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What Counts as 'What Works':  
Expertise, Mechanisms and Values in Evidence-Based Medicine

Sarah Wieten  
A thesis submitted for the degree Doctor of Philosophy  
Philosophy Department  
Durham University  
2018

### Material Abstract

My doctoral project is a study of epistemological and ethical issues in Evidence-Based Medicine (EBM), a movement in medicine that emphasizes the use of randomized controlled trials. Much of the research on EBM suggests that, for a large part of the movement's history, EBM has considered expertise, mechanisms, and values as forces contrary to its goals and has sought to remove them from both medical research and the clinical encounter. I argue, however, that expertise, mechanisms, and values have important epistemological and ethical roles to play and can be incorporated within the existing EBM movement.

Statement of Copyright

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## Table of Contents

Chapter 1: Outline and a Textual History of Evidence-Based Medicine	8
Outline	
Chapter 1	
Chapter 2	
Chapter 3	
Chapter 4	
Chapter 5	
Textual History of Evidence-Based Medicine	
Original Texts	
1992: The “Debut” Article	
Description of EBM	
A Note on a “New Paradigm”	
Implications for Medical Education	
Who Were the Evidence Based Medicine Working Group?	
David Sackett	
Gordon Guyatt	
Deborah Cook	
1996: An Effort at Clarification	
2002: A More Holistic EBM	
A Note on Further History: Semmelweis, Snow, Lind and Fisher	
The Rise of the Manuals	
A Manual Example: Users’ Guides to the Medical Literature	
Critical Appraisal by Clinicians	
Move Toward Pre-Evaluated Evidence	
Critical Response: Philosophers, Clinicians and Others	
Randomization Doesn’t Do What EBM Thinks it Does	
Mechanisms are Crucial in Medicine	
Medicine Requires an Expanded Role for Clinical Expertise	
Adaptation and Renaissance	
Renaissance/Crisis?	
New Greenhalgh book	
A Traditional Account of Progress	
EBM Manifesto	
Chapter 2: Expertise	39
Introduction	
Overview of EBM Treatment of Expertise	
The Pyramid Model	
The Tripartite Model	
The Amalgamation Model	
Problems with EBM Models of Expertise	
Internal vs External distinction	
Applying the Internal/External Distinction	
The Search for a Legitimate Role for Internal to Evidence Expertise	
How the Internal/External Distinction is a Problem for the EBM Models	
Other Expertise Problems for EBM	
Arguing for an Augmented Account of Expertise	
The Dreyfusian Account	

The Five Stages of Skill Acquisition	
Against the Calculative Rationality Model	
What Problems Would the Dreyfusian Account Solve?	
Problems with the Integration of the Dreyfusian Account and EBM	
Rejection of the Dreyfusian Account for EBM Expertise Augmentation	
Turner Account	
The Turner Types of Expertise	
The Application of the Turner Account to EBM Players	
What Problems Would the Turner Account Solve?	
Problems with the Integration of the Turner Account and EBM	
Rejection of the Turner Account for EBM Expertise Augmentation	
The Bishop and Trout Account	
What is Expertise for Bishop and Trout?	
Problems in the Bishop and Trout Account	
What Problems Would the Bishop and Trout Account Solve?	
Problems with the Integration of the Bishop and Trout Account and EBM	
Rejection of the Bishop and Trout Account for EBM Expertise Augmentation	
The Collins and Evans Account	
The Collins and Evans Periodic Table of Expertise	
Dispositions	
Specialist Expertise	
Meta-Expertise and Meta-Criteria	
What Problems Would the Collins and Evans Account Solve?	
Problems with the Integration of the Collins and Evans Account and EBM	
Acceptance of the Collins and Evans Account for EBM Augmentation	
Chapter 3: Mechanisms	103
The “Scope Problem”	
The Russo-Williamson Thesis and its Critics	
But What Kind of Mechanism?	
Two Worries by a Critic	
The Strevens Account	
Practical Applications: Nutrition in Bangladesh and Statins for Stroke	
An Objection and a Few Replies	
Medicine is not a Science: The “Primacy of the Practical”	
Implications for EBM and Mechanisms	
Chapter 4: Values	122
Introduction	
Early EBM Accounts of Values	
Critiques of Early EBM Accounts of Values	
Values-Based Practice Account of Values	
VBP Case Study: The Artist’s Need to “See” Color	
Problems with the VBP Account of Values	
Possible Improvements to Values in VBP	
What Can We Learn About EBM Values from GOBSAT?	
GOBSAT as a Charge of Exclusion and Rationalism	
Implicit Values in EBM	
Values that Fit: Guidance for Adopting Values in Science	
A Critique of Universal Illegitimate/Legitimate Distinctions	

A Proposal for Guidelines: Locality, Context-Dependency and Transparency	
A Note on “Adoption”	
Case Study: Statins for Stroke	
Objections and Replies	
“Fact-Based Values”: Why the Fact/Value Dichotomy Plays Too Large of a Role in Critiques of “Evidence-Based Ethics”	
A History of Evidence-Based Ethics: Roots in EBM	
Origins of the Fact/Value Distinction in Hume	
Analysis of Goldenberg’s Critique	
Two Strategies for Problematizing the Fact/Value Distinction	
Putnam on Thick concepts	
Historical Case Studies in Philosophy of Science	
Douglas Case Study: Rat Liver Slides in Dioxin Cancer Studies	
New Developments in Values in EBM	
Chapter 5: Personal and Precision Medicine: The End of EBM?	176
Introduction	
From “Personalized” to “Precision” Medicine	
Replacing EBM with Precision Medicine: Why a Delay?	
But Wait: Why Think Evidence Can Be Replaced?	
New Trend, Same Issues	
Expertise in Precision Medicine	
Mechanisms in Precision Medicine	
Values in Precision Medicine	
Implications of Problem Consistency for Philosophy of Medicine	
Chapter 6: Conclusion	196
Chapter 1	
Chapter 2	
Chapter 3	
Chapter 4	
Chapter 5	
References	202
Appendix I	214
Appendix II	216
Appendix III	217



## Chapter 1: Outline and a Textual History of Evidence-Based Medicine

### Outline

Chapter 1

Chapter 2

Chapter 3

Chapter 4

Chapter 5

### Textual History of Evidence-Based Medicine

#### Original Texts

1992: The “Debut” Article

Description of EBM

A Note on a “New Paradigm”

Implications for Medical Education

Who Were the Evidence Based Medicine Working Group?

David Sackett

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1996: An Effort at Clarification

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A Note on Further History: Semmelweis, Snow, Lind and Fisher

#### The Rise of the Manuals

A Manual Example: Users’ Guides to the Medical Literature

Critical Appraisal by Clinicians

Move Toward Pre-Evaluated Evidence

#### Critical Response: Philosophers, Clinicians and Others

Randomization Doesn’t Do What EBM Thinks it Does

Mechanisms are Crucial in Medicine

Medicine Requires an Expanded Role for Clinical Expertise

#### Adaptation and Renaissance

Renaissance/Crisis?

New Greenhalgh book

A Traditional Account of Progress

EBM Manifesto

## Chapter 1: Outline and Textual History of EBM

In this chapter, I provide an outline of the work as a whole and a short analysis of some of the most important texts within the Evidence-Based Medicine (EBM) movement. These texts give shape to the EBM movement, beginning with a few classic claims about the quality and uses of evidence, continuing through the production of a plethora of manuals to bring these claims into practice, enduring a period of strong critique from many fronts, and a recent period of reflection, renaissance, attempts to improve implementation, and conceptual expansion. This analysis provides the foundation for the discussion of the treatments of particular concepts, including expertise, mechanisms and values, in EBM in the chapters that follow.

## Chapter 2: Expertise

In this chapter, I examine the three models of expertise developed by EBM over the course of the movement. I argue that despite interesting shifts between the models, all three models are unclear on the question of any evidence-internal role for expertise, and what evidence-external roles for expertise are to be encouraged. This lack of clarity results in divergent recommendations for the role of expertise in medical education. As a result, I argue that EBM needs to develop a clearer account of expertise in medicine.

However, this improved account of expertise need not be created from scratch. The disciplines of philosophy, artificial intelligence, sociology, cognitive science and psychology all have accounts of expertise which could be good resources for EBM. These accounts include those put forward by Dreyfus, Turner, Collins and Evans, and Bishop and Trout, and I examine each in turn. I argue that while none of these accounts can be adopted wholesale by EBM without EBM taking a stand on the internal/external issue of expertise and evidence, the Collins and Evans account fits best with EBM.

## Chapter 3: Mechanisms

In the third chapter, I examine the debate about mechanisms in medicine, specifically about the appropriateness of mechanisms *as a kind of evidence* for the use of a particular

intervention. While philosophers of science have asked what kind of evidence might be needed in order to say that a mechanism is in place, the question in EBM has been instead should mechanistic knowledge be used reliability to support claims about whether interventions work.

Historically, EBM has encouraged a distrust in knowledge of mechanisms as a way of selecting interventions and has even claimed that the investigation of causes is not the goal of medicine. These theses have been argued for by the use of a set of historical case studies in which interventions were endorsed for use based on a rationale about how or why they worked without evidence about efficacy, with poor results. Such examples include bloodletting, anti-arrhythmic drugs, and thalidomide, among others.

In other sciences without this history of mistrust, mechanisms and causality remain important and legitimate concepts. Perhaps as a result of contact with these fields, philosophers of science have attempted to rehabilitate mechanisms in medicine. While there are many philosophers who have undertaken a version of this project, the version put forward by Federica Russo and Jon Williamson and further clarified by Phyllis Illari, has gained particular traction in the field. Since the Russo-Williamson thesis already has significant uptake in the field, not to mention a few engaged clinician-critics, I argue that this conception of mechanisms should be rehabilitated for use in medicine—with one large modification which addresses a main concern of critics. This additional component is a restriction of the scope of a mechanism inspired by the work of Michael Strevens on *ceteris paribus* laws. Because a main critique of the Russo-Williamson thesis is the worry that mechanisms are so expansive that it is impossible to make a list of all the required parts, the Strevens account, which places the scope of a mechanism neatly between traditional “Empty” and “Boring” accounts of mechanisms, is an important component of making mechanisms useful for EBM.

## Chapter 4: Values

It is clear that medicine is saturated with values. Work by scholars like Miriam Solomon, Alison Wylie, Helen Longino, and Phillip Kitcher has made clear the importance of values in science. Medicine, insofar as it participates in some of the practices of science, is no different. However, the particulars of medicine (the causal complexity of epidemiological evidence, the wide range of factors to be taken into account in diagnosis, uncertainty about what counts as evidence of treatment efficacy, and concerns about which methods provide clinicians with the best evidence to make treatment decisions) mean that it is especially difficult and especially necessary to be clear about what the proper roles are for values in medicine.

In this chapter, I follow the changing roles of values in EBM. Early accounts of EBM said very little about values. Later accounts added a role for patient values back into EBM clinical practice, but without much direction about what clinicians should do should patient values conflict with other components, such as the best evidence component. Partly because of the way in which this addition did not address the values of other stakeholders in the clinical encounter, Bill Fulford developed Values-Based Practice (VBP), which takes care to discuss the ways in which the values of the patient, family, clinicians, support staff, social workers, and others can impact clinical practice. While VBP is occasionally overly optimistic about sorting out conflicts between these kinds of values, it represents a great improvement over the treatment of values in EBM.

So far, the discussion in EBM has centred around the values of particular individuals which come in contact in the clinical encounter. What about the values which are present within EBM itself? The EBM literature says very little explicitly about what its values are, but some of these can be pieced together from value-laden commentary in the literature, such as the GOBSAT joke, which I discuss in detail. However, this both leaves an incomplete picture of the values in EBM leaves open the possibility that these implicit values are not the values EBM would adopt upon reflection. Do we have any way to distinguish those values that are acceptable for use in a scientific project from those values that are unacceptable?

A possible solution to concerns about how to distinguish values that should be used in medicine from values that have no place in medicine comes from the values in science literature: the legitimate/illegitimate distinctions. These distinctions use different metrics, including epistemic content and the completeness of the non-value involved evidence (the “lexical-priority” metric), to differentiate between legitimate and illegitimate value inclusion in science. I argue that this set of distinctions is not the solution to the problem of values in medicine, or even more broadly, in science.

This section on illegitimate and legitimate values in medicine proceeds in three parts. First, I critique the legitimate/illegitimate distinctions based on the two line-drawing metrics suggested in the literature: epistemic content and the completeness of the non-value involved evidence (the “lexical-priority” metric). I argue that both these distinction-drawing metrics fail to be universally applicable across all sciences and fail to assist in practical distinction drawing. In a larger second part, I argue for transparent, local, and context-based value adoption in particular sciences and provide an example case for use in statins medical research. In a brief third part, I entertain possible counter-arguments to my account of transparent, local, and context-based value adoption, including worries about relativism and the “entrance” of politics into science. If what must be done is more than asking, “Is this value legitimate based on metric X?” this will require more training, more communication and transparency, more philosophical involvement and more forums for debate and discussion about adopted values both in clinical practice and in medical research.

Values have also been used to critique a spin-off from EBM: Evidence-Based Ethics (EBE). While EBE is in need of critique, I am critical of a current popular method of achieving this, which relies on a strong demarcation between science (facts) and ethics (values) which is thought to fall out of the is/ought distinction in Hume.

Finally, coming full circle on the use of values in EBM, I examine some very recent work on values in EBM. This recent work suggests that the prescriptions about values in EBM put forward in this work may reach a receptive audience.

## Chapter 5: After EBM

In this chapter, I consider the possibility that precision or personalized medicine may overtake EBM as the primary movement in medicine. I follow the shift from personalized medicine to precision medicine in the literature. This possibility of precision medicine has not yet been realized: I consider in principle and in practice reasons for this. However, if this shift were to take place it would have downstream effects for the epistemological and ethical agenda in medicine. Would such a change mean that the issues of expertise, mechanisms and values are no longer salient, and the philosophical recommendations suggested in works like this are no longer necessary? I argue that this is not the case, and that even in the face of such a shift of priorities, these three issues would still play a major role, though the kinds of philosophical recommendations to be made regarding them would differ in this new context.

### EBM Textual History

While there might be many ways to trace the influence and content of EBM over time (development of journals, institutions, conferences, changes to clinical practice, popular media acclaim), one of the easiest ways to see the changes in philosophically interesting content in EBM is to look at the texts produced by those within the movement and those criticizing the movement. In what follows, I trace the shape of the EBM movement from its original texts to the rise of manuals, to its critique by philosophers and others, through to the most recent period of renaissance, reflection and reconsideration.<sup>1</sup> These texts provide the foundation and context for the more in-depth considerations of individual philosophical concepts in the chapters which follow.

### Original Texts

#### 1992: The “Debut” Article

In 1992, the Evidence Based Medicine Working Group published their paper

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<sup>1</sup> This discussion of main texts in the history of EBM is not exhaustive. For a more complete overview, see Bluhm and Borgerson 2011 or Howick, Kennedy, and Mebius 2015.

“Evidence-Based Medicine: A New Approach to Teaching the Practice of Medicine” in Journal of the American Medical Association (JAMA). Since then, it has been cited nearly 4000 times and is now generally considered to be the “debut” of the EBM movement, although many other historical precedents have been cited.<sup>2</sup> But what exactly was claimed in this seminal paper in the EBM field? Three major claims were put forward: the paper described the new approach, Evidence-Based Medicine, claimed that this new approach was a “new paradigm” in a Kuhnian sense, and claimed that an important effort of this new approach would be to reform medical school pedagogy.

### Description of EBM

The Evidence-Based Medicine working group described EBM saying, “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” (EBMWG 1992, 2420). The process of EBM is further illustrated with a case study. When faced with the following clinical scenario, what should a resident do?

A junior medical resident working in a teaching hospital admits a 43-year old previously well man who experienced a witnessed grand mal seizure. He had never had a seizure before and had not had any recent head trauma. He drank alcohol once or twice a week and had not had alcohol on the day of the seizure. Findings on the physical examination are normal. The patient is 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 nonspecific findings. The patient is very concerned about his risk of seizure recurrence. (EBMWG 1992, 2420)

In the past, the resident would ask for advice from her attending clinician, who would tell her, (and she would relay to the patient) that the risk of seizure recurrence was high and that the patient should avoid driving, take the prescribed medication, and come in for a follow up.

In contrast with this old-fashioned solution, in the mode of EBM the resident recognizes that she does not know the prognosis<sup>3</sup> of a first seizure. Then she goes to the

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<sup>2</sup> See the later section, “A Note on Further History: Semmelweis, Snow, Lind and Fisher” in this chapter.

<sup>3</sup> It is interesting that this very first example of how to do EBM hinges on a question of prognosis. In the literature which follows this debut article, EBM focuses on decisions about intervention, largely by-passing additional questions about prognosis and prevention.

library to do a computerized search using relevant search terms and narrows the results based on relevance and critical appraisal. In a manner that rather dates this debut article, the authors note that, “the entire process (including the trip to the library and the time it took to make a photocopy of the article) took half an hour” (EBMWG 1992, 2420). She returns with a precise risk of recurrence for the patient. This example is taken to show the way in which practice under EBM is to be different from the status quo.

#### A Note on a “New Paradigm”

In the movement's debut article, the EBM working group writes,

Thomas Kuhn has described scientific paradigms as ways of looking at the world which define both the problems which can legitimately be addressed and the range of admissible evidence which may bear on their solution. When defects in an existing paradigm accumulate to the extent that the paradigm is no longer tenable, the paradigm is challenged and replaced by a new way of looking at the world. Medical practice is changing, and the change which involves using the medical literature more effectively in guiding medical practice is profound enough that it can appropriately be called a paradigm shift. (EBMWG 1992, 2420)

It is not clear that the description of EBM that follows the above claim conforms to the description of a Kuhnian paradigm given by proponents of EBM. According to them a “new paradigm” generally entails a change in problems tackled and evidence taken to be admissible. Insofar as EBM did not change what counts as the important problems for medicine (cures for new diseases, advances in the accuracy of tests, improvements in palliative care), instead providing a new method for tackling those familiar problems, and did not change what counts as evidence, instead providing a new way for that evidence to be ranked in order to make decision making easier, it seems difficult to say that, even by the account given by supporters of EBM, EBM counts as a “new paradigm.”

However, the supporters of EBM continue, giving a history and a series of examples of the applications of their new paradigm, writing,

The foundations of the paradigm shift lie in developments in clinical research over the last 30 years. In 1960, the randomized clinical trial was an oddity. It is now accepted that virtually no drug can enter clinical practice without a demonstration of its efficacy in clinical trials. Moreover, the same



randomized trial method increasingly is being applied to surgical therapies, and diagnostic tests... A number of major medical journals have adopted a more informative structured abstract format which incorporates issues of methods and design into the portion of an article the reader sees first... Textbooks which provide a rigorous review of available evidence, including a methods section describing both the methodological criteria used to systematically evaluate the validity of the clinical evidence and the quantitative techniques used for summarizing the evidence, have begun to appear. Practice guidelines based on rigorous methodological review of the available evidence are increasingly common. A final manifestation is the growing demand for courses and seminars which instruct physicians on how to make more effective use of the medical literature in their day-to-day patient care. (EBMWG 1992, 2421)

This list of changes does seem to show that EBM has come to prominence. However, none of these changes suggest that the rise of EBM has changed the goals or main problems of medicine or that what counts as evidence at all has changed, since proponents of EBM make so clear that the old ways of judgment and experience have a place in EBM, just a lower place on the hierarchical pyramid.

The question of EBM's status as a "new paradigm" is not the most important question for later authors in the EBM canon. This discussion explicitly in terms of "new paradigms" is missing from other important works in theoretical EBM literature, such as Sharon Straus et al.'s *Evidence Based Medicine: How to Practice and Teach EBM* and Jeremy Howick's *The Philosophy of Evidence-Based Medicine* (Straus et al. 2005; Howick 2011). Both of these works appear several years after the original article from the EBM working group appeared and emphasize the ways in which EBM actually fits into the traditional medical framework, rather than upends it. Indeed, Howick only says of the pronouncement of a "new paradigm"<sup>4</sup> that it was a "rhetorical tour de force" before moving on to discuss the ways that medicine "has always been evidence-based by definition" and argues that what EBM has done, far from beginning a revolution, is simply to make explicit which evidences are best and most applicable in a new and clear manner (Howick 2011, 4). In this way, although noting that others have called the movement a paradigm shift, Howick generally supports the idea that

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<sup>4</sup> Quotes original.

EBM is a reform within a standard practice of medicine, not a revolution of the entire discipline.

Straus et al., whose book specifically targets the busy clinician and is featured in this chapter's later "Rise of the Manuals" section, makes clear that EBM is a change within a familiar medical landscape, rather than a radical revolution. They write, "The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research" (Straus et al. 2005, 2).

The emphasis given here on integration with earlier medical practice, including clinical judgment, rather than revolution or replacement, makes clear the authors' lack of commitment to EBM as a paradigm shift in the sense that the working group had in mind in the debut article.

For early supporters of EBM, even discussion of a paradigm shift actually functions within the current paradigm. The popularity of the Kuhnian vocabulary of paradigm shifts is so strong and so commonly used that discussing a new discovery, or reform, or method as just that is no longer enough. In order to be taken as a truly novel contribution worthy of the medical and scientific community's attention, the vocabulary of "paradigm shift" is used as a signal of a development that is worthy of attention and consideration. Use of this vocabulary of the paradigm shift does not seem to carry with it the implications or meaning that Kuhn originally had in mind.

### Implications for Medical Education

Right from the beginning, EBM proponents placed issues of pedagogical reform in medicine front and center in their movement. In this first article they write, "An important goal of our medical residency program is to educate physicians in the practice of evidence-based medicine. Strategies include a weekly formal academic half-day for residents, devoted to learning the necessary skills; recruitment into teaching roles of physicians who practice evidence-based medicine; sharing among faculty of approaches to teaching evidence-based

medicine; and providing faculty with feedback on their performance as role models and teachers of evidence-based medicine” (EBMWG 1992, 2420). Indeed, the article contains an explicit endorsement of the Internal Medicine Residency Program at McMaster University, which includes these specific components (EBMWG, 1992, 2422). From the very beginning, EBM was not just about a change in practice, but a change in pedagogy.

### Who Were the Evidence Based Medicine Working Group?

The 1992 article by the Evidence Based Medicine Working Group was an important text for the Evidence Based Medicine movement. But who exactly was this group? In what follows I will describe the group as a population, trace the popularity of the 1992 article, discuss work done by the Evidence Based Medicine Working Group after the 1992 article, and provide brief career sketches of some of the group members who went on to become leaders in the EBM Movement. A list of the authors on the 1992 article and their academic credentials and affiliations is provided in Appendix III.

The Working Group was comprised of 25 men and 6 women, for a total of 31 group members. While all members had at least an MD, 15 participants had both an MD and an MSc, 15 had only an MD. Of 31 total members, 24 had at least one McMaster affiliation. Only 7 members had no McMaster affiliation. Many of those who reported an affiliation with McMaster in the 1992 article are still currently affiliated with McMaster. Other affiliations included the Department of Medicine, University of North Carolina, Chapel Hill, USA, Centre de Medicine Trezentize Cardio-Vasculaires, Paris, France, and Department of Medicine, University of Texas, San Antonio, USA. Only 1 group member had an affiliation outside of North America. Only 5 group members had an affiliation outside of Canada. Of 31 total members, 24 had some background in epidemiology or biostatistics, where this is defined as an affiliation with a biostatistics or epidemiology department (16) or authorship in at least 5 peer-reviewed publications in academic journals in this field before the 1992 article (8)(Evidence Based Medicine Working Group, 1992).

This information can help us to get a clearer picture of the group. They were mostly men with MDs, some background in epidemiology, and overwhelmingly affiliated with

McMaster University in Ontario, Canada. While it is difficult to assess the group's intention in naming themselves as they did, choosing the name, "the Evidence-Based Medicine Working Group" without any mention of either McMaster or the geography of the group might have served to make the pronouncements of the group seem more international, and therefore perhaps universal, than might otherwise have been. The high level of engagement of the group with epidemiology and biostatistics can perhaps explain the way in which the debut article of EBM emphasized that knowledge of the content and methods of epidemiology and biostatistics could improve medical practice. This clearer picture of the make-up of the group also makes the 1992 article's explicit endorsement of the McMaster educational programming in this area unsurprising.

The debut article has been cited over 4000 times according to PubMed. In 2001, when the New York Times listed "Evidenced-Based Medicine" as the "E" in their "The Year in Ideas: A-Z" round-up, author Jack Hitt explained the origin of EBM in the following way; "six doctors in Canada came up with the idea of skimming the most dependable studies and crunching the results into an accessible, reliable database (Hitt, 2001)." Although we are not given a citation for this claim, it seems likely that this is a reference to the McMaster based Evidence Based Medicine Working Group. It was in this way that EBM was fully introduced to the American public at large.

The Evidence Based Medicine Working Group never published another article as such. However, several prominent McMaster-based members of the group wrote a series of "Users' Guide" articles for the Journal of the American Medical Association between 1993 and 2000.<sup>5</sup> These guides are listed as being written by a few primary authors with the note "for the Evidence Based Medicine Working Group" at the end of the author list. There is no indication that this means that the rest of the members of the original working group had any direct authorship role in the writing of these guides, but instead that the project grew out of work originally visualized by the working group. The Users Guides include "II: How to Use an

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<sup>5</sup> The series has been revived outside the manual in JAMA itself in recent years.

Article about Therapy or Prevention A. Are the Results of the Study Valid?,” “XXV. Evidence-Based Medicine: Principles for Applying the Users' Guides to Patient Care,” and “XX. Integrating Research Evidence With the Care of the Individual Patient” among others (Guyatt et al. 1993; Guyatt et. al. 2000; McAlister et al. 2000). Eventually, these “Users' Guides” articles were compiled into one of the most successful EBM manuals, *Users' Guides to the Medical Literature: Essentials for Evidence-Based Clinical Practice*. This manual is currently in its 3<sup>rd</sup> edition and lists Gordon Guyatt, Drummond Rennie, Maureen O. Meade and Deborah J. Cook as its editors. Guyatt and Cook were part of the original Evidence Based Medicine Working Group, while Rennie and Meade were not (Guyatt et al. 2014).

Many members of the Evidence Based Medicine Working Group went on to interesting careers. For example, Patrick Brill-Edwards went on to help develop a vaccine for HPV (Bezruki, 2014), Virginia Moyer has led efforts to prevent over-screening for prostate cancer in the United States (Park 2011), Murray Enkin led efforts to professionalize midwifery in Canada and internationally, and argued successfully for more partner involvement in delivery (Sakala and Swenson 1999), and Allan Detsky, in addition to being one of the foremost experts on economics and health policy in the world, also became a producer on Broadway, notably working on the Atlantic-Canada-set-musical, “Come From Away” (Stasio, 2017). However, three of the Evidence Based Medicine Working Group became especially recognizable leaders of the EBM movement; David Sackett, Gordon Guyatt, and Deborah Cook. What follows is a brief biographical sketch of each.

#### David Sackett

Although he was born in the United States in Chicago, Sackett was one of the first to be recruited to be chair of epidemiology and biostatistics at the brand new medical school at McMaster University in 1967 (the first students arrived in 1969). This was after completing his medical education at the University of Illinois in 1962, and his epidemiological education at Harvard University in 1967 (Watts 2015). At McMaster Sackett was known for his insistence that biostatistics and epidemiology be integrated with other kinds of medical

coursework, rather than taught separately. In 1985 he began to write *Clinical Epidemiology: a Basic Science for Clinical Medicine*, which contained much of the methodological background for what would become Evidence-Based Medicine (Sackett, Haynes and Tugwell 1985).

In 1994, following the success of the 1992 EBM debut article, Sackett left McMaster to run the Centre for Evidence Based Medicine at Oxford. At Oxford, he was known for referencing RCTs and meta-analyses as well as calculating number needed to treat/harm at the bedside during student rotations (Smith 2015). In 1996, Sackett was first author on an article further defending and explaining EBM and created the most commonly-used definition of EBM, "Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients (Sackett, 2016)." This article has been cited over fifteen thousand times according to PubMed. Believing that experts tend to be a liability rather than a boon to the subjects they champion after around ten years, he gave a last talk on EBM in 1999 (Watts 2015).

But Sackett is perhaps most well known for a spirit of consistency. For example, in response to his own studies which suggested that older physicians were less likely to be informed about new findings in their field the further out they were from their residency, he repeated his own residency voluntarily, twenty years after he completed this part of medical education for the first time (Smith 2015). Sackett died in 2015, at the age of eighty.

### Gordon Guyatt

Guyatt was born in Hamilton Ontario, also home to McMaster University, 1953. He received his MD from McMaster in 1977 (Canadian Medical Hall of Fame 2016). Guyatt was first author on the 1992 debut article (EBMWG, 1992). Guyatt is usually considered the source of the name "Evidence-Based Medicine" after an earlier attempt, "Scientific Medicine," was met with indignation by clinicians who already considered themselves to be doing science-based work (Smith and Rennie 2014).

Guyatt was a leader in creating Grading of Recommendations Assessment, Development and Evaluation (GRADE). Published in 2008, this system for assessing the

strength of the evidence on a particular topic, treatment, or study, in a more sophisticated way than the original EBM Pyramid Model, has been adopted as a standard assessment by many in the field, such as the Cochrane Collaboration (GRADE Working group 2008).

Guyatt was an author on 34 of the Users' Guides articles, and one of the editors of the resulting manual. Indeed, he has remained active in the group, writing on contemporary topics like the use of EBM in assessing efficacy of surgical procedures (Evaniew et al. 2016) and the use of adjusted analysis in studies on harm (Agoritsas et al. 2017) with a new generation of EBM researchers. Guyatt is currently Distinguished Professor of Clinical Epidemiology and Biostatistics at McMaster University. In 2016 he was inducted into the Canadian Medical Hall of Fame ([Canadian Medical Hall of Fame 2016](#)).

#### Deborah Cook

Part of younger generation of EBM researchers with Guyatt, Cook received her MD and MSc from McMaster in 1985. When she was part of the authorship of the 1992 debut article, she was fresh from a Critical Care Fellowship at Stanford University (The George Institute for Global Health 2018).

She was an author on 19 of the "Users' Guide" EBM article in JAMA and was one of the editors of the Users' Guide EBM manual (Guyatt et al. 2014). She has spent most of her career in the critical care setting. A major focus of her work was championing EBM principles into the critical care setting (Cook 1998, Cook and Levy 1998).

She continued to insist, along with Guyatt and several other familiar faces, on the importance of critical appraisal methodological skills for all practitioners, even when EBM began to move towards a more forgiving, less independent model of pre-assessing the literature for physicians (Guyatt et al. 2000).

In 2014, she was named to the Order of Canada for her work on improving critical care procedure and creating a network for critical care research (Nolan 2014). Cook's recent work has included trials for different treatments for septic shock in the ICU (Mehta et al. 2013) and a cohort study comparing survival of aboriginal and non-aboriginal Canadians in the 2009-2010 H1N1 flu outbreak (Jung et al. 2017), among many other projects. Cook is

currently practices intensive care medicine at St. Joseph's Hospital in Hamilton Ontario and is the academic chair of Critical Care Medicine at St Joseph's and McMaster (The George Institute for Global Health 2018).

### 1996: An Effort at Clarification

In 1996, Sackett et al. attempted a clarification of EBM in response to a few very early critiques in their article, "Evidence based medicine: what it is and what it isn't." It is in this article that the most commonly cited definition of EBM appears: "Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research" (Sackett et al. 1996, 71).

This definition, in addition to emphasizing the place of the evidence base as seen in the earlier 1992 description, also includes clinical expertise as an element. Clinical expertise is defined in this article as, "the proficiency and judgment that individual clinicians acquire through clinical experience and clinical practice. Increased expertise is reflected in many ways, but especially in more effective and efficient diagnosis and in the more thoughtful identification and compassionate use of individual patients' predicaments, rights and preferences in making clinical decisions about their care" (Sackett et al. 1996, 71). Concepts of expertise are discussed in detail in this work in Chapter 2, but their inclusion in this short article is a reason for its continued importance in the history of EBM.

### 2002: A More Holistic EBM

EBM pivoted to a more expansive and holistic self-conception in the 2002 article by Haynes et al., "Clinical expertise in the era of evidence-based medicine and patient choice."<sup>6</sup>

The authors here claim that they are putting forth a "more advanced model for evidence-

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<sup>6</sup> Because this pivot was at least in some way a response to ten years of strong critique from many different disciplines, this article could also be classified as belonging in the "Adoption and Renaissance" portion of this chapter. However, because of its high citation count, close ties in argumentation to the 1996 Sackett et al. article and the 15-year gap between this article and many in the "Adoption and Renaissance" section, I have retained this article as part of the "original set" of EBM texts.



based decisions,” although they do continue to reference the Sackett et al. 1996 explanation, “the integration of best research evidence with clinical expertise and patient values,” as the definition of EBM (Haynes et al. 2002, 36). In addition, this text moves the role of expertise to an amalgamating function, emphasizes that taking patient preferences into account may mean disregarding clinician preferences, and introduces a new component, “the clinical state and circumstances” which highlights that social, political, economic and geographical forces can intervene to mean that true standardization of practice will not be possible. For example, “people who find themselves in remote areas when beset by crushing retrosternal chest pain may have to settle for aspirin, whereas those living close to a tertiary care medical center will probably have many more options—if they recognize the symptoms and act promptly!” (Haynes et al. 2002, 37) Together these changes mean that EBM as depicted by Haynes et al. is a broader undertaking than that depicted in earlier articles, which focused on methods for clinicians to access research in response to bedside questions about diagnosis, prognosis and intervention.

This article is also framed with a clinical case study— this time concerning a man with hypertension and a gastrointestinal bleed who fears stroke because of a family history. In this case, based on the EBM approved evidence, appropriate interventions include warfarin, with a higher risk reduction, although this intervention comes with weekly blood checks, or aspirin, with a lower risk reduction, but no time-consuming blood checks. In addition to this evidence, the article suggests the patient’s preferences and circumstances will need to be taken into account in order to choose between the evidentially indicated treatments and that, “clinical expertise is needed for follow up and monitoring” (Haynes et al. 2002, 38).

While this article does point to a strong expansion of the goals of EBM, its authors are aware that it is not all inclusive, and still, remains so idealistic as to be normative, not descriptive. They write, “Our model does not depict all of the elements involved. For example, we have not included the important roles that society and healthcare organizations

play in providing and limiting resources for health services...It is also impossible to implement the model as prescribed...Thus our model is conceptual rather than practical and remains under development..." (Haynes 2002, 38).

#### A Note on Further History: Semmelweis, Snow, Lind and Fisher

It is worth noting that in many of these texts and the manuals discussed in the following section, a set of consistent historical examples are discussed as the "roots" of EBM. These examples centre on several different historical figures, but most often feature the stories of Semmelweis,<sup>7</sup> Lind, Snow, and Fisher. Ignaz Semmelweis, by comparing the results in two largely similar hospital wings between 1844-1848 in a kind of proto-trial, found that when all personnel were required to wash their hands with chlorinated lime, "childbed" or "puerperal" fever rates were reduced in hospital maternity wards (Tulodziecki 2013). Nearly 100 years before, James Lind found that a diet that included citrus fruits was much more effective than the current standard practices for treating and preventing scurvy in British sailors, again using a kind of proto-trial after completing a review of the current practices in the field, sometimes thought to be an early systematic review (Lind 1753). The Cochrane collaboration library is named the James Lind Library in honour of this figure. As one contender for the honour of "father of epidemiology," the work of John Snow is also often cited as an important precursor to EBM. Snow worked to understand the origin, spread, and containment of cholera (Snow 1855; Fine et al. 2013). Given the importance of statistical methods to EBM, the inclusion of Fisher as one of these historical role models is not surprising; his work in 20<sup>th</sup> century statistics has a dizzying array of practical applications (Efron 1998).

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<sup>7</sup> The Semmelweis story is especially important to EBM as a kind of cautionary tale. There is still some debate regarding the reason his suggested reforms were not taken up, possibly saving many lives (Scholl 2013; Tulodziecki 2013; Persson 2009; Gillies 2005). One of these proposed reasons is because of his failure to correctly articulate an appropriate mechanism by which his proposed intervention worked. From the point of view of EBM proponents, such a mechanism was superfluous-demonstrating that an intervention led to good outcomes is all that is required for implementation on the EBM view. This view will be discussed in more detail in Chapter 3. For now, the story of Semmelweis's demise and inability to effect change serve, not just as a way of anchoring EBM in history, but also as a warning of giving too much weight to explanatory mechanisms.

The scientific contributions of these historical figures were diverse. However, in the role they play in EBM origin myths, they are roughly equivalent in that they relate the newness and the statistical sophistication of EBM in general and Randomized Controlled Trials (RCTs) specifically with earlier, historical, common sense practices (Sackett et al. 1996; Djulbegovic and Guyatt 2017). They serve to suggest that although some of the statistical tools used in EBM might seem new and unnatural to the clinicians who are now being asked to use them, they naturally flow from any attempts to answer the questions about effective interventions that patients and clinicians care about.

These early EBM texts and the historical case studies mentioned within them continue to be an important force in defining the movement as a coherent unit. They articulated the set of problems that EBM sought to fix and defined the movement, if in ways which were not exactly consistent between texts. They emphasized EBM's break with the medical status quo of the past and that their movement would require a revolution in medical pedagogy. How exactly this could be achieved was to be more clearly articulated in a different kind of EBM literature; the EBM clinical manual.

### Rise of the Manuals

After these classic texts provided the framework for the EBM movement, its practice was cashed out in a series of “how-to” manuals (Greenhalgh 2010; Guyatt et al. 2014; McKibbin et al. 1999; Moore and McQuay 2006; Straus et al. 2005). These manuals were generally addressed to practicing clinicians, and were formatted to be slim books, well suited to fit in the front pocket of a lab coat. While there were some EBM manuals directed at individual specialties (for example: Craig et al 2012; Hansen and Roach 2010), most manuals steered clear of particular content, instead focusing on methods of obtaining and applying evidence in any specialty.

### A Manual Example: Users' Guides to the Medical Literature

*The Users' Guide to the Medical Literature: Essentials of Evidence-Based Clinical Practice* by Gordon Guyatt, Drummond Rennie, Maureen Meade and Deborah Cook is one

of the most popular of these manuals. They explain the need for an evidence-based method as follows:

What is the nature of the *evidence* in EBM? We suggest a broad definition: any empirical observation constitutes potential evidence, whether systematically collected or not. Thus, the unsystematic observations of the individual clinicians constitute one source of evidence; physiologic experiments constitute another source. Unsystematic observations can lead to profound insights and wise clinicians develop a healthy respect for the insights of their senior colleagues in issues of clinical observation, diagnosis, and relations with patients and colleagues. At the same time, our personal clinical observations are often limited by small sample size and by deficiencies in human processes of making inferences. Predictions about an *intervention's effects* on patient-important outcomes based on physiologic experiments usually are right but occasionally are disastrously wrong...Given the limitations of unsystematic clinical observations and physiologic rationale, EBM suggests a number of hierarchies of evidence, one of which relates to issues of *prevention* and treatment. (Guyatt et al. 2014, 6-7)

These manuals also clarified the components of the EBM Hierarchy of Evidence in ways that the classic texts did not. For example, the Guyatt et al. manual includes a "Hierarchy of Strength of Evidence for Prevention and Treatment Decisions," which lists the kinds of evidence in descending order of strength as follows:

- N-of-1 randomized trial
- Systematic reviews of randomized trials
- Single randomized trial
- Systematic review of observational studies addressing patient-important outcomes
- Single observational study addressing patient-important outcomes
- Physiologic studies (studies of blood pressure, cardiac output, exercise capacity, bone density, and so forth)
- Unsystematic clinical observations (Guyatt et al. 2014, 7)
- 

The aims of these manuals were bold and revolutionary. They explicitly sought to transform day-to-day clinical practice. For example, authors of the above manual write,

This book, now in its second edition, is designed to change all that. It's designed to make the clinician fluent in the language of the medical literature in all its forms. To free the clinician from practicing medicine by rote, by guesswork, and by their variably integrated experience. To put a stop to clinicians being ambushed by drug company representatives or their patients, telling them of new therapies the clinicians are unable to evaluate. To end their dependence on out-of-date authority. To enable the practitioner to work from the patient and use the literature as a tool to solve the patient's problems. To provide the clinician access to what is relevant and the ability to assess its validity and whether it applies to a specific patient. In other words, to put the clinician in charge of the single most powerful resource in medicine. (Guyatt et al. 2014, xiii)

It is not clear that these ambitious goals were achieved. Indeed, some of the practical advice presented to these clinicians in these manuals was problematic. Some of the most concerning passages in this manual have to do with study applicability. According to Guyatt et al., it is best to assume that a study does apply to a particular patient, unless the clinician can think of a reason that it shouldn't; that is generalizability is assumed, perhaps because of randomization,<sup>8</sup> and situations where studies do not generalize are the exceptions. They write,

What if that individual does not meet a study's eligibility criteria? The study result probably applies even if, for example, he or she was 2 years too old for the study, had more severe disease, had previously been treated with a competing therapy, or had a comorbid condition. A better approach than rigidly applying the study inclusion and exclusion criteria is to ask whether there is some compelling reason why the results do not apply to the patient. You usually will not find a compelling reason, and most often you can generalize the results to your patient with confidence. (Guyatt et al. 2014, 103)

This assumption has been criticised by Jonathan Fuller, who argues that instead of assuming a study applies to your patient and checking for reasons it might not, clinicians should in each case look to find reasons to think that the study does apply (Fuller forthcoming).

### Critical Appraisal by Clinicians

These manuals often differ on the topic of critical appraisal. Critical appraisal is a systematic process for the quality assessment of evidence. Because of improvements in information technology since the publication of the classic EBM texts, this appraisal is now assumed to be done in real time at the bedside. Most early manuals had high hopes for the feasibility of this practice to be adopted by clinicians "at the coalface." These manuals include in-depth instructions for the evaluation. They see individual critical appraisal as an important component of their goals, writing, for example, that step 3 of the EBM process involved, "critically appraising that evidence for its validity (closeness to the truth), impact (size of the effect) and applicability (usefulness in our clinical practice)" (Straus et al. 2005,

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<sup>8</sup> This issue of the assumed relationship between randomization and generalizability will be further discussed in the section "Critical Response: Philosophers, Clinicians and Others" in this chapter.

3).<sup>9</sup> For example, in order to evaluate the results of individual studies about therapies, *Evidence-Based Medicine: How to Practice and Teach EBM* suggests that clinicians be able to answer the following questions about the intervention:

1. Was the assignment of patients to treatment randomized?
2. Was the randomization concealed?
3. Were the groups similar at the start of the trial?
4. Was the follow up of patients sufficiently long and complete?
5. Were all the patients analyzed in the groups to which they were randomized?

