Research problems and methods in the philosophy of medicine

Chapter 2. Research Problems and Methods in the Philosophy of Medicine

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Introduction

What is the philosophy of medicine? What problems does this discipline solve and how does it go about solving them? There are some, of course, who still maintain that philosophy has no business whatsoever in medicine, the latter being a science, and the former being the sort of idle speculation one engages in when lacking sound research evidence for one's conclusions. As one internet blogger[i] puts it, philosophy is "largely ignored by science." In a characteristically simplistic and dismissive account of the views of two renowned philosophers of science, John Worrall and Nancy Cartwright, on the nature of causality, the blogger quips:

> Many words are spent on defining causality but, at least in the clinical setting the meaning is perfectly simple. If the association between eating bacon and colorectal cancer is causal then if you stop eating bacon you'll reduce the risk of cancer. If the relationship is not causal then if you stop eating bacon it won't help at all. No amount of Worrall's 'serious thought' will substitute for the real evidence for causality that can come only from an RCT.[ii]

It is symptomatic of the blogger's disdain for philosophical methods that he sees no reason to defend his own conception of science, and thinks that banal or "common sense" observations about bacon substitute for any efforts to understand, let alone to respond to, the quite extraordinarily detailed arguments on the nature of science and causal explanations developed by the thinkers he swiftly dismisses. On such a view the philosophy of medicine is presumably something one does if lacking the scientific background to do real medicine, and the idea of "research problems and methods in the philosophy of medicine" represents something of an oxymoron.

The willingness to examine critically one's own underlying assumptions is a pre-requisite for engaging in philosophical thinking and discourse (Loughlin et al., 2015). It is therefore not unreasonable to expect authors in any area of applied philosophy to have considered the nature and limitations of their activity and its relationship with the practices it hopes to inform. While these anti-philosophical ideas about the relationship between medicine, science, and philosophy do not, we believe, stand up to serious intellectual scrutiny, they do represent a conceptual framework with a lengthy intellectual heritage, and one whose influence needs to be understood if we are to confront the methodological questions facing the philosophy of medicine. Were such responses confined to the blog pages of a bizarre, secular science counterpart to the Reverend Fred Phelps[iii] they could perhaps be ignored. But the very fact that they can be articulated—and treated as effectively "just plain obvious"—in such popular media (on a site which apparently commands a large following) is indicative of their pervasive influence.

We return to the issue of causation in medicine later in this chapter, and hopefully say enough to indicate that the issue is not perfectly simple, nor have the significant controversies on this question been resolved.[iv] The claim that we need evidence (indeed, real evidence) to answer causal questions in medicine is what is known as a *platitude*: no reasonable person could dispute it. In contrast, the assertion that only a Randomised Controlled Trial (RCT) can provide evidence relevant to the causal reasoning that necessarily informs clinical decision-making is not only controversial, but apparently represents what a prominent defender of evidence-based medicine (EBM) describes, in his contribution to this volume, as a "straw man" version of EBM (see Howick, Chapter 5). On his view, even the more popular and credible position, that RCTs provide better evidence than observational studies and/or mechanistic reasoning, needs modification if it is to be intellectually defensible. Whatever one thinks of this argument, the insertion of the otherwise superfluous qualifier "real" in the

quotation above is indicative of an implicit philosophical claim. While practitioners in all manner of clinical contexts might treat context-specific features of situations as vital evidence about causal factors affecting the symptoms patients present (Greenhalgh, 2012; Macnaughton, 2011), the only semantic content supplied by the term "real" here is to imply a contrast, to express the background assumption that such forms of evidence are *not* real—that the information such personal observations embody cannot qualify for the term "evidence" in the way that the results of RCTs can. Of course, the only defence of this claim in the blog derives from running it together with a platitudinous declaration, that we need evidence as the basis for causal conclusions, and given the blogger's avowed disdain for philosophy, he is unable to recognise, let alone defend, his own distinctly philosophical commitments.

Ironically, it is from academic philosophy itself that such anti-philosophical ideas originate. The idea that the only source of real knowledge is a fairly narrowly defined conception of empirical science owes its intuitive plausibility to what is sometimes called the "legacy of positivism" (Achinstein and Barker, 1969) and an associated atomistic approach to knowledge that has had a profound effect on the development of biomedicine (Macnaughton, 2011). Logical positivism (or empiricism) bolstered the view that only empirical data acquired in certain quite specific ways could provide objective evidence, giving rise to an intellectual culture in which judgement, personal experience, and context-specific information were regarded with suspicion as subjective factors (Kirkengen and Thornqvist, 2012; Loughlin et al., 2013). While this philosophical position has been subjected to extensive criticism, and the problems it creates for scientific practice have been well documented (Kinkaid et al., 2007; Maxwell, 2004; Nagel, 1986), there is no consensus regarding the most appropriate alternative epistemological framework to understand the relationship between science, knowledge, experience, theory, judgement, and value. Indeed, the debate between broadly empiricist and rival rationalist positions in epistemology is far

from being resolved, and we discuss the specific implications of this debate for current accounts of medical causality later in this chapter.

What is more, there are serious questions about the nature and status of the philosophy of medicine and there is by no means a general consensus in the area as to how they are resolved. Two features of philosophy contribute to this situation. Firstly, the already noted characteristic trait of the philosopher to examine underlying assumptions. Secondly, another required trait of consistency: to be a philosopher is to be willing to follow a line of thinking to its logical conclusion, however uncomfortable or counter-intuitive it may initially appear.

