted in hermeneutics, ethnography, sociology, and anthropology, regard evidence as primarily narrative, subjective, and historical in nature. Unlike the impersonal and generalizable measures undertaken in EBM, this conception of evidence is illustrated in case histories, clinical encounters, and qualitative studies such as

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[300] Evans, (2003), "Patient-centred medicine: Reason, emotion, and human spirit? Some philosophical reflections on being with patients." Med Humanit 29(1), p. 8.

[301] See, for example, Buetow (2002), "Beyond evidence-based medicine: Bridge-building a medicine of meaning." J Eval Clin Prac 8(2); Upshur *et al* (2001), "Meaning and measurement: an inclusive model of evidence in health care." J Eval Clin Prac 7(2); Djulbegovic *et al* (2000), "Evidentiary challenges to evidence-based medicine." J Eval Clin Prac 6(2).

[302] Upshur *et al* (2001), "Meaning and measurement: an inclusive model of evidence in health care." J Eval Clin Prac 7(2), p. 91.

in-depth interviews and focus groups.[303] The features of the medical encounter and the illness experience emphasized by medical phenomenologists and proponents of a more "humane" medicine suggests the need to reconsider what constitutes the goals of medicine[304] *and* flips EBM's hierarchy of evidence on its head. The quantitative measures and generalizations that come out of controlled trials and biostatistical analysis are not conducive to the questions of meaning that medical phenomenology wants to address and make central to medicine.

One notable exception to this view comes from Greenhalgh's characterization of "narrative based medicine", where she denies the apparent irreconcilability between the narrative nature of the illness experience and the intuitive and subjective aspects of clinical method with the principles of EBM. She maintains that the positivist image attributed to EBM is inaccurate; far from obviating the need for subjectivity in the clinical encounter,

> genuine evidence based practice actually presupposes an interpretive paradigm in which the patient experiences illness in a unique and contextual way. It is only within such an interpretive paradigm that a clinician can meaningfully draw on all aspects of evidence—his or her own case based experience, the patient's individual and cultural perspectives, and the results of rigorous clinical research trials and observational studies—to reach an integrated clinical judgment.[305]

Rather than EBM being positivistic, the hermeneutic perspective is held by Greenhalgh to resonate strongly with "the call from evidence based circles for the 'truth' of the instrumental text (that is, the results of diagnostic tests) to be interpreted judiciously on

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[303] Upshur *et al* (2001), "Meaning and measurement: an inclusive model of evidence in health care." J Eval Clin Prac 7(2) p. 94.
[304] Toombs (1995), "Chronic illness and the goals of medicine." Second Opinion 21; Toombs (1993), The meaning of illness: A phenomenological account of the different perspectives of physician and patient; Cassell (1982), "The nature of suffering and the goals of medicine." N Engl J Med 306(11).
[305] Greenhalgh (1999), "Narrative based medicine: Narrative based medicine in an evidence based world." BMJ 318(7179), p. 325.

the basis of Bayesian pretest probabilities determined by the history and physical examination."[306] Thus genuine evidence based practice "*presupposes* an interpretive paradigm in which the patient experiences illness in a unique and contextual way."[307]

Clinical method is explained to be a necessarily interpretive act which draws on narrative skills to integrate the overlapping stories told by patients, clinicians, and test results. Against the critics' charges that "the evidence based approach to clinical decisionmaking holds clinical observation to be totally objective and should, like all scientific measurements, be reproducible"—she cites Tanenbaum's scathing indictment of EBM's "fundamental separability of expertise from expert and of knowledge from knower"[308] as an example—she protests that it was pre-EBM medical training that incorrectly taught students to view medicine as a dispassionate science, where the doctor served as impartial investigator and diagnostic decisionmaking followed an identical protocol to scientific inquiry (the discovery of "facts about a patient's illness").[309] EBM, in contrast, does not hold this understanding. To illustrate, she cites how in *Clinical Epidemiology*,[310] Sackett and colleagues, take interest in clinical disagreement between clinicians, and argue that we should acknowledge and measure the amount of disagreement between different clinicians in different circumstances rather than dismiss it or attribute it to error or inexperience.

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[306] Greenhalgh (1999), "Narrative based medicine: Narrative based medicine in an evidence based world." BMJ 318(7179), p. 325.
[307] Greenhalgh (1999), "Narrative based medicine: Narrative based medicine in an evidence based world." BMJ 318(7179), p. 325; my emphasis.
[308] Tanenbaum (1995), "Getting from there to here: evidentiary quandaries of the US outcomes movement." J Eval Clin Prac 1(2), p. 102.
[309] Greenhalgh (1999), "Narrative based medicine: Narrative based medicine in an evidence based world." BMJ 318(7179), p. 323.
[310] Sackett *et al* (1991), Clinical epidemiology: A basic science for clinical medicine.

This example, however, is not compelling, as calling attention to the phenomenon of clinical disagreement is not necessarily a sign that the authors value the highly interpretive art of clinical decisionmaking. In fact, the interest in understanding and measuring clinical disagreement may be done with the intention of eradicating it by way of more reliable diagnostic measures. A further difficulty with Greenhalgh's defense of EBM concerns her interpretation of how the EBM founders regard clinical observation. EBM has been criticized for being *silent* on the workings of clinical observation and practice while simultaneously being remarkably attentive to the generation of the evidence that is supposed to serve clinical practice. This silence makes it difficult to substantiate Greenhalgh's claim that they do not hold an objectivist understanding of clinical method. The *silence* on the matter has understandably been interpreted by the critics to suggest that clinical method follows suit with EBM's objective evidentiary schema.

Greenhalgh fails to persuade me that EBM has been grossly misunderstood in her admission that

> those who have studied the phenomenon of clinical disagreement, as well as those of us who practice medicine in a clinical setting, know all too well that clinical judgments are usually a far cry from the objective analysis of a set of eminently measurable "facts"[311]

For one, the authors of clinical epidemiology were not described as having *studied* the phenomenon of clinical disagreement, but rather called attention to the *need* for its study. Furthermore, EBM is a normative methodology that serves to challenge habits of thought and practice in medicine. Thus anything that practitioners "know all too well" is open for revision and change. Lastly, EBM's rigid hierarchy of evidence will be demonstrated in

[311] Greenhalgh (1999), "Narrative based medicine: Narrative based medicine in an evidence based world." BMJ 318(7179), p. 323.

later chapters to be largely irreconcilable with the interpretive nature of clinical practice. Greenhalgh's defense of EBM's phenomenological dimensions may be another example of proponents appropriating the criticisms as having been done, understood, or accommodated by EBM "all along".[312] The fault therefore lies not in EBM, but in the critics' misunderstanding of EBM. While I challenge Greenhalgh's characterization of EBM *as is*, the question remains whether EBM can integrate the interpretive dimensions of clinical practice with its evidentiary methods—what Greenhalgh calls "narrative based medicine"—or whether such a union requires abandoning EBM and replacing it with a different approach to medicine.

The model of medicine that arises from the phenomenological emphasis on patient experience has been described as a "medicine of the intertwining" that negotiates both the physiological and existential dimensions of illness, understanding them to be mutually implicatory in their different contributions to the therapeutic encounter.[313] This *intertwining* presumes that our notions of disease and treatment would always involve "a chiasmic blending of biological and existential terms", where the terms are not ultimately oppositional, but instead involved in intricate "logics" of information exchange.[314] When disease is understood to have an existential dimension no less important than its physiology, the methods and meanings of clinical diagnosis and treatment shift. This is readily apparent in diseases with psychosocial dimensions.[315] For instance, hypertension cannot be properly treated without knowledge of and efforts to reduce the sources of

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[312] See Lambert's criticism on p. 57.
[313] Leder (1992), "A tale of two bodies: The Cartesian corpse and the lived body." The body in medical thought and practice.
[314] Leder (1992), "A tale of two bodies: The Cartesian corpse and the lived body." The body in medical thought and practice, p. 28.
[315] Leder claims that this list is evolving. As research into the psychosocial dimensions of disease evolves, very few conditions are being found to safely resist psychological and social dimensions.

stress in the patient's life. Yet, even in cases with unambiguous organic etiologies—for example, fractured bones sustained through a random and unpreventable accident—phenomenological factors, while no longer implicated in *causing* this dysfunction, are involved in constructing a *response* to treatment.[316]

With this elevation of phenomenological dimensions of illness to be on a par with the physiological factors, EBM's hierarchized valuing of RCTs over qualitative methods is both inappropriate and unjustified. Because the clinical data from RCTs represent an average effect of the intervention on a homogenous trial population that met admission criteria, the inescapable and important existential components of illness—considerations that are necessarily subjective or personal—are excluded. The concerns over the applicability of trial data to individual patient care are heightened in the context of intertwined medicine. Recall that in the tPa case discussed earlier, the clinicians did not have the necessary information for clinical subgroups and were therefore arguably limited in their ability to provide the best treatment options. This spoke to the treatment of the physiological components of the patient's condition. The shortcomings of the applicability of the evidence to patient care, and the possibility of an evidence *based* medicine, are now two-fold with the additional challenge in addressing the existential dimensions of illness that implicate clinical diagnosis and treatment response.

Distinguishing EBM from pre-EBM: Nothing New in the EBM Critique?

To summarize our findings so far, the epistemological critique of EBM reveals a radical empiricist concept of evidence as "given" or "self-apparent" and a closely-linked objectivist account of knowledge as (preferably) detached and disinterested. We saw that

[316] Leder, (1992), "A tale of two bodies: The Cartesian corpse and the lived body." The body in medical thought and practice, pp. 29-32.

these positivist commitments have been severely discredited within the past half-century of epistemology of science research for failing to properly capture the (social) nature of knowledge production. This approach was thought to objectify the embodied patient as a passive site for examination rather than as an active knowledge source, a move that leads to impersonal/inhumane medical practice. While I generally concur with these conclusions, their impact in discrediting the evidence based approach is limited because these lines of criticism predate EBM. In this section, I offer another critical perspective on EBM, political economy analysis, that manages to incorporate some features of the postpositivist critique just offered with some of the new content that EBM brings to medicine in a power/knowledge analysis that applies uniquely to EBM.

Biomedicine was criticized for supporting problematic positivist commitments well before the advent of EBM, which is still a relatively new approach to medical research and clinical decisionmaking. For example, in the *Journal of Medicine and Philosophy*'s December 1978 edition on "Medicine and Knowledge", which chronicled emergent themes in medical epistemology, McWhinney[317] and Harding[318] pondered the detriment to patient care that can accompany the rise of technology in biomedicine, Reiser[319] lamented the decline of clinical dialogue, and Savodnik[320] called for humanity and holism in medicine. The EBM debate's well-worn distinctions between scientific knowledge and clinical practice, and "algorithmic procedures" versus "human judgment" are even invoked in Wartofsky's[321] introductory editorial to the volume's critical examination of (pre-EBM) biomedicine. In light of these findings, one might conclude

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[317] McWhinney (1978), "Medical knowledge and the rise of technology." J Med Phil 3(4).
[318] Harding (1978), "Knowledge, technology, and social relations." J Med Phil 3(4).
[319] Reiser (1978), "The decline of clinical dialogue." J Med Phil 3(4).
[320] Savodnik (1978), "Psychosomatic medicine." J Med Phil 3(4).
[321] Wartofsky (1978), "Editorial." J Med Phil 3(4), p. 268.

that some of the critics have been correct in charging EBM with offering nothing new to medicine.[322] A fair assessment of EBM certainly requires consideration of what unique problems the decisionmaking technology brings to medicine, and not merely a rehearsal of what equally challenged its biomedical predecessor. We must also recognize and appreciate the momentous advancements in healthcare that are credited to scientific medicine despite its epistemological difficulties when considering where medicine must go from here.

On the Power/Knowledge of EBM: The Political Economy of Evidence Based Decision Making

The controversies surrounding the ascendancy of formulaic guidelines and population-based research and the diminishing of clinical judgment, patient perspectives, and individual patient care are frequently framed as struggles over the locus of authority in medicine, where power disputes are argued as debates over knowledge. This is not to say that epistemic considerations are beside the point, only that the sociopolitics of EBM are widely regarded as central analytic categories for understanding the evidence based approach to medicine. Political economy incorporates forms of neo-Marxist analysis that explore the relation of the social, political, and cultural to the organization of capitalist economies.[323] It is the most popular form of scholarly critique of contemporary macro-relations of healthcare within the English literature, and this perspective has been central to social science analyses that treat new developments in the healthcare field as effects of

[322] See, for example, Benitez-Bribiesca (1999), "Evidence-based medicine: A new paradigm?" Arch Med Res 30(2).
[323] Armstrong *et al* (2001), Unhealthy times: Political economy perspectives on health and care in Canada, pp. 10-15.

structural changes in relations between the state, capital, and professionals.[324] While frequently hinted at throughout this analysis, the social and political implications of the evidence based approach to medicine will now be explicitly discussed in a political economy critique of EBM.

It has already been noted that many of EBM's methodological and epistemic claims seem common sense. However, their seeming obviousness results from them having been stripped of the social context of medical practice. Just as feminist epistemologists have demonstrated how this alleged value-neutrality distorts scientific practice, the same concerns arise in medicine. In an age where the institutional power of medicine is suspect, a model that represents biomedicine's power as disinterested (or merely "scientific") should give pause for thought. In this vane, Keith Denny reads EBM as a discourse that problematically resists contemporary challenges to established medical authority by consumer advocacy groups and proponents of complementary and alternative medicine. While EBM may appear to question the authority of individual physicians by demanding responsibility to the literature and in the epistemic silencing of clinical judgment and experience, it actually reinforces this power by regulating the conditions under which a physician may speak authoritatively about health and illness. Furthermore, EBM does *not* question the institutional authority of medicine itself to the rest of society, the way healthcare dollars are allocated for the necessary clinical research,

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[324] Mykhalovskiy and Weir (2004), "The problem of evidence-based medicine: Directions for social medicine." Soc Sci Med 59(5), p. 1060; see, for example, Armstrong *et al* (2001), Unhealthy times: Political economy perspectives on health and care in Canada.; Armstrong and Armstrong (2002), Wasting away: The undermining of Canadian health care.; Leys (2001), "The British National Health Service in the face of neoliberalism." Unhealthy times: Political economy perspectives on health and care in Canada; Light (2001), "Comparative institutional response to economic policy managed competition and governmentality." Soc Sci Med 52(8); Navarro, ed. (2002), The political economy of social inequalities: Consequences for health and quality of life; Navarro (1993), Dangerous to your health: Capitalism in health care.

and what role the pharmaceutical industry plays in setting the research agenda. EBM's pairing of medical science with the contemporary discursive alignment of information/truth/freedom is argued to reassert a commitment to Western scientific paradigms and to have permitted EBM's dominant status in medicine.[325] To understand and appreciate Denny's provocative thesis, more needs to be said about political economy analysis and how it has been used in the context of EBM critique.

The priority setting and health policy literature has acknowledged a trend in recent years toward greater transparency in decisionmaking, where increasing demand is being placed on decisionmakers at all levels to use more explicit methods of decisionmaking[326] for the sake of accountability.[327] Evidence based decisionmaking has been proffered as a means for explicitly justifying solutions to the classic resource allocation dilemma between the scarcity of resources and our potentially unlimited health care wants.[328] It has been argued that much of EBM's appeal lies in its perceived fairness. EBM seems to offer the promise of consistent and impartial evidence about the benefits and harms of treatments due to the transparent use of high quality primary research in systematic reviews and meta-analyses. These results are then applied in equally transparent processes to make clinical decisions. Justice in providing health care is critically important, since equity in this area may go some way toward redressing health inequalities, which are inescapably linked to socioeconomic and other disadvantages both within and between countries.[329] Evidence based approaches have

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[325] Denny (1999), "Evidence-based medicine and medical authority." J Med Humanit 20(4).
[326] Coast *et al* (1996), Priority setting: The health care debate.
[327] Shore and Wright (2004), "Whose accountability? Governmentality and the auditing of universities." Parallax 10(2).
[328] Dobrow *et al* (2004), "Evidence-based health policy: Context and utilization." Soc Sci Med 58(1), p. 207.
[329] Rogers (2004), "Does evidence-based medicine offer fair benefits for all?" Ethics J Am Med Assoc 6.

come to play an increasingly important role in many national health systems. In addition to guiding clinical practice, evidence based decisionmaking has also become instrumental in shaping research agendas, formulating policy, and allocating financial resources.[330] The move from EBM to "evidence based health policy" represents a shift from the individual/clinical to the population/policy level, where the decisionmaking context becomes more uncertain, variable, and complex.[331] The growing interest in evidence based health policy[332] has made it increasingly clear that existing models of evidence based decisionmaking that focus largely on the "evidence base" (i.e. the *quality* of the evidence) while neglecting the "decisionmaking context" are inadequate.[333]

The evidentiary focus of current evidence based decisionmaking models cannot adapt to the contextual features of broader policy environments.[334] Dobrow et al. propose that conventional political decisionmaking is largely context-driven, with low evidentiary input. The largely contextual political decisionmaking framework is placed in opposition to EBM, which focuses on the quality of evidence while attempting to minimize the role

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[330]See Lambert *et al* (2006), "Introduction: Gift horse or Trojan horse? Social science perspectives on evidence-based health care." Soc Sci Med 62(11), p. 1. On the level of national health care, for example, Britain's Department of Health for the National Health Service, Canada's Ministry of Health, and the United States' National Institute of Health and Agency for Health Care Policy and Research all have mandates and health initiatives which stress the principles of EBM. For US and Britain, see Pope (2003), "Resisting evidence: The study of evidence-based medicine as a contemporary social movement." Health 7(3); For Canada, see Ministry of Health (Canada) (2006), "Health Canada." http://www.hc-sc.gc.ca/index_e.html

[331] Dobrow *et al* (2004), "Evidence-based health policy: Context and utilization." Soc Sci Med 58(1).

[332] Black (2001), "Evidence based policy: Proceed with care." BMJ 323; Harries *et al* (1999), "Evidence-based policy-making in the NHS: Exploring the interface between research and the commissioning process." J Pub Health Med 21; Klein (2000), "From evidence-based medicine to evidence-based policy?" J Health Serv Res Policy 5; MacIntyre *et al* (2001), "Using evidence to inform health policy: Case study." BMJ 322(7280); Dobrow *et al* (2004), "Evidence-based health policy: Context and utilization." Soc Sci Med 58(1).

[333] We have already seen EBM being charged with being too general because of its population based methods and therefore challenged with respect to application to individual care. Here, the critics counter EBM from the other direction, claiming that it cannot accommodate population-based or general level concerns either.

[334] Dobrow *et al* (2004), "Evidence-based health policy: Context and utilization." Soc Sci Med 58(1), p. 216.

or impact of the decisionmaking context. Political decisionmaking frameworks generally regard evidence as only one of a number of contributors to the decisionmaking process, and it is both the internal and external contextual factors that provide the basis for political decisionmaking. It also typically lacks a clear mechanism for defining or utilizing evidence appropriately or effectively, a tendency that is now being challenged in the push for accountability.[335] For example, for policy regarding implementing a colorectal cancer screening program, traditional political decisionmaking would typically address the relative need for a screening program, influenced largely by the interplay of key internal contextual factors, such as purpose, participants, and process, and the impact of external contextual factors, including the political and economic implications of a population-wide program, extra-jurisdictional factors (i.e. do similar programs existing other jurisdictions?) and disease-specific characteristics (i.e. which populations groups stand to most benefit by such a program?). The quality of the scientific evidence available would be only one of several factors considered, if at all.[336] The authors see in evidence based health policy the potential of a middle ground between EBM and standard political decisionmaking and they offer a framework for "*context-based* evidence based decision making" to serve this end.[337]

Critics coming from the tradition of political economy critique worry that such an effort at correcting the shortcomings of evidence based decisionmaking may be inadequate and politically naïve, as the decisionmaking technology is already a political

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[335] For further analysis of the relation between evidence and social policy, see Miller and Safer (1993), "Evidence, ethics, and social policy dilemmas." Edu Pol Anal Arch 1(9).

[336] Dobrow *et al* (2004), "Evidence-based health policy: Context and utilization." Soc Sci Med 58(1), p. 211.

[337] The details of Dobrow et al.'s "context-based evidence based decisionmaking framework" will not be discussed here. Like the example of "evidence based patient-centred care" provided earlier, this model represents yet another attempt at integrating oppositional concepts in an effort to correct the shortcomings of the evidence based approach.

instrument serving corporate interests in medicine. The EBM movement is characterized by the likes of Rodwin[338] and Belkin[339] as the latest expression of "scientism", modernity's rationalist dream that science can produce the knowledge required to emancipate us from scarcity, ignorance, and error. These efforts are argued to disguise political interests in the authority of so-called "scientific evidence". The configuration of policy considerations and clinical standards into questions of evidence conveniently transform normative questions into technical ones. Political issues are not resolved, however, but merely disguised in technocratic consideration and language. Thus the goals of medicine and other normative considerations lie just below the surface of these evidentiary questions, and evidence becomes an instrument, rather than a substitute, for politics.

Within this line of critique, the increased interest in transparent decisionmaking and accountability is interpreted not as a push for democracy insofar as decision makers are made answerable to their constituents, but rather a technocratic fix for normative issues that effectively silences democratic debate. In his writing on managed care, Gary Belkin has argued that the particular organization of payer and provider introduced by managed care organizations was not an inevitable response to cost control, economic inefficiency, and a drive to improve medical practice, but instead fits within a history of appeals to standardized and ostensibly objective measures and models of human behaviour to resolve contentious issues in complex and modern capitalist democratic

[338] Rodwin (2001), "The politics of evidence-based medicine." J Health Pol Policy Law 26(2).
[339] Belkin (1997), "The technocratic wish: making sense and finding power in the "managed" medical marketplace." J Health Pol Policy Law 22(2).

societies.[340] Belkin urges us to pay attention to the historical moment in which we find ourselves, when the challenges and questions raised by the recreation of the medical subject as an economic actor or average probability seem "obvious".

The political economy tradition provides the analytic resources to examine EBM as a political phenomenon. Indeed, this seems like a promising framework given the significant social impact of EBM. The remarkable enthusiasm that has met EBM on the part of the elites in academic medicine—a group that is typically resistant to change[341]—has led to the formal incorporation of EBM into editorial policies, spawned new journals, and is now routinely taught in medical schools throughout North America and most of Western Europe.[342] The political economy perspective frames the EBM movement as a constituent of both institutional transformation in healthcare and contests for power associated with the neoliberal restructuring of the welfare state. Discussions tend to be grand in scale, organized as abstract critiques of EBM rather than as empirical research of particular cases of its development or use.[343] EBM has, for instance, been represented as an ideological resource that the medical profession uses to buttress its authority, primarily by reinforcing the scientific character of medical practice[344] and as a movement that serves the interests of capital.[345]

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[340] Belkin (2003), "Shifting the focus: the historical meaning of managed care and the search for ethics in mental health." Rationing sanity: Ethical issues in managed mental health care, p. 14; see also Denny (1999), "Evidence-based medicine and medical authority." J Med Humanit 20(4).

[341] This phenomenon is seen, for instance, in the harsh opposition to alternative medicine expressed by prominent members of the medical establishment. See, for example, the editorial co-authored by the *New England Journal of Medicine*'s executive editor and editor-in-chief, Angell and Kassirer (1998), "Alternative medicine--the risks of untested and unregulated remedies." N Engl J Med 339(12).

[342] Mykhalovskiy and Weir (2004), "The problem of evidence-based medicine: Directions for social medicine." Soc Sci Med 59(5), p. 1060.

[343] Mykhalovskiy and Weir (2004), "The problem of evidence-based medicine: Directions for social medicine." Soc Sci Med 59(5), p. 1061.

[344] See Denny (1999), "Evidence-based medicine and medical authority." J Med Humanit 20(4).

[345] See Rodwin (2001), "The politics of evidence-based medicine." J Health Pol Policy Law 26(2); Belkin (1994), "Numbers and the politics of health care." J Health Pol Policy Law 19(1).

Within late modernity's affinity for resolving policy issues by transforming them into problems of measurement,[346] medical knowledge is argued to be reformulated, replacing expert judgment with technical formulas, and face-to-face interaction with standardized information shared by anonymous individuals.[347] Interestingly, it satisfies the strong wish that we have for open, reliable, and presumably objective methods for the resolution of controversy. It also fits into a history of employing aggregate measures and standardized processes and products to mobilize and deploy large amounts of capital.[348] The expansion of markets made opportunities for face-to-face interactions less possible. In the grain trade, for example, grain grading was introduced to make pricing possible without on-site inspection. The logic of standardized measurement is confirmed by late-20th and early-21st century capitalism. From this market phenomenon, a confidence in standardized measuring emerges, and so the epistemic problem of summing experience (the "subject as aggregate") to determine medical truth and reality can be comfortably ignored.[349]

Statistical inference is pursued precisely for its superficiality and its ability to measure broad rather than individual experience. Its ability to isolate more general variables and phenomena that permit more open and egalitarian debate about social questions caught the attention of democrats such as Auguste Comte and Otto Neurath. Yet generalizations and standards contain implicitly socially framed and mediated values

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[346] Belkin (2003), "Shifting the focus: the historical meaning of managed care and the search for ethics in mental health." Rationing sanity: Ethical issues in managed mental health care.

[347] Belkin (2003), "Shifting the focus: the historical meaning of managed care and the search for ethics in mental health." Rationing sanity: Ethical issues in managed mental health care; Tanenbaum (1993), "What physicians know." N Engl J Med 329(17).

[348] Frankford (1994), "Scientism and economism: regulating health care." J Health Pol Policy Law 19(4); Belkin (2003), "Shifting the focus: the historical meaning of managed care and the search for ethics in mental health." Rationing sanity: Ethical issues in managed mental health care.

[349] Belkin (2003), "Shifting the focus: the historical meaning of managed care and the search for ethics in mental health." Rationing sanity: Ethical issues in managed mental health care, pp. 12-13

with a range of implications that *can* order and enhance but also tyrannize aspects of our lives. The success of generalization is achieved at the expense of contingent and contextual knowledge that needs to be filtered out. Certain critical lines of thinking in science and technology studies hold the strong suspicion that quantification is a tool to manipulate objectified objects and create an illusory "natural" and often oppressive language of normal and abnormal.[350]

The "technology of patient experience" is inherently limited insofar as only certain kinds of experience can be quantified and only certain questions explored. The challenge for those working in the evaluative sciences is to avoid developing measures of patient experiences and treatment performance that ignore the contingent, probabilistic and selective nature of such knowledge. In "Scientism and Economism in the Regulation of Health Care", Frankford argues that data-driven approaches to patient care narrow our ability to effect actions in clinical encounters, as statements of averaged probability become unquestioned laws of possibilities.[351] They limit appreciation of the subtleties and exceptions that characterize all efforts to diagnose and treat illness and displace the critical and vast source of information for treatment, diagnosis and meaningful management of illness that is found in human interaction. Furthermore, they ignore the uncertainty and contingency of medical knowledge. Certainly efforts to capture such encounters in aggregate terms have become increasingly sophisticated and thorough, yet the limitations just mentioned are part and parcel of epidemiological methods and simply cannot be overcome.

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[350] Hacking (1990), The Taming of chance.
[351] Frankford (1994), "Scientism and economism: regulating health care." J Health Pol Policy Law 19(4).

In addition to the view of EBM as an ideological tool established to serve corporate interests is the position that EBM is part of the rationalization of health services. This understanding of EBM is informed by the longstanding concern about the growing infiltration of health care by market relations,[352] and it also relies on the established conceptual resources of political economy research on health care, most notably medical dominance, a state-centred conception of power, and the state/capital/professions relation.[353] For instance, consideration of the cost containment imperative influencing healthcare decisionmakers at both the micro- and macro-level has led some commentators to locate EBM practice guidelines within a trajectory of state policies that draw on population-based knowledges to reduce the utilization of medical services. From this perspective, evidence based guidelines are considered to be a form of external control over medical practice, where physicians must place fiscal considerations into their decisionmaking practices. In "The Politics of EBM", Rodwin positions EBM within forms of quantitative aggregate knowledge that renders individual clinical judgment vulnerable to administrative control.[354] The market organization of managed care is thought to encourage this transformation of medicine, now founded on population-based research, into a complex series of protocols, guidelines, and other forms of administrative management. These measures are all said to be justified by the public interest in accountability and the widespread standardization and use of best practice procedures.

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[352] See, for example, Belkin (2003), "Shifting the focus: the historical meaning of managed care and the search for ethics in mental health." Rationing sanity: Ethical issues in managed mental health care; Frankford (1994), "Scientism and economism: regulating health care." J Health Pol Policy Law 19(4).
[353] Mykhalovskiy and Weir (2004), "The problem of evidence-based medicine: Directions for social medicine." Soc Sci Med 59(5), p. 1061
[354] Rodwin (2001), "The politics of evidence-based medicine." J Health Pol Policy Law 26(2).

Operating in conjunction with the political economy perspective is the humanist view that technology dehumanizes the patient. Frankford, for instance, situates EBM within a long history of technologically influenced practice, which tends to "reduce patients to technological objects and physicians to technocratic managers."[355] This phenomenological perspective reads EBM as stripping patients of their stories and the meaning of their experience, reducing them to passive recipients of healthcare. This critique is performed in the name of *holism* and against the fragmentation and reification of the subject.[356] Managed health care is thought to operate within the "technocratic wish",[357] where technical solutions to what should properly be political debates over the direction of the health system, making these questions into a matter of expertise to resolve through population-based research. EBM is construed as subverting the integrity of clinical reasoning and doctor-patient communication, subordinating these to health-system goals that have not been decided upon through due democratic process.

Mykhalovskiy and Weir have proposed that political economy critiques of EBM are helpful sources of discussion that explore how EBM is implicated in the broad organization of healthcare, but that these analyses are significantly flawed. This analytic perspective offers the important insight that during times of cost control, EBM, especially in association with outcomes research, can render medicine vulnerable to administrative scrutiny, whether by the state or private enterprise. The shortcomings of the political economy analyses of EBM, however, are that much of the research is empirically thin and the high levels of abstraction at which significant claims are made are difficult to

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[355] Frankford (1994), "Scientism and economism: regulating health care." J Health Pol Policy Law 19(4), p. 776.
[356] See Denny (1999), "Evidence-based medicine and medical authority." J Med Humanit 20(4).
[357] Belkin (1997), "The technocratic wish: making sense and finding power in the "managed" medical marketplace." J Health Pol Policy Law 22(2).

justify. The authors argue that the literature's

> rhetorical gestures involve broad characterizations of numerically based knowledge that have an almost "anti-numbers feel", and that tend to overstate the subsumption of EBM within a bluntly formulated economic or administrative squashing of medical judgment.[358]

The treatment of EBM as part of a justificatory regime is frequently more conjectural than evidential, and has relied on a fairly narrow focus on the evidence based "protocol", which is taken to necessarily restrict physicians' clinical autonomy.[359] Political economy discussions of EBM's rationalization processes are charged with collapsing EBM and outcomes/cost-effectiveness research within an overall project of rationalization directed by healthcare management, a move that instrumentalizes EBM and ignores the varieties of ways in which EBM is both understood and deployed.[360] Also, while the technology certainly has been deployed to achieve fiscal ends, EBM's strategy for best practices does not exclude the possibility of determining the most expensive treatment for any given condition to be the most effective.

Furthermore, political economy analyses frequently focus on weak correlations yet treat them like they determine causal connection. For example, the claim that EBM's valuing of standardized measures and aggregate behaviour) are *consistent* with the logic of the medical marketplace and managed care may be taken to ground an underlying corporate interest in EBM. This forging of sloppy connections between disparate phenomena verges on what some refer to as "conspiracy theory". Mykhalovskiy and Weir maintain that their negative regard of political economy critiques of EBM is not

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[358] Mykhalovskiy and Weir (2004), "The problem of evidence-based medicine: Directions for social medicine." Soc Sci Med 59(5), p. 1061.