Some finer points:

6. Were patients, clinicians, and study personnel kept blind to treatment?
7. Were groups treated equally, apart from experimental therapy? (2005, 117)

After this determination of the “validity” of the trial, the manual suggests that the clinician calculate the Relative Risk Reduction (RRR), the Absolute Risk Reduction (ARR) and the Number Needed to Treat (NNT) in order to answer the questions, “What is the magnitude of the treatment effect?” and “How precise is the estimate of the treatment effect?” (Straus et al. 2005, 125). A final set of appraisal questions are designed to facilitate the application of this kind of population generated evidence to a patient (Straus et al. 2005, 132). All this information is reproduced not only in the manual, but on a set of brightly coloured laminated index cards which come with the manual, for ease of use.

### Move Toward Pre-Evaluated Evidence

Perhaps because, “fewer [clinicians] claimed to understand (and to be able to explain) the ‘appraising’ tools of Number Needed to Treat (NNT) (35%) and confidence intervals (20%)” (Straus et al. 2005, 6), the emphasis on critical appraisal as the indication of EBM in practice waned in these manuals. In its stead, “pre-evaluated evidence sources” and guidelines rose in prominence. These replacements, while intended to lower the previously high bar of critical appraisal for clinicians, were nevertheless not universally appreciated.

Trisha Greenhalgh writes,

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<sup>9</sup> However, because this is a later edition of the Sackett/Straus, they stipulate that, “For conditions we encounter less often...we conserve our time by seeking out critical appraisals already performed by others who describe explicit criteria for deciding what evidence they selected and how they decided it was valid. We leave out the time-consuming step 3 (critically appraising) and carry out just step 2 (searching) but restrict the latter to sources that have already undergone rigorous critical appraisal” (Straus et al 2005, 5).

Never was the chasm between front-line clinicians and back-room policymakers wider than in their respective attitudes to clinical guidelines. Policy makers...tend to love guidelines. Front-line clinicians...often have a strong aversion to guidelines...Clinician resistance to guidelines has a number of explanations. These include: clinical freedom, debates among experts about the quality of the evidence, lack of appreciation of the evidence by practitioners, defensive medicine, strategic and cost constraints, specific practical constraints, failure of patients to accept procedures, competing influences of other non-medical factors, and the lack of appropriate, patient-specific feedback on performance. (Greenhalgh 2010, 132)

These kinds of guidelines were meant to free individual clinicians from the burden of replicating for themselves a critical appraisal process on the results of relevant studies.

While it is true that there is less emphasis on individual critical appraisal in the EBM contemporary literature, a new problem has arisen: the proliferation of difficult to apply and sometimes contradictory guidelines that were meant to take the place of critical appraisal.

EBM manuals which suggest that pre-evaluated evidence can replace individual critical appraisal in some cases suggest several possible source journals for this information, including, “the ACP Journal Club, Evidence Based Medicine, Evidence Based Mental Health, Evidence Based Nursing, Evidence Based Health Care Policy and Practice, Evidence Based Cardiovascular Medicine, and a number of others. Synoptic journals do what traditional journals wish they could do in selecting the best studies, finding the best articles from all relevant journals and summarizing them in one place” (Straus et al. 2005, 45).<sup>10</sup> The shift from individually accomplished critical appraisal to advocating for clinician trust of identified journals which promised good evidence was a major change for EBM.

### Critical Response: Philosophers, Clinicians and Others

The response to these classic texts and manuals from clinicians and philosophers was varied and critical. While there is a very large body of critical literature on EBM, this literature can be broadly sorted into categories based on the kinds of claims made. The most

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<sup>10</sup> Given that this manual also includes the helpful advice, “If you still have the no luck...then you can try Google (<http://www.google.com>). It is incredibly fast and you can retrieve a product monograph...Google is the fastest way to get to almost any service on the internet...” (Straus et al. 2005, 40), it is worth considering if this list is similarly dated.

often made critical claims are, “Randomization doesn’t do what EBM claims it does,” “Mechanisms are crucial in medicine,” and “Medicine requires an expanded role for clinical expertise.” I will consider some of the literature in support of each of these claims in turn.

### Randomization doesn’t do what EBM thinks it does

While being attentive to the ways in which the classic texts do make mention “in the fine print” of the usefulness of non-randomized evidence, John Worrall, in his article, “What Evidence in Evidence-Based Medicine?” interrogates the reasons EBM gives for randomization; why is it that we need randomization at all? He investigates four main reasons. First, because frequentist statistical significance testing only works if the populations are randomized to the comparison arms. Second, because randomization controls for all factors, known and unknown. Third, because randomization helps to prevent selection bias- that is, where the agent doing the selecting places promising looking individuals in the intervention arm for various reasons. Fourth, because empirical work has shown that non-randomized studies over-estimate the size of treatment effects.

The first reason, says Worrall, only makes sense if you think that frequentist statistical significance testing is something we should be doing; and plenty of Bayesians and others don’t. The second is trivially untrue-even correctly done randomization can result in skewed arms in relation to some factor or another. But what about a modification of this claim? Worrall suggests, “Randomization controls for all factors, known and unknown, at least in ‘some probabilistic sense’”(Worrall 2002, S322) This might be true, but only if the experiment were to be run many times. RCTs tend not to be, or this repetition is considered waste. The third reason is an interesting example of the way in which blinding and randomization are tightly related. Worrall concedes that avoiding selection bias is a useful reason to do randomization but notes that the real work here is done by blinding or masking, and randomization is simply one way to achieve this. The fourth reason only makes sense if you are already assuming that the RCT comparator in each case shows the true effect size; it is the other side of coin of the worry that RCTs so often *under-estimate* effect sizes.



Additionally, newer empirical work of the kind cited for this claim has come to quite different conclusions.

In sum, according to Worrall, randomization only does one of the four things it is proposed to do.<sup>11</sup> There are many other arguments in this vein in the critical literature (Borgerson 2009; La Caze 2009; Senn 2012; Teira and Reiss 2013) but Worrall's article has received significant uptake.

There are additional knock-on effects that EBM sometimes claims for randomization. These are often claims about the ease of generalizability of RCTs. As discussed in the earlier "Rise of the Manuals" sections, EBM manuals often claimed that one of the reasons for the importance of randomization is that it allows for the application of trial results to patients who were not in the trial, unless the clinician could think of some reason these results do not apply. This is presumably meant to be supported by the claim that randomization "controls for all confounders, known and unknown," as discussed in the Worrall article.<sup>12</sup> This claim of generalizability has met with strong critique (see Deaton and Cartwright 2016 for an example, though the focus here is on economic applications).

#### Mechanisms are crucial in medicine

An additional kind of criticism levelled at EBM by philosophers was that EBM proponents failed to appreciate the ways in which mechanisms are crucial in medicine (Clarke et al. 2014; Anderson 2012; Bluhm 2013; Howick et al. 2013, Illari 2011). This literature is discussed at length in Chapter 3, so I will not dwell on it here, but just note it as an important group of criticisms.

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<sup>11</sup> In a later article, Worrall argues that in addition to these ways in which randomization falls short of its privileged status, additional roles for randomization as causally important suggested by philosophers are also not fulfilled (Worrall, 2007).

<sup>12</sup> Interestingly, RCTs are also critiqued as particularly difficult to generalize in the pragmatic trial literature (see MacRae 1989, McMahon 2002, and Roland and Togerson 1998 for example). I am planning future work on this issue, but do not focus on it here.

### Medicine requires an expanded role for clinical expertise

An additional critical claim often made by philosophers and others is that medicine requires a larger role for clinical expertise than that allowed for in the various forms of EBM (Tonelli 1998; Tonelli 2009; Feinstein and Horwitz 1997; Naylor 1997). While it is true that the classical texts often mention clinical expertise or clinical judgement as an important component of EBM, the details of this role are often left unclear (Greenhalgh 1999). Again, this literature is discussed at length in Chapter 2.

### Adaptation and Renaissance

In the last few years, proponents of EBM have engaged in a significant amount of reflection, debate and dialogue about new directions in the EBM movement. While this discussion has resulted in a considerable variety of textual outputs, four texts stand out as indicating new directions for EBM; “Evidence-based medicine: A movement in crisis?” by Trisha Greenhalgh, Jeremy Howick, Neal Maskrey and the Evidence Based Medicine Renaissance Group, “Progress in evidence-based medicine: a quarter century on” by Benjamin Djulbegovic and Gordon H. Guyatt, Trisha Greenhalgh’s new book “How to Implement Evidence-Based Medicine,” and “Evidence based medicine manifesto for better healthcare” by Carl Heneghan, Kamal R. Mahtani, Ben Goldacre, Fiona Godlee, Helen Macdonald and Duncan Jarvies.

### Renaissance/Crisis?

According to the authors of “Evidence-based medicine: A movement in crisis?” a series of developments have corrupted EBM since its beginnings. These include the influence of vested interests, such as pharmaceutical companies, in determining what counts as good evidence and good outcomes in medicine, the incredible volume of evidence that has been created, especially an excess of guidelines created for clinical practice, the overpowering of trials so that even very small effect sizes are statistically significant (if not clinically significant), the proliferation of templates and point of care prompts which encourage mechanical rather than thoughtful engagement (which looks suspiciously like the

“cookbook” charge levelled by many critics) and a refusal to consider the practical problems of an explosion of multimorbidity in a system which does not and cannot provide evidence pertaining to patients with multimorbidity (Greenhalgh et al. 2014, 2).

In response to these problems, the authors write that,

[R]eal evidence-based medicine has the care of individual patients as its top priority, asking, ‘what is the best course of action for this patient, in these circumstances at this point in their illness or condition?’ It consciously and reflexively refuses to let process (doing tests, prescribing medicine) dominate outcomes (the agreed goal of management in an individual case.) It engages with an ethical and existential agenda (how should we live? When should we accept death?) and with that goal in mind, carefully distinguishes between whether to investigate, treat or screen and how to do so. (Greenhalgh et al. 2014, 3)

This description of EBM has a few features in common with earlier descriptions of the movement. The first part, with its references to attempting to individualize care based on patient preferences and clinical circumstances, echoes concerns first put forward in the Sackett et al. 1996 article and the Haynes et al. 2002 article. The emphasis on refusing to let processes trump outcomes serves a similar purpose as the Sackett et al. 1996 denial that EBM could ever be “cookbook medicine.” However, the last portion about an engagement with an “ethical and existential agenda” has not been emphasized previously in EBM literature. This is perhaps a result of the inclusion of various philosophers in the Evidence Based Medicine Renaissance Working Group. Additionally, many of the components of the plan to implement “real” EBM, while not ruled out or considered inappropriate, were not at all the focus of the movement in earlier iterations. These include encouraging patients to advocate for better evidence and personalization, pedagogy to hone expert judgment and shared decision making, resistance to evidence created by vested interests (and helping policy makers to resist this as well), and supporting research into the experience of illness (research philosophers might call phenomenology of illness). This expansion does not enjoy universal support; some responses to this article doubled-down on the traditional clinical research components of EBM as most important to its future (Tovey et al. 2014; Oliver 2014).

A particularly interesting feature of this paper is the authors' insistence on framing what is the most expansive EBM project of all, including many aspects of medicine not originally included as targets of reform by EBM, as a return to EBM's original values. The EBM depicted in this article is unrecognizable when compared with the goals of the Evidence Based Medicine Working Group, and yet is not described as novel. Instead, the article contains several references to a, "Return to real evidence-based medicine" (Greenhalgh et al. 2014, 3) and argues for "a return to the movement's founding principles— to individualize evidence and share decisions through meaningful conversations in the context of a humanistic and professional clinician-patient relationship" (Greenhalgh et al. 2014, 5). While this could cynically be described as a rhetorical device designed to appeal to a discipline that is tired of heralding new movements, it is possible that at least some early EBM practitioners had read into the original movement calls for such vast changes, though to an outside observer they are difficult to see in the 1992 and 1996 articles (see Fuller et al. 2014 for one take on this). Regardless of the idealism or cynicism of such a framing, it can do much to obscure the ways in which criticism and dialogue with critics both inside and outside medicine forced EBM to adapt and change over time. While only a few years old this article has already been cited several hundred times,<sup>13</sup> and looks likely to become a classic in the EBM literature.<sup>14</sup>

### New Greenhalgh book

Given how often the literature on EBM categorizes itself as ideal or prescriptive (Haynes et al. 2002), for example, passing off the messy problems of implementation, Trisha

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<sup>13</sup> It is important to note that a good portion of these citations are by critics- I am not making the mistake that many citations indicates universal agreement, only a high amount of engagement.

<sup>14</sup> For this work, the author's adoption of the Dreyfus account of expertise is of particular interest. They write, "The Dreyfus brothers have described levels of learning, beginning with the novice who learns the basic rules and applies them mechanically with no attention to context. The next two stages involve increasing depth of knowledge and sensitive to contest when applying rules. In the fourth and fifth stages, rule following gives way to expert judgments, characterised by rapid intuitive reasoning informed by imagination, common sense and judiciously selected research evidence and other rules" (Greenhalgh et al. 2014, 3). While this is not the most careful description of the Dreyfus account of expertise, its inclusion is worth noting given that I argue in chapter 2 that the Dreyfus model of expertise is incompatible with EBM, regardless of its enthusiastic uptake in nursing. I stand behind that argument, given the strong differences, noted here and by many others, between EBM as traditionally depicted and the EBM in the Greenhalgh et al. 2014 article.

Greenhalgh's new book, *Implementing Evidence Based Healthcare* is a welcome addition to the literature on EBM. The book explicitly builds on the vision of Evidence Based Health Care (EBHC), the term preferred due to the diversity of practitioners involved, set out in the previously discussed "Renaissance" article (Greenhalgh 2017, 2). As a result, the scope of the book is ambitious, sweeping from problematizing theories of evidence, to examining patterns of human behaviour and rationality that bound and sometimes block implementation of new epistemic practices, to challenging technological determinism, to the often-ignored realities of policy creation (Greenhalgh 2017, 6). If it is ever the case that EBM suffers for being too broad rather than too narrow, it is in the iteration put forward by this work. This movement toward broadening EBM may be encouraging to philosophers and clinicians in that it means the integration of many of their critiques and the inclusion of many more types of evidence. However, this broadening also brings with it the worry that this new EBM is so inclusive that no particular message can be heard; that the new movement is to be so broad as to be vacuous.

#### A Traditional Account of Progress

"Progress in evidence-based medicine: a quarter century on" by Benjamin Djulbegovic and Gordon Guyatt, represents a newly philosophically-oriented restatement of more traditional EBM goals. The authors, themselves lifelong proponents of EBM, count among the movement's achievements its pivot from consideration of evidence quality alone, to other components of the clinical encounter including patient preferences (while remaining rather weak in explaining the role of clinical expertise), as well as the development of more sophisticated hierarchies of evidence like GRADE, and the development of systems to produce clinical guidelines (Djulbegovic and Guyatt 2017, 1). This is in contrast to the work of Greenhalgh et al., in which the proliferation of guidelines derived from EBM was a flaw rather than a feature of the movement.

The authors concede that attempts to insist that each clinician learn and practice critical appraisal have largely failed, as I suggested earlier in this chapter in the section, "The

Rise of the Manuals,” writing, “a decade of efforts to teach EBM to medical trainees had revealed that few clinicians would ever have the skills—and those with the skills would seldom have time—to conduct sophisticated assessment of the evidentiary basis for their practice” (Djulbegovic and Guyatt 2017, 4).

This paper is the clearest case of a work solidly within the EBM literature proper which explicitly frames what is new and worthwhile about EBM as a set of epistemic claims; other work does this implicitly. The authors write that EBM is at its core, a set of two epistemic claims, first, “that not all evidence is created equal, and that the practice of medicine should be based on the best available evidence,” and second, “that the pursuit of truth is best accomplished by evaluating the totality of the evidence, and not selecting evidence that favors a particular claim” (Djulbegovic and Guyatt 2017, 2). The acceptance of a role for philosophical explanation and critique in EBM made clear in this article by such strong proponents of the movement suggests that future philosophical suggestions, such as the content of this work, may fall on interested ears; this certainly has not always been the case.

### EBM Manifesto

A final text which importantly represents new directions in EBM is the so-called “EBM Manifesto.” This manifesto consists of a set of identified problems in current EBM and a set of goals, identified by the authors and others participating in the Oxford Centre for Evidence Based Medicine’s yearly “Evidence Live” conference.

These problems include the extent to which trial results are not published (this is especially the case for “unsuccessful” trials), the exorbitant cost of trial research and the amount of financial waste, the lack of harm reporting, the use of non-evaluated decision aids, and the extent of pharmaceutical conflict of interest. These goals include an expanded role for patients and clinicians in research, the traditional call for more systematic use of existing evidence in practice, a reduction in unethical research practices, transparent drug and device regulation, improved clinical guidelines, and pedagogical improvements for the next generation of EBM leaders (Heneghan et al. 2017, 2).

While these seem to be a strong articulation of at least some of the current problems related to EBM as well as an admirable set of goals for the movement going forward, the key step of how exactly to move from these problems to these goals seems to be missing. For this reason, the manifesto remains an aspirational document rather than a concrete plan for change.

What makes this effort at recalibrating the movement unique is the extent to which the authors have called for participation from clinicians, philosophers and the wider public, not only by drafting the Manifesto through input at their academic conference but by inviting a broader audience to comment and critique it online. The Manifesto and the ongoing discussion around it can be found at: <http://evidencelive.org/manifesto>.

## Chapter 2: Expertise

## Introduction

## Overview of EBM Treatment of Expertise

- The Pyramid Model

- The Tripartite Model

- The Amalgamation Model

## Problems with EBM Models of Expertise

- The Internal vs External Distinction

- Applying the Internal/External Distinction

- The Search for a Legitimate Role for Internal to Evidence Expertise

- How the Internal/External Distinction is a Problem for the EBM Models

- Other Expertise Problems for EBM

## Arguing for an Augmented Account of Expertise

## The Dreyfusian Account

- The Five Stages of Skill Acquisition

- Against the Calculative Rationality Model

- What Problems Would the Dreyfusian Account Solve for EBM?

- Problems with the Integration of the Dreyfusian Account and EBM

- Rejection of the Dreyfusian Account for EBM Expertise Augmentation

## The Turner Account

- The Turner Types of Expertise

- The Application of the Turner Account to EBM players What

- Problems Would the Turner Account Solve for EBM?

- Problems with the Integration of the Turner Account and EBM

- Rejection of the Turner Account for EBM Expertise Augmentation

## The Bishop and Trout Account

- What is Expertise for Bishop and Trout?

- Problems in the Bishop and Trout Account

- What Problems Would the Bishop and Trout Account Solve for EBM?

- Problems with the Integration of the Bishop and Trout Account and EBM

- Rejection of the Bishop and Trout Account for EBM Expertise Augmentation

## The Collins and Evans Account

- The Collins and Evans Periodic Table of Expertise

- Dispositions

- Specialist Expertise

- Meta-Expertises and Meta-Criteria

- What Problems Would the Collins and Evans Account Solve for EBM?

- Problems with the Integration of the Collins and Evans Account and EBM

- Acceptance of the Collins and Evans Account for EBM Expertise Augmentation



## Chapter 2: Expertise

### Introduction

Since EBM's debut article (EBMWG 1992), the movement has struggled to articulate the relationship between expertise and evidence. In this chapter, I mean by expertise knowledge gained by subjects in the course of clinical interactions, in contrast with knowledge gained from sources such as journal articles reporting on the findings of RCTs, meta-analyses and systematic reviews or explicit medical education. As such, references to 'experience,' 'expert opinion', 'clinical skills,' and 'judgment' are all relevant to the discussion of expertise, though they emphasize different aspects of this method of knowing. In spite of the historical development of three different models of expertise integration in EBM, little has been done to flesh out exactly what is involved in each model of expertise, leading to confusion. Clarity about the role of expertise in EBM is essential for the practical application of EBM principles to the clinical context, but is also important for practitioners in other fields, such as educators and social workers, looking to develop their own evidence-based practice. Clarity about the role of expertise in EBM is also important for theorists of expertise in a variety of fields, such as sociology, education, and science and technology studies (STS). Without this clarity, these theorists can only receive muddled feedback about which concepts and frameworks assist practitioners. Given the way in which the nursing literature has discussed and debated the Dreyfus account of expertise as a description of their own practice, this account might be seen as the logical first choice to fill this theoretical gap in EBM (see Benner, 1984, 2004, 2009; Rashotte and Thomas, 2004; Koch, 1995; McHugh, 2010; Pena, 2010 for a brief history of the debate surrounding Dreyfus on expertise in nursing).

In this chapter, I argue that there have been three different models of the integration of expertise with other components of the clinical encounter in EBM, and all three models have difficulties. The account of expertise in EBM is still impoverished in ways that make practical implementation of EBM goals and methods difficult. I will show this through a

discussion of the various models and an analysis of the weaknesses and inconsistencies of these models. I then suggest that other disciplines provide a wealth of potential conceptions of expertise that might augment the problematic EBM models. I argue, that the Dreyfusian account is unsuitable for use in the EBM movement, regardless of its uptake in nursing. There are, however several other candidates including the accounts of Turner, Bishop and Trout, and Collins and Evans which I consider in detail in turn. I judge the Collins and Evans account to be best suited to the current needs of EBM and suggest several ways in which its use can improve EBM practice. In the final section, I argue that until EBM makes some basic clarifications about the role of expertise in its programme, none of the resources from other disciplines on the subject of expertise, not even Collins and Evans, can be successfully taken up. In order to remedy this situation, I suggest several desiderata for the creation of a useful conception of expertise for EBM.

#### Overview of EBM Treatment of Expertise

EBM began as an explicit attempt to remove or de-emphasize the role of intuition and clinical expertise in medicine, replacing them with rules, decision matrices, and best practices derived (in the best-case scenario) from randomized controlled trials (RCTs). RCTs differ from other kinds of studies because they involve the random allocation of participants to intervention groups and may involve various masking/blinding practices. These studies, and sometimes meta-analyses or systematic reviews, are considered the gold standard of evidence in EBM. A meta-analysis is a statistical technique that combines the populations of smaller studies to form a larger sample, in hopes of improving statistical power before analyzing the treatment for effectiveness (Lang 1997, 255). Systematic reviews are distinct from meta-analyses but are sometimes listed alongside them because both studies amalgamate evidence. Howick defines a systematic review as, “[a] synthesis of all relevant evidence” (Howick 2011, 17), but generally these also involve a set of standard practices for the selection of search terms, explicit inclusion and exclusion criteria for sources, and a commitment to include all studies which fit within these criteria, including work from the grey

(i.e., unpublished) literature. RCTs, systematic reviews and meta-analyses are compiled into sets of guidelines and best practices of clinical decision-making that health professionals use during the clinical encounter. Over time, the EBM literature added two models of the EBM clinical encounter that include expertise as an important component, in contrast with the original model which advocated the de-emphasis of expertise from the EBM method.

Overall, there is surprisingly little literature addressing the role of expertise in EBM. This is especially clear in comparison to the large amount of literature explicating, critiquing, and modifying EBM's account of evidence, especially evidence hierarchies (Cartwright 2012; Worrall 2002; Bluhm, 2005; Clarke et al, 2014; Fiorentino 2015; Stegenga 2011). However, over time, three main models for the role of expertise in EBM were developed.

### The Pyramid Model

The first of these models is the traditional pyramid-shaped EBM evidence hierarchy. There are many versions of this pyramid model, but most place “expert opinion” or “background knowledge” at the bottom followed by observational studies, single RCTs, and then meta-analysis and systematic reviews at the very top. Methods placed towards the top of the pyramid are to be preferred, and those toward the bottom are only to be used if research from “higher quality” methods are not available (and perhaps not even then). In this model, expert opinion is a source of evidence, but it is a low-level source. If others are available, practitioners are encouraged to look to these other sources rather than expertise. This model fits nicely with the “debut” article of EBM: “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*” (EBWG 1992, 2420).<sup>15</sup> In this first model, though expertise had a low place on the hierarchy, it was still included as a possible source of *evidence itself* rather than, for instance, given an external to evidence amalgamation role.

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<sup>15</sup> Emphasis mine

There is also an amended version of this first model. Worried that pyramid-style hierarchies left something to be desired by not allowing for variations in the quality of different evidence methodologies (i.e., the possibility of clinicians overestimating the usefulness of a poorly run RCT) the Centre for Evidence-Based Medicine (CEBM) at the University of Oxford developed the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. In this system, like the Pyramid model, RCTs begin at a high position and observational studies at a lower one, but RCTs or observational studies can be upgraded or downgraded based on the quality of the study as actually carried out. In principle, this allows an excellently executed observational study to be considered better evidence than a very poorly executed RCT (GRADE Working Group 2004, 926). This additional vector of consideration—quality of execution—was not included in the original formulation.

However, because the model still creates a hierarchy of evidence with expert opinion at an internal but very low position, I here classify it as a version of the Pyramid Model. The GRADE system creators had this to say about expertise: “Systems that classify ‘expert opinion’ as a *category of evidence*<sup>16</sup> also create confusion. Judgment is necessary for interpretation of all evidence, whether that evidence is high or low quality. Expert reports of their clinical experience should be explicitly labelled as very low-quality evidence, along with case reports and other uncontrolled clinical observations” (GRADE Working Group 2004, 925). This passage achieves two aims. First, it affirms the original Pyramid Model description of expert opinion as “very low-quality evidence.” This suggests that GRADE is properly thought of as a version of the Pyramid Model. However, it also introduces an ambiguity into the role of expertise in EBM, suggesting that expertise as judgment, that is, as *external* to evidence, will always be required in EBM, regardless of the low place of expertise as *internal* to evidence in the hierarchy. It is tempting to hang this distinction on the difference between the terms “judgment” and “expertise.” However, because of the inconsistent usage of these

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<sup>16</sup> Emphasis mine

terms, I prefer here to discuss this issue in terms of a unitary kind of knowledge, which I here have called expertise. This unitary kind of knowledge nevertheless has dual functions or roles: external or internal to evidence. I discuss this dual notion of expertise in more detail in the section “Problems with the EBM Models of Expertise,” as it remains central to the controversy around the term.

### The Tripartite Model

A second model of expertise in EBM was introduced a few years later (Sackett et al, 1996). This model features three interlinking rings, with the central overlap labelled “EBM.” The three constitutive rings are labelled “Best External Evidence” which perhaps includes a pyramid style hierarchy, “Patient Values and Expectations,” and “Individual Clinical Expertise.” In contrast to the Pyramid Model, which de-emphasizes the use of expertise, the Tripartite Model suggests that expertise can be an essential, constitutive part of EBM.

Sackett et al. write of an EBM with integrated clinical expertise,

Because it [EBM] requires a bottom up approach that integrates the best external evidence with individual clinical expertise and patients' choice, it cannot result in slavish, cook-book approaches to individual patient care. External clinical evidence can inform, but can never replace, individual clinical expertise, and it is this expertise that decides whether the external evidence applies to the individual patient at all and, if so, how it should be integrated into a clinical decision. Similarly, any external guideline must be integrated with individual clinical expertise in deciding whether and how it matches the patient's clinical state, predicament, and preferences, and thus whether it should be applied. (1996, 72)

This explanation of the Tripartite Model makes clear an external role or roles of some kind for expertise, as it is not evidence itself, but a category outside of evidence. However, it is not clear if expertise is taken to be one of many inputs to be amalgamated in the clinical encounter, or the force that does the amalgamating, or perhaps both.

### The Amalgamation Model

A third model of expertise that debuted in an article by Haynes et al. (2002) keeps this structure of interlocking rings, but adds an additional component and shifts the role for expertise. In the Amalgamation Model, the three main interlocking rings are labelled “Patients’ Preferences and Actions,” “Research Evidence,” and “Clinical State and

Circumstances.” These components interlock in a similar way to the Tripartite Model, although no centre portion is labelled “EBM.” Additionally, a fourth component, “Clinical Expertise,” encompasses the other three components, holding them together. Haynes et al. write, “Clinical expertise includes the general basic skills of clinical practice as well as the experience of the individual practitioner. Clinical expertise must encompass and balance the patient's clinical state and circumstances, relevant research evidence, and the patient's preferences and actions if a successful and satisfying result is to occur” (Haynes et al. 2002, 37). The account of the Amalgamation Model emphasizes, again, an external role for expertise, but specifies that the role of expertise is the amalgamation of other factors, rather than being one of the factors amalgamated, as was perhaps the case in the Tripartite Model.

#### Problems with EBM Models of Expertise

With this group of models in mind, clinicians and philosophers might worry that the EBM models of expertise fall short in a few ways. These models are not conceptually cashed-out, leaving most of the emphasis on the hierarchy of evidence. This is in line with the *goals* of the models. The Pyramid Model was created to differentiate between the quality of different kinds of evidence available to clinicians and to make claims about which kinds of evidence should be used most often. The Tripartite Model and the Amalgamation Model were created to make claims about the content of the EBM movement as a whole, to make clear that the well-known pyramid hierarchy of evidence was not the whole of the practice. In no case were these models created *in order to explain expertise*; their treatment of expertise was instrumental, in the service of other goals. This is not a strong critique of EBM, but rather an account of what makes it so difficult to say much of substance about expertise in EBM. Expertise is discussed, but it is rarely the main point of the discussion. We have these models developed for various purposes which include expertise, but they themselves do not tell us much.

There are however some points of the EBM treatment of expertise which do deserve critique. For example, the Tripartite Model and the Amalgamation Model do not provide any guidance on how to perform the required integration, or on how high-quality expertise might

be distinguished from low-quality expertise. Additionally, in some cases these models leave the distinction between the kinds of work done by “internal” and “external” expertise implicit, or insufficiently described. In looking for an account of expertise in other sources that might enrich EBM, I will privilege accounts that can handle these problems.

### Internal vs External Distinction

One important issue that an account of expertise that fills in the lacuna in the current EBM account of expertise needs to make a stand on is the issue of differing roles for expertise. While there are many different roles that expertise could serve in medicine, the roles typically discussed can usefully be categorised into two kinds; *internal* to evidence expertise and *external* to evidence expertise.<sup>17</sup>

*External to evidence expertise* is expertise which is meant to play some role besides counting as evidence in its own right. These roles include: applying population-based evidence to particular patients, tacit expertise in taking in and acting on signs, symptoms, and patient histories, making decisions about the proper manner of patient communication, and amalgamating different kinds of evidence, among others. These kinds of roles for expertise could also be described as “non-claim making” roles for expertise in a particular narrow sense; they do not involve making a claim that expertise is evidence guiding decision-making. These roles for expertise are much less controversial. Nearly every account of proper clinician behaviour when working in EBM methodology allows or even requires one or more of these roles for expertise.

*Internal to evidence expertise* is expertise which, in itself, counts as evidence. This role for expertise could also be cashed out in terms of “making a claim.” When a clinician cites internal to evidence expertise, she is making a claim that her expertise should be taken as evidence for putting in place a particular intervention or making some other kind of

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<sup>17</sup> I am using this distinction based on status as evidence, rather than something like a judgement vs testimony distinction for two reasons. The first reason is because of the importance of the concept of evidence for EBM. Expertise will be treated radically differently in this movement if it is a kind of evidence than if it not. The other reason is because of the plethora of definitions of “judgement” in medicine.

decision. This kind of role for expertise is much more contentious than the various external to evidence roles for expertise. However, a thorough investigation of the concept of expertise requires that I charitably consider the possibility of a legitimate internal to evidence role for expertise.<sup>18</sup>

### Applying the Internal/External Distinction

Where do these roles for expertise show up in the various models of expertise discussed in EBM? While the EBM literature does not make use of the internal/external distinction that I draw here, the decisions made about expertise in each model differ along the lines of this distinction. In the Pyramid Model, expertise (sometimes discussed as “expert opinion”) is treated as internal to evidence. It is a part (although the lowest possible part) of the pyramid-shaped hierarchy of evidence. Expertise here is in line with my definition of internal to evidence in that experts are taken to be making a claim, something like, “My expertise on Y should be taken as evidence for the use of intervention A to treat condition B, provided that intervention A and condition B fall within the purview of Y.”

This is not the case in the Tripartite Model and the Amalgamation Model. In both the Tripartite Model and the Amalgamation Model, the expertise discussed is not taken to be a kind of evidence, since expertise is either a separate category from evidence which sometimes interacts with evidence (Tripartite Model), or is an amalgamating force which brings together other components including evidence, but isn’t itself evidence (Amalgamation Model). This kind of expertise could be said to “not make a claim” in contrast to internal to evidence expertise.

Of course, all of this is complicated by the possible “nesting” of the models. If we take the “Evidence” component included in the Tripartite Model and the Amalgamation Model to be the Pyramid Model itself, then the Tripartite Model and the Amalgamation Model include

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<sup>18</sup> This distinction is in some ways similar to the direct/indirect role for values distinction put forward by Douglas discussed in Chapter 4. They have in common that the more direct role is the one which is controversial. While I criticize that distinction because I do not believe it is the case that some values are always appropriate and others always not appropriate, this kind of distinction is close to what I mean here.



both internal to evidence and external to evidence concepts of expertise within the same model. That is, both the Tripartite Model and the Amalgamation Model include a ring which is meant to represent “best evidence,” best evidence which is still arranged in a hierarchy as in the Pyramid model. Thus, if the models are “nested,” both the Tripartite Model and the Amalgamation Model are to include within them the Pyramid Model. This “nesting” interpretation remains controversial because it is not clear whether these models are meant to replace each other, or to build on each other as subsequent models were introduced. If they are meant to replace each other, as is sometimes claimed when strong criticisms continue to be made against the Pyramid Model by those outside of EBM, then we should not take them to be nested.

#### The Search for a Legitimate Role for Internal to Evidence Expertise

So, what is it that makes internal to evidence roles for expertise so problematic? It is possible that expertise collapses into the list of facts which an expert knows, in which case, it is not the expertise which is doing the work of being evidence, but instead these facts which make up expertise. The expertise itself in this case adds nothing above and beyond these facts. On the other hand, internal to evidence expertise sometimes is described as whatever ideas about what should be done that are left when all the explicit facts an expert can marshal are left aside— a fact-free gut feeling about what should be done. If this is what is meant by expertise and it is to be used as evidence, the worries here are clear; such gut feelings will not be consistent from person to person, do not take into account any facts, never mind the quality of those facts, and cannot be articulated to others in order to work toward a consensus or be checked by a second party. So, with these worries in mind, what, if any, possible legitimate uses are there for internal to evidence expertise?

One possibly defensible use of an internal to evidence role for expertise involves Bayesianism. Bayes Theorem,

$$prob(X|Y, I) = \frac{prob(Y|X, I) \times prob(X|I)}{prob(Y|I)}$$

can be rewritten as:

$$Prob(hypothesis|data, I) \propto prob(data|hypothesis, I) \times prob(hypothesis|I)^{19}$$

As Sivia and Skilling write in their book, *Data Analysis: A Bayesian Tutorial*,

The quantity on the far right,  $prob(hypothesis|I)$ , is called the *prior* probability; it represents our state of knowledge (or ignorance) about the truth of the hypothesis before we have analysed the current data. This is modified by the experimental measurements through the *likelihood* function, or  $prob(data|hypothesis, I)$ , and yields posterior probability,  $Prob(hypothesis|data)$ , representing our state of knowledge about the truth of the hypothesis in light of the data. In a sense, Bayes theorem encapsulates the process of learning. (Sivia and Skilling, 2006, 6)

In this account, our priors provide an important baseline of knowledge. When confronted with new information, our priors are what we adjust in order to digest the new information and take it into account in our decision-making. While most of the “action” in Bayesianism happens after the priors have been determined, differences in the status of priors between agents can make an important difference in their predictions.<sup>20</sup>

For example, imagine an expert cardiologist and an untrained but scientifically literate non-expert are presented with evidence from a well-designed and well-carried-out RCT for the use of statins in stroke before they are asked to suggest a course of action for a patient who is at high risk of having a stroke. Because of differences in their knowledge statuses, before they see the results of this study, the expert cardiologist’s priors suggest that perhaps statins might be a good idea for this patient- the non-expert has no such prior inkling. Suppose this study suggests that statins were successful in treating stroke on average in some population, and our patient is very similar to the population on which the test was

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<sup>19</sup> This equation contains an often left out component,  $I$ . Sivia and Skilling write, “We have made the probabilities conditional on  $I$ , to denote relevant background information at hand, because there is no such thing as absolute probability... Although the conditioning on  $I$  is often omitted in calculations, to reduce algebraic cluttering, we must never forget its existence. A failure to state all the relevant background information, and assumptions, is frequently the real cause of heated debates about data analysis” (Sivia and Skilling 2006, 5). This seems to be a worthy consideration, so I have included this notation.

<sup>20</sup> A response here might be to claim that differences in priors “wash out” over time, so my claim that what internal to evidence expertise does is produce higher quality priors isn’t particularly important- it might be true, but is over all not important. As I said earlier, the idea here is to suggest something useful expertise might do, not to enter into ongoing debates in Bayesianism, but there seems to be some evidence that this washing-out defense only works in the very long run, and not at all in the short or medium runs (Earman 1996, 58).

done. Both the expert and the non-expert might conclude that the patient should take statins as treatment for a possible stroke. While it is true that they have both been presented with the same evidence, and both came to the same conclusion, and so in some sense have the same knowledge, in a Bayesian sense their responses cannot be the same, because of the differences in their priors. This suggests at least one legitimate role for internal to evidence expertise: in a Bayesian framework, it provides higher quality priors.

It is tough to say exactly what exactly I mean by “higher quality priors.” I am tempted to say that higher quality here just means “more warranted” priors, but there is a question of how priors can be warranted at all, given that they are taken to include general background knowledge and values. Instead, perhaps higher quality priors are just those priors which are “closer” to the revised knowledge status, such that individuals with internal expertise “travel” less far in getting from the prior to the posterior. This suggestion avoids the debate about warrant, in that it makes no claims about warrant itself, instead noting that some priors require less “effort” in moving to a particular revised knowledge status than others. It looks like we could comfortably identify these priors as being derived from expertise.

#### How the Internal/External Distinction is a Problem for the EBM Models

So, a distinction can be made between (1) expertise that constitutes evidence in itself (“internal”) and (2) expertise that is or does something else (“external”). The “something else” might consist of making judgments about the quality of the evidence, integrating best evidence with patient values, or improving the benefits of interventions (e.g., through the placebo effects associated with “good bedside manner” or successful task performance which comes through continued repetition, such as recognizing symptoms, signs, taking measurements, or performing surgery).<sup>21</sup> Often the various models of expertise in EBM take the details of this distinction for granted, leaving it unclear which type of expertise is being

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<sup>21</sup> This dichotomy goes by several names: internal/external, constitutive/contextual, experience/judgment, expert opinion/judgment, or simply bad expertise/good expertise. There are other axes along which we might differentiate kinds of expertise—for example, a bodily/cognitive distinction. However, given the important role of evidence in EBM, a distinction that clarifies the relationship between evidence and expertise is of primary importance here, and is therefore the focus of this section.

discussed. In the Pyramid Model, it seems fairly clear that internal expertise is being deemphasized, given that the model itself is a ranking of different kinds of evidence. It is less clear if the expertise(s) involved in the Tripartite Model and the Amalgamation Model is internal or external or both. This starts to look like a possible contradiction between the models, especially if we consider, as is sometimes suggested, the Pyramid Model to be nested inside the “evidence” portions of the Tripartite Model and the Amalgamation Model. Such a contradiction makes advice about when expertise is to be encouraged and when it is to be de-emphasized difficult to follow.

### Other Expertise Problems for EBM

In addition to worries about the two kinds of work done by expertise, it is not clear that the uptake of each new model involves the abandonment of the previous model. It could be that we are expected to consider all three models at once, given continual references to a Pyramid Model outlook in EBM work published long after the introduction of the Tripartite and the Amalgamation models, such as the GOBSAT acronym joke (Greenhalgh, 2010; Howick, 2011; Wollersheim, 2009). The GOBSAT (Good Old Boys Sit Around a Table) joke about the kind of expertise on display at consensus conferences suggests that in some ways, expertise remains framed as a force in opposition to EBM, rather than an element to be incorporated.<sup>22</sup> The fact that Pyramid Model is in direct conflict with the Tripartite Model and the Amalgamation Model, in that it allows an internal role for expertise while the Tripartite Model and the Amalgamation Model do not, is problematic if we consider all three models to be current and helpfully descriptive.

However, even if we should “replace” the older model with the new one each time, and so currently just consider Amalgamation Model, there are still questions. What prompted the extensive changes, including the move from internal to external, from Pyramid Model to the Tripartite Model and the Amalgamation Model? How does the integration required by the

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<sup>22</sup> The GOBSAT joke is discussed in more detail in Chapter 4 on values. In this chapter, it just serves as evidence that some kinds of EBM opposition to expertise continued after the introduction of the Tripartite Model and the Amalgamation Model.

Amalgamation Model work? How do we distinguish high-quality from low-quality expertise?  
And how do we develop this high-quality expertise?

### Arguing for an Augmented Account of Expertise

Many arguments might be given in defence of allowing the EBM conception of expertise to remain as it is, in an impoverished state. I consider several of these arguments (the “already dealt with” argument, the “everybody knows” argument, the “wishy-washy” argument, and the “but what about value-freedom!” argument) in turn, together with their counterarguments. I conclude that despite the range of arguments suggesting that what has already been said by EBM about expertise is sufficient, confusions and problems about expertise in EBM remain. A public discussion about the role of expertise in EBM could provide many benefits to EBM and the health care sector generally. Having this conversation with patients and practitioners should be a prime concern for EBM proponents. These proponents include groups such as the “EBM Renaissance” movement at Oxford, as well as traditional centres of EBM thought like McMaster and York University. The section concludes with recommendations for which questions regarding expertise should be regarded as most pressing for these stakeholders. These questions centre around the nature of expertise, tools for distinguishing between “good” and “bad” expertise, and a careful investigation into the possibility of expertise as evidence itself.

The first of these arguments for no future work on expertise in EBM I call the “Already Dealt With” Argument. The Sackett et al. articles of 1997 and 1996, upon which the Tripartite Model is based, and the Haynes et al. article of 2002, upon which the Amalgamation Model is based, both discuss expertise. Sackett et al. write,

The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. By individual clinical expertise we mean the proficiency and judgment that individual clinicians acquire through clinical experience and clinical practice. Increased expertise is reflected in many ways, but especially in more effective and efficient diagnosis and in the more thoughtful identification and compassionate use of individual patients' predicaments, rights, and preferences in making clinical decisions about their care. (1996, 71)

Haynes et al. write, “Clinical expertise includes the general basic skills of clinical practice as well as the experience of the individual practitioner. Clinical expertise must encompass and balance the patient’s clinical state and circumstances, relevant research evidence, and the patient’s preferences and actions if a successful and satisfying result is to occur” (2002, 38). The popular EBM textbook, *Evidence-Based Medicine: How to Practice and Teach EBM*, includes expertise in step 4, the final step of the EBM process, writing that this step requires, “integrating the critical appraisal with our clinical expertise and with our patient’s unique biology, values, and circumstances” (Straus et al. 2010, 3). In fact, this relatively short text mentions expertise 24 times! It looks as if an EBM proponent could be rightfully exasperated at the demand for more coverage of expertise in EBM as it is already talked about so much.