In combination, these two features lead philosophers themselves to ask difficult questions about what philosophy is—what its methods are, what sort of questions it can meaningfully answer, and consequently its limitations as a form of academic enquiry. It was this ruthless consistency that led logical positivists, influenced by ideas inherited from the great empiricist philosophers Locke and Hume, to conclude that it was not the business of philosophy to discover truths, but simply to solve [linguistic] puzzles, so as to assist in the project of empirical science—the only means for discovering genuine, non-trivial truths (Ayer, 1987, pp. 34-5). Arguably, under the leadership of the positivists, academic philosophy became something of a suicidal discipline, dismissing the questions that preoccupied its greatest thinkers over the centuries—about the nature of reality, the value of life, how human beings should live and practice—as either meaningless or purely subjective, in some cases apparently revelling in the practical irrelevance of its increasingly obscure, exclusive, technical discourse (Loughlin, 2002, pp. 119-26).

Key to arriving at this suicidal conclusion was the positivists' model of philosophical methodology, typically characterised as deductivist because it effectively equates rational argument—the presentation of *good reasons* to believe a conclusion—with logical validity. A

deductively valid argument is one in which the conclusion follows logically from the premises presented, meaning that to deny the conclusion while asserting the truth of the premises is to be guilty of a formal contradiction. Hume's consistent application of the view of knowledge and reasoning as consisting, strictly, in the processes of observation and deduction, led him ultimately to question the rational basis of so many of our everyday beliefs that the plausibility of his own conception of reasoning was itself called into question.

Hume is credited with discovering the problem of induction, noting that our inherent disposition to discover patterns in experience, to see particular conjunctions of events as indicative of broader, general or universal laws, goes beyond the processes of observation and deduction, and therefore would seem to be non-rational. While we may be happy to regard the patterns observed by the witch-doctor (or perhaps the homeopath) as unwarranted generalisations lacking any rational basis, as Russell famously notes, unless we regard induction as an inherently rational process, we must "forego all justifications of our expectations about the future," in which case we would have to admit that: "we have no reason to expect the sun to rise tomorrow, to expect bread to be more nourishing than a stone, or to expect that if we throw ourselves off the roof we shall fall" (1967, p. 38).

No-one denies that rationality *minimally* requires the avoidance of contradiction and compatibility with empirical evidence. But if we limit our conception of reasoning to these essential characteristics then we risk regarding as non-rational the human capacities and dispositions that make us able to distinguish good generalisations from bad (and consequently science from prejudice and superstition) and that enable us to be both good reasoners and good observers in practice:

> Consider the claim that "my mother is unhappy today." I might come to believe this on the basis of certain evidence: her facial expressions, the tone of her voice, her

> mannerisms as she goes about certain mundane tasks. The fact that someone who does not know her so well might encounter the same behaviour but fail to come to the same conclusion shows that the evidence for the claim does not logically entail the conclusion (Loughlin, 2002, pp. 40-1).

Does it follow that such evidence does not provide us with a good reason to believe the conclusion, that it is not real evidence? Would a principled refusal to accept such evidence make us better, more rigorous thinkers or bad practitioners and (more generally) practically inept human beings? If a theory about rationality causes us to reject the use of our interpretive and other human faculties that in fact make practical reasoning possible, then we have reason to reject that view of rationality.[v]

Despite these problems, deductivism in its various forms has had a huge influence over thinking about clinical reasoning, effectively determining the methodological assumptions of dominant approaches to both medical epistemology and medical ethics. Tonelli (2014) points out that, in EBM, the results of empirical research function as the major premises from which conclusions about particular cases are deduced, while in biomedical ethics, the approach called principlism attempts to derive particular conclusions from the application of general principles, whose justification is presumably either self-evidence or just their general acceptability. (Though for the positivist, no major moral premise, however widely accepted, can claim anything other than "subjective" justification, rendering the whole idea of "moral reasoning" inherently problematic.)

Though overused and misused by some authors[vi], the phrase associated with Toulmin (1982), that medicine "saved the life" of philosophy, has a more than a ring of truth about it. Toulmin argued that by returning their attention to the concrete—to the problems of particular, real cases in medical discourse—philosophers had found their subject "coming

alive again" and had regained the sense of engagement with practical matters that had characterised the discourses of Socrates and Aristotle. Toulmin's specific focus was on the revival of moral philosophy:

> By reintroducing into ethical debate the vexed topics raised by particular cases, they [medicine and law] have obliged philosophers to address once again the Aristotelian problems of practical reasoning, which had been on the sidelines for too long (1982, p. 749).

Instead of regarding moral philosophy as a body of theory, and then raising sceptical questions about how, if at all, this body could be applied to the real world, (what practical conclusions, if any, could be deduced from its major premises, etc.), philosophers engaging in interdisciplinary debate treated philosophy as an activity—a style of thinking that enables us to describe the logical structure of arguments, to identify and analyse key assumptions and concepts, and to clarify debates by exposing ambiguities and errors of reasoning. And as Toulmin notes (with practical illustrations), in making this contribution to a genuine *dialogue* with practitioners, philosophers were sometimes able to assist in discovering a level of consensus about the (non-trivial) truth in particular cases that would astonish the positivists and ethical subjectivists.