[359] Berg (1997), "Problems and promises of the protocol." Soc Sci Med 44(8). The same concern regarding protocols and professional autonomy is found among other healthcare professionals, for example nursing: Winch *et al* (2002), "Governing nursing conduct: The rise of evidence-based practice." Nurs Inq 9(2).

[360] Mykhalovskiy and Weir (2004), "The problem of evidence-based medicine: Directions for social medicine." Soc Sci Med 59(5), p. 1061.

meant to excuse EBM from political analysis, but instead to propose that the relationship of EBM to health services research and health management deserves further examination. Political economy critiques raise significant concern about how EBM can be used and misused to achieve state and corporate interests at the expense of the users of any healthcare system. However those worrisome incidents have yet to be established as actualized. The authors argue that folding EBM into an established trajectory of analyses, such as the focus on the power struggle among capital, the state, and the medical profession, discourages the more mundane investigations into the workings of EBM—what it is, how it works, how it has been used, how it can be deployed—as these investigations may be regarded as pedantic or politically naïve. They argue that a more complex understanding of EBM invites better determinations of how its mechanisms are implicated in contemporary relations of power in health care. The worry is that it is rather the broad abstractions being taken and the unestablished correlations presumed between a concept as complex as EBM to the equally complex sectors of health services and management that inappropriately direct EBM analysis.

While the concerns raised regarding political economy critique are worthy of consideration, I contend that Mykhalovskiy and Weir seem to condemn a certain naïve version of the political economy analytic perspective that—to use their phrasing, "folds EBM into an established trajectory of analysis" with little regard for the actual workings of the subject of analysis (EBM). Indeed, previous discussions have showed that EBM appears to fit within a political and economic model of healthcare rationalization that encourages privatization of services and market-driven pricing to the detriment of public

access and market controls on healthcare costing (i.e. capitation).[361] Furthermore, the detection of EBM's links to market-driven managed care is not premised on some presumed inherently corrupted capitalist ethos, but on a faulty positivist-empiricist epistemology that has been rebranded as "evidence based". Lastly, the claim that the valuing of standardized measures, aggregate behaviour, and radically fragmented medical knowledge seems to be consistent with the market rationality that managed care first introduced to health care does not need to be understood to be conspiratorial—no causal link is necessarily being suggested in the political economy critiques of EBM. Instead it calls important attention to the politico-economic dimensions of the hubris of EBM. The logic of the medical marketplace *can* be supported by such knowledge technologies as clinical epidemiology, outcomes research, medical informatics, and, of course, evidence-based medicine, all of which can further the economistic imperatives of the healthcare marketplace in the name of "better science". Cost-cutting strategies frequently compromise patient care, and so EBM's (actual or potential) connection to such political agenda ought to be regarded with some level of suspicion. The enthusiasm for standardized measures in clinical practice, consistency among professionals in therapeutic interventions, and gold standards of clinical science reflect a medical rationality that prefers abstracted measure over individualized history and pathology. Medical authority is, therefore, no longer framed in scientific discourse but in late 20th/early-21st century capitalist discourse with its ideological extolling of the importance of "information"—a move that co-opts demands for democracy and holism in

[361] Compare, for example, the millions of uninsured Americans to Canada's universal access. Also, the higher cost for pharmaceuticals in the US compared to Canadian prices, which are government regulated.

medicine.[362] This is done by appeal to "the evidence"—the unbiased bottom line. Evidence can therefore serve as a tool to maintain power in its use to resolve politically contentious issues.

With these considerations in mind, Denny's thesis, presented at the start of this discussion on political economy, becomes clearer. The proposal that EBM protects the institutional authority of medicine in relation to society by presenting clinical discourse as objective and uncontroversial fits with emerging themes in political economy analysis that question the democratic effects of accountability, transparency, information, and other virtues of the "audit culture".[363] It was in the name of "better science" that outcomes research was initially advanced primarily by prominent physicians and medical institutions as a response to the noted economic irresponsibility in medicine; effectiveness research was thought to promote more empirically-based practices and it also seemed to legitimate physicians as arbiters of the health care dollar.[364] However it was precisely the scientistic enthusiasm of the emerging Health Services Research field that led to questioning the need for physicians at all in determining whether resources were used appropriately. The completeness with which certain aggregate measures define success and failure is extremely compelling given the grave consequences of uncertainty in medicine. The cultural power and authority of knowledge derived from reproducible gross measures was underestimated and the corporatization of health care delivery was legitimated by this configuration of scientific authority. Managed care was

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[362] Denny (1999), "Evidence-based medicine and medical authority." J Med Humanit 20(4), p. 260.
[363] The "audit culture" refers to the widespread adoption of apparatuses of documentation and review at all levels of governance in many large organizations. A critical discourse on the audit culture is growing regarding its place within institutes of higher education. See, for example, Dentith (2002), "English and the audit culture: An introduction." Higher Edu Acad On-Line Newsletter 3; Shore and Wright (2004), "Whose accountability? Governmentality and the auditing of universities." Parallax 10(2).
[364] Belkin (1997), "The technocratic wish: making sense and finding power in the "managed" medical marketplace." J Health Pol Policy Law 22(2).

able to ascend as a viable means of distributing health care by such appeals to scientific objectivity. Ellwood and his allies were wonderfully successful in constructing "a universal language" to "bring order and predictability to the American health care system".[365] Such knowledge upholds the image of medicine as universally accessible, objective, and quantified knowledge, and thus manipulable and interpretable by persons uninvolved in the processes the data describe. This knowledge can be detached quickly from the context of the work of the experts who devise it.[366] To argue that a symptom checklist should be interpreted in a certain way and for specified purposes means admitting the degree that medical practice is craft-work.[367]

When the felt ambivalence over the fairness and universality of measurement and practice guidelines is coupled with the increased cynicism regarding the presumed wisdom of the unfettered marketplace to allocate healthcare resources wisely and to enforce standards of care,[368] much of the initial "obviousness" of EBM begins to diminish as it begins to look like a devise of the medical marketplace. Tanenbaum reveals that the US outcomes movement has been invoked to support efforts to increasingly privatize healthcare.[369] Because EBM legitimates the distillation of medical truth outside of the clinical encounter, where statistical information is privileged over the physician in clinical decisionmaking, the logic of a healthcare marketplace populated by independent and rational buyers and sellers is validated.

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[365] Ellwood (1988), "Outcomes management: A technology of patient experience." N Engl J Med 318(23), p. 102.
[366] The preferred distance between observer and observed is a telltale sign of positivist thinking and methodology.
[367] Belkin (1994), "Numbers and the politics of health care." J Health Pol Policy Law 19(1).
[368] Frankford (1994), "Scientism and economism: regulating health care." J Health Pol Policy Law 19(4), p. 803.
[369] Tanenbaum (1995), "Getting from there to here: evidentiary quandaries of the US outcomes movement." J Eval Clin Prac 1(2).

The motivation for Mykhalovskiy and Weir's caution to avoid over general abstractions and empirically-thin claims is appreciated, however, as, similar to me, the authors want to decipher what is unique about EBM and what particular problems the evidence based approach brings to medicine. Fitting EBM into familiar trajectories of analysis can obscure the unique content of EBM by, for instance, collapsing it into a generic dehumanizing medical technology that merely furthers the technologizing of biomedicine (and subsequent detriment to the practitioner-patient relationship) that has been happening for decades. Brody et al., in fact, deny the alleged loss of the individual patient via the evidence based approach on the grounds that there was no prior "individual" to be lost. They draw from the popular critical histories of biomedicine[370] to argue that

> at least since the triumph of anatomical pathology and the demise of humoral medicine, conventional medicine...has approached the problems of diagnosis and treatment of the individual patient by trying to disassemble the patient into the component, lower-level natural systems [i.e. cells, tissues, organs, organ systems].[371]

In doing so, conventional medicine directs its investigative attention away from the features that make individual persons unique and instead attends to the parts that make us the same. Illness and disease are framed as deviances from the norm (i.e. healthy lungs, normal white cell count). Indeed,

> if the hallmark of the diagnosis and treatment of adult-onset diabetes is insulin deficiency and peripheral insulin resistance, for example, the individual patient ceases to be an individual and becomes merely a member of a population of humans, all of whose cells and tissues function in comparable ways.[372]

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[370] For example, Foucault (1994), The birth of the clinic: An archaeology of medical perception; Vogel and Rosenberg, eds. (1979), The therapeutic revolution: Essays in the social history of American medicine.
[371] Brody *et al* (2005), "Evidence-based medicine: Watching out for its friends." Persp Biol Med 48(4), p. 574.

The authors turn the tables on the popular criticism of EBM by proposing that EBM in fact elevates the individual from its previous denigrated status. By refusing to discuss diabetes solely in terms of cellular and tissue function observed in a controlled setting, and insisting instead that outcome data from population-based studies must be addressed, EBM in fact subverts the sub-specialized approach to diabetes research (endocrinology) in favour of a broader perspective of the patient. With this shift in focus, the authors propose,

> the individual has in fact been promoted. Instead of being treated as a bundle of tissues that demonstrate certain biochemical responses, the patient is now a member of a population that demonstrates more or fewer major complications of diabetes, such as premature death, blindness, and loss of limbs.[373]

This "promotion" is, of course, not even close to the vision of patienthood being called for by advocates of more humane and "patient-centred" medicine, as this new population-based group membership is still impersonal. Brody et al. manage, however, to deftly make the point that the criticism that EBM erases the individual needs rethinking. At the very least, the proposal should not be framed as a desire to *return* to the holism of pre-EBM.

In Conclusion

In chapter one, EBM was distinguished from alternative biomedical approaches, with the differences lying in the strengthened reliance on the RCT, the hierarchy of evidence, and the evidence-based penchant for applying epidemiological and statistical methods to clinical medicine. We saw in this chapter that the various knowledge

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[372] Brody *et al* (2005), "Evidence-based medicine: Watching out for its friends." Persp Biol Med 48(4), p. 574.
[373] Brody *et al* (2005), "Evidence-based medicine: Watching out for its friends." Persp Biol Med 48(4), p. 575.

technologies utilized in the healthcare quality movement's focus on the acquisition and use of knowledge and evidence in health care by way of outcomes research, clinical epidemiology, and EBM, worries critics because they are taken together to initiate a new program for medicine that supports use of "the evidence" as the reductive bottom line. This positivist agenda is often accompanied with the rhetoric of pluralism and equity in the advocacy of economic measures for justifying rationing decisions in healthcare distribution.

The formulation of evidence used in EBM has been demonstrated to be problematic by post-positivists, feminist epistemologists, and medical phenomenologists. Relying on "the facts" or "the evidence" to adjudicate between competing clinical practices or scientific beliefs assumes that the evaluative standards of EBM are transparent, neutral, objective, and universal. The numerous accounts of scientific knowledge as "situated knowledges"[374] offered by post-positivist, feminist, and phenomenological thinkers suggest that this understanding of evidence is far too simple and no longer a tenable position in science studies. Furthermore, against the position that modern science stands out as the only objective method of knowledge-gathering, feminist epistemologists and phenomenologists demonstrate the biases implicit in the modern scientific worldview and offer ways of conceiving evidence differently.

Evidence is not self-apparent or "given" when gathered from even the most idealized and controlled observational setting. The critiques of positivist philosophy contest the seemingly unproblematic nature of "evidence" that underlies EBM by emphasizing different features of the social nature of science. The appeal to the authority

[374] Haraway (1988), "Situated knowledges: The science question in feminism and the privilege of partial perspectives." Feminist studies 14(3).

of evidence that characterizes evidence-based practices does not increase objectivity but rather obscures the subjective elements that inescapably enter all forms of human inquiry. EBM's privileging of quantitative over qualitative methods of research stems from a picture of knowledge being more objective when it is distanced from experiential or phenomenological filters. Abstracted from the social context of medicine, EBM seems common sense and the connections between power and knowledge are obscured. Relying on empirical evidence is, of course, not new to scientific medicine. However the evidence based approach is uniquely charged with using "the evidence" not merely to justify medical decisions, but to covertly introduce bold new normative content to medicine.

We began this chapter with the acknowledgment that the question of what constitutes evidence is undeniably central to the EBM discourse. Having uncovered devastating problems with the current configuration of evidence that underlies EBM, a revised account is in order. The next chapter addresses the challenges surrounding alternative theories of evidence.

CHAPTER FOUR

Rethinking Evidence and the Problem of Relativism

We have seen so far that the concept of evidence is being avidly embraced in health care as a symbol of legitimacy, thoroughness, and truth. However, the crude enthusiasm surrounding evidence based approaches has made evidence more like a slogan or branding that draws people in with its seductive promises. Because EBM has not yet overcome many methodological difficulties and has failed to provide insight and direction into how to face the ethical, normative, and social dimensions of health care, its integration into "patient centred" clinical care remains not only unrealized but also uncharted. Without such a program, the movement's acclaim appears to be premature. By remaining silent on integration issues and on how to understand and incorporate patient preferences, EBM has "stopped where the most urgent problems arise and the need for creative and innovative thinking [is] most critical."[375]

Within the many life and social science disciplines striving to become increasingly evidence based, there is a minority of critical voices that have fairly uniformly identified inadequate configurations of evidence as the root of the problems with evidence based practices.[376] The critics do not want to abandon evidence, but desire a more "honest" process for incorporating clinical research into patient care that recognizes the social dimensions of medicine and the multiple facts of knowledge that

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[375] Upshur (2005), "Looking for rules in a world of exceptions: Reflections on evidence-based practice." Persp Biol Med 48(4), p. 488. The challenge of integrating patient perspectives into EBM will be further discussed in chapter 5.

[376] See, for example, Upshur (2005), "Looking for rules in a world of exceptions: Reflections on evidence-based practice." Persp Biol Med 48(4); Upshur *et al* (2001), "Meaning and measurement: an inclusive model of evidence in health care." J Eval Clin Prac 7(2); Djulbegovic *et al* (2000), "Evidentiary challenges to evidence-based medicine." J Eval Clin Prac 6(2); Cott *et al* (2001), "Client-Centred Rehabilitation." Arthritis community research and evaluation unit; Holmes *et al* (in press), "Necrospective: Evidence, virulence, and the disappearance of nursing knowledge." Worldviews Evid Based Nurs.

informs the discipline. The goal of rethinking evidence is to provide a more nuanced account that will correct the shortcoming of the evidence based approach to medicine.

We previously saw that in response to the constructive challenge of formulating an alternative account of evidence, antifoundationalist thinkers working within critical science studies have broadened the standards of evidence to properly admit the social features of science that are missing from the evidence based perspective. The pragmatic refusal to lay down pre-established limits of the scope of what counts as evidence also acknowledges the multiple and interdependent sources of knowledge that inform medicine. In this chapter, it will be argued that despite their critical effectiveness at undermining the philosophical underpinnings of EBM, postpositivist views fail at the constructive task of providing a defensible and useful alternative conception of evidence, as the problem of relativism arises. The problem of relativism is the charge that the social and historical contextuality of truth and knowledge renders these concepts epistemically useless and/or meaningless. This is not only a philosophical problem, but also a failure to provide a useful alternative concept for practitioners who may be wary of EBM's claims and methodologies, yet find themselves still needing, in the end, to make a clearly justified medical decision. The contemporary reconfigurations of evidence in critical science studies offered by Longino in *Science as Social Knowledge*[377] and Nelson in "On Evidence"[378] will be demonstrated to fail to offer guidance in medical decisionmaking—in fact, they may further complicate it—by being so unrestrictive regarding what counts as evidence. As a result the evidence based program may be confounded rather than corrected.

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[377] Longino (1990), Science as social knowledge: Values and objectivity in scientific inquiry.
[378] Nelson (1993), "A question of evidence." Hypatia 8(2).

Longino and Nelson's reconfigurations of evidence are both holistic insofar as they *widen* the concept beyond the previous bounds of the so-called "factual" to include "evaluative" categories. In this chapter, the inadequacy of holistic constructions of evidence for furthering the EBM debate will be argued to be a consequence of certain antifoundationalist epistemological commitments characteristic of critical science studies. Specifically, epistemologist Sharyn Clough's charge that critical science studies relativizes evidence by retaining a representationalist metaphysics will be considered as an explanation for the deficiency that I am proposing.[379] The demonstration by postpositivists that the divide between the objective and the social world is insurmountable (that is, our interpretive lenses block access to "the real") will be argued to properly reign in the overstated veritistic capacity of empiricism by classical and positivist empiricists, yet open up the persistent problem of relativism with respect to effecting normativity in science, as theory choice now becomes relative to worldview. Global scepticism is also made coherent under the representationalist framework. While efforts within critical science studies to deflect accusations of relativism have been valiant, they have required what Clough has called "a hasty retreat from evidence", where the representationalist's inescapably filtered access to reality forces her to attend to the epistemic virtues and worldviews that she wants science to uphold rather than investigating and interrogating evidence itself. This "hasty retreat" serves to explain why the evidentiary accounts offered by postpositivist epistemologists of science fail to offer a defensible alternative to EBM that is useable in the clinical setting and sets the stage for the Davidsonian repair that will be offered in the next chapter.

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[379] Clough (2003), Beyond epistemology: A pragmatist approach to feminist science studies; Clough (2003), "A hasty retreat from evidence: The recalcitrance of relativism in feminist epistemology." Siblings under the skin: Feminism, social justice and analytic philosophy

Antifoundationalist Epistemology: Scientific Holism and Relativism

The link between evidence and empiricism was already made in chapter one in the proposal that the dictionary definition of evidence—" an observation, fact, organized body of information that supports a belief"—betrays empiricist commitments, as it presumes the existence of an external world of "fact" that comes to bear upon our subjective beliefs. Evidence is thought to justify our beliefs about the existence of the real world. However it does not justify our belief that the real world exists independently of our cognitive and emotive processes. Quine[380] refers to empiricism as, at bottom, a theory of evidence and Lynn Nelson adds that there is currently no viable alternative theory.[381]

Quine and Nelson have already been identified in chapter three as post-positivist thinkers that disavow configurations of empirical science that regard observational data as foundational in its pretheoretical and objective representations of the external world. Against the position that observational claims provide a platform on which to build the objective basis of science (what Nelson refers to as the "autonomy of science"[382]), observations are held to be unavoidably theory-laden. This charge that observations, by their nature, cannot be pretheoretical has already been explained to be damaging to the positivist-empiricist understanding of science, as the influence of theory (frameworks, worldviews, etc.) on observation is regarded as a threat to the objectivity of the process of testing and verifying theories. If theories are allowed to, indeed required to, select their own evidence and then to give meaning and credibility to the observations, the testing process could become unavoidably circular and self-serving. Discrediting the presumed

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[380] Quine (1981), "On the very idea of a third dogma." Theories and things
[381] Nelson (1990), Who knows: From Quine to feminist empiricism, p. 9.
[382] Nelson (1990), Who knows: From Quine to feminist empiricism, pp. 79-80.

independence of theory and observation is thought to unavoidably strip science of its objective knowledge-gathering capability and lead to the situation in which incommensurable positions hold equal weight (relativism). This is why practitioners are left without the basis that they need to justify their actions.

Proponents of the "theory-ladenness" thesis deny the claim, however, that the scientific method is discredited by the reliance of observation on theory, and that because science fails to meet its own standards of objectivity, scientific knowledge claims are just relative. This recourse only seems surprising if one fails to notice that the criticisms against the dominant picture of empiricism only challenge the *foundationalist* picture of empirical knowledge, and not empiricism all together. The traditional account posits that all empirical knowledge is founded upon a set of independently intelligible and credible observation claims. The "theory ladenness" critique demonstrates that there are no such "basic" claims, and that the doctrine that all empirical knowledge could rest on such a claim is incoherent.

The difficulty that needs to be overcome is that the critical accounts of evidence not only discredit EBM but also discredit evidence *as such*. What needs to be rehabilitated is the idea of having good reason or justification to select one explanation, theory, or action over another. To get at *why* critical accounts of evidence falter (and how evidence can be restored), the basic antifoundationalist philosophy of science program will be established in the next section via Feyerabend's programmatic essay "How to be a Good Empiricist"[383] and Longino's[384] influential critical account of science as social knowledge. The broad characteristics of a theory of evidence that arises from

[383] Feyerabend (1998), "How to be a good empiricist: A plea for tolerance in matters epistemological." Philosophy of science: The central issues.
[384] Longino (1990), Science as social knowledge: Values and objectivity in scientific inquiry.

these epistemological commitments are then found in Longino's[385] contextualist analysis of evidence and Nelson's[386] naturalized account of evidence. Both Longino and Nelson also carry major themes of feminist epistemologies of science into theories of evidence that are antifoundationalist, postpositivist, and holistic.

Antifoundationalist Science

Rather than regarding the theory-ladenness of observations as a potentially destructive challenge to empiricism, Feyerabend[387] argues that it is positivistic practices in empiricism (which rely on the assumed division between observation and theory[388]) that undermine the empiricist programme. Furthermore, the methodological incorporation of the "theory-ladenness" thesis would in fact make us *good* empiricists, as metaphysics stands to improve rather than hinder empirical knowledge. The role that observations as *facts* or *data* plays in positivistic empiricism, namely as a motivator and a test for theory, is argued to *decrease* our empirical knowledge about the world by reifying current theories and eliminating the alternative metaphysical schemes that are needed for good critical inquiry and comprehensive fact-finding.

In his desire to retain the anti-dogmatic programmatic of empiricism that allegedly spurred science into modernity, Feyerabend challenges us to become *good* empiricists. He purports that modernist empiricism fails at its anti-authoritarian knowledge-seeking agenda because the assumption that theories can be justified on so-called "empirical grounds" is bound to lead to "dogmatic petrification" and the

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[385] Longino (1990), Science as social knowledge: Values and objectivity in scientific inquiry.
[386] Nelson (1993), "A question of evidence." Hypatia 8(2).
[387] Feyerabend (1998), "How to be a good empiricist: A plea for tolerance in matters epistemological." Philosophy of science: The central issues.
[388] Feyerabend challenges the empiricist privileging of observational statements over theoretical statements in Feyerabend (1980), "Science without experience." Challenges to empiricism.

establishment of a rigid metaphysics.[389] Much like modernity has been regarded as totalitarianism in the name and guise of democracy by members of the Frankfurt school,[390] empiricism is thought to reify its metaphysics by its rejection of metaphysics and penchant for supposedly democratic methods of experimentalism and knowledge gained through "experience". Empiricism's enemy, by Feyerabend's account, is no longer the Church and medieval thinking, but *logical positivism*, as it is the latter that works against scientific progress.[391]

The spectacular scientific advances of Galileo, Faraday, and Einstein, according to Feyerabend, could not have been achieved within positivist empiricism's method of confirmation.[392] Contrary to the popular regard of Galileo as a paradigm empiricist, who rejected the empty speculations of the Aristotelians and based his own laws upon facts which he carefully collected, Feyerabend argues that the observational-theoretical dichotomy was not well maintained by either school of thought. In fact, the Aristotelians engaged in observational experimentation, while the Copernican thesis regarding the earth's trajectory was not yet supported by independent observational data at the time of Galileo. Furthermore, the thesis was inconsistent with numerous facts and highly confirmed physical theories at the time. Thus modern physics did *not* originate, as many empiricists claim, as a strictly observational enterprise, but rather as an observationally unsupported speculation that was inconsistent with highly confirmed laws.[393] This

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[389] Feyerabend (1998), "How to be a good empiricist: A plea for tolerance in matters epistemological." Philosophy of science: The central issues, p. 926.
[390] For example, see Horkheimer and Adorno (2002), Dialectic of enlightenment: Philosophical fragments.
[391] Feyerabend (1998), "How to be a good empiricist: A plea for tolerance in matters epistemological." Philosophy of science: The central issues, pp. 922-3.
[392] Feyerabend (1998), "How to be a good empiricist: A plea for tolerance in matters epistemological." Philosophy of science: The central issues, p. 165.
[393] Feyerabend (1964), "Realism and instrumentalism: Comments on the logic of factual support." The critical approach: Essays in honour of Karl Popper

characterization of modern physics' genesis significantly undermines the positivists' maintenance of the observational-theoretical divide, which is thought to be a natural extension of the empirical hypothesis that experience is the only true source and testing ground of knowledge.[394] Feyerabend's numerous accounts of actual scientific practice[395] demonstrate that modern science has always relied on both observational and theoretical content in its developments and advances.

"Dogmatic petrification in the name of [observation and] experience" is understood to occur because *good* empiricism requires the availability of many alternative fully-developed theories to compare against the current theory in question, rather than having only a single point of view stand up against the evidence of experience. Theoretical adequacy involves not only its comparison with the facts but also confronting metaphysical alternatives. Far from circumventing empirical research, metaphysical systems are "the only means at our disposal for examining those parts of our knowledge which have already become observational and which are therefore inaccessible to a criticism 'on the basis of observation'."[396]

A science that alleges to be *free* from metaphysics becomes a dogmatic metaphysical system because it endorses theoretical monism and therefore limits its procedure for ascertaining theoretical adequacy to an insufficiently critical observational method. By making theory only responsible to "the facts", it is the facts—in their assumed autonomy—that dictate the need for theory change (i.e. when incompatible facts

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[394] This hypothesis is refuted in Feyerabend (1980), "Science without experience." Challenges to empiricism.

[395] Feyerabend (1998), "How to be a good empiricist: A plea for tolerance in matters epistemological." Philosophy of science: The central issues; Feyerabend (1964), "Realism and instrumentalism: Comments on the logic of factual support." The critical approach: Essays in honour of Karl Popper; Feyerabend (1981), Problems of empiricism.

[396] Feyerabend (1998), "How to be a good empiricist: A plea for tolerance in matters epistemological." Philosophy of science: The central issues.

arise), yet a critical look at incompatible *alternatives* would make the scrutiny more rigorous.[397] This call for methodological pluralism stems from John Stuart Mill's programmatic for critical philosophy, found in *On Liberty*.[398] Mill insisted that a society that contains many traditions side-by-side has a superior means of judging each single tradition than a monistic society. It also enhances both the equality of the traditions and the maturity of its citizens, as we can learn a lot from, say, the indigenous cultures about the care of the elderly, social organization, and anthropology. These alternative traditions contrast our own in a way that we can reflect critically on our own habits and taken-for-granted practices.[399]

Feyerabend proposes that not only is the autonomy of facts implausible, and scientific inquiry undermined by such an assumption, but empirical investigation is in fact *furthered* by metaphysical pluralism, as some facts cannot be unearthed without an alternative theory. For instance, quantum theory is a highly adaptable theory, as many apparent empirical inadequacies can be accounted for in an ad hoc manner by adding suitable mathematical operators rather than recasting the whole structure.[400] A refutation

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[397] Feyerabend (1998), "How to be a good empiricist: A plea for tolerance in matters epistemological." Philosophy of science: The central issues, p. 934.

[398] Mill (1989), "On liberty." On liberty and other writings.

[399] For Feyerabend's discussion on Mill, see Feyerabend (1981), "Two models of epistemic change: Mill and Hegel." Problems of empiricism.

[400] This has to do with the probabilistic nature of quantum mechanics, which stems from the act of measurement. When a quantum system interacts with a measuring apparatus, their respective wave functions become entangled, and so that the original quantum system ceases to exist as an independent entity. In the formalism of quantum mechanics, the state of a system at a given time is described by a complex wave function. This abstract mathematical object allow for the calculation of probabilities of outcomes of concrete experiments. For example, it allows for the computation of the probability of finding an electron in a particular region around the nucleus at a particular time. Unlike classical mechanics, one cannot ever make simultaneous predictions of conjugal variables, such as position and momentum. Electrons may be considered to be located somewhere within a region of space—a contour of probability or "cloud" surrounding an atom's nucleus—but their exact positions remain unknown. Faced with unavoidable imprecision, mathematical modeling is used for computation in quantum mechanics. *Schrödinger's equation* is a differential equation which describes the evolution of those wave functions that characterize quantum particle when there is no force acting upon a particle. At this point, its potential

of the formalism of quantization would therefore demand proof to the effect that there is no conceivable adjustment of the operators which makes the theory conform to a given fact. Such a general statement can only be provided by an alternative theory.[401] Therefore, Feyerabend suggests, empiricism severely *limits* its empirical investigation when it subscribes to a reductionist consistency condition.[402]

Empiricism demands that the empirical content of our knowledge be increased as much as possible and therefore the invention of alternatives is argued by Feyerabend to constitute an essential part of the empirical method.[403] The consistency condition, which eliminates alternative theories, and the sole reliance on observation and experience as "facts" to test a theory's adequacy, are anti-empiricist since they hinder the growth of empirical knowledge. Specifically, the refusal to consider alternatives can result in the elimination of potentially refuting facts.[404] Furthermore, lack of fully developed theoretical alternatives can lead to theory reification, as the elimination of facts reinforces the seeming uniqueness and truth of the current theory.[405]

Because many facts only become available with the help of alternative theories,[406]

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energy is zero and the Schrödinger equation for the particle *can* be exactly solved. The solution to this 'free' particle can provide a useful way to find approximate solutions to problems which otherwise could not be easily solved.

[401] Feyerabend (1998), "How to be a good empiricist: A plea for tolerance in matters epistemological." Philosophy of science: The central issues, p. 948. This alternative theory must of course be detailed enough to allow for independent and crucial tests (see p. 187 of the same text).

[402] The consistency condition eliminates alternative theories that are in disagreement with current scientific knowledge (as they are deemed to be "theoretically implausible"). This method, while efficacious, is problematic in its assumption that the facts provide all of the testing that a theory needs.

[403] Feyerabend (1998), "How to be a good empiricist: A plea for tolerance in matters epistemological." Philosophy of science: The central issues, p. 936.

[404] Feyerabend (1998), "How to be a good empiricist: A plea for tolerance in matters epistemological." Philosophy of science: The central issues, p. 937.

[405] Feyerabend (1998), "How to be a good empiricist: A plea for tolerance in matters epistemological." Philosophy of science: The central issues, p. 937.

[406] Postcolonial science studies similarly endorse such a position in the suggestion that there are laws of nature that today's modern sciences are ill-designed to discover. See, for example, Harding (1998), Is science multicultural? Postcolonialisms, feminisms, and epistemologies.

and because these facts could potentially expose the faults, or even irreparable inadequacy, of the current going theory, alternative theories are, therefore, the most rigorous challenges available. Furthermore, Feyerabend proposes that this is precisely the method which brought about such spectacular advances of knowledge as the Copernican Revolution, and the transitions to both relativity and to quantum theory.[407]

Feyerabend advises the "good empiricist" not to "rest content with the theory that is in the centre of attention and with those tests of the theory which can be carried out in a direct manner."[408] The best critical tests for theory are produced with the help of alternatives, and therefore the good empiricist should try to invent such alternatives.[409] The elimination of metaphysics does not increase empirical content, but rather decreases it and potentially turns theories into dogma. A *good* empiricist must therefore be a critical metaphysician.[410]

Similar to Feyerabend, Longino[411] argues that the fact that evidence gains its credibility or relevance from the context of inquiry and by background beliefs does not make science relative. Even though science is socially constructed, it already has good procedure for achieving objectivity. The integrity of empiricism no longer rests on the neutrality of our observations, as Longino proposes a *social* conception of objectivity and a *contextual* understanding of evidence, neither of which relies on a neutrality criterion. The fact that evidential relations depend on the subjective beliefs of the individual

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[407] See Feyerabend (1964), "Realism and instrumentalism: Comments on the logic of factual support." The critical approach: Essays in honour of Karl Popper

[408] Feyerabend (1998), "How to be a good empiricist: A plea for tolerance in matters epistemological." Philosophy of science: The central issues, p. 943.