These sources do include references to “expertise” but say very little about what expertise is, how good expertise can be differentiated from bad, or indeed anything at all. So, while it is the case that EBM does mention expertise often, this high quantity of mentions does not provide much of substance to help clinicians understand how to integrate and evaluate expertise. The “Already Dealt With” argument does not provide a reason to avoid additional in-depth discussion of expertise in EBM.

The second possible argument against attempting to understand more about expertise in EBM might be called the “Everyone Knows” argument. This argument suggests that it is intellectual overkill to bring in additional theoretical resources to explain a concept that there is no confusion about. Such additional theorizing is unnecessary and weighs down EBM with unnecessary and confusing jargon-indeed, perhaps worsening the problem (lack of clarity about expertise) that it is trying to solve.

While this argument might seem to be the same as the “Already Dealt With” argument at first glance, it is importantly different. While the first argument leans on the number of mentions of expertise in the EBM literature to make its case, the second argument leans on the pedestrian accessibility of the term to suggest that there is nothing else to say

about it—surely a dictionary definition or the common understanding of it in the community is more than enough explanation?

This is far from the case. Expertise plays importantly different roles in all three main models of EBM as discussed in the previous section. Because of these conceptual differences, it is far from the case that everyone already knows what is meant by expertise. The “Everyone Knows” argument does not provide a reason to avoid additional in-depth discussion of expertise in EBM.

Perhaps surprisingly, an additional possible argument runs in exactly the opposite direction from the “Everybody Knows” argument, but with the same conclusion. The “Wishy-Washy” argument suggests that, far from everyone knowing what expertise is already, expertise is a non-standard wishy-washy term, a term that different speakers make very different use of in very different contexts. The project of trying to get clearer about what expertise is in EBM is bound to fail on this account because of this multitude of possible and equally plausible candidates for what expertise means. There are no criteria, this argument might insist, by which we could distinguish which among the conceptions of expertise is the one which ought to be endorsed by EBM.

It is a mark of the confusion around this topic that both the “Already Knows” and the “Wishy-Washy” arguments are presented as defensible. It is true that there are many uses of the word “expertise” in play in EBM and in medicine generally, but this does not mean that nothing can be done to make distinctions between these uses or to weed out some accounts of expertise that do not fit well with other EBM values or clinical need. Conceptual tools like the internal to evidence/external to evidence distinction can be used in order to pull apart some of the many meanings of expertise. There are in fact some well-developed accounts of expertise that can be rejected as a poor fit with EBM goals. I will reject several of these accounts in what follows in this chapter.

A final concern about a further investigation of expertise in EBM charges that this project is not in some way properly objective. I call this the “No Longer Value-Free”

argument. This argument claims that discussion about what expertise *is* is a matter of values and preferences, not a matter of facts, and because of this, an investigation of expertise is an inappropriate project for EBM. Such a project would compromise the value-free purity of EBM.

While I disagree with the conclusion of this argument, (because I think much of the work EBM supporters need to be doing has to do with clarifying values), I do agree that a further investigation of expertise in EBM will be a matter of values. I discuss the role of values in EBM more thoroughly in Chapter 4, but here I will just briefly say that EBM is not value-free, and what is more, should not be value-free. Projects which discuss values in EBM, far from being contaminants, are desperately needed if the EBM project is to continue. Because of this fundamental disagreement about the role of values in EBM, I do not find the “No Longer Value-Free” argument compelling.

Because the project of improving the account of expertise in EBM is not often suggested, these arguments are not directly stated in the literature. I have cobbled them together from other kinds of methodological remarks and arguments made in EBM and responded to them as charitably as I can. Now that I have made this proposal, it is possible that EBM proponents will suggest some new, not yet considered reason to leave the account of expertise in EBM as it is. I will eagerly consider and respond to these arguments as they arise.

However, these arguments against investigating expertise in more depth are unconvincing. I argue that EBM should adopt a more robust account of expertise. What would a more robust account of expertise in EBM achieve that has not already been accomplished by these models? This account should give us guidance on how to perform the integration of evidence required by the Tripartite Model and the Amalgamation Model. This guidance should include what is to be done when the demands of one of the component parts (patient values, evidence from the hierarchy and clinical expertise in the Tripartite Model, and patient values, evidence from the hierarchy and the clinical circumstances,



mediated by clinical expertise in the Amalgamation Model) come into conflict with the others, as examples from bioethics, such as cases in which religious commitments conflict with best evidence for effectiveness, suggest that they will. This will inform clinician's deliberations regarding how to weigh the various portions of the EBM encounter. It will also make clear whether or not the expertise in mind includes expertise as evidence (internal), expertise as other nonevidentiary roles(external), or some combination of both. This will determine which kinds of expertise to cultivate and which to avoid. Lastly, a more robust account of expertise should include an explanation of how expertise is acquired: how do we become experts? This explanation will allow for programmes of medical education to include components designed to encourage the development of expertise.<sup>23</sup>

It is for these reasons that the EBM account of expertise needs to be developed in more detail. However, it is not necessary to create a bespoke account of expertise for EBM. Many other disciplines including philosophy, sociology, computer science, science and technology studies, and artificial intelligence have ready-made conceptions of expertise (Dreyfus and Dreyfus 1986; Dreyfus 1992; Turner 2013; Bishop and Trout 2004; Epstein 1998; Collins 2004; Collins and Evans 2007).

Of these, perhaps the most widely discussed is the Dreyfusian account of expertise in the philosophy and artificial intelligence literature. This account has already been taken up in the nursing literature. Of course, it might be the case that nursing and EBM are significantly different such that an account being preferred by nursing is no reason to suppose that the account will be a good fit with EBM. However, because including expertise in EBM is a way of showing that EBM is responsive to the needs and worldviews of clinicians, examining a clinician-discussed account of expertise is a good place to start. Of the suggested possible accounts above, the Dreyfus account is the only one to boast

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<sup>23</sup> It is possible to see a lack of clarity about expertise as a kind of boon for EBM. A multifaceted and nondifferentiated expertise could be considered a balm, a stop-gap, for all uncertainties left when the evidence has been consulted. For another possible take on the role of uncertainty and expertise in EBM, see Timmermans and Angell, 2001.

clinician endorsement. Can the Dreyfusian account of expertise flesh out the EBM account of expertise in these three models?

### The Dreyfusian account

The Dreyfusian<sup>24</sup> account of expertise development<sup>25</sup> arose out of their critique of the artificial intelligence(AI) program at the Massachusetts Institute of Technology (MIT), but was eventually extended to AI programs in general. They suggest that these programs are the inheritance of various philosophers (e.g., Plato, Descartes, Leibniz, Husserl) who argue that cognition is a matter of representation of the outside world within our minds, that wisdom can be articulated in explicit principles and rules, and that complex problems can be broken down into their parts in order to grasp the whole's underlying rules for putting them together (Dreyfus and Dreyfus 1986). Dreyfus and Dreyfus find themselves more in line with what they call the “anti-philosophers” (e.g., Merleau-Ponty, Heidegger, Pascal, Wittgenstein). They claim that, “Human understanding was a skill akin to knowing how to find one's way about in the world, rather than knowing a lot of facts and rules for relating them. Our basic understanding was thus a *knowing how* rather than a *knowing that*” (Dreyfus and Dreyfus 1986, 4). The work of these “anti-philosophers” pointed them towards a problem that, they argued, poses insurmountable difficulties for the AI project. They called this problem “the frame problem.”

The frame problem is, “the attempt to capture human temporal, situated, continuously changing know-how in a computer as static, desituated, discrete, knowing...more specifically it is the problem of representing in some systematic way that as time passes and/or actions are performed, some but not all facts change and only a few of the changes are relevant to

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<sup>24</sup> I am most closely examining the account laid out in *Mind Over Machine*, which is written by two Dreyfus brothers, Hubert (a philosopher) and Stuart (an industrial engineer and early computer programmer). Hubert went on to develop the account further in several other books including *What Computers (Still) Can't Do*. When referring to work done by both brothers, I reference plural authors, but otherwise make reference to “the Dreyfusian” account, encompassing both the co-authored and single-authored work.

<sup>25</sup> The Dreyfus brothers are answering a slightly different question than the one I am interested in. Their work answers the question, “How does one become an expert?” while I am explicitly interested in the question, “What is expertise?” However, their answers to their question have important bearing on my question.

the current action” (Dreyfus and Dreyfus, 1986, 82). Dreyfus and Dreyfus argued that no matter how many pieces of data were stored within computers, since computers do not “have a world” they could not, just on the basis of these facts, find the relevant facts to deal with changes in their environment.

With this in mind, Dreyfus and Dreyfus sought to provide an account of expertise that explains why, rather than a building-up of facts, expertise involves a deepening of our understanding of which knowledge is relevant in a given situation. Such knowledge allows the expert to react to changes in the environment by recognizing which elements are similar to situations the expert has been in before, and which elements are importantly new. It is important to emphasize that a Heideggerian account of the world (on which Dreyfus is relying) includes other people—the world into which we are thrown and from which we gain this kind of expert, context-dependent understanding is fundamentally social. We learn what “one” does in particular situations from the actions of others.

Understanding the details of the Dreyfusian work is required in order to evaluate the “fit” between the gap in EBM and the solution that the Dreyfusian account offers, which has been readily taken up in some parts of medicine. What follows is a brief sketch of those details.

### The Five Stages of Skill Acquisition

The Dreyfusian account of expertise involves five progressive stages. The first stage they call “novice.” In this stage, the novice's attention is drawn to facts and is generally presented with information as a set of usual rules that are “context free” in order to make them cleaner and clearer. Dreyfus and Dreyfus use a series of ongoing specific examples to illustrate their stages. One of these follows the development of expertise in a nurse,<sup>26</sup> which

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<sup>26</sup> Dreyfus does not differentiate between the sort of jobs we might think of as trades (Heidegger has often been accused of romanticizing and overemphasizing this kind of work) from those we think of as intellectual. His list, “the expert business manager, surgeon, nurse, lawyer or teacher is totally engaged in skillful performance” includes both the sort of labor that we might easily accept as best operating using a smooth flow of experienced effort (say carpentry, or in this list, surgery) and the sort of occupations and activities that we often take to be very cerebral and involving explicit decision-making and deliberation (like teaching or lawyering). For Dreyfus, there is not a divide here; insofar as someone is an expert at any of these activities or occupations, they will, provided everything is going well, smoothly go about their business without explicit deliberation.

is relevant to the question at hand. In the novice stage the nurse is “taught how to read blood pressure, measure bodily outputs, and compute fluid retention and is given rules for determining what to do when those measurements reach certain values” (Dreyfus and Dreyfus 1986, 22).

The second stage is called “advanced beginner.” In this step, the learner begins to recognize regularities in her particular situation based on “perceived similarities with prior examples” which are not given in the “context free” rules provided to her as a novice. The advanced beginner nurse, “learns from experience how to distinguish the breathing sounds that indicate pulmonary edema from those suggesting pneumonia. Rules of treatment can now refer to the presence or absence of such sounds” (Dreyfus and Dreyfus 1986, 23). At this point, rules are still involved, and now that the learner has enough experience to understand the proper references, even more rules can be meaningfully used.

Upon reaching stage three, “competence,” the learner can recognize both the appropriate context-free rules and situational elements of various kinds in a given circumstance. At this stage, the two kinds of information seem to be equally relevant and can become overwhelming. The learner, having trouble ranking the vast amount of experience-gained insight and context-free rules that may apply (and possibly disagree) in a given situation, must eventually attempt a hierarchical plan to synthesize which experience-gained insight or context-free rule to apply first.

To apply this to a medical setting, Dreyfus and Dreyfus write,

The competent nurse will no longer automatically go from patient to patient in a prescribed order but will assess the urgency of their needs and plan work accordingly. With each patient, such a nurse will develop a plan of treatment, deciding that if certain signs are present a certain number of days after surgery, say, the time has come to talk with a patient about his wound and its care outside the hospital. When discussing the matter, various medical aspects of the patient's condition will be ignored, and psychological effects will become important. (Dreyfus and Dreyfus 1986, 26)

In this example, it is especially clear that on the Dreyfus model, expertise is both evidence itself and a way of amalgamating evidence. The nurse has expertise in knowing when a patient is ready to go home, but expertise can additionally be a way of pulling together other

data (number of days after the surgery, the look of the patient, the condition of the wound etc.) to come to the conclusion that the patient is ready to go home.

To be clear, for Dreyfus and Dreyfus, the creation of this plan cannot be done with a set of meta-rules for, say, work-planning. It would be all too easy to fall into a regress here, creating rules, then rules for work planning, then rules for planning work planning. They write, “Choosing a plan is no simple matter for the competent individual. There is no objective procedure like the novice's context-free feature recognition” (Dreyfus and Dreyfus 1986, 26). Because this choice of a plan is the first part of the expertise that the learner does not just follow (like rules) or recognize (like experience patterns), but creates herself, it is at this level that the learner first feels responsibility for her actions.<sup>27</sup> I will later show that this is the highest stage that can be acceptable to EBM, as the two highest levels of skill are “characterized by a rapid, fluid, involved kind of behaviour that bears no apparent similarity to the slow detached reasoning of the problem-solving process” (Dreyfus and Dreyfus 1986, 27), a description that comes into conflict with the goals of EBM.

In the fourth step, proficiency, learners will not only experience tasks as things they are responsible for but will have a particular perspective on the task at hand. It is at this point that something like an expert's “voice” or “style” becomes clear. This perspective, itself developed without a set of concrete rules, is essential in allowing the learner to depend even less on explicit rules and guidelines, but to go about her tasks smoothly. This is unpacked using our familiar nursing example: “The proficient nurse will *notice* one day, without any conscious decision-making, that the patient is psychologically ready to deal with his surgery and impending release. However, during the conversation, words will be carefully and

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<sup>27</sup> An important part of the Dreyfus and Dreyfus system is their account of where and when responsibility comes into the picture for learners along the expertise continuum. In the Dreyfus and Dreyfus account, responsibility only becomes involved when rules and explicit instructions become less important and less necessary. If this is in fact true, one of the implications of EBM's dependence on, and lauding of, explicit guidelines and evidence supported rules is a reduction in the amount of responsibility health care professionals could possibly feel for their actions. If the use of explicit rules relieves health professionals of their responsibility (or perhaps never allows this responsibility to develop), this could have very large implications for the discipline of bioethics and would make a substantial portion of the literature on topics like physician regret seem misinformed.

consciously chosen” (Dreyfus and Dreyfus 1986, 30). The emphasis here is generally on the lack of choice or deliberation in the shifts of attention that occur, while denying that the Dreyfus account makes a virtue of thoughtlessness. While expertise may mean fewer explicit rules, a Dreyfusian expert need not be thoughtless regarding patient communication. Proponents of EBM methods might be concerned that this lack of deliberation would lead to poor patient outcomes. However, on the Dreyfusian account, this is just how we live the majority of our lives in realms in which we are comfortable. Importantly, this ability is categorized as “intuitive,” bringing into play one of the key concepts EBM was created to de-emphasize in medicine (EBMWG, 1992). Intuition is further clarified this way in the section “Problems with the Integration of the Dreyfusian Account and EBM.”

“Expertise” or “skilled coping” is the fifth and final stage. This stage involves the learner moving away from a “problem solving” mode of operation, to a simple, mature knowledge of what needs to be done. This knowledge will not stand out to the expert as something she must struggle for or produce, but instead be instant and invisible, even to her. Dreyfus and Dreyfus compare this relationship to skilled knowledge with our relationship to our own body, writing, “an expert’s skill has become so much a part of him that he need be no more aware of it than he is of his own body” (Dreyfus and Dreyfus 1986).<sup>28</sup>

For Dreyfus, the expert, far from needing checklists<sup>29</sup> or other materials with statements of guidelines or rules, can actually be hindered by these rules as they take her back to the stage of competence, if not further, perhaps resulting in poor patient outcomes.

In saying this, the authors are not saying that deliberation never occurs; it just occurs with less frequency and upon different things than those who find EBM methods salient might think. They write,

In the idealized picture of skilled coping I have just presented, it might seem that experts never think and are always right. Of course, in reality, things are otherwise...when time permits and outcomes are crucial, an expert will

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<sup>28</sup> This parallel drawn between the immediacy of the body and the immediacy of expert skill might suggest that interesting work could be done to discuss expertise using the work of Maurice Merleau-Ponty (2013).

<sup>29</sup> With Dreyfus’ account in mind we might more easily see how, though they seem to be effective, experts might be unenthusiastic about the introduction of checklists into the medical profession (Gawande 2009).

deliberate before acting. But... this deliberation does not require calculative problem solving but rather involves critically reflecting on one's intuitions. (Dreyfus and Dreyfus, 1986, 31)

At first it seems that with this admission, Dreyfus will open the door to EBM-style insistence on continual overt evidence-based deliberation, but by suggesting that what is deliberated upon is actually intuition, this door is shut firmly.<sup>30</sup>

### Against the Calculative Rationality Model

By creating this account of the stages of expertise, the authors are attempting to refute a “calculative rationality” model of knowledge and skill. This was the sort of model used by the artificial intelligence lab at MIT in which both brothers were involved. The gist of this model (which might be seen as in line with EBM methodologies) is that skills and knowledge are made up of facts and rules about how and when to apply those facts. If skills or knowledge have not been attained, the problem is a lack of proper facts or rules. The addition of more facts or rules will solve the problem. Instead, Dreyfus and Dreyfus predicted “success with simple mechanical forms of information processing, then great expectations, and finally failure when confronted with more intuitive forms for intelligence” (Dreyfus and Dreyfus 1986). The Dreyfusian model, with its emphasis on the epistemic work done by our bodies’ interaction with the world provides an alternative to the Calculative Rationality Model and explains some of that model’s failures.

### What problems would the Dreyfusian account of expertise solve for EBM?

The Dreyfusian account can augment what EBM has already said about expertise in several ways. It takes a stand on the role of expertise: on the Dreyfusian account, expertise is both evidence and the process for amalgamating evidence. This issue is left uncertain in

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<sup>30</sup> Some readers may hear something in this passage of Kahneman’s Two System Theory from his very popular book, *Thinking Fast and Slow*. In this theory of cognition, “System 1 operates automatically and quickly, with little or no effort and no sense of voluntary control. System 2 allocates attention to the effortful mental activities that demand it, including complex computations. The operations of System 2 are often associated with the subjective experience of agency, choice and concentration” (2011, 20). In so far as Kahneman is interested in the investigation (and salvaging the reputation) of System 1, he and the Dreyfus brothers could be considered allies. However, their underlying commitments and worldviews are quite different and their systems are far from equivalent. For example, on the Kahneman account, certain kinds of activities are just always done by System 1, rather than (as perhaps the Dreyfusian account would have it) activities done by System 2 originally and eventually only needing System 1. There is not the same emphasis as in the account given by Dreyfus and Dreyfus on a developmental progress; on the same activity requiring over time less active attention and instead being done in a skillful flow.

EBM's current account of expertise. It also provides a clear account of how we end up with good experts by including the developmental processes that are necessary to facilitate the training of good experts. In a Dreyfusian account this requires that developing experts first be given rules and procedures to follow, but as their expertise develops, that they are given the opportunity to take responsibility for their actions and develop patterns of practice not obviously called for in explicit rules. Taking up the Dreyfusian account of how to produce good experts has implications for practices in medical education. For example, a Dreyfusian influenced medical education might have coursework of a shorter duration and a longer period of residency. Adopting the Dreyfusian account of expertise would add clarity to EBM's current stance on the matters of expertise as amalgamating force and pedagogy which encourages the development of good expertise.

#### Problems with the Integration of the Dreyfusian Account and EBM

Dreyfus is critiquing a particular "calculative" conception of rule-based rationality and decision-making. This critique is in line with EBM's insistence that it is not "cook-book medicine" as claimed by Sackett and his co-authors in their well-cited article. However, given that rule adherence remains a backbone component of EBM practice, the Dreyfusian account of expertise remains at odds with EBM components.

Proponents of EBM are eager to claim that dependence on rules and guidelines does not entail that that EBM is "cook-book medicine." Sackett writes, "Evidence based medicine is not 'cook-book' medicine. Because it requires a bottom-up approach that integrates the best external evidence with individual clinical expertise and patient choice, it cannot result in slavish, cook-book approaches to individual patient care...any clinical guideline must be integrated with individual clinical expertise..." (Sackett 1996).

These fears about cook-book medicine derive both from a fear of a lower status for health professionals and worries about a lack of responsibility that over-dependence on guidelines might allow. Although supporters want to make clear that EBM is not cook-book medicine, this does not negate the fact that in practice, in terms of use in medical education



and in the clinical encounter, EBM is based on a system of systematic reviews and meta-analyses that work as guidelines for best practices in various circumstances. And although supporters of EBM added a role for clinical judgment in their overall system, the emphasis is still on decision-making and intervention selection based on rules created from test results (Sackett, 2000). These are the emphasized commitments for EBM practitioners of all kinds, not just medical students and new clinicians. In fact, EBM founding mythology and central texts emphasize that mid- and late-career researchers and practitioners are also susceptible to the kind of lapses in evidence-based practice that they are seeking to avoid (see chapter 1). While EBM supporters might declare that there is still a role for judgment and expertise in deciding to apply findings, at a basic level formal rules are taken to be the building blocks of decision making for EBM. This commitment to rule-based action places EBM squarely in the camp of those traditional philosophers and AI scientists that are subject to the Dreyfusian critique.

It might be possible for EBM proponents and texts to accommodate this sort of conception of expertise, but the accommodation would not be complete and any accommodation would happen in such a way as to undermine the critique Dreyfus and Dreyfus were hoping to make clear. One might also think that EBM proponents could insist that the continual creation of additional evidence means that it is appropriate for health care professionals operating within EBM to just remain at the level of novice in the Dreyfus and Dreyfus account. These health professionals ought never to reach the Dreyfus and Dreyfus level of expertise, because this would require too much distance from the explicit rules and guidelines that are so important to EBM. Given that the reason for discussing the Dreyfus and Dreyfus account in the context of EBM was to deepen the EBM concept of *expertise*, a solution which does not leave open the possibility of health care professionals reaching the stage of expertise on that model does not provide a useful solution. Is there any way in which the Dreyfus and Dreyfus account remains a good fit for this goal of deepening the account of expertise in EBM.

The first three stages of the Dreyfusian system are in some ways perfectly in line with what EBM tells us about expertise, especially in relation to the Tripartite Model and the Amalgamation Model. On this version of EBM, a learner is initially given experience-free, evidence-based rules. Then she progresses and receives some experience such that more rules have meaning and can be understood and applied, and then, overwhelmed by the pull of different rules, she builds a hierarchical plan in order to manage the different sets of rules. But here is where proponents of EBM would say that their health professionals ought to stop moving up the stages of expertise to proficiency and then skilled coping (Dreyfus and Dreyfus 1986).<sup>31</sup> Health professionals who move on from this stage have left behind the proper role of evidence-informed clinician and are now operating without the *direct* support of that evidence. This follows from the EBM injunction to avoid operating independent of the “findings of the best available evidence.” This situation, which supporters of EBM see leading to inconsistency, hubris, and poor patient outcomes, is where Dreyfus sees the beginning of a “flow” of actual involved expertise. This makes for a poor fit between EBM and the Dreyfusian account. The other reason the Dreyfusian conception of expertise might be a poor fit to fill in the relatively shallow account of expertise in EBM because of the radical difference between the two parties’ accounts of intuition and rationalization. Dreyfus writes of rationalization,

The nurse's desire to rationalize her intuition shows the pressure which often leads to rationalization, especially in our modern Western culture. There are, of course, two interrelated senses of the word 'rationalization.' Once a decision intuitively presents itself, rationalization in the first sense describes the attempt to find a valid explanation by identifying the elements of the situation and combining those elements by a decision rule to justify the chosen decision...She [the nurse] realizes, however, that 'all I am really trying to do is find words within the jargon to talk about something that I don't think is particularly describable.' If, indeed, elements and principles play no role in mature, practiced decision-making, rationalization in this sense amounts to the invention of reasons—rationalization in its second and generally derogatory sense. (Dreyfus and Dreyfus 1986, 35)

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<sup>31</sup> EBM might also be somewhat accepting of a reversal of Dreyfus' steps. This reversed set of steps would begin with intuition-based expertise and then move “up” to expertise based on the application of abstract principles, but this acceptance might also be based on the difference in “intuitions” discussed. In addition, I see no reason to think that Dreyfus would accept as meaningful the use of his stages if inverted.

It is clear from this description that Dreyfus thinks of rationalization not as a fundamental and necessary step for being a proper expert, but instead as a pasted-on explanation for something for which there is no explanation, for which there “are no words.” For Dreyfus, rationalization is ultimately synthetic and deceptive, as it does not represent the way we go about our work as experts.

EBM is based on the premise that the delivery of superior care depends on immediate access to rational evidence (as well as some combination of values, circumstances and expertise). In the interest of attaining this superior care, “clinicians should regularly consult the original literature (and read and be able to critically appraise the ‘Methods’ and ‘Results’ sections) in solving clinical problems and providing optimal patient care” (EBMWG 1992, 2421). Much emphasis is placed on the ability to consistently make reference to the published evidence upon which a health professional is acting. This emphasis has softened somewhat over time, as clinicians are now directed to pre-approved EBM resources, rather than expected to do the critical appraisal themselves (see Chapter 1).

This is in contrast with Dreyfus' model in which, though “that type of carefully thought out behaviour certainly occurs, frequently for learners of new skills and occasionally even for the most skillful, an unbiased examination of our everyday behaviour shows it to be the exception rather than the rule” (Dreyfus and Dreyfus 1986, 28). Given that EBM is interested in trying to modify everyday behavior, and Dreyfus and Dreyfus are interested in basing their account of expertise on our unchanged current behavior, this suggests that their account is not a good fit.

With this deep divide separating the EBM conception of rationalization from the Dreyfus conception of rationalization, it is no surprise that Dreyfus' conception of expertise looks incompatible with the goals of EBM. But this is not the most radical difference between the two accounts. The most radical difference between Dreyfus and those who support the EBM movement, the reason that will ultimately prevent the acceptance of the Dreyfus and Dreyfus account of the stages of expertise, is the difference in their concepts of intuition.

In accounts of the goals of EBM, intuition is depicted as an imprecise relic from physicians' authoritarian past that is best avoided. In the movement's debut article, the evidence-based working group writes, "one must be cautious in the interpretation of information derived from clinical experience and intuition, for it may at times be misleading" (EBMWG 1992). In so far as intuition may have any role in the clinical setting, it is to provide the first idea behind a possible testable hypothesis. The debut article suggests that the fruits of intuition may "prove extremely useful, and ultimately be proved valid through rigorous testing" (EBMWG 1992). But intuition is certainly not to be the basis for everyday decision-making in EBM. In this way, intuition may overlap with external expertise, the kind of expertise involved in the Tripartite Model and the Amalgamation Model, in that it has uses, but these uses do not count as evidence in itself. If it could be clarified that the expertise which is permitted in the Tripartite Model and the Amalgamation Model was only external expertise and not internal expertise, perhaps an argument could be made that intuition is compatible with EBM as depicted the Tripartite Model and the Amalgamation Model. However, the possible "nesting" or cumulative use of the models makes this distinction impossible to make without additional information about the models provided by EBM. That is, if the models were nested, the Tripartite Model and the Amalgamation Model would be compatible with intuition at a macro level but would include within them a "nested" component, the Pyramid Model, which explicitly rejects an internal role for intuition. If this were to be the case, in EBM models the Tripartite Model and the Amalgamation Model intuition would be strictly limited to these external roles and, even then, only used when other options are not available. This is in contrast with the Dreyfus account in which intuition plays a non-negotiable, bedrock role in the skilled-coping of an expert.

For the Dreyfus brothers, intuition is clearly described in order to avoid confusion. This is important, as it would be easy to misconstrue the sort of intuition their conception of expertise relies on. They write, "intuition or know how, as we understand it, is neither wild guessing nor supernatural inspiration, but the sort of ability we all use all the time as we go

about our everyday tasks” (Dreyfus and Dreyfus 1986, 29). For the Dreyfusian account, intuition is the hard-won result of the development of a perspective, a perspective that can only arise from a situatedness in the world.

We can see from this explanation that they too seem to discount the sort of intuition that EBM has historically worried about—the “guesses” and the “metaphysical feelings.” But for all that agreement, the Dreyfusian account still finds a sort of intuition that is worth protecting (which indeed represents the best sort of “flow” and skillful coping), in direct conflict with the EBM goal of deemphasizing intuitions as described in the debut article (EBMWG 1992). If EBM wants to continue to suggest that intuition should be de-emphasized in the clinical encounter, it will remain incompatible with a Dreyfusian account of expertise.

#### Rejection of the Dreyfusian Account for EBM Expertise Augmentation

Despite its uptake by the medical community, the Dreyfus account of expertise is not a good fit with EBM. It is because of radical differences in these concepts of rationalization and intuition that those who support any model of EBM are likely to be suspicious of Dreyfus’ account of expertise, as well as Dreyfus’ underlying goal of offering an alternative to the Calculative Rationality Model. Because of the central place of these issues in EBM, it seems unlikely that proponents would be willing to sacrifice them in order to gain an improved account of expertise. However, this rejection of the Dreyfusian account is not the end of EBM’s concern with expertise. The account provided within the EBM literature remains impoverished and requires augmentation. Accounts of expertise from other disciplines stand ready to be examined for fit with the framework of EBM. In order to be a satisfactory account of expertise for EBM an account should, in addition to not being in conflict with the main components of EBM, take a stand on the issue of expertise as internal or external, explain a method for any required amalgamation, differentiate high quality from low quality expertise and consider how to produce high quality expertise. Supporters of EBM should continue to look to the rest of the rich interdisciplinary literature on expertise for augmentation and deepening of the account gestured toward in their three models. Additional information from

EBM supporters about what it requires for a useful account of expertise would also be helpful to expertise theorists who would seek to offer varied accounts of expertise for use. The adoption of one of these accounts of expertise would be of interest, not only to the EBM community, but also to would-be Evidence-Based practitioners in other fields and expertise theorists in many disciplines. In what follows I begin such a project, investigating accounts of expertise provided by Turner, Bishop and Trout, and Collins and Evans.

### The Turner Account

The sociologist and philosopher Stephen Turner offers a different model of expertise in works like *The Politics of Expertise* and “What is the Problem with Experts?” (Turner 2013; Turner 2001). Unlike the Dreyfusian account, Turner’s account of expertise does mesh with the implicit worries about expertise in EBM. In this section I will explain Turner’s account of expertise in the context of political philosophy and social systems. Lastly, I draw on the few EBM depictions of expertise, mainly as a form of authoritarian control that was privileged before EBM to show how Turner’s account fits with what EBM has said about expertise and can further clarify EBM’s concerns about expertise.

For Turner, the discussion of experts and expertise is an important component of political philosophy and sociology. Of specific importance is the rise of experts as a political and bureaucratic force within liberal societies during the 19<sup>th</sup> and 20<sup>th</sup> centuries. This rise poses a problem for liberalism in that expertise,

is a kind of violation of the conditions of rough equality presupposed by democratic accountability. Some activities... are apparently out of the reach of democratic control...precisely because of imbalances in knowledge, simply because “the public” as a public, cannot understand the issues... So, we are faced with the dilemma of capitulation to ‘rule by experts’ or democratic rule which is ‘populist’—that is to say, that valorizes the wisdom of the people even when ‘the people’ are ignorant and operate on the basis of fear and rumor. (Turner 2013, 159)

That is, a political system which relies on experts for much of its decision making and administration, as ours does, undermines the very conditions of assumed equality which make liberal democracies possible. Alternatively, if we think of differences in knowledge not as levels of access to a substance to which access is unequally distributed, but instead as a

series of equally relevant viewpoints, then the work that governments do in an attempt to force equality of knowledge (a standardized science education, the public support of experts whose work is measured in terms of its impact on the public) also constitute an infringement of what Turner takes to be fundamental liberal principles; impartiality and neutrality. Taken together, these two problems place liberal democracy in a troubling position; “If experts are the source of the public’s knowledge and this knowledge is not essentially superior to unaided public opinion, not genuinely expert, the ‘public’ itself is presently not merely less competent than the experts but is more or less under the cultural or intellectual control of the experts” (Turner 2013, 161). In other words, experts represent a sort of modern oligarchy, and, though this oligarchy is needed for the everyday working of a liberal democracy, it also undermines it.

In order for experts to attain this status, they must first have established their authority. In his discussion of the development of authority, Turner takes as his paradigm case the expert physicist. Authority begins in an audience’s general knowledge of the efficacy of the products and technologies based on physics; in this case, nuclear energy and nuclear weapons. Given that the audience is aware of the efficacy of these outputs of physics, Turner claims that we can say that non-experts do know when to give authority to experts without knowing as much as the experts or relying on a kind of blind faith (Turner 2013, 166). However, what makes different types of experts different is their relationship to the various audiences they have persuaded of their expertise, who then confer upon the experts their authority. For Turner, there are five kinds of experts, and each group is demarcated by differences in their relationships with the different groups which confer authority upon them. Type I consists of experts whose authority is universally acknowledged. Type II consists of experts whose authority is accepted by a particular non-universal group or sect. Type III is made up of experts whose expertise is tested and accepted by private individuals. Type IV is made up of “experts whose audience is the public but who derive their support for subsidies from parties interested in the acceptance of their opinions as

authoritative” (Turner 2013, 177). And Type V consists of experts whose “audience is bureaucrats with discretionary power, such as experts in public administration whose views are accepted as authoritative by public administrators” (Turner 2013, 177). According to Turner, Type I experts have authority conferred upon them by the most universal of audiences, while Type V experts the least universal. I will examine each group in turn, giving examples of these kinds of experts and noting the dangers liberalism faces from these various kinds of experts.

### The Turner Types of Expertise

For Turner, the Type I expert is exemplified by the expert physicist. The audience who confers authority upon the expert physicist is not a niche part of society, but instead society at large. Turner writes, “In the case of physics...there was a kind of generalized approbation and acceptance on the grounds of indirect evidence of the physicist’s claim to expertise, and the claim to exercise powers of self-regulation and certification that should be honored by the public at large” (Turner 2013, 175). Since, according to Turner, authority is given to physicists based on a broad knowledge of the functioning of the products of physics by society at large, this type of expert poses little threat of undermining the foundations of the liberal state. Indeed, by relying so strongly on near universal acclaim, and requiring neither faith nor perfect knowledge of those who give them authority, these experts are actually quite in line with the egalitarian spirit underlying liberalism.

The Type II expert is the first sort of expert which Turner claims poses a threat to liberalism. This type is best exemplified by the theologian or the prophet. They are given authority by a large and organized sect of the population. Given that they have no claim to universally derived authority, as Turner says the physicist does, they do not warrant as far reaching legitimization as the physicists do. However, given that, perhaps a very large portion of the population considers these experts to be experts, and that liberalism does make use of experts in deciding on policy, the liberal is left with a difficult issue- since various theologians and prophets do not have the same advice to offer the state, not all of



their advice can be consulted. The liberal state does have a standard response to this predicament. As Turner writes,

The religious sectarian is excluded by way of the concept of the neutrality of the liberal state; the domain of politics is delimited, by agreement, to preclude the state, as the First Amendment puts it, from establishing a religion. But literally 'establishing' religion and at the same time restricting it (on, for example, the model of the established churches of European states), can serve the same purpose of both separating religion from politics and assuring that the boundaries of the domain of the political are decided politically rather than by religious experts. (Turner 2013, 168)

Given this standard response, Type II experts are effectively eliminated as threats to liberalism, according to Turner.

The Type III expert is best represented by writers of self-help books or massage therapists. The audience which confers authority in this case is not the general public, but instead those who read the books or used the services and found them helpful. Writers of self-help books or massage therapists may not have the level of professional training or licensure that is commonplace in the case of the physicist but given that these authors have no claim on an authority derived from a general public, but rather just from their readership or those who found their therapy to be effective, this training is not necessary according to Turner. This type of expert also poses little threat to the liberal state because of the nature of the group conferring authority. Because the group has no significant ties other than a feeling that "X worked for me" and because their interaction with these experts take place as private individuals, usually through the means of consumption, nor is there any idea that only certain people have the epistemic resources to belong to the group bestowing the authority, the liberal state has no reason to interfere with this group of experts.

Type IV experts pose more of a difficulty. According to Turner, this group was created more recently, "at the end of the 19<sup>th</sup> century in the United States, and developed hand-in-hand with the development of philanthropic and charitable foundations" (Turner 2013, 169). These experts are "those who are subsidized to speak as experts and claim expertise in the hope that the views they advance will convince a wider public and thus impel them into some sort of political action or choice" (Turner 2013, 169). Turner takes as his

examples advocates for civil improvements such as city playgrounds and sewers or groups like the Sierra Club, who were not originally conferred authority by anyone, but devised methods, including the social survey, to depict their knowledge to those with means as generally authoritative expertise worthy of public attention. Turner writes,

Experts of the fourth kind, whose audience is the public, do not support themselves by persuading the public directly of the worthwhile character of their services or advice... but by persuading potential subsidizers of the importance of getting their message out to the public and accepted as legitimately expert...the purpose of the survey was not to advance knowledge but to demonstrate to the public how far below the standards their community was and thus, to spur it into action. (Turner 2013, 171)

However, in an attempt to leave the specific subsidizers out of the picture presented to the public, who might reject these “experts” as not neutral if their funding practices were completely transparent, Type IV experts attempt to project the neutrality and authority granted by a general population to a Type I expert. However, given liberalism’s experience in dealing with these kinds of non-neutrality, in both historical and contemporary examples, governments were able to exert pressure on Type IV experts to create separate and more disinterested boards to allocate funding, causing these experts to more closely resemble Type I experts. Thus, there is a strong precedent for the disarming of Type IV experts before they can represent a serious threat to the liberal state.

It is not clear that there is a hard difference between Type IV experts and Type V experts. Instead Type V seems to be a subset of Type IV. Turner writes, “The fifth type of expert is distinguished by a crucial difference in this triad: the fact that the primary audience is not the public, but the individuals with discretionary power, usually in bureaucracies” (Turner 2013, 172). The reason for this more specific subset of what in Type IV was an appeal to general subsidizers is the content of these experts’ expertise; it must be the kind of subject which is not in the purview of the general population. The example given by Turner is public administration. To be clear, the claim here is not that the general population, say, has a deep and nuanced knowledge of physics, but not about public administration, but instead that the public is aware of the efficacy of the outputs of physics, and is less aware of how public goods come to be, and even what successful public administration looks like. The

audience which confers authority on public administrators, according to Turner, is other professional public administrators, “who are not accepted as experts by the public (and ordinarily are not even known to the public)” (Turner 2013, 172). But what exactly makes these kinds of experts dangerous to liberalism? Turner writes, “In the case of the experts I have been discussing here, there is, in contrast, a discrepancy between the sectarian character of their audience and their role in relation to political authority. Since a great deal of political authority in modern democratic regimes resides in discretionary actions of bureaucrats, the control of the bureaucracy by a sect can amount to the denial of the original premises of liberal regimes” (Turner 2013, 174). In addition to the sort of difficulties Type IV experts present to liberalism, the obscurity of the subject in which Type V experts are experts and the in-group nature of the sect which confers authority upon them create the opportunity for extra difficulties for liberalism.

#### The Application of the Turner Account to EBM players

Now that the main structure of Turner’s account of expertise has been laid out, where within this structure would the main players in EBM fit in? What type of expert is your local practitioner? How about the industry sponsored biomedical researcher? What type is celebrity anti-vaccine activist Jenny McCarthy? An explanation of these players in the EBM world will provide additional insight into the possibility of the application of these principles developed by Turner for use in the historical example of public administration and civic activism to the medical world, specifically EBM.

Generally, an orthodox general practitioner can, I think, be best described in this account as a Type I expert. Of the offered type examples, in this case, the medical practitioner most closely resembles the physicist. While it is certainly true that the general public does not have a nuanced and complete knowledge of medicine, the public is aware of

the general efficacy of the outputs of medicine.<sup>32</sup> It is from this general audience that medicine derives its authority.

Especially lately, various kinds of alternatives to traditional western medicine have gained popularity. These include homeopathy, acupuncture, massage therapy, and chiropractic, among others. Because these alternatives often have underlying accounts of medicine which are at odds with those in play in EBM and because their practices are sometimes particularly difficult to test using RCTs, these practitioners are regarded as suspect by EBM supporters. But does this mean that they have a different expert status from traditional medical practitioners? EBM supporters might want to say they are not experts at all, because of the suspect nature of the fields in which they practice. However, in Turner's account of expertise, these sorts of practitioners would be categorized as Type III experts. Indeed, Turner uses the example of massage therapists to illustrate his conception of Type III experts. These other practitioners follow a similar model and are granted authority by a group of (otherwise unconnected) satisfied customers who testify that the unorthodox treatment in question works. According to Turner, the diffuse nature of the sect which supports Type III experts and the consumerist bent of the expert's interactions with this sect means that Type III experts pose little threat to liberalism. However, it seems likely that these groups may soon find it to their benefit to engage in political activism, attempting to convince a general audience of the benefits of their services.

Other important players in the EBM paradigm have different expert types. Given EBM's implications for decision-making about which research programmes to privilege and which to dismiss, the biomedical researcher is another relevant expert. Given that in the US almost 94% of biomedical researchers have financial ties to pharmaceutical companies

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<sup>32</sup> This is not to say that the public as a whole completely trusts medicine. Indeed, a significant portion of philosophy of medicine is dedicated to investigating (or in certain cases, encouraging) public distrust of medicine (Navin 2015; Stegenga forthcoming; Collins and Pinch 2005 and many others). Here I am thinking of the way in which medical technologies are often given as reasons for thinking that science more broadly is a successful endeavor, or the way in which people who work in health care are treated socially with additional deference and respect.

(Reiss 2010, 437; Campbell 2007, 1746), a typical biomedical researcher would be either a Type IV or V expert, depending on the extent to which governmental bureaucracy with explicit liberal commitments is also involved (for example the Food and Drug Administration or the National Institutes of Health in the United States). Given the large body of literature attempting to defend pharmaceutical company involvement in biomedical research, this classification remains controversial. It is not the case that *in itself* involvement with pharmaceutical companies necessitates this lower ranking of these experts. Rather, in this case pharmaceutical companies take on the role played by large philanthropic trusts like the Rockefeller Trust in Turner's original example. Because experts must appeal to this kind of subsidiary group, rather than creating their own persuaded sect of the general population, appealing to an already created sect of the population, or appealing to the public at large, they qualify for inclusion in the Type IV or possibly V group.

A last sort of expert who might be relevant to a discussion of EBM might be the celebrity activist. Where does someone like Jenny McCarthy, an entertainer famous for her claims that the Measles, Mumps, and Rubella vaccine caused her son's autism, fit in this schema? She has no medical or science degree and cites the debunked work of Andrew Wakefield as evidence of the proof of her claims. Surely, she is no kind of expert at all? In fact, on Turner's account, she fits quite nicely into the Type III expert category. Her authority is derived from a small sect of the general population who found her theories and advocacy compelling and propelled the issue into the national spotlight. While it is true that this relationship between Type III expert and her audience is less commercial than the other examples given, it does still seem to be the case that her audience has "bought" something and is pleased enough with their purchase to recommend that others buy in as well. None of these requirements for inclusion in the group Type III expert mean that we cannot consider McCarthy's role to be political as well. Turner writes of his paradigmatic Type III expert "...Dr. Ruth might run for the Senate, for example, or promote some political cause, such as sex education in elementary schools..." (Turner 2013, 168).