It was not only ethics that stood in need of revival, nor could its revival be achieved in artificial separation from other aspects of philosophical thinking. Ethical questions—about what we should do in any given situation—are embedded within whole understandings of the situation, inseparable from our beliefs about what is the case (the traditional concern of those areas of philosophy termed ontology or metaphysics), what it is that we feel we can claim to know (epistemology) and our broader beliefs about reasoning (logic), as well as the meaning we ascribe to different aspects of the situation or to our perception of it (phenomenology)

(Loughlin et al., 2015, p. 358). Since the publication of Toulmin's paper, medicine and healthcare have raised a host of pressing problems about the nature of health, disease, care, clinical judgement, evidence, causation, reasoning and knowledge in clinical practice and the relationships between scientific explanations of disorder and human experience. Just as Socrates found in the market place scope to explore with his interlocutors the vast range of questions that formed the canon of philosophy, so, by applying their critical and analytical skills to debates in medicine and healthcare, contemporary philosophers have regained what Toulmin (1982) characterised as "a seriousness and human relevance" for their discipline.

Toulmin's case-based approach to practical reasoning is often labelled casuistry, and its contemporary defenders note that it challenges some of the most entrenched assumptions of traditional analytical philosophy. In particular, it has been argued that casuistry problematizes the sharp distinction between fact and value, which owes its origins to the work of the empiricists (again, most notably Hume) and via the positivists has massively influenced the understanding of evidence in clinical medicine—in particular in the EBM movement. Tonelli (2014, pp. 238-40) argues that the fact-value dichotomy is a theoretical construct that can distort clinical reasoning. This is because, in real cases, there is no necessarily clear divide between factual and evaluative aspects of a situation: even our characterisation of particular observed facts is bound up with explicit or implicit value-judgements. Whether or not we agree with this specific claim, it reminds us that the dialogue between medicine and philosophy must be a genuine dialogue, not a one-way process in which something called philosophical theory is applied to the resolution of practical problems, whose nature is (by implication) philosophically unproblematic (Loughlin, 2002, pp. 143-6). Even our description of a background situation, and the identification of some features of it as representing the problem, embody assumptions that can be questioned (see below) and theoretical distinctions can be called into question if they fail to serve some useful purpose: the way to defend them

(if they are defensible) is to show that they do, in fact, contribute to a way of understanding a real situation that can help us to deal with it more adequately.

Critics of casuistry have focussed on its ability, celebrated by Toulmin, to drive consensus in particular cases, arguing that this consensus can reflect implicit shared values amongst the participants in a dialogue—for instance, on what represents an adequate characterisation of a problem and what it means to respond adequately to that problem (Kopelman, 1994). Unless these shared, underlying values are identified and subjected to critical scrutiny, the process runs the risk of "self-confirming bias" (Fulford, 2014, p. 159). This criticism raises serious and unresolved philosophical questions about the relationship between the consensus of belief in a given group, the truth of the matter and what individuals have good reasons to believe. No credible defender of casuistry (certainly not those we have cited) would wish to defend the idea that the correct answer in any give case is defined with reference to an uncriticised consensus. The very idea of intellectual progress seems to depend on the willingness of individuals to challenge the consensus on a given issue, to recognise that our shared assumptions at any given point in time may simply be wrong. To fail to consider this possibility is to become the sort of unreflective dogmatist criticised at the beginning of this chapter, to adopt the standing assumption that "intellectual history came to an end…at just the point that we arrived on the scene" (Loughlin et al., 2013, p. 136).

This is precisely why we stated the willingness to examine critically one's own assumptions as a pre-requisite of philosophical thinking. All thinking, in any area of life and practice, requires us to conceptualise the data of experience in some way, categorising data according to different types or patterns, and a great virtue of philosophical thinking is that it enables us to focus on the *way* we do this, to bring our background assumptions and theories into the foreground of thought, to understand how they help us to frame our experience. That way, we can at least come to consider alternative ways of framing experience, alternative

ways of seeing the world and characterising problems. Advocates of what is sometimes called the "therapeutic" view of philosophical method (Hutchinson, 2008) argue that, even when presented with an apparently compelling argument for a given conclusion, we sometimes have a "suspicious sense"—the idea that there is something wrong but we cannot quite put our finger on it. The explicit reasoning may be valid, but the object of our suspicion may not be what is said as much as the assumptions that underlie it. It may not have occurred to us to identify, let alone question, these assumptions until now. But until we do so, we cannot free ourselves from their influence, so we cannot release our potential to think creatively, to explore alternative conceptualisations of our circumstances, ones which may prove more valuable (Loughlin, 2002, p. 18). Consider the arguments in Rachel Cooper's contribution in this volume (Chapter 11), on the nature of disability. A lot hinges on what we see as the problem for the disabled person: whether we see that problem as located in the person herself, or in the social world in which she is required to live her life. Is her difficulty in moving about in that world a consequence of the fact that she is inherently damaged, or is it because that world has been designed and constructed without reference to, without due consideration for, the need to accommodate her specific mode of being? Whatever conclusion we come to, we can hardly be said to have given the issue serious consideration if we have not even tried out the alternative ways of framing the problem and at least started to explore some of their implications for its solution.