[409] Feyerabend (1998), "How to be a good empiricist: A plea for tolerance in matters epistemological." Philosophy of science: The central issues, p. 943.

[410] Feyerabend (1998), "How to be a good empiricist: A plea for tolerance in matters epistemological." Philosophy of science: The central issues, p. 944.

[411] Longino (1990), Science as social knowledge: Values and objectivity in scientific inquiry.

researcher is *not* incompatible with scientific objectivity when one recognizes that scientific knowledge is the product of a community of scientists and that evidence does not need to be context- or value-free.

In her "contextual analysis of evidence",[412] Longino distinguishes between *constitutive values* and *contextual values* and argues that values are only a problem for scientific objectivity when scientists' (inescapable) contextual values— the social and practical interests that form background beliefs—function as the constitutive or cognitive values that determine what counts as good scientific judgment. When contextual values are recognized *as* contextual values, we can identify these background beliefs independently and demonstrate how certain states of affairs have been rightly or wrongly taken as evidence for a hypothesis. Such processes are social and public, for they depend upon a scientific community sharing a common language with which to describe experience and intersubjective agreement that screens out idiosyncratic and subjective elements.[413] Most importantly, since the scientific community rather than the individual scientist is the knower, enhanced attention to the role of criticism is crucial for overcoming power imbalances within such a community that can result in the devaluation of legitimate criticisms.[414]

Longino and other proponents of the social view of science argue that scientific progress requires two practices: (i) the widespread testing of theoretical hypotheses to confirm or invalidate current understandings, and (ii) the challenging of widely held background assumptions. Most scientists engage in the first type of activity, and the

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[412] See chapter 3 of Longino (1990), Science as social knowledge: Values and objectivity in scientific inquiry.
[413] Longino (1990), Science as social knowledge: Values and objectivity in scientific inquiry, pp. 40-48.
[414] Longino (1990), Science as social knowledge: Values and objectivity in scientific inquiry, p. 79.

second needs more engagement and a more diverse community of scientists to be done effectively. Because science is understood to be an inherently self-critical activity that welcomes collegial debate as a core practice, objectivity is gained by the communicative practice of admitting a wide variety of assumptions and practices to critical investigation by all qualified members of the community. It is in this respect that objectivity is *social*. Scientific knowledge is therefore social knowledge. As such, it emerges through a process of criticism, such as peer review, based on shared community standards.[415] The social nature of objectivity does not guarantee that science will be free from all subjective preference, but if certain criteria are met—she lists four: (i) recognized avenues for criticism; (ii) shared standards; (iii) community response; (iv) equality of intellectual authority—science will be objective to that extent.[416] Thus science can be objective if its social organization permits and encourages criticism of its beliefs. Furthermore, objectivity depends not on the methodological rules by which individuals judge and select hypotheses, but on the way that the scientific community is organized. Longino argues that successfully challenging widely held background assumptions requires a culturally diverse community of scientists, as "alternative" perspectives can help illuminate problems with assumptions that appear "natural" and unproblematic to those who share the prevailing cultural perspective. These marginal perspectives are not thought to be privileged in the sense of being closer to the truth. However the position as "outsider" makes one more likely to perceive problematic aspects of the background

[415] Longino (1990), Science as social knowledge: Values and objectivity in scientific inquiry, p. 69. She calls this "contextual objectivity".
[416] Longino (1990), Science as social knowledge: Values and objectivity in scientific inquiry, pp. 76-80.

assumptions.[417] By bringing the dominant culture's background assumptions into critical view, alternative perspectives are supposed to facilitate correction of implicit errors, and those modifications ultimately result in more reliable scientific theories. The neutrality thesis is therefore challenged, as Longino claims that it is mistaken to assume that contextual values necessarily compromise the objectivity of science.

Drawing from both Longino and Feyerabend, we see that the antifoundationalist program, in the end, entails a picture of empirical science as a self-critical activity that does not require the neutrality of observations (and therefore can accommodate the "theory ladenness" of observations). Longino's social view of science emphasizes the sociality of the pursuit of knowledge, as it is practiced in cooperation with others in the context of a set of shared background assumptions and according to shared beliefs about appropriate method. Central to these background beliefs and values of science is a self-critical picture of science that welcomes collegial debate as a core practice and is rigorous and thorough in its attempts to test hypotheses and evaluate interpretations. Feyerabend expands on the actual practices of a critical science, suggesting that it is metaphysical inquiry and *not* the elimination of metaphysics (in favour of objective observational methods) that increases empirical knowledge. The theory-ladenness of observation is therefore not a challenge to the plausibility of empiricism, but testimony to the actual nature of objective scientific practice as critical metaphysics. This thesis is partly normative, as it suggests that the foundationalist picture ought to be abandoned for being both inaccurate and misleading. Similarly, "evidence based" has been found to entail a questionable and seemingly innocuous technique of deferral to the evidence that obscures

[417] Here, Longino's position sounds very similar to standpoint theory. See Harding, ed. (1993). Rethinking standpoint epistemology: What is strong objectivity?; Harding, ed. (2004). The feminist standpoint theory reader; Quine (1981), "On the very idea of a third dogma." Theories and things.

the multiple and complex considerations that unavoidably go into health care decision-making.

Widening Evidence: Antifoundationalist and Holistic Accounts of Evidence

So far, attention has been given to a critical account of science. However our interest is in the configuration of evidence that arises out of the antifoundationalist epistemological purview. Longino's[418] contextualized analysis of evidence is one source, where she draws from her social account of science to argue that background assumptions must be acknowledged in evidential reasoning. Longino proposes that contextual values play an active role not just in the context of discovery, but also in the context of justification.[419] Given that theory is always underdetermined —that is, theory choice is always based on something more than the data—an accurate theory of evidence must include the role of contextual values in mediating from data to theory.[420]

Longino's move of widening evidence to include background beliefs into the evidential equation is characteristic of the antifoundationalism of critical science studies in its contestation of the possibility of value-free objectivity. What counts as evidence is understood to be conditioned by sets of beliefs which cannot be neatly disentangled into so-called "factual" and "evaluative" categories. The antifoundationalist call for self-critical and anti-dogmatic science has been taken up by many within critical science studies via naturalized and pragmatic approaches—thus making Quine an important figure—as both naturalism and pragmatism are thought to be unassuming in their methods of empirical investigation by offering no prior established theoretical

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[418] Longino (1990), Science as social knowledge: Values and objectivity in scientific inquiry.
[419] This claim about contextual value is similar to Kuhn's on paradigms. Kuhn (1996), The structure of scientific revolutions.
[420] Longino (1990), Science as social knowledge: Values and objectivity in scientific inquiry, p. 57.

commitments. Such an evidentiary account is offered in "A Question of Evidence",[421] where Lynn Nelson outlines a naturalized[422] and holistic configuration of evidence. By Nelson's account, standards of evidence emerge within the processes through which we generate knowledge; these processes have been demonstrated by feminist epistemologists to be numerous and diverse in their origins from broad sources of experience and understanding that extend well beyond the traditional scope of analytic epistemology.[423] The naturalized view of epistemology endorsed by Nelson[424] views knowledge production as radically interdependent with other knowledges and undertakings. Nelson proposes that just as individual theories are thought to neither develop nor face experience in isolation, empirical evidence should be similarly contextualized. The relevant evidence available to us is in fact broader in scope than previously acknowledged and includes such factors as our going theories, assumptions, projects, and values. This view of evidence is holistic in its inclusive scope, as it does not erect artificial boundaries between politics and science, and recognizes a broad system of theories and practices, including those of science, "everyday" experiences and events, and politics, as constituting part of the evidence for reasonable beliefs. This account is also naturalistic, for the expansion of evidence to include such factors as politics has emerged concomitantly with feminist experience and knowledge.

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[421] Nelson (1993), "A question of evidence." Hypatia 8(2).

[422] By "naturalism", I refer to naturalistic epistemology, an approach to the theory of knowledge that emphasizes the application of methods, results, and theories from the empirical sciences. It contrasts with approaches that emphasize *a priori* conceptual analysis or ignore scientific insight into cognition. Quine is credited with initiating the contemporary wave of naturalistic epistemology with his essay, "Epistemology Naturalized." In that essay, he argues for conceiving epistemology as a "chapter of psychology," and for seeing epistemology and empirical science as containing and constraining one another. See Quine (1998), "Epistemology naturalized." Epistemology: The big questions.

[423] See Alcoff and Potter, eds. (1993), Feminist epistemologies.

[424] Nelson (1990), Who knows: From Quine to feminist empiricism; Nelson (1993), "Epistemological communities." Feminist epistemologies; Nelson (1993), "A question of evidence." Hypatia 8(2).

Feminist science studies have demonstrated that the experiences and knowledge that we bring to bear on scientific theorizing will include those shaped by such social relations of gender, race, and class that characterize our society. Furthermore, stricter methodological controls cannot (and should not) "filter out" these factors and relationships.[425] Within epistemology, the call for more authentic accounts of the connections between knowledge and sociopolitical relations[426] broadens the factors relevant to our knowledge and undertakings (including science) to encompass social relations, politics, values, and other factors long regarded as a threat to objectivity, if not the very antithesis to evidence.

To demonstrate the workings of this holistic account of evidence, Nelson provides the example of subatomic particles, which are never observed directly yet are regarded in physics as real entities. Their existence is inferred from the detectable electromagnetic "tracks" left from collisions by particles in a high-tech detector. What supports the view that electromagnetic tracks and debris are evidence of new subatomic particles is a body of theory, accepted practices, and methodological commitments in physics, mathematics, and technology. Furthermore, a theory that posits subatomic particles is supported in part by so-called "common sense" knowledge of macroscopic objects and events, such as what happens when these objects collide at high speeds. It is only by analogy that the instrument readings within the detector can offer explanation of particle movement and therefore evidence for subatomic particles. There is also the further presumption of broad

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[425] Harding (1986), The science question in feminism; Harding (1991), Whose science? Whose knowledge? Thinking from women's lives; Longino (1990), Science as social knowledge: Values and objectivity in scientific inquiry; Nelson (1990), Who knows: From Quine to feminist empiricism; Tuana, ed. (1989). Feminism and science; Seigfried (1990), "Second sex: second thoughts." Hypatia reborn: Essays in feminist philosophy.

[426] For example, Nelson (1990), Who knows: From Quine to feminist empiricism, p. 49.

metaphysical commitments such as the existence of objects and events that are not directly observable, the belief that these objects explain systematically what happens on the macroscopic level, and the notion that macroscopic events like instrument readings are evidence of this.

This is one example illustrating that the theories, methods, and commitments that have emerged as supportive of knowledge claims about subatomic particles – some within science and some of broader reach—constitute a larger part of the evidence for those claims.[427] According to coherentist theories of knowledge, knowledge claims fit within a "web of beliefs"[428] where each theory, practice, or other broad epistemological commitment serves as a "piece" supporting (serving as evidence for) and being supported by others.[429] Knowledge about subatomic particles is not isolatable from a larger system of theories, practices, and standards of evidence. Hence there is no discrete piece of evidence that warrants them.[430]

Feminist philosophers have paid significant attention to science because they recognize political stakes in knowledge. The exclusions and harms that have been suffered by women in the name of science underscore the need for normative content in feminist revisioning of science. Nelson points out that her account of evidence manages to underwrite certain important themes from feminist scholarship: first, that knowledge is socially constructed but still constrained by empirical evidence, and second, that social

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[427] See also Nelson (1993), "Epistemological communities." Feminist epistemologies.
[428] Quine (1960), Word and object.
[429] Quine (1960), Word and object.
[430] Further justification will need to be given, of course, to support the feminist science studies' claim that that *gender* shapes theory formation. The presumption listed above in the example of particle physics, namely that there are non-observable events, is rationally supportable, while presumptions based on existing gender relationships, in contrast, are presumably *not* rationally defensible. The justification of this feminist claim will be discussed by example of "man-the-hunter" versus "woman-gatherer" archaeological theories in the next chapter.

relations, including gender, race, and class, are epistemologically significant. This view from *here* rather than *nowhere* denies the possibility of observational evidence being "given" or pretheoretical; the empirical or sensory underpinning also protects against what Nelson regards (unfairly, I think) as the postmodern view from *anywhere*.[431]

Without pretheoretic notions of evidence, standards, or methods laid down prior to theory construction to explain and predict experience, notions and standards of evidence emerge within and concomitantly with the unfolding of our various epistemological projects in daily life, science, philosophy, or politics. Pragmatism is also associated with Quine, and it involves a rejection of foundationalism and a commitment to the empiricist position that that evidence is ultimately sensory. In naturalized accounts of epistemology, the property at issue is not *truth*, but *justification* by the empirical evidence (as reasonable belief is not derived from unshakable foundations or certitude). This is why Quine understands empiricism to be a theory of evidence and not a theory of truth.[432] Critics such as Clough maintain that because naturalized epistemology is still philosophically normative, the distinction between truth and justification is difficult to maintain[433]—this point will become clearer as we progress with the argument. Quine's naturalized empiricism permits this theory of evidence only "after physics, physiology, and psychology, not before,"[434] and is supposed to support the position that all knowledge is socially constructed while precluding wholesale scepticism about evidence by permitting a robust realism regarding the existence of an independent external world. Naturalism reconciles the "barren scene" of social constructivism with an "unswerving

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[431] Nelson (1993), "A question of evidence." Hypatia 8(2), p. 173; Nelson (1990), Who knows: From Quine to feminist empiricism, p. 42.
[432] Nelson (1993), "A question of evidence." Hypatia 8(2), p. 172.
[433] Clough (2003), Beyond epistemology: A pragmatist approach to feminist science studies, p. 9.
[434] Quine (1966), "On mental entities." The ways of paradox and other essays, p. 212.

belief in external things - people, nerve endings, sticks, stones...." by recognizing that "it is within science itself, and not in some prior philosophy that reality is to be identified and described."[435]

This coherence theory of evidence is therefore supposed to retain the normativity that is commonly thought to be lost when the one-to-one correspondence of theory and the world is denied. Nelson demonstrates, for example, that this account provides stronger support for the feminist charges of sexist bias within mainstream science. The evidence supporting Ruth Bleier[436] and other feminists'[437] claims that research into sex-differentiated lateralization is unwarranted, for instance, is no longer limited to methodological flaws and sloppy androcentric assumptions that are incorporated into the research, but also includes the historical context of the suspicious fascination within the sciences to study or establish sex differences, the history of dubious biologically-based explanations invoked to explain women's cognitive inferiority and lower social status, and the political implications of how this interest in sex difference research intensifies during periods of public debates about women's status and social position.[438] This example strongly supports the fundamental point running through the critical perspectives discussed above: the broadening of the scope of relevant evidence does not render it arbitrary or unable to be evaluated. While there is no simple formula for distinguishing viable theories or research programs for nonviable ones, the inevitable need for extensive and multifaceted evaluation does not amount to relativism.

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[435] Quine (1981), "Things and their place in theories." Theories and things, p. 21.
[436] Bleier (1984), Science and gender.
[437] Longino (1990), Science as social knowledge: Values and objectivity in scientific inquiry; Nelson (1990), Who knows: From Quine to feminist empiricism.
[438] Nelson (1993), "A question of evidence." Hypatia 8(2), pp. 183-184.

Antifoundationalism, Evidence, and the Problem of Relativism

Despite Nelson and Longino's claims to the contrary, Clough[439] argues that the critical science studies literature has relativized evidence. She maintains that regardless of whether one posits a priori *or* concludes a posteriori (through naturalized inquiry) the existence of an independent external world, a separation between "the objective" and "the social" (or "content" and "scheme") is created,[440] and this metaphysical gap hinders our ability to rethink evidence. The methodological holism found in critical science studies highlights the interrelatedness of content and scheme. However, it still holds them to be distinct entities, as seen in the postpositivist position that we always comprehend the world through language, culture, filters, or standpoints.[441] The demonstration by post-positivists that the divide between the objective and the social world is insurmountable (that is, our interpretive lenses block access to "the real") properly reigns in the overstated veritistic capacity of empiricism by classical and positivist empiricists, yet opens up the persistent problem of relativism with respect to effecting normativity in science, as theory choice now becomes relative to worldview. In this framework, political preferences alone support the selection of feminist over androcentric explanatory theories in science. Global scepticism is also made coherent within the

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[439] Clough (2003), Beyond epistemology: A pragmatist approach to feminist science studies; Clough (2003), "A hasty retreat from evidence: The recalcitrance of relativism in feminist epistemology." Siblings under the skin: Feminism, social justice and analytic philosophy

[440] Davidson refers to this phenomenon as "representationalism" in Davidson (2003), "A coherence theory of truth." Siblings under the skin: Feminisms, social justice and analytic philosophy

[441] The concept of explanatory or interpretive *filters* is puzzling to some (myself included). James L. Nelson has asked: if these filters allow us to comprehend the world, how is it that we comprehend the presence and content of these filters themselves? Is a meta-filter required or do we simply understand the filter *through* the filters we have. If it is the latter, then our filters are apparently transparent with respect to filters. Therefore, we really do see through filters that all seeing goes through filters and we really can understand what's true about filters, even though we can only know filters through filters. (Private correspondence with James L. Nelson, May 2006)

representationalist framework. What results is "a hasty retreat from evidence",[442] where our inescapably filtered access to reality forces us to attend to the epistemic virtues and worldviews that we want science to uphold rather than investigating and interrogating evidence itself.

The popular position within critical science studies seems to be that once we recognize an uninterrogated conception of empirical adequacy to be insufficient to act as a criterion of theory choice, we need to pay attention to what epistemological virtues we want our theories to additionally display.[443] Feminist epistemologists of science seize this important opportunity, as it is here that it is possible for our philosophy of science to be explicitly politicized, and cognitive and social aims brought into play to ensure that our scientific narratives are answerable to the evaluations and commitments of the communities they serve.[444]

Clough charges critical science studies with an inappropriate reliance on empiricist epistemology,[445] where foundationalism has been identified as the problem in the devastating critiques of classical and positivist empiricism while the empiricist core has been retained. Feyerabend and Longino certainly followed this course, as their critical accounts of scientific practice interrogated the influence of the subjective (society, culture, theory, etc.) on the integrity of scientific investigation without challenging the

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[442] Clough (2003), "A hasty retreat from evidence: The recalcitrance of relativism in feminist epistemology." Siblings under the skin: Feminism, social justice and analytic philosophy

[443] See, for example, Harding (1991), Whose science? Whose knowledge? Thinking from women's lives; Longino (1990), Science as social knowledge: Values and objectivity in scientific inquiry; Code (1993), "Taking subjectivity into account." Feminist epistemologies. The notion of epistemic virtues does not, however, seem to originate with the postpositivist turn in science studies. Scientists and philosophers of scientists had long encouraged such virtues as "simplicity" and "repeatability" in scientific practice.

[444] Lennon (1998), "Natural sciences." A companion to feminist philosophy, p. 192.

[445] Lynn Nelson has correctly pointed out that many of the critiques of empiricism focus on "naïve" (classical or positivist) forms of empiricism and not the contemporary reformulations inspired by Quine. When I address "empiricism", I refer to features of this epistemology that are present in foundationalist *and* nonfoundationalist accounts (such as feminist empiricism).

empiricist-realist thesis of an independent external world of facts and evidence. I propose that this serves to explain why postpositivist critiques of science are so capable of pointing to major flaws in EBM by undermining the positivist notion of evidence underlying the approach (see chapters one and two), yet fall short in providing an alternative conception of evidence that corrects the deficiencies of EBM. In the context of EBM, the evidence based approach has been criticized for valuing the quantitative at the expense of the qualitative, and the aggregate over the personal. However, Clough's thesis proposes that many contemporary antifoundationalist epistemologies in fact inadvertently support this evidentiary preferencing, as they do not contest the framework in which the qualitative and the personal are less reliable or are *relative*.

Clough[446] argues that because foundationalism is the sole critical focus, the situation arises where while evidence is at issue in post-positivist critiques, attention is deflected instead to such foundationalist concepts as "objectivity", "observation", "experience", and "epistemic individualism". "Evidence" is seen as safely empiricist and therefore does not receive the attention that the foundationalist concepts just mentioned do. Therefore it is not rigorously rethought. She proposes that when antifoundationalists dispute objectivism by claiming that no one can access the "real" world unbiased by one's cultural presuppositions or interpretive lenses, they make a troubling move: they accept the empiricist presupposition that interpretation is the barrier to the real/true. Thus they retain the empiricist-realist dualism between "the social" (theories, worldviews, etc.) and the physical world. This division between the world and the worldview supports the evidence based approach's reductive understanding of evidence by hindering the

[446] Clough (2003), Beyond epistemology: A pragmatist approach to feminist science studies.; Clough (2003), "A hasty retreat from evidence: The recalcitrance of relativism in feminist epistemology." Siblings under the skin: Feminism, social justice and analytic philosophy.

possibility of meaningful alternatives. The problem of relativism hinders consideration into the interpretive features of evidence and the truth-value of anecdotal and testimonial evidence.

I propose that this charge of a "hasty retreat from the evidence" extends even to Longino's and Nelson's efforts to retheorize evidence, as their epistemic commitments narrow their ability to rethink and challenge the concept. In the end, they produce not much more than inclusive accounts of evidence that fail to offer much to the EBM debate. Both Longino and Nelson exhibit the representationalism that Clough regards as promoting relativism. Indeed, Longino even admits that her position relativizes evidence.[447] To begin with Longino's contextual analysis of evidence, Longino explains that background assumptions must be included in our conception of evidence because "explanatory models serve as background assumptions against which data are ordered, in light of which data are given status as evidence for particular hypotheses and as a context within which studies gain significance."[448] This separation of content ("data") and scheme ("explanatory models") in Longino's exegesis of evidence indeed leads, by the author's own admission, to the relativism of evidence. She admits that her disavowal of a direct correspondence between theory and evidence relativizes what counts as evidence, and that "by relativizing what counts as evidence to background beliefs or assumptions,

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[447] Standpoint theory encounters the same problem, as the proposal that all beliefs are filtered through the social standpoint of the believer forces theorists like Harding to disavow the claim that the standpoints of women or feminists will produce true beliefs about reality—just less partial and less distorted ones than those produced by "anti-liberatory interests" (p. 185 of Harding (1991), Whose science? Whose knowledge? Thinking from women's lives. See also Harding, ed. (1993). Rethinking standpoint epistemology: What is strong objectivity?). Since values cannot be separated from science, many feminist thinkers recommend that we need to consider *which* values *ought* to enter. This prescription is somewhat tenuous and feminist epistemologists not surprisingly find themselves defending their claims from criticisms of relativism.

[448] Longino (1990), Science as social knowledge: Values and objectivity in scientific inquiry, p. 195.

hypothesis acceptance on the basis of evidence is also relativized."[449] In this admission, correspondence remains the ideal sort of relation to bridge the metaphysical gap between the world and us, yet the promise of theory-independent standards of evaluations is unreachable. She adds that "in the absence of that clear and distinct perception of the truth of assumptions...the choice of background assumptions is as relative as the determination of evidential relations."[450]

In light of such a grim prognosis for science, Longino's refusal to abandon objectivity seems courageous. In chapter four of *Science as Social Knowledge*, she introduces a restricted notion of "contextual" objectivity that, she claims, avoids the pitfalls of relativism and scepticism by being relative to the social dynamics of various science communities. She argues that the role of background assumptions in evidential reasoning

> is grounds for unbridled relativism only in the context of an individualist conception of scientific method and scientific knowledge. If our conception of the methods of knowledge construction in science is broadened to embrace the social activities of evidential and conceptual criticism, we see how individual subjective preferences are minimized in the final products.[451]

In the end, her call for more democratic science, that is, the expansion of the scientific community to include more diverse perspectives, is somewhat uninspiring, as it offers a far weaker substitute for scientific evidence's now discredited rigorous adjudicative ability. Objectivity for Longino is "by degree"—it is the *least subjective* method for judging which conceptual schemes, filters, and interpretive frameworks make for the least opaque filter between us and the world. Clough argues that within this framework

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[449] Longino (1990), Science as social knowledge: Values and objectivity in scientific inquiry, p. 61.
[450] Longino (1990), Science as social knowledge: Values and objectivity in scientific inquiry, p. 61.
[451] Longino (1990), Science as social knowledge: Values and objectivity in scientific inquiry, p. 216.

of contextual objectivity, global scepticism looms, as the possibility that *all* representations may be unbridgeable must be entertained.[452]

Nelson also commits to a representationalist metaphysics when she makes the claim that "we experience the world through the lens of our going theories."[453] Her representationalism is tied into her naturalism: "our collective experience indicates that nature is a point of resistance with which we need to contend, and the hypothesis that there is a world that constrains what is reasonable to believe is woven through most of our theories because it makes the most sense of what we experience."[454] Using the language of "lenses", Nelson, like Longino, proposes that our subjective conceptual schemes filter our gathering of evidence in belief acquisition. This presumes a representationalist scheme where "the evidence" and our feminist "political values" emanate from two metaphysically separate spheres: the objective external world and the subjective internal mind.

It is, therefore, somewhat surprising that Nelson's difficulty with the correspondence theory of truth is the very representationalism that Davidson finds in Quine (and, by extension, Quineans like Nelson). Correspondence, Nelson writes, is "beset with problems. Not the least of these is that correspondence presumes a dualism of 'organizing schemes and that which is waiting to be organized'[455]."[456] According to

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[452] Clough (2003), "A hasty retreat from evidence: The recalcitrance of relativism in feminist epistemology." Siblings under the skin: Feminism, social justice and analytic philosophy, p. 100. To continue the previous comments regarding the puzzling nature of conceptual filters (see nn. 441), it remains unclear how it is that Longino (and her allies in critical science studies) can know what makes a filter more or less opaque. What is the epistemic character of the evidence they use to support their assessment of the opacity or otherwise of their filters? (Personal correspondence with James L. Nelson, May 2006).

[453] Nelson (1990), Who knows: From Quine to feminist empiricism, p. 112.

[454] Nelson (1993), "A question of evidence." Hypatia 8(2), p. 176.

[455] Davidson (1974), "On the very idea of a conceptual scheme." Proceedings and addresses of the American Philosophical Association.

[456] Nelson (1993), "A question of evidence." Hypatia 8(2), p. 176.

Clough's Davidsonian account, Nelson's coherence theory of evidence repeats the same offence. It is ironic that Nelson promotes the empiricist framework as best suited for feminist science scholarship *because* empiricism is supposed to save social constructivism from the problem of relativism.[457] The postpositivist admission that we can never access the real (due to the theory-ladenness of observational evidence) invites scepticism regarding the justification of knowledge claims.[458] Sensory experience is thought to assist with the problem of relativism by limiting what counts as reasonable belief.[459] In this antifoundationalist formulation, empirical adequacy no longer acts as the criterion for theory choice, but rather as a constraint on our creative theory production. Clough indicts the representationalism underlying feminist empiricism as inviting sceptical doubt and undermining feminist advances in science studies.

Rethinking the Evidence of EBM

The difficulty with the antifoundationalist broadening of the standards of evidence is that the radical holism promoted by critical science studies diminishes the relevance of evidence in medical decisionmaking. While social critique effectively humbles us in our knowledge pursuing activities, it often leaves us without guidance on what to believe. The task of epistemology is to investigate what normative criteria might be used to adjudicate between competing knowledge claims, and these widened accounts of evidence offer a fairly open-ended answer: all data and relevant (however defined) background assumptions, including political values. Rather than residing solely in the factual, evidence now straddles two metaphysically distinct spheres, which leads to

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[457] Nelson (1993), "A question of evidence." Hypatia 8(2), p. 174.
[458] Knowledge claims can, at best, be deemed trustworthy through democratic debate or comparison to alternatives.
[459] Nelson (1993), "A question of evidence." Hypatia 8(2), p. 174.

challenges in application. Evidence's normative ability is presumably lessened by the increased complexity of the concept, as there will undoubtedly be disputes regarding what factors get included into any given evidentiary analysis. While a pre-graded hierarchy of evidence is not the solution (Nelson would call the desire for such certainty of be an "article of faith"[460]), these accounts of evidence do not seem to offer much for furthering the debates in EBM. Instead of offering a more nuanced concept of evidence for use in medical decisionmaking, these holistic accounts may instead confound such decision-making efforts. In applying this theory of evidence, how do we adjudicate between competing claims regarding what constitutes relevant epistemic criteria? If broadening the community of knowers makes this response less subjective, how broad must that community be? While these questions may be necessary and worth the effort of pursuing, we must acknowledge that we have moved far away from the questions about therapeutic efficacy that EBM is interested in.[461]

Yet, as we direct our search for more prescriptive accounts of evidence that support the clinical context, we do not want to fall (back) into pernicious scientism. Thus it important not to lose the valuable negative project, namely the demonstration of EBM's untenable evidence base discussed in chapter three. Any workable alternative account of evidence must not undermine the important critical insight offered by postpositivist and antifoundationalist insight into science studies.

In Conclusion

By not questioning the inescapable separation of "the objective" and "the social" in empiricism (and *not* just positivism), the question of evidence leaves

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[460] Nelson (1993), "A question of evidence." Hypatia 8(2), p. 181; Nelson (1993), "Epistemological communities." Feminist epistemologies, p. 133.

[461] Clinicians also need fast and clear methodologies to keep up with the demanding pace of clinical care.

antifoundationalist theorists with the following conundrum: while it is positivist (and, therefore, problematic) to think that evidence can resolve the uncertainties that accompany medical practice, we are left with the predicament where anything less than the one-to-one correspondence *relativizes* evidence. Even holistic conceptions of evidence retain the metaphysical gap between the world and our worldviews. Because we cannot access the real or unfiltered world, we are forced to attend to the filters in our justificatory practices. This drives us away from evidence question. Post-positivist critiques invest their energies into non-evidentiary considerations and leave "the evidence question" untouched for the most part.[462]

While answerability of theory to evidence remains central to critical scientific inquiry, this postpositivist widening of what counts as evidence creates challenges for application, as the range of epistemological virtues that our sciences should promote in addition to empirical adequacy is highly contested. This challenge forces attention to the constitution of scientific communities by whose practices these virtues become established. For Nelson, our assessment of evidence is a communal enterprise, and "my claims to know are subject to knowledge and standards constructed by the various communities of which I am a member."[463] For Longino,[464] such a community must contain diversity to enable the background assumptions, against which an assessment of relevant evidence is made, to be visible. Even for standpoint theorists like Harding,[465] attention to the perspectives of those who have been marginal in the production of

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[462] Clough (2003), "A hasty retreat from evidence: The recalcitrance of relativism in feminist epistemology." Siblings under the skin: Feminism, social justice and analytic philosophy.
[463] Nelson (1993), "A question of evidence." Hypatia 8(2), p. 186.
[464] Longino (1990), Science as social knowledge: Values and objectivity in scientific inquiry; Longino (1993), "Subjects, power, and knowledge: Description and prescription in feminist philosophies of science." Feminist epistemologies.
[465] Harding (1991), Whose science? Whose knowledge? Thinking from women's lives.

knowledge brings into relief sources of evidence invisible to dominant groups, makes explicit background assumptions which are otherwise taken for granted, and exposes ideological structuring of narratives. What is shared here is the "hasty retreat from evidence", where investigating what counts as evidence requires us to attend to considerations other than the evidence, such as the makeup of epistemic communities.