### What Problems Would the Turner Account Solve for EBM?

I stipulated that in order to be a satisfactory account of expertise for EBM an account should, in addition to not being in conflict with the main components of EBM, take a stand on the issue of expertise as internal or external, differentiate high quality from low quality expertise and consider how to produce high quality expertise.

The Turner account has little to say about other important components of the EBM literature, such as the viability of the particular EBM hierarchy of evidence, and so can reasonably be said to not be in conflict with the main components of EBM. This is less because of sustained agreement than because of a lack of topic overlap between these two literatures. The Turner account also does take a stand on the issue of taking expertise to be internal to evidence or external to evidence. On the Turner account, expertise is external to evidence. Expertise is, on the Turner account, something that is conferred on various individuals by various publics based on the trust those publics have in those individuals and in the technological interventions put forward by those individuals. Evidence does not play a role in this conception of expertise, making it easy for the Turner account to take a stand on this question: expertise is external to evidence.

However, given Turner's goals and topic, his account quite reasonably says very little about differentiating high quality expertise from low quality, or about developing pedagogical techniques for encouraging medical students to become high quality experts. This is because the Turner concept of expertise is set up to categorize expertise in terms of their threats to liberal democracy. Perhaps it might be possible to develop a set of public relations or rhetorical strategies for ensuring that the various relevant publics did indeed confer expert status on an individual who desired that outcome. However, the relational nature of expertise as described by Turner makes it difficult to see how such expertise could be conceived as high quality or low quality or could be taught. The Turner account is unable to provide a satisfactory answer to these expertise issues in EBM.

### Problems with the Integration of the Turner Account and EBM

The picture Turner paints of expertise, which is relational and conferred by social groups based on contingent power-circumstances and public perception, suggests that expertise is just the kind of thing EBM is right to be suspicious of. These suspicions are reflected in the early literature of EBM which is filled with stories of early EBM proponents pushing back against the socially-conferred authority of their instructors.

The Turner account, for all it can do in providing a typography of the major players in EBM in terms of expert types, fits very poorly with the Tripartite Model and the Amalgamation Model. It's not clear how Turner expertise could be used in concert with evidence and clinical circumstances in the case of the Tripartite Model or used to amalgamate evidence, clinical circumstances and patient values in the case of the Amalgamation Model. The Turner account leaves something to be desired, which may not be surprising, because it is developed to address socio-political concerns rather than the more immediate epistemic concerns that especially early EBM focuses on.

One might be tempted to say that the Turner account is of use to EBM in that it identifies a kind of expert, the Type I expert, that EBM practitioners should hope to become. However, even this would be a poor fit with the goals of EBM, because EBM seems likely to insist that the authority of their experts should not be conferred by the public (as occurs in the Turner account) or anyone else for that matter. Instead, expertise should be the result of something about the experts themselves- either their knowledge or experience or judgement, or something else. Stipulating that expertise comes from authority conferred by other persons, as Turner does for all his expert types, is not a good fit with EBM.

### Rejection of the Turner Account for EBM Expertise Augmentation

Though the Turner account provides an interesting genealogy of relationally conferred expertises which illuminates the nature of some traditional EBM players, my discussion points to its being a poor account with which to augment the current simplistic EBM account of expertise.

### The Bishop and Trout Account

In their book, *Epistemology and the Psychology of Human Judgement*, Michael Bishop and J. D. Trout put forward a very different account of expertise. While they are both trained in philosophy, the book also incorporates work from many other disciplines, including psychology, statistics and decision theory.

Explaining expertise is, as in the case in EBM, not the explicit goal in this work, but rather is a required step in their related argument. Their goal is to argue that psychology, specifically Ameliorative Psychology, can legitimately dispense normative advice on the basis of Statistical Prediction Rules (SPRs). This results in a new concept of epistemology, which they call Strategic Reliabilism, which “holds that epistemic excellence involves the efficient allocation of cognitive resources to robustly reliable reasoning strategies applied to significant problems” (Bishop and Trout 2004, 4). They embrace this goal because they think that epistemology, like ethics, should be used to call people to account when things go wrong in practical situations. Indeed, they claim that many issues which look to be ethical failures, such as opposition to “policies that would provide opportunities and services to the disadvantaged” (Bishop and Trout 2004, 6), are in reality failures of reason, failures that they say we currently lack robust tools for intensifying and condemning. They call an epistemology that could rise to this challenge, “deeply naturalistic” (Bishop and Trout 2004, 7).

What do they mean by a “deeply naturalistic” epistemology? Perhaps the distinction lies in what they take an epistemological theory to be doing. They write, “Traditional epistemological theory is supposed to account for or explain. Traditional epistemological theories aim to provide a theory that captures our considered epistemic judgements, in particular, our considered judgements about knowledge and justification. Our epistemological theory aims to uncover the normative assumptions of a branch of science” (Bishop and Trout 2004, 8). The Bishop and Trout worry about current mainstream epistemology is that epistemology assumes that most of our current epistemic judgements



*get things right*. Mainstream epistemology attempts to explain how all this good judgement making comes about. Bishop and Trout think this first assumption is terribly dangerous, especially given research into the prevalence of bias and heuristic use in psychology. They worry about the ways in which proposals in traditional epistemology are rejected by reference to the ways in which they conflict with intuitions. Bishop and Trout call this the conservatism of traditional epistemology.

Instead, they, “view epistemology as a branch of philosophy of science. From our perspective, epistemology begins with a branch of cognitive science that investigates good reasoning. It includes work in psychology, statistics, machine learning and Artificial Intelligence” (Bishop and Trout 2004, 11-12).

Bishop and Trout take their cues on the topic of expertise from the 1954 book by Paul Meehl, *Clinical Versus Statistical Prediction: A Theoretical Analysis and a Review of the Evidence*. They write, “Meehl reported on twenty experiments that showed that very simple prediction rules were more reliable predictors than human experts” (Bishop and Trout 2004, 12). This finding, they claim, has been repeated many times in this literature, and has resulted in “The Golden Rule for Predictive Modeling: When based on the same evidence, the predictions of SPRs are at least as reliable, and are typically more reliable, than the predictions of human experts” (Bishop and Trout 2004,12). Bishop and Trout support the robustness of this Golden Rule with reference to 10 different studies in which SPRs beat out expert prediction in a wide range of fields, including; psychology (predicting success of electroshock therapy, diagnosing patients as neurotic or psychotic, predicting progressive brain dysfunction, predicting the presence, location, and extent of brain damage, predicting violence), criminology (predicting recidivism), education (predicting academic success), banking (predicting default), medicine (predicting Sudden Infant Death Syndrome (SIDS)), and oenology (predicting the quality of Bordeaux wine).

Based on this impressive list, Bishop and Trout suggest that these findings have a normative force; when one of these good SPRs is available, *it should be used in place of*

*expertise*. When one is not available, predictive modelling may still have suggestions for augmenting or improving human reasoning in their place (Bishop and Trout 2004,15).

### What is Expertise for Bishop and Trout?

For Bishop and Trout, expertise is consistently used in their work as the control arm of experiments about the best ways to reason or make predictions. That is, their goal is not to articulate an account of expertise (like Dreyfus and Dreyfus did) or a kind of genealogy of expertise (like Turner did). Instead, experts play an important role in their work by being the bar that their SPR's need to clear in order to be considered successful. Experts are the other possible option for prediction making for Bishop and Trout. So, what makes these experts *experts* for Bishop and Trout? Generally, these control arms include individuals who do have professional credentials; terminal degrees and eminent status are both referenced in the studies that make up the Golden Rule of Predictive Modeling. But these experts are also supposed to be operating on "bare judgement." This seems to mean that they are assumed not to have had any information on the sort of methods for improving reasoning championed by Bishop and Trout.<sup>33</sup>

We learn more about what expertise is for Bishop and Trout in their Appendix, in which they respond to possible objections to their general account of epistemology. One of these concerns was about the possibility of the abuse of SPRs. In response they write,

We must compare the threat of the increased use of SPRs to the threat posed by expert judgement. Perhaps those who are suspicious of SPRs supposes that while expert judgement is inferior in accuracy, it is also less prone to abuse. But this is by no means obvious. As Robyn Dawes has pointed out many times, expert judgement is more mysterious, more covert and less available to public scrutiny than SPRs. (Bishop and Trout 2004, 176)

So, per Bishop and Trout, expertise is inferior in accuracy to SPRs and at least as, if not more, prone to abuse because of its mystery, covertness and lack of transparency. For Bishop and Trout, expertise is that which allows us to make predictions (for better or worse) without assistance from SPRs.

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### What Problems Would the Bishop and Trout Account Solve for EBM?

Bishop and Trout's account of expertise seems to be quite amenable to the needs of EBM. In order to be a satisfactory account of expertise for EBM an account should, in addition to not being in conflict with the main components of EBM, take a stand on the issue of expertise as internal or external, differentiate high quality from low quality expertise and consider how to produce high quality expertise.

The Bishop and Trout account of expertise is not the centre of their work, but rather a side effect of it; experts are the baseline against which more systematic and explicit tools for reasoning are measured. As such, this expertise is non-explicit and in principle not explainable, perhaps even mysterious. Experts on their account are largely identified through credentialing; perhaps in virtue of special degrees, awards, years in the field, or public and disciplinary recognition.

The Bishop and Trout account of expertise is not in conflict with many components of EBM. In fact, the goals of Bishop and Trout's larger epistemological project of naturalizing epistemology seem quite in line with EBM. This account does not use the language of comparing roles for expertise internal to evidence and external to evidence, but they do focus on a kind of internal role for expertise, in that their concept of expertise is always a type of evidence, a type against which other more systematic evidences are measured. For Bishop and Trout, there is not really a way to differentiate high quality from low quality expertise—all expertise is low quality reasoning for them, in that expertise is consistently beaten in the frequency of correct predictions by SPRs. However, Bishop and Trout do think that reasoners (including experts presumably) can improve their reasoning using many techniques uncovered by Ameliorative Psychology. Experts who benefit from these systematic improvements in reasoning could perhaps be said to have higher quality expertise and making use of these techniques could be considered pedagogy for producing good expertise. However, since Bishop and Trout seem, in using expertise as their consistent contrast class, to be committed to expertise as "bare" or "pure" judgement,

meaning that an expert who makes use of these improvement techniques is no longer acting solely out of expertise at all. With this in mind, it cannot be said that Bishop and Trout provide anything like pedagogical advice on how to produce high quality expertise, since on their account, such high-quality expertise does not exist.

Because we had hoped to find an account for use in EBM, and because one of the questions about expertise that remains to be answered in EBM is if expertise can be taught and if so how, it matters that this question does not even make very much sense to ask about in the Bishop and Trout account. Rather than providing suggestions regarding how to produce high-quality expertise, their project is a wholesale replacement of expertise with SPRs- that is, a kind of rule.

But even without fulfilling these last two requirements, it might seem as if we have reason to think the Bishop and Trout account of expertise would be a good fit to augment the current lack of explanation about expertise in EBM. Indeed, EBM's early placement of expertise at the bottom of the hierarchy of evidence could even be bolstered by the empirical work at play in the Bishop and Trout work. The use of the Bishop and Trout account of expertise could provide warrant for the normative claims made by EBM in the Pyramid Model. Why should health professionals be wary of relying on expertise? Because in decades worth of tests in a variety of fields, expertise consistently performs worse than SPRs.

#### Problems with the Integration of the Bishop and Trout Account and EBM

However, the Bishop and Trout account of expertise fits less well with expertise as expressed by EBM in the Tripartite Model and the Amalgamation Model. Recall that these models seek to include expertise in some larger practice, either as a component alongside evidence and clinical circumstance, or as a force for the amalgamation of evidence, patient preferences and values, and clinical circumstances. On the Bishop and Trout account, expertise is always a second-rate kind of evidence. On their account, if you have evidence from a more other source, especially an SPR, you would be wise to ignore the predictions of

experts. Thinking of expertise this way, it is hard to see any reason to want to include expertise in the larger process of EBM, either as a component or as an amalgamative force.

#### Rejection of the Bishop and Trout Account for EBM Expertise Augmentation

The Bishop and Trout account of expertise fits nicely with the way EBM presents expertise in the Pyramid Model but very poorly with the way it is presented in the Tripartite Model or the Amalgamation Model. It might remain possible to consider the Bishop and Trout account for use in EBM if we had good reason to think that most important or most representative model was the Pyramid Model. Indeed, given the continued popularity of the Pyramid Model as a symbol of EBM, this is tempting. However, because of the recent insistence on the Tripartite Model or the Amalgamation Model, the Bishop and Trout account is not a good fit with EBM.

#### Collins and Evans' Account

An additional possibly useful account of expertise for EBM to make use of in order to augment its own seemingly contradictory skeleton account of expertise is that put forward by Harry Collins and Robert Evans in their book *Rethinking Expertise* and elsewhere. While the reader at this point may despair of ever finding a useful account of expertise to assist with the lacuna in EBM, I will eventually argue that this account of expertise is the currently existing account which is best suited to assist EBM, although additional clarification of a very particular type from within EBM would be very helpful.

Unlike the Bishop and Trout project, which explored the topic of expertise only in the service of a larger project of reforming epistemology, the Collins and Evans account<sup>34</sup> is focused explicitly on expertise. They motivate their project through discussing a brief history of science in the late 20<sup>th</sup> century. In their telling, a series of technological mishaps and disasters as well as theoretical shifts such as the publication of Kuhn's non-progressive and

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<sup>34</sup> I will refer in this work to the "Collins and Evans account" of expertise. I will, however, also be referencing works in which Collins defends or extends the ideas in "Rethinking Expertise" either as a solo author or with additional co-authors who are not Evans. I will still call the account here the "Collins and Evans account" for simplicity and because of the unity of the ideas involved, while making more specific citation information available.

paradigm-based account of science undermined the previously privileged place of science in society. They write in their introduction, “In today’s world the scales upon which science is weighed sometimes tip to the point where ordinary people are said to have a more profound grasp on technology than do scientists. Our loss of confidence in experts and expertise seems poised to usher in an age of technological populism” (Collins and Evans 2007, 2). As a result, they propose that their book will be an analysis of experts, that is, “people who know what they are talking about,” with the normative goal of encouraging society to listen to these people and implement the interventions they suggest, even if science itself does not progress as straightforwardly or is not as truth conducive as we may have once thought.

They characterize their account as taking expertise to be “real and substantial” and, therefore, not “relational.” According to them, “relational approaches take expertise to be a matter of experts’ relations with others. The notion that expertise is only an “attribution”—the, often retrospective, assignment of a label—is an example of a relational theory (Collins and Evans 2007, 2). On this definition, both the Turner and the Bishop and Trout accounts of expertise are relational. Given that those accounts did not prove to be a good fit for the EBM problem we are looking to solve, that Collins and Evans are taking a new approach is possibly encouraging for their account.

Their rejection of the relational account does not entail a wholesale rejection of the notion that expertise is social, however. They make much of the social components of achieving expertise; that is, being involved in a community of current experts who pass on their knowledge. They sometimes cash this sociality out in terms of tacit knowledge, which they define as, “the deep understanding one can only gain through social immersion in groups who possess it” (Collins and Evans 2007, 6), or variously, “things you just know how to do without being able to explain the rules for how you do them” (Collins and Evans 2007, 13), or “an understanding of rules that cannot be expressed” (Collins and Evans 2007, 17). On their account, “individuals may or may not possess expertise independently of whether others think that they possess expertise” (Collins and Evans 2007, 3). This is in

contrast to accounts that rely on credentials (Bishop and Trout) or public conferral of authority (Turner) as the creators of expertise. They claim that taking this stance not only makes them realists about expertise, a bolder claim than that made in many accounts of expertise, but also means they avoid the problem of equating an expertise that is commonly possessed in a particular society with a lack of expertise. For example, while many people speak French at an expert level in France, the ubiquity of the skill does not mean it is not expertise. This places the Collins and Evans account, on this topic at least, in relative harmony with the Dreyfus account, which some have found baffling for including relatively common activities like driving a car as an expert skill.

### The Collins and Evans Periodic Table of Expertise

The Collins and Evans account of expertise centres around a “periodic table of expertises” which is, “a classification of the expertises that individuals might draw on when they make technical judgements” (Collins and Evans 2007, 11). This table includes *dispositions*, *specialist expertises*, *meta-expertises* and *meta-criteria*. This table is included in the Appendix. It is important to make a note about how this table is to be used. In contrast to the Dreyfus account, which was divided into stages through which a novice advanced to become an expert, this table is not a list of stages. Indeed, it is not even clearly a hierarchy given that distinctions in the complexity of the expertises listed advance on multiple axes. Instead it is better thought of as a concept map, creating a taxonomy of the different kinds of expertise and attempting to demonstrate various relations between them.

Dispositions are “personal qualities” such as linguistic fluency and analytic flair (Collins and Evans 2007, 13). They are divided into interactive abilities and reflective abilities (Collins and Evans 2007, 14). As they are neither novel nor particularly politically charged concepts, Collins and Evans spend little time explaining or defending them. They are included on the periodic table of expertise because of their important relation to interactional and contributory expertise (Collins and Evans 2007, 38-39).

Specialist expertise is divided into two more specific groups: first, *ubiquitous tacit knowledge expertises*, which include beer-mat knowledge, popular understanding and primary source knowledge, and second, *specialist tacit knowledge* which includes interactional expertise and contributory expertise. Because the concept of interactional expertise is especially novel in accounts of expertise, the authors defend this new category in the remainder of the book. I will discuss each of these kinds of expertise in turn.

First of the ubiquitous tacit knowledge expertise is so-called “beer mat expertise.” This category is named after the practice of printing trivia-style facts on beer mats for patrons to read in bars. When one has read facts on a beer mat, or has learned a list of rules for how to play a game like chess, in what sense is one an expert? Collins and Evans give the example of knowing the rule for moving the bishop in chess; “the bishop may move, only diagonally, any distance, backwards or forwards” (Collins and Evans 2007, 18). Someone who had read this information on a beer mat could then answer the trivia question, “In chess, what is the rule for moving the bishop?” However, the authors write, “Crucially, knowing the bishop’s move in that way does not imply that one knows much about what it might mean” (Collins and Evans 2007, 19). Knowledge that would allow you to successfully move the bishop would require all kinds of background information about relevant chess units of movement, turn taking, chess win conditions and that not all the bishops on the board are yours to move. Beer mat expertise, then, does not allow anyone to do anything more than answer directly relevant questions.

The next category of ubiquitous tacit knowledge expertise, more complex than beer mat knowledge, is “popular understanding.” While Collins and Evans do not specify the content of many other kinds of expertise, here they specify that they have in mind a particular content of the knowledge, that is science. Popular understanding can be obtained through mass-media and by reading popular books, or from talking to another person who does. This understanding makes more of claim on meaning than beer mat knowledge and permits some basic creative application and interpretation of the included knowledge. In



cases where the science is relatively settled, Collins and Evans claim that differences between popular knowledge and deeper kinds of scientific understanding are unproblematic, in that they will result in the same judgements and support the same policies. However, where the science is not settled, differences between popular understanding and deeper forms of expertise are the source of disputes which claim to pit expertise against democracy. Collins and Evans explain these difficulties by noting that in popular understanding, “distance lends enchantment” (Collins and Evans 2007, 20); that is, to those outside the science, things can seem clearer, less detailed and therefore less fraught and more certain than it may seem to those with expert knowledge of higher kinds.

The final category of ubiquitous tacit knowledge expertise is “primary source knowledge.” Primary source knowledge is a deeper kind of knowledge than beer mat knowledge or popular understanding and “comes with reading primary or quasi-primary literature” about a topic (Collins and Evans 2007, 22). However, it can be easy to overstate the depth of this knowledge because, “reading the primary literature is so hard and the material can be so technical, that it gives the impression that real technical mastery is being achieved. It may be that the feeling of confidence that comes with a master of the primary literature is a factor feeding into the folk wisdom view” (Collins and Evans 2007, 22). Part of the reason that Collins and Evans do not equate understanding of primary sources with higher kinds of expertise is because of their commitment to a social understanding of expertise. Without the knowledge and interaction of a group of experts, the possessor of primary source knowledge is liable to make poor inferences based on their reading of the primary literature, fail to detect disagreement or even outright fraud in the literature, apply knowledge from the primary literature to inappropriate situations or to fail to hold the grounding assumptions about what is so basic that it need not even be included in the primary literature.

After the final category of ubiquitous tacit knowledge, the authors turn to expertises which involve specialist tacit knowledge. Collins and Evans credit the work of philosophers

like Heidegger, Merleau-Ponty and Polanyi with a shift in the concept of expertise toward a kind of practicality; expertise as located in socially and culturally embedded practice, rather than in texts or minds (Collins and Evans 2007, 23). This practicality and social-embeddedness are what separate the expertises in the ubiquitous tacit knowledge group from the specialist tacit knowledge. The latter require immersion in a community while the former just require literacy. The authors identify two kinds of ubiquitous tacit knowledge: interactional expertise and contributory expertise. Although interactional expertise is to be considered the shallower form of expertise, Collins and Evans first briefly explain the more traditional contributory expertise. A more in-depth explanation of the novel concept of interactional expertise follows.

Collins and Evans write that contributory expertise, “enables those who have acquired it to contribute to the domain in which the expertise pertains: contributory experts have the ability to do things within the domain of expertise” and is “the traditional category of ability to perform a skilled practice” (Collins and Evans 2007, 24). Such a definition is in line with the emphasis on practicality in expertise identified above.

One problem with the Collins and Evans account might be that it includes as one of its components the Dreyfus account of expertise. The Collins and Evans section on contributory expertise is almost entirely explained in terms of the Dreyfus account. Recall that at the beginning of this chapter the Dreyfus account was ruled unable to do the work that the thin EBM account of expertise leaves undone because of serious differences between this account and EBM on the issues of rationalization, intuition and the calculative rationality account. If the Collins and Evans account contains within itself the Dreyfus account, then perhaps it too can be rejected on the same grounds the Dreyfus account was rejected. However, contributory expertise is only one of many kinds of expertise that Collins and Evans analyse. Indeed, they seem to take it to be rather uninteresting, spending only a few pages on it before moving on to their original contribution, interactional expertise. Although the Dreyfus and Collins and Evans accounts overlap, the Collins and Evans

account includes a great deal of additional material, material which may be helpful in doing the work for EBM we are looking to get done. For this reason, including a kind of expertise, contributory expertise, which is based on the Dreyfus account I have already rejected does not rule the Collins and Evans account out of consideration.

In addition, Collins and Evans do not take on the Dreyfus account wholesale. Indeed, they criticize the Dreyfus model for neglecting the social, writing, “A problem with the five stage model, even as a discussion of contributory expertise, is its individualistic nature” (Collins and Evans 2007, 26). As a result, their account of contributory expertise includes a further distinction between mimeomorphic actions and polymorphic actions. They write,

Mimeomorphic actions, however complex, and however hard to master, do not turn on social understanding and can, in principle, be reproduced by mimicking fixed behaviours—though sometimes these will be too complex in practice to be accomplished...On the other hand polymorphic actions, which do depend on social understanding, require that behavior fits changing social circumstances, and they cannot be mastered by machines, failing a way of making machines that fit as smoothly into social life as humans. (Collins and Evans 2007, 27)

They introduce this concept as a way of dealing with what they see as the lack of sociality in the Dreyfus account. However, the Heideggerian grounding that is at play in the Dreyfus account means that Dreyfus would in fact deny the possibility of mimeomorphic actions at all, because all actions performed by an agent are a result of the inescapable “thrown” nature of that agent. While they focus on this distinction in relation to contributory expertise, they note that it could perhaps be included as an additional dimension of distinction in all portions of the periodic table. The mimeomorphic/polymorphic distinction is more fully described and defended in the Collins and Kusch work, *The Shape of Actions: What Humans and Machines Can Do* (Collins and Kusch 1998).

In contrast, interactional expertise is, “expertise in the language of a specialism in the absence of expertise in its practice” (Collins and Evans 2007, 28). They argue that this type of expertise has been overlooked because of the way in which work on expertise focuses on the formal/informal dichotomies. Interactional expertise is neither fully formal, requiring that mastering a domain requires only the acquisition of propositional knowledge nor fully

informal, requiring full immersion in a form of life to achieve mastery. Since both theoretical critiques and failures with artificial intelligence suggest that the formal account is mistaken, the informal account has been assumed to be correct. This overlooks the possibility of interactional expertise, which does not make claims only about propositional knowledge, nor requires full social immersion. However, Collins and Evans do place interactional expertise closer to the informal than the formal because of its emphasis on being embedded in a social community. They make their claim about the nature of interactional expertise in a way which echoes the Turing test.<sup>35</sup> They argue that “the strong interactional hypothesis states that, in principle, the level of fluency in the language of a domain that can be attained by someone who is only an interactional expert is indistinguishable from that which can be attained by a full-blown contributory expert” (Collins and Evans 2007, 31). The original example they give of individuals who are likely to be interactional, but not contributory, experts are sociologists<sup>36</sup>, but we can also imagine philosophers, managers, journalists, and interdisciplinary workers of all kinds to be likely to be interactional experts (Collins and Evans 2007, 32). Sociologists of science are a particularly useful example, because it may be the case that in order to be a contributory expert in their own field they will also have to be an interactional expert in another field. For example, in order for Collins to do his work as a sociologist of physics, specifically working on the theory of amorphous semiconductors, he needed to know more about physics. His lack of expertise made it difficult to know what his subjects were talking about, and a great deal of time was wasted in his sociological interviews when his subjects attempted to explain the basics of their field to him and got little chance to say anything of substance. If he had instead been an interactional expert from the beginning, say Collins and Evans, these frustrating instructional sessions could have been replaced with real conversations.

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<sup>35</sup> The relationship between their strong claim of interactional expertise and the Turing test is more thoroughly discussed in chapter 4 of *Rethinking Expertise*.

<sup>36</sup> They do however want to leave open the possibility that sociologists can become contributory experts in a scientific field but note that without extensive additional training in the relevant field, this is very rare.

For Collins and Evans, the content of these conversations is an important marker that an agent has reached the level of interactional expertise. Hallmarks of a conversation between someone with interactional expertise and someone with contributory expertise include: the possibility that the interactional expert will explain a technical concept to the contributory expert, ask them a question which is surprising and new to them, and that the contributory expert will take seriously criticisms of the field levelled by the interactional expert. Additionally, both interlocutors will be able to enjoy and appreciate discipline-specific jokes. In short, the contributory expert should not be able to tell from the conversation that the interlocutor is an interactional expert and not in fact another contributory expert.

There are additional differences between interactional expertise and contributory expertise for Collins and Evans. One of these is pedagogical: they claim that contributory expertise is something that can be taught by contributory experts to create new contributory experts. Contributory experts might also teach in a different manner to produce new interactional experts, but interactional experts cannot teach interactional expertise to create new interactional experts. They write,

Contributory expertise—such as gravitational wave physics—can be taught to new recruits and is passed on from generation to generation by apprenticeship and socialization; someone who has the contributory expertise can pass it to someone who does not have it...It is not at all clear that interactional expertise, which, in practical fields, is always interactional in another expertise, can be passed from one person or generation to another (in the absence of contributory expertise). Interactional expertise in a specialism seems to be learned exclusively through interaction with communities who have contributory expertise in that specialism, not persons who have interactional expertise in that specialism. (Collins and Evans 2007, 35)

Collins and Evans do make a few claims about the relationships between these kinds of expertise. They claim their account of expertise is transitive, which here means, “If you possess one of the higher levels you will possess, at least in principle, all of the lower levels, but not vice versa” (Collins and Evans 2007, 36). The “in principle” hedge here allows for a few specific exceptions. The first is when expertise is latent, that is, not felt by the practitioner. The second is when those who we might otherwise take to have the top kind of

expertise, contributory expertise, actually only have second-hand knowledge of the primary literature, part of the third kind of expertise, primary source knowledge. The third exception is the possibility that, “specialists in general knowledge quizzes and the like could have a greater breadth of knowledge than a domain specialist” (Collins and Evans, 2007, 36).

In addition to being transitive, Collins and Evans also claim their kinds of expertise are unequally distributed. That is, as you go up the scale of Specialist Tacit Knowledge, fewer and fewer people will qualify as having that expertise (Collins and Evans 2007, 36-37).

### Meta-expertises and Meta-criteria

The Collins and Evans periodic table of expertises contains another section; meta-expertises and meta-criteria. Meta-expertises are, “expertises used to judge other expertises” (2007, 45). These include *external meta-expertise*, which does not require the acquisition of the expertise itself, and *internal meta-expertise*, which does involve “an acquaintance with the substance of the expertise being judged” (Collins and Evans 2007, 45).<sup>37</sup>

The most basic kind of external meta-expertise is ubiquitous discrimination. This is the kind of judgement which often uses social cues in order to determine “if someone knows what they are talking about,” not only in the scientific or other technical fields, but in navigating everyday life. Collins and Evans identify this kind of meta-expertise as what makes it possible for most citizens to avoid believing in conspiracy theories, such as the somewhat prevalent claim that the moon landing by NASA in 1969 was faked, and the press-circulated film of the event was created in the American desert. They write, “it is beyond the bounds of sociological credibility, even ordinary people’s sociological credibility, that the thousands of people involved in the Moon missions could all have been organized to lie so constantly and consistently; we know that if there were any possible credence to the story of

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<sup>37</sup> While Collins and Evans are here using the terms “internal” and “external” to make an important distinction in their account, this distinction does not map on to my “internal to evidence” and “external to evidence” distinctions about expertise itself.

the fake, the Russians, deeply involved in the cold war as they were, would have exploited the doubts—yet they did not” (Collins and Evans 2007, 47).

In a more scientific realm, external meta-expertise is claimed to be responsible for the public’s (or at least the parts of the public who are “reasonably literate members of Western Society”) eventual recognition of the failure of cold fusion. Collins and Evans claim that, “This knowledge has nothing to do with scientific competence. On the contrary, it was vital to ignore scientific credentials, and even track records of success, if a socially appropriate judgement was to be made” (Collins and Evans 2007, 47).

A second kind of external meta-expertise is local discrimination. According to Collins and Evans, this is the kind of expertise exhibited in Cumbrian sheep farmers, who had important information to share with the larger world after their pastures were contaminated by radioactive fallout. Brian Wynne’s work on this phenomenon in the 80’s and 90’s coined the term “lay expertise” to describe the knowledge of these Cumbrian sheep farmers, but Collins and Evans do not adopt this terminology. They claim that,

‘lay expertise’ was an unfortunate choice of term because of its potential to cause confusion. For example, the term has often been interpreted as meaning that laypeople possess specialist expertise [in virtue of being laypeople]. It would have been better if Wynne had talked of experts without formal qualifications. For example, the sheep farmers are not laypersons; they are experts in sheep farming who happen to have no paper qualifications. The sheep farmers have a specialist contributory expertise. (Collins and Evans 2007, 49)

In this chapter however, a different aspect of the sheep farmer case is salient. The farmers have local discrimination, a kind of meta-expertise, which allows them to make judgements about the veracity of statements from commercial and governmental officials about the safety status of their fields based on the source of the statements. This is meta-expertise in that the farmers are making judgements about whether or not they should take the authors of these statements to be legitimate experts. Collins and Evans write, “the farmers...had long experience of the nuclear industries pronouncements concerning radioactive contamination; they knew that these pronouncements could not be taken at face

value. An outsider with less experience of discussions of radioactive contamination in this particular social and geographical location, would not have been able to judge the pronouncements with such finesse” (Collins and Evans 2007, 49).

It is unclear how “local” this example is however. Surely more universal principles which suggest exercising scepticism about pronouncements from industries about issues which involve significant conflicts of interest would do this same work, without the sheep farmers expertise about the state of their pastures and the behaviour and health of their sheep. Nevertheless, it is surely the case that in some circumstances, if not this example situation, localized knowledge, not just social indoctrination, is needed in order to make judgements about expert claims, and that this kind of local discrimination is open not just to experts with paper qualifications, but to all of the public which is in a particular locality.

Both these kinds of external discrimination have the same kinds of difficulties and are not to be considered scientific. Because they do not involve any knowledge of the content at hand of the experts being judged, they must rely on non-technical and social cues to come to correct judgments. These kinds of external discrimination, “are very unreliable because of the temptation to read too much into stereotypical appearances and stereotyped behaviour. It was this tendency to read too much into appearance that was exploited by the ‘scientists in white coats’ who for many years, assumed, and were given licence to speak with authority on almost any subject” (Collins and Evans 2007, 51). So, while it is useful, perhaps especially in democratic societies, to discuss and make use of this kind of discrimination which is available to all, external discrimination cannot be relied upon.

The other kind of meta-expertise is internal discrimination; that is, judgements which are based on content knowledge in the field in question. Collins and Evans are quick to point out this does not cleanly map on to the group “credentialed experts” by looking at the well-known case study of AIDS activism, as reported by Epstein’s 1996 book, *Impure Science: AIDS, Activism and the Politics of Knowledge*.



AIDS activists formed pressure groups such as ACT UP (the AIDS Coalition to Unleash Power) which lobbied scientists, the Food and Drug Administration and pharmaceutical companies to change drug testing practices. This was in response to both the speed of the disease, and the serious restrictions placed on those with AIDS enrolled in randomized controlled trials, who were instructed not to undergo other interventions and were sometimes in placebo arms of the studies, thereby receiving no treatment. At first, these activists largely relied on their lived experience of the disease to make their case and were largely ignored by scientists. However, these activists educated themselves using the primary scientific literature on these issues to a very high standard and were able to make their voices heard via this technical expertise. Robert Gallo, co-discoverer of HIV and credentialed medical researcher, said of one of these activists “It’s frightening sometimes how much they know and how smart some of them are” (Epstein 1996, 338). The success of these groups suggests that credentialing and group membership are not by themselves satisfactory ways of sorting out who is an expert and who is not. Some other methods will be needed at the level of internal meta-expertise, given the prevalence of frauds and hoaxes and the high stakes that are often involved in making judgments about expertise. The three methods for making these judgements, separating experts from frauds, according to Collins and Evans, are credentials, track record and experience.

While Collins and Evans do include credentials as a possible way of differentiating experts and frauds because of the usual dependence on this method they highlight its flaws. Many areas in which we want to make judgements about expertise do not have credentialing systems. They write, “there are no credentials for fluency in one’s native language, nor for moral judgement, nor for political judgement...Above all, there are no credentials for experts such as the Cumbrian sheep farmers or the AIDS activists” (Collins and Evans 2007, 67).

Collins and Evans agree with philosopher Alvin Goldman that track record might be a better criterion for distinguishing expertise than credentialing (Goldman 2001). However, they worry that relying on track records will inappropriately exclude those who are working in

new fields, as well as examples like the Cumbrian sheep farmers and the AIDS activists, but who they wish to include as true experts.

But Collins and Evans have the most faith in their third criterion, experience, to demarcate experts and frauds. This is partly because of its inclusivity; it nicely allows in the Cumbrian sheep farmers and AIDS activists which the other two criteria rejected. However, it is not very clear what this experience consists in. They write, “We know from the outset that without experience within a technical domain, or experience at judging the products of a technical domain, there is no specialist expertise. Without the experience of doing science, talking to scientists, playing or listening to violin playing, or looking at and discussing bathroom tiling, the minimal standards for making judgements in these areas have not been met” (Collins and Evans 2007, 68). But this is all that they tell us about experience. What is this experience? It must not be expertise, since kinds of expertise are what they are attempting to describe, and it would be odd to use the concept you are trying to describe to do most of the work in the description. But experience must also be something besides repeated past successes at an action, because this would collapse into the separately discussed track record criterion. So, while Collins and Evans see the experience criterion as the most promising tool for making judgements about the expertise of others, it is not clear what this experience amounts to.<sup>38</sup>

#### What Problems Would the Collins and Evans Account Solve for EBM?

In order to be a satisfactory account of expertise for EBM an account should, in addition to not being in conflict with the main components of EBM, take a stand on the issue of expertise as internal or external, differentiate high quality from low quality expertise and consider how to produce high quality expertise.

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<sup>38</sup> There might be a worry here that the Collins and Evans account is unacceptably permissive. While wanting to broaden the definition of expert so that their examples of AIDS activists and sheep farmers can count as experts, they have unintentionally forced us to accept, say, astrologists as experts. They might respond that their first two criteria, credentials and track record of success will rule out astrologists, in that there are no respectable institutions from which a credential could be obtained in astrology, and no possibility of a track record of astrological success given that the happenings of human life are not impacted by particular planetary movements.

Collins and Evans investigate the question of how to produce high quality expertise when they distinguish interactional expertise from contributory expertise based on pedagogical possibilities. They claim that contributory experts must be the ones to teach novices who are interested in becoming contributory experts, but that interactional experts cannot teach interactional experts. Indeed, they write, “One would guess that, if the attempt were made to transmit interactional expertise in the absence of contributory expertise in the absence of contributory expertise over several generations, it would rapidly become distorted...” (Collins and Evans 2007, 35). This attention to matters of pedagogy in expertise is one reason to turn to the Collins and Evans account.

The Collins and Evans account of expertise might be especially useful for EBM because of its distinction between the two top levels of specialist tacit knowledge; interactional expertise and contributory expertise. EBM has long struggled with the question of how much individual responsibility for the production and assessment of research to place on the shoulders of individual practicing clinicians. In early EBM manuals like the 1992 Evidence-Based Medicine Working group article and *Evidence-Based Medicine: How to Practice and Teach It*, clinicians were expected to formulate a searchable question which would assist in their clinical problem, find the evidence related to that questions, assess the quality of that evidence and put the answer they found to work in their practice (EBMWQ 1992; Sackett 2000). While all four of these steps can be difficult without proper training and access to research resources, the third step, personally assessing the quality of the evidence available, came to be seen by clinicians as particularly taxing. In later works, this criterion was dropped, and clinicians were instead directed to sources of evidence which had been pre-assessed by experts (Guyatt and Djulbegovic 2017).

I am concerned about what this distinction might mean for expertise in EBM. If we once considered statistical knowledge, knowledge about the hierarchy of evidence, and knowledge about how to recognize a well-done trial a kind of expertise of EBM, we now seem to have two levels of experts. One level is made up of clinicians who need to be able

to talk about and put into practice knowledge about statistics, the hierarchy and well conducted trials, and one level is made up of researchers who need knowledge about statistics, the hierarchy and well-conducted trials in order to create the research that clinicians will use. This distinction between clinicians and researchers maps nicely onto the distinction between interactional and contributory experts in the Collins and Evans account. EBM has been characterized (perhaps unfairly) as a stick with which researchers beat clinicians into epistemic submission. Being able to account for the differences and yet the worthiness of the two groups' expertise may ease this tension. Although this was not one of the top listed items for a useful account of expertise to provide for EBM, this additional helpful piece of conceptual apparatus should count in Collins and Evans' favour.

Related to this, the Collins and Evans account provides a nuanced account of expertise both as internal and external to evidence. Expertise can be internal to evidence in that expertise provides a reason to act on a particular intervention and policy, and expertise can be external to evidence, in that it allows experts to do many additional kinds of activities (application, amalgamation, even joke-telling). The distinction discussed above allows for the possibility that expertise might be both internal and external to evidence and provides additional vocabulary for talking about these differences in kinds of expertise. Given the EBM confusion on this issue, an account of expertise which has the flexibility to talk about expertise in both ways is a real boon.

Another possible reason to take the Collins and Evans account as useful to supplement the EBM account of expertise is because of the methods that they use to determine who has interactional expertise. They claim that an agent has interactional expertise when, "the level of fluency in the language of a domain that can be attained by someone who is only an interactional expert is indistinguishable from that which can be attained by a full-blown contributory expert" (Collins and Evans 2007, 31). In order to ascertain who has interactional expertise, Collins and Evans ran a series of tests on experts in the field in which it seemed possible that Collins might be an interactional expert—in this

case gravitational wave physics. One of the authors, Collins, participated in this test because of the sociological work he had done over several years on this topic. They hypothesized that Collins was an interactional expert. Their hypothesis would be confirmed if an expert judge failed to choose the “real” contributory expert when offered the answers that Collins and the “real” contributory expert produced to a standard set of non-mathematical technical questions about current debates in the field when asked to identify the “true” expert. For their results they found that, “out of nine judges, two chose Collins as the gw [gravitational wave] physicist and seven were unsure...Collins then had demonstrated his interactional expertise according to the standards of the test” (Collins and Evans 2007, 107).

The use of these kinds of experiments that approximate as best as possible an RCT<sup>39</sup> might be another reason to take the Collins and Evans account seriously as a good fit for EBM. Not only are they not in conflict with EBM principles, they themselves seem to make use, as best they can given the content involved, of the kinds of methods that EBM champions. This is different from the way in which expertise was used as the control group in the Bishop and Trout case; there, providing an account of expertise was an accidental symptom of their goal of founding a new kind of epistemology, not a goal itself. This is not a feature of any other account of expertise here considered, and so might make this account especially appealing to EBM supporters.

#### Problems with the Integration of the Collins and Evans Account and EBM

However, a closer look at what seems to be methodology in the Collins and Evans account which is close to EBM might give us pause. The final arbiters of who counts as an expert are experts themselves. In addition, the interviews of these judging experts suggest a significant amount of inconsistency in the reasons they gave for thinking one set of answers rather than another belonged to an expert. One judging expert used a principle of fluidity to

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<sup>39</sup> The experiments that Collins and Evans design do not feature randomization (the R of RCT) because of the content they are testing. Unfortunately, it is not possible to randomize people before they begin their academic careers to become either experts in physics proper or sociologists with a high level of physics knowledge. Such restrictions might be seen to be similar to issues in public health in which it would be useful to be able to randomize individuals to smoke or not to smoke, but not ethical, and not respectful of individual choice.

decide between the sets of answers he was provided with; the expert was the one who had produced the answers which sounded the most casual and smooth, and the least like a textbook. He writes, “Set [P, not Collins] looked more like they had been answered by looking up a book. Set [Q, Collins] looked as if they came rapidly out of the mind” (Collins and Evans 2007, 107). Other experts attempting to make this distinction relied on another aspect of style: hastiness. “Collin’s style was preferred because his answers were shorter and thus bore the hallmarks of someone who was answering impatiently —this suggested a scientist to other scientists” (Collins and Evans 2007, 107). One expert chooses the Collins’ answers because they are casual and non-technical and another chooses them because they are short and impatient. These answers tell us something about what experts think other experts are like —experts are comfortable enough with the topic not to need to lay on the jargon too thickly, and they are very busy people, with little time to fill out a simplistic survey about their discipline in a thorough fashion. However, all of this has gotten rather far from the EBM methodology that was supposed to be a particular benefit of the Collins and Evans account, and might provide a reason to think that the indistinguishability criterion is dubious epistemically.