Clinical practice and theory

Returning then to our original questions, we can at least now begin to give some qualified answers, to say something about what the philosophy of medicine must be if it is to be worth doing. On the one hand, it must not consist in the application of preconceived

theoretical perspectives to practice, with the goal of correcting the perceptions and practices of those involved from an epistemically privileged position. The problems it investigates must be problems that arise within practice, within the lived experiences of practitioners and patients. On the other hand, it cannot take the current consensus on any particular issue—be it the nature of medical evidence or clinical reasoning, or the role of value-judgements in the diagnosis of medical problems—as an unchallenged given. Usual practice may be the necessary starting point for the philosophy of medicine, but that does not mean that this starting point is somehow beyond criticism. Indeed, the more radical movements in the philosophy of medicine have been those which took it upon themselves to critique common practices, and to argue that the goals of medicine were better served by significant—sometimes revolutionary—changes in the methods employed by practitioners in diagnosing and treating illness.

Any perceived tension between these two constraints upon research methods in the philosophy of medicine may be resolved by reminding ourselves of the point made in the previous section—that our current thoughts and practices exist within a history that is on-going. We are not at the end of this history, in a place where all problems and puzzles have been eliminated. At times within the history of medicine, there have been problems arising from within practice that have not been entirely resolved by the application of business as usual, giving rise to a sense that all was not well—a frustration with how things are. Theoretical innovation has been one aspect of the continued intellectual evolution of clinical practice: movements to transform or revolutionize practice have been declared by their advocates to be natural responses to medicine's failure to practice consistently, with reference to its own avowed values and standards—be they of scientific rationality or compassionate humanity. So it was that early exponents of EBM appealed to the language of a paradigm shift, a term taken from Thomas Kuhn (1970). They appealed to this language because in

Kuhn's work a paradigm shift occurs when those working within a tradition begin to recognise that it no longer makes sense in its own terms and that it gives rise to problems that it cannot solve.

> 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 (EBM Working Group, 1992, p. 2420).

Medicine's desire to treat patients in a way that maximised the likelihood of achieving the best outcomes was inconsistent with a failure to utilize the growing evidence-base made possible by "developments in clinical research over the last 30 years" and its continued reliance instead on sources of evidence that were (the authors claimed) inferior (EBM Working Group, 1992, p. 2420).

More recently, advocates of "person centered" approaches to medicine and healthcare have argued that contemporary medicine faces "a crisis of knowledge, care, compassion and costs" because "the exaltation of the biomedical model of clinical practice has led to a fascination with the molecular and cellular basis of disease and organ dysfunction" (Miles and Asbridge, 2013, p. 1). While they acknowledge that "pharmacological and technological innovations have mediated huge shifts in individual and population health," they argue that, having at one point facilitated progress, the current dominance of this "biomedical reductionism" now stands in the way of the progress that is needed (Miles and Asbridge, 2013, p. 1).

> [T]here is a growing sense of unease that all is not well, with observations increasingly made that medicine has lost sight of the human dimension of illness. An exclusionary participation with the physical and a consequent neglect of the psychological, emotional and spiritual dimensions of patient care, together with the ongoing shift towards

> superspecialization, are pushing healthcare services into compartmentalization, fragmentation and reduction (Miles and Asbridge, 2013, p. 1).

In each case, problems arising from within clinical practice have (according to the authors) required a radical shift in the nature of practice itself. They have inspired critical reflection on the underlying assumptions that frame conventional practice, which give practitioners their sense of what they are doing—the purposes, values, and methods of their own practices. These problems have caused some to question and re-evaluate at least some of those assumptions, and to conclude that business as usual needs to be altered in accordance with some new framework. To think in this way about medical practice is to think philosophically about medicine.

It follows that a fundamental research problem for the philosophy of medicine has been understanding the nature of practice itself. What is clinical practice? And, what should it be? Different understandings of practice can be characterised in terms of different models, but how should we choose between competing models of practice? Even that question contains an assumption worth interrogating, that distinct models of practice are in competition, such that we must choose between them. Do these models represent alternative and mutually incompatible conceptions of practice—of what it is or what it should aspire to be—or do they represent distinct but compatible aspects of the correct characterisation of what clinical practice is or should be?

In this section, we tackle each of these questions in turn (returning to the final one in the concluding section of the chapter). We discuss what clinical practice is and what it should be, by examining the evolution of three influential models of clinical practice: EBM, patient-centered medicine (PCM) and values-based practice (VBP). Each of these approaches offers a new model of clinical practice and in so doing, locates fault within some aspect of usual

clinical practice (UP). By examining these models' portrayals of UP, we can begin to sketch out what clinical practice is, and then compare it to at least three versions of what it should be. This exercise requires reflection on what criteria should be used to judge UP and these or any other models.

What is clinical practice, and what should it be?