The postpositivist theorists discussed in this chapter presumably do not see the relativism that they are inviting because it is an inherent feature of empiricist epistemology, and not just positivism or foundationalism. In the end, the presumed existence of an independent external world by empiricists supports EBM's reductionist understanding of evidence by hindering the possibility of meaningful alternatives. In the next chapter, an alternative account of evidence will be forwarded that draws from Donald Davidson's work in the philosophy of language and Clough's advancement of Davidson's nonrepresentationalist themes within the philosophy of science and epistemology. It will be demonstrated that Davidson's rejection of the scheme/content divide permits evidence to be broadened beyond the current positivistic empiricist framework, but without lapsing into the relativism seen among the postpositivist positions examined thus far. Davidson's nonrepresentationalism will then be deployed in chapter six for a re-understanding of EBM and a rethinking of its critiques.

CHAPTER FIVE

Advancing Evidence: A Davidsonian Repair

After articulating the evidentiary relativism that arises out of the antifoundationalist representationalism of critical science studies, Clough attempts to salvage evidence by applying Davidson's holistic model of language use to a theory of meaning and evidence.[466] Clough draws from Davidson's theory of language an evidentiary thesis that, like others in critical science studies, acknowledges the social and contextual features of evidence,[467] but avoids the problem of relativism by denying the relativist use of the underdetermination thesis. This is the position that two opposing theories are *equally* supported by the evidence and therefore theory choice depends on nonevidential considerations like political commitments and subjective preferences. Instead, no two theoretical beliefs can both conflict with each other in drastic ways *and* have the same truth conditions. Davidson's non-representationalist theory of evidence will be outlined in this chapter and then demonstrated in the next chapter to be more useful for resolving the evidentiary difficulties surrounding EBM than what has been previously offered in critical science studies. Davidson's position reclaims the adjudicative force of evidence from relativism without promoting an untenable objectivism, and so the framework is not only epistemically defensible but also clinically useful and useable.

Davidson's Model of Language Use

Davidson's theory of evidence begins similarly to other postpositivist epistemologies with respect to his denial of the objectivist view that sensory data can be

[466] Clough (2003), "A hasty retreat from evidence: The recalcitrance of relativism in feminist epistemology." Siblings under the skin: Feminism, social justice and analytic philosophy, pp. 102-110.
[467] This is important to the overall EBM critique, because we are assured that the Davidson framework can still support the critical perspectives offered by the postpositivist critique.

used to justify beliefs. Davidson distinguishes himself, however, by faulting this positivist understanding of evidence for failing to incorporate our *awareness* of the detection of sense data. Because this awareness is simply another belief, there is no possibility for sensory data to stand as an evidential entity independent from our beliefs.[468]

What separates Davidson from the other antifoundationalist views is that his rejection of objectivism does not lead him to concede the relativism of evidence. Instead, he retains a justificatory scheme for empirical beliefs by committing to a non-representationalist metaphysics. Antifoundationalists like Longino and Nelson are charged with supporting the representationalist claim about the belief-independence of empirical evidence in their allegiance to the existence of cultural filters that block our access to the real. By committing to the underdetermination of theory by evidence, and claiming that adjudication between theories can only be made on the basis of our political values, they presume a representationalist view that the "evidence" and our "political values" emanate from two metaphysically distinct spheres—the first from the objective, external world and the second from the subjective internal mind(s). Davidson's metaphysical monism also avoids the metaphysically troubling "filter", which is neither empirical nor a belief.[469]

Davidson's position that the marshalling of empirical evidence in support of a belief or theory requires awareness of empirical evidence, and that awareness is itself another belief, distinguishes him from representationalists because this account of epistemic justification does not involve an independent evidentiary entity that stands

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[468] Clough (2003), Beyond epistemology: A pragmatist approach to feminist science studies, p. 103.
[469] See nn. 441 in the previous chapter.

outside of our belief system (to which we may or may not be able to directly appeal). The evidence for a belief must *itself* be a belief, and so both our political values and our more straightforwardly empirical commitments are beliefs of this evidential sort. On Davidson's model, even Longino and Nelson's feminist political beliefs must have some web-like relation to empirical evidence if they are to have any content.

Davidson invokes the concept of the "radical interpreter" as a device for describing the condition of the possibility of interpretation and for furthering a model of language use that provides a "*reason* for supposing most of our beliefs are true that is not a form of *evidence*."[470] The reason is that detection of false beliefs requires that we have a background of true beliefs against which the error of false beliefs can be measured.

The radical interpreter is a derivative of the "radical translator" first introduced by Quine[471] to explain the means of translation between mutually incomprehensible languages. Quine argued that linguists might produce translation manuals with terms which are empirically equivalent - they "pick out the same scattered portion of the world" - yet incompatible in meaning. Therefore we can never be assured of success in translation. In his famous example, we could never determine whether it was correct to translate the word "gavagai", used whenever a rabbit appears, as "rabbit" or as "undetached rabbit part". Being empirically equivalent, there is no further fact to decide between them. Much like different translation manuals, our embedded view of the world is relative to a frame of reference. Deciding among equivalent systems of the world turns finally on pragmatic grounds such as simplicity, refutability, fecundity and generality

[470] Davidson (2003), "A coherence theory of truth." Siblings under the skin: Feminisms, social justice and analytic philosophy, p. 126.
[471] Quine (1960), Word and object.

(and *not* transcendent metaphysics).[472] In this thought experiment, we see the seeds of the evidentiary relativism that concerns Clough: the notion of incomplete access to the "real" provided by the available evidence leaves us in the predicament where adjudication between theories or hypotheses require consideration of nonevidentiary considerations or "frames of reference".[473] Davidson objects to the indeterminacy of radical translation (where a single sentence must always be taken to have more than one different meaning) proposed by Quine, and introduces the alternative and charitable "radical interpreter" to avoid the scepticism regarding successful or accurate translation.

Like the radical translator, Davidson's radical interpreter finds herself in a foreign land where she must learn the language by observing the native speakers. Because the speakers' semantic content is not directly accessible to the radical interpreter,[474] she learns by watching for correlations between the types of sounds uttered by the speakers and the kinds of events that prompt the utterances. At this early stage, she does not have any preconceived notion of the particular semantic role that is played by any particular noises uttered by the native speakers. Rather, it is the radical interpreter's accurate identification of the environmental reference that prompted the native speakers' utterances, which provides those noises with semantic content in the first place.[475]

Language use develops at this early stage via a shared causal relationship between the interpreter, the native speakers' utterances, and the objects and events in the world

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[472] Feminist readings of Quine have added political grounds too. Nelson argues that this feminist addition is consistent with Quine's theoretical framework in Nelson (1990), Who knows: From Quine to feminist empiricism.

[473] This is the relativist use of the underdetermination thesis.

[474] Radical translation occurs when a linguist endeavors to translate a target language into her home language without the benefit of consultation with bilinguals. The linguist therefore has only observable stimuli and responses to go on.

[475] Clough (2003), Beyond epistemology: A pragmatist approach to feminist science studies, p. 104. Davidson (2001), "Radical interpretation." Inquiries into truth and interpretation (philosophical essays of Donald Davidson), pp.125-39.

that prompt these utterances. What is also required is that the interpreter assumes the native speakers are speaking truthfully about their beliefs. While this does not guarantee that the assertions are true, the assumption must be made that belief and truth correlate in order for interpretation to occur. This "principle of charity"[476] is regarded by Davidson to be necessary because in order for the radical interpreter to identify her teachers as having *any* beliefs, she must assume the beliefs they hold to be true. It is only once she has established an empirical base of correlations between their sentences and hers that she can start to make judgments of inconsistency and falsehood. Davidson undercuts global scepticism by maintaining that before that point, identifying her teachers' beliefs as false would deplete the empirical base for which she needs to begin her interpretive project in the first place. Language and interpretation are founded on a coordinate of shared meaning and this requires the charitable interpretation—the presumption in favour of truth.[477]

If the principle of charity is a precursor for successful interpretation, this means that truth must be held primitive for words and sentences to be meaningful. The meaning of an utterance is given by its truth conditions, and not the reverse. The radical interpreter is invoked to support Davidson's extensionalist claim that in the simplest cases of beliefs, the events and objects that cause those beliefs (the extension of the beliefs) also determine their contents or meanings (the intension of the beliefs).[478] This means that in the simplest cases, there cannot be wholesale slippage between our

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[476] Davidson (2003), "A coherence theory of truth." Siblings under the skin: Feminisms, social justice and analytic philosophy, p. 128.
[477] Davidson (2003), "A coherence theory of truth." Siblings under the skin: Feminisms, social justice and analytic philosophy, p. 130.
[478] Clough (2003), "A hasty retreat from evidence: The recalcitrance of relativism in feminist epistemology." Siblings under the skin: Feminism, social justice and analytic philosophy, p. 105.

understanding the meaning of a sentence and our understanding of the conditions that would make that sentence true. Most of our basic beliefs cannot be false because we do not first form concepts and then discover what they apply to; rather, in the basic cases, the application determines the content of the concept.[479] In these cases, the meaning of the radical interpreter's utterances is determined by their being used correctly in the presence of another speaker and the event in the world that caused the utterance.

In response to Davidson's position that most of our beliefs must be true, one might insist that just because there must be agreement between the radical interpreter and the native speakers about the truth of basic beliefs, this does not guarantee that those beliefs are in fact true. The Davidsonian response is to examine the concept of truth itself.[480] The very concept of objective truth, he explains, comes from shared language; unless a language is shared, there is no way to distinguish between using the language correctly and using it incorrectly. Only communication with another can supply an objective check. Communication, of course, only starts by assuming agreement on what makes utterances true – the principle of charity.[481]

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[479] Davidson (1991), "Epistemology naturalized." Dialectica 45(2), p. 195.

[480] Davidson (2003), "A coherence theory of truth." Siblings under the skin: Feminisms, social justice and analytic philosophy, p. 132.

[481] For the sake of clarifying the different positions held by the logical positivists, Quine, and Davidson, their *different linguistic approaches* to philosophical inquiry are worth highlighting. They are all part of the "linguistic turn" in 20th century analytic philosophy, where language and linguistic analysis came to be seen as the primary tools for resolving philosophical problems. Both the members of the Vienna Circle and Quine tend towards a linguistic "formalism" (although Quine greatly differs significantly from the former in his famous rejection of reductionism as the "second dogma" of modern empiricism), where philosophical problems are resolved by formalizing the way in which philosophical statements are made. We have already seen that logical positivism entails an idealized view of scientific knowledge (where all knowledge is scientific knowledge), which originated in 19th century positivist thought. This scientism was coupled with the ideal-language meta-philosophical and methodological current in 20th century analytic philosophy (logical atomism). This union of idealized scientific knowledge and language is apparent in the verification theory of meaning, a novel way of dismissing certain non-scientific views by declaring them not merely wrong or false, but meaningless. Along with (early) Wittgenstein, the logical positivists concluded that the bulk of traditional philosophy consisted in meaningless pseudo-problems generated by the misuse of language, and that the true role of philosophy was to establish and enforce the limits of meaningful

To claim that beliefs are by their nature generally true is to separate true belief from what constitutes knowledge, as Davidson's general presumption of truth does not make beliefs "globally right".[482] What it does do is provide "the background against which we can accuse them of error."[483] Davidson's causal analysis of belief provides us less-than-radical interpreters with a *presumption* in favor of the truth of any particular belief, but not a guarantee. Davidson cheerfully admits that the truth of each particular belief is up for grabs, though not all or even most of these beliefs can be up for grabs at once. It is the veridicality of beliefs *generally,* as understood through his causal account, that makes "meaningful disagreement" over *particular* beliefs possible.[484] Our beliefs have no content unless we have established a common convergence between ourselves, another speaker (or speakers), and a shared environmental stimulus. We know that because radical translation and interpretation is undertaken without the benefit of bilingual speakers, the linguist has only observable stimuli and responses to go on. The most obvious utterances to begin translating are those that seem most tied to observable events conspicuous to both the linguist and the native. Initial hypothesis testing will, therefore, concern assent to and dissent from such "occasion sentences",[485] which provide the entry points for the desired convergence between speaker, interpreter, and the world.

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language through linguistic analysis. In Wittgenstein's Tractatus, the world is conceptualized as the existence of certain states of affairs, all of which can be expressed in the language of first-order predicate logic. It follows that a fairly comprehensive picture of the world can be built up by expressing atomic facts in atomic propositions, and linking them using logical operators. Davidson, in contrast, uses a naturalized linguistic approach, where one comes to understand philosophical ideas by a close and careful examination of the natural language used to express them – usually with some emphasis on the importance of common sense in dealing with difficult concepts—and not by examining the abstract logic of language.

[482] Davidson (2003), "A coherence theory of truth." Siblings under the skin: Feminisms, social justice and analytic philosophy, p. 133.

[483] Davidson (2003), "A coherence theory of truth." Siblings under the skin: Feminisms, social justice and analytic philosophy.

[484] Davidson (1974), "On the very idea of a conceptual scheme." Proceedings and addresses of the American Philosophical Association.

[485] See §7-9 of Quine (1960), Word and object.

Once we have established a pattern of successful convergence, or semantic "firmness", then we can say of any particular belief that it is false. One has to be right about a large background of beliefs before the validity of particular beliefs can be critically examined. Similarly, successful communication with others indicates that you know many things about your world.[486]

Davidson's position undermines global scepticism by demonstrating that on the model of the radical interpreter, the precondition for such wholesale doubt—a metaphysical gap between language users and the world—is unthinkable. On the representationalist view, beliefs are conceived as "inner" or subjective representations of the outer natural realm. In contrast, Davidson makes the case for viewing beliefs as the production of a triangular causal relationship between ourselves, other speakers, and our shared environment. From the perspective of the radical interpreter, our ability to use language comes from direct, unmediated causal contact with the world, which in turn, guarantees that we have an established background of true beliefs against which our false beliefs can be measured.

Davidson on Evidence

Without the looming problem of global scepticism, Davidson does not need to concede the evidentiary relativism that stymied efforts to reconceptualize medical evidence in the context of EBM. Applying Davidson's model of language use to a theory of language, we are cautioned against the metaphysical bifurcation of inner, subjective, *political* reasons for scientific beliefs from external objective, *evidential* reasons for these beliefs. In support of Davidson's position that empirical evidence and beliefs are

[486] Davidson (1989), "The myth of the subjective." Relativism: Interpretations and confrontations; Davidson (1990), "The structure and content of truth." J Phil 87(6).

metaphysically similar entities (as evidence for a belief is itself a belief, and our political values have empirical content), Clough revisits Longino's treatment of the "man-the-hunter" versus "woman-the-gatherer" archaeological interpretations of certain chipped stones. Longino claims that both explanatory accounts are equally supported by the evidence (the stones) and therefore theory choice is *relative* to our underlying political commitments, namely androcentrism or feminism, respectively.[487] Clough argues instead that *feminist political values are themselves beliefs with empirical content* that can, in turn, provide good evidential reasons for rejecting the man-the-hunter interpretation. Rejection of this interpretation is not relative to the extra-evidential world of feminist politics.

The *evidence* supporting the "woman-the-gatherer" thesis includes feminist political analyses of past scientific practices, which have revealed the well-documented pattern that theories of human bodies and behaviour that ignore *women's* bodies and behaviour are inaccurate. The feminist archaeologist who disputes the man-the-hunter theory, in spite of the equivocal evidence provided by the chipped stones, still has *good inductive evidence* based on her feminist political views to support her decision. The man-the-hunter theory leaves out the role of women in the human development of technology and culture. The feminist archaeologist who chooses to interpret the chipped stones on the basis of a theory that includes or even highlights the role of female agrarian behaviour is making her choice based on past *evidence* that ignoring the role of women is to get the "human" story drastically wrong. Her decision is not merely relative to feminist politics; it is not based on some nonevidentiary belief entity brought in when all

[487] Longino (1990), Science as social knowledge: Values and objectivity in scientific inquiry, chapter six; p. 109.

the objective evidence, independent of belief, is equivocal. Rather it is a decision well supported by inductively observed instances of past scientific errors.

On Clough's nonrepresentationalist view, then, the man-the-hunter and the woman-the-gather interpretations are not equally well supported by the evidence. The former is *not* supported by feminist analyses of past scientific practice. It is not the case, as Longino suggests, that faced with interpretations equally well supported by the "belief-independent" empirical evidence, we are forced to rely on our inner belief world of politics to make our choice. Neither is it the case that feminist normative beliefs are *supported* by the historical evidence, derived from past feminist analyses, that a theory of human development that cannot account for women's activities fails as an explanatory theory. Davidson's proposal is that normative beliefs *are* evidentiary; to propose that the latter supports the former invokes the scheme/content split that was demonstrated in the last chapter to invite relativism.

Rethinking Evidence: Differentiating Clough from Nelson

Clough's Davidsonian evidentiary defense of the "woman-the-gatherer" archaeological theory seems, at first glance, somewhat similar to the evidentiary support that was provided by Nelson of feminist science studies' repudiation of sex-based lateralization.[488] There are, however, important points of difference between the two that allows the former to avoid the evidentiary relativism found in the latter. These differences begin with Clough and Nelson's respective allegiances to Davidsonian and Quinean models of language use. Davidson regards the key difference between Quine's method of radical translation and his own method of radical interpretation to be the choice of causes that govern interpretation. While Quine understands interpretation to

[488] See p. 137 of this dissertation.

depend on patterns of sensory stimulation, Davidson makes it depend on the external events and objects the sentence is interpreted as being about. Thus Quine's notion of meaning is tied to sensory criteria, which he also treats as evidence. This leads Quine to assign epistemic significance to the distinction between observation sentences and other sentences, since the former are supposed, by their direct conditioning to the senses, to have a kind of extra-linguistic justification. Davidson argues that sensory stimulations are indeed part of the causal chain that leads to beliefs, but cannot, without confusion, be considered to be evidence or a source of justification for the stimulated beliefs.[489]

While Nelson and Clough similarly invoked past feminist analyses as evidentiary support for the respective hypotheses proposed in feminist science studies, only Clough regarded those theories as directly tied to the empirical world. Nelson broadened the scope of relevant evidence when she proposed that "part of the evidence for objects is provided by the larger systems of theories and practices in which such objects figure",[490] but did not challenge the metaphysical bifurcation between the empirical "objects" that traditionally comprised evidence in its entirety and the intersubjective "theories and practices" that she had just introduced into the evidentiary fold. Nor did she see that not doing this led to evidentiary relativism in the end. Clough proposes that feminist political values are beliefs *with empirical content*; thus they do not merely filter the real, but actually constitute part of it. Unlike the filtering conceptual schemes invoked in the writings of Longino, Nelson, and Feyerabend, Davidson views our language use as a guarantee of an unmediated causal relationship between most of our beliefs and the world. Unlike correspondence theories, however, this unmediated contact does not

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[489] Davidson (2003), "A coherence theory of truth." Siblings under the skin: Feminisms, social justice and analytic philosophy, p. 131.
[490] Nelson (1993), "A question of evidence." Hypatia 8(2), p. 183.

justify *particular* beliefs. Davidson's model does not regard empirical beliefs as having better metaphysical links to the outer, independent objective world than do our political beliefs,[491] just as our political beliefs are no more closely related than our straightforwardly empirical beliefs to our inner subjective world. But this is because, on Davidson's view, there *is* no inner or outer world and no metaphysical bifurcation. There is only a world, an objective view of which can be made meaningful only by the language users who are part of it.

One might object that because all beliefs have a causal relation to the world, there are features of the world that prompt the development of not only feminist beliefs, but misogynist theories too. Furthermore, because most beliefs are presumed to be true, more needs to be said about how political views are sorted out. However, Davidson's general presumption of truth does not guarantee the veracity of particular beliefs. It only provides the backdrop for judging theories to be false. This permits the honest and comparative evaluation of competing theories, where neither option can be selected based on one's political allegiances or preferences, as evidence cannot equally justify yet undermine both theories. Additionally, the argument has been made that the rigour of empirical inquiry is increased by consideration of alternative theories and metaphysical systems. The comparison of competing theories is far more challenging than limiting testing to observational examination.

Davidson's truth-theoretic treatment of meaning, where the meaning of an utterance is given by its truth, ensures that changes in empirical beliefs can, and must, in principle, affect more theoretical beliefs, even if the effect is only slight. Therefore, no

[491] This distinguishes Davidson from Quine, who regards observation sentences as situated on the periphery of the web of beliefs, while other more theoretic sentences reside closer to the centre (see Quine (2003), From a logical point of view).

two theoretical beliefs can both conflict with each other in drastic ways *and* have the same truth conditions; the radical interpretation model denies the relativist interpretation of the underdetermination thesis: the condition where two opposing theories are *equally* supported by the direct evidence and therefore theory choice depends on nonevidential considerations like political commitments and subjective preferences. This is denied because the commitments and preferences *are* evidential—they are of the same *kind* as empirical evidence. Furthermore, because all beliefs depend on a causal relationship with the external world, all beliefs can be adjudicated by the radical interpreter via the identification of the belief's causal history, a move that avoids the relativism that Nelson and other feminist epistemologists of science fall into when they cannot strongly justify the primacy of their feminist worldviews over other androcentric filters.

Thus Clough can make a stronger case for feminist science than Nelson,[492] as she, unlike Nelson, does not need to justify the legitimacy of our feminist interpretive *filters*; instead she argues for the truth of feminist science. There is no need for us to doubt the evidence of our feminist political values as long as we conceive of such evidence as that which is provided by other beliefs in our web. Clough proposes that "our scientific theories and our beliefs about oppression and justice are not merely relative to our feminist conceptual schemes, they are *justified* by the evidence and they are *true*."[493]

Beyond Epistemology: Empirical Inquiry, not EmpiricISM.

The natural conclusion of Davidsonian repair is abandonment of traditional epistemological pursuits—hence the title of Clough's book, *Beyond Epistemology.* The

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[492] Recall that this is important to this investigation into EBM because feminist epistemology was identified early on as offering the tools for investigating the relation between epistemology and ethics/social.
[493] Clough (2003), "A hasty retreat from evidence: The recalcitrance of relativism in feminist epistemology." Siblings under the skin: Feminism, social justice and analytic philosophy, p. 110.

entirety of the Western epistemological pursuit has been proposed by Rorty to be framed by representationalist metaphors,[494] a framework that Clough suggests to result in an "objectivism-to-relativism" slide where anything less than a one-to-one correspondence of theory and the world amounts to relativism.[495] Given this antagonistic relationship between epistemology, representationalism, and self-refuting scepticism, she recommends that feminist science studies forsake its current preoccupation with epistemology in favor of a return to the local, empirical research that characterized early feminist science studies (hence the subtitle of her book, *A Pragmatist Approach to Feminist Science Studies*).

Clough maintains that epistemology is an unworthy focus because the discipline is premised on the coherence of global scepticism *and* consistently fails to defeat it.[496] This begins with the representationalist metaphysics underlying both foundationalist and antifoundationalist epistemologies of science. It has already been discussed that both foundationalists and antifoundationalists view beliefs or theories as representing the world. The ontological task presented by the representationalist model is then the identification of those normative properties that indicate the level of interference or filtering between the representations and their (real) referents.[497] *Epistemology* is a process of adjudicating between representations, based on the detection of these normative relational properties.[498]

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[494] Rorty (1991), "Pragmatism, Davidson, and truth." Objectivism, relativism, and truth: Philosophical papers, volume 1; Rorty (1991), "Representation, social practice, and truth." Objectivism, relativism, and truth.
[495] Clough (2003), Beyond epistemology: A pragmatist approach to feminist science studies, chapter 5
[496] Clough (2003), Beyond epistemology: A pragmatist approach to feminist science studies, chapter 2.
[497] Clough (2003), "A hasty retreat from evidence: The recalcitrance of relativism in feminist epistemology." Siblings under the skin: Feminism, social justice and analytic philosophy, p. 89.
[498] Clough (2003), "A hasty retreat from evidence: The recalcitrance of relativism in feminist epistemology." Siblings under the skin: Feminism, social justice and analytic philosophy, p. 90.

Yet scepticism arises from this representationalist model of the relationship between knowers and the world. If beliefs are only internal copies or representations of the external world, then it is possible that somewhere in the copying process an error might have occurred, rendering the copy inaccurate. Indeed, *all* of our representations could be inaccurate because their content has been filtered through the schemes of our perceptual apparatus, language, cultural worldview, and/or theoretical allegiance. We can never be sure of the fidelity of our representations because we do not have direct access to the empirical world that caused them. The epistemological search for the set of properties that is defining of knowledge,[499] in other words, the relational properties that ensure the reliability of our representations of reality, therefore arises as a response to this global scepticism. The possibility of wholesale independence of our theories and the world can only be avoided by specifying the normative relational properties that anchor them together. In the ongoing epistemological debate between objectivists and relativists, objectivists hope to defeat scepticism with various theories of correspondence, while relativists seem resigned to the sceptical view that the filtering of our beliefs make truthful representations impossible and coherence between beliefs our only hope.[500] It is representationalism that makes coherent the sceptic's worry that the two worlds may not be bridgeable—*all* of our subjective theories about external reality may be inaccurate—and it is this worry that necessitates epistemology, the specification of normative relational properties that secure our theories to the "bits of the world they purport to

[499] The set of properties are typically abstracted from context, subjects, and practices. Some exceptions include DeRose (2003), "Contextualism and knowledge attributions." Epistemology: The big questions; Code (1993), "Taking subjectivity into account." Feminist epistemologies; Tanesini (2003), "The practices of justification." Epistemology: The big questions.

[500] Clough (2003), Beyond epistemology: A pragmatist approach to feminist science studies, pp. 12-13.

describe".[501]

While there are few epistemologists who would still claim that the identification of normative criteria increases our certainty in our beliefs, the search for these criteria continues in numerous scaled-back forms. It is the motivation for this search that concerns Clough, as she sees epistemology to be motivated by the threat of global scepticism, more specifically, the threat that our beliefs about the world may be disconnected from the truth about the world.[502] If it were otherwise, we would be able to abandon the epistemological pursuit. Within the epistemology of science, scepticism arises as the concern that if the criteria for detecting normative properties cannot be identified, then knowers will have no way to rationally adjudicate between competing knowledge claims. If, as Longino argues, the evidence for our scientific theories is continually filtered by our gendered background beliefs, then we need epistemology to provide normative guidelines for minimising the resulting error.[503]

Davidson argues that what stands in the way of global scepticism of the senses is the fact that in the context of basic beliefs and simple occasion sentences, we must "take the objects of a belief to be the causes of that belief. And what we, as interpreters, must take them to be is what they in fact are."[504] Thus the scepticism invited by the representationalist model can never be answered from within epistemology – only a nonrepresentationalist approach avoids the pitfalls of relativism. Because it is unencumbered by the demand of answering to sceptical doubt, it invites a pragmatic

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[501] Clough (2003), "A hasty retreat from evidence: The recalcitrance of relativism in feminist epistemology." Siblings under the skin: Feminism, social justice and analytic philosophy, p. 90.
[502] Clough (2003), Beyond epistemology: A pragmatist approach to feminist science studies, p. 10.
[503] Clough (2003), Beyond epistemology: A pragmatist approach to feminist science studies, pp. 9-10.
[504] Davidson (2003), "A coherence theory of truth." Siblings under the skin: Feminisms, social justice and analytic philosophy, p. 131.

approach to science studies.

A Pragmatist Approach to Science Studies

Clough's concern is that when feminist epistemologists of science embark on the quest for normative ontological properties and the best epistemic methods for their detection, they invite sceptical doubt: when the adjudication of knowledge claims are construed as an epistemic process prior to and independent from the local, empirical justification of those claims, we unnecessarily invite the worry that our claims about the oppression of women, for example, while well supported by empirical evidence, might not meet the epistemic criteria that stands independent of this evidence. Yet, Davidson's argument is that the measure for true belief is other true beliefs, not externalist evidentiary properties or reliable belief-forming processes. Thus epistemology's task of specifying the normative relational properties that make a theory maximally objective "*remains separate from the everyday ad hoc question whether any* particular *knowledge claim is justified by the evidence.*"[505]

Clough recommends refocusing feminist science studies away from its current preoccupation with epistemology to the more mundane questions of justifying particular beliefs, as epistemological investigations are less effective at promoting the interests and avoiding the harms of women through science. Specifically, the feminist move from science to epistemology has entailed a shift in focus toward overgeneral accounts of "science" and/or "method" and away from the specific agents responsible for harming people.[506] Clough endorses the methodological inquiries that characterized early feminist

[505] Clough (2003), "A hasty retreat from evidence: The recalcitrance of relativism in feminist epistemology." Siblings under the skin: Feminism, social justice and analytic philosophy, p. 90 (my emphasis).
[506] Clough (2003), Beyond epistemology: A pragmatist approach to feminist science studies, p. 121.

interventions in science as properly capturing this pragmatic direction. Most of the feminist interventions from the mid-nineteenth to the early twentieth centuries were directed at the level of methodological critique, attempting on a case-by-case basis to counter faulty sexist and racist practices with more accurate data and methods. Early feminist criticisms of science, such as Mary Calkins[507] and Helen Thompson Woolley,[508] addressed the methodological flaws underlying various Darwinian claims, including claims about the inferiority of European women and non-European women and men. The late 1970s and 1980s saw a shift, as feminist scientists and science commentators moved away from empirical critique toward more philosophical diagnoses and treatment. Harding,[509] for example, advocated this shift from "feminist critiques of bad science" to the more philosophical feminist critiques of "science as usual" or "science at its best" because identifying individual cases of bad science as laden with sexist values and ideology misses the larger point that *all* our science, even that produced within the highest of our current evidential standards, is value-laden or ideological.[510] Clough is critical of this philosophical focus and argues that epistemology is not the most effective focus for feminist science criticism. Specifically, philosophical examinations of truth, method, and evidence do not clearly assist in identifying and addressing those scientific practices that systematically disadvantage marginalized people.[511] Furthermore, many epistemological problems are unanswerable because of the scepticism invited by the representationalist model (which, it has been argued, cannot be overcome within

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[507] Calkins (1896), "Community of ideas of men and women." Psych Rev 3(4).
[508] Woolley (1910), "Psychological literature: A review of the recent literature on the psychology of sex." Psych Bul 7(10).
[509] Harding (1986), The science question in feminism.
[510] Harding (1986), The science question in feminism, pp. 21-24.
[511] Clough (2003), Beyond epistemology: A pragmatist approach to feminist science studies, pp. 1-2.

epistemology).

To better understand Clough's differentiation of epistemology of science from a pragmatic approach to science (or empiricism from empirical inquiry), consider the different research questions explored. Epistemological investigations, she explains, explore the question "By what normative criteria can we adjudicate between competing knowledge claims?" or "Do these criteria indicate the presence of normative properties such as truth or (at least) maximal objectivity?", while pragmatic scientific inquiry asks the narrower empirical question, "is this scientific theory true?". Answering questions about the truth or justification of any particular knowledge claim or set of knowledge claims has already been proposed to be a separate task from the broader epistemological questions about the properties that make beliefs true, maximally objective, or even empirically justified. Specifically, empirical inquiry involves a local assignment of truth and justification. It is only when we elevate empirical investigation of a specific claim to the prescriptive level of empiricist epistemology that we encounter scepticism and relativism.[512]

Empirical inquiry involves the fairly uncontroversial practice of comparing the knowledge claim in question with the current ongoing theories and experiences of the world. Examinations of the empirical question are typically dynamic, and often ad hoc, processes of comparing the specific theory in question with an ongoing body of theories and with past and present experiences and data. The assignment of truth, evidential justification, or maximal objectivity, is site-specific and is adjusted as new information comes in; that is, it is fallibilistic. For example, Helen Montague and Leta Stetter

[512] Clough (2003), Beyond epistemology: A pragmatist approach to feminist science studies, p. 15.