What looked to be quite close to an EBM approved methodology for determining membership in a particular kind of expertise instead is based in two of the concepts that EBM originally sought to de-emphasize. The experiments make use of the expertise, in that the “answer keys” are provided by expert judges. The experiments make use of mechanisms, in that these follow up interviews about how the judges came to their conclusions are taken to be explanations for their choices which do their explaining by identifying the components of these choices and then how those parts work together. If it is true that the Collins and Evans account has the kind of intuitions about empiricism that EBM has approved of in the past, it is also true that they make use of expertise and mechanisms, which EBM has de-emphasized in the past. This puts the Collins and Evans account of expertise on par with EBM- they have similar commitments to the creation of empirical

evidence, and find themselves, perhaps against their declared wishes, making use of expertise and mechanisms in order to create this evidence.

A possible problem for the Collins and Evans account's fit with EBM could be one of their exceptions to the transitivity they claim for their account. Recall that by calling the contributory part of their account transitive, they mean that if you have a higher kind of expertise, you will also have the lower kinds of expertise which come before it. They claim that one way in which their account isn't transitive, is that one could be a contributory expert and yet not have the knowledge of the primary sources, instead learning about the literature second-hand. This allowance is in conflict with the early EBM commitment to appraising evidence at an individual level as discussed in the above section on the usefulness of the interactional/contributory expertise distinction for EBM.

#### Acceptance of the Collins and Evans Account for EBM Expertise Augmentation

Because the Collins and Evans account does not conflict with the central components of EBM, takes a stand on the matter of expertise as internal or external to evidence, makes a distinction between high-quality and low-quality expertise, and provides suggestions about the kind of pedagogy needed to develop each kind of expertise, while also providing additional conceptual tools that are useful for EBM (like interactional/contributory expertise), I suggest that it is the most useful current account of evidence available in the literature. I recommend that those within the EBM literature consider making use of this conceptual resource to deepen and clarify their current account of the role(s) of expertise in EBM.

## Chapter 3: Mechanisms

### The “Scope Problem”

- The Russo-Williamson Thesis and its Critics

- But What Kind of Mechanism?

- Two Worries by a Critic

- The Strevens Account

- Practical applications: Nutrition in Bangladesh and Statins for Stroke

- An Objection and a Few Replies

### Medicine is Not a Science: The “Primacy of the Practical”

- Implications for EBM and mechanisms



### The “Scope Problem”

The current philosophical discussion about causes and mechanisms is diverse and robust. This literature includes debates regarding causal/non-causal explanations, the possibility of a causality without necessity, and mechanisms as instances of invariance (or at least constant conjunctions) (See Mumford and Anjum 2011, Cartwright 2009, Illiari et al. 2011 for a sample). However, the debate on the role of mechanisms in the philosophy of medicine is unique. Because the history of medicine is riddled with cases of what looks like the terrible (and deadly) consequences of poor mechanistic reasoning,<sup>40</sup> clinical medicine is currently characterized by an aversion to mechanistic approaches. In contrast, paradigms such as Evidence-Based Medicine (EBM) rely on large-scale studies of the efficacy of interventions, while attempting to avoid the additional concern with mechanisms which lie behind this efficacy.

In this chapter, I argue that in order for mechanisms to be given the important role for intervention selection that the Russo-Williamson thesis, (RWT)<sup>40</sup> affords them, additional theoretical work is needed. The RWT is, roughly, the claim that evidence from both mechanisms and probabilistic relations is needed to warrant causal claims. This work is needed to narrow the *scope* of mechanisms in response to concerns raised in EBM manuals and by RWT critics, who contend that mechanisms may be so large, that is, include so many components, when possible confounders are included that it is impossible to articulate them in a way that is useful for intervention decision-making. If all confounders are not accounted for, we will draw wrong, often very wrong, conclusions. In short: the worry is that what it takes to make a usable mechanistic claim that allows us to draw roughly reliable conclusions is just too demanding. This narrowed-scope can be provided by the Strevens account of *ceteris paribus* hedges (Strevens 2013), which allows for a formalization of mechanisms

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<sup>40</sup> These often-cited historical cases include bloodletting for any number of ailments, anti-arrhythmic drugs for myocardial infarction, and putting babies to sleep on their stomach in order to avoid SIDS. (Howick 2011) <sup>40</sup> The RWT is not at all the only thesis of its kind, with significant philosophical precursors, but given its uptake in current debate, I focus on it here.

which avoids traditional ‘Empty’ and ‘Boring’ accounts of dealing with possible confounders to leave us with more manageable “sized” mechanisms. Addressing the “size” of the mechanisms in question will help to bring RWT in line with concerns expressed by critics, but disagreements remain. One reason for these disagreements is a difference in the understanding of the relation of knowledge to the goals of medicine.

I develop this argument in four sections. First, I discuss the points of tension between medicine’s historical distrust of mechanisms and those who insist that mechanisms have an essential role to play in medicine, such as Russo and Williamson of the RWT. I argue that this tension stems from the assumed impossibility of understanding mechanisms in light of their immense scope. Second, I present the Strevens account of *ceteris paribus* hedges and argue that the “scope reducing” power of this account can help address concerns about the RWT. Third, I consider a possible objection to my modification of the RWT. Finally, I discuss what makes medicine not a science (or a science and an art) and how a clarification about the goals of medicine could also help to simplify the conceptual knots that surround the issue of mechanisms in medicine.

### The Russo-Williamson Thesis and its Critics

The RWT claims that mechanisms play a crucial role in medicine. Specifically, they argue that generally both probabilistic relations (the kind of evidence often produced by randomized controlled trials (RCTs)) and mechanisms are required for warranting claims about the results of a particular intervention. Both components are necessary because each compensates for the methodological weaknesses of the other (Russo and Williamson 2007). Probabilistic relations, they argue, can mistake correlation for causation. In Clarke et al.’s 2013 article, this is illustrated with the example of a RCT on remote, retroactive intercessory prayer to shorten the length of stay in hospital. While the RCT found a significant correlation between the two variables, mechanistic evidence can help us to suggest that “current science holds no place for any mechanisms that can explain the putative effect in terms of

the putative cause” (Clarke 2013).<sup>41</sup> This flaw, mistaking correlation for causation, can be combated by including mechanistic evidence, which does not have this weakness.

On the other hand, mechanistic knowledge cannot on its own warrant a causal claim because, “it may be the case that the purported cause, although prior to the effect and mechanistically connected to it, actually makes little or no difference to it” (Russo and Williamson 2007). Such cases parallel the famous storm-barometer case; although a falling barometer reading happens prior to a storm and is in some way mechanistically connected to it, the low barometer reading does not cause the storm (Lewis 1973). The authors illustrate this point with the claim, “smoking causes cancer.” Until information about probabilistic relations was provided, hypotheses like that of Fisher, who suggested that perhaps some common cause was responsible for both cancer and smoking, could not be ruled out. This problem can be addressed through the addition of probabilistic relations obtained through methods such as RCTs, because they do not have this methodological frailty.

In this way, Russo and Williamson argue that *only together* can probabilistic relations and mechanisms provide a reason for the adoption of particular medical interventions.<sup>42</sup> This thesis is in direct conflict with the presuppositions of the EBM movement, which privileges RCTs, systematic reviews or meta-analyses of RCTs. Rather than being required alongside evidence from RCTs, mechanisms are considered dangerous or are only allowed to play a role when no research of a “higher” methodological type in the hierarchy is available (EBMWG 1992; GRADE working group 2008). Russo and Williamson write, “We argue that the health sciences make causal claims on the basis of evidence *both* of physical mechanisms and of probabilistic dependencies. Consequently, an analysis of causality *solely* in terms of physical mechanisms or *solely* in terms of probabilistic relationships does not do

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<sup>41</sup> In his 2011 article, Howick argues that there are non-mechanistic reasons to doubt the outcome of the Leibovici RCT.

justice to the causal claims of these sciences” (2007).<sup>43</sup> Russo and Williamson do not argue for the superiority of one approach to the study of causality (as there are many), or for a general, indefinite pluralism about causal information. Rather, they argue only that causal claims in the health sciences should include a mechanistic component and a component that demonstrates a probabilistic relationship.

### But what kind of Mechanism?

It seems important to clarify what is meant by “mechanism” within the context of the RWT. At least in the 2007 article, the authors remain agnostic on this important issue, writing, “Exactly what constitutes such mechanisms will not concern us here—some view mechanisms to be processes transmitting conserved physical quantities; others claim that mechanisms are composed of chains of probabilistic or counterfactual dependencies, others that they are composed of chains of theoretical explanations” (Russo and Williamson 2007). Howick, in his critique, follows the lead of Russo and Williamson, saying, “A problem with exploring how mechanisms provide evidence is that ‘mechanism’ has recently been characterized in several ways...for present purposes these definitions are sufficiently similar. The heart (as a pump), the brain (as a ‘control center’), and the liver (as a detoxifying agent, among other things) are all mechanisms in the senses described above” (Howick 2011).

### Two Worries by a Critic

Given the RWT’s opposition to traditional historical narratives in medicine about the danger of relying on mechanistic reasoning, it is not surprising that the RWT has received strong resistance. While Howick has other worries with the RWT, including attempting to argue that access to resources like “the principle of total evidence” and assessments of RCT quality might eliminate any need for mechanisms, he does have two worries about

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<sup>43</sup> Emphasis original. In this passage, Russo and Williams are very comfortable talking about the production of causal claims in medicine. In another passage, they write “It is quite uncontroversial that the health sciences look for causes, namely causes of disease and for effective treatments.” I am not sure this is the case in medicine, although it may be true in other sciences. There is significant language in the medical literature to suggest that the discipline views looking for causes themselves as a vain and impractical goal, a goal which demonstrates a commitment to the satisfaction of curiosity above the production of interventions. However, pressing this point is outside the scope of this chapter.

mechanisms themselves—worries that he says are “overlooked” (Howick 2011b, 927). I argue that these two worries both stem from a concern with the “scope” or “size” of mechanisms.

The first problem, according to Howick, is that mechanisms are difficult to identify. He points to cases from the EBM historical literature on mechanisms to suggest that medicine has often been wrong about particular mechanisms, including “bloodletting, placing babies to sleep on their stomach, anti-arrhythmic drugs and many other[s]” (Howick 2011b, 934). Howick offers an explanation by example for these historical errors; even mechanisms we take to be basic, such as metabolism, which is important in all drug-based interactions, are very complex. In the example mechanism of metabolism, Howick emphasizes a complex diagram with 49 notes highlighting areas of the mechanism where we lack knowledge, as well as possible confounders to the system. He writes, “The partial ignorance about the metabolic mechanism means that we cannot be sure what mechanisms are eventually activated by any drug (or its metabolites) that have been swallowed. More generally, the complexity of the human body makes it difficult to identify all relevant mechanisms activated by an intervention” (Howick 2011b, 936).

The second problem for Howick is “that it is difficult to predict how mechanisms will behave under interventions” (Howick 2011, 936). Here Howick has in mind cases where a particular drug can either alleviate or aggravate a particular disorder, depending on additional mechanistic confounders in an individual patient or environment. He writes, “Smith et al. have listed many drugs that sometimes worsen the condition for which they are indicated. To name a few, antiepileptic drugs can both prevent and cause seizures, antidepressants can both ameliorate and worsen depressive symptoms, and antiarrhythmic drugs can cause arrhythmias (Howick 2013, 284).” He also emphasizes how mechanisms can impact each other, producing unexpected results such as cases in which mechanisms act as possible confounders for each other (Howick 2011, 936).

These two concerns—the difficulty of identifying mechanisms and the difficulty of predicting how mechanisms will behave under interventions—are related. The underlying worry here is that if mechanisms are large enough to account for the environmental changes that bring about these paradoxical effects, that is, ambitiously attempt to include information about all possible confounders, then they are so large that it is nearly impossible to have knowledge of all the relevant conditions, to fill in all the gaps. To capture all the relevant factors, mechanisms have to be so large as to be exceptionally unwieldy and perhaps impossible to fully describe. Even those who do think of mechanisms as providing important information for causality and explanation are aware of this problem. Craver writes, “Few if any mechanistic models provide ideally complete description of a mechanism. In fact, such descriptions would include so many potential factors that they would be unwieldy for the purposes of prediction and control and utterly unilluminating to human beings” (Craver 2006, 5). As a result, obtaining knowledge of mechanisms is an incredibly high epistemic bar—so high that other methods, even those that do not provide causal explanations, but also do not require so many epistemic (and economic) resources, are preferred. So, we seem to be at an impasse: mechanisms which are “large” enough in scope to be useful seem very difficult to have knowledge of. But what if there were a way to make reference to large and inclusive mechanisms, and to work on filling in as much information as was needed to make decisions about mechanisms, without needing complete knowledge of all the components to go forward? This kind of solution might be available in a slightly different literature: the literature on the non-vacuous use of *ceteris paribus* hedges in scientific laws.

### The Strevens Account

Based on this analysis of an important critique of the RWT, a large problem with mechanisms is their “size.” In his article, “*Ceteris Paribus* Hedges: Causal Voodoo That Works,” Strevens suggests a possible way to restrict mechanisms to a manageable “size.” A *ceteris paribus* hedge is a constraint clause, usually added to a law, which stipulates that the law holds “all else being equal.” Like Howick, many have worried about the “size” of *ceteris*

paribus hedges. Do we need to list all the components of the “all else” in order to say that we understand a process or to manipulate it? Is this exhaustive listing even possible? Can we avoid this problem without making the vacuous claim that there exists some set of conditions, all of which are possible confounders, that *ceteris paribus* hedges address? Strevens’ answer to these questions provides a way of constraining the size of mechanisms.<sup>44</sup>

Strevens allows us to move beyond two unemployable conceptions of what is going on in *ceteris paribus* hedges, which I call the “Empty” and the “Boring” accounts. His account manages to be both well-formulated and useful and, in so doing, avoids some of the traditional critiques of *ceteris paribus* hedges. His articulation points us to a conception of mechanism which is neither empty of specifics nor so expansive that it is impossible to describe.

In the Empty account, *ceteris paribus* hedges are expressed as follows:

If  $\Phi$ ,  $F \rightarrow G$

If conditions  $\Phi$  obtain,  $F$  brings about  $G$ .

Under this account, a *ceteris paribus* hedge is not even understandable as a functioning claim, since there is no attempt to describe the content of  $\Phi$ , without which this expression cannot have truth value. While this rendition matches what we often seem to mean when employing *ceteris paribus* hedges, it leaves much to be desired.

In the Boring account, *ceteris paribus* hedges are expressed as follows:

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<sup>44</sup> What I have in mind here is similar to “mechanism sketches” as discussed by Machamer, Darden and Craver 2000 and Craver 2006. These are mechanisms which are incomplete because of gaps of various kinds. These authors argue that these sketches can be useful for many purposes, though they are incomplete. Carver writes, “[Mechanism sketches] characterize some parts, activities and features of the mechanism’s organization, but it has gaps.” My version is somewhat different in that the content of the gaps in my manageable mechanisms are all confounders, rather than having gaps for a variety of unknown elements. In a recent conference talk, Darden presented a mechanism sketch she is currently working in a biological applications lab, which featured several black boxes for components the team did not yet fully understand. When asked when they could stop worrying about the black boxes, Darden laughed and said, “When the application works!” (Darden 2017).

$\Sigma\Phi(\text{If } \Phi, F \rightarrow G)$

There exists some set of conditions  $\Phi$ , such that if  $\Phi$  obtains, F brings about G.

This account has the benefit that *ceteris paribus* hedges state functioning claims. The replacement of the  $\Phi$  with  $\Sigma\Phi$  avoids the problem of the Empty account; it stipulates the existence of some set  $\Phi$ , but there is no requirement that  $\Phi$  be filled in with content before the statement can have truth value and count as a claim. Unfortunately, this work-around weakens the claim until it is Boring. Of course, there *is* some set of conditions for which, should they hold, F brings about G—any set of circumstances in which it does not fail that F brings about G.

The Boring account gives rise to one of the traditional concerns about *ceteris paribus* hedges, that they are vacuous (and therefore useless). All they really say is “F brings about G unless it doesn’t.” Merely stipulating that there *is* some set of circumstances provides little guidance to the prospective mechanism-user.

In contrast with these two accounts, Strevens offers an account that has content—*useful* content—without listing each individual component feature in the set of circumstances where F brings about G (which is not generally a practical possibility).

The Strevens account—“By way of the target mechanism M, the conditions Z and the property F bring about G”—can be formalized as follows:

If M, [(F+Z)→G]

If the mechanism M obtains, conditions Z and the property F bring about the result G. In restating *ceteris paribus* hedges in terms of mechanisms, Strevens avoids the problems of both the Empty and the Boring accounts. First, since there is no unspecified  $\Phi$ , an actual truth value bearing claim is made. Strevens supposes that the context and practices are sufficient to secure reference to the intended mechanism in the *ceteris paribus* hedges he addresses.



In contrast with the Empty account, on Strevens' account *ceteris paribus* hedges have content because in any concrete *ceteris paribus* hedge, M is filled in (if only implicitly) by a term that refers to a specific mechanism. Even though the identification of the mechanism is less specific than if it were identified by a list of the individual properties that make it up, we can still refer to the mechanism and, I argue, make use of the *ceteris paribus* hedge in predicting and making changes in the world. Additionally, the Strevens account is more interesting than the Boring account because *ceteris paribus* hedges do not turn out to be trivially true. That is, *ceteris paribus* hedges express something more than “F brings about G unless it doesn’t.” They could be false, because the intended mechanism does not give rise to the regularity described in the law, or they could be without truth value because M does not after all refer to any mechanism. So Strevens shows that mechanisms are the way that we can “make cp claims without delimitating cp conditions” (Strevens 2012). This saves us from having to give up on the project of uncovering laws because of the infinite length of conditions we would need to stipulate to be sure that those laws hold and prevents us from saying something vacuous about these conditions.

The usefulness of Strevens' formulation becomes even more apparent when employed in a simple mechanical situation. In Cartwright's traditional example, this is expressed in “toaster terms” as follows:<sup>45</sup>

In M [(F+Z)→G]

“In toasters, the pushing of a lever causes toast.” (Cartwright 2007)

Where the mechanism “toaster” picks out a relevant set of circumstances whereby pushing a lever causes toast, the mechanism portion identifies the relevant set of features

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<sup>45</sup> These kinds of “toaster examples” are not universally appreciated. Howick writes in his 2013 article, “Cartwright cites the example of a toaster’s mechanism. But mechanisms in the human body and social world, especially those that are pertinent to clinically relevant outcomes, are generally far more complex than toasters and other mechanical machines” (284). While this is possibly true, my list of possible confounders and intervening forces on toasters suggests that toasters can be pretty complex systems themselves. Toaster examples here are meant as models.

and their arrangement that gives rise to the regular association between pressing the lever and toasting.

However, the identification of a mechanism “toaster” does not contain all the possible reasons for there to fail to be toast when a lever is pushed. Confounders like electrical outages remain outside of the purview of the mechanism. This is why in Cartwright's rendition there is always some additional caveat on how M operates, like “properly shielded” or “without disturbance” (Cartwright 2007). So, just as Strevens posits, along with Cartwright and other mechanists, that there *are* mechanisms that give rise to the regularities reported in *ceteris paribus* hedges, they must also posit interfering conditions external to the mechanism that we can refer to even if we cannot list them one-by-one that must also be mentioned (if only implicitly) for the cp hedge to be true.

On Strevens' account, the conditions involved do not exist without specification, but are not included in the mechanism themselves. Not all confounders are to be considered part of the mechanism. This significantly shrinks the “size” of the mechanism to a much more manageable level.

#### Practical applications: Nutrition in Bangladesh and Statins for Stroke

Worries about the complications of listing all possible needed conditions for a given effect are especially salient in real world policy situations. Take, for example, the case of the Intensive Nutrition Programme (INP) developed in Tamil Nadu and exported for use in Bangladesh (Cartwright and Hardie 2012). The idea was to improve the quality of children's nutrition by providing mothers with nutrition education and additional funds for the children's food. While the program was declared to “work” in Tamil Nadu, it was a failure in its transplant environment of Bangladesh. While Hardie and Cartwright explain why the program “working” in Tamil Nadu should not have been taken as evidence that it would work elsewhere, here I want to focus on how the Strevens account can help us identify a manageable mechanism.

Of course, making a list of all the possible conditions that must be in place before the Tamil Nadu intervention might work in Bangladesh is too high a bar: there must be food; families; no interference with the transportation of food; no weather conditions that limit local agriculture; workers willing to provide the educational nutrition classes; no political or labor disputes that mean that such workers are unavailable, an accessible time and location for the classes, childcare for the classes...we could go on indefinitely. This is not a practical way to delineate a mechanism.

However, the Boring and the Empty accounts would not help us either. The statement:

“If all the right conditions are in place, then the INP will bring about improvements in children’s nutrition.”

a version of the Empty account of *ceteris paribus* hedges:

If  $\Phi$ ,  $F \rightarrow G$

If conditions  $\Phi$  obtain, F brings about G.

does not tell us what we need to know. Because it does not fill in the content of  $\Phi$ , this statement does not even have truth-value. This will not help us to identify relevant causal factors differentiating Bangladesh from Tamil Nadu.

The Boring account is also unhelpful;

“There exists some set of conditions  $\Phi$ , such that if  $\Phi$  obtains, the INP brings about improvements in children’s nutrition.”

A version of the Boring account of *ceteris paribus* hedges:

$\Sigma\Phi(\text{If } \Phi, F \rightarrow G)$

There exists some set of conditions  $\Phi$ , such that if  $\Phi$  obtains, F brings about G.

does not do anything more useful than the empty account. In so far as it only stipulates the existence of some set of conditions, it avoids lacking truth-value, but instead begins the circularity we have been trying to avoid: “The INP causes improvements in children’s nutrition, unless it doesn’t.” This does not allow us to express what happened in the case of the INP.

But the Strevens’ account does allow us to express what happened, in that it allows us to point to a mechanism, or a coherent group of interrelated causes—one that is more than a stipulation of the existence of some relevant causes and less than an exhaustive list of all the causes involved. In this case, the relevant mechanism is family structure; in Tamil Nadu, the mother ran the household, had access to money and made food shopping decisions. In Bangladesh this position was filled by the mother-in-law. Since the mother-in-law might privilege the well-being of different members of the family and was not the family member sent to the nutrition education workshops, the mother’s education about pediatric nutrition did not translate into improved nutrition for her children (Cartwright and Hardie 2012).

For a brief medical example, consider the construction of a manageable mechanism for the use of statins to treat stroke. Statins are a widely proscribed class of drugs used to treat a variety of cardiovascular diseases. However, a 2011 Cochrane review found that there was not yet enough evidence to show if statins are effective in treating stroke (Squizzato 2011). When considering a possible manageable mechanism for the treatment of stroke with statins, what do we need to consider? Howick’s critique would have us include a broad range of possible confounders (perhaps all of them if we could). This broad range might include not only metabolization, but also patient non-compliance and interactions with diet and exercise (which might also be prescribed for a variety of cardiovascular diseases, including for stroke prevention). While we need to take care to include some relevant confounders (perhaps a difference between ischemic and hemorrhagic strokes), including all possible confounders makes a mechanism too large to be manageable.

### An Objection and a few Replies

Perhaps the most serious objection to my augmentation of RWT has to do with one of the most widely accepted uses for mechanisms: generalizability. It has been argued that one of the most important things mechanisms can do for us is provide information about whether “what worked there, will work here (Clarke 2013; Russo and Williamson 2007; Bennetti 2012; Illari 2011. Reiss 2007 also considers the question but concludes that a plurality of methods might result in generalizable explanations).”

Arguing that mechanisms provide generalizability is outside the scope of this work. For my purposes, it is enough to show that it is often taken to be an important ability of mechanisms. My augmentation of the RWT with a Strevens style account of mechanisms weakens mechanisms’ ability to do the work of generalizing.

This augmentation constrains the content of mechanisms to stipulate that they need not contain all possible confounders. This allows knowledge of mechanisms to become less daunting and narrows the content of mechanisms to a manageable size. However, this manageability comes with a trade-off; confidence about generalizability. When mechanisms were larger and unwieldy we could be reasonably certain that they would contain the information needed to confidently make generalizability claims; since all information about possible confounders was (ideally) contained within these expansive mechanisms, they were all that were required to make strong generalizability claims. However, the augmented RWT does not have this character. Because not all confounders are included within the mechanism, more information than just a mechanism, so defined, will be required in order to make confident claims about generalizability. By narrowing mechanisms in order to bring them within our epistemic reach, I have lost some of the power mechanisms are said to have for generalizability.

There are several possible responses here. One would be to say that making confident claims about generalizability will require more than just mechanisms—it will require

a “tangle” of evidence of all kinds (Cartwright 2013). However, this answer would mean significant modification to the RWT, which claims that mechanisms and knowledge of probabilistic relations are all that is required and say little about other forms of evidence reinforcing claims about generalizability.

Another possible response might be to admit that my augmentation does mean some loss of the power of mechanisms to generalize, but that is not all that mechanisms can do. They can also provide explanations, justify pursuit and suggest hypotheses. They can do all of this better while they are epistemically possible and manageable, that is, without including all possible confounders.

I have argued that one reason for the lack of uptake of mechanisms in medicine is uncertainty about the “size” of mechanisms; if they are large enough to include all confounders, then they are likely too large to ever successfully know. I follow Strevens in suggesting that mechanisms need not include all confounders, which reduces them to a manageable epistemic “size.” However, with this manageability comes a trade off in generalizability, which may be a particular problem for the RWT as currently formulated.

#### Medicine is not a Science: the “Primacy of the Practical”

It is not surprising that the role of mechanisms and causality in medicine should be fraught territory. This is because clarifying this role requires a particular understanding of what medicine itself is, an understanding that is not captured by declaring that medicine is both an art and a science. In what follows, I argue that attempts which use this dichotomy to explain the nature of medicine neglect what I call the “primacy of the practical.” That is, what is foundational in medicine is helping patients to be well (See Gilewski 2001 for good example of a clinical view on this “helping”).<sup>46</sup> Yes, this will have an epistemological

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<sup>46</sup> Cashing this out in practice would be much easier if we could agree on crucial definitions of concepts like “health,” “disease,” and “well-being,” either in naturalistic (for example: Boorse 1977;1997) or normative (for example: Kingma 2010; Nordenfelt 2007) terms. These definition projects have proved notoriously difficult for the philosophy of medicine to answer and are some of the field’s most important questions. They are not, however the subject of this work. For my purposes, it is enough to say that the goals of medicine are practical,

component in order to be successful, but unlike in other sciences, this epistemological component is not foundational, but a mere means to an end. There is a tension in medicine because of this biological, biochemical, anatomical, epidemiological and many other kinds of knowledge are necessary for its success, but the use of this knowledge to help patients is the true goal. Efforts to gain knowledge must always be explained and justified in terms of these practical aims. Perhaps science is interested in discovering true things, (or true-enough things (Elgin 2004)) about the world through making causal claims, but that is not the main goal of medicine.

This tension is evident in the EBM literature, where bench scientists or clinician researchers are accused of inappropriately abstract interests in. John Ioannidis cites Sackett as expressing the problem well, “The issue is that basic medical scientists have hijacked the granting bodies and have erected their own research policies that place greater value in serving their own intellectual curiosities than in serving sick people” (Sackett 2004). That is, knowledge gained for its own sake is treated with suspicion, the suspicion that that kind of medical researcher has lost sight of the goal of medicine: helping patients.

Of course, other sciences have applications that can help (or harm) people. And sometimes science is done specifically with these applications in mind. The lucrative nature of the applications of science are part of the reason for its success. However, medicine is not quite a science, because unlike science, where the desire for knowledge leads and useful applications sometimes follow, the goal of medicine just is these useful applications that help sick people, and knowledge through understanding causes sometimes follows and feeds into future development of applications.

Sometimes the strange status of medicine as not exactly a science is cashed out by saying that medicine is both an art and a science (Battista et al. 1995; Gilewski 2001;

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to do with improving “health, mitigating “disease,” and supporting “well-being.” Since we don’t know exactly what those terms mean, it is true that we can’t be too clear about what exactly this requires, but we can say that medicine is foundationally practical, not epistemological.

Saunders 2000; many others). The additional component “art” is meant to explain why medicine isn’t exactly a science. It has other requirements of its practitioners that they must learn in order to say that they practice medicine. These might include “rules of thumb” (Gilewski 2001, 20), “rapport” (DiMatteo 1979, 12), and “sympathetic understanding” (Peabody 1927/2015). While this addition of “art” can help explain the practices and the pedagogy involved in medicine, it does not get at what makes medicine different from science, since this is not about either practice or pedagogy, but about goals and motivations.

### Medicine is Not a Science: Implications for EBM and Mechanisms

How is this cashed out in the debate on mechanisms? From the very beginning, Russo, Williamson, Illari and Clarke and others<sup>47</sup> in the pro-mechanisms camp take what medicine to be up to is finding the causes of illness. They take the goal of medicine to be an epistemological goal (improving knowledge) which then has very important practical implications (helping people to be well). We can see this in their statements of what they take EBM to be doing. They write:

“Evidence-based medicine (EBM) makes use of explicit procedures for grading evidence for causal claims. Normally, these procedures categorise evidence of correlation produced by statistical trials as better evidence for a causal claim than evidence of mechanisms produced by other methods” (Clarke et al. 2014, abstract).

“According to current hierarchies of evidence for EBM, evidence of correlation (e.g., from RCTs) is always more important than evidence of mechanisms when evaluating and establishing causal claims” (Clarke et al. 2013, abstract).

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<sup>47</sup> Here I write as if Russo, Williamson, Illari, Clarke and others always act as a unified group with a consistent view. This is not the case, although they do often co-author work together and are active members of the EBM+ research group (which, fair disclosure, I am also a part of). I do believe it is fair to claim that they all hold this “epistemology first” concept of medicine based on the literature they have produced.



“In this article, I will be examining mechanistic evidence and I will say comparatively little about any other kind of evidence. But I do not believe that mechanistic evidence can replace good difference-making evidence, such as that gained from well-conducted RCTs. My aim, along with Russo and Williamson, is to examine how good mechanistic evidence can complement good difference-making evidence in establishing causal claims” (Illari, 2011, 140).

“We argue that the health sciences make causal claims on the basis of evidence both of physical mechanisms, and of probabilistic dependencies” (Russo and Williamson 2007).

All of this assumes that the goal of EBM, (a kind of medicine) is *making causal claims*, an epistemic goal. This gets things the wrong way around from the very beginning. It is true that causal claims are often made in medicine- I am not disputing that. But this is not the *goal* of medicine as discussed above.

While it is clear from the previous section that I am sympathetic to the goals of the Russo-Williamson project to reintegrate mechanisms and kinds of causal reasoning, I think this lack of agreement about the goals of medicine is another obstacle to this reintegration. If you think that making causal claims is the goal of medicine, as it might be in some sciences, then it will be very clear why EBM should talk about mechanisms. Mechanisms improve our knowledge about what is going on in our interventions. If you think that improving patients' health is the goal of medicine, mechanisms can still help, but their role is less clear and less fundamental. Epistemic goals about improving our knowledge of interventions can serve the goal of improving patient health, but it is no longer a goal in itself, and may seem like a luxury, given that it does not always contribute to improving patient health.

It might seem that EBM is also “epistemology first.” After all, especially in the classical texts of EBM, all the focus is on which methodologies lead to trustworthy evidence. But this discounts the fact that, right from the beginning, EBM emphasized techniques for

accessing this evidence so that it could be brought to bear on practice. While it is true that EBM didn't always give the best advice about how to apply population-based evidence to patients, the patients were always the goal. In EBM, epistemology is (sometimes clumsily) in service to patient outcomes, not an end in itself.

## Chapter 4: Values

### Introduction

#### Early EBM Accounts of Values

##### Critiques of Early EBM Accounts of Values

#### Values-Based Practice Account of Values

##### VBP Case Study: The Artist's Need to "See" Color

##### Problems with the VBP Account of Values

##### Possible Improvements to Values in VBP

#### What Can We Learn About EBM Values from GOBSAT?

##### GOBSAT as a Charge of Exclusion and Rationalism

##### Implicit Values in EBM

#### Values that Fit: Guidance for Adopting Values in Science

##### A Critique of Universal Illegitimate/Legitimate Distinctions

##### A Proposal for Guidelines: Locality, Context-Dependency and Transparency

##### A Note on "Adoption"

##### Case Study: Statins for Stroke

##### Objections and Replies

#### "Fact-Based Values": Why the Fact/Value Dichotomy Plays Too Large of a Role in

#### Critiques of "Evidence-Based Ethics"

##### A History of Evidence-Based Ethics: Roots in EBM

##### Origins of the Fact/Value Distinction in Hume

##### Analysis of Goldenberg's Critique

##### Two Strategies for Problematizing the Fact/Value Distinction

##### Putnam on Thick concepts

##### Historical Case Studies in Philosophy of Science

##### Douglas Case Study: Rat Liver Slides in Dioxin Cancer Studies

#### New Developments in Values in EBM

## Introduction

In this chapter, I trace the ways in which values have played important roles in EBM. Early in the movement's history values were not emphasized at all, as the emphasis was on the creation and defence of a hierarchy of evidence. Later models of EBM did include a discussion of values, but only as patient values, one of many factors which are to be taken into consideration in the EBM clinical encounter. Partly in response to this, Bill Fulford created a parallel movement, Values-Based Practice (VBP) in order to take into consideration, not just patient values, but the values held by all participants in the clinical encounter—clinicians, social workers, carers, and family members. While VBP has some theoretical difficulties, it remains an important improvement over EBM's early account of values.

However, neither EBM nor VBP address a different role for values; values which are not held by particular individuals interacting with EBM, but instead are in evidence in the movement itself. EBM does not discuss these values explicitly. I argue that we can learn something about what these values are in other ways, like the oft-repeated GOBSAT joke. Because these values are implicit, EBM proponents do not have the opportunity to reflect on these values and perhaps attempt to modify them. To this end, I argue for a set of guidelines for adopting values which avoid the problems of wishful thinking and relativism, along the way critiquing previous attempts to provide these guidelines and defending my system from a series of objections. While these guidelines can go far in emphasizing the way in which facts and values work together in scientific projects, the traditional fact/value distinction is still made use of.

One such use is in criticizing a new trend called Evidence-Based Ethics. While I agree that the trend is in need of critique, I argue that using a sharp distinction between facts and values as a tool for disciplinary demarcation is a flawed way of going about this critique. Finally, I examine very recent work by EBM proponents on the importance of values for their project. While this work suggests that the movement has come a long way in its thinking on

values since 1992, there remain areas in which my suggested guidelines for value adoption, and the philosophical values in science literature writ large, can be of help.

### EBM's early accounts of values

Early EBM had little to say about patient values as the priority of the movement was on providing the best evidence, as illustrated in the hierarchy, for use in the clinic. At this early stage EBM, “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” (The EBMWG 1992, 2420). Creating a systematic way of ranking and using evidence was the most important goal of the movement at this early stage.

Later models of EBM sought to integrate values.<sup>48</sup> While it is difficult to say exactly what brought on this sea change in the role for values in EBM, the timing of this change corresponds with several other movements. These include the rise of patient-centered care and other forms of patient activism and values-based practice. Given this background, the expansion of EBM to deal with the role of patient values in the clinical encounter is not surprising.

Once the EBM movement accepted this larger role for values, they envisioned a three (or in some accounts four) part system.<sup>49</sup> The three components are the much-discussed pyramid of evidence, with meta-analysis of RCTs at the top, balanced with clinical expertise and the patient's values and preferences (Sackett et al. 1996). The 4-part version includes the evidence pyramid, patient values and preferences, and the clinical situation (climate, socio-economic situation, transportation, availability of space) with clinical judgement as a fourth part, the glue that holds it all together (Haynes et al. 2002). In either

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<sup>48</sup> See the brief history in Chapter 1 for a more in-depth discussion of these texts.

<sup>49</sup> These models are additionally discussed in the sections, “the Tripartite Model” and “The Amalgamation Model” of chapter 2.

case, the patient's values are to be taken into consideration. Indeed, according to these models, we can infer that they are to be given as much weight as the evidence.

### Critiques of Early EBM Accounts of Values

There are multiple lines of critique that could be deployed against these early EBM accounts of values. In this section, I focus on three important uncertainties left open by these early accounts. First, how should these patient values be ascertained? EBM seems to point in two very different directions on this, sometimes suggesting that patient values should be gleaned from social science work on what subgroups of patients value on average and then applied to particular patients, other times suggesting that speaking with individual patients is necessary for fulfilling this portion of EBM. Secondly, it is not clear if this set up, in which patient values are a separate category from evidence, clinician expertise and clinical circumstance, entails that there are no values at work in evidence, clinician expertise and clinical circumstance. Finally, by emphasizing that it is patient's values which are to be taken into consideration, does EBM mean to privilege patient values above the values of other stakeholders, like clinicians and carers, or to claim that clinicians should attempt to be value-free, to avoid having any values which will affect the clinical encounter at all?

The source of these integrated values in EBM is unclear. One popular handbook for the use of EBM suggests that information about patient values should come from the work of social science. In this case, average patient values should be determined based on survey data from a particular population, and then applying average data to particular patients, mirroring the EBM process for finding and applying the best evidence. The authors write,

Linking treatment options with outcomes is largely a question of fact and a matter of science. Assigning preferences to outcomes is a matter of values...Clinicians should look for information about who was involved in assigning values to outcomes or who, by influencing recommendations, was implicitly involved in assigning values. Such expert panels may be subject to intellectual, territorial and financial biases...Clinicians using a decision analysis will not face the huge problem of implicit and hidden value judgments that affect practice guidelines. The reason...is that decision analysis requires explicit and quantitative specification of values. These values, expressed as utilities, represent measurements of the value to the decision maker of the various outcomes of the decision...*For analyses built to inform clinical policy, credible ratings could come from 3 sources. First, they may come from direct measurements from a large group of patients with the disorder in question...Second*

*ratings may come from other published studies of quality of life judgments by such patients...Third, they may come from ratings made by an equally large group of people representing the general public. (Guyatt et al. 2015, 15)<sup>50</sup>*

Criticism of this way of looking at patient values does not come, as some might think, only from ethicists or philosophers. EBM supporter Greenhalgh is sharply critical of this type of account of values, writing, “Perhaps the most powerful criticism of EBM is that, if misapplied, it dismisses the patient’s own perspective on their illness in favour of an average effect on a population sample, or a column of QALYs calculated by a medical statistician (Greenhalgh 2010, 12).” For Greenhalgh, the authors of the *Users’ Guide* go too far in their attempts to avoid bias and end up ignoring individual patient values in favour of data about values in populations.

It is not the case that EBM is consistently interested in values as discovered by large population studies. In the same influential handbook, the authors write, “The *preferences* or *values* that determine the correct choice when weighing benefit and risk are those of the individual patient. Great uncertainty about how best to communicate information to patients and how to incorporate their values into clinical decision making remains. Vigorous investigation of this frontier of evidence-based medicine is, however, underway” (Guyatt et al. 2015). The authors do not cite any additional research here which would tell us which methods of value incorporation EBM finds to be at least most promising. However, even this short paragraph conveys a very different message than seen elsewhere in the book. Here the emphasis is on communicating with an individual patient (as difficult and unstructured as that might be) in order to determine and integrate the individual patient’s values. This is in contrast to the earlier passage which suggests that “integrating patient’s values” might not require communication with any specific patient, but rather knowing what social science has told us about what large populations of people similar to the patient in question tend to value. Even within one prominent text it is unclear what kind of stance EBM has on values; are they

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<sup>50</sup> Emphasis mine.

individual and require communicating with the patient, or are they derivable from population data?

This is not an argument to avoid this kind of social science investigation into patient preferences. Social science work on these topics can be incredibly helpful in policy-making and hospital administration, when decisions are made about which resources to invest in for patient use. Given these uses for this work, the critique that information about patient preferences should be gathered from individual patients should not be taken as a criticism of doing this work at the population level at all, but a worry about using these average calculations of patient values as stand-ins for a particular patient's values.

In both preference-inclusive accounts of EBM, values are a separate sphere, a separate component. Labelling a portion of the movement "patient values" suggests that the other spheres, the hierarchy of evidence and the clinical situation, have no relevant values to consider or investigate. This eliminates the need to consider possible values in play within the hierarchy itself, a problematic simplification. These possible values may include preferences for quantification, preferences for the testing of interventions which are easily compared or for which we have a useful placebo, and certain kinds of scientism and reductionism.

In addition, in these models of EBM only patients are supposed to have values which require consideration. It could be argued that because of the trend towards patient-centred care, patient values are the only ones we care about. But additionally, portraying patients as the only ones with values that need considering reinforces the image of clinician as morally neutral scientist, an image that is difficult to uphold. These three reasons, that it is unclear where EBM intends to gather information about patient values, that values are structurally separated from the evidence and patients are the only people supposed to have values worth considering, make clear that EBM's inclusion of patient values leaves something to be desired.



### Value Based Practice Account of Values

Value Based Practice (VBP) was part of a series of movements in medicine in response to EBM. VBP was developed by Bill Fulford in the field of psychiatry before being generalized to all health professions. VBP was to be a “new partner’ for evidence-based practice” (Fulford 2008,10). VBP “offers a new and primarily skills-based approach to working with complex and conflicting values in medicine” (Fulford 2008,13). A main component of this ‘new partner’ is the expectation that in addition to a standard history, clinicians working in the mode of VBP also take a systematic account of the patient’s values.

In this account values are “preferences, needs, hopes, [and] expectations” (Fulford 2008, 10). According to VBP, many conflicts in medical decision making have their root in unexplored differences in values. Since it is not only patients who have conflict-causing values, the values of other stakeholders including healthcare professionals, social care workers, family and carers are also to be taken into consideration.

VBP is also unique in the extent to which it is willing to take values as difference making components in decision making. It might be clear that it helps to know about the patient’s values in order to communicate effectively with patients; knowing what news to break gently or the best way to frame choices.<sup>51</sup> VBP goes farther than this. In VBP, values not only impact how a clinician communicates with a patient but may change which intervention is chosen. This is clear in Fulford’s case study involving an artist, which is discussed at length in the next section. This possibility of intervention change suggests that VBP is not interested in learning about patient values for merely instrumental reasons, for example, to make communication easier, but also to include as part of the decision-making process.

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<sup>51</sup> EBM says very little about what is to be done in cases in which the evidence conflicts with the patient’s values, cases which are sure to arise. Given the various ways in which evidence was prioritized in early EBM it seems likely that this version of EBM would sacrifice the patient’s wishes to the direction of the evidence. It is less clear how EBM as represented by later models like the Tripartite Model and the Amalgamation Model would suggest in this case. Critics like Tonelli have charged that EBM struggles to actually integrate patient values into practice, except in areas of “professionalism” like the communication case above (Tonelli 2006).