We take UP to be what doctors do in the course of providing care to patients. Its goal is the cure or, if not possible, the palliation of disease, accomplished through two main objectives: diagnosis and treatment of patients' problems. Over the last thirty years, a variety of new approaches to medical practice or specific aspects of medical practice have emerged from different corners of the health professional world. These include EBM, whose origins reflect synergies between clinical epidemiologists and researchers in internal medicine and critical care; PCM, authored by scholars and practitioners in family medicine; and VBP, inspired by a specific application of philosophy to psychiatric care. In addition, approaches to specific aspects of clinical practice have also been developed. These include shared decision-making, which aims to strengthen the active participation of patient and clinician in clinical decision-making; relationship-centered care, which emphasizes the importance of the quality of the clinician-patient relationship for both clinical care and on health outcomes; and the patient-partner movement, which aims to increase patient participation and leadership in individual care as well as to incorporate patients' voices into clinical service development, health professional education, and research planning.[vii]

In this section, we focus specifically on EBM, PCM, and VBP, because they represent models of clinical practice, which—if not complete—are intended to be comprehensive.[viii] In addition, these models are well-known and influential: their theoretical foundations and

practical applications have been well-documented, enshrined in policy documents and guidelines in health services across the globe.

Evidence-based medicine

The phrase "evidence-based medicine" first appeared in the published medical literature in the early 1990s and since then has become a dominant discourse in clinical practice. Although it can count at least a few distinct sources of intellectual inspiration, the principles of its current iteration (1992 onwards) were articulated through the application of the methods of clinical epidemiology to clinical problems. It has been taken up across the medical specialities and has even expanded into health services and policy evaluation. EBM has also generated enormous debate because, in part, of its portrayal of UP. Compared to "the traditional paradigm of medical practice," EBM's proponents place lower value on unsystematic clinical experience, pathophysiologic rationale, and authority (Guyatt et al., 2008, p. 10). These proponents characterize UP as a situation in which practitioners engage in clinical decision-making about patient care, often guided by sources of information of dubious epistemic value, or even to the detriment of patients' health.

Why would clinicians practice in such a manner? EBM's advocates located the fault both in medical training and in UP. Traditionally, medical training did not teach trainees how to understand clinical research studies, interpret their data, and then apply these data to clinical decisions. These trainees would then go on to the milieu of UP, which lacked mechanisms to require or even to promote these activities. By contrast, EBM teaches physicians that decisions about diagnostic tests, prognostication, which treatments to offer, and the prediction of harm should be guided by research studies; that certain types of research studies produce data which are more valid (defined as "closeness to truth") than others; and

that research methods and the data they yield can therefore be ranked hierarchically. The specific steps involved in practising EBM include:

1. Converting the need for information (about prevention, diagnosis, prognosis, therapy, causation, etc.) into an answerable question;

2. Tracking down the best evidence with which to answer that question;

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

4. Integrating the critical appraisal with clinical expertise and with the patient's unique biology, values, and circumstances; and

5. Evaluating the effectiveness and efficiency in executing steps 1 to 4 and seeking ways to improve them for the next time (Strauss et al., 2011, p. 3).

By learning the principles of EBM and the skills needed to put them into practice, practitioners would be able to achieve two things:

1. Base their own clinical decisions on valid sources, and

2. Argue against ill-founded practices being used by others.

EBM does not question the goal of medicine (cure or palliation of disease). Instead, it reminds readers that the physician's job is to ensure that patients are presented with valid research data in the service of meeting these objectives, during the process of clinical decision-making. Nor does EBM question the objectives of clinical practice (diagnosis and treatment of disease); but, it contends that following its rules enables practitioners to meet these objectives more effectively. According to EBM, clinical practice should be evidence-

based practice in equipping clinicians with the skills to practice in accordance with its rules. Thus, EBM offers an epistemic remedy to UP.

Patient-centered medicine

There are now several movements that go by similar names: PCM, patient-centered care (Berwick, 2009), and person-centered medicine. The relationships between them are still a matter for debate, with some exponents stressing the similarities and others arguing that the language of *person*-centeredness represents a broader approach than PCM. Historically, the concept of a patient represented a semantic contrast to that of an agent, so the traditional distinction in medicine between practitioner and patient arguably reveals philosophical presuppositions that may be questioned.[ix] A leading exponent of person-centered medicine, Andrew Miles, argues in his chapter to this volume that this approach is required to give full consideration of the agency of all parties to the clinical encounter, being informed by philosophical work on personalism and built on a relational concept of the person. A proper working out of that philosophy, he argues, reveals its incompatibility with approaches he regards as reductionist (and he would include EBM in this category, in this respect differing from the version of PCM we now discuss). In this section, we focus primarily on PCM since it is an important historical point of reference for other related movements (Suchman, 2005; Mezzich, 2011).

PCM was born in the milieu of Canadian family medicine, which was, and remains, a key entry point for accessing health services. Many of these patients have complex psychosocial needs falling outside the boundaries of UP. PCM is by its own terms "a new clinical method." The term "patient-centered" stands in contrast to the characterization of UP, which PCM advocates argue is disease-centered. By this is meant that the goals of clinical

practice should be go beyond those of UP, in order to address some of these additional needs. PCM advocates aim to improve clinical practice by expanding UP's objectives of diagnosis and treatment to include understanding the person, meaning the patient's experience of illness, concept of good health, and social context. PCM places the patient's account of health and illness on an equal footing with the doctor's and with UP's. This means that the formulation of the problem and appropriate targets for therapeutic intervention ought to be negotiated with patients. PCM does not aim to abandon the goal of UP—to cure or palliate disease—but instead asserts that patient-centered clinical practice may be more successful in achieving this goal than UP itself (Stewart et al., 2014, p. 12).