Hollingsworth[513] are noted by Clough for providing important empirical critique of sexist conclusions drawn from evolutionary theory regarding white European men's superior physiological and mental capability. By conducting careful empirical testing on infants (to control for confounding sociological factors) of both sexes, the scientists disproved the theory that human males presented with greater physiological variability over females. The slim empirical data indicating mental variability were found to be better explained sociologically than biologically.[514] Such sound empirical challenges capture the localized form of inquiry customary to the pragmatic approach to science. Because global scepticism is not a threat within the Davidsonian evidentiary scheme, there is no reason to elevate investigation from the mundane empirical to the level of epistemological inquiry.[515]

> Philosopher of science, Arthur Fine, has argued that epistemologists
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> see science as a set of practices in need of an interpretation, and they see themselves as providing just the right interpretation. [However] science is not needy in this way. Its history and current practice constitute a rich and meaningful setting. In that setting, questions of goals or aims or purposes occur spontaneously and *locally*.[516]

The pragmatic approach to science involves the truth of our individual beliefs and scientific theories being assigned locally, and of course, fallibly. This sort of empirical assignment is typically ad hoc and dynamic – the criteria are always being adjusted as new information comes in. Davidson holds that while empirical data plays a causal role

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[513] Montague and Hollingsworth (1914), "The comparative variability of the sexes at birth." Am J Soc 20(1).

[514] Clough concedes that the shift in feminist science studies to larger philosophical questions were largely the result of such sound empirical challenges to sexist science as offered by Montague and Hollingworth being ignored by the scientific community. She still insists that pragmatic science is preferable for feminist liberatory mandates because it at least does not damage feminist credibility in science. See Clough (2003), Beyond epistemology: A pragmatist approach to feminist science studies, pp. 19-20.

[515] Clough (2003), Beyond epistemology: A pragmatist approach to feminist science studies, pp. 15-19.

[516] Fine in Clough (2003), Beyond epistemology: A pragmatist approach to feminist science studies, p. 121.

in establishing the content of *all* beliefs, those causal connections to the empirical world are not normative properties contained by those beliefs that are true or maximally objective. Davidson's nonrepresentationalist view of belief entails *causal connections playing no epistemological or justificatory role.*[517] Thus scientific inquiry is not a valuable pursuit because it provides privileged access to truth. Instead its ability to establish the truth of particular beliefs comes from its democratic tenor. Rorty[518] endorses a pragmatic view of scientific investigation as a set of open and democratic values that seeks *truth* in the local sense, where "the best way to find out what to believe is to listen to as many suggestions and arguments as you can."[519] This is not a metaphysical claim about the connection between human reason and the nature of things. As language users, we have direct causal contact with our world, but this connection does not justify the truth of any one belief. This causal connection only ensures that we cannot be wrong in *all* beliefs. Davidson and Clough's endorsement of democratic scientific practice rather than epistemology is not supported by metaphysical or epistemological assurance of our connection with reality. Instead, Davidson "simply makes the point that if we try to give up the world, we must also give up language."[520]

Confronting the Critics

As one might expect, Clough's provocative reading of feminist science studies and her radical suggestions for repair have been contested. Specifically, the accuracy of Clough's characterization of certain feminist philosophers of science as Davidsonian

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[517] Clough (2003), Beyond epistemology: A pragmatist approach to feminist science studies, p. 110.
[518] Rorty (1991), "Science as solidarity." Objectivism, relativism, and truth: Philosophical papers, Volume 1.
[519] Rorty in Clough (2003), Beyond epistemology: A pragmatist approach to feminist science studies, p. 122.
[520] Ramberg in Clough (2003), Beyond epistemology: A pragmatist approach to feminist science studies, p. 110.

representationalists has been challenged, as has the utility of feminist thinkers going "beyond epistemology". These challenges will be reviewed in this section, and their impact on the question of evidence in EBM considered.

We have seen so far that the representationalist view involves the ontological split between sensory 'data' that is completely unconceptualized and values that are non-cognitive (i.e. not amenable to evidence or reason). The human mind must filter this unconceptualized "stuff" through concepts before the stuff can be understood as anything (red, smooth, a ball, etc.). Minds have no direct access to the world except through these conceptualized data or "representations".[521] Feminist scholars are charged by Clough with keeping the vestiges of this position by maintaining that theories of science depend upon the political schema and values scientists use to interpret data. Relativism arises insofar as theories are relative to political and other such values, and this outcome is self-defeating since feminist critics of science still hold that some theories are better than others. While the feminist theorists examined explicitly reject relativism, "each is left with a watered-down prescription for feminist scientific method that is restricted to detecting how the filter of culture intervenes between the world and scientific knowledge" and advocating that scientists pick feminist views.[522] Not only does this position hinder feminist liberatory projects, but the metaphysical split is false. Values, Clough argues, are not different in kind from factual beliefs, as both are based on experience and reason. The notion of a filtering process that underlies both objectivism and relativism is therefore incoherent, as the value-laden schemes that structure and organize beliefs are themselves also empirical beliefs. Denying the dualism, and

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[521] Potter in Potter *et al* (2006), "On the very idea of a feminist epistemology for science. [Review symposium]." Metascience 15(1), p. 1.
[522] Clough (2003), Beyond epistemology: A pragmatist approach to feminist science studies, p. 92.

therefore avoiding the traditional debate between objectivism and relativism, would recognize the success of human cognitive practices, such as science, and also substantiate the value of at least some feminist perspectives. Instead of seeking universal epistemological standards, Clough argues that science studies must accept local empirical practices and standards and use these to test or evaluate competing accounts of the world. Feminist scholars should therefore stop doing epistemology.

In a 2004 review symposium of *Beyond Epistemology*,[523] Elizabeth Potter and Moira Howes challenged Clough's reading of Longino and Ruth Bleier as representationalists. Potter contests Longino's alleged representationalism on the bases that Longino does not regard conceptual filters to be non-cognitive values and she does not see data as pretheoretic. In *Science and Social Knowledge*, Longino proposes that there is no unique or intrinsic evidential relationship between evidence and the hypothesis or model for which it functions as evidence. Instead, the connections or regularities we appeal to in assessing evidential relations are connections or regularities from some point of view and always subject to change. The objects, events, and states of affairs providing evidence for hypotheses are not empirically apparent; instead, how one determines evidentiary relevance depends upon one's background beliefs or assumptions.[524] Longino says that a *background belief enables us to see evidence for a hypothesis*;[525] in other

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[523] The symposium, featuring Elizabeth Potter, Moira Howes, Nancy McHugh, Catherine Hundleby, and Sharyn Clough, took place at the inaugural meeting of the *Association for Feminist Epistemologies, Methodologies, Metaphysics, Science Studies* in Seattle, November 2004. The proceedings of the symposium later appeared in print as Potter *et al* (2006), "On the very idea of a feminist epistemology for science [Review symposium]." Metascience 15(1).

[524] Longino (1990), Science as social knowledge: Values and objectivity in scientific inquiry, pp. 43-45.

[525] Longino writes that background assumptions are "beliefs in the light of which one takes some x to be evidence for some h and to which one would appeal in defending the claim that x is evidence for h" in Longino (1990), Science as social knowledge: Values and objectivity in scientific inquiry, p. 44.

words, our background assumptions make the evidence for a given hypothesis plausible.[526]

Furthermore, the "man-the-hunter vs. woman-gatherer" example examined by Clough reveals, according to Potter, that Longino does not regard data to be unconceptualized. Here the data are *already* conceptualized as chipped stones; it is only from there that they can be further interpreted as tools used either by men for hunting or by women for food preparation. Thus the data are not the unconceptualized "stuff" of representationalism, but already identified as objects (chipped stones).

Potter maintains that while Longino does argue that the available anthropological data are so few as to underdetermine the choice of hypothesis regarding the chipped stone's use, and so the majority support for "man-the-hunter" interpretation comes in part from unexamined gender assumptions, this does not indicate social and political values to be non-cognitive. Longino in fact rejected the distinction between cognitive and non-cognitive values in favour of a distinction between constitutive and contextual values, that is, those values that constitute recognized criteria for theory choice, such as simplicity or consistency, and those non-constitutive values arising from the context in which knowledge is produced.[527]

Similar to Potter, Howes defends a feminist philosopher of science, this time Ruth Bleier, from Clough's charge of representationalism. Howes proposes that the Bleier's "sceptical sounding" language that is flagged by Clough does not demonstrate representationalist commitments, but rather deeply self-critical tentativeness about

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[526] Potter *et al* (2006), "On the very idea of a feminist epistemology for science [Review symposium]." Metascience 15(1), pp. 3-4.
[527] Potter *et al* (2006), "On the very idea of a feminist epistemology for science [Review symposium]." Metascience 15(1), p. 4.

Bleier's *own* susceptibility to bias. Howes concedes that Bleier's language certainly makes her vulnerable to Clough's charges of scepticism in her use of such tentative language as:

> I actually engage in the very activity I warn readers to question, if not distrust. Put differently, I present 'facts' to refute "facts", which I claim have been made [up] in the interests of the dominant group – white men. I offer feminist interpretations to replace patriarchal interpretations, which I say reflect the ideology, desires, and necessities of a particular interest group. I am indeed caught in my own trap![528]

But, Howes argues, Bleier follows this admission with a statement that suggests that she sees her critiques to be amenable to confirmation, correction, and falsification in light of evidence:

> But perhaps I am not. As I will try to maintain throughout my work, I see any theory – feminist or patriarchal – as flexible and open to change. In fact, as a scientist and a political being, my mind lingers with pleasure when I encounter theories that allow for constant change, interaction, contradiction, ambivalence.[529]

Bleier is characterized by Howes as standing firm in her ability to evaluate scientific theories, not merely to prefer certain values over others. In *Science and Gender*, she demonstrates a number of basic conceptual and methodological flaws in sociobiology, for instance, setting standards that are neither relativist nor sceptical in nature.[530] The language interpreted by Clough to court scepticism can instead be read as deep concern over critical self-reflection. Bleier speaks of

> the courageous and difficult task of examining and questioning all of our assumptions and the structure of our thought processes, all clearly born and bred within a profoundly stratified, hierarchical, patriarchal culture.[531]

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[528] Bleier (1984), Science and gender, p. 13.
[529] Bleier (1984), Science and gender, p. 13.
[530] Howes in Potter *et al* (2006), "On the very idea of a feminist epistemology for science [Review symposium]." Metascience 15(1), p. 11.
[531] Bleier (1984), Science and gender, p. 206.

She sees this self-reflection to be problematically missing from androcentric scientific thinking, and its addition as enhancing rather than hindering or relativizing science.

In Clough's response to the charge that she misapplies the representationalist label to feminist philosophers of science, she insists that Longino does in fact construe data to be unconceptualized in her representatalist characterization of data as "dumb" and her claim it is our conceptual frameworks that give the data voice as evidence.[532] Clough outlines a two-step detection process for determining thinkers to be representationalist. She instructs us to ask, first, whether the facts construed as separate from, because they are filtered by, values. Second, if values are filters for facts, does this indicate that the analysis is invoking an *ontological* split between internal, filtered, representations and the external world that is represented, *or* was the filtering language used merely as a metaphor describing the complex relationship between beliefs about values and beliefs about facts, making clear that the two sorts are ontologically continuous? The latter use is fine by Clough, and she admits that it is frequently used. For instance, "we safely use this sort of filtering language...when we want to acknowledge the fallibilistic nature of our own beliefs, including those of our beliefs that act inappropriately as biases affecting the acquisition of new beliefs."[533] She agrees with Howes that Bleier and many other feminists use this filtering language to acknowledge their own biases, thereby modeling a laudable level of intellectual honesty. The trouble is that Bleier, in particular,

> mixes this more innocuous discussion of 'biases as filters' with what...is a more metaphysically dangerous vocabulary that moves her beyond the acknowledgement of the fallibility of any given belief, to a Cartesian

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[532] Longino (1990), Science as social knowledge: Values and objectivity in scientific inquiry, p. 111.
[533] Clough in Potter *et al* (2006), "On the very idea of a feminist epistemology for science. [Review symposium]." Metascience 15(1), pp. 35-36.

skepticism about belief acquisition *simpliciter.*[534]

In fact, the bias-as-filter language can even lead feminist theorists to an unnecessary level of scepticism. The language permits an easy slide from a proper attitude of fallibilism about our beliefs to a more sceptical and relativistic position whereby values (sexist or feminist) are construed not as beliefs but as filters that organize beliefs, a conceptual distinction that "keeps us from treating our feminist values as the well-justified beliefs that they are."[535]

A difficulty for even the most careful reader of Clough is that her schema allows for non-representationalist use of "filtering" language to explain our beliefs about 'facts' *and* our beliefs about 'values', both of which are testable against the evidence of our experience and our ongoing theories. These non-representationalist filters have the same metaphysical status as empirical evidence and "can be understood as very complicated nodes of empirical information that function in much the same way as representational filters in the distortion of evidence."[536] The empirical status of these filters means that they are amenable to correction and improvement. As Clough's two-step deciphering process indicated, the presence of "filtering language" does not necessitate representationalist metaphysics. That language needs to be evaluated in order to determine whether the values being invoked are beliefs about the world, available to objective adjudication (non-representationalist filters) and *not* cognitive filters *for* beliefs (representationalist filters). The opposing readings of Longino and Bleier—both of

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[534] Clough in Potter *et al* (2006), "On the very idea of a feminist epistemology for science. [Review symposium]." Metascience 15(1), p. 35.
[535] Clough in Potter *et al* (2006), "On the very idea of a feminist epistemology for science. [Review symposium]." Metascience 15(1), p. 36.
[536] Howes in Potter *et al* (2006), "On the very idea of a feminist epistemology for science. [Review symposium]." Metascience 15(1), p. 12.

which seem like plausible interpretations—demonstrate the difficulty of making this determination, and so disagreement regarding who is and who is not a representationalist will certainly be tough to overcome. Because it is also easy for the non-representationalists to unwittingly slide into representationalism, we may even need to permit *degrees* of commitment to or intentional versus unintentional representationalist metaphysics. A thorough reading of all science studies texts in question would be required to create a tentative and contestable separation of representationalists and non-representationalists. This delineation is beyond the scope of this project; Howes's suggestion that Clough must work to further clarify the distinction between representationalist and non-representationalist ideological filters in feminist critiques of science seems warranted.

Thus we must leave undecided the question of whether Longino's and Nelson's antifoundationalist accounts of evidence were unhelpful in our effort to rethink evidence in the context of EBM *because* they were representationalist. For now, it stands as a plausible explanation for the problem. What may be more crucial for our investigation, however, is whether Clough's proposal to abandon epistemology is appropriate course for alleviating the difficulties surrounding EBM. A surprising feature of Clough's project is her characterization of epistemology as largely defined by the question "by which epistemic criteria might we adjudicate between competing knowledge claims?"[537] Such a characterization is particularly surprising in the context of feminist science studies, as feminist epistemologists seem to be interested in other questions, such as "who

[537] Clough (2003), Beyond epistemology: A pragmatist approach to feminist science studies, p. 120.

knows?/what can she know?"[538] and "what don't we know?".[539] Clough is charged with envisioning epistemology too narrowly—i.e. that she is not referring to *all* epistemology, but only "modern" or "mainstream" epistemology, according to Nancy McHugh,[540] and "positivist" epistemology, according to Catherine Hundleby[541]—and therefore she does not see the other avenues that epistemology has taken through pragmatist and feminist science studies.[542] McHugh criticizes Clough for only relying on neo-pragmatists in her investigation, and proposes that for classical pragmatists like Dewey, James, Locke, and Mead, epistemology was a political and social project rooted in the methodology of experimental inquiry that demanded an engagement with the material world. In Charlene Seigfried's historical treatment of feminism and pragmatism, pragmatist epistemology is argued to make clear that theorizing about knowledge, and doing it as embodied and socially embedded knowers that recognize the political stakes involved in getting to label who knows, how she goes about knowing, and what she should and does know, is too important for us to relinquish.[543] Not to engage in pragmatist epistemology means losing the import of the relation between knowing and doing that was so essential for social and political change and so important for knowing and doing "better".[544] Feminist scientists and philosophers of science, according to McHugh, recognize a significant stake in the

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[538] Nelson (1990), Who knows: From Quine to feminist empiricism; Code (1991), What can she know? Feminist theory and the construction of knowledge.
[539] I am alluding to Charles Mills' "epistemology of ignorance." See Mills (1997), The racial contract. See also McHugh's treatment of Mills in her critical review of *Beyond Epistemology* in Potter *et al* (2006), "On the very idea of a feminist epistemology for science [Review symposium]." Metascience 15(1).
[540] McHugh in Potter *et al* (2006), "On the very idea of a feminist epistemology for science [Review symposium]." Metascience 15(1), p. 16.
[541] Hundleby in Potter *et al* (2006), "On the very idea of a feminist epistemology for science [Review symposium]." Metascience 15(1), p. 23.
[542] McHugh in Potter *et al* (2006), "On the very idea of a feminist epistemology for science [Review symposium]." Metascience 15(1), p. 20.
[543] Seigfried (1996), Pragmatism and feminism: Reweaving the social fabric.
[544] McHugh in Potter *et al* (2006), "On the very idea of a feminist epistemology for science [Review symposium]." Metascience 15(1), p. 17.

link between epistemology, science, and ethics, and going "beyond epistemology" would problematically detract liberatory projects with respect to knowledge production.

McHugh's trepidation about abandoning epistemology seems justified, given that doing so would mean the loss of numerous intellectual tools for identifying and correcting power/knowledge imbalances. Furthermore, the suggested turn toward empirical projects has limited utility in the context of EBM, as the *evidence* for EBM has already been discussed to be not only lacking, but potentially impossible to generate (see p. 14). And wouldn't this effort to gather the evidence supporting or refuting EBM take us right back to the rudimentary epistemological question regarding what evidence counts? Perhaps it is because EBM *is* an epistemology of medicine that the epistemological questions cannot be ignored and/or overcome. Thus, it is in the interest of interrogating EBM that I would not follow the suggestion to go beyond epistemology, and instead support the overarching pragmatist project of "an epistemology that is produced by material bodies in transaction with a material world confronting the epistemological problems that are characteristic of political, scientific and social discourse and action."[545]

In Conclusion

The appeal of the Davidsonian account to the current investigation into EBM is that it surpasses prior postpositivist evidentiary configurations by not only calling attention to the social and contextual features of evidence, but also providing a framework for retaining this more holistic evidentiary accounts' adjudicative force. It was argued that in the ongoing epistemological debate between objectivists and

[545] McHugh in Potter *et al* (2006), "On the very idea of a feminist epistemology for science [Review symposium]." Metascience 15(1), p. 19.

relativists, objectivists hope to defeat scepticism with various theories of correspondence, while relativists seem resigned to the sceptical view that the filtering of our beliefs makes truthful representations impossible and coherence between beliefs our only hope. This resigned relativism is not only epistemically troubling, but also impractical for clinicians who are forced to act and to do so with justification. So far, this investigation into Davidson's theory of evidence has been largely an assembly of key critical positions. The next step is evaluation in the context of EBM. In the next chapter, the "Davidsonian repair" undertaken in this chapter is applied to the EBM debate in order to offer a usable and defensible theory of evidence for clinical practice.

CHAPTER SIX

Recasting EBM and its Critics

In this chapter, we return to the EBM debate bearing the conceptual tools advanced by Clough's Davidsonian framework. While I ended the previous chapter rejecting the suggestion to abandon epistemological pursuits, Davidson's distinction between epistemology and pragmatic science proves to be useful in this investigation and will be deployed in this chapter to recast both EBM and its critics. As a caveat, however, I would rename the distinction to be between *objectivist* epistemology and pragmatic *epistemology*. Reframing the EBM discourse in light of this distinction will be shown to allow for a more nuanced analysis of EBM than previously offered that is not "either/or" in its evaluation of the decisionmaking technology as *either* iconoclastic *or* creedal. This new eye on EBM also brings the shortcomings of the standard EBM critiques into relief. Specifically, the challenges to EBM have focused almost exclusively on the positivistic features of EBM—namely, its narrow and reductive account of evidence—with disregard of EBM's pragmatic methodological commitments and tendencies. Aside from offering an incomplete account of EBM, the popular critiques of EBM's standard of evidence lead to the problem of relativism. Specifically, the critics' championing of the fallibility of scientific knowledge serve to challenge some of EBM's methodologies and epistemic assumptions, but fail to enable the formulation of alternative decisionmaking models. Much like the feminist epistemologists examined by Clough, the EBM critics find themselves unable to justify any one schema for managing the social and interpretive dimensions of both science and evidence.

The EBM critics are redirected towards non-representationalism in order to avoid the relativism that can accompany acknowledging the fallibility of knowledge. I propose

that just as Clough offered *evidence* that the woman-as-gatherer theory was more defensible, a framework can be established where medical decisions can be made through the evaluation of the relevant evidence. Rather than being "evidence based", however, this model relies on the Davidsonian position that all theories have a causal relation to the world. Methodological pluralism and openness to different traditions can assist in evidentiary investigations, and so the evidence based ranking of research methods must be rejected (as it will only limit this effort). A broad range of health research—basic science, epidemiology, social science, humanities—and a genuinely transdisciplinary, collaborative, and integrative agenda will be recommended in order to establish these causal connections.

Return to the EBM Debate: Where we've Come From and Where we're Going

To recap and review the present investigation, the current vogue of evidence-based practices in both life and social sciences has been demonstrated to warrant critique regarding the overreliance on a rigid hierarchy of evidence to dictate best practices. The critique is two-fold: first is the pragmatic criticism that EBM's stratification of evidence is unlikely to lead to better recommendations for therapy because of considerations such as the gap between clinical trial populations and actual patient populations seeking care. Second, we have the overlapping yet distinct epistemological criticism that focuses on the role of values and contingent social practices in belief formation and justification. It is within this critical orientation that the problems of positivism and relativisms arise. The evidence based approach has been criticized for valuing the quantitative at the expense of the qualitative, and the aggregate over the personal. While the antifoundationalist epistemology critiques characteristic of critical science studies were

able to undermine the positivistic configuration of evidence underlying EBM, they could not provide an adequate framework for formulating alternatives. Clough's critical reading of postpositivist science studies offers an intriguing explanation for this problem in her indictment of representationalism.[546] She finds in many critical epistemologies of science inadvertent support for EBM's evidentiary preferencing, as they do not contest the framework in which the qualitative and the personal are less reliable or *relative*. When postpositivist thinkers dispute objectivism by claiming that no one can access the "real" world unbiased by one's cultural presuppositions or interpretive lenses, for example, they are conceding too much: they accept the empiricist presupposition that interpretation is the barrier to the real/true. By doing this, they retain the representationalist dualism between "the social" (theories, worldviews, etc.) and the physical world. This metaphysical bifurcation can be argued to unintentionally support EBM's reductive understanding of evidence by hindering the possibility of meaningful alternatives. Consideration into the interpretive features of evidence and the truth-value of anecdotal and testimonial evidence are marred by the problem of relativism. Davidson and Clough offer an alternative framework for understanding evidence that is consistent with the critical anti-positivist dimensions of the former critiques, but differs with respect to human judgment not needing to distort the real but rather forming part of its valid foundation. In this framework, evidence is not the link between theory and the world; rather it is the foundation on which the real is framed. The discourse surrounding EBM will be reconsidered in light of this new insight.

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[546] The confrontation with Clough's critics in the previous chapter should have affirmed my general support for Clough's position, however I recognize that her framework is still incomplete. For example, more work must be done to distinguish between representationalist and nonrepresentationalist filters in the major science studies texts. With more clarity in this area, there will be less room for disagreement regarding who is and who is not a representationalist.

Pragmatism vs. Epistemology

Davidson's pragmatic approach to science involves the truth of our individual beliefs and scientific theories being assessed locally and, of course, fallibly. This sort of empirical assignment is typically ad hoc and dynamic – the criteria are always being adjusted as new information comes in. These features are part of what separates a pragmatist empirical project from the troublesome (objectivist) epistemological attempt to identify and apply general normative recipes for truth, or its functional equivalents, in science. Clough proposes that our energies can instead be devoted to the empirical task of analyzing the causal relations between our theories and the world. However, to the extent that we construct epistemological guidelines for identifying which features of the causal stories indicate truth, we will continually be chasing after new recalcitrant features. The very scepticism the epistemological position was constructed to solve will be reintroduced leaving us to doubt the general reliability of our connections with the world around us.[547]

EBM: Pragmatic and *Epistemological*

When the distinction between pragmatic science and epistemology is brought to bear upon EBM, EBM noticeably demonstrates affinity to both. EBM demonstrates clear allegiance to scientific inquiry in its preference for experimental methods of inquiry that bracket past habitual thinking in favour of purely empirical investigation. Indeed, "the application of the best research evidence to medical decisionmaking" could have been

[547] Clough (2003), Beyond epistemology: A pragmatist approach to feminist science studies, p. 5; I have mentioned already that I reject Clough's disavowal of epistemology. Not only does (some forms of) epistemology seem like a worthwhile pursuit, but Clough does not seem to be actually rejecting all forms. Instead she condemns only objectivist epistemology. Interestingly, in her reply to the critics at the *Beyond Epistemology* review symposium, Clough conceded that she was mistaken in her use of nomenclature. She supports nonobjectivist epistemology, such as pragmatism, providing that it is built upon a nonrepresentationalist understanding of the world. See Clough in Potter *et al* (2006), "On the very idea of a feminist epistemology for science. [Review symposium]." Metascience 15(1).

achieved by strictly pragmatic scientific methodology. The critics who charge EBM with being "nothing new" certainly think that this is all there is to EBM. Furthermore, the randomized controlled trial is a pragmatic methodology in certain respects. RCTs temporarily suspend prior knowledge of human physiology, disease, and pharmacology – knowledge that might allow for inferences regarding the effectiveness of a particular drug in treating a given condition – and determine whether a treatment works by *trying* the treatment in a large number of cases under controlled conditions.[548] Because RCTs are unhindered by the pretheoretic expectations and commitments that can more readily bias the deductive methods of basic science and the less systematic experimental methods of clinical experience and observational studies, RCTs are thought to best promote the democratism of empirical science. Without the influence of anticipated outcomes, scientists should be more open, when faced with recalcitrant empirical data, to revising even well-established views about treatment efficacy.[549]

Against this pragmatic spirit, however, the examination in chapter two of what is unique to EBM drew from the movement's epidemiological origins to highlight the famed hierarchy of evidence. This feature of EBM is notably non-pragmatic, as pragmatism carries no pretheoretical notions of evidence. Quine insisted that no standards or methods are laid down prior to the business of constructing theories to explain and predict what we experience. There is simply "no simple formula for distinguishing viable theories or research programs from nonviable ones", but rather an

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[548] Sehon and Stanley (2003), "A philosophical analysis of the evidence-based medicine debate." BMC Health Serv Res 3:14.

[549] In Sehon and Stanley's (*op cit.* 548) analysis of EBM as a new Quinean web of belief (rather than a Kuhnian paradigm shift), they promote RCTs as the most reliable of the alternatives, namely clinical experience or observational studies. In Quinean terms, the controls imposed by RCTs give us firmer observational checkpoints and stronger inferences from observations to conclusions, particularly conclusions about interventions.

"inevitable need for extensive and multifaceted evaluation."[550] RCTs, for instance, have proven their worth for answering certain intervention questions, but its placement at the top of a rigid hierarchy of evidence has yet to be justified by anything other than a priori epistemic speculation.[551] Davidson and Clough would add that not only is the hierarchy non-pragmatic, but it is also distinctly epistemological, that is, it offers an a priori normative guide for ensuring the maximal objectivity of our representations of the world.

The open-ended and ad hoc style of pragmatic scientific inquiry stands in contrast to the rigid and rule-based hierarchy of evidence. The analysis of the hierarchy undertaken in chapter three demonstrated the ranking to be based on levels of certainty.[552] The hierarchy of evidence stands as EBM's point of departure from pragmatic science to epistemology, as the protocols and pre-graded methodological rankings move EBM away from the mundane question of justifying particular biomedical theories and beliefs to the epistemological provision of normative guidelines for minimizing the resulting error that our representations can incur.

The hierarchy of evidence also distances EBM from the pragmatist emphasis on democracy in science. Classical and feminist pragmatism's political stake in "getting to label who knows, how she goes about knowing, and what she should and does know"[553] clashes with the supposed universality of the hierarchy. Within the EBM critiques, the hierarchy is the point at which evidence based methodology is charged with authoritarianism. Amidst the EBM discourse reviewed so far, there has been politicized debate regarding whether EBM presents a democratizing or repressive force in

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[550] Nelson (1993), "A question of evidence." Hypatia 8(2), p. 184.
[551] We will return to this point momentarily.
[552] Sackett *et al* (1991), Clinical epidemiology: A basic science for clinical medicine.
[553] See previous chapter, p. 153.

biomedicine. EBM certainly proposed to be iconoclastic in its programmatic literature and it invoked pragmatic methods meant to rid medicine of unwarranted habits of thought and practice. Yet EBM also committed to the rigid hierarchy of evidence that is supported by a positivistic view of evidence and an objectivist account of science. As a result, EBM struggles to account for the social features of medicine and is ethically tenuous due to its admitted difficulties incorporating patient values into its decision-making schemas.[554] Furthermore, the extension of EBM into the domain of health policy has generated the worry that this technology will be used as a political tool for corporate interests in biomedicine.

EBM's initial manifesto captured the movement's anti-authoritarian spirit. The Evidence Based Medicine Working Group stated that

> the new paradigm puts a much lower value on authority. The underlying belief is that physicians can gain the skills to make independent assessment of evidence and thus evaluate the credibility of opinions being offered by experts.[555]

In Upshur's recollections of his medical training in clinical epidemiology at McMaster University by many of the faculty members who later initiated the Evidence Based Medicine Working Group, he remembers being attracted to its critical rationality. During rounds, students and residents where challenged to explicitly justify their proposed diagnostic strategy or therapeutic regimen with the pointed question, "what is your evidence?" The call for evidence in this context "was a call for something more than preference or convention, a call to an external standard that could be adjudicated and

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[554] Rogers (2002), "Evidence-based medicine and practice: Limiting or facilitating patient choice?" Health Expect 5; Haynes (2002), "What kind of evidence is it that evidence-based medicine advocates want health care providers and consumers to pay attention to?" BMC Health Serv Res 2(3).

[555] Evidence Based Medicine Working Group (1992), "Evidence-based medicine." JAMA 268(17), p. 2421.

discussed."[556] The transparency and accountability of critical appraisal techniques and EBM's procedural emphasis on enhancing the cognitive skills of clinicians suggested a certain democratic iconoclasm that greatly appealed to earnest new physicians like Upshur.

> We would read it for ourselves and make our own judgments whether to get prostate-specific antibodies as screening for prostate disease on all men or not. Clinical Evidence went even further. It made no judgments. It assembled the evidence in one spot so that the practicing doctors could judge and decide for them. Practicing doctors were expected to be able to think and judge. You might not do it for every case, but you could look up the evidence on women's incontinence today and screening for colon cancer tomorrow.[557]

Despite EBM's apparent populism, numerous critics (including Upshur) associate EBM with authoritarianism. Rosenfeld tracks EBM's historical movement *from* populism in its early years to its authoritarian present. She argues that "evidence-based medicine at first promised to be a popularistic movement, bringing the fruits of research to all practicing physicians. Instead it has created its own religion and dogma, further codifying daily practice."[558]

> During the last 3 years, EBM has gone from a tool to a religious doctrine and fixed dogma. There are its priests – men and women who are known for practicing and preaching EBM and changing the books and literature. You have to have one of these priests on every board and journal, or you are not up to date. Anyone who speaks against these priests is blaspheming EBM, and obviously unscientific or backward. There are thousands of acolytes, those who have heard the word and will accept nothing else.[559]

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[556] Upshur (2005), "Looking for rules in a world of exceptions: Reflections on evidence-based practice." Persp Biol Med 48(4), p. 480.
[557] Rosenfeld (2004), "The view of evidence-based medicine from the trenches: Liberating or authoritarian?" J Eval Clin Prac 10(2), p. 154.
[558] Rosenfeld (2004), "The view of evidence-based medicine from the trenches: Liberating or authoritarian?" J Eval Clin Prac 10(2), p. 153.
[559] Rosenfeld (2004), "The view of evidence-based medicine from the trenches: Liberating or authoritarian?" J Eval Clin Prac 10(2), pp. 154-155.