Fulford insists that VBP need not be seen as a replacement for or competitor to EBM, writing, “A particular feature of values-based practice is that...it is fully complementary to and supports evidence-based approaches” (Fulford 2008, 13). Since EBM and VBP differ in their explanation of where clinicians should obtain information, Fulford makes use of the traditional fact/value distinction to carve out a distinct place for VBP that does not encroach on the territory of EBM. The structure of the partnership with EBM makes clear the traditional dichotomy; EBM is seen to deal in factual evidence and VBP to deal in the values of all the relevant actors in a medical decision-making arena. Fulford writes,

Thus, we can think of values-based medicine as being to values what evidence-based medicine is to *evidence*. Just as evidence-based medicine offers a process for working more effectively with complex and conflicting evidence in medicine, so values-based medicine offers a process, albeit a different process, for working more effectively with complex and conflicting *values* in medicine. (Fulford 2008, 12)

Regardless of Fulford’s insistence on seeing VBP and EBM as partners with separate theoretical territory, newer versions of EBM which attempt to integrate values suggest that there is more overlap, and therefore more possibilities for conflict, than he suggests (Haynes et al. 2002; Sackett et al. 1996; Gupta 2011).

#### VBP Case Study: The Artist’s Need to “See” Color

In Fulford’s illustrative example of the role of VBP in the clinical setting, an artist begins taking lithium to control her bipolar disorder on the advice of her clinician. From a traditional medical point of view, this treatment was very successful—the lithium controlled her mood swings and she had few side effects. However, she stopped taking the lithium because it blunted her perception of colour. This side effect, which had not seemed important enough to take into consideration in previous studies of the intervention, was well documented in the patient narrative literature. It was of paramount concern to this patient because of her set of values related to her role as an artist. Armed with this clarification of values, the artist and her clinician were able to find a more suitable intervention. In this case, the doctor’s values (e.g. use of best practices, importance of efficacy) were at first assumed

to be paramount to the patient's values (e.g. quality of life, artistic functioning) as the patient's full assortment of values was not made clear in the original encounter (Fulford 2008). This case makes clear the benefit of taking values, as well as evidence, into consideration in clinical decision making. In this case, however, the patient was able to continue to express the ways in which her treatment was not in line with her values, even while experiencing the condition in question. In other cases, for example, in patients with depression, it is not as clear that this will be possible.

### Problems with the VBP Account of Values

I argue that while the VBP account of values in clinical practice has several flaws, it is markedly more attentive to individual patients than the rival EBM procedures for taking values into account. These EBM procedures largely focus on using data from social science to create population-based accounts of patient values. I claim VBP procedures ought to be used in place of the EBM procedures given the inconsistency of EBM's stance on values, current calls for Patient-Centered Care (PCC), and the uncertainty of the appropriateness of using the same methods to compare and discuss values and evidence.

Fulford's VBP account of values has several problems. These include a tendency to take values to be static, insufficient information about how to proceed in the face of medical conditions which shift or erode values, and a lack of procedure for dealing with values that are truly in conflict.

Fulford takes values to be static. Even in cases when it seems clear that values have shifted over time, for example, in the maturation process of a teenager, becoming a parent, or undergoing a mental health crisis, values are discussed in terms of "uncovering true values" rather than values themselves changing (Fulford, Peile, and Carroll, 2012). While this stipulation that values do not change would greatly simplify the process of engaging with values, it is not reflected in our everyday experience. If the ambiguity caused by shifts in values cannot be handled by VBP, this is a reason to look to improve VBP.

There is one instance in which Fulford seems to contend with the possibility of shifting values. In his 1994 article written with Andrew Moore and Tony Hope entitled “Mild Mania and Well-Being,” Fulford and his co-authors examine the case of Mr. M, a patient who was diagnosed with “mild mania” (though his treatment with lithium begins after a depressive episode). Over the course of Mr. M’s treatment—including his time on and off lithium, periods in which he was manic or depressed, and periods of relative stability—Mr. M articulated a wide range of values; sometimes, “He found his wife and family boring and claimed that his marriage had never been good...openly expressing his intention to divorce his wife and to marry his girlfriend,” other times “he...described his relationship with his girlfriend as superficial and unimportant” (Moore et al. 1994, 167).

In light of the difficulties inherent in taking seriously these shifts in values, the authors argue that we should cease to take the immediate values of the patient into account, writing, “...In the case of hypomania, it is the long-term welfare of the person concerned rather than his or her immediate express wishes, which is the relevant measure of his or her best interest” (Moore et al. 1994, 167). While Fulford and his co-authors seem aware of difficulties involved in changing and shifting values in the case of severe psychiatric disorders, their attempts at making sense of such values is quickly abandoned in favour of a more objective notion of the patient’s “well-being.” However, further disagreements about what constitutes well-being, as well as which kinds of well-being the clinician should aim to achieve for his patient, lead the authors towards paternalism.

While Fulford and his co-authors fail to develop an unproblematic notion of well-being in their article, it is even more important to note that Fulford, in his subsequent works, returned to the idea of taking patients’ values seriously. However, rather than finding a new way to approach the problem of shifting values, he begins to rely exclusively on cases in which values do not change.

Fulford's failure to address adequately the ways in which values can shift and change over time is a potential obstacle to the implementation of VBP in clinical practice. Fulford has been able to avoid confronting this obstacle by maintaining a methodological pluralism in regard to the question of how to actually obtain knowledge of a patient's values. By portraying the process of obtaining knowledge of values as something distinct from the way in which one should use these values to make decisions in VBP, he has been able to avoid deeper questions about how we gain our values, how they develop, and how they can be altered in cases of severe psychiatric disorders.

When Fulford is faced with a case study that might be interpreted as a dramatic change in values, he typically interprets it as a discovery of one's true values, rather than a fundamentally new way of valuing. It might be the case that an individual's values are hidden or undisclosed and a practitioner skilled in VBP must uncover them, but they do not change. This holds in cases in which patients pass through puberty, confront major illnesses, and undergo radical changes in goals. Even in the case of a teenager with schizophrenia who discloses after an episode that she is no longer as committed to her art as she once was and wishes to change her career goals in a way that will require a change in treatment program, her values are taken as unchanged by either maturation or psychosis. Instead, her "true" values were simply covered over by her artistic talents and her parents' wishes for her future (Fulford, Peile, and Carroll 2012, 50). In contrast, a hermeneutic phenomenologist would interpret this as a major life event that fundamentally altered the teenager's value set. While it is true that static values are much simpler to negotiate, it seems unlikely that an individual's values will remain consistent from childhood through old age, in spite of major life events, changes in circumstances, or mental illness.

In addition, VBP does not account for how clinicians are to respond to patients whose condition impacts their ability to value anything at all. For example, in some patients, depression results in a degradation or sometimes the complete loss of the ability to value anything at all. What is a clinician who is committed to VBP to do in this case? Take the

patient's previously held values (if known) as their current values? Take the current lack of values seriously, even though they may not be coherent with the rest of the patient's history? Ask for the help of a surrogate (friend, family member) in determining the patient's current or former values? Given the current epidemic of depression, it is important that VBP be able to answer this question.

A last reason to worry about VBP is the lack of procedure for dealing with situations in which the values of different stakeholders in the clinical encounter are truly in conflict. Especially in his clinical workbook, Fulford does a good job discussing the way in which values are “squeaky wheels”—that is, they are always underlying the clinical encounter, but only tend to be noticed when they are causing conflict. Even in these “squeaky wheel” encounters, Fulford orchestrates examples in such a way that a mutually beneficial solution is always possible with all parties' values intact and unchanged. Fulford even relates that an early reviewer of the book was confused that there were “no villains” in the cases studied; that is, Fulford gave no examples in which conflicting values could not be reconciled (Fulford, Peile, and Carroll, 2012). While the cases may not need “villains” to be compelling, it does seem unlikely that all values can be brought into accord—surely there are cases in which the differences in values between clinicians and patients are problematic and irreconcilable.

Because of the static nature of its account of values, the lack of protocol for dealing with individuals who can no longer value at all, and the lack of guidance when values truly remain in conflict, VBP still has some worrisome kinks to work out in dealing with values in the clinical setting.

#### Possible Improvements to Values in VBP

Supporters of VBP can remedy this failure to address the shifting nature of values or diminished ability to have values at all that occurs in disorders such as depression in several ways. The first, and perhaps most problematic remedy is to take the shift in values or the

inability to have values seriously. This might involve making changes to the individual's plan of intervention based on the individual's new values or new lack of values. This solution seems problematic in that, at least in the case of depression, this new set of values or this new lack of values might be understood as episodic, or transient. If this is the case, clinicians would want to plan interventions that are in line with the individual's pre-episode values.

Another option is a pre-episode clinical encounter in which the clinician and the patient set out to discuss and record the patient's values and preferences for future treatment. This option seems promising in that it most explicitly captures the values of the individual. In addition, this option provides a resource for the clinician to refer to in the future. However, this solution also presents some difficulties. First, episodes of depression and other disorders often arise with little warning, not allowing for a pre-episode interview in which a statement of values can be produced. In addition, this one-time clinical capture of values seems to suggest, as much of VBP does, that values are static and will not legitimately change over time—a problematic assumption. A solution to this might be more frequent, thorough discussions of values.

A third possible solution to the difficulty of shifting or diminishing values for values-based practice is the use of proxies. In other health care settings, the use of proxies, a relationship in which the decisions of a designated family member or friend stand in for the decisions of the patient herself, is standard practice. When applied to values-based practice, a proxy would be a designated individual whose job is to be an advocate for interventions that are in line with what they believe to be the patient's values.

A reason to prefer Fulford's methods, even with their flaws, is the current demand for patient centred care (PCC). Clinical practitioners of all kinds, as well as patients, are making this call. While the movement is itself fractured, we can take these three definitions of patient centred care as somewhat representative.

Martin and Felix-Bortolotti define PCC as, “a strong moral prerogative in health care delivery that entails a deep respect for unique living persons, and the obligation of health professionals and decision makers to care for them on their terms” (2014, 1). Here the emphasis is on the moral aspect of the charge and on the uniqueness of each individual, which suggests that making use of values derived from population level studies would not fulfil the requirements of PCC.

The Institute of Medicine defines PCC as “providing care that is respectful of and responsive to individual patient preference, needs and values, and ensuring that patient values guide all clinical decisions” (2001, 6). Again, the emphasis on the individuality of the patients in question suggests that this will not be possible through the use of population level sociological data.

Ekman et al. write, “Person-centred care highlights the importance of knowing the person behind the patient – as a human being with reason, will, feelings, and needs – in order to engage the person as an active partner in his/her care and treatment” (2011, 2). This definition especially draws attention to the active role of the patient, in all their particularities, in their treatment.

While these definitions do have some important differences, it seems quite safe to say that none of them have room for the practice of relying on “ratings made by an equally large group of people representing the general public” to determine a particular patient’s values, in place of communicating with the patient. Based on this diverse selection of definitions it is clear that such practices would not be patient-centred, providing another reason to prefer Fulford’s account, in which communication with the actual individual patient or other stakeholder in question is paramount (Fulford 2013). Of course, for compliance with PCC to count as a reason to prefer the VBP account of values to the EBM account, we must assume that PCC is a worthy goal. Defending this claim is well outside the scope of this section, but the wide acceptance of the goals of PCC by groups like the National Institute of Health and the National Health Service suggest that it remains an important concept.



A final reason to prefer Fulford's method of working with values is EBM's assumption that empirical methods will work just as well dealing with values as they do with evidence. The methods of EBM are set up to endorse evidence. A randomized controlled trial of patients similar in relevant ways to your patient is supposed to produce evidence that will tell you something about the evidence in your case, more or less given the quality of the study and the similarity of the patient to the population.<sup>52</sup> The same cannot be said of values; even a very well-constructed poll of what thousands of other patients preferred need not tell you anything about what your patient prefers, regardless of how many characteristics they have in common with the polled population. As I noted earlier, an important EBM manual, one of the only places a clinician could learn how EBM suggests to ascertain and integrate patient values, suggests exactly this method.

These are not the only options for the discovery and investigation of values. There is a significant literature discussing possible methods for choosing the best values for use in science, once we have accepted that a value-free ideal is not possible or indeed, even to be hoped for (Douglas 2007, de Melo-Martin and Intemann 2016). These methods are quite diverse and may mirror the kinds of methods individuals use to choose their values. This literature includes suggestions to choose values based on the pragmatics of which values produce the best science historically (Clough, 2013), based on the standpoint of particular oppressed and marginalized groups (Wylie, 2003), based on empirical accounts of what the members of the community already value, or based on the results of encouraging a plethora of conflicting values so that in time the most radical are "washed out" (Longino 1990). My contribution to this debate follows in a later section, "Values that Fit: Guidance for Adopting Values in Science."

That there are many possible ways of systematically and thoughtfully choosing values is not a reason to think that any way is as good as any other, but instead is another

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<sup>52</sup> It is far from clear that this even occurs in the case of randomized controlled trials. See (Worrall, 2002), (Cartwright, 2012) and (Fuller forthcoming) for more information about the limitations of RCTs.

reason that it is dangerous to believe that values can safely be assumed to be shared over populations. And while there are methods to determine values, and some of these have an empirical basis, it is much too quick to assume that the methods considered most successful for dealing with evidence, like the hierarchy, can also be considered most successful for dealing with values.

Of course, none of this is to say that there is a strong line between facts and values, or that fact-finding practices are not themselves shot through with values, but if investigating values is our goal, it is not clear that we can use the same empirically based methods we use to produce evidence.

It is because of this inconsistency in what EBM has to say about values and how they should be ascertained, the failure of EBM value practices to be patient-centred, and EBM's attempt to use methods for evidence creation inappropriately on values that I suggest the use of Fulford's system, flawed though it might be, as the current best practice for investigating and integrating patient values into clinician practice.

Given that there are these competing discussions of how to take patient and other stakeholder values into consideration in medicine, the above discussion of the features and flaws of VBP and EBM on values can be helpful for those considering the adoption of one of these systems. However, this is far from the only way that issues of values enter EBM and medicine as a whole. Neither EBM nor its more recent competitor VBP explicitly take into account a different use of values; values which are not held by individuals in the clinical encounter but are an integral part of the EBM movement itself. An awareness of these values could be very useful for the EBM proponent, in that it would allow the proponent to measure the appropriateness of new developments in EBM against these previously held values, or to consider and critique the appropriateness of these values to begin with. Because these values are not explicitly stated, (indeed, EBM sometimes attempts to claim that it is value-free) EBM values must be deduced from the writings of EBM proponents on

other topics. One particularly telling topic is the widely circulated GOBSAT joke. In the next section, I discuss what we can learn about EBM's unstated values from this joke.

### What Can We Learn About Values from GOBSAT?

EBM supporters have coined a term for the kind of medicine they see themselves as replacing: GOBSAT medicine (Good Old Boys Sit Around a Table)(Hartung 2009; Pitts 2004; Howick 2011). This term was first featured in Greenhalgh's book, *How to Read a Paper: The Basics of Evidence-Based Medicine*. She writes,

When I wrote the first edition of this book in the mid 1990's, the commonest sort of guideline was what was known as a *consensus statement*—the fruits of a weekend's hard work by a dozen or so eminent experts who had been shut in a luxury hotel, usually at the expense of a drug company. Such 'GOBSAT (Good Old Boys Sit Around a Table) guidelines' often fell out of the medical freebies (free medical guides and other 'information sheets' sponsored directly or indirectly by the pharmaceutical company) as pocket-sized booklets replete with potted recommendations and at-a-glance management guides. But who says the advice given in a set of guidelines, a punchy editorial, or an amply referenced overview is correct? (Greenhalgh 2010, 7)<sup>53</sup>

I argue that there are two critiques implicit in this somewhat humorous, pejorative term. First, expressed by "good old boys" is the claim that pre-EBM medical traditions suffer from unsurmountable exclusion in terms of inviting only certain members of the scientific community to participate and neglecting to take into consideration the testimony of others, perhaps others who are most likely to productively disagree. Second, expressed by "sit around the table," is the charge that pre-EBM medical traditions are rationalist; that is, that they seek to understand the causes or mechanisms behind diseases or interventions, rather than focusing the results of Randomized Controlled Trials (RCTs). For an EBM supporter, this sort of "rationalist" reasoning is what led to disastrous medical interventions such as bloodletting and anti-arrhythmia drugs and is dangerous to continue.

I argue, first, that EBM is itself not free from the very critiques it levels in this joke:

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<sup>53</sup> Other philosophers, Miriam Solomon in particular, have investigated the evidential practices involved in consensus conferences and found them to be much less problematic than here depicted. Since I am focusing on the way in which the GOBSAT joke reveals values in EBM, rather than how it functions as a critique of consensus conferences, I do not focus on this work here. See Solomon 2007 for a good explanation of consensus conferences.

there is both more exclusion, because of the high “start-up cost” of RCTs, and more “rationalism” in EBM than supporters often imagine. In response to the charge of rationalism, I argue that the reasons that EBM has given to worry about rationalism are unsatisfactory, and that a mix of rationalism and empiricism is needed for effective medical research and practice. Finally, I examine what this GOBSAT description of the kind of medicine EBM seeks to displace can tell us about the values implicit in EBM. I offer two possible sample values that can be implied from the GOBSAT joke. This investigation of the implicit values in EBM through the GOBSAT joke can help us to see the role that values play in EBM itself, as a movement, rather than only considering how patient values, or clinician values work within EBM.

#### GOBSAT as a Charge of Exclusion and Rationalism

The first charge implicit in the GOBSAT joke is a charge of exclusion, or, a lack of diversity. This exclusion most often takes the shape of inviting only certain members of the scientific community to participate and neglecting to take into consideration the testimony of others, perhaps others who are most likely to productively disagree. This critique portrays medicine before EBM as necessarily conservative and defensive, even against those from within the profession who are, say, younger, from various under-represented groups, or those who occupy different positions in the health care field, such as nurses or social workers. Given that medical debate around the content of guidelines doesn’t seem to be worth very much if it is only composed of members likely to immediately agree, this is a serious charge indeed.

Second, expressed by “sit around the table,” is the charge that pre-EBM medical traditions are rationalist;<sup>54</sup> that is, that they seek to understand the causes or mechanisms behind diseases or interventions, rather than focusing the empirical results of Randomized

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<sup>54</sup> Even if the reader is not convinced that this charge is implied in the GOBSAT joke, it is reasonable to infer because of the replication of this charge elsewhere. For a good explanation of the debate around empiricism and rationalism in EBM see (Bluhm 2017).

Controlled Trials (RCTs). For an EBM supporter, this sort of “rationalist” reasoning is what led to disastrous medical interventions such as bloodletting and anti-arrhythmia drugs and is dangerous to continue.<sup>55</sup>

I argue that these critiques do more to inform us about the goals and values underpinning EBM than they do to suggest that EBM is so very different from the medical traditions which preceded it. First, these critiques (the barring of diverse voices in evidence consideration and rationalism) might also be levelled at EBM. In the same way that the GOBSAT joke implies that in older medical traditions diverse voices are not allowed, EBM sharply restricts the methodologies which can easily be brought to bear on the consideration of a particular intervention. While it might seem what is meant by a lack of diversity in GOBSAT situations is quite different from the lack of methodological diversity in EBM, these lacks are at least analogous and the negative outcomes are the same. In each case, opportunities for capturing a fuller picture of the relevant viewpoints and information is lost because of the homogeneity of accepted voices. This is the case even in the newer GRADE system, where RCTs are still to be prized from the outset and observational studies are given a low starting value, although each may be awarded additional merits or demerits based on the quality of the particular study (GRADE working group 2008).

In addition, like GOBSAT, EBM needs to make use of some “rationalist” thinking in order to begin the research process. Activities like hypothesis generation and selection, which are important for EBM, will require “rationalist” elements, such as mechanistic reasoning and the results of basic science.

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<sup>55</sup> Of course, in Greenhalgh’s explanation of GOBSAT, we also see a concern about the role of industry in consensus conferences. It used to be thought that RCTs might provide a defense from industry involvement, but now most EBM supporters, including Greenhalgh, recognize that industry involvement continues regardless of RCTs (Greenhalgh 2014). Indeed, the high cost of a large well conducted RCT makes EBM especially susceptible to industry involvement. However, I will not deal with this charge in this work, as many others such as Ben Goldacre (2012) and Bennett Holman (2016) have admirably stepped up to the task of investigating industry involvement in various parts of the process of medical experimentation and implementation.

I follow others in suggesting that in order to be successful, EBM needs to take into account both empirical and rationalist considerations (Kelly and Moore 2012, Bluhm 2017). Without rationalist considerations, we can't know where to next direct our inquiry and without empirical considerations, our theories are not yet fleshed out by data.

### Implicit Values in EBM

The GOBSAT joke can point us toward some implicit values in EBM. EBM does claim to be value-free in some foundational texts. *The Users' Guides to the Medical Literature* states, "Linking treatment options with outcomes is largely a question of fact and a matter of science. Assigning preferences to outcomes is a matter of values..."(Guyatt 2015). This passage seeks to separate the "value-laden" work of applying evidence from the supposedly "value-free" creation of evidence. In addition, part of the reason for the emphasis on evidence in the classic texts of EBM is as an arbiter of the subjective, authoritative, and value-laden teaching of medicine before EBM.<sup>56</sup>

I argue in the "Values that Fit" section later in this work that a declaration of value freedom is to be discouraged in comparison to a declaration and defence of a clear set of values. Reasons to prefer a transparent account of values to a declaration of value-freedom include clarity of purpose and the opportunity for those within and outside of EBM to challenge and amend those stated values. What might EBM values include?

Given EBM's mockery of GOBSAT, a brief moment where we can infer what the values of EBM itself are, we can learn that EBM values include diversity (as opposed to the exclusion that supporters of EBM see in GOBSAT) and an empirically-driven engagement with the world (not armchair rationalism).

Perhaps these are not the values that supporters of EBM would choose to adopt for their movement. I welcome the replacement of these values gathered from implicit sources

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<sup>56</sup> See the "Classic Texts" section of Chapter 1 for more on this.

with explicit statements of values from within EBM itself. There is some movement by EBM advocates in this direction, which I discuss in the section “New Developments in Values in EBM.” It is not until these values are made explicit that the movement can be evaluated to see if these are in fact the values it wants to embrace, and how well the chosen values are being lived up to.

I have argued that despite its lightweight content, the retelling of the GOBSAT joke can reveal quite a bit about EBM. It can reveal the complicated relationship EBM has with rationalism and exclusionary practices, in that these are critiques made of pre-EBM strategies that might also show up in EBM itself. And it suggests a set of values at play in EBM, values which shape both the hierarchy itself and its application in the clinic. While in the future EBM may choose to begin the hard work of explicitly adopting values, for the time being the values implicit in the GOBSAT joke will have to do as a starting point.

But it is not just EBM that struggles in this aspect; many other scientific projects struggle to identify, articulate and adopt values. This is partly because of worries about relativism and wishful thinking in science that is not value-free, but also because of the lack of a systematic structure for doing so. In the next section, I respond to concerns about relativism and wishful thinking and provide such a systematic guideline.

#### Values that Fit: Guidance for Adopting Values in Science

Philosophers have argued that the value-free ideal is neither possible nor to be wished for with increasing regularity over the last 50 years. This need not entail, however, that science be guided by just any values; it is important to think through what values matter to scientific work, state them clearly and transparently, and ask the scientific community to help them to live up to these stated values through peer review and other kinds of feedback. What are the methods for determining the values which are relevant to a scientific project? It seems unlikely that the usual empirical methods are up for this task. Biddle sums up this concern nicely: “If it is either impossible or inadvisable to screen out all contextual factors from transiently underdetermined research, what kinds of contextual factors should be

allowed and which should we seek to exclude?” (Biddle 2013)<sup>57</sup> Is there a principled way to adopt values in science?

Currently the most popular justifications for choosing some values rather than others to guide scientific practices are based on various distinctions between illegitimate and legitimate values. These distinctions include the indirect/direct role distinction, the epistemic/non-epistemic distinction, and the lexical priority distinction.

In this section, I will argue that current attempts to adopt values for use in science based on illegitimate/legitimate distinctions are unhelpful. I will then suggest a set of three new guiding principles to use in their stead: locality, context-dependency, and transparency. I provide an example of the use of these guiding principles for values adoption in a hypothetical scientific project: a randomized controlled trial for the use of statins in stroke. I conclude by examining a few likely objections to my proposal and offering some replies.

#### A Critique of Universal Illegitimate/Legitimate Distinctions

In this section, I criticise the current proposals for regulating the place of values in science more generally.<sup>58</sup> These proposals differ in terms of the nature of the principle by which they attempt to make a distinction between acceptable and unacceptable values. These principles include the indirect/direct distinction, the non-epistemic/epistemic distinction, and the principle of “lexical priority.” I will characterize each of these principles in turn, but first I will say something about the class of illegitimate/legitimate distinctions as a whole.<sup>59</sup>

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<sup>57</sup> Here as elsewhere, Biddle avoids value-based language to talk about this issue, preferring to speak of the issue of the “epistemic purity of science” rather than “values in science.” He has various worries about this older and more common terminology, which may be of interest to the reader. However, since I am interested in connecting the issues discussed here with larger problems related to the so-called “fact/value” dichotomy I will retain the use of value language.

<sup>58</sup> I make use of the methods for demarcating acceptable from unacceptable values in science generally, because no separate methods have been developed more specifically for medicine or EBM. For more on the relationship between science, medicine, and EBM, see Chapter 3.

<sup>59</sup> While I write that I am critiquing universal illegitimate/legitimate distinctions as a whole and additionally am providing an account of the particular difficulties which each attempted distinction, it could be said that really my own account (presented in “A Proposal for Guidelines”) is actually just another kind of illegitimate/legitimate distinction. I am, after all, attempting to provide a way to delineate projects in which values are being used appropriately from cases in which they are not; this is not “anything goes” chaos. However, my account remains



This class of distinctions is to be praised for responding to the literature on values in science by attempting to carve out some role for values in science. However, these distinctions sometimes signal, rather than a rejection of the value-free ideal of science, instead only the admission that regardless of our policing, values will creep into science. These distinctions still function within a paradigm that longs for value-free science; but since value-free science is impractical in the world we live in, the pragmatic response is to limit the spread of values to particular zones of science. This pragmatism seems to overlook the more radical literature suggesting that value-free science is not just not attainable, but not even to be wished for (de Melo-Martin and Intemann 2016).

One possible distinction on which to distinguish acceptable values from unacceptable values is the epistemic/non-epistemic distinction. On this account, certain values have a special relationship with truth. In her critique of this distinction (2009), Douglas lists predictive accuracy, explanatory power, scope, and simplicity/economy as examples of epistemic values, a list she inherits from Kuhn (1977). Longino suggests accuracy, consistency, simplicity, scope and fruitfulness, in contrast to feminist values such as novelty, applicability and ontological heterogeneity (1996). The special relationship to truth that these values are taken to have holds universally, across scientific disciplines and projects. That is, for Longino, simplicity is always considered an epistemic (and therefore acceptable) value, regardless of the scientific project or field under consideration. It is not clear if this relationship is at root a simple pragmatist point that projects guided by these values have in the past had the good consequence of increasing our knowledge, or some kind of stronger, perhaps necessary, relationship. All other values are understood not only to not have this special relationship with truth, but to be socially based.<sup>60</sup>

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different in kind from those I am critiquing because I am not attempting to provide a universal for identifying proper roles for values for all scientific projects throughout space and time. Instead, in my proposal, appropriate values are indexed to the particularities of the project in question. My proposal remains different from those discussed in this first section.

<sup>60</sup> The additional implication is that this tie to social forces means that these values function to move us further from the truth. I argue elsewhere that this additional claim linking social values with an increasing distance from truth is not the case, but it seems to be taken as given by this account.

The first argument against this distinction takes aim at the assumption implicit within it that there is a universal set of values which lead to truth (or more weakly, at least a more pragmatic epistemic success) across scientific fields and projects. This argument has its roots in older critiques of reductivism and the unity of science (Cartwright 1999; Hacking 1996; Dupre 1993). For example, simplicity is a value generally considered to be epistemic, but it does not have this special relationship to truth universally.<sup>61</sup> It is generally taken to be the case in physics and mathematics that simplicity is a value which leads to truth (or epistemic success).<sup>62</sup> However, in other scientific disciplines, such as economics, simplicity need not be such a value. Indeed, given the complex social and psychological factors at play in economics, a dependence on the value of simplicity may in fact lead away from truth or epistemic success. It seems difficult to chalk this difference up to a deficiency, either in discipline maturity or rigor, of economics, as differences between social and other sciences sometimes are. Instead, it is just the case that the values that count as epistemic vary across disciplines. This example illustrates that the set of values considered epistemic is not in fact universal. As a result, the epistemic/nonepistemic distinction loses one of the factors that made it preferable to other distinctions —its clarity and consistency. However, this argument does not show that the epistemic/ nonepistemic distinction cannot work, only that the determination of which values have this special relationship with truth must be local and not universal. These issues of locality and context-dependency will be taken up in section 2, my positive proposal for guidance for adopting values.

A second critique of the epistemic/non-epistemic distinction (itself a kind of legitimate vs illegitimate distinction) is the literature of inductive risk, recently led by Douglas, but rooted in older work by Hempel and Nagel (2009). This critique of the epistemic/nonepistemic distinction takes aim at the possibility of some values always being acceptable

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<sup>61</sup> Exactly what the value of simplicity consists of is in some ways not settled. See Rochefort-Maranda (2016) for an example. <sup>62</sup>Emphasis original

<sup>62</sup> See (Sober 2015) for an interesting investigation into why we might think this is the case.

(“cognitive” or “epistemic”) and others (“social”) always unacceptable and argues instead that social values have a role to play in proper scientific process.

Douglas’ inductive risk arises because of what Biddle would call, “transient underdetermination,” the idea that “*some theories, hypotheses and models are underdetermined by logic and the currently available evidence*” (Biddle 2013).<sup>62</sup> Given this state of affairs, decisions will have to be made in the face of uncertainty. According to the Douglas account of inductive risk, it might be best to limit values’ direct influence on decision-making, values cannot be fully removed from decision-making because the amount of evidence that is required in order to accept a hypothesis or make a decision will be raised and lowered based on values; values regarding the possible consequences of getting the choice wrong. That is, this view highlights issues of uncertainty and levels of required evidence for acceptance as important areas which require values in scientific projects. Because in some sense the “stakes” will matter in each scientific project, there will be uncertainty in each project, which means there will be values in each project. The important thing is to separate these indirect and irremovable values components from direct and inappropriate values components.

This argument has been enormously successful in challenging the value-free ideal and has resulted in a large amount of scholarly activity. However, I (and others) think that it does not go far enough or describe enough of the relevant phenomena surrounding values and scientific practice (de Melo-Martin and Intemann 2016; Biddle and Kukla 2016). The role that the inductive risk argument carves out for values is small and specialized. Values are thought only to come legitimately into play in the context of accepting a hypothesis or deciding how much evidence you need to accept a hypothesis, as opposed to throughout the scientific process.<sup>63</sup> For these reasons, although discussions of inductive risk are helpful in critiquing the value-free ideal and the epistemic/non-epistemic distinction, they do not go far

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<sup>63</sup> It might be possible to adopt both the inductive risk account and the indirect/direct distinction as they are compatible, but the problems with the direct/indirect distinction still stand independently.

enough to characterize the roles of values in science. This point is contentious because this is an unusual riff on the usual tactic regarding the appropriate place of values in science; carving out some area where values are barred. The Douglas account remains in this tradition, though this account allows that values might legitimately play a role in science in a “new” area; not the determination of what questions we should ask, but instead the determination of how much and what kind of evidence we will need in order to accept a theory, hypothesis, or model.

The most recently proposed of these “legitimate vs illegitimate” distinctions is the indirect/direct distinction. According to this distinction it is acceptable for values to have an indirect role in science but not a direct role. Douglas articulates the most popular version of this distinction in 2009, writing,

In the *direct* role, values determine our decisions in and of themselves, acting as stand-alone reasons to motivate our choices. They do this by placing value on some intended option or outcome, whether it is to valorize the choice or to condemn it. The value provides warrant or reason in itself, to either accept or reject the option. In this direct role, uncertainty is irrelevant to the importance of the value in the judgment. The issue is not whether the choice will somehow come out wrong in the end, but whether the choice, if it comes out as expected, is what we want. This role for values is crucial for some decisions, but we will see that it must be restricted to certain decisions made in science and excluded from others. The integrity of the scientific process cannot tolerate a direct role for values throughout the process.

The *indirect* role, in contrast, can completely saturate science, without threat to the integrity of science. This role arises when there are decisions to be made but the evidence or reasons on which to make the decision are incomplete, as they so often are, and thus there is uncertainty regarding the decision. Then values serve a crucial role of helping us determine whether the available evidence is sufficient for the choice and that the importance of the uncertainty is, weighing the potential consequences of a wrong choice and helping to mitigate against this possibility by requiring more information when such consequences are dire...If we find new evidence, which reduces the uncertainties, the importance of the relevant value(s) diminishes. In the indirect role, more evidential reasons in support of a choice undercut the potency of the value consideration, as uncertainty is reduced. The value only serves as a reason to accept or reject the current level of uncertainty or to make the judgement that the evidence is sufficient in support of a choice, not as a reason to accept or reject the options per se. (Douglas 2009, 96-98)<sup>64</sup>

The idea here is that while values play a role in scientific activities like project choice, planning, and technology regulation after discovery, it is inappropriate to use values to guide

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<sup>64</sup> Emphasis original

the scientific project itself- that this kind of direct role for values is at its core nothing more than “wishful thinking,” the spectre that haunts many accounts of values in science. The worry about wishful thinking is that a scientific project which incorporates values might be a scientific project which finds only what a scientist wishes to find (which may be expressed in their values) rather than what is “really” out there.<sup>65</sup> Douglas describes the problem of wishful thinking saying, “...simply because a scientist values (or would prefer) a particular outcome of a study does not mean the scientist’s preference should be taken as a reason in itself to accept the outcome. Values are not evidence; wishing does not make it so” (Douglas, 2009). Wishful thinking of this kind is a problem in scientific projects if the scientists on a given project will find results that are in line with the values they hold regardless of that is “out in the world.”<sup>66</sup> The problem of wishful thinking has been especially salient in discussions about the possibility of feminist scientists. Here the worry was that scientists who identified as feminists would be more likely to come to conclusions that supported equality between men and women via inappropriate methods or reasoning in projects like looking for brain differences between men and women in neuroscience or investigating the roles of men and women in hunter-gather societies in archeology.

Douglas suggests this distinction as an improvement on the epistemic/non-epistemic distinction. She claims the indirect/direct distinction is an improvement over the epistemic/non-epistemic distinction in that it does not say that certain values are always acceptable and others always unacceptable, but instead indexes the acceptability of the values to the role they are playing in the scientific project.<sup>67</sup> I sympathize with this type of

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<sup>65</sup> Sometimes the problem of wishful thinking is treated as if it requires a robust commitment to a particular brand of realism in order to show up as a problem at all. I do not think this is the case- it seems to me we can describe what is wrong about wishful thinking while remaining fairly skeptical about what we can know about the world. Because it is not required to describe the problem of wishful thinking, this section does not include any strong claims about realism or anti-realism, which remains outside the scope of this work.

<sup>66</sup> Elliott has also been critical of the Douglas account, worrying that the direct/indirect distinction is not clear enough to do the work it is assigned. For more on this, see (Elliott, 2011a).

<sup>67</sup> In addition, while the indirect/direct distinction is put forward as a new distinction, an improvement over older accounts, the indirect portion of the distinction seems to be indistinguishable from the lexical priority of evidence distinction, an older idea which will be critiqued in this section as well.

critique, but want to take it still further, indexing the appropriate values not to the *role* they are playing in a scientific project, *but to the content details of the scientific project itself*.

My main concern with the indirect/direct distinction is that, in order for it to work, the scientific process must be divided up into discreet categories which do not seem particularly responsive to the messy way that science is done in practice. Douglas points to a few situations in which a direct role for values might be acceptable, most of which occur “in the early stages of a research project;” the decision of which scientific projects to undertake, funding decisions in science, the choice of which methodology to pursue. However, after this early stage has passed, “any direct role for values must be restricted to unusual circumstances when the scientist suddenly realizes that additional direct values considerations must be addressed” (Douglas 2009, 101).

In order for the indirect/direct distinction to be useful, there needs to be a consistent way of disentangling indirect situations from direct situations. Largely this has been done temporally, by delimiting different chronological stages in the scientific process.<sup>68</sup> This project of slicing up a linear process of science into sections, some of which could be protected from the influx of values, was a project that paired nicely with attempts in philosophy of science to articulate a distinct and consistent scientific method. Douglas situates her contemporary work as inspired by the work of Heil (1983), but it is similar to other older accounts. For example, Reichenbach’s context of discovery vs. context of justification distinction is similar in that the early part of the scientific project in which a direct role for values is allowed by Douglas largely maps on to the context of discovery and the later stages of the scientific project in which Douglas says only indirect roles for values are permitted maps onto the context of justification (Reichenbach 1951, Schickore and Steinle 2006).

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<sup>68</sup> Another option would be to designate specific activities, regardless of when they are done, as indirect or direct. This may, however, undo the indexing to roles that Douglas cites as a reason to prefer her account to the epistemic/non-epistemic distinction.

This idealized, linear conception of science seems far removed from what happens in practice, in which tinkering and revision are not “unusual” but play large parts. It seems unlikely that direct roles for values can be segregated in the early stage of project planning (or a late stage of implementation, although Douglas does not focus on this possibility), leaving a “pure” middle section of the scientific process, because the activities which Douglas stipulates as allowing a direct role for values do not take place either before a project is begun or afterward during a non-scientific implementation, but occur throughout the process, a process which includes multiple planning and decision-making phases. My critical strategy here is not new. Biddle argues, “In many areas of research, such factors have an influence throughout the research process, including the characterization of data, the choice of methodologies (including the choice of a level of statistical significance), the choice of models and research subjects and so on” (2013). Because the indirect/direct distinction relies on this linear concept of science to do its segregation of acceptable from unacceptable roles for values (a linear conception of science which is not borne out in practice) this distinction cannot do the work which needs to be done to make clear which values should be in play in scientific projects.<sup>69</sup>

A final distinction which has been used to separate values which are illegitimate from those that are legitimate is the “lexical priority of evidence” distinction. This criterion is identified by Brown as underlying arguments about value inclusion which proceed from both inductive risk and underdeterminism (2013). The lexical priority account suggests that values do have a role to play in science but only in cases where the evidence is not definitive. It is in these cases that values “fill the gap” left by available evidence, allowing a decision to be made. In order to prevent an “anything goes” relativism, evidence always has “lexical priority.” So according to this way of thinking, values are legitimate when they enter into a

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<sup>69</sup> If my critique of the indirect/direct distinction hangs mostly on this linear idealization of science, it is important to ask if this linear idealization is something foundational to the Douglas view, or something merely incidental. Apart from the possibility of listing certain actions, regardless of when they occur in a project, as either direct or indirect, which I mentioned earlier, I do not see an alternative to this linear idealisation for getting the Douglas distinction off the ground.

situation where the evidence is not settled. Values are illegitimate when they play a role in a situation where the evidence is settled. However, according to this distinction, values can only fill such a gap- they should never be the primary consideration, and should not be considered at all in cases in which there is sufficient evidence. That is, “values do not compete with evidence when the two conflict” (Brown 2013, 834).

For Brown, this is problematic in several ways. It implies that no value judgments are needed to evaluate the quality of the evidence, a possibly dangerous assumption. In addition, he worries that this account of values takes them to be nothing more than preferences, noting that, “[the lexical priority rule] denies that we can have good reasons for our value judgments” (Brown 2013, 836). While those who champion the lexical priority distinction might respond that these measures are necessary to avoid the problem of wishful thinking, as previously discussed, Brown argues that there are other ways to avoid this problem. These include clarifying separate but necessary roles for evidence and values (Kournay 2010) or evidence, theory, and values (Brown 2012).

Generally, I agree with Brown’s critique and appreciate his call for alternative methods of avoiding the problem of wishful thinking. However, in that his proposals remain universal about finding the proper roles for evidence, theory, and values in all cases in all scientific projects, I believe he is overstating the unity of science.

#### A Proposal for Guidelines: Locality, Context-Dependency and Transparency

Now that I have discussed difficulties in the current options for adopting values based on universal concepts of legitimacy and illegitimacy which rely on distinctions such as epistemic/non-epistemic, indirect/direct and complete evidence base/non-complete evidence base, I offer my positive account of a better way forward. This positive account is especially needed if we are concerned with the work of the last 50 years of arguments that science is shot through with values. My positive account does not attempt to reargue for that empirical claim, but takes it as given. My account also does not attempt to provide a different distinction for a universal illegitimate/legitimate principle, allowing for a new characterization



of values as legitimate or illegitimate (although this does not entail that I think all values are legitimate). Indeed, this method of attacking the investigation of values seems destined to fail given the diversity of non-unified scientific disciplines and projects. Instead, I am interested in providing criteria for determining if the values in place in a scientific project *fit that project*. I offer three criteria for “values that fit;” *locality, context dependency, and transparency*. I will discuss each of these in turn.

The first of my proposed criteria for values that fit is locality. By this I mean that the values in question should be reflective of the norms and particularities of the field or fields in which the project is located. For example, as I argued in the previous section, simplicity is sometimes taken to be a paradigmatic case of a universal epistemic value in science; explanations and theories which capture the phenomena while remaining as simple as possible are to be preferred above others. This is, however, not actually reasonable in many social sciences, including in, for example, economics. In economics, a simple account is generally to be viewed with suspicion as the subject of economics is itself highly complex, including many social factors. Another possible example is the importance of the value of first-person experience in social sciences which make use of ethnography. This value would seem strange in a project based in physics, but fits well with a project based in sociology. This is not just a mistaken contingent tendency of the field, but rather a logical preference given the subject matter of the field.

An adoption of values which are not local might mistakenly attempt to adopt simplicity, with its “universal” status credibility, as a value for a project in economics. Such an adoption of value would be inappropriate given the empirical information we have about the subject matter of economics. Obeying a criterion of locality can help avoid this and other related mistakes in values adoption. For this reason, I suggest locality as one desideratum for values adoption.

A second criterion for providing guidance for applying values that fit in science is context dependency. This criterion is concerned with adopting values which are sensitive to

the history and concerns which are particular to a scientific project.<sup>70</sup> For example, Hicks highlights a case study in which feminist values were instrumental in allowing archaeology to progress (Hicks 2014). In the 80s and 90s, feminist values in archaeology allowed for a re-examination of dominant conceptions of the development of agriculture. Traditionally women were thought to be responsible for plant gathering in pre-agrarian societies, while men were assumed to be responsible for plant domestication among other roles. Feminist values were appropriate, given that a history of sexism had hidden particular possibilities for women in the communities under study from archeologists (Wylie 2001; 2002; 2007). Without this awareness of history and the adoption of values which were sensitive to this context, progress could not be made. Similar cases from primatology are familiar from Haraway's work (1989;1991).

The third guideline for values adoption I propose is transparency. Values which are transparent are adopted values which are accessible to those in the scientific community who are not involved in the project. By accessible, I mean not necessarily that others in the scientific community will agree with these values, but that an explicit articulation of values will allow others in the field to understand which values are in play. This guideline allows for the possibility of a sort of "peer review" of values; if a scientific project is failing to live up to the other two criteria, this criterion of transparency allows this failure to be visible to the community at large for debate and correction.