Clinicians are to carry out PCM through a series of four complementary spheres of action when working with patients:

1. Exploring health, disease and the illness experience;

2. Understanding the whole person;

3. Finding common ground; and

4. Enhancing the patient-clinician relationship (Stewart et al., 2014, p. 7).

At the same time, PCM's advocates are committed to EBM, believing that PCM is compatible with it, and indeed incorporates it. They do not view EBM as a clinical method as such but instead as a method for "acquiring the best available evidence" about issues in health care that can then be used in the practice of PCM (Stewart et al., 2014, p. 15). Yet, it is not clear how this compatibility works in practice. For example, one of PCM's four components is finding common ground with the patient, including formulation of the problem and identifying the goals of treatment. EBM is oriented towards determining which interventions are most effective towards achieving certain outcomes, both the interventions

and outcomes having been pre-selected by researchers of the studies that clinicians are meant to consult. But what if patients want an intervention that is not evidence-based or to pursue unstudied outcomes? How does the physician practising PCM, seeking to find common ground, reconcile his or her approach to EBM at that point? Does the PCM practitioner practice EBM until the patient rejects something that EBM promotes? Does this mean PCM practitioners can take or leave EBM depending on the particular circumstances?

This is no doubt one reason why some contemporary exponents of the approach write under the label person-centered medicine (see Chapter 9 by Miles) and prefer the terminology of evidence-informed to evidence-based medicine (Miles and Loughlin, 2011). These exponents note that the concept of evidence in EBM has been modified from a very broad, common-language conception (where evidence simply refers to any piece of information which gives us a reason to believe a conclusion—such as your mother's facial expression and mannerisms giving reason to believe she is unhappy) to a more specialist, scientific conception of evidence, closely associated with the findings of clinical research. They prefer to treat medicine as a human practice "informed by" science, and not a science or a practice "based on" scientific evidence, and they maintain that "excellence in clinical practice will remain out of reach until clinicians apply advances in biomedicine and technology within a humanistic framework of care" (Miles and Ashbridge, 2014, p. 3).

Values-based practice

VBP builds on the work of the philosopher and psychiatrist Bill Fulford, who developed the approach in the UK in the early 2000s. While Fulford initially targeted mental health practice, he believes that VBP can apply across specialities and health professions. VBP's central idea is that patients and practitioners alike hold diverse values which may come into

conflict in the course of clinical decision-making. VBP finds fault in UP's lack of recognition of this diversity of values and portrays decision-making in UP as a process through which physicians may impose professional, institutional, social, or even personal values on patients' decision-making. At best, patients might be able to accept or refuse physician-recommended interventions through legal mechanisms, such as the requirement for informed consent. But Fulford does not see a legalistic approach as serving the needs of the ongoing, collaborative process of clinical decision-making that is required in the domain of mental health, where there is greater diversity about such value-laden questions as what constitutes good health. According to Fulford (2011, p. 977), VBP is a tool whose goal is to facilitate balanced judgements in individual cases where values are complex and conflicting. While VBP does not reject diagnosis and treatment as the objectives of clinical practice, it adds its own objective which is to recognize the diversity of individual values and to incorporate this diversity through its specific approach to clinical decision-making. But apart from seeking to implement its decision-making process, VBP does not promote any specific goal. The goals of practice arise in clinical encounters from VBP deliberation.

Like EBM and PCM, VBP offers a series of elements that comprise the practice. These include four practice skills:

1. Awareness of values;

2. Reasoning about values;

3. Knowledge of values and facts; and

4. Communication.

They also include six claims or principles:

5. Services ought to be user-centered;

6. Multidisciplinarity;

7. EBM and VBP work together;

8. We only notice values when there is a problem;

9. Increasing scientific knowledge increases choices which can demonstrate divergence in values; and

10. VBP involves providers and users making decisions in partnership.

Fulford notes that there are other tools for working with diverse and potentially conflicting values in clinical encounters, such as the methods of clinical ethics, but he sees clinical ethics as allocating moral authority to rules. By contrast, VBP believes that moral authority for a given decision can only be achieved on a case by case basis by giving any and all values a fair hearing through an open-ended, deliberative process (Fulford, 2014, pp. 151-2).

Fulford states that VBP works alongside EBM. The complementarity of the two approaches is emphasised by the claim that medicine rests on the "two feet" of evidence (as characterised by EBM) and values (as revealed by the processes explained in the literature on VBP) (Peile, 2014, pp. 24-5). While VBP recognizes the pervasiveness of values in health practice, it claims that EBM represents the facts of medicine. As noted in the previous section, this attempt to divide practical reasoning in medicine into two distinct components (albeit both needed for decision-making)—regarding the facts, as revealed by scientific research and regarding the values of the parties involved, ascertained through the processes of VBP—is contentious, with some arguing it represents a false dichotomy (Tonelli, 2014). This categorization also seems to ignore the values that underlie EBM, such as the values underlying the process of knowledge production and its products, including the research data

that are the basis of evidence-based practice. If values are pervasive in all areas of practice, why would EBM be exempt? Furthermore, EBM already offers its own process for working with values in clinical decision-making (Gupta, 2014). VBP does not discuss how these two work together. Does it propose that in using the VBP method, the clinician should set aside EBM's method for incorporating values? The meaning of the two models working alongside each other is not clear.