As a result, she argues that "we *have* come full circle to faith-based medicine,"[560] where we have replaced one form of authority, namely the habits and opinions passed down from one generation of clinicians to the next, with another—EBM. This charge of EBM dogmatism is legitimated in part by EBM proponents' confidence in evidence based methodology despite no empirical evidence being available to demonstrate EBM's superiority.[561] In a 2004 special edition of the *British Medical Journal* dedicated to philosophical issues surrounding EBM, one contributor surmised:

> Few would disown the EBM hypothesis—providing evidence-based clinical interventions will result in better outcomes for patients, on average, than providing non-evidence-based interventions. This remains hypothetical only because, as a general proposition, it cannot be proved empirically. *But* anyone in medicine today who does not believe it is in the wrong business.[562]

When pressed to locate the point where EBM shifted from being iconoclastic to becoming a creed, the critics typically point to the hierarchy of evidence as well as EBM's penchant for guidelines and the resulting codification of daily clinical practice. Both similarly eschew EBM's initial democratic and iconoclastic spirit by legitimating the expert opinion of EBM proponents over the reasoned arguments of skilled individual clinicians. The hierarchy of evidence, interestingly, promotes methodological transparency and encourages reasoned argument by providing a highly rationalized

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[560] Rosenfeld (2004), "The view of evidence-based medicine from the trenches: Liberating or authoritarian?" J Eval Clin Prac 10(2), p. 153. See also De Simone (2006), "Beyond 'faith-based medicine' and EBM." J Eval Clin Prac 12(4).

[561] Haynes (2002), "What kind of evidence is it that evidence-based medicine advocates want health care providers and consumers to pay attention to?" BMC Health Serv Res 2(3); Upshur and Tracy (In Press), "Precision versus clinical experience: Family medicine does not need more evidence-based medicine than at present." Ideological debates in family medicine. The near impossibility of empirically demonstrating the superiority of EBM over any other mode of medical care by the methods regarded as persuasive by EBM itself has been recognized from the outset. EBM's initial manifesto states: "The proof of the pudding of evidence-based medicine lies in whether patients cared for in this fashion enjoy better health. This proof is no more achievable for the new paradigm that it is for the old, for no long-term randomized trials of traditional and evidence-based medicine are likely to be carried out" (Evidence Based Medicine Working Group (1992), "Evidence-based medicine." JAMA 268(17), p. 2424.

[562] Reilly (2004), "The essence of EBM." BMJ 329(7473), p. 991; my emphasis.

method for evaluating clinical research, yet the hierarchy *itself* has no empirical legitimacy. The entire edifice of evidence hierarchies has been argued by Upshur and Tracy not to be based on systematic research or empirical data, but upon expert judgment or consensus. They charge that

> the structuring of evidence according to a hierarchy is by no means natural, intuitive, or even logically justified. In other words, the warrant or justification for viewing evidence on such a hierarchical structure rests on what EBM proponents consider the lowest form of evidence: the beliefs of a few.[563]

They propose that the initial creation of an evidence hierarchy was intended to link the quality of evidence to the soundness of the recommendations based on the evidence. This stance was grounded in an unsubstantiated epistemological position that favours certain study designs (randomized controlled trials and meta-analyses) on the belief that these methods are less susceptible than observational designs to bias. The key is the ability of randomization to eliminate selection bias and the unprovable claim that randomization balances all relevant known and unknown factors in a probabilistic sense.[564] The hierarchy attributes lower reliability to expert judgment, and specifically subordinates theory and pathophysiological reasoning to designs with randomization. The reasoning behind the latter subordination is unclear, as pathophysiology often provides more fundamental understanding of causation, and is in no way scientifically inferior. Thus, the authors conclude, the hierarchy has been advanced on the basis of expert opinion

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[563] Upshur and Tracy (In Press), "Precision versus clinical experience: Family medicine does not need more evidence-based medicine than at present." Ideological debates in family medicine

[564] Worrall (2002), "What evidence is evidence-based medicine?" Phil Sci 69(3).

rather than reasoned argument—a move unbefitting of evidence based thought and practice.[565]

EBM guidelines and clinical summaries invoke charges of authoritarianism for codifying daily practice and creating a hierarchy of EBM expertise. Given the demands of keeping up with the literature, the time associated with evaluating the abundance of clinical research, and the importance of "getting it right", it did not take long for EBM to replace its call for individual critical appraisal of the evidence by practicing clinicians with a veritable industry of systematic review and meta-analysis. While thought by many to be timely and useful, the availability of meta-analyses and clinical summaries immediately derails EBM's early anti-authoritarian programmatic. The initial program of equipping all practicing physicians with critical appraisal skills was intended to democratize medicine by discarding the hierarchical nature of expert opinion and received wisdom. That very authoritarianism is argued to be restored by the creation of "expert" EBM sources that proliferate clinical guidelines, meta-analyses, educational products, electronic decision support systems, and all things worthy of the brand name "evidence based medicine" to a captive and paying audience of clinicians who desire to be "evidence based practitioners". The various EBM organizations, such as the Cochrane Collaboration, Best Evidence, and the Task Force are further criticized for being secretive institutions.[566] Rosenfeld asks,

> Who are these people? We know where they are located and sometimes their names, but we must blindly believe in their methods. They come up

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[565] Upshur and Tracy (In Press), "Precision versus clinical experience: Family medicine does not need more evidence-based medicine than at present." Ideological debates in family medicine.

[566] This system not terribly different from the prior methods of peer review with respect to assuring credible professional literature, however the internalizing of medical expertise *within* the various evidence based institutions diminishes the likeliness of receiving disinterested (i.e. external) reviews. Even if the current system creates evidence that is no worse than before, EBM had proposed that it could do better.

> with conclusions that are published and then the conclusions become codified. The Cochrane conclusions and abstracts are published on the web, but only those who pay can get the full written method and evidence. Few practicing doctors will pay for access to the Cochrane database. Who knows how Problem-Oriented Evidence that Matters (POEMs) decide their evidence? The practicing doctor has little access to these articles. Even Clinical Evidence, that source that believed the practicing doctor can make his or her own conclusions, has published "Concise" conclusions. Are we too busy, too stupid, or too unreliable to use EBM for ourselves?[567]

Rosenfeld's chronicle suggests that similar to EBM's hierarchy of evidence, there is now a hierarchy of EBM. Specifically, "only a few sources are now considered 'true' or reliable EBM. Some organizations list 11–15 'proper' and 'acceptable' sources of EBM. All else, including good research, books, and reviews, are not evidenced-based, and may not be used."[568] This EBM structure is indeed commercially profitable, and has generated concern about financial conflict of interest and publication bias within the medical literature. Upshur et al., for example, expose the BMJ Publishing Group's significant stake in the EBM market through its production and sales of costly EBM textbooks and evidence databases. The conflict of interest is suggested by the authors' finding that a significantly greater number of EBM studies have been published in the *British Medical Journal* as compared to the similarly ranked *New England Journal of Medicine*, which has no commercial investment in EBM.[569]

While it would be premature to suggest that there is a link between epistemology and authoritarianism, the threat of global scepticism that motivates the former can certainly minimize tolerance of fallibilism and ad hoc and local investigative practices—

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[567] Rosenfeld (2004), "The view of evidence-based medicine from the trenches: Liberating or authoritarian?" J Eval Clin Prac 10(2), p. 155.
[568] Rosenfeld (2004), "The view of evidence-based medicine from the trenches: Liberating or authoritarian?" J Eval Clin Prac 10(2), p. 155.
[569] Upshur, Ross E. G. *et al* (2006), "Can academic and clinical journals be in financial conflict of interest situations? The case of evidence based incorporated." J Eval Clin Prac 12(4).

the very characteristics of science proper—among more ideological proponents of science. This sort of patterning has been invoked to explain the appeal and rapid uptake of EBM. We have seen how the positivist account of evidence underlying EBM is criticized for not recognizing the fallibility of scientific evidence in its untenable objectivism. The worry that all of our representations could be wrong can motivate the search for epistemic certainty, and trouble arises because this quest is undertaken using a method of inquiry that is supposed (and even desirable) to be irrevocably fallible. Critics argue that this promise of medical certainty is unrealistic and suggest that evidence-based decision-making must be replaced with a more nuanced model of knowledge translation that can grapple with contingency and the uncertain path of application of knowledge in practice.[570]

The proposal that the quest for certainty drives science and scientific medicine is a familiar thesis within critical science studies. Feyerabend has described science as being obsessed with its own mythology of objectivity and universality,[571] while in medicine, Katherine Montgomery has argued that medicine mis-specifies itself as a science with an image of science that is antiquated and that does justice to neither medicine nor science.[572] Science has also been described as a repressing ideology that started as a liberating movement. [573] EBM reinforces these images, to a certain extent, with its objectivist account of scientific medicine and rigid hierarchy of evidence. If the hierarchy of evidence was put in place to refute scepticism and ensure certainty, it stands as an example of what Feyerabend abhorred: science making claims to truth well beyond

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[570] Champagne *et al* (2004), "Introduction: Toward a broader understanding of the use of knowledge and evidence in health care." Using knowledge and evidence in health care: Multidisciplinary perspectives.
[571] Feyerabend (1978), Against method.
[572] Montgomery (2006), How doctors think.
[573] Feyerabend (1978), Against method.

its actual capacity. Science, the critics insist, cannot fulfill this epistemic quest for certainty. Science is at best - and is *at its best* when it is recognized to be - democratic, ad hoc, and fallible.

However, the philosophical obsession with scepticism is not necessarily the driver of EBM. The knowledge problems motivating the evidence based approach are regarded by some to be much more local and modest, for instance, the presence of small area variations, and the desire for increased reliability and access to the best confirmed interventions. Brody et al.'s distinction between "crude" versus "sophisticated" EBM distinguished between the different ways in which EBM has been employed by supportive practitioners.[574] It also manages to capture the ideological/truth-seeking versus practical motivation for adopting an evidence based approach to medicine. The more "practical" users being described here are those clinicians who find in EBM no more than a tool to assist in clinical decisionmaking, a task fraught with difficulties *for the very reason* that the context always carries elements of uncertainty. We see here that it is inappropriate for both supporters and detractors to ascribe the appeal of EBM to *one* mindset or sensibility among its clinical following.

EBM Critics: From Fallibilism to Relativism

In addition to the importance assigned to democracy in science, the Davidsonian theme of *fallibilism* is also present in the EBM critiques. However, recognizing the fallibility of science will be demonstrated to be insufficient for advancing critical alternatives to EBM. The EBM critics, who challenge EBM on the grounds of the fallibility of empirical evidence and the underdetermination of theory, cannot offer guidance for adjudicating between competing subjective and interpretive filters that

[574] Brody *et al* (2005), "Evidence-based medicine: Watching out for its friends." Persp Biol Med 48(4).

inescapably enter into clinical decisionmaking. Thus, Davidson's evidentiary account not only provides for a more nuanced critical account of EBM, where the movement's positivism and objectivism were admonished and its nonpositivist features vindicated, but also highlights the flaws within the standard postpositivist and critical science studies EBM critiques. The EBM critics typically over focus on the positivist features of EBM in their epistemic critique and miss important and even desirable dimensions of the technology/movement.

Fallibilism was highlighted in the previous chapter as an important theme in Davidson's account of evidence and promotion of pragmatic science. Davidson claims that "as beliefs are by their nature veridical, all beliefs are justified in this sense. This leaves open as an empirical question the issue of whether any particular belief, or set of beliefs, is justified in some particular context."[575] The pragmatic approach to science, which was also sketched in the last chapter, serves to investigate those particular scientific theories and beliefs. According to Davidson, external, empirical data provides the basis for synthetic knowledge, but empiricism cannot be used as an epistemological theory for deciding which particular data are normatively foundational. By re-establishing the causal connection between beliefs and the world, contra the postpositivists, yet denying the foundationalist position that this connection establishes truth, contra the positivists, the scientific method is vindicated from postpositivist critique.[576]

Fallibilism is maintained through adherence to ad hoc, site-specific rules, such as repetition and controls. Clough insists that such experimentalism sufficiently provides

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[575] Clough (2003), Beyond epistemology: A pragmatist approach to feminist science studies, p. 109.
[576] Clough (2003), Beyond epistemology: A pragmatist approach to feminist science studies, p. 110.

the knowledge-seeking framework required for scientific inquiry. Problems only arise when empiricists and objectivists use those methods to try to answer the epistemological questions. Fallibilism admits to local and tentative assignments of truth, while epistemologists have in mind the higher standard of satisfying any and all future sceptics. Objectivists, for instance, seek to articulate, either a priori or from a naturalized perspective, those properties of our methods and theories that would indicate truth or a normatively functional variant such as objectivity.[577] Difficulties arise because no matter what normative property we identify in a particular theory, we still must fallibly acknowledge that future evidence might show the theory to be false. What Clough is describing is nothing more than empirical science *proper*, where experimental methods identify the most reliable knowledge, but *not* the truth. Objectivism involves the overextension of science to answer questions of truth by discovering unequivocal and certain knowledge. EBM has been demonstrated to fall into this scientific objectivism through its scientistic hierarchy of evidence.

Within the critical EBM literature, Upshur attempts to raise the EBM discourse away from earlier polemics by characterizing medical evidence as ultimately *fallibilistic* in nature.[578] He proposes that acknowledging the fallibilism of medical evidence will improve our understanding of the role of evidence in clinical practice and health policy. Medical evidence, by his account, is: (1) Provisional; (2) Defeasible; (3) Emergent; (4) Incomplete; (5) Constrained; (6) Collective; (7) Asymmetric. These "seven characteristics of medical evidence" are used by Upshur to support a theory of fallibilism and underdetermination. The provisional, defeasible, and emergent properties of

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[577] Clough (2003), Beyond epistemology: A pragmatist approach to feminist science studies, p. 120.
[578] Upshur (2000), "Seven characteristics of medical evidence." J Eval Clin Prac 6(2).

evidence show that the ultimate structure of medical evidence is fallibilistic. Fallibilism is thought to best describe the nature of health care evidence because it captures how our opinions and beliefs about the external world may turn out to be false, and so our deliberations always involve some level of uncertainty. He cites Charles Peirce and Karl Popper as major proponents of the fallibilistic account of science. Pierce, in particular, held that natural science could only rest on experience, and experience can never result in absolute certainty, exactitude, or universality.[579]

While the fallibilism highlighted by Upshur is notably missing from the evidence based approach, which has been demonstrated to operate with a positivist account of evidence, it is not logically inconsistent with the tenets of EBM. EBM is foundationalist in its commitment to making empirical evidence the *basis* of medical decisionmaking, thus minimizing, if not denying, the interpretive dimensions of clinical practice. However, there is nothing about EBM's methodology that fundamentally entails an objectivist (non-fallible) understanding of empirical evidence. Empiricism "proper" recognizes the fallibility of evidence and science and therefore seeks maximal reliability in our beliefs. There is no inconsistency in an evidence based approach to medicine that strives for added reliability and not truth or certainty in its evidence and practices.

When I presented this observation to Upshur in a private conversation, he responded that he had written the "Seven Characteristics" paper "back in the days" when he felt more optimistic about the possibility of both engaging in a genuine critical discourse with EBM and creating a more philosophical account of EBM. The paper served as an effort to move EBM away from foundationalism to see that a Peircean

[579] Upshur (2006), "The complex, the exhausted and the personal: reflections on the relationship between evidence-based medicine and casuistry. Commentary on Tonelli (2006), Integrating evidence into clinical practice: an alternative to evidence-based approaches." J Eval Clin Prac 12(3) p. 96.

fallibilism was more in keeping with clinical reasoning. Upshur agrees that EBM could logically/without inconsistency drop its pursuit of truth and certainty in favour of the (properly) empirical pursuit of maximally reliable beliefs. However, the mix of personalities, hubris, and politics within "EBM Inc."[580] makes him think that this more moderate pursuit will never be recognized.[581]

Returning to the seven characteristics of evidence, the incomplete and constrained (#4 and #5) properties of evidence show that explanatory theories are underdetermined by the evidence. Consequently, Upshur argues that there is an interpretive dimension to the understanding of evidence that is neglected by proponents of EBM, who seem to believe that an algorithm or decision tree will precisely determine the meaning and interpretation of evidence.[582] Lastly, the collective and asymmetric (#6 and #7) features indicate that evidence is a social process subject to the forces and vagaries of social life. This finding draws attention to the importance of reflecting on the unarticulated or unacknowledged extra-evidential considerations such as values and ideological commitments that factor into evidentiary analysis.[583]

To ask whether EBMers can be Piercian is to question whether or at least to what extent EBM can accommodate the numerous challenges put forward or does a theory of medical decisionmaking that properly incorporates the interpretive and fallible

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[580] Upshur *et al.* (2006). Can academic and clinical journals be in financial conflict of interest situations? The case of evidence based incorporated. J Eval Clin Prac 12(4).

[581] My own far briefer involvement within the EBM debate has generated some concurring experiences, notably having my published views on the positivist tendencies within EBM (Goldenberg (2006), "On evidence and evidence-based medicine: Lessons from the philosophy of science." Soc Sci Med 62(11)) being fervently and angrily denied by a professor of medicine at Brown University as "postmodernists take another whack at EBM" in a posting on a large evidence based health list serve in November 2006. The hostility of the posting was surprising—no doubt, I had pushed some buttons!—and consistent with Upshur's above comments on the unwillingness of many EBM supporters to critically reflect on the approach.

[582] See Upshur (1999), "Priors and prejudice." Theor Med Bioeth 20(4).

[583] Upshur (2000), "Seven characteristics of medical evidence." J Eval Clin Prac 6(2), p. 96.

dimensions of evidence require abandoning EBM and starting from the beginning. This is a difficult question to evaluate given the different interpretations of what EBM represents, what it *can* involve, what it *does* involve, what it *should* involve. We will focus, instead, on what characteristics an account of clinical reasoning should exhibit.

The seven characteristics of evidence espoused by Upshur legitimate the shared themes of critical science studies: the antifoundationalism, underdetermination, and sociality of science. Upshur concludes that, against the evidence based approach, there are inherent limitations of basing clinical practice solely on evidence. Here we see difference between Upshur's endorsement of fallibilism and Clough's. While both would agree with the general critique that EBM leaves interpretive practices out of its decision making schemas, Clough would not endorse the position that clinical decision making and practice must be based on other things than evidence—the "extra-evidential considerations". Instead, there is nothing else that clinical practice can be based on, as all evidence is belief, and all beliefs are empirically based (and are, therefore, evidentiary). To suggest that there is anything out there in the world that is not evidentiary is to commit to a representationalist metaphysical gap and an objectivism-to-relativism slide. We saw that Upshur argued for an interpretive dimension *to* the understanding of evidence, and similarly, that theory could be underdetermined by the evidence.

This different invocation of fallibilism, which Clough would characterize as representationalist versus non-representationalist, is of practical consequence, as the EBM critique in fact leads to the relativism that worried Clough. In "A Popperian Perspective of the Term 'Evidence-Based Medicine'," Shahar similarly invoked a theory of fallibilism to critique the EBM account of evidence. Drawing from the work of

Popper, he makes the case against the logical possibility of medicine being *based* on the evidence. Popper's well-known theory of falsification demonstrates that evidence cannot *prove* scientific theories, but only *falsify* them. Thus medicine needs much more than evidence in order to make informed treatment decisions. Scientific hypotheses are forever conjectural and open to refutation. This has to do with the incompleteness of experiential evidence; no number of successful trials provides logical support to the theory that a treatment is *always* superior to a placebo, just as no number of negative trials can support the theory that the treatment is *never* superior to placebo. Popper and others have relentlessly argued against the possibility of constructing a system of inductive logic.[584] Similar to Upshur, the incompleteness of evidence and the fallibility of our theories and beliefs are invoked to make the case that *even when* the latest, best, and most relevant clinical research is consulted, more goes into medical decision making than the (experimental) evidence.

Shahar does not end his critique with the many practical problems of applying evidence to medicine, and instead continues with the difficulties surrounding the production and interpretation of clinical data. The current challenges to trial design and statistical analysis will not be discussed here;[585] what is significant to this discussion is the fact that there is no unanimity within the scientific community regarding how research questions ought to be tested, and how the resulting trial data ought to be interpreted.[586] While there are certain broad rules of experimentation to minimize methodological bias, scientists must rely heavily on subjective preferences regarding

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[584] Shahar (1997), "A Popperian perspective of the term 'evidence based medicine'." J Eval Clin Prac 3, pp. 110-111.

[585] Some of those issues were already discussed in chapter one.

[586] Shahar (1997), "A Popperian perspective of the term 'evidence based medicine'." J Eval Clin Prac 3(2), pp. 112-113.

experiment design or data interpretation and practical constraints, such as budget and available resources, when conducting scientific trials. The next step of interpretation of trial data adds another level of subjective content, as cases have been documented where the same data generates more than one, even opposing, conclusions, as researchers disagree on the *meaning* of the data.[587]

These problems are recognized by Shahar to similarly apply to both EBM and *pre*-EBM. Furthermore, he finds the term "evidence based medicine" to indistinguishable from "medicine" (i.e. nothing new about EBM). He finds problem in the term "*evidence based*", however, as "evidence" is a term that is linked with the assumption that it is scientifically objective and readily discerned by trained scientists. As we have seen already, EBM is problematic in part because of its either untenable or unrealized *promises* of objectivity and democracy in science.

Shahar's challenges to the supposed objectivity of clinical trials lead him to the pessimistic conclusion that

> the results of a clinical trial hardly deserve the title *evidence*, not only because every interested scientist can question various statistical and design aspects, but also because the whole process of data analysis, presentation, and interpretation contains many subjective elements.[588]

Of course, the theory-ladenness of evidence and the underdetermination of theory by the evidence do not comprise the entirety of Shahar's challenge of the *evidence* of evidence-based medicine. Even in instances where the data is consistent and there is agreement regarding the interpretation of data, it is still unclear "at what point of time we have

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[587] This, of course, will be true of pre-EBM scientific medicine. However, these findings certainly challenge the self-professed superiority of EBM.

[588] Shahar (1997), "A Popperian perspective of the term 'evidence based medicine'." J Eval Clin Prac 3(2), p. 113.

gathered 'enough evidence' to justify an action."[589] Furthermore, when is there "'enough evidence' to practice evidence-based medicine...?"[590] For Shahar, "the answer is simple: there is enough evidence...whenever the mind of a doctor decides so."[591] In some cases, all doctors similarly decide and agree on a proposed endpoint. However, in cases where disagreement arises, those who espouse EBM will accuse doctors with opposing interpretations of practicing non-EBM. He concludes that

> there is no rule of logic that can help us decide whose interpretation of empirical experience is *the evidence*, [instead] we can formulate many rules of preference.[592]

Shahar fears that since preferences have no logical content, use of the term "evidence based medicine" calls for a new type of authoritarianism in medicine.[593] He detects a theoretical deficit hidden beneath the mantra of "evidence based medicine" that permits certain interests and agendas to go unchecked.

Shahar's conclusion that clinical trial data "hardly deserves the name evidence" puts scientific medicine in a precarious place. If clinical research cannot justify medical treatment decisions, what does? He writes that the "permanent uncertainty" that cloaks medical decisionmaking require doctors to decide "on the basis of some interpretation of empirical experience - a subjective exercise with no universally accepted logical

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[589] Shahar (1997), "A Popperian perspective of the term 'evidence based medicine'." J Eval Clin Prac 3(2), p. 114.
[590] Shahar (1997), "A Popperian perspective of the term 'evidence based medicine'." J Eval Clin Prac 3(2), p. 114.
[591] Shahar (1997), "A Popperian perspective of the term 'evidence based medicine'." J Eval Clin Prac 3(2), p. 114.
[592] Shahar (1997), "A Popperian perspective of the term 'evidence based medicine'." J Eval Clin Prac 3(2), p. 114.
[593] Shahar (1997), "A Popperian perspective of the term 'evidence based medicine'." J Eval Clin Prac 3(2), p. 115.

rules."[594] Shahar provides an account of the numerous layers of subjective interpretation that go into the formulation of empirical or experiential evidence and into the subsequent clinical decision-making process. He concludes that the underdetermination of theory requires that we ask the important question: *whose* evidence is the evidence? While there is wisdom in this recommendation, he also states that no interpretation of empirical evidence "deserves a special place of honour."[595] This admission is alarming, as we presumably want our treatments to be based on more than the whims and preferences of physicians. This is precisely how EBM advocates characterized pre-EBM or "traditional" biomedicine, and the proposal to make medical decisionmaking more rational and justified was what made EBM so appealing. If Shahar is correct that EBM is no better than pre-1990's biomedicine, and if there is no way to decide which filters, interpretive frameworks, or standpoints are preferable, then all patients are in a terrible predicament.[596] Then again, if the successes in biomedical patient care seem to be grounded in something more than luck, then Shahar is perhaps overstating the problem.

In "Who's Evidence? Lessons from the Philosophy of Science", Harari similarly takes the "lesson from the philosophy of science" to be the inadequacy of positivist empiricism's account of knowledge production, on which he claims the evidence-based approach is predicated. Against the misplaced confidence in the power of empiricist principles to determine what constitutes reliable knowledge, Harari echoes Upshur's theme of fallibilism in characterizing clinical practice as requiring

> intellectual flexibility, tolerance of ambiguous and discordant information

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[594] Shahar (1997), "A Popperian perspective of the term 'evidence based medicine'." J Eval Clin Prac 3(2), p. 115.
[595] Shahar (1997), "A Popperian perspective of the term 'evidence based medicine'." J Eval Clin Prac 3(2), p. 114.
[596] We will see in the next chapter that this is not just an epistemic, but also an ethical, concern.

> obtained by different methods from differing viewpoints at different conceptual levels, the judicious yet knowingly fallible, theory-derived construction, selection and interpretation of observations and empathically derived experiences.[597]

Similar to both Upshur and Shahar, he concludes with the representationalist statement that "a plurality of theoretical moves have to be made beyond the observation statements themselves to explain any particular set of observations."[598] His metaphysical bifurcation between observation statements and all other statements leads him to the same sceptical doubt as Shahar about the truth of our knowledge claims: "we cannot understand 'facts' free from the influence of previous learning and conceptual framework that selects and organizes the observations at different conceptual or epistemic levels."[599] The "lessons from the philosophy of science" apparently do *not* include a way out: an account for how to manage the social and interpretive dimensions of both science and evidence.

Thus we see the familiar situation among EBM critics where, much like the feminist epistemologists of science in the previous chapter, chastising EBM's objectivism and articulating the fallibilism of evidence, while critically important, does not open up possibilities for alternatives to EBM.[600] The critics cannot offer alternative decisionmaking frameworks that can adjudicate between the competing conceptual filters that invariably enter into clinical decisionmaking. We saw in the previous chapter that Clough allows for a proper "attitude" of fallibilism about our beliefs—that is, the self-critical recognition that our beliefs can be false—but lamented the easy slide from such a

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[597] Harari (2001), "Whose evidence? Lessons from the philosophy of science and the epistemology of medicine." Austr N Zea J Psychiatry 35(6), p. 729.
[598] Harari (2001), "Whose evidence? Lessons from the philosophy of science and the epistemology of medicine." Austr N Zea J Psychiatry 35(6), p. 726.
[599] Harari (2001), "Whose evidence? Lessons from the philosophy of science and the epistemology of medicine." Austr N Zea J Psychiatry 35(6), p. 728.
[600] In fact, it's worse. It leaves us apparently unable to explain the rational superiority of modern to premodern medicine.

position into scepticism where values act as non-belief filters. She distinguished between representationalist filters, where filters are *for* beliefs, and non-representationalist filters, where filters *are* beliefs about the world. While there certainly are difficulties with distinguishing between the two—recall the opposing readings of Longino and Bleier—because of the same "filtering language" being used in both instances, Clough *is* indeed proposing two distinct ontological positions. We have seen so far that the non-representationalist position is preferable because it avoids the puzzling metaphysics of a filter being *neither* empirical *nor* a value. This framework is also supposed to avoid the relativism encountered by the EBM critics by making the interpretive frameworks that invariably accompany all production, presentation, and utilization of clinical evidence open to evaluation. The success of this non-relativist framework in addressing the challenges of EBM is yet to be determined, of course, as considerable work must be done to establish the causal links for beliefs. In the next section, I will initiate a health research program to establish the broad empirical research that establishes those links.

Initiating an Alternative Health Research Agenda

Clough advocated going beyond epistemology because the epistemological program invited scepticism by limiting the intellectual terrain to either objectivism or relativism. She endorsed a pragmatic framework because evidence could maintain its normativity without subscribing to scientific objectivism. While I have already denied Clough's prescribed strategic reversal of abandoning epistemological pursuits in favour of the critical empirical science of early feminist science studies,[601] I support her effort to reinvigorate the normativity of evidence found in objectivist epistemologies *without* the

[601] While feminist science's shift from critical empirical science to epistemology was seen by Clough to be understandable within its historical context, Clough advocates a strategic reversal because epistemology created more problems than it solved.

objectivism while avoiding the relativism of evidence thought to accompany contextualist theories of knowledge.

Just as Clough denied Longino's conclusion that the feminist interpretation of archaeological findings was politically preferable but evidentially equivalent to its androcentric challenger, Shahar's resignation that no one social filtering of medical evidence should be honoured over another can be similarly rejected. Medical decisions should be made through the evaluation of the relevant evidence. All theories, according to Davidson, have a causal relation to the world. Because all evidence involves belief, and all beliefs are evidential, a plurality of methods is needed to establish the relevant causal connections. As a result, medical research must not be pared down to a rigid, pre-graded hierarchical methodological system. Instead, a broad range of health research, which includes basic science, epidemiology, social science, and humanities, and a cross-disciplinary and integrative research agenda are required to establish these causal connections.

The details of the course of investigation into the use of evidence in medical decisionmaking still need to be established. We have seen that the epistemological investigation undertaken in this project unpacks some of the background presuppositions and preoccupations that play into the question of evidence and offers certain avenues for further pursuit while denying other possible directions. In the next chapter, we will return to the ethical analysis of EBM found to be wanting in chapter one, but now enriched by a more substantial understanding of the "evidence" that plays so centrally in an "ethics of evidence". Already, a link between the epistemology and the ethics is being forged. Underlying this broad health research programme is the assumption that

methodological pluralism and openness to different traditions can only assist in evidentiary investigations. In the interest of democratic science, research agendas and funding formulas should not be shaped by questions that can fit into evidence-based criteria. Instead the evidentiary criteria should be made to fit the question that needs to be addressed. Medical research cannot be constrained by narrow accounts of evidence and the limited range of methodologies capable of gathering this data set. Instead health research must be construed more broadly and incorporate the efforts of variously trained health scientists, clinicians, and medical humanities researchers.