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<sup>70</sup> Of course, it is possible that, as a result of the history of a group of projects in the discipline, inclusion decisions made under this criterion could also be made on the basis of the locality criterion. For example, the worry about simplicity stems from a particular history in economics. In cases like this, guidance from the locality and the context dependency requirements will look the same: it does not fit to use simplicity as a value in projects in economics, for two reasons- a violation of the locality criterion, and a violation of the context-dependency criterion (which in this case, but not all, is the foundation for the existence of the locality criterion.) I include the additional requirement of context-dependency to account for cases in which the history of particular projects suggests values which are not necessarily captured by the locality requirement. For example, the history of the Human Genome Project, in which great interventional advances were promised but not delivered, might render "humility about results" an especially important value for projects in that tradition of genomics. This concern would not have been brought out if the requirement of locality were in place as neither medicine nor biology need have "humility about results" as a particularly salient value.

The fulfilment of this transparency guideline could take many forms, from a brief statement in a scientific paper, to the completion of a more complex and detailed values protocol, which supports and records the reflection and deliberation on values by those involved in a scientific project throughout the stages of the project. It has been brought to my attention that some scientific projects already use a form of values disclosure. For example, the Drugs for Neglected Diseases initiative, (DNDi) includes a “vision” statement in its research.<sup>71</sup> Its goals are, “to improve the quality of life and the health of people suffering from neglected diseases by using an alternative model to develop drugs for these diseases and by ensuring equitable access to new and field-relevant health tools” (DNDi 2013). In future work, I hope to design a protocol for values consideration throughout the scientific projects which includes these kind of value statements in publication.

Since many scientific bodies already require or encourage the registration of scientific projects before they begin, values could also be recorded at this point, as a way to compare and map shifts in values over the course of the project. This is an especially important guideline, since without it, we have no epistemic access to see if the other two guidelines are being followed. For this reason, even if the other two other desiderata, locality and context-dependency, are deemed too difficult to follow, the guideline of transparency remains a crucial first step for beginning to understand the ways in which values are at play in scientific projects.

Though there might perhaps be other useful guidelines for the adoption of values in scientific projects, at the current time my proposal suggests that locality, context dependency, and transparency are a good start towards adopting values that fit.<sup>72</sup>

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<sup>71</sup> Thank you to Erman Sözüdoğru for this example.

<sup>72</sup> The work of Kevin Elliott has suggested the importance of including criteria that are somehow responsive to the public (perhaps a requirement that the values adopted be “democratic” or “public”) (2011b). Additionally, Intemann suggests something similar, particularly in the realm of climate science (2015). I have not included such a component. I believe that such a component would be attempting to accomplish either one of two things-either work towards transparency of the kind I believe my proposal is already handling, or to hold scientific projects accountable to the public. While I think that it is important that science be responsive to those who will be impacted by its technologies, (and therefore support movements like patient-centered medicine) phenomena like

### A Note on “Adoption”

Throughout my proposal on values, I have been careful to speak of “values adoption” in contrast to “values choice” or “values selection.” I have made this choice of words deliberately and with two specific goals in mind. First, “adoption” is meant to make reference to the minimal sense in which values are explicitly held, expressible, accessible and therefore changeable. Second, “adoption” is meant to express a communal and social process. I will expand on the importance of each of these two reasons for talk of “adoption” below.

“Adoption” serves to flag the way in which there are additional epistemic constraints on values, as opposed to beliefs or thoughts perhaps. Even individually, the values which we know we hold and can explicitly identify are just a small portion of the values which influence our decision-making. We know that we do not have a complete account of the values that we hold because of cognitive phenomena, for example, implicit bias.<sup>73</sup> Implicit bias is the phenomenon whereby even those who explicitly embrace gender and racial equality and reject sexism, racism, and ableism retain implicit, subconscious preferences based on these characteristics (Saul 2013). This suggests that while an individual may explicitly hold values like equality and fairmindedness, other implicitly held values, inaccessible to them, may also play a role in how they act. Learning about the values we hold is not as simple as reflecting and making a list, though I might wish that it were. Given this example, it seems clear that even on an individual level values are layered, entangled and perhaps contradictory. Such values may exist in trade-off relations, meaning that a commitment to one may make others untenable (Khosrowi 2016). All of this should serve to undermine any attempt to take my proposal as a straightforward selection of values from a menu. If it is the case that at last

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the “disability paradox,” make me wary of placing too much faith in the determinations of the public on matters of medicine and science (Carel 2016).

<sup>73</sup> Thank you to Rebecca Kukla for this point.

some of the values that we hold are not epistemically accessible to us, we must be modest about our claims to explicate and modify values.

Philosophy has a history of locating action and decision-making in the rational autonomous individual agent. Recent work from a variety of disciplines (such as ethics of care, feminist political philosophy and social epistemology) suggests that this is perhaps beginning our investigation of values in the wrong place. Instead, it might be beneficial to take a community or society as our unit of investigation. This seems especially to be the case in deciding on a unit for the investigation of values in science. I believe “adoption” rather than “choice” or “selection” can serve as a reminder that the process I am discussing will always be a social process, a deliberation undertaken by a group, with all of the additional messiness and complications that implies. Of course, using the word “adoption” does not remove these problems, but it can perhaps remind us to keep these issues in mind, rather than covering them over. There will be nothing neat about this endeavour, which means guidelines of the sort I have suggested here may be the most structure that can be offered to the process.

However, this modesty about the kind of epistemic access we can have to values can sometimes improperly escalate into full blown scepticism about the possibility of modifying values at all. If such a large portion of our values are not even obvious to us, the argument goes, how could they possibly be explicated and modified by a group? A look at some historical case studies, including work in primatology and archaeology can quiet this scepticism (Hicks 2014; Haraway 1989;1991). Since activism has modified values in the past, there is some reason to suppose that it is not in principle impossible.

#### Case Study: Statins for Stroke

To make clearer how my proposal might work in scientific practice, I will give an account of how values impact one future scientific project: a randomized controlled trial (RCT) for the use of statins in stroke patients.

Suppose you are a medical researcher investigating the use of statins in stroke patients. While statins have been (controversially) studied and approved for the treatment of other cardiovascular events and conditions, the most recent Cochrane review on statin use reported that there was “not enough evidence” to support their use in case of stroke. They write, “The available evidence does not confirm any benefit or harm of statin administration in the acute phase of cerebrovascular ischemic event, in particular ischemic stroke” (Squizzato et al. 2011). What kind of values are in play in a research project to design and carry out a RCT for the use of statins in stroke patients?

To answer that question, we need to know a bit more about the proposed intervention. Statins are a class of drugs commonly used to lower cholesterol. They are some of the most commonly prescribed drugs in the United States and have a similar record of use in the UK and Canada (Stegenga 2016).

While supporters of EBM, like many at the Cochrane Collaboration, are loath to spend much time discussing intervention causality or mechanisms, they write in a short section entitled “How the intervention might work,”

The potential positive effects of statins during an acute cerebrovascular ischemic event are two-fold: a neuroprotective effect, limiting damage and improving recovery from the presenting event (in particular for major stroke); and an antithrombotic and endothelial effect, preventing early recurrence (in particular in TIAs [transient ischemic attack] and non-disabling stroke. Some clinical data apparently support these potential mechanisms. However, recent published data from the Fast Assessment of Stroke and TIA to prevent Early Recurrence (FASTER) study seem not to support the latter hypothesis...(Squizzato 2011)

That is, statins intervene on stroke by preventing damage and improving recovery, or preventing additional strokes. Because strokes often involve similar systems and problems to other cardiovascular events like myocardial infarctions, events statins are approved interventions for, it has been suggested that statins might help improve stroke outcomes.

There is a history of reports of muscular problems from patients who take statins. These problems manifest in many different ways from myopathy (muscle aches) to rhabdomyolysis, a serious condition which can cause extreme pain and death (Stegenga

2016). While there are many patient reports of these kind of effects Cochrane did not find many instances of these problems in their review, writing, “No cases of rhabdomyolysis (the breakdown of muscle fibres resulting in the release of muscle fibre contents (myoglobin) into the bloodstream) occurred in 274 patients enrolled in three studies” (Squizzato, 2011).

In the case of statins, many values are in play. For example, the choice of RCT as a methodology might suggest “rigor” and “generalizability” as values, at least rigor as defined by EBM.<sup>74</sup> <sup>74</sup> In tension with these values might be the value of timeliness- in order to achieve the required power, RCTs often take years to recruit and follow up on many participants. Other methodologies might be more appropriate if we have reason to think that timeliness or thrift are particular values of the project. In addition, it is likely that profitability is a value in play here, either very explicitly in that this research is carried out by a company hoping to have good news for their shareholders or somewhat implicitly in that any grants or patents that are given to a public institution for this research will impact that institution’s bottom line. In that the project has chosen to study statins, a drug which is already widely available which does not require any new complex delivery system, perhaps implementability is an important value. Institutional commitments might require that research be patient-centred, making that a value under consideration. Other values that might be in play include; fruitfulness, simplicity, justice, scope, and equality-of-access. Since many of these values exist in trade-off relations and a project guided by different values can produce different results, some method will be needed to sort through and adopt values which are suited to the project; values that fit.

What if we were to subject this tangle of conflicting values to my proposed guidelines? My first requirement was that the values we adopt be local-that is, appropriate to

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<sup>74</sup> Indeed, the choice of RCT as method may indicate that the whole group of values implicit in EBM are in play.

<sup>74</sup>I am not making the claim here that rigor and generalizability are guaranteed by the use of an RCT. I am claiming that the use of the RCT methodology can be reliability taken as a signal of some of the values in play.

the values of the science in which the project is taking place. In this case that would be most broadly medicine, but perhaps also epidemiology and public health. This criterion can help us to reject some values as inappropriate. For example, while simplicity is an important value for other sciences like physics, it does not make very much sense as a value for a project in these scientific disciplines. Therefore, locality can rule out these value-candidates.<sup>75</sup>

My second criterion, context dependency, can continue to narrow the field of possible values for our RCT of statins for use in stroke. The guideline of context dependency asks us to consider the history of the discipline in which the scientific project is taking place, as well as the history of more specific similar projects. In this case, it is important to know the history of patient-centred health care; a movement undertaken by patients and clinicians to ensure that care and research are focused on outcomes that patients care about and which takes the patient perspective into account (Bechtel and Ness 2010). This movement was a response to the historical paternalism and authoritarianism in medicine, both in the sense of the egregious oversights recorded in the history of bioethics and also in the opportunity costs associated with research driven by academic interests or pharmaceutical company's bottom lines, rather than patient needs. This information is combined with the specific information we do have about patient reported muscular problems. So, in the case of an RCT for statin use in stroke, the context dependency guideline requires that, in response to this particular history, a patient-centred trial which investigates these muscular problems is undertaken and that an appropriate value for our research is patient-centeredness.

The final requirement, transparency, might be satisfied many different ways. The simplest might be to include as a standard practice, a section of this kind, perhaps just after the "methods" section of the project's write up: "In designing this study, we made decisions in light of particular values, including methodological rigor, patient-centeredness, and ease of implementation. We adopted these values based on the history of the discipline and the contemporary concerns of users." However, a more thorough dedication to this guideline might require the use of a formal Values Discussion Protocol. In future work, I hope to



develop such a protocol including concepts taken from the philosophical “values in science” tradition as well as from the value-based practice (VBP) movement in health care. Even though a more rigorous process may seem excessive, it more fully satisfies the guideline of transparency as previously discussed and helps to avoid the “tick box” objection I will discuss later. For these reasons, I would, in our hypothetical statins for stroke case, encourage the use of such an extended protocol.

While this set of guidelines cannot definitively guard against the worry of wishful thinking when it comes to values in science, they are good first step towards adopting values that fit particular scientific projects without universally declaring that some values are acceptable and others not, as has been the trend in the values in science literature up until now. This set of guidelines works tightly together, in that the transparency requirement asks for explicit deliberation about values, without which this whole project is impossible, while the context-dependency and locality requirements allow us to learn from the rich histories of different scientific projects to prevent poorly adopted values of the past from rearing their heads again. Given that the alternatives to the kind of program I offer here is to insist that science is value free (allowing values to enter into scientific projects without judgement or deliberation) or to insist that some values are universally acceptable and others universally unacceptable (which does not respect non-reducible differences between scientific projects) I believe the sort of guidelines I offer here are our best option, even if they cannot promise a watertight avoidance of the problem of wishful thinking, or ensure that future scientific projects will always adopt prudent values.

### Objections and Replies

In this section, I consider three possible objections to my positive account of desiderata for values inclusion. These objections are the “entrance of politics” objection, the “too high a bar” objection and the “what about relativism?” objection. I will answer the first only briefly and the second and third at greater length.

The firsts of these objections, the “entrance of politics” objection, is the most general. The idea here is that my suggestion that encourages the adoption of values which are local, context-dependent and transparent is a problem, not because of the details of the proposal, but because it advocates the inclusion of values in science at all. Since philosophers have been writing about the ways science is shot through with values for at least 50 years, it may seem repetitive or dated to continue to respond to this sort of critique. Nevertheless, as the value freedom of science remains an important assumption for the public as well as for parts of science itself, it is important to continue to engage with these kinds of critiques.

In response to this objection, I argue that far from introducing corrupting values into an otherwise objective, value-free science, I am instead promoting a systematic method for identifying and documenting appropriate adopted values. Since values are already in science, my proposal cannot be accused of introducing values. Values are present in each stage of science from the production of hypotheses to the choice of which projects to pursue to the collection of data to the design of experiments to the presentation of findings to the scientific and wider community. This has been well argued by many (Longino 1990; Biddle 2013; many others). My proposal does not bring values into science; they were always already there.

It is of course important to note that while political values are the ones often worried about, the category “values” is much broader. Once we have in place some systematic method for documenting and suggesting values for use, we may well find that there are many values we would not choose to have our research guided by. These might well include some kinds of politically-based values.

In fact, once this kind of critic is convinced of the ubiquity of values in science, convinced that science is already “contaminated” with values, my proposal may be a welcome source of structure and transparency. While I do not share with these critics their strong worries about the damaging or dangerous effects of values, we would share the view that more transparency about these values and how we got to have them is better than less.

A second possible objection to my proposal might be the “too high a bar” objection. This objection states that the reason not to adopt my proposal is that it makes improperly high demands on scientists. Scientists, such a view holds, have their hands full with the practice of science and do not have the time or resources to investigate, reflect on, and adopt values as well. In addition, the argument goes, even if they did have the time or the resources, scientists are not trained to think about values. Overall, one could use these reasons to suggest that my proposal simply sets the bar too high.

I would respond to such a critique by suggesting that while my proposal might set a high bar, it is a bar scientists are already routinely surpassing. Scientists in many disciplines are already having important debates about the values within their fields, albeit often implicitly and without resources or systems for recording and reporting their decisions. The DNDi value statement is one example of an explicit concern for values on the part of scientists—there are many more (DNDi 2013). Scientists from a variety of disciplines are already considering value concerns. My proposal does not therefore “set the bar too high” but instead suggests an explicit and systematic set of desiderata for doing work scientists are already doing.

Perhaps there is the additional claim here that what makes the bar too high is my insistence on these particular guidelines—that adopted values should be local, context dependent and transparent. If I had called instead for the inclusion of values in science but have asked for values which were, say, absolutely unified and held throughout all space and time, perhaps this would not set the bar too high. If this is what had been proposed, such a set of values might be provided once and for all, for all sciences, by non-involved values experts; perhaps philosophers. So, it is not just that the project of investigating, reflecting on and documenting values for the sciences is difficult, although it might be, but also that the specific desiderata that I have included make the project even more difficult. However, the problems that these kind of universal distinctions have continued to face, as detailed in

section one, suggest that the project of finding universal acceptable values for science, or even universal rules for deciding which values are illegitimate or legitimate will be unfruitful.

A third possible objection my proposal might face is the charge of relativism. The argument here is that my proposal is relativistic in that it admits of many possible values. The worry is that this attempt to let a hundred value-flowers bloom makes criticism of scientific projects impossible. When confronted with a critique, members of the project being critiqued can simply point to a difference of values to defuse criticism. In this way, all sorts of poorly done science would be allowed to proceed unrestrictedly. Rigor, long considered an important deliverable of science, will be lost.

I can respond to this critique in two ways. The first and weaker response I call the agnostic response; the second, which is much stronger, I call the not-even-close-to-anything-goes (NECTAG) response.

A first way of responding would be to remain agnostic on the issue of relativism. Perhaps there is some set of scientific values which are always the right ones, allowing significant criticism of particular scientific projects which use values that are not part of this universal set. However, without implementing my proposal, we have no way of systematically documenting what values are going on in science at all. Might we find that some projects have used values that are unacceptable in some way and want to have the epistemic strength to criticize those projects? Yes, but this requires as a first step systematically documenting and discussing values, as suggested by the requirement of transparency, not insisting that science is value free. Relativism might be a problem but it is not our first problem, and its possibility does not dissolve the importance of my proposal. This style of answering puts lots of weight on the inclusion of “transparency” as a component of my proposal.

Another possible response which does not attempt to dissolve the charges of relativism but instead meets it head on is ‘NECTAG.’

NECTAG references the Feyerabend “anything goes” form of relativism —the claim that no value is inappropriate or bared from consideration and inclusion (Feyerabend 1975).<sup>75</sup> My proposal has two components which make clear that it is NECTAG-locality and context-dependency. For those who will worry that my proposal will leave us with no way to critique science which uses values like, “I will believe whatever is most profitable to be true” or “I will prioritize outcomes which are in line with my political beliefs, regardless of my findings” need not worry. My proposal, far from supporting an anything goes relativism, actually gives us two additional criteria, locality and context dependency, with which to critique these kinds of issues. This critique might go as follows: values like “believe whatever is most profitable to be true” or “prioritize outcomes which are in line with my political beliefs, regardless of my findings” fail both to be respectful to the fields in which these projects occur (locality) and to the history of value failings in those fields (context-dependency). While I have said that appropriate values vary from discipline to discipline and context to context, this does not entail that all values are permitted. This kind of response requires a shared weight between the context-dependent and local criteria and the historical content of the various special sciences. These two arguments can do much to deflate the threat of relativism in my proposal. While I stand behind the stronger second response (NECTAG), I include the first (agnosticism) because even the most stringent critic must surely admit that much.

As a way of further explaining how these three criteria can constrain inappropriate values in science (without necessarily claiming that they prevent all instances of the problem of wishful thinking), consider an example from pharmacology, a value which is a variation on the above “believe whatever is most profitable to be true” value worry. In this example, a particular drug X is the great financial hope of pharmaceutical company A. Considerable time and resources have been put towards developing this drug. However, RCTs for drug X have come back with a p value of .10, higher than the usually accepted .05. That is, for drug X,

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<sup>75</sup> While Feyerabend is often charged with being a relativist or postmodernist, this view is being challenged. See Kidd (2016).

assuming the drug did nothing, you would obtain the observed difference between patients who did and did not get drug X, or a greater difference, in 10% of studies due to random sampling error. As a result, the company is considering lowering its usual p value threshold from the traditional .05 to .10 for this drug and publishing these results as “significant” without remarking on the difference in standard. What can my three criteria say about this possible value (something like “fit your statistical tests to your financial needs”)?

If my first criteria, transparency, were to be followed in this case, the researchers on drug X would be asked to articulate and reflect on their reasons for working on this scientific project in the ways in which they are. They would be asked to articulate the values in play in this particular case, hopefully using a systematic values finding system, perhaps similar to that used by the Toolbox Project in the Michigan State Philosophy department (Gonnerman et. al 2015).<sup>76</sup> In the course of this systematic articulation and reflection on values, they would perhaps say things like, “the bottom line is just really what drives our choice of tools,” “the most important thing to make sure that the statistics we use show the potential of the product” or “it was really important to show the value of drug X this quarter in whatever way we could, regardless how the trials were going.” It is true that transparency itself is the normatively weakest of the criteria- it only makes possible the normative judgements preformed by the other two criteria. However, without transparency as a criterion we might not have access at all to the internal understanding of the values in play in a particular scientific project. Transparency thus provides an important first step towards rejecting the value “fit your statistical test to your financial needs,” as inappropriate.

My second criteria, locality, requires that we look into the types of values which fit with the goals of the science in question, which is in this case, pharmacology. In this case, while we can find that there is at present an interesting and important debate about the use and abuse of significance testing in general (American Statistical Association 2016;

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<sup>76</sup> In future work, I would like to develop my own system for values articulation and reflection, but my work will owe much to the Toolbox system. The Toolbox system works as an example of the kind of activities which would fulfill the transparency criterion for current purposes.

Wasserstein and Lazar 2016), and specific motions to modify traditional p values levels (say, from .05 to .005) (McShane et al 2017; Benjamin et al 2018), these debates are motivated by differing views on statistics, and worries that both scientists and the public understand these concepts in a flawed manner. We will not find here any defense of modifying p values for purely financial reasons. My second criterion would additionally defend against the acceptance of the value “fit your statistical tests to your financial needs” as acceptable.

My third criteria, context dependency, would have us examine the history of pharmacology to discover the appropriateness of this proposed value, given inappropriate value-based failures in this science in the past. This examination would bring to light a history of statistical manipulation for financial gain with bad consequences in pharmacology. (Fries and Krishnan 2004, Biddle 2007, Goldacre 2012 for a sample). My third criterion would provide additional reason not to accept “fit your statistical test to your financial needs” as an acceptable value for a scientific project in pharmacology.

A final kind of objection to my proposal might be the worry that this description and systemization of values will actually lead to less, rather than more, reflection on values in the sciences. Such worries might come from imagining a not-too-distant future in which, in alignment with my proposal, a section labelled “values” is included in every scientific paper. However instead of this being the result of serious reflection and debate among the research group, this section is replicated verbatim from previous research. Perhaps even worse, the existence of this formalized paragraph discourages reflection or discussion of values since this paragraph means that “values are taken care of.”

Such calcification of the process of values adoption is not difficult to imagine, especially given the extent to which research ethics has been similarly simplified. While such calcification is surely possible, it can perhaps be avoided by the development of manuals or guidelines for “how to write a values section” similar to the current literature on how to write a methods section. And while it is true that many methods sections are formulaic, they still allow for differences and deliberation about best practices from project to project. While it is important to consider the possibility of calcification, especially given the current state of

research ethics, my proposal need not result in this kind of values calcification and is an important step forward toward explicit values adoption.

This program for value adoption, which acknowledges the role of values in scientific practices but prevents just any values at all from being adopted via three desiderata, can do much to help philosophers and scientists to think about the ways in which values and science can work together. However, in other debates about values and science, it is argued that values and facts are very different things; so different that their differences support a strong demarcation between the study of values done in projects like ethics, and the study of facts done in projects like science. In the following section, I argue that the split between facts and values is not as clean as is often claimed, meaning that calls for demarcation between science and ethics cannot be done via the fact/value distinction.

“Fact-Based Values”: Why the Fact/Value Dichotomy Plays Too Large of a Role in Critiques of “Evidence-Based Ethics”

In this section, I examine the way in which the fact/value dichotomy is utilized in the demarcation of normative ethics and, more specifically, the role this dichotomy plays in critiques of calls for “Evidence-Based Ethics.” Since the debut of Evidence-Based Medicine in 1992, the “evidence-based” methodology has become ubiquitous in the health professions and has spread to other disciplines such as education and social policy. Especially given the close relationship between the health professions and bioethics, it is unsurprising that “evidence-based” methodology and rhetoric would soon be manifest in bioethics. This movement has been called “Evidence-Based Ethics.”<sup>77</sup> There have been many different attempts to criticize this application of “evidence-based” methodology to bioethics, and ethics generally. These critiques often have in common that they make use of the fact/value dichotomy, traditionally attributed to Hume, to suggest that while “evidence-based” methods might aid in producing properly vetted facts needed for decision making in fields like

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<sup>77</sup> See (Strech 2008) for a good overview of the movement



medicine and education, these methods cannot assist with the content of ethics, that is, values. I will argue that because the fact/value dichotomy is much less unproblematic than we might think, it would be unwise to make too much use of this trope in attempting to demarcate bioethics and the science of medicine. I do this using separate arguments from philosophy of language and feminist philosophy of science. I agree that calls for “Evidence-Based Ethics” deserve examination and critique. I will conclude my paper by offering a strategy for the critique of “Evidence-Based Ethics” that does not lean on the fact/value distinction for strength.

### A History of Evidence Based Ethics: Roots in Evidence Based Medicine

Evidence-Based Ethics, part of what has come to be called the “empirical turn” in ethics, is part of a set of “evidence-based” disciplines, including nursing, chaplaincy, education, and health policy that followed in the wake of EBM. While versions of Evidence-Based Ethics vary within the literature, generally the idea here seems to be that ethics should take into consideration relevant evidence, evidence that is arranged in a hierarchy that is more or less similar to that used by EBM, during moral investigations. One proponent defined Evidence based ethics this way, “As in medical decisions based on evidence-based medicine, 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 promote better informed and better justified ethical decision making” (Major-Kincade et al. 2001), but the definition remains controversial in the literature (Strech 2008).

This might seem problematic for a number of reasons and require careful critique. One sort of critique is levelled by Maya Goldenberg in her 2005 article, “Evidence-based ethics? On evidence-based practice and the empirical turn from normative bioethics.” Her project of critiquing Evidence-Based Ethics (a project I have much sympathy for) takes the fact/value distinction as an important component, a move I warn against. This move is also made in nearby debates about the possibility of moral expertise, in a similarly problematic

way. However, before I go too much further with this, I should say more about what the fact/value distinction is.

### Origins of the Fact/Value Distinction in Hume

The is/ought or fact/value distinction is generally attributed to Hume. He writes in *A Treatise of Human Nature*,

In every system of morality, which I have hitherto met with, I have always remarked, that the author proceeds for some time in the ordinary ways of reasoning, and establishes the being of a God, or makes observations concerning human affairs; when all of a sudden, I am surprised to find, that instead of the usual copulations of propositions, *is*, and *is not*, I meet with no proposition that is not connected with an *ought*, or an *ought not*. This change is imperceptible; but is however, of the last consequence. For as this *ought*, or *ought not*, expresses some new relation or affirmation, 'tis necessary that it should be observed and explained; and at the same time that a reason should be given; for what seems altogether inconceivable, how this new relation can be a deduction from others, which are entirely different from it. (Hume 1739/2000, 335)

This has been taken to mean that the projects of various kinds of empirical research and the projects of moral investigation must be kept separate from each other. Whether this parse is respectful to the context in which Hume made these original comments, if this is what Hume had in mind in his comments, and the relation of this original meaning to the fact/value distinction as now commonly referenced in philosophy now are questions outside the scope of this work. For the time being, let it suffice to say that that previous parse is what we mean when we talk about the fact/value dichotomy.

### Analysis of Goldenberg's Critique

This distinction appears in Goldenberg's critique of Evidence-Based Ethics. She articulates her worries as follows,

Much like positivism threatened ethics by rendering it 'senseless' an evidence-based approach proposes to make moral deliberation redundant as it offers a method to resolve ethical and political questions about healthcare spending and practice by appeal to technical measure. The normative issues therefore get coopted by supposedly neutral technique. An evidence-based ethics would therefore threaten bioethics' normative mandate. (Goldenberg 2005, 7)

She continues, writing, "therefore along with wavering on the fact/value distinction, evidence-based ethics threatens bioethics' normative mandate" (Goldenberg 2005, 7). Goldenberg is

here engaging in a project of subject demarcation, in the hope of retaining this mandate, suggesting that evidence-based approaches might work fine in medicine and science, the realm of facts, but may threaten the sovereignty of the realm of values, ethics. It is true that her larger goal is the retention of a clear mandate for a strictly normative realm of thinking, but in order to protect that mandate, she is willing to use the fact/value distinction as a demarcation tool, a critical move in her larger argument.

None of this suggests that Goldenberg is unaware that a reliance on the fact/ value distinction is problematic (she suggests as much in a footnote) but only that it is not problematic enough to avoid as a strategy. Indeed, she is not at all alone in her use of this trope: the concept is mentioned in passing in much of the critical literature on Evidence-Based Ethics.

### Two Strategies For Problematizing the Fact/Value Dichotomy

Now I want to problematize the Goldenberg critique of Evidence-Based Ethics by suggesting that the fact/value dichotomy is not as strong or clear as we might think. I do this in two ways. The first strategy makes use of arguments by Hillary Putnam in the philosophy of language. The second strategy makes use of arguments put forth by feminist philosophers and philosophers of science arguing against the value-free ideal in various special sciences.

### Putnam on Thick Concepts

The distinction between thick and thin value concepts was used by Putnam to illustrate a difficulty in the traditional hard distinction between facts and values. Putnam writes,

When we think of facts and values as independent, we typically think of 'facts' as stated in some physicalistic or bureaucratic jargon, and 'values' as being stated in the most abstract value terms, e.g. 'good', 'bad'. The independence of value from fact is harder to maintain when the facts themselves are of the order of 'inconsiderate', 'thinks only about himself', 'would do anything for money.' (Putnam 1981, 139)

These "thick terms" are meant to complicate what seems at first to be a clear distinction. In the previous quote, "thin" concepts are the "the most abstract value terms e.g. 'good', 'bad'." In other works, Putnam writes that a list of "thin" value terms might include "good", 'ought',

'right' and their opposites 'bad', 'must not', 'wrong' as well as 'virtue', 'vice', 'duty', 'obligation' and so on" (Putnam 2004, 35). What makes these terms "thin" is that they seem to only praise or blame without any other content.<sup>78</sup> This is in contrast to "thick" terms. "Thick" terms, in addition to praising or blaming, also carry some additional description. Such terms might include, "generous', 'elegant', 'skillful', 'strong', weak,' or 'vulgar'" although the list includes many others as well (Putnam 2004, 35). The term 'cruel' is one that Putnam spent significant time meditating upon. He writes,

The sort of entanglement I have in mind becomes obvious when we study words like 'cruel.' The word 'cruel' obviously – or at least it is obvious to most people even if it is denied by some famous defenders of the fact/value dichotomy – has normative and indeed ethical uses. If one asked me what sort of person my child's teacher is, and I say, 'He is very cruel' I have both criticized him as a teacher and criticized him as a man... Yet 'cruel' can also be used purely descriptively, as when a historian writes that a certain monarch was exceptionally cruel... 'Cruel' simply ignores the supposed fact/value dichotomy and cheerfully allows itself to be used sometimes for a normative purpose and sometimes as a descriptive term. (Putnam, 2004, 35)

So, we have established that cruel is a "thick" term, one that has both evaluative and descriptive meanings. Additionally, these dual meanings are intertwined. If we are uncomfortable with this duality, what are our options?

Here we seem to have two options according to Putnam's account of traditional non-cognitivists. They are,

1. To simply insist that thick ethical concepts are plain factual concepts and not ethical or normative concepts at all. This is the response of R.M. Hare (in the case of 'rude') and of John Mackie (in the case of 'cruel').
2. To claim that the thick ethical concepts are "factorable" into a purely descriptive component and an "attitudinal" component. The descriptive component then states the matter of fact that the predicate corresponds to, and the attitudinal component expresses an "attitude" (an emotion or volition) exactly as in noncognitivist accounts of the function of 'good,' 'ought,' and so on. (Putnam 2004, 35-36)

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<sup>78</sup> I might argue that "duty" and "virtue" have more than simple "praise and blame" as content, but this is not the place for it.

Neither of these options seem to be respectful to the value content in thick concepts. The first option denies that there is such a thing as value content in thick concepts. I would ask those who espouse such an option how they account for the fact that we use such concepts to praise or blame, if they are really mere descriptions of facts. For example, no one thinks that I have made an objective value-free description when I describe my child's teacher as "cruel;" it is clear in this situation that I mean to blame my child's teacher for poor treatment of some kind or another in a way which does not leave open the option of being a good teacher or a good person (Putnam 2004, 34).

In the second option, the thick concept is divided into two portions. The "attitudinal" component is described as either an emotion or volition and plays little role in the additional analysis of the concept. The descriptive component can then be compared to facts-in-the-world to determine its truth. It is not clear why we should think that these concepts can be easily divided into these portions; why not think instead that the concept is "shot through" with values? Neither of these two options for dealing with the normative/descriptive duality of thick concepts seems satisfactory and no other options present themselves in Putnam's work.

In discussing the way in which some terms seem to "cheerfully" be both descriptive and normative, to be like facts and to be like values, and the ways in which attempts to wrest these terms apart to fit in these categories fail, I hope to have shown that depending on the fact/value dichotomy to demarcate ethics from sciences and thus critique Evidence Based Ethics is problematic. However, taking a lone argument from philosophy of language, with all the baggage of that field, does not seem to be enough. There is another way to critique the fact value distinction which comes from a group of philosophers of science with feminist leanings.

#### Historical Case Studies in Philosophy of Science

As I have noted previously, for the last 50 years various arguments have been put forward by philosophers of science to suggest that science, the traditional realm of facts, at

least *was not* value-free, but perhaps *should not* be value-free. Some provided examples in which work in science was entangled with values. Examples of this kind of work include Heather Douglas's arguments about inductive risk based on the case study of the use of values in reading rat liver slides in dioxin cancer studies, among others.

### Douglas Case Study

In her 2000 article, "Inductive Risk and Values in Science," Douglas explained her concept of inductive risk via a case study on the examination of images of rat livers in toxicology studies. She writes,

In dioxin cancer studies, rodents (the animal group of choice because of their relatively short lifespan and rapid breeding cycle) are dosed for two years, close to a natural life-span. At the end of two years, full-body autopsies are performed on the animals to gather the endpoint data. Because dioxins appear to affect more than one organ site, all potential areas for cancerous growths are checked. In the studies relied upon by regulators about dioxins, tissue and organ samples have been mounted on slides to be evaluated by toxicologists...The female rat liver slides have undergone at least three evaluations by pathologists, with different results. (Douglas 2000, 17-18)

It might seem strange that multiple evaluations by pathologists should produce different results—surely there is a clear fact-of-the-matter about whether these slides do or do not depict patches of cancerous growths. Douglas writes, "As evidenced by the lack of agreement among expert pathologists, the judgement of whether a tissue sample has a cancerous lesion or not has proven to be more subtle than one might initially suppose (Douglas 2000, 19)." Douglas attributes these differences to what she calls non-epistemic values; practitioners have different levels of concerns about the consequences of getting their judgements wrong. Douglas calls this phenomenon inductive risk and argues that it accounts for the different judgements in cases like the rat liver slides. In this case study, it is clear that what looks like an endeavour about facts has important components which are dependent on values consideration. These two components are, in the Douglas case study, and perhaps elsewhere, impossible to separate in the way which those who seek to use the fact/value dichotomy as a demarcation tool suggest.

Others have gone farther, arguing that sciences should not be value-free but require the use of certain values to improve the science, given particular histories. Often, the

prescribed values here were to be feminist values, invoked to improve sciences which are restricted by sexist history. Examples of this kind of work include Helen Longino's work on prenatal determination of gender role behaviour and Donna Haraway's famous work on primate behaviour.<sup>79</sup> This source of rich examples goes far to suggest that far from being unproblematic, calling upon the fact/values distinction to carve out a sovereign role for bioethics, as was an important move in Goldenberg's critique of Evidence-Based Ethics, treads on shaky ground indeed.

In conclusion, though thorough and rigorous critique of Evidence-Based Ethics is an important project, it is however a project which can be undertaken without depending on the is/ought distinction as a dubious demarcation tool to provide the boundary between ethics and the sciences, including medicine.

#### New Developments in Values in EBM

There is some evidence that EBM is one scientific arena which is ripe for the kind of guidelines for adopting values that I have sketched in this chapter. In 2015, Michael Kelly, Iona Heath, Jeremy Howick and Trisha Greenhalgh, all members of the Evidence Based Medicine Renaissance Group (Greenhalgh et al. 2014) published "The importance of values in evidence-based medicine" in BMC Medical Ethics. In this article, they argue that,

Consideration of values can enhance every aspect of EBM, including: prioritizing which tests and treatments to investigate, selecting research designs and methods, assessing effectiveness and efficiency, supporting patient choice and taking account of the limited time and resources available to busy clinicians. Since values are integral to the practice of EBM, it *follows that the highest standards of EBM require values to be made explicit, systematically explored, and integrated into decision making.* (Kelly et al. 2015, 1)<sup>80</sup>

An important upshot of their article is that there will be values in EBM, regardless of if we discuss them or not. By avoiding or downplaying a discussion of values, we do not keep

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<sup>79</sup> Wylie's case from archeology on the gendered attribution of early agricultural domestication, discussed in the section entitled, "A Proposal for Guidelines: Locality, Context-Dependency and Transparency," would be an additional example of this kind of work.

<sup>80</sup> Emphasis mine.

scientific projects free from values but instead risk, “introduce[ing] new (mostly covert and unacknowledged) biases” (Kelly et al. 2015, 2).

The authors discuss fairly traditional places to point out values in a scientific project; determining which questions to ask and applying research findings in order to make clinical decisions. But importantly, they do not shy away from discussing roles for values which go right to the very heart of the scientific project of EBM. These include method selection (traditional RCT or “pragmatic” trial) and what they call “values in the broader sense,” which is explained in a section in which they examine the utilitarian values that underpin most of EBM (“value for money”), which come into conflict with the primarily deontological values of the clinic (physician’s duty of care to patients).

This article is an exciting step forward for the discussion of values in EBM. However, it perhaps paints too rosy a picture of what values can do. The traditional worries of pernicious relativism and wishful thinking, which occupy such an important place in the larger values in science literature, are not discussed here. This article establishes that EBM needs to talk about values; more work is needed to make sure this can be done without undermining the project of EBM. There is still a need for my guidelines, as discussed in the section entitled, “A Proposal for Guidelines: Locality, Context-Dependency and Transparency” here, though EBM seems to have made great progress in its discussion about values.

It would be too quick to say that this article itself represents a sea change in EBM on values. Several of these authors critique various aspects of EBM in other work, so perhaps they are not its most conservative supporters (Heath 2016; Kelly 2009; Greenhalgh 2015). Additionally, this article was published in a medical ethics journal, rather than a more mainstream medical journal, which perhaps indicates the authors’ awareness of where they were likely to find a friendly audience. Nevertheless, their interest discussing new and expanded roles for values suggests that EBM is one scientific project which might in the future be open to the previously described guidelines for purposefully adopting values.



## Chapter 5: Personal and Precision Medicine: The End of EBM?

### Introduction

From “Personalized” to “Precision” Medicine Replacing  
EBM with Precision Medicine: Why a Delay?

But Wait: Why Think Evidence Can Be Replaced or Have Competition?

Reasons for Delay

New Trend, Same Issues

Expertise in Precision Medicine

Mechanisms in Precision Medicine

Values in Precision Medicine

Implications of Problem Consistency for Philosophy of Medicine

## Introduction

In medicine, excitement about genetics has produced a new goal: personalized or precision medicine. This may seem to be such a different goal from Evidence-Based Medicine (EBM) that the issues discussed in this work will no longer be at issue. While it is true that personalized or precision medicine will have its own set of issues, I argue that many of the same concerns discussed by philosophers in the context of EBM would still be relevant in a “new paradigm” of personalized or precision medicine. These perennial problems include the problem of expertise, the problem of mechanisms, and the problem of values.

This chapter contains four sections. First, I trace this new movement in medicine from the original label “personalized” to the currently accepted “precision” medicine. Next, I present the case that EBM will soon be replaced by genetics-based precision medicine. While many have promised this paradigm shift, it has not yet taken place. There are two possible kinds of reasons for this; reasons why precision medicine, as popularly promised, cannot take place in principle, and reasons why precision medicine has not yet taken place in practice.

In my third and main section, I discuss three issues which have been raised in relation to EBM and the ways in which these issues crop up again in new forms in precision medicine. These include the problem of expertise, the problem of mechanisms, and the problem of values. The problem of expertise in EBM included worries about how important, and yet under-articulated and under-theorized, expertise was in this trend, which, if not augmented, could have serious consequences for the implementation of EBM for the clinic and for medical education. This issue would remain important in precision medicine. The problem of mechanisms was the difficulty of making clear the role of mechanisms as evidence in EBM, either within the evidence hierarchy or augmenting it in some way. This issue also includes the problem of stipulating how many and which confounders need to be included in an informative mechanism so that a useful picture of how the intervention worked was gained, without this becoming unnecessarily epistemologically burdensome. In precision

medicine, concern about the interaction of mechanisms and the hierarchy in producing evidence drops out, but worries about the possibly unmanageable scope of mechanisms remain. Lastly, in EBM, the problem of values was the difficulty of finding good ways to identify, reflect on and adopt values for use, once it became clear that EBM was not a value free enterprise. This challenge remains in full force in precision medicine.

In my fourth section, I suggest that we should consider the consistency of these issues as a feature, rather than a flaw of philosophy of medicine. While medical movements might come and go, philosophy of medicine can still find footing for interaction with clinical practice.

#### From “Personalized” to “Precision” Medicine

The term “personalized medicine” has been tightly tied to outputs and applications of the Human Genome Project (Collins 2010). However, in their paper reviewing 143 interviews with, “proponents of personalized genomic medicine—including scientists, translational researchers, commercial and non-profit developers, research funders, clinician researchers, clinicians in private practice, health professional educators, medical journal editors and health insurers,” Juengst et al. found that, “By 2012...powerful opinion leaders were abandoning ‘personalized medicine’ as a usefully descriptive name for their cause in favor of a new label: ‘precision medicine’” (2016). Why has this shift in terminology come to pass? What does it mean?

While there are several possible origins for the term “precision medicine,” it was at least in use by 2008, when Clayton Christenson of Harvard Business School used it in his book, *The Innovator's Prescription: A Disruptive Solution for Health Care* to describe the good the molecular diagnostics could bring to medicine in removing clinical intuition (Christensen 2008; Katsnelson 2013).

There were two main reasons for this shift away from “personalized” to “precision” medicine, according to Juengst et al.; first, decoupling the movement from patient empowerment efforts and second, an emphasis on lowering expectations from individually

tailored and unique interventions to improving interventions by learning more about smaller groups of patients with similar genomic disease risk associations.

Juengst et al. argue that, “the operation of ‘precision’ equipment, large scale ‘datamining’ activities, and the targeting of ‘smart bombs’ are the domains of professionals, not amateurs. In fact, with the shift to ‘precision medicine’ patient-driven decision making seems almost completely jettisoned as the revolution’s signature virtue” (2016, 25). This is in contrast to personalized medicine, which had retained connections to patient advocacy groups. This move is described by Juengst’s interviewees as necessary to avoid overburdening the patient as the “data tsunami” associated with genomic outputs continues to grow (2016, 25-26).

In addition to reclaiming medicine as thoroughly the domain of the professional, on Juengst et al.’s account, precision medicine more honestly reflects the promise of using genetic and genomic information to improve interventions by emphasizing the way in which, “molecular information improves the precision with which patients are categorized and treated” (Katsnelson 2013). The unit at which interventions will be designed based on precision medicine, cannot quite be the individual, but can make claim to interventions tailored to very specific subgroups (Juengst 2016, 28). These interviewees also expressed hope that these groups based on DNA markers might replace problematic traditional social and racial categories.