Choosing between models: assessment criteria

Each of the three models discussed above offers itself as a candidate to replace or modify UP. Which, if any, of these models should be chosen? And, on what basis? Each model criticizes UP for failing to achieve its goals or for having the wrong goals. Because of these failures, each model implies that UP does not meet the ends of medicine. While a serious discussion of the ends of medicine lies beyond the scope of this chapter, they have traditionally been related to preserving life, relieving suffering, and promoting flourishing. The third of these is more contentious than the others, with some claiming that promoting flourishing (an Aristotelian term related to the idea of "the good life") equates to health enhancement, when the goal of medicine should more modestly be disease prevention (Kottow, 2002, pp. 78-9) and others suggesting that, at least in some areas (notably mental health) the goal of promoting "the good life" can be a recipe for authoritarian practice (Fulford, 2014, p. 157). Even the first two goals may of course be called into question in specific cases, for instance, when they are thought to be in conflict. Thus, the debate about the ends of medicine cannot be neatly separated from wide-ranging debates about what kind of life is worth living, what kinds of suffering are worth relieving, and what kinds of flourishing should be targeted (if at all).

Do all or any of the three models discussed above achieve the ends of medicine better than UP? Do any of the models achieve these ends better than any other? The models do not concern themselves directly with the question concerning the ends of medicine. Instead, they leave this question untouched but rather offer perspectives on how this question might be answered in daily clinical practice and by whom. EBM would leave this question to the researchers who produce the data to be applied to clinical decisions. By offering patients evidence-based options, researchers determine what medicine should be about, for whom, and under what circumstances. It is not clear where PCM and VBP stand on this point. Because of their commitment to EBM, it seems that PCM and VBP accept the same state of affairs, allowing individuals to negotiate and debate their values regarding the evidence-based options on offer. Or, it may be that practising in a patient-centered or values-based manner means precisely that EBM can be overridden under certain circumstances.

If the above models do not differentiate themselves by their ability to achieve the ends of medicine, then by what criteria should we judge them and assess their ability to serve as models of clinical practice? To compete with UP, a candidate model should be comprehensive (cover all the tasks of clinical practice), effective (be able to achieve what it says it will achieve), and feasible. Given that there are practitioners who state that they are practising according to each of the three models, we accept that they are feasible. Below we discuss comprehensiveness and effectiveness.

UP is comprehensive by definition as it includes everything that doctors do in patient care. Any model of clinical practice should be able to offer guidance on this same terrain. Let us consider one example of an important area of practice in which guidance by the different models may prove to be insufficient or confusing, namely, the interface between clinical practice and legal requirements. In many jurisdictions, there are aspects of practice framed by

law (e.g. informed consent). In UP, legal requirements must be respected. Does the same stand according to the models? And if so, is this consistent with their own logic?

Suppose researchers could conduct a clinical trial to evaluate the effectiveness of obtaining informed consent (defined as better informed and more health-promoting clinical decision-making) in a specific patient group (patients with generalized anxiety disorder). In the trial, the patients who participate in the informed consent process find it anxiogenic, refuse treatment, and end up feeling worse (more anxious), while those who do not participate in the process accept the treatment and get better. How should the evidence-based practitioner handle this situation? Should the practitioner advocate against informed consent for such patients because the evidence-based option seems to lead to better health, or opt to ignore the evidence because that is what is legally required? The patient-centered practitioner would come to understand that the patient feels overwhelmed by too much information about risk and would prefer to accept the doctor's recommendation rather than engage in the informed consent process. Does this give the patient-centered practitioner warrant to omit the informed consent process? Or would the physician have to default to UP, because PCM does not cover this aspect of practice? Meanwhile, the values-based practitioner would encourage an open discussion of the values at stake: the patient's trust in the physician's recommendation versus the physician's duty to respect the law. But before any true deliberative process could occur, the practitioner would simply have to overrule the patient's values due to the legal prescription. The point here is that if a model of clinical practice is *not* comprehensive, the practitioner has no choice but to default to UP for those areas that are not covered. Therefore, in order to evaluate a model, we need to know which areas of practice are covered, and under what circumstances.

Any model of practice should also be effective, that is, it should achieve what it claims to be able to achieve. Here we refer back to the goals of each model. Are they able to achieve

their goals? How would we tell? EBM proponents state that its effectiveness cannot be evaluated according to its own standards of evidence, but point to certain RCTs that demonstrated treatments previously thought to be effective were actually harmful (Gupta 2014, 125). Alternatively, they claim that the ultimate goal of EBM is to be good at implementing the 5-step procedure outlined above (Strauss et al., 2011, p. 3). PCM's exponents, meanwhile, report on the evaluation of their model through various research methods (Stewart et al., 2014, pp. 333-75) including the standards of EBM (Stewart et al., 2014, pp. 346-52). They argue that systematic reviews show that training practitioners in patient-centered interaction improves elements of practitioner communication and patients' health outcomes (Stewart et al., 2014, pp. 346-51). VBP's proponents agree that this kind of empirical base is necessary for VBP as well (Fulford. 2013, p. 543). UP can meet its goal—cure or palliate disease—sometimes. Whether or not the models do the same, do it better, or do something altogether different, remains to be seen.