Feyerabend has, in fact, insisted that methodological pluralism is part and parcel of scientific inquiry and investigation. In both *Against Method*[602] and *Science in a Free Society*,[603] he argues that there have historically been no methodological rules which are always[604] used by scientists. Examining episodes in science that are generally regarded as indisputable instances of progress, such as the Copernican revolution, he demonstrated that all common prescriptive rules of science were violated to some extent.[605] He adds that attempts to adhere to the rules in those historical situations would actually have prevented scientific revolution. Thus, not only does he offer a controversial *description* of science, but he objects to science's *ideal* of methodological uniformity. He objects to any single prescriptive scientific method on the grounds that any such method would limit the activities of scientists, and hence restrict scientific progress. Democratic science, he proposes, requires "theoretical anarchism": methodological pluralism,

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[602] Feyerabend (1978), Against method.
[603] Feyerabend (1979), Science in a free society.
[604] But one can still allow that there were more popular or preferable methods.
[605] Feyerabend (1978), Against method, pp. 93-98.

openness to alternative traditions, and input from non-scientific domains.[606] The benefit to scientific inquiry gained by such anarchistic measures is that pluralistic methodology that involves making comparisons between competing theories forces defendants to improve the articulation of each theory.[607] In this way, scientific pluralism improves the critical power of science.

More now needs to be said to justify this appeal to epistemological anarchism, as Feyerabend's position is very controversial and has invoked hostile reactions by many within science studies, most notably the famous labeling of the author as "the worst enemy of science".[608] One of Feyerabend's most contentious theses is the "principle of proliferation", which advocates the generation of incommensurable alternatives to current orthodox theories. His endorsement of such provocative slogans as "anything goes" and "epistemological anarchism", not to mention his impassioned defenses of witchcraft, astrology, and faith-healing, no doubt contributed to Feyerabend's notorious reputation of being antiscientific, irrational, antimethodological, antireason, and a relativist.[609] Elizabeth Lloyd has persuasively argued, however, that Feyerabend's statement "anything goes" should not be read as an anarchistic (anti-)methodological recommendation for the conduct of scientific research, but rather as a *reductio* against certain forms of rationalism.[610] Feyerabend himself stated that "*'anything goes' does not express any conviction of mine, it is a jocular summary of the predicament of the*

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[606] Feyerabend (1978), Against method, p. 17.
[607] Feyerabend (1978), Against method, p. 47.
[608] Theocharis and Psimopoulos (1987), "Where has science gone wrong." Nature 329(6140).
[609] On Feyerabend's anti-science reputation, see Lloyd (1996), "The anachronistic anarchist." Phil Studies 81(2).
[610] Lloyd (2000), "Feyerabend, Mill, and pluralism." The worst enemy of science? Essays in memory of Paul Feyerabend.

rationalist."[611] Specifically,

> if you want universal standards, I say, if you cannot live without principles that hold independently of situation, shape of world, exigencies of research, temperamental peculiarities, then I can give you such a principle. It will be empty, useless, and pretty ridiculous—but it will be a "principle". It will be the "principle" "anything goes".[612]

Thus, Lloyd maintains, the slogan does not represent Feyerabend's own positive methodological program. However, the misreading likely stems from his genuine belief that the proliferation of *all* views and methods adds value to science. It has already been mentioned that Feyerabend frequently traces his arguments for the importance of proliferation to Mill's essay, *On Liberty.*[613] He endorsed Mill's position that pluralism is supposed to lead to *truth*[614] and often quoted the following passage from *On Liberty*:

> The peculiar evil of silencing the expression of opinion is that it is robbing the human race...If the opinion is right, they are deprived of the opportunity of exchanging error for truth: if wrong, they lose, what is almost as great a benefit, the clearer perception and livelier impression of truth, produced by its collision with error.[615]

It is in this vain that Feyerabend wrote, in *Science in a Free Society,* that "the only way of arriving at a useful judgment of what is supposed to be the truth, or the correct procedure, is to become acquainted with the *widest possible range* of alternatives."[616] While his subsequent defenses of witchcraft, astrology, and other nonscientific worldviews may make one question how much tolerance to alternative ideas is meaningful to the pursuit of

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[611] Feyerabend (1978), Against method, p. 188.
[612] Feyerabend (1978), Against method, p. 188.
[613] See pp. 125-126 of this dissertation.
[614] Lloyd (2000), "Feyerabend, Mill, and pluralism." The worst enemy of science? Essays in memory of Paul Feyerabend.
[615] Mill (1989), "On liberty." On liberty and other writings, p. 20. See also chapter 2, "Of the Liberty of Thought and Discussion". Mill's arguments for the freedom of expression of opinions cannot be discussed here. For an excellent overview, see Lloyd (2000), "Feyerabend, Mill, and pluralism." The worst enemy of science? Essays in memory of Paul Feyerabend, pp. 117-119. For Feyerabend's appropriation of Mill in the context of science, see pp. 119-121 of the same essay.
[616] Feyerabend (1979), Science in a free society, p. 86.

truth, they should not be read as a total disregard of empirical evidence by Feyerabend. Instead they are part of a Mill-inspired rejection of blind belief in the superiority of scientific expertise as being themselves strong enough to rule out alternative forms of expertise. Indeed, Feyerabend continued his (above) endorsement of proliferation in order to arrive at truth with the statement: "the reasons [for proliferation] were explained by Mill in his immortal essay *On Liberty.* It is not possible to improve upon his arguments."[617]

Lloyd proposes that seeing Feyerabend as attempting to enact and embody these views of Mill provides a valuable interpretive framework for his more peculiar actions and extreme views, such as his defense of astrology. Mill held that a position can only be rationally held once one has heard and sincerely considered both arguments in favour and against it. This requires consultation with proponents of alternative views, so that the seeker of truth

> brings [the arguments] into real contact with his own mind. He must be able to hear them from persons who actually believe them; who defend them in earnest, and do their utmost for them. He must know them in their most plausible and persuasive form; he must feel the whole force of the difficulty which the true view of the subject has to encounter and dispose of; else he will never really possess himself of the portion of truth which meets and removes that difficulty.[618]

Furthermore, "if opponents of all important truths do not exist, *it is indispensable to imagine them, and supply them with the strongest arguments which the most skilful devil's advocate can conjure up.*"[619] Feyerabend, Lloyd proposes, followed Mill's mandate by championing minority views *for the sake of rational discussion.* When questioned about his support of astrology, Feyerabend tellingly stated:

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[617] Feyerabend (1979), Science in a free society, p. 86.
[618] Mill (1989), "On liberty." On liberty and other writings, pp. 38-39.
[619] Mill (1989), "On liberty." On liberty and other writings, p. 39; my emphasis.

> My use of examples from astrology should not be misunderstood. Astrology bores me to tears. However it was attacked by scientists, Nobel Prize winners among them, without arguments, simply by a show of authority and in this respect deserved a defense.[620]

Lloyd's interpretation of Feyerabend as a champion of Mill's pluralist agenda has a few hints of weakness. For one, *On Liberty* focuses explicitly on religious cases where there was no promise of factual evidence to which appeal could be made. Furthermore, Mill's treatise on scientific reasoning, *System of Logic*,[621] is recognized by Lloyd to configure "physical science" more narrowly in terms of norms and expectations than Feyerabend allows it to be. Thus Feyerabend may have misappropriated Mill's arguments *or* Lloyd may be misreading Feyerabend. Yet, Lloyd defends Feyerabend's move, arguing that Mill explicitly stated that *On Liberty* was not primarily about the limits of government interference.[622] *On Liberty* focused on the cultivation of attitudes and skills needed for the genuine flourishing of human intelligence and creativity, such as tolerance and nonconformist attitudes, and Mill explicitly included the sciences in his recommendation of "absolute freedom of opinion and sentiment on all subjects, practical and speculative, scientific, moral, or theological."[623] This is meant not only to support the principle of liberty, but for attaining scientific truth, as "even in natural philosophy, there is always some other explanation possible of the same facts; some geocentric theory instead of heliocentric, some phlogiston instead of oxygen."[624] Lloyd concludes that

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[620] Feyerabend (1991), Three dialogues on knowledge, p. 165.
[621] Mill (1974), A system of logic, ratiocinative and inductive: Being a connected view of the principles of evidence and the methods of scientific investigation.
[622] Lloyd (2000), "Feyerabend, Mill, and pluralism." The worst enemy of science? Essays in memory of Paul Feyerabend, p. 121.
[623] Mill (1989), "On liberty." On liberty and other writings, p. 52.
[624] Mill (1989), "On liberty." On liberty and other writings, p. 38.

Feyerabend's application of Mill's views to science is consistent and appropriate.[625]

Feyerabend's reading of Mill can in fact be justified on further grounds than those offered by Lloyd, specifically the normativity of science fits it under the jurisdiction of Mill's principle of liberty. In *On Liberty,* Mill was principally concerned not with protecting minority religious views from the interference of government, as Lloyd correctly indicates, but about social norms, where he claimed that protection is needed against "the tyranny of prevailing opinion and feeling."[626] The political reading of EBM that has been rehearsed throughout this dissertation—underscored by a compelling picture of science as social knowledge—supports this reading of Feyerabend as a disciple of Mill in his promotion of radical pluralism. Even if Mill did fail to appreciate the full scope of science's social normativity (as suggested by his *System of Logic*), Feyerabend's rereading is defendable in light of more contemporary interpretations of science.

Thus the alleged worst enemy of science has been argued to instead be science's most eccentric defender—a tactician that aimed to promote rational discussion, critical consideration, and even the pursuit of scientific truth through the expression of alternative methods and views. While Lloyd laments being unable to ask Feyerabend just how extensive his intentions were to enact the wide context of alternative positions,[627] it is fair to assume that Feyerabend would have strongly objected to EBM's silencing of certain forms of knowledge through its methodological hierarchies.

It is with the same concern regarding hegemonic discourses that Holmes et al. argue that the widespread endorsement of the Cochrane Collaboration's hierarchy by so

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[625] Lloyd (2000), "Feyerabend, Mill, and pluralism." The worst enemy of science? Essays in memory of Paul Feyerabend, p. 122.
[626] Mill (1989), "On liberty." On liberty and other writings, p. 9.
[627] Lloyd (2000), "Feyerabend, Mill, and pluralism." The worst enemy of science? Essays in memory of Paul Feyerabend, p. 124.

many of the health science's academic institutions has served to exclude of certain forms of knowledge production. The authors, most of whom are professors of nursing, charge that

> it is becoming increasingly evident that an unvarying, uniform language – an ossifying discourse - is being mandated in a number of faculties of health sciences where the dominant paradigm of evidence-based health science has achieved hegemony. This makes it difficult for scholars to express new and different ideas in an intellectual circle where normalization and standardization are privileged in the development of knowledge.[628]

Because dissenters risk being marginalized by their colleagues, and because the evidence-based approach now represents the "ladder of success" in academic and research settings, the challenges associated with resisting the dominant discourse are great. The authors object to EBM's exclusivity with respect to scientific knowledge not only because of the hindrance to intellectual freedom, but also because this stratifying and segmenting tendency goes against the general belief that health sciences research requires a plurality methods and views.[629] They argue that "scholars have not only a scientific duty, but also an ethical obligation to deconstruct these regimes of power."[630] Against the intellectual violence that they see arising from EBM's silencing of alternative knowledges, they recommend a resurgence of free speech and a plurality of views and methodologies within the health sciences.

Many EBM critics emphasize the value of methodological pluralism in health research. Worrall, for example, insists that EBM's methodological hierarchy is flawed in

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[628] Holmes *et al* (2006), "Deconstructing the evidence-based discourse in health sciences: Truth, power and facism." Int J Evid Based Healthc 4(3), p. 182.
[629] Holmes *et al* (2006), "Deconstructing the evidence-based discourse in health sciences: Truth, power and facism." Int J Evid Based Healthc 4(3), p. 182.
[630] Holmes *et al* (2006), "Deconstructing the evidence-based discourse in health sciences: Truth, power and facism." Int J Evid Based Healthc 4(3), p. 180.

its failure to recognize that non-experimental evidence, such as observational studies, and the range of qualitative methodologies, are as important and informative to family medicine as RCTs, and will be necessary to address the problem of applying population based research onto individual patient care.[631] Davidson's nonrepresentationalist metaphysics expands the scope of "non-experimental evidence" to include such formerly non-evidentiary considerations as ethics, politics, and sociology (and, of course, crystal gazing, tea leaves, and wishful thinking; some constraints seem appropriate). This move avoids the relativism previously encountered when forced to adjudicate between competing social filters or standpoints.

To illustrate, Davidson's evidentiary account can assist EBM with its difficulty integrating patient values and perspectives into its model of clinical decisionmaking.[632] It has been noted that "nowhere in the EBM process is listening to patients and their concerns and legitimizing their questions regarded as important."[633] While EBM's model of clinical decisionmaking offers steps for posing the clinical question, searching the terms in order to find the best evidence, and finally, applying it to the individual patient, there is no point in which the voice of the patient is heard (except insofar as it voices pathological information that can be transformed into searchable terms). In what has been referred to as an "extract and apply" method of clinical decisionmaking,[634] it is no wonder that EBM still struggles to integrate patient values and perspectives into its

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[631] Worrall (2002), "What evidence is evidence-based medicine?" Phil Sci 69(3)
[632] Tonelli (2006), "Integrating evidence into clinical practice: An alternative to evidence-based approaches." J Eval Clin Prac 12(3).
[633] Upshur (2005), "Looking for rules in a world of exceptions: Reflections on evidence-based practice." Persp Biol Med 48(4), p. 480.
[634] Upshur and Tracy (2004), "Legitimacy, authority, and hierarchy: Critical challenges for evidence based medicine." Brief Treatment Crisis Intervention 4.

methods.[635] *Because EBM is focused on finding and applying 'evidence', however defined, identifying something as non-evidentiary suggests from the outset that it is less valuable than those bits of information considered "evidentiary".* Indeed, patient values and perspectives are considered to be nonevidentiary. Gupta has made the interesting move of challenging this status. She begins with the observation that when the EBM literature mentions (and struggles with) integrating patient values, it is writing from the point of view of the practitioner, where the notion of "patient values" refers to the fact that people have values, and not the content of the actual values themselves.[636] This insight can be taken further: EBM's scope of evidence is limited to medical evidence—coming from the "third person" scientific perspective only, with no consideration given to the first person phenomenological perspective of the patient's lived experience.[637] Thus, patient perspectives are nonevidentiary on two counts: they are anecdotal, and therefore methodologically flawed, and they are outside of the scope of relevant evidence because they do not offer *clinical* evidence.

Gupta argues that patient values can, in fact, be (scientifically) evidentiary in certain cases. Certain treatment options may be opened up or closed by the patient's perspective regarding, say, the withdrawal of life-sustaining treatments or the use of assisted reproductive technology. What counts as evidence, in this context, is determined by the knowledge or information in question being *evidence for something*, and does not

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[635] See, for example, Haynes (2002), "What kind of evidence is it that evidence-based medicine advocates want health care providers and consumers to pay attention to?" BMC Health Serv Res 2(3)

[636] Gupta (2006), "Beyond 'evidence'. Commentary on Tonelli (2006), Integrating evidence into clinical practice: an alternative to evidence-based approaches." J Eval Clin Prac 12(3), p. 249.

[637] This distinction between third- and first-person perspectives comes from Husserl's important phenomenological division between the scientifically described world of natural science and the "lifeworld" of everyday experience. See Husserl (1970), The crisis of European sciences and transcendental phenomenology.

depend on where or how it was derived.[638] In this case, the context permits the patients' values to be relevant evidence for treatment decisionmaking and certain prognostic considerations (such as the patient's likely compliance with the treatment regiment), despite the data being low on the hierarchy of evidence. Gupta's characterization of evidence as being any information that can support an inference converges with Davidson's evidentiary account because it does not permit any knowledge source to be predetermined as always, never, or minimally evidentiary in the context of decisionmaking about individual patient care. Just as a patient's values can be evidentiary, clinical data can, in some cases, be flawed to the point of lacking in credibility or unlikely to increase the probability of some inference being true.

Yet Gupta's position may seem overstated if the distinction between first and third person evidentiary perspectives is not kept in mind. The evidence offered by patients' preferences is typically not *treatment evidence*, which is the evidence in which EBM is interested. Patient values frequently do not provide evidence in favour or against a course of treatment, but instead are simply dispositive. For instance, it is not a matter of evidence but rather a matter of moral respect that bars a clinician from implementing a treatment regime against the wishes of a competent patient. But the matter of compliance mentioned by Gupta *is* a matter of the evidence that some treatments will work while others will not. Thus EBM's maligning of anecdote (clinical or otherwise) is further destabilized. Furthermore, the challenge to EBM is that an evidence based decisionmaking technology should not be resistant to phenomenological evidentiary perspectives when negotiating the clinical context for the very reason that the clinic is the

[638] Gupta (2006), "Beyond 'evidence'. Commentary on Tonelli (2006), Integrating evidence into clinical practice: an alternative to evidence-based approaches." J Eval Clin Prac 12(3), p. 250.

site where research evidence meets actual patients.

In Conclusion

EBM has been argued to maintain both pragmatic and epistemological allegiances. EBM is pragmatic in its commitment to the comparative analyses offered by RCTs rather than basic science's interest in causal understandings of treatment interactions. On the other hand, EBM's hierarchy of evidence delves into non-pragmatic epistemology as the pre-graded ranking of research methods offers a priori normative properties for ascertaining maximal objectivity. Davidson and Clough would presumably propose that EBM's pragmatic features are worth keeping, while the rigid hierarchy of evidence, as we saw, leads to considerable problems for EBM. The EBM critics, writing from the postpositivist philosophy of science tradition, have amply demonstrated these problems. Yet just as the representationalism of the Western epistemological framework led critical epistemologists of science to relativism, the EBM critics, who challenge EBM on the grounds of the fallibility of empirical evidence and the underdetermination of theory, similarly fall into relativism. The critics can offer no guidance for adjudicating between the competing subjective and interpretive filters that inescapably enter into clinical decisionmaking.

Following Davidson's advancement of a normative but non-objectivist account of evidence, the argument was made that medical decisions *can* be made through the evaluation of the relevant evidence. The key is not to narrow "evidence" into an authoritarian hierarchy that is supported by a rigid and confused epistemology of science. Health research must be construed broadly in both scope and methodology. It is in this spirit of methodological pluralism, where evidence is construed broadly (but still

empirically) to include the cultural filters that befuddled EBM critics and encouraged a "hasty retreat from the evidence", that I will revisit the ethical analysis of EBM in the next (and final) chapter to synthesize the epistemic, methodological, and political challenges to EBM that have been examined throughout this dissertation.

CHAPTER SEVEN

Revisiting the Ethics of EBM: On the Normativity of the Technical

A plausible explanation for why considerations of the ethics of EBM has been limited to consequentialist considerations regarding EBM is because this underdeveloped area of research treats EBM instrumentally; EBM is regarded as a morally neutral tool or means for either achieving or hindering the independently derived goals of medicine. The entirety of this dissertation has forwarded a more philosophically complex understanding of the evidence-based approach in its investigation of the rationale for grounding a philosophy of medicine in the supposed objectivity of evidence. EBM has been demonstrated to introduce new epistemological commitments to medicine, thus it plays a part in *creating* the aims and goals, and not just carrying them out. The ethical analysis undertaken in this chapter aims to incorporate this broadened understanding of EBM and its moral significance.

EBM has been widely criticized for being blind to the social context that it operates in, which renders invisible its inherent values and norms. An ethical analysis of EBM that uncovers and evaluates those obscured features could advance the EBM debate significantly. I undertake this task by examining *evidence based ethics*, the application of the evidence based approach to bioethical deliberation. Because ethics is an explicitly value-laden and normative enterprise, examining evidence based ethics assists this investigation by bringing the internal logic and inherent values of the evidence based approach into stark relief. It also illustrates the limited purview of the current ethics of EBM discourse, which focuses exclusively on the consequentialist analysis of EBM's effect on health outcomes. Thus this "detour" into evidence based ethics will be brought

to bear on the ethics of EBM, which I have broadened to include consideration of the ethics of evidence.

The Ethics of Evidence

In "Outcomes Research and the Quality of Health Care: The Beacon for an Ethics of Evidence",[639] Valerie Miké advocates the rigorous development and proper use of evidence as an integral part of medical ethics. She coins the term "ethics of evidence" to denote the moral implications of developing and applying evidence and to promote the role of statistical evidence in ethical medical decision making.

Miké's "ethics of evidence" offers an approach for managing medical uncertainty. The ethics of evidence calls for the creation, dissemination, and use of the best possible scientific evidence as a basis for every phase of medical decision making, as high quality evidence is regarded to be integral for ethical practice in medicine. True to her profession, Miké, a biostatistician, holds that the best evidence comes from carefully controlled trials and statistical inference. Without accurate evidence, she explains, the four "principles of biomedical ethics"[640] cannot be upheld. A patient's autonomy cannot be respected via the informed consent process if, say, the proposed procedure has not been properly evaluated. The principles of beneficence and nonmaleficence also implicate the quality of evidence as they call for consideration of the risks and benefits of a course of treatment or nontreatment. It is presumably unethical to use powerful medical procedures without careful evaluation of their safety and effectiveness. Miké suggests that studies without proper statistical design are in violation of the Nuremberg Code's stipulations that experiments "should be such as to yield fruitful results for the

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[639] Miké (1999), "Outcomes research and the quality of health care: The beacon of an ethics of evidence." Eval Health Prof 22(1).

[640] Beauchamp and Childress (2001), Principles of biomedical ethics.

good of society" (Rule 2) and that they "should be so designed...that the anticipated results will justify the performance of the experiment" (Rule 3).[641] Lastly, the principle of justice, which Miké interprets to call for increased access to high quality health care, could be furthered via better evaluation of all medical procedures and the subsequent elimination of those that are worthless and even harmful. Similar to the "waste theory" described in chapter one, Miké proposes that clinical evidence could be used to alleviate the fiscal crisis in health care and relieve funds to cover the poor.

Because EBM is the formalization of the aim to promote health care based on evidence, it is hardly surprising to see Miké regard EBM as promoting "wonderful initiatives for achieving excellence in health care."[642] However, "EBM is only as good as the available evidence."[643] The solution, of course, is more outcomes research. In the end, Miké's ethics of evidence establishes a moral imperative for outcomes research in ethical medical decisionmaking. The Belmont principles are argued to rely on the application of the most reliable medical evidence, which the author takes to be statistically-derived evidence.

In the next section, "evidence based ethics" will be examined as a contrast to the ethics of evidence in order to bring into question the increased certainty allegedly gained by the evidence based approach in light of the evidentiary concerns that arose in previous chapters. The ethical implications of the normative obfuscation that must take place in order for EBM to ground decisionmaking in the supposed objectivity of the evidence will

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[641] Nuremberg Code (1949), "Trials of war criminals before the Nuremberg Military Tribunals under Control Council Law no. 10."
[642] Miké (1999), "Outcomes research and the quality of health care: The beacon of an ethics of evidence." Eval Health Prof 22(1), p. 18.
[643] Miké (1999), "Outcomes research and the quality of health care: The beacon of an ethics of evidence." Eval Health Prof 22(1), p. 18.

also be investigated.

Evidence Based Ethics[644]

In an editorial introducing two qualitative studies determining the effectiveness of current ethical oversight of research involving children, Jeremy Sugarman insists that "the time is ripe for evidence-based ethics."[645] The first study, "Communication of Randomization in Childhood Leukemia Trials", evaluated the transfer of information from investigator to parent regarding her child's participation in a randomized trial. Interviews conducted shortly after the investigator-parent conference in which consent forms were signed revealed that 50% of parents did not understand randomization. The authors concluded that to make informed consent more effective, future research must seek to improve communication during this critical interchange.[646] The second study, a telephone survey assessing how 188 randomly selected Institutional Review Board (IRB) chairpersons apply the federal risk standards for pediatric research to a series of fictitious cases, found the chairs' application of the federal risk and benefit categories for pediatric research to vary significantly. Some applications even contradicted the available data on risks and the regulations themselves. The researchers concluded that to protect children from excessive risks while allowing appropriate research, IRB chairpersons need guidance on applying the federal risk and benefit categories and also need data on the risks children face in daily life and during routine physical or psychological tests.[647] Sugarman commends the authors of both papers for offering "reasonable"

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[644] A similar version of this section on evidence based ethics appears in publication as Goldenberg (2005), "Evidence-based ethics? On evidence based practice and the "empirical turn" from normative bioethics." BMC Med Ethics 6(11).

[645] Sugarman (2004), "Determining the appropriateness of including children in clinical research: how thick is the ice?" JAMA 291(4), p. 495.

[646] Kodish *et al* (2004), "Communication of randomization in childhood leukemia trials. " JAMA 291(4).

[647] Shah *et al* (2004), "How do institutional review boards apply the federal risk and benefit standards for pediatric research? " JAMA 291(4).

recommendations for improving protections for children. However "these recommendations would have even more utility if they were subjected to rigorous testing, preferably with randomization when ethically permissible to do so".[648] Sugarman fails to explain what role he thinks randomization will play in increasing the utility of these recommendations. Instead, he ends the editorial with a rehearsing of the evidence based mantra:

> in both medical and ethical investigations, it is important to 'raise the bar' on what evidence is acceptable to determine the most effective approaches.[649]

Moreover, "data derived by using more rigorous methods [RCTs] would be privileged in [both of] these venues."[650]

Given the currency of EBM, it is hardly surprising to find the evidence based approach being considered as an innovative strategy for moral decisionmaking.[651] "Evidence based ethics" (EBE) is also supported by the "empirical turn in bioethics", a growing interest over the past two decades in empirical methods of research in bioethics. Examining the norms and implications of both empirical approaches to bioethics and EBM, however, reveals the evidence based approach to be incompatible with bioethics' normative mandate and therefore EBE should not be pursued. This conclusion will then

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[648] Sugarman (2004), "Determining the appropriateness of including children in clinical research: How thick is the ice?" JAMA 291(4), p. 496.

[649] Sugarman (2004), "Determining the appropriateness of including children in clinical research: How thick is the ice?" JAMA 291(4), p. 496

[650] Sugarman (2004), "Determining the appropriateness of including children in clinical research: How thick is the ice?" JAMA 291(4), p. 496.

[651] Jansen (1997), "Evidence-based ethics and the regulation of reproduction." Hum Reprod 12(9); Roberts (2000), "Evidence-based ethics and informed consent in mental illness research." Arch Gen Psych 57(6); Tyson (1995), "Evidence-based ethics and the care of premature infants." Future Child 5(1); Major-Kincade *et al* (2001), "Training pediatric house staff in evidence-based ethics: an explanatory controlled trial." J Perinatol 21(3); Halpern (2005), "Towards evidence based bioethics." BMJ 331(7521); Kim, Scott Y. H. (2004), "Evidence-based ethics for neurology and psychiatry research." J Am Soc Exper NeuroTherapeutics 1(3).

be brought to bear on the ethics of EBM, as many of the challenges to EBE serve to destabilize the presumed moral mandate to practice EBM.

Empirical research in bioethics (or "empirical ethics") is "the application of research methods in the social sciences (such as anthropology, epidemiology, psychology, and sociology) to the direct examination of issues in [bioethics]."[652] In contrast to normative bioethics, which employs the analytic methods of Anglo-American moral philosophy to answer the ethical questions that arise in health care, empirical approaches aim to describe (rather than prescribe) "particular state[s] of affairs that [have] some moral or ethical relevance."[653] Empirical bioethics also proposes to enrich bioethics by calling attention to the social, cultural, and cross-cultural aspects of morality accessed via the opinions, interests and beliefs of patients, families, physicians, nurses and others involved in care-giving.[654] For example, empirical research can help describe cultural beliefs about the appropriateness of informing the patient of a diagnosed life-threatening illness, which will inform deliberation about the extent to which it is morally important for clinicians to provide comprehensive information to patients in different cultural contexts.[655] Similarly, empirical research can delineate popular attitudes and experiences related to contentious issues such as abortion, cloning, stem-cell research, and physician-assisted suicide for consideration in discussions and policy formulations.[656] Empirical investigation can also map the effects of particular interventions aimed at improving how clinicians or policy makers attempt to meet ethical obligations, such as whether a particular method of presenting health related information to a patient actually

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[652] Sugarman *et al* (2001), "A decade of empirical research in bioethics." Methods in medical ethics, p. 20.
[653] Sugarman *et al* (2001), "A decade of empirical research in bioethics." Methods in medical ethics, p. 21.
[654] Hoffmaster (1992), "Can ethnography save the life of medical ethics?" Soc Sci Med 35(12).
[655] Sugarman (2004), "The future of empirical research in bioethics." J Law Med Ethics 32(2), p. 227.
[656] Sugarman (2004), "The future of empirical research in bioethics." J Law Med Ethics 32(2), p.227

improves the patient's understanding of her circumstances and the quality of informed consent.[657]

It is likely because proponents of empirical approaches to bioethics focus on differentiating this area of bioethics from normative ethics that the literature tends to use such loose overarching descriptors as "an amalgam of empirical contributions"[658] and "methodological roots in social sciences...to gather quantitative and qualitative data about ethical issues"[659] when characterizing empirical ethics. The ease with which both empirical ethics is generalized and the differences between the various social scientific disciplines represented under this heading are glossed over may also be assisted by the common presumption that empirical research presents "only the facts". This understanding leads to underappreciation of the values typical to each discipline as well as the beliefs of the individual practitioner that influence the data gathering and interpretation.[660] While presumably no one would deny the different orientations, research agendas, and methods, of, say, psychology and sociology, the emphasis placed on similarities or shared features in order explain the novelty of empirical ethics and distinguish it from philosophical approaches to bioethics takes important attention away from the relevant differences between the social scientific disciplines that may render some empirical approaches incompatible with the goals of ethical inquiry. I aim to show this to be the case with one method of empirical ethics—evidence based bioethics—which is grounded in clinical epidemiology and supported by the discipline's most distinctive application, EBM.

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[657] Sugarman (2004), "The future of empirical research in bioethics." J Law Med Ethics 32(2), p. 228
[658] Sugarman (2004), "The future of empirical research in bioethics." J Law Med Ethics 32(2), p. 230.
[659] Borry *et al* (2005), "The birth of the empirical turn in bioethics." Bioethics 19, p. 41.
[660] Nelson (2001), "Knowledge, authority, and identity: A prolegomenon to an epistemology of the clinic." Theor Med 22(2), p. 13.

Some commentators on the "empirical turn in bioethics" have regarded the interest in empirical research as representing a loss of confidence in the typical normative and analytic methods of bioethics.[661] While many describe those "typical" methods inaccurately—offering "straw man" accounts of applied ethics where absolutely no empirical considerations are included in the deductive process of ethical deliberation[662]—they are at least correct in recognizing a felt ambivalence regarding the possibility of negotiating competing values in a pluralist society that respects difference. Evidence based decision-making offers what seems like a solution to this so-called "postmodern" problem, as it proposes to ground decisions in something concrete and universal, namely the evidence. The allure of evidence should not be underappreciated, as it is thought to be able to assist us in seeing past our habits, biases, and mistakes to decipher "best practices". The rapid ascendancy of the evidence based movement, which started in medicine and quickly spread to other professional disciplines, speaks to the movement's enormous appeal.[663] There are considerable difficulties with an "evidence based" approach to bioethics, however, that require consideration.

While evidence based ethics arises within the momentum of the empirical turn, it draws unique content from EBM. Evidence based ethics has been defined in the literature as follows:

> As in medical decisions based on EBM, ethical decisions based on evidence based ethics would involve conscientious and judicious use of the best evidence relevant to the care and prognosis of the patient to

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[661] Ashcroft (2000), "Giving medicine a fair trial." BMJ 320(7251).
[662] For example, see Hedgecoe (2004), "Critical bioethics: beyond the social science critique of applied ethics." Bioethics 18(2).
[663] As I write this, the incredible popularity of the *CSI* television series—which depicts "evidence based" police work *par excellence*—demonstrates how the stability, fairness, and truth of "the evidence" have captured our imagination.

promote better informed and better justified ethical decision making.[664] What this actually entails in practice is somewhat vague, as there are numerous ways in which empirical research can inform ethical decision making, numerous types of evidence that are relevant to the care and prognosis of patients, and numerous measures of *best* evidence. What *is* clear, however, is evidence based ethics' close methodological proximity to EBM, as the language of "conscientious and judicious use of best evidence" is recognizably lifted from the early programmatic literature on EBM.[665] The implications of this relationship are the focus here, as EBM offers a distinct accounting of the nature of evidence, what evidence counts, and what role the evidence plays in the decision-making process. Understanding evidence based ethics requires comprehension of the evidence based approach to medicine.