Both of these shifts were moves to moderate earlier rhetoric about the promise of future interventions which may have contributed to inflated hype among patients and their families. The words of Maynard Olsen, a genome scientist at the University of Washington, have been widely repeated as summing up the difficulties leading to this change; “I think ‘personalized medicine’ was perhaps a useful rubric with which to launch this activity, but it sends a misleading message—actually both to ourselves and the broader community” (Katsnelson 2013; Juengst et al. 2016). At the same time, there has been some recent

philosophical work on personalized medicine, although not as much as on other trends in medicine such as EBM and narrative medicine. At the end of her book, *Making Medical Knowledge*, Solomon turns briefly to personalized medicine. She writes that personalized medicine is, “a term that has been widely used since about 2000, primarily to describe therapies that are tailored to individual biochemistry such as the sequence of the somatic cell genome (or proteome) or the cancer cell genome” (Solomon 2015, 227). She suggests that personalized medicine has been less readily adopted than other trends in medical epistemology, including EBM, translational medicine, consensus conferences and narrative medicine, and that when it has been adopted it was largely as a rhetorical device. This rhetorical appeal has allowed new biotechnologies to be presented to the public not as alarming but as part of individualized, tailored care. She writes, “Personalized medicine is rhetorically successful, bringing cutting-edge genomic science together with a rhetoric of individualized care, but it remains to be seen what substance lies behind the rhetoric” (Solomon 2015, 228).

The move from “personalized” to “precision” when the rhetorical usefulness of “personalized” has worn thin is reflected in many recent initiatives. These include the 2013 creation of the Institute for Precision Medicine, a joint venture between Weill Cornell Medical College and the New York Presbyterian Hospital, conferences in 2013 at the University of California- San Francisco and Cold Spring Harbor Laboratory, and uptake by pharmaceutical companies in describing the virtues of certain of their products, such as the cancer drug Xalkori created by Pfizer (Katsnelson 2013). The popularity of the term was solidified by a 2011 report on creating disease taxonomies based on molecular information rather than symptom clusters from the United States National Research Council named “Toward Precision Medicine” (Katsnelson 2013), and U.S. President Barack Obama’s call in 2015 for precision medicine (Ashley 2015; The White House 2015).

However, that there is a strong difference between the terms is not, of course, universally accepted. Edward Abrahams, the president of the Personalized Medicine

Coalition, says, “there is not one iota of difference” between the two terms. Because of this lack of difference, and the public’s comfort with the term “personalized” in relation to various patient empowerment movements, “personalized” is to be preferred according to Abrahams for rhetorical reasons (Katsnelson 2013). Roden and Tyndale write, “To us, this [the use of the term precision medicine] seems premature at best...The term ‘precision medicine’ carries an expectation of perfect outcomes that not only is unrealistic but runs the risk of overhyping the potential of the field to patients and their families. We prefer to continue and expand the use of ‘personalized medicine’” (2013, 171). In contrast to the earlier expressed hope that precision medicine corrected for the high expectations created by “personalized medicine,” these authors worry that it is “precision medicine” that sets expectations too high.

Some work uses both terms, or one as a subset of the other, without additional clarification (Mirnezami et al. 2012; Jameson and Longo 2015; Joyner and Paneth 2015). Additional concerns about precision medicine come from public health, including authors like Ronald Bayer and Sandro Galea, who worry that “that an unstinting focus on precision medicine by trusted spokespeople for health is a mistake — and a distraction from the goal of producing a healthier population,” in that precision medicine solidifies research and financial support for clinical medical interventions, when many of the improvements in health in the last few decades have come from improvements in various kinds of prevention and public health (2015). Because of the way in which it expresses that the target or the trend is not, in fact, individuals, but instead smaller, more precise subgroups, I will use the term “precision medicine” in what follows.

### Replacing EBM with Precision Medicine: Why a Delay?

Regardless of the encouraging rhetoric around personalized medicine and the clarification of the movement as precision medicine, it has yet to overtake or even challenge EBM as a dominant trend in medicine. Reasons for this delay might be practical or in principle.

But Wait: Why Think Evidence Can Be Replaced or Have Competition?<sup>81</sup>

Why think that EBM could ever be “surpassed” in any sense? Surely no future movement in medicine will be able to get rid of the demand for evidence? If some movement *were* to do this, they would be in a great deal of epistemological trouble. How would such a field police claims about interventions to see if they were warranted if not by reference to evidence? Such a movement would have much more fundamental issues than those which are leveled at EBM in this work.

Indeed, a medicine which “surpasses” EBM and is therefore unmoored from evidence would be unrecognizable as anything like medicine at all. There are a few confusions which together create this kind of worry. The first is just an error about what the content of EBM is. As detailed in the brief textual history of EBM in Chapter 1 of this work, the content of EBM was never *just* a claim that evidence was needed in order to decide on a course of treatment, as this worry seems to suggest. Instead, EBM included a set of much more specific claims about what evidence counts as good evidence, how to create and find this good evidence and how this good evidence might apply to individual patients in clinical settings. Again, these claims have changed and expanded over time in ways detailed in Chapter 1.

A second confusion that is causing the above worry is a lack of clarity about what it might mean for another movement to “surpass” EBM.<sup>82</sup> For the above worry to make sense, a movement that surpasses EM must not share any of the claims that EBM makes. This would assume a very strong kind of reactionism. Or perhaps those who have this worry are reading too much into claims made by those in EBM or other movements that these

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<sup>81</sup> Thank you to Nancy Cartwright for requesting this clarification.

<sup>82</sup> Of course, it is not the case that there can only be one trend which shapes medicine at any one time. For example, narrative medicine, which has not been the focus here, has been practiced largely at the same time as EBM though their goals and methodologies are deeply in tension (Solomon 2015). However, the narrative of precision medicine as someday replacing or overtaking EBM is well worn in the literature, perhaps because the units of measure and processes of reasoning to clinical intervention are so different in the two different trends (EBM as primarily population based and focusing on RCTs, precision medicine as individual based and focusing on individual gene testing and modification).

movements are “new paradigms” in a strict Kuhnian sense. This would result in successive paradigms being “incommensurable,” which comes close to the charge being leveled in the above worry.

However, as I discuss in Chapter 1, EBM at least is not a new paradigm in the strict Kuhnian sense, regardless of what early proponents of this movement might have suggested. In addition, a similar sort of argument can be run to argue that personalized/precision medicine is not a new paradigm, at least not in a way that threatens to condemn us to Kuhnian incommensurability- either his strong earlier, or weaker later versions of the concept. Therefore, there is no reason to think that the surpassing of one movement in medicine with another in prominence requires that these two movements share no claims or are unable to use similar concepts to talk about goals and methods. In fact, although precision medicine focuses on smaller subgroups (ideally the individual) and methods derived from genetic testing and editing, and EBM focuses on evidence from populations derived from RCTs, they share in common a set of “puzzles” and goals regarding improving human well-being.

So, this worry confuses the content of EBM and assumes a strict lack of overlap between medical movements. Yes, movements which come after and surpass the current movement in terms of influence or popularity (or even perhaps correctness) will likely share with EBM the demand for evidence to ground their claims about interventions. What will differ in this case is that for EBM what counts as good evidence will be obtained at a population level, using a particular set of techniques (randomization, blinding, and various statistical methods) while in a precision medicine setting good evidence is obtained on an individual or small subgroup level and will depend on other methods like CRISPR/Cas9, comparison work with the Human Genome Sequence and massive non-randomized cohort studies. Both agree that evidence is required to show our claims in medicine are warranted. However, this bare agreement is pretty empty—the reason these count as importantly different movements is because of the ways in which these details about evidence are filled in.



### Reasons for delay

One major reason for this delay is that contrary to some popular accounts of genetics, there is rarely a one-to-one relationship between genotype and phenotype. That is, it is only in very rare cases that an intervention on a single gene can have an impact on a particular disease or condition, regardless of popular accounts of “genes for” everything from loneliness to obesity (Davis 2016; Winch 2016). These cases so far include cystic fibrosis, Huntington’s disease, some kinds of cancer, and early onset Alzheimer’s disease.<sup>83</sup> Most other phenotypes we are interested in are either attributable to the cumulative very small effects of many genes or some combination of genes and some non-genetic environmental factors (Schaffner 2016; Barnes and Dupre 2008). Diagnostic tests to identify biomarkers which suggest the possibility of a particular phenotype may not take into consideration this cumulative effect of many genes, interaction of different genes, or the impact of a particular environment. Attempts to systematically study relevant environments may help to surmount part of this problem (Schaffner 2016).

An additional possible reason for delay is the relative immaturity of the field. Genetics, even charitably, beginning with Mendel’s original work (lost to a wider scientific audience for many years), is only a 150-year-old endeavor. Perhaps it has just not progressed enough either in technique development or indeed in public trust such that it could take on a daunting application such as precision medicine.<sup>84</sup>

Another reason for the delay in precision medicine is the current regulatory climate surrounding genetics. For example, in the United States, large public funding bodies like the National Institute of Health and the Food and Drug Administration, have banned research which involves gene editing in human embryos, although this ban may be softened or removed in the near future (Reardon 2015a; Reardon 2015b; Kaiser 2017). Research of this

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<sup>83</sup> Additionally, it is not the case that precision medicine is necessarily successful in the development of interventions even in cases where this simpler relation holds, as Solomon reminds us using the case of cystic fibrosis (Solomon 2014).

<sup>84</sup> This worry about an immaturity of practice and methods is also echoed in Solomon 2014.

kind has been undertaken by scientists in China, the United Kingdom and Sweden (Kaiser 2017), but the US prohibition removes a crucial source of funding from a global perspective. Such research may be legally undertaken in the US using private funds, but the lack of public funding for this issue is one practical reason that precision medicine has yet to emerge as a viable trend in medicine.

Precision medicine may not yet have surpassed EBM is because precision medicine is de-incentivized by both academia and industry. In academia, a shift to precision medicine is de-incentivized by publication practices. Very few medical journals publish case studies or any other type of research which features small sample sizes. Precision medicine, given the emphasis on therapies targeted to small subgroups, is likely to produce research in which the sample is small. Given the increasingly high pressure on academics to publish more, faster, these kinds of projects which produce findings many journals will not publish are de-incentivized. And since neither the “publish or perish” culture of academia nor the custom of journals to discount small sample research looks to change in the future, these problems remain a practical block to the implementation of personalized medicine.

Precision medicine might also be practically delayed because of the ways in which it would require industry to participate in de-incentivized activities. Currently, pharmaceutical companies are most interested in creating products which are of interest to large groups of people who can afford to buy these products for long periods of time. This explains the large range of drugs available for wide-spread chronic conditions which are common in the first world, such as depression and high blood pressure. Precision medicine intends to turn this model on its head, producing interventions which are tailored to very specific subgroups and whose effects are hoped to be permanent-that is, the intervention takes place once, and the phenotype is modified for the rest of the patient’s life. The current goal of pharmaceutical companies is to produce profits for their shareholders; precision medicine does not in any immediately obvious way further that goal. Thus the disincentive for industry to pursue

treatments of this kind might be a practical reason for the lack of adoption of precision medicine.<sup>85</sup>

### New Trend, Same Issues

It might be tempting to think that the issues discussed in this work, issues surrounding the concepts of expertise, mechanisms and values, arise as interesting to philosophy of medicine only in the context of EBM. That is, if EBM were to fall from prominence, these issues would no longer be of interest to the philosophical community, and the kind of prescriptions offered in works such as this would be of little use.

In the sections that follow, I argue that these particular issues, and philosophical recommendations and prescriptions regarding them, remain salient and rich even were there to be a switch in emphasis in medicine from EBM as a leading movement to precision medicine as a leading movement.<sup>86</sup>

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<sup>85</sup> It is worth noting that some pharmaceutical companies are attempting to make the pivot to a precision mindset. Pfizer, creator of the aforementioned Xalkori cancer drug for patients with particular biomarkers, has committed resources to doing this kind of work in collaboration with Medco Health Solutions (Pfizer, 2011). It is not clear that this represents a feasible business model, since this collaboration is a very small part of the Pfizer operation.

<sup>86</sup> These three are not the only issues from EBM that are likely to carry over into precision medicine. EBM, to oversimplify greatly, is particularly interested in promoting randomized controlled trials (RCTs) and methodologies derived from them, such as systematic reviews and meta-analysis. EBM's reliance on RCTs has been the subject of criticism from many sides. However, an especially important source of critique of the EBM dependence on RCTs is the "problem of generalizability." The evidence that comes from a RCT is population based evidence-by definition, RCTs can tell us nothing about particular patients, but instead about average effects sizes in a particular population in a particular place and time. Problems arise however, because generally the results of RCTs are not taken only to apply to the group which participated in the trial itself, but also in some larger application population. Indeed, one of the reasons given for elevating the methodology of RCTs so high in the evidence hierarchy (especially given their high cost) is the assumption that they deliver "once and for all knowledge," that they tell us what works, everywhere and for everyone. This is a faulty assumption and has been critiqued by many (Bluhm and Borgerson 2011, Cartwright 2007a; Cartwright and Hardie 2012; Fuller 2013, Worrall 2002; as well as many others). If these critiques are to be believed, then we have a problem; do we have any good reason to think that "what worked" there and then, will "work" here and now? This is the problem of generalizability.

The problem of generalizability seems to be particular to EBM because of the movement's uniquely strong claims about what RCTs can do. Does this mean that the problem of generalizability is unique to EBM, and is therefore likely to just fall out in the event that EBM is overtaken by a different medical movement such as precision medicine? This is not the case. EBM has drawn particular fire for assuming it has solved the problem of generalizability through the use of RCTs when in fact it has not, but other methodologies have the same problem. We cannot know just from a cohort study that the results of a cohort study apply anywhere but in the cohort. The problem of generalization would also continue to be a problem in the event that precision medicine was to replace EBM, but on a very different scale. Precision medicine explicitly avoids population based evidence and interventions and instead is supposed to operate on a much smaller scale. As a result, the problem of generalization too moves to a different scale; the worry here is that interventions designed to work with particular genes may not consistently generalize to different patients because of other confounding forces within the genome or within the environment. The problem of generalization would remain a concern in a precision medicine, but since it has not been the focus of this larger work, a more in depth consideration of this issue is not possible here.

### Expertise in Precision Medicine

In EBM, the role of expertise was and remains contested. In early EBM articles, expertise was part of what EBM sought to replace, the kind of authoritarian learning that was claimed to prevent progress in medicine (EBMWG 1992). Under later models, some role for expertise was added back, although the details of that role were not clear (Haynes 2002). It remains unclear if expertise is taken to be internal or external to evidence; that is, if expertise is to count as a kind of evidence itself, or perform other roles, such as the amalgamation of evidence and other aspects of the clinical encounter. It remains unclear if EBM takes the skills of expertise to be teachable, and if so how. Earlier in this work, I argued that the detailed theoretical account of expertise put forward by Collins and Evans could provide needed conceptual clarity for the EBM conception of expertise.

The problem of how to explain, teach and make use of expertise would remain an issue in a new precision medicine movement, although perhaps in a slightly different manner. Because precision medicine does not have the same emphasis on making distinctions about kinds of evidence, concerns about whether expertise is internal or external to evidence may drop out. However, the issue about how to recognize and teach “good expertise” will remain. Indeed, because of the difficulties of interpreting new genomic data for individual patients, expertise may be an even greater issue than it was for EBM itself (Yatsenko et al 2015).

### Mechanisms in Precision Medicine

EBM has been uncomfortable talking about causality and mechanisms. Despite many philosopher’s claims that what science (and therefore to some extent medicine) is interested in is making causal claims in order to understand and manipulate the world, (Cartwright 2007b; Russo-Williamson 2007; Illari 2011) EBM has largely avoided or marginalized talk of causes or mechanisms. They are placed at a very low position on EBM hierarchies, when they are included at all. At best, EBM manuals suggest that mechanisms can help us to select promising hypothesis for research, decide between two interventions when the other

evidence is “of low quality” or non-existent, reconstruct what went wrong when a intervention expected to be effective is ineffective, or possibly apply evidence about populations to specific patients; at worst, they are considered better avoided all together (EBMVG 1992; Greenhalgh 2010; Sackett 2000).

The usual reason given for this avoidance has been a historical and ethical one; that throughout history, the use of reasoning from mechanisms or talk about causality has resulted in bad consequences for patients. For example, for some time antiarrhythmic drugs including encainide and flecainide were prescribed to treat arrhythmia with the intention of preventing myocardial infarctions (Howick 2011b). There was a proposed mechanism for how this intervention was supposed to have a good effect; since the arrhythmias often preceded myocardial infarctions, it was thought that stopping the arrhythmia might stop the myocardial infarctions. Drugs like encainide and flecainide were thought to stop the arrhythmias, so it was thought that they would have the downstream effect of preventing the myocardial infarctions. This was not the correct account of the mechanism as became clear during the 1986 Cardiac Arrhythmia Suppression Trial (CAST). This randomized control trial of anti-arrhythmia drugs had to be stopped early because the differences between the trial arms were so large. Patients taking anti-arrhythmia drugs were having myocardial infarctions, sometimes followed by death, at a much higher rate than those who were not. These drugs were taken off the market and are now rarely prescribed (Pratt and Moyé 1995; Moore 1995). This kind of story can be told many times throughout the history of medicine about many interventions that were eventually shown to be non-efficacious or indeed, even very harmful. These include bloodletting, stomach sleeping for infants for the avoidance of SIDS, and hormone use for menopausal women (Howick 2011b).

It could be argued that in these cases the source of the problem is not the use of reasoning from mechanisms at all, but getting the mechanism wrong, or failing to recognize the entire range of mechanisms an intervention triggers. A new, revised account of the mechanism or mechanisms in question might well prove important for future research, at the

very least for activities such as hypothesis generation. It is these sorts of revisions to mechanisms which motivate many philosophers to argue that in contrast to EBM's hesitancy to make use of mechanisms, mechanisms have the potential to be very useful for health research.

However, this rehabilitation of mechanisms remains contentious in EBM. I have argued previously in this work that this is in part because of a lack of clarity about the size of mechanism-how much do we have to know before we can say that we know enough to take action based on a mechanism? Some philosophers and EBM activists, above and beyond these historical concerns, worry that we must know an incredible amount before we can say that we understand a mechanism, because we must know, according to them, all the possible confounders for a particular intervention (Howick 2011a; Howick 2011b).<sup>87</sup> This is the case even for very foundational processes, such as the metabolization of drugs; even here there remains a remarkable amount of uncertainty. Howick writes, "The partial ignorance about the metabolic mechanism means that we cannot be sure what mechanisms are eventually activated by any drug (or its metabolites) that have been swallowed. More generally, the complexity of the human body makes it difficult to identify all relevant mechanisms activated by an intervention" (Howick 2011a).

Others have slightly less high or less clear standards, but still worry that any gaps in our understanding mean that our mechanistic knowledge is flawed such that it is unusable. Other philosophers suggest not just that reasoning from mechanisms is a viable option in EBM, but that it is required, alongside the kind of evidence EBM usually champions,

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<sup>87</sup> This "all possible confounders" standard of knowledge for mechanisms may have been chosen by these critics because of a mistaken idea that RCTs "control for all confounders, known and unknown" (Howick 2011b; Suresh 2011, many others). Since some have thought that RCT's have this power of control, a rival strategy must do just as well or better in order to be adopted. Many authors have argued that in reality, RCTs themselves do not have this power so mechanisms need not meet this criteria in order to be as good or better evidence for the use of a particular intervention. In addition, since RCTs do not have any particularly privileged position in personalized medicine, given that movements preferences for very large non-randomized cohort studies and individual gene-editing intervention, there is an additional reason not to use this standard of knowledge to say we understand a mechanism.

“probabilistic evidence,” in order for an intervention to be put into practice with good evidential support (Clarke et. al. 2014; Illari 2011; Russo-Williamson 2007). Until there is some clear way of determining the scope of a particular mechanism, it seems unlikely that the two groups will come to any kind of consensus.

What of these problems would remain after a shift from EBM to precision medicine? Given precision medicine’s lack of interest in universal or absolute evidence hierarchies, concerns about if mechanisms, or evidence which comes from them, belong on a hierarchy and if so, where, do fall away. However, the ongoing ontological and epistemic debate about what exactly is included in a mechanism and the follow-up concern about how much we need to know in order to say that we understand and can reliably make use of a mechanism will continue (Darden 2008). Given that genetics and precision medicine seem to exhibit the same kind of hesitancy about causation that often marks EBM (Schaffner 2016), it will continue to be unclear exactly what the proper role of mechanisms is, regardless of their size. In addition, since association studies, an important component of genetics, require a particular kind of mechanism-motivated hypothesis generation, the selection of a “candidate gene,” precision medicine will no doubt at least make use of mechanisms to this end (Schaffner 2016).<sup>88</sup>

### Values in Precision Medicine

Especially in its earliest forms, EBM subscribed to the value-free ideal. Part of the movement was a reaction against authoritarian forms of medical school pedagogy, in which students were instructed to do as their instructor or attending clinician said without much recourse to independent investigation (Sackett 1996). Given this history, implicitly subscribing to the value-free ideal was a way of more closely allying medicine with other

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<sup>88</sup> It might be tempting to worry about the claim that mechanisms or causal reasoning will be used in a methodology called association studies, given the popularity of catchphrases like “association is not causation.” However, within the literature, these are the kinds of studies used to eventually produce “proof of concept” for precision medicine interventions. In this context, the tension that philosophers might assume exists between association and causation is not present (Lewis and Knight 2012).

sciences, in order to access science's prized status as objective and truth-seeking and help patients by improving knowledge.

Over time, however, values began to creep into an explicit place in EBM. An early example of the discussion of values in EBM comes in the Sackett and Haynes models of the functioning of EBM (Sackett 1996, Haynes 2002). In these early Venn diagram style models, EBM is to take into account additional concerns alongside "best evidence." In both models, one of these additional concerns is "patient values and preferences." In these cases, the values of patients were the only values said to be taken into consideration; health care professionals remained objective, impartial, "value-free." This was to change with the debut of Bill Fulford's Values-Based Practice (VBP). According to Fulford,

Just as we need evidence-based medicine because of the increasing complexity of the *evidence* underpinning medical decision-making, so, increasingly, do we need values-based medicine because of the increasing complexity of the *values* underpinning medical decision-making. Thus, we can think of values based medicine as being to values what evidence-based medicine is to *evidence*. Just as evidence-based medicine offers a process for working more effectively with complex and conflicting evidence in medicine, so values-based medicine offers a process, albeit a different process, for working more effectively with complex and conflicting *values* in medicine. (Fulford 2008)

In this system, which Fulford explicitly claims to work alongside, and not in conflict with, EBM, the values of a much larger range of participants in the clinical encounter are to be taken into account. These participants with values worth taking into consideration in VBP include patients, health care workers, family and friends of the patient, social workers and other support workers. Fulford is perhaps a bit too optimistic that circumstances in the clinical setting will not make a difference to the ability of all these participants to have their values heard and too confident that any conflicts between the values aired by these participants can be navigated with goodwill and without explicit moral principles. (Fernandez and Wieten 2015; Thornton 2011) However, his VBP guidelines and workbooks represent some of the most important attempts to integrate values into an EBM-friendly framework.

However, the problem of values for EBM that I am pointing to in this chapter is not the issue of how to take patient and other stakeholder's values into account in the clinical



encounter. Instead, the issue is how to adopt values which appropriately guide EBM as a scientific project, given that the value-free ideal is neither feasible, nor to be desired (de Mello-Martin and Intemann 2016, Hicks 2014, Biddle 2013). The goal here is to make clear that adopting goals need not result in a science of wishful thinking. Allowing a place for values does not mean an end to objectivity. Earlier in this work I have argued that three important guiding ideas can help to narrow the field of values for specific scientific projects; locality, context-dependency, and transparency. In EBM, the use of these guidelines might result in the adoption of the values like rigor, replicability, and waste-avoidance. However, given that many in EBM are still invested in the value-free ideal and that the value-adoption procedure I suggest should be replicated on a regular basis, values in EBM remain an issue.

Will this problem of values be replicated in precision medicine, should it succeed EBM as the next “new paradigm?” Like all other scientific projects (and indeed, like many other kind of endeavors) precision medicine will be guided by values. The value-free ideal is not a viable option. The only options are denial about the values in play (allowing them to go unexamined and unchanged) or awareness of the roles of possible values and beginning the hard work of examining, adopting and living up to values which fit the project. Given the long history of denying this guiding role of values, it is unlikely that precision medicine will escape the problem of values which has played a role in EBM. Precision medicine has different goals and priorities from EBM and so will require different values; differences in the “shape” of the project will mean that different values “fit” the project. But precision medicine will deal with the same “problem of values” which has plagued EBM.

#### Implications of Problem Consistency for Philosophy of Medicine

The third section of this chapter suggested that many of the problems faced by EBM would also be faced by precision medicine, should it be the next big medical trend; the problems of expertise, mechanisms and values. It might be tempting to see this consistency as reason for concern. The worry could be that the trends in medicine are consistently problematic (and not even in new or different ways!), or that philosophy of medicine makes

so little progress with these problems of expertise, mechanisms and values which continue to be relevant, even if EBM were to end tomorrow and be replaced by precision medicine.

However, there are other options. Both of these concerns can be explained in part by the serious disconnect between medicine and philosophy of medicine. Philosophers might like to think that new medical trends must be put in place with an awareness of the kind of problems that have been discussed by philosophers and historians in the past. However, in reality, there are different factors which contribute to the rise of particular trends in medicine. If the problem here is one of communication between philosophy of medicine and medicine, rather than one of a lack of progress in philosophy of medicine, or a lack of imagination in medicine, then the consistency in theoretical issues this chapter has demonstrated across medical trends can be a feature, not a flaw, because what we learn about these problems of expertise, mechanisms and values in one trend might be useful in the next.

## Chapter 6: Conclusion

Chapter 1  
Chapter 2  
Chapter 3  
Chapter 4  
Chapter 5  
Chapter 6

## Chapter 6: Conclusion

### Chapter 1

In chapter 1, I provided an outline of the overall work, and a short textual history of Evidence Based Medicine, as a way of grounding the reader in some of the important components of the movement I examined. This does not, of course, include all the relevant texts of EBM, but rather a representative sampling. I discuss what I have called the “original texts,” including the “debut” article of EBM in 1992, the 1996 Sackett et al. article which provides the most often used definition of EBM, and the 2002 Haynes et al. article that marked a move to a more holistic style for EBM. This discussion of texts also provided an opportunity to discuss EBM as a possible paradigm shift in the Kuhnian sense, and an exploration of the make up of the Evidenced-Based Medicine Working Group, a largely McMaster-based consortium of physicians with interests in epidemiology and biostatistics, the authors of the 1992 article.

After the “original texts” I discussed a group of works which did much to shape the dissemination of EBM; clinical manuals. I looked specifically at *the Users’ Guide to the Medical Literature*, which was compiled from a group of articles in *JAMA* published by members of the Evidence Based Medicine Working Group. This manual advocates for individual clinical assessment of the evidence at bedside. That is, it asks that health professionals have a working knowledge of research methodology and statistics such that they can evaluate the quality of the evidence and amalgamate the findings of different related studies when making clinical decisions. While this requirement was once taken to be a very important feature of EBM, I traced the way in which this requirement has been loosened, and EBM advocates now provide pre-assessed evidence to practitioners, reverting to a divided system of epistemic labour.

Next, I focused on the responses, by philosophers and others, to the claims made in these original texts and manuals. My analysis of this critical response identified three especially common critiques. First, that randomization is in some way different or less powerful than EBM takes it to be. Second, that mechanisms, largely set aside in EBM, are

crucial for the practice of medicine in various ways. Third that medicine requires an expanded role for clinical expertise, in a way in which EBM cannot or has not allowed for.

Finally, I examined recent work in the EBM movement, which has coalesced around the themes of adaptation and renaissance. These works have asked if EBM is currently in crisis due to the involvement of monied interests and a failure to respond to critiques, attempted to persuade readers to accept a traditional view of EBM progress, proposed the addition of new theoretical resources, even farther than philosopher critics have called for, and attempted to produce a new Manifesto (to be discussed at this year's Evidence Live conference at the Oxford Centre for Evidence Based Medicine) with significant online input from a variety of concerned parties.

## Chapter 2

Chapter 2 focused on expertise. I explained that EBM had articulated the relationship between expertise and evidence in three different influential models; The Pyramid Model, the Tripartite Model and the Amalgamation Model. These three models signaled very different things about the role of expertise in EBM. It remained unclear if expertise should be taken to be a kind of evidence, or a way to bring evidence together. As a way of improving our vocabulary around this problem, I suggested a new distinction; is expertise internal or external to evidence? It was also unclear if EBM is meant to make use of all three models of expertise, or if each previous model was to be dropped as a new one was proposed. Given these problems, I claimed that EBM is in need of augmentation from other fields on the topic of expertise. I additionally examined a few arguments which might be given to suggest that no more needs to be said about expertise in EBM and found these arguments wanting.

I then examined several different accounts of expertise from fields such as sociology, philosophy, computer science, and science and technology studies. These included accounts by the Dreyfus brothers, Stephen Turner, J. D. Trout and Michael A. Bishop, and Harry Collins and Robert Evans. Each account was evaluated as to how well it was able to deal with some of the problems faced by the current clouded account of expertise in EBM. These included not conflicting with other important EBM claims, taking a stand on question of if

expertise was internal or external to evidence, explaining what makes for useful expertise, rather than authoritarian expertise, and an account of how this useful expertise might best be taught. On these grounds, I rejected the Dreyfus brothers' account, which is the most commonly suggested account of expertise for EBM (which had found particular uptake in the nursing literature) and instead thought that the Collins and Evans account would be most helpful for EBM. This assistance from the Collins and Evans account will, however, only be made useful by clarifications from EBM itself on questions of expertise raised in the earlier part of the chapter.

### Chapter 3

In my third chapter, I discussed an important debate in the EBM literature: the place of mechanisms in medicine. One group, proponents of the Russo-Williamson thesis, claim that both mechanisms and “probabilistic relationships,” the kind of evidence you can get from an RCT, are required in order to justify the use of an intervention. This is because of the methodological frailties of each which can be adjudicated by the other. EBM proponents, including Howick, have argued that RCTs do not have the methodological frailties identified, and that mechanisms have additional frailties that justify their diminished status in EBM. These frailties are articulated with reference to a standard set of historical examples where reasoning from mechanisms led to poor, sometimes devastating, outcomes.

I suggested that at the root of this debate are two issues. The first is relatively straightforward; neither group is particularly clear about what exactly they think a mechanism is, and both state that they do not think this has much bearing on the debate. I suggested that additional clarity about what mechanisms are might improve the quality of the debate. Second, given the kinds of worries articulated by Howick, and dismissed by defenders of the Russo-Williamson thesis, I claimed that the underlying issue is the perceived “size” of mechanisms; how much about the world, about the conditions that allow or disallow a mechanism to do what it does, do you need to know before you can say that you have a mechanism that you can use to make decisions? The Russo-Williamson thesis assumes this is not a problem, while the Howick position is very focused on this issue. I suggested that we

could make use of a Strevens account of ceteris paribus laws in order to suggest that mechanisms can be useful without including all possible confounders.

I then discussed an important reason for the lack of consensus about mechanisms in medicine; a disagreement about medicine's goals and status as a science. Those who claimed that mechanisms have a clear role in medicine claim this in part because they see knowledge gathering as a primary goal of medicine, while those who deny the role of mechanisms see knowledge gathering not as primary, but only useful insofar as it serves what they take to be the main goal of medicine- the caring for and curing of patients. While I was sympathetic with the first group on the topic of the usefulness of mechanisms, I claimed that the second group can claim a better grasp of the, in some ways "unscientific," nature of medicine.

#### Chapter 4

Chapter 4 focused on values. As mentioned in chapter 2, values were taken to have a role in EBM in later models of the movement, but the values in question were always stipulated to be patient values. In response to this, Bill Fulford created his Values Based Practice workshops, workbooks, and other texts. Fulford wanted to take into account the values of all players in a clinical encounter, not just the values of the patient, and was careful to state that he created Values Based Practice as a compatible partner, rather than competitor, with EBM. After articulating his account and examining a case study, I critiqued his account of values as assuming values are static, which is a particularly problematic assumption in the health, and especially mental health, fields.

But all of this had said little about the values at play in EBM, rather than how individual patient, or other actor, values are to be treated by EBM. I claimed that while EBM says little about its values explicitly, we have some resources to learn about EBM's values implicitly. One of these is the Good Old Boy's Sat Around a Table (GOBSAT) joke, a story often referenced as an explanation of what was humorously problematic about clinical decision-making before EBM. I suggested that these kinds of rhetorical tropes can help us to

see what values EBM holds; in this case the values of empirical research (instead of armchair rationalism) and a diversity of perspectives (rather than authoritarian exclusion).

However, perhaps these are not the values EBM would have upon reflection or are somehow inappropriate values. This concern brings us to a larger debate in the values in science literature. In the last 50 years, scholars have argued quite persuasively for the existence of values in science. Now the problem is, how can we distinguish between legitimate and illegitimate values in science? After critiquing the various options for legitimate and illegitimate distinctions currently on offer, I offered my own three guidelines for beginning to constrain values in scientific projects: locality, context-dependency and transparency.

I then articulated some concerns about a possible value-related cousin to EBM: Evidence Based Ethics. Some critiques of Evidence Based Ethics have placed considerable weight on the fact/value distinction to motivate their critique. While I agreed that there are reasons to be critical of this trend, I do not think that the fact/value distinction is the way to go about this critique. I pointed to two separate kinds of concern here; an argument by Putnam in the philosophy of language which suggests that some kinds of “thick” concepts do not split neatly into fact and value components and an example from the recent philosophy of science which suggests that the creation of our facts is shot through with values.

I concluded this chapter with a discussion of some new work on values from within EBM which suggests that the movement may look favorably on the recommendations I gave in this chapter.

## Chapter 5

In chapter 5, I looked to future possible trends in medicine, namely, precision or personalized medicine. I discussed the difference (if any) between precision and personalized medicine, and what it would mean for precision medicine to “overtake” EBM as the dominant movement in medicine. These preliminaries handled, I claimed that the issues I have raised in EBM, issues of the roles of expertise, mechanisms, and values, would remain controversial even in a newly dominant precision medicine.



In precision medicine, the problem of expertise would remain largely the same. It is true that since precision medicine need not use the models used in EBM, the question of say, whether expertise is internal or external to evidence may lose some of its motivation. However, more general questions regarding what expertise is, how you can tell someone has it, if it is relational or not, and if it is possible to teach, will remain important. Indeed, given the way in which genomic data will be interpreted by clinicians for individual patients, it may well be an even more pressing issue in precision medicine.

It is likely that if precision medicine, rather than EBM, were the order of the day, concerns about where mechanisms are included (if they are included at all) on the hierarchy of evidence would likely not be of greatest importance, given that precision medicine may not operate with these traditional models. However, the continuing debate about the ontological and epistemic qualities of mechanisms, as well as general concerns about the proper role of mechanistic reasoning in the clinic, will remain important, should this shift take place.

It seems most clear that the problem of values will continue to be important for medicine, even if the medical world shifts its attention from EBM to precision medicine. These will however be different values, given that some of the priorities and methods of precision medicine differ from the priorities and methods of EBM. But in this scientific project, just as in many other kinds of scientific projects, values will continue to play a role. This means the problem of attempting to determine which of these values are legitimate and for the best, and which are illegitimate and problematic, will continue to be relevant.

Finally, I examined what this consistency of problems across very different movements might mean for the philosophy of medicine. It might be the case, for instance, that this consistency of the issues of expertise, mechanisms, and values, which have been, in varying forms, the subject of many philosophers of medicine over time, indicates that our field is failing to make a difference, that our critiques and suggestions are not being heard, and (perhaps) should therefore be abandoned. I, however, claim instead that this just indicates both the broader relevance of the issues at hand and the difficulty of interdisciplinary work and communication. I urged philosophers of medicine not to see this

consistency as an indication of the impossibility of our task, but instead of the enduring difficult nature of the problems at hand.

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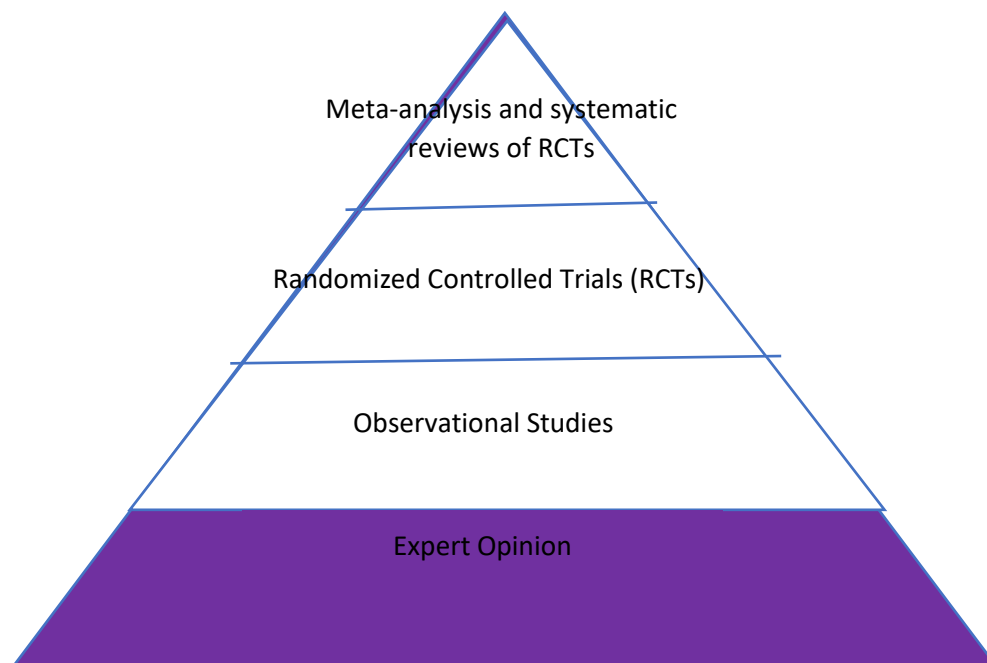
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Appendix A  
Model Visualizations<sup>89</sup>

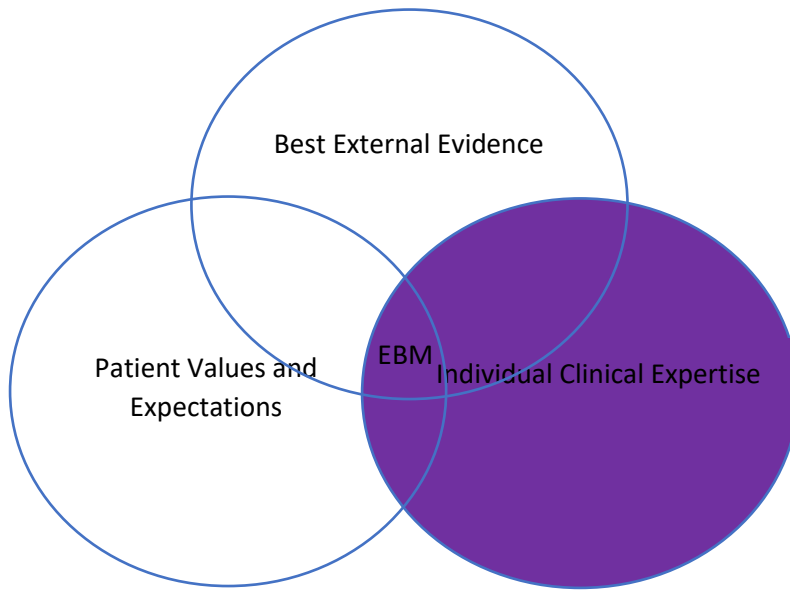
Pyramid Model



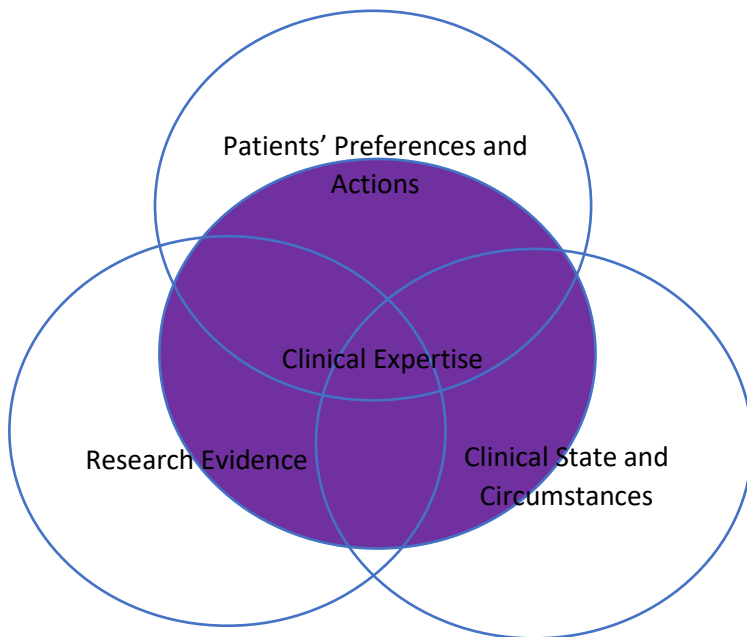
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<sup>89</sup> These model depictions come from a variety of sources. These images, with their emphasis on the place of expertise, were created by the author. Pyramid Model is based on written information in EBMWG, 1992. Model 2 is based on written information in Sackett et al., 1996. Model 3 is based on written information in Haynes 2002. Images very similar to these appear in Howick 2011.

Tripartite Model



Amalgamation Model





Appendix II:  
 Periodic Table of Expertises  
 From Collins and Evans, *Rethinking Expertise*

<b>PERIODIC TABLE OF EXPERTISES</b>					
<b>UBIQUITOUS EXPERTISES</b>					
<b>DISPOSITIONS</b>	Interactive Ability Reflective Ability				
<b>SPECIALIST EXPERTISES</b>	<i>UBIQUITOUS TACIT Knowledge</i>			<i>SPECIALIST TACIT Knowledge</i>	
	Beer-mat Knowledge	Popular Understanding	Primary Source Knowledge	Interactional Expertise	Contributory Expertise
<b>META-EXPERTISES</b>	<i>EXTERNAL</i>		<i>INTERNAL</i>		
	Ubiquitous Discrimination	Local Discrimination	Technical Connoisseurship	Downward Discrimination	Referred Expertise
<b>META-CRITERIA</b>	Credentials	Experience		Track-Record	

## Appendix III:

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Jim Gibson, MD	Department of Medicine, McMaster University
Roman Jaeschke, MD, MSc	Department of Medicine, McMaster University
Anthony Kerigan, MD, MSc	Department of Medicine, McMaster University
Alan Neville, MD	Department of Medicine, McMaster University
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