Sugarman's prior appeal for rigorous methods and his attention to experimental methodology recall the hierarchy of evidence's consistent privileging of randomized controlled trials and systematic review of these trials over less objective measures such as surveys or qualitative research. The founding of EBM by clinical epidemiologists and biostatisticians explains this methodological privileging, as randomized controlled trials produce the clinical data required for health outcomes research.

Keeping in mind evidence based ethics' subscription to the "evidence based" doctrine, it becomes apparent that the term "evidence based ethics" has been misunderstood and misused by some of its alleged proponents. In Robert Jansen's "Evidence-Based Ethics and the Regulation of Reproduction",[666] the author uses the term

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[664] Major-Kincade *et al* (2001), "Training pediatric house staff in evidence-based ethics: an explanatory controlled trial." J Perinatol 21(3).
[665] See Sackett *et al* (1996), "Evidence-based medicine: what it is and what it isn't." BMJ 312(7023).
[666] Jansen (1997), "Evidence-based ethics and the regulation of reproduction." Hum Reprod 12(9).

to mean the testing of ethical arguments, statements, and the background assumptions informing those arguments, by means of empirical research. Jansen argues that Canada's prohibitions on sex selection for human reproduction relies on the untested empirical claim that sex selection often leads to some index of family dysfunction. He finds it ironic that Canada insists on evidence based approaches for medical services but not for the social restrictions on reproductive medicine proposed by the *Report of the Royal Commission on New Reproductive Technologies*, which, he claims, made determinations of "women's true interests" without properly surveying the relevant attitudes and behaviours exhibited by the public. Against what Jansen perceived as the Commission's "hijacking" of ethical questions and their treatment of empirically verifiable hypotheses about the social consequences of permissive policies as "self-evident moral truths", he recommends a publicly accountable empirical approach that encourages debate and the determination of facts.

Jansen's understanding of evidence based ethics seems to be no different from the empirical ethics already in circulation insomuch as it serves to *inform* moral deliberation (and therefore does not introduce a new empirical/ethics relation).[667] It is worth noting that even prior to the incipience of empirical ethics, empirical content always informed ethical deliberation, whether to determine the actual or probable consequences of actions for consequentialist reasoning or to specify the norms of deontological consideration. In bioethics, surveys or in-depth interviews that gauge patients' or clinicians' attitudes or behaviours often serve as the data that philosophically-trained bioethicists reflect on in

[667] This is not to say, however, that this "informational" model, where empirical data *informs* moral deliberation, is without certain difficulties. While the failings of the qualitative tendencies in empirical ethics are beyond the scope of this dissertation, Ashcroft offers a thoughtful analysis of how social research evidence plays a part in the construction of the social order in: Ashcroft (2003), "Constructing empirical bioethics: Foucauldian reflections on the empirical turn in bioethics research." Health Care Anal 11(1).

order to draw moral conclusions.[668] Jansen's call for more *empirical ethics* is appropriate for the situation he describes considering that the Commission failed to bring in the relevant empirical content to their deliberative process. This, however, is not evidence based ethics.

The EBM hierarchy of evidence's maligning of the very techniques that empirical ethics so often employs suggests dissimilarity between empirical ethics and evidence based bioethics. The surveys and in-depth interviews that are commonly used to determine the attitudes and behaviours of patients, clinicians, or the general public regarding bioethical issues are less valued and are ranked lower than the carefully controlled and quantified evidence that is derived from randomized controlled trials and other more objective methods. This suggests evidence based ethics to be a distinct moment within the "empirical turn in bioethics" rather than, as Pascall Borry and colleagues' historical account seems to suggest, more of the same.[669]

The second sense in which evidence based ethics is used is as "the necessary grounding of ethical decisions in the best available scientific evidence."[670] Jon Tyson's[671] and Terri Major-Kincade et al.'s[672] work on clinical determinations of whether or not to treat severely disabled premature newborns enlist this use of the term "evidence based bioethics", which I read to be a more accurate interpretation of the term because of its consistency with the methods of EBM. Tyson's and Major-Kincade et al.'s work offers decision-making techniques for determining whether or not to treat the patient that rely

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[668] An exhaustive account of the difficulties with this division of labour along "fact" and "value" or "empirical" and "normative" lines is beyond the scope of this chapter.
[669] Borry *et al* (2005), "The birth of the empirical turn in bioethics." Bioethics 19(1).
[670] Borry *et al* (2005), "The birth of the empirical turn in bioethics." Bioethics 19(1), p. 68.
[671] Tyson (1995), "Evidence-based ethics and the care of premature infants." Future Child 5(1).
[672] Major-Kincade *et al* (2001), "Training pediatric house staff in evidence-based ethics: an explanatory controlled trial." J Perinatol 21(3).

almost exclusively on the projected survival and disability outcomes of these infants. Major-Kincade et al. even employ a controlled trial to demonstrate the efficacy of their educational curriculum for teaching evidence based ethics to NICU residents.

Addressing his peers in the *Journal of Perinatology*, Tyson laments the difficulty of making treatment decisions for severely compromised newborns, which involves "highly complex medical and ethical issues."[673] He finds the U.S. legislation on the issue—the Child Abuse and Treatment Act (Public Law 98-457), often referred to as the revised Baby Doe regulations—to be unsatisfactory in what he determines to be skewed promotion of disability rights over the suffering of the infant and family and the financial burden of expanding neonatal intensive care programs.[674] Furthermore, many state laws seem to contradict the federal legal standard by putting more emphasis on quality-of-life considerations and parental decisionmaking.[675] Tyson also finds problems with the perinatologist's other decisionmaking support, the hospital bioethics committee.[676] Its members might not know enough about the patient's medical problems or might be biased by institutional concerns. He recognizes that these committees might be useful as advisory bodies to address ethical questions by clinical staff or disagreement between parents and physicians. However he does not think they should routinely participate in

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[673] Tyson (1995), "Evidence-based ethics and the care of premature infants." Future Child 5(1), p. 166.
[674] In one surprising statement, Tyson proposes that the negative effect of the Baby Doe regulations "*appears to be exactly those intended by its proponents*—diminished parental autonomy, reduced consideration of infant suffering and future quality of life, and expanded use of neonatal intensive care" (page 162; my emphasis). This suggests that Tyson reads sinister intent rather than unfortunate outcome in this child protection act.
[675] Tyson (1995), "Evidence-based ethics and the care of premature infants." Future Child 5(1), p. 162.
[676] While nomenclature varies in different healthcare institutional settings, Jansen is referring to what is frequently called the "clinical ethics" committee, the body responsible for addressing ethical issues that arise in clinical practice. Hospitals also have separate "research ethics" committees—called "Research Ethics Boards" in Canada and "Institutional Review Boards" in the U.S.—which monitor the research that takes place in healthcare institutions.

treatment decisions for high-risk neonates.[677] With the legal and ethical instruction being so feeble, Jansen presumably does not find it surprising to discover considerable variations in practices among North American and Western European NICUs. The scope ranges from clinics that treat almost all high-risk neonates, as the prognosis is believed to often be indeterminable at birth, to much more selective administration of treatment, depending on the projected clinical benefit to the patient.[678]

It is hardly surprising that, faced with the perceived problem of small area variations, unhelpful legislation, and ethics committee that may lack knowledge and hold bias, the evidence based approach is brought to the rescue. Tyson's diagnosis of the challenges to ethical decisionmaking mirror the account of the troubles surrounding to medical decisionmaking held by EBM proponents. It follows that he similarly supports their solution:

> Under the usual rules of evidence in medicine, the only mandatory interventions are those for which there is credible evidence that the benefits outweigh the hazards and burdens. Evidence-based decision making allows consideration of the level of care that is reasonable, based on the quality of evidence available; the identified benefits, hazards, and costs of treatment, and as is crucial in a pluralistic society, the values and preferences of the patient or surrogate. Thus, medical reasonableness is a more broadly acceptable criterion than is futility for deciding whether to forego or administer neonatal intensive care.[679]

Tyson describes evidence based ethics as involving multiple considerations in its determination of what constitutes "*reasonable care*" that include: (i) the quality of evidence available; (ii) the identified benefits, hazards, and costs of treatment; and (iii) the values and preferences of the parent or surrogate. In Major-Kincade et al's complementary paper detailing the implementation of an evidence based ethics

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[677] Tyson (1995), "Evidence-based ethics and the care of premature infants." Future Child 5(1), p. 164.
[678] Tyson (1995), "Evidence-based ethics and the care of premature infants." Future Child 5(1), p. 161.
[679] Tyson (1995), "Evidence-based ethics and the care of premature infants." Future Child 5(1), p. 164.

educational intervention, the "evidence" was specified to mean mortality and disability outcomes for infants that receive intensive care.

Given that Tyson claims to appreciate that treatment decisions for extremely premature infants involve highly complex ethical issues and multiple considerations, it comes as a surprise when he proposes, in the end, an algorithm[680] for instances of "*mandatory*", "*unreasonable*", and "*optional*" treatment based entirely on the projected outcomes (that is, survival rates and disability-free years) for neonates of particular birth weights, gestational ages, and health conditions. Even the professed importance of considering the parents or surrogates' values and preferences is limited to situations where the infant's clinical indicators fit her into the category of "*optional*" treatment. While the description of the multiple considerations that go into evidence based ethical decision-making sounded reasonably comprehensive at first glance, certain limitations on how evidence is understood, what constitutes a "benefit" or a "harm" and who determines and measures them, and even when the parents' values play in, all narrow the deliberative process to a decision based on projected outcomes and an imposed cost per value calculation of Quality Adjusted Life Years and Disability Adjusted Life Years relative to financial cost of treatment. Mandatory treatment, for example, occurs when there is "credible evidence that benefits outweigh burdens",[681] with no mention of who determines these criteria and how they are measured. These determinations were formulated against the backdrop of standardized clinical protocols being simply assumed

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[680] Despite defenders of EBM's considerable attempts to deflect accusations of offering "cook book medicine", that is, treating patients strictly according to a formula or algorithm derived from a research study, even Brian Haynes, one of the movement's founders, admits that much of the programmatic literature regarding evidence-based medicine does not "clearly emphasize that evidence from research can be no more than one component of any clinical decision" Haynes (2002), "What kind of evidence is it that evidence-based medicine advocates want health care providers and consumers to pay attention to?" BMC Health Serv Res 2(3).

[681] Tyson (1995), "Evidence-based ethics and the care of premature infants." Future Child 5(1), p. 164.

to be preferable, more transparent, and fairer than case-by-case decision-making. These assumptions will soon be demonstrated to be consistent with the "epidemiological and biostatistical ways of thinking" that the founders of EBM so strongly promoted.

The evidence based doctrine problematically assumes that the presence of reliable evidence ensures that better decisions will be made.[682] Medical decision-making, however, draws upon a broad spectrum of knowledge (or multiple dimensions of evidence), including scientific evidence, personal experience, personal values, economic and political considerations, and philosophical principles. It is not always clear how practitioners integrate these factors into a final decision, but what *is* clear is that medicine can never be entirely free of value judgments.[683] Normative content seems to enter at all levels of decision-making, even in the production and presentation of the scientific evidence that is supposed to univocally inform evidence based decisions.[684] The very notion of evidence and the boundaries of what counts as evidence is a social construct, as evidence is always the product of a socially produced question. Even "evidence based" is a normative concept.

The fact that EBM has a naïve epistemology does not, of course, deny the possibility that its methods could improve patient care. Prior to EBM, defenders of bench science made momentous medical advancements despite being having poor philosophical understanding and epistemic justification for their practices. My proposal, however, is that the evidence based disregard of its value judgments and underlying theoretical

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[682] It would be acceptable to defend the claim that reliable evidence *tends* to improve decisionmaking. But because EBM offers so little on *how* better data could improve medical decisionmaking (the "knowledge translation" part of the decisionmaking process), they appear to be making the stronger and, as I stated, problematic claim that better evidence necessarily leads to better decisions.

[683] Kerridge *et al* (1998), "Ethics and evidence based medicine." BMJ 316(7138), p.1151.

[684] Molewijk *et al* (2003), "Implicit normativity in evidence-based medicine: a plea for integrated empirical ethics research." Health Care Anal 11(1).

presuppositions hinders patient care and does so because of flaws unique to EBM. For instance, in Tyson's attention to systematic measures and formulaic approaches, he glosses over the value judgments that go into the evaluation of "*reasonable*" and "*unreasonable*" actions. He similarly takes as "given" the implicit normativity in his "medical cost relative to value" formula for deciding how to use limited health care resources. In his accounting, the cost utility of neonatal intensive care is expressed as the cost per quality-adjusted life-year (QALY) gained as a result of neonatal intensive care. The life-years gained are then reduced according to the number of disabled survivors and the severity of those disabilities. While Tyson seems to think that deferral to measurement is transparent and fair—presumably because the life circumstances of individual families do not bias the clinical evaluation—the values implicit in these measures go unchecked. Even his recognition of "the fact that it is difficult to know how to adjust appropriately for disability and disease, in part because quality of life in the presence of handicaps and chronic illnesses may be rated higher by those affected than by other persons" does not seem to deter him from formulating an evidence based decision-making algorithm and assuming the justice of measurement in general.

By this account of evidence based ethics, one might ask how evidence based ethics differs from EBM, as both involve making health care decisions based on the best evidence, where evidence is narrowly defined as having to do with systematic observations from certain types of scientific research. Alternatively, one might question whether evidence based ethics represents a misappropriation of the word "ethics".[685]

[685] This suggestion was made by a member of the audience at a presentation of my work on evidence based ethics at the annual meeting of the *Canadian Society for the Study of Practical Ethics* in June 2005 in London, Ontario.

While "evidence based" is typically read in medicine and other life and social sciences as the empirically-adequate standard of reasonable practice and as a means for increasing certainty, the evidence based movement in fact gains consensus by *displacing* normative discourse with aggregate or statistically-derived empirical evidence as the "bottom line". Whether applied to medicine or bioethics, the techniques invoked in the name of "evidence based" decision-making require a positivistic reliance on "the evidence" in its epistemological promise to ascertain increased certainty by examination of the evidence. These techniques act to obscure the multiple and complex considerations that unavoidably go into health care decisions at both the micro- and macro- level and allows for the promotion of particular political agendas and interests under the guise of "better science".[686] In health care justice and policy, we see appeals by liberal thinkers to allegedly neutral markers like "species normal functioning". We know, of course, that these measures are not neutral, as people with disabilities and chronic illnesses and elderly people consistently fare poorly in this political calculus. Popular thinking holds, however, that if it is neutrality that is desired, numbers are the pinnacle. In this age of the ascendancy of health outcomes research, where statistical analysis dominates health policy decisionmaking, "evidence" is tantamount to *measure* and not *meaning*.

Bioethicists are typically attuned to the multiple dimensions of the illness experience that eludes quantification and measurement. Science, according to medical humanists, is just one layer of description of the phenomenological world. EBM's reliance on scientific evidence has been criticized for mischaracterizing modern health care's constitution by diverse academic traditions and knowledges—including the

[686] Goldenberg (2005), "Against evidence based bioethics [Letter]." BMJ 331(7521).

humanities, social sciences, and the pure and applied sciences—that rely on equally diverse notions of evidence.[687] While bioethicists attend to the normative features of medical decision-making, evidence based ethics suggests a moment of inattentiveness to the normativity of moral decision-making. Recognition of the plurality of values and meanings in operation complicates our use of moral and ethical terms and categories; however, the quick turn to various truth-producing strategies labeled "empirical" that has taken place warrants careful consideration. While the "empirical turn" in bioethics signals a need for reconsideration of the methods used for moral evaluation and resolution, the options should not include obscuring normative content by seemingly neutral technical measure.

In Conclusion

In this chapter, the numerous epistemological challenges to EBM were introduced into the ethical analysis of EBM, thus broadening the initial consequentialist investigation of the impact of EBM on patient care into an ethics of evidence. How one understands the nature and role of evidence was demonstrated to have ethical import, as seen in the differences between Miké's "ethics of evidence" and "evidence based ethics". It is also the hubris surrounding the largely uncritical adoption of EBM that invites application of the evidence based approach onto moral decisionmaking, with results that are morally disconcerting. Tyson's evidence based approach to resolving the vexing ethical problems surrounding the treatment of severely disabled newborns minimized the difficult negotiation of values and social considerations in favour of a systematic measure of projected clinical outcomes. This case therefore supports the earlier proposal that

[687] Upshur *et al* (2001), "Meaning and measurement: an inclusive model of evidence in health care." J Eval Clin Prac 7(2).

evidence based approaches obscure normative issues under the guise of technical consideration and language.[688] Just as an "evidence based" ethics would threaten bioethics' normative mandate, an "evidence based" medicine threatens to obscure the normative dimensions of medicine in favour of technical resolve.

Jansen's misuse of the term "evidence based ethics" was also instructive, as there is confusion regarding what exactly EBM *is*. It has already been discussed that it is at times understood to represent no more than reliance on the evidence in medical decisionmaking, a definition that warrants the charge of "nothing new". Yet we have already seen that this understanding is incorrect, as EBM introduces epistemological and methodological innovation to medicine. By doing so, it also narrows the range of questions that can be investigated. What Jansen was calling for was *empirical ethics*—surveys, interviews, and other qualitative modes of data gathering—as randomized controlled trials cannot produce the information that Jansen wants to know. This is not to say that RCTs could never provide any data of ethical interest, of course.

Lastly, Jansen's and Tyson's call for evidence based ethics shared a similar motivator: the perceived injustice and irresponsibility of ethically-charged legislation by ill-informed bureaucrats who enforce regulations "without demonstrating broad societal support, a consistent or coherent rationale, or a manifest commitment to improving the

[688] My proposal that problems associated with evidence based ethics are similar to those confronted by evidence based medicine will likely encounter initial resistance. The warnings against an evidence based approach to moral decisionmaking may be more easily accepted as warranted, given that bioethics is understood to have a fundamentally normative mandate. Medicine, however, is also a normative discipline, as the culture of science and medicine has been argued to be a dominant force in social life. The relationship between science and values (and politics) receives considerable attention within science studies, and many of the arguments regarding their inseparability have been rehearsed in this dissertation vis-à-vis EBM.

[lives of patients]."[689] The original anti-authoritarian spirit of EBM, as well as the spectre of justice pervading much of the evidence-based health policy discourse, strongly mark the rationale for an evidence based ethics. Yet much like positivism threatened ethics by rendering it "senseless", an "evidence based" approach proposes to make moral deliberation redundant by co-opting the normative issues with supposedly neutral technical measures.

[689] Tyson (1995), "Evidence-based ethics and the care of premature infants." Future Child 5(1), p. 162.

CONCLUSION
Advancing an Ethics of Evidence

Throughout this project, there has been some variety in the accounts of what precisely constitutes EBM. EBM has been represented both in the literature and in this investigation as a technology, a host of methodologies, a paradigm, a tool, and a movement,[690] all of which are intended for varied usage in clinical decisionmaking, depending on how EBM is initially construed. For instance, a tool for organizing mass quantities of clinical data plays a far more modest role than does a hierarchical decision-support technology, paradigm, or movement in the decisionmaking process. While some critics have accused EBM proponents of capitalizing on the ambiguities surrounding what EBM is and how it is practiced to fend off criticism,[691] as critics are easily rebuffed for allegedly misunderstanding EBM,[692] I propose that there is some accuracy in *all* of the representations of EBM. It may be most fitting to describe EBM as a philosophy of medicine, a rich concept that incorporates practical methods and goals, as well as abstract commitments, such as an ontology of medicine, an epistemological framework, and an ethical rationale. It has already been stated that some components of the evidence based philosophy of medicine are being admirably worked out in the critical literature, while others, specifically the ethical issues surrounding EBM, are thin in content. The call for a more robust ethical analysis acknowledges the broader ethical relevance of EBM, as there are connections between the components comprising EBM.

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[690] Jennifer Gibson pointed out this variety of descriptors after reading an earlier draft of this dissertation, leading me to consider how they did or did not fit together.

[691] Lambert (2006), "Accounting for EBM: Notions of evidence in medicine." Soc Sci Med 62(11)/

[692] See, for example, Sullivan and MacNaughton (1996), "Evidence in consultations: Interpreted and individualized." Lancet 348(9032); Evidence Based Medicine Working Group (1992), "Evidence-based medicine." JAMA 268(17); Goodman (2005), "Ethics, evidence, and public policy." Persp in Biol Med 48(4).

We saw in chapter two that the ethics of EBM is currently limited to questions regarding the impact EBM has on patient care. Supporters view EBM as significantly contributing to patient autonomy and informed consent, while detractors view the evidence-based standards of best practices and clinical protocols as limiting patient choice to "take it or leave it" by eliminating therapeutic options that patients may have reason to favour because it is not supported by the evidence. Yet the complex understanding of EBM just proposed, and what we saw to be significant epistemological and methodological novelty brought to medicine by the evidence based approach, supports the plausibility of the working hypothesis that the ethics of EBM is far more extensive than its current narrow scope. The actual extent of EBM's ethical relevance can be determined by critically analyzing EBM. The examination in chapters one and three revealed eight distinct yet overlapping challenges to the evidence-based approach.

> *1. EBM's construal of evidence ignores the social and political factors present in observations and the evaluation of the evidence. Empirical evidence is not self-apparent or "given" even when gathered in the most rigorously controlled settings.*
>
> *2. EBM fails at its methodological task of providing "best evidence" because of the shortcomings of randomized controlled trials, the problems of application for individual care, especially for patients who are not properly represented among research subject populations, and the bias that can arise due to funding and publication bias.*
>
> *3. EBM is reductionist and privileges quantitative over qualitative data.*
>
> *4. The privileging of quantitative over qualitative research occurs because EBM values knowledge that is divorced from personal experience and non-phenomenological.*
>
> *5. EBM promotes the separation of technical and normative and the silencing of democratic debate.*
>
> *6. The clinical judgment and experience of practitioners are subordinated in EBM's overreliance on epidemiological and statistical methodology.*

7. EBM promotes a political and economic model of health care rationalization that is premised on a faulty positivist-empiricist epistemology.

8. EBM's fusion of positivism and market capitalism validates a view of healthcare as consisting of independent rational buyers and sellers.

At the heart of the critiques of EBM is dissatisfaction regarding what counts as evidence (#1). From here, further epistemological as well as methodological problems arise concerning what EBM regards as legitimate and valid knowledge and how such knowledge is best attained (#2- #4). These findings lead to political critique regarding the minimizing of physicians' and patients' input within the decisionmaking context, as well as the quelling of democratic debate over normative questions regarding rationing and healthcare spending (#5, #6). Finally, this quieting of political debate in healthcare can potentially allow for the promotion of certain political interests under the guise of "best practices" (#7, #8). The more politicized critiques (#5-#8) denote a return to the individual, not as a subject of experience or as a phenomenological being (see critique #4), but as an individual qua citizen (#5), consumer (#8), and client. This new subjectivity is linked to the epistemic objectivism criticized in #1 via feminist epistemology's critique of atomistic individualism and the notion of the modest witness's unbiased and pure empirical gaze. The criticism that EBM promotes a political and economic health care rationalization that is premised on a faulty positivist-empiricist epistemology (#7) rounds out this critical investigation by tying the political commentary to the initial epistemic claim.

As the name "evidence based" should suggest, evidence is key to the model of medical practice being promoted. Thus the construction of evidence surely has ethical relevance beyond the impact on patient care. The problem of relativism and the

uncertainty of our knowledge claims regarding the veracity of our beliefs was examined in chapters three, four, and five of this ethical analysis of EBM because evidentiary problems are not only an epistemic concern in the context of health care, but also a deeply moral problem. Medical uncertainty and incorrect knowledge may inflict suffering, illness, disability, and death on those for whom health care professionals have a duty to care.

The shortcomings of EBM's notion of evidence are readily apparent. However, rethinking evidence proves to be difficult. EBM critics effectively utilize major lines of postpositivist thought in the philosophy of science to demonstrate the inadequate configuration of evidence underlying the evidence based approach. Despite the critical effectiveness of those views, they fall short when it comes to providing a defensible and useful conception of evidence. The more holistic accounts of evidence provided by feminist philosophers of science, Longino and Nelson, counter the narrow configuration underlying EBM, but in fact fail to offer concrete guidance in medical decisionmaking. These concepts may even further complicate the process by being so unrestrictive regarding what counts as evidence. As a result, the evidence based program may be confounded rather than corrected by this critical undertaking. Discrediting the presumed theoretical independence of evidence is thought to unavoidably strip science of its objective knowledge-gathering capability and lead to the situation in which incommensurable positions hold equal evidentiary weight. Regardless of whether there is an antiquated understanding of science operating here, practitioners are faced with the more tangible problem that they do not have the basis on which they need to act. Longino's call for more democratic science, and Nelson's reassurance that the

unconstrained and uncontained theory of evidence is unavoidable, may come across as fanciful or impractical to clinicians, as it offers a far weaker substitute for scientific evidence's now discredited rigorous adjudicative ability. This result may keep even enlightened clinicians from straying from the evidence based curriculum, as the critical science perspectives do not help with the decisions that have to be made and the literature that needs to be synthesized.[693]

The turn to Davidson's evidentiary account opens up possibilities by resolving the loss of adjudicative force in evidence. The Davidsonian feminist pragmatism constructed by Clough manages to not only address the first and third critiques regarding social features of knowledge production and the legitimacy of qualitative research, but to also respond to #4 by ascribing comparative value to subjective experience and phenomenological knowledge.[694]

In the final chapter, the largely epistemological challenges to EBM were finally brought to bear on the ethics of EBM. The nature of evidence and the idealized hierarchy of knowledge motivating this evidentiary preferencing do not solicit much attention in bioethics. However its effect on the goals, scope, and practices of medicine suggests that it warrants critical attention. Indeed, there is something peculiar about EBM's promotion of a rigid pre-graded hierarchy of evidence, considering that the EBM programmatic literature explicitly states that "the clinical problem...must determine what type of

[693] Jim Nelson has suggested that it may be worse yet. In this situation, clinicians may reasonably argue that, since it is beyond doubt that scientific evidence rigorously adjudicate between many kinds of important alternatives, any view that implies otherwise must be false. (Private correspondence with James L. Nelson)

[694] To be clear, acknowledging the comparative value of experiential knowledge is not to say that all beliefs stand in equally powerful evidentiary relationships to each other. Ethical beliefs may be evidentiary, but will not provide much evidence toward, say, resolving the question whether streptokinase is more effective at busting blood clots after CVA.

evidence should be sought".[695] To have evidence is to have some warrant for belief or action, and the kind of evidence needed will typically depend on the belief in question. Medical research, especially "evidence based" medical research, however, converges resoundingly on a single methodology—the double-blinded randomized controlled trial—as the bona fide "gold standard" of medical investigation, despite the wide range of hypotheses being tested. The supposed objectivity gathered from evidence based methods is epistemically untenable and troubling in the way that political agendas can be introduced into healthcare decisionmaking under the guise of best practices and accountability. The potential compromise to patient care is far greater than the loss of choice in the decisionmaking context. Against the claim that EBM offers "nothing new", EBM promotes innovative methodological practices and epistemological commitments that must be considered on ethical grounds.

Drawing from the philosophical work on evidence (see chapters two, four, and five) and the application of evidence in the context of clinical decisionmaking (chapters three and six), it seems fair to conclude that the concept of 'evidence' may be resistant to a single analysis applicable to all circumstances in which we use the term. The task of EBM critics therefore should not be to replace EBM's singular account of evidence with an equally singular alternative to be readily applied to a host of health research problems. Instead, a broad framework must be established for context-specific, and content-rich, integrated health research.

This call for integrated health research led to the formulation of my postdoctoral research project, an investigation into evidence based approaches to women's health (EBWH) from an embodiment perspective. Within the women's health community, there

[695] Davidoff *et al* (1995), "Evidence based medicine." BMJ 310(6987); See also p. 1 of this dissertation.

is currently disagreement regarding the utility of the evidence based approach. Supporters argue that EBWH will improve health outcomes by critically analyzing the evidence base of women's health research. Critics worry that the new methodology will limit meaningful research into the sociopolitical determinants of women's health by narrowing the range of admissible research methods and the types and sources of reliable evidence. Similar to other debates over evidence based approaches, the disagreement is thought to largely hinge on how one understands evidence. Embodiment has not yet been a point of analysis within the EBWH debates, as this philosophical framework is not thought to offer insight into evidence and evidence based approaches. Here, the conceptual divide between qualitative and quantitative perspective is seen to be firmly in place. Drawing from the groundwork covered in this dissertation, I will challenge the low evidentiary status of embodiment perspectives in women's health. EBWH holds out the promise of offering the best evidence for women's health. If women's health is a distinct specialty in medicine *because* of its unique patient population, EBWH must properly account for the embodied subjectivities, differences, and life experiences of the women it serves. [696]

There are numerous measures of "best evidence" within the broad healthcare literature; EBM focuses on controlled measures of therapeutic effectiveness, while more holistic and alternative healing models frequently lean toward such patient-centred

[696] Embodiment studies theorize the body, and this area of scholarship is important to health research because conceptions of the body are understood to be inextricably interconnected with definitions of health and illness, constructions of disease etiology, and with corollary notions of appropriate care. Thus it provides important nuanced perspectives to an evidentiary investigation into women's health research. On embodiment theory, see Price and Shildrick, eds. (1999), Feminist theory and the body: A reader.

measures as individual experiences and sensations.[697] Controls such as blinding are thought to disrupt the healing context rather than ensure objectivity. Thus EBM can and has been challenged on the grounds of Feyerabendian "incommensurable alternatives", that is, medical modalities and discourses that fail to fit into medicine's evidence base. In some cases, it is over disputed evidentiary criteria. For instance, many advocates of complementary and alternative medicine challenge EBM's methodology on the grounds that holistic healing practices cannot *fit* into the reductive confines of experimentalism.[698] People living with chronic conditions frequently insist that they offer invaluable experiential insight into the management of their condition.[699] Other problems arise regarding the uptake of evidence. Marginalized healthcare techniques sometimes find that their evidence fails to be incorporated into policy, such as the case of positive outcomes for midwife-led births in the U.S.[700] The broad health research agenda being advocated here encourages investigation into instances of ill-fit as well as plural perspectives in accounting for evidence. The ethics of evidence, which examines the production and presentation of empirical evidence and the establishment of credible knowledge from an ethics perspective, calls attention to the significant concern about the power/knowledge relationship that arise from a seemingly innocuous clinical decisionmaking tool.

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[697] Barry (2006), "The role of evidence in alternative medicine: Contrasting biomedical and anthropological approaches." Soc Sci Med 62(11);Leibovici (1999), "Alternative (complementary) medicine: a cuckoo in the nest of empiricist reed warblers." BMJ 319(7225).

[698] Barry (2006), "The role of evidence in alternative medicine: Contrasting biomedical and anthropological approaches." Soc Sci Med 62(11).

[699] Toombs (1995), "Chronic illness and the goals of medicine." Second Opinion 21(1).

[700] Bodgan-Lovis and Sousa (2006), "The contextual influence of professional culture: Certified midwives' knowledge and reliance on evidence-based practice." Soc Sci Med 62(11).

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