Summary

In the last few decades, numerous commentators have surveyed the domain of clinical practice and found it lacking in its goals, its objectives, or its methods for achieving them. Various new models of practice have been developed, and the three models discussed above have received considerable attention and resources from the clinical community, health policy-makers, and clinical researchers. Their emergence and influence raise a number of philosophical questions including what clinical practice is, what it should be, and how we can know if any new model is a good model of clinical practice or not. The models cannot be adequately assessed in isolation from broader assumptions about the ends of medicine, and it

is also worth noting that they embody conceptions of the relationship between medicine and science, as well as the nature of science as applied to medical practice.

Science and medicine

We have seen that some authors argue that medicine is not a science but a value-laden practice informed by science, and that this distinction is crucial to the right understanding of medicine. Although the role that science can play in medicine, and the specific sciences that are most useful and relevant, are both open to debate, there is no doubt that medicine relies on the results of scientific research. This section sketches some of the scientific areas that are of current interest to philosophers, briefly outlining some of the questions being addressed, and then turns to the broader question of what philosophy of science can say about the contribution that science can and should make to clinical practice and to health policy.

There are two major kinds of medical research: (1) population-level research, including clinical research that draws on epidemiological methods to examine the relationship between risk factors and/or interventions, on the one hand, and clinical outcomes, on the other, and (2) pathophysiological research, which involves investigating disease processes (and, to a lesser extent, the mechanism of action of interventions). Different disciplines and research areas tend to focus on one or the other of these approaches, though, as we show below, the extent to which they incorporate information from the other approach, and/or assumptions about what is occurring at the other (population or mechanism) level, will vary.

Two sets of related philosophical questions can be asked about the biomedical sciences. One set focuses on the sciences themselves, while the other looks at the role of the sciences in clinical medicine. We begin with the second set of questions. Philosophers of medicine have

distinguished between rationalist and empiricist approaches to medicine. Medial rationalism focuses on understanding disease mechanisms, and is therefore closely aligned with the physiological research described above. Medical empiricism, by contrast, is described as being concerned with patient outcomes (Newton, 2001), independent of examining and understanding the mechanisms that give rise to those outcomes, and with the careful description and categorization of clinical phenomena (Wulff et al., 1990, p. 33). Although many areas of biomedical research that take an empiricist approach focus on populations, the link between medical empiricism and population-level research is not as close as that between physiological research and medical rationalism, as we show below.

Wulff et al. (1990) describe historical approaches to medicine in terms of this dichotomy, though they use the term realism instead of rationalism. They suggest that historically, medicine has been dominated by speculative realism. This philosophical approach to medicine has involved the development of theories regarding the causes of disease. The most famous of these is the Hippocratic system, on which diseases were understood as imbalances in the body's four humours. This system is realist, because it posits the existence of an underlying disease mechanism, and it is speculative because its followers believed that "it was possible by armchair reasoning alone to ascertain the nature of that disease mechanism" (Wulff et al., 1990, p. 31). Similarly, some forms of medical empiricism do not take sufficient account of medical rationalism; Wulff et al. point to attempts in the 18th century to categorize diseases without reference to the underlying disease mechanisms. The classification systems amounted to "no more than divisions and subdivisions of ill-defined symptoms, and they had no lasting effect on the development of modern medicine" (Wulff et al., 1990, p. 34). Wulff et al. describe the ideal approach as one of "realism under empirical control" (1990, p. 32); when this occurs, the search for disease mechanisms is not speculative, but is based on careful observation and often also on experimentation.

Both the empiricist concern with observation and the realist concern with mechanisms can be also observed in contemporary medicine and medical research. Until very recently, medical research took a rationalist approach by focusing on physiological knowledge. Newton (2001) attributes this in part to the influence of the Flexner report, published in 1910. Although the purpose of the report was to examine medical education, Flexner's emphasis on the importance of understanding the mechanisms of disease "created a template of medicine, in which the high priests are scientists who illuminate the basic processes of disease" (Newton, 2001, p. 303). Medical school curricula and clinical training were both focused on understanding disease mechanisms.

As we have seen, our understanding of what it means to have a scientific understanding of medical causation has, since the early 1990s, been massively influenced by medical empiricism, in the form of EBM. One of the most famous definitions of EBM is "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients" (Sackett et al., 1996, p. 71)—a definition that might well lead us to assume that EBM considers any form of evidence to be relevant, when in practice, the relevant evidence comes from well-designed studies that rank high on EBM's hierarchy of evidence. Moreover, most of what has been written about EBM, by its proponents in both medicine and philosophy, has focused on studies that examine treatments (as opposed, for example, to prognosis, or of diagnostic tests).

According to the evidence hierarchy for treatment studies, the best evidence comes from systematic reviews or meta-analyses of randomized controlled trials, or, where only one study is available, a single RCT. Nonrandomized studies (reviews of multiple studies, then a single study) fall below this on the hierarchy. Note that all of the top levels of the hierarchy look at treatment outcomes in groups of patients; the methods here are similar to those used in epidemiology (we return to this point below). Below these studies come case reports and

case series (reflecting the unsystematic observations of a single clinician or a small group of clinicians) and then research from laboratory studies that examines physiological processes or outcomes.

Philosophers have both defended and criticized EBM.[x] Here, we use the hierarchy of evidence to introduce questions about the potential contributions of population level research and physiological research to medicine. As noted, EBM's hierarchy of evidence claims that the best research evidence comes from population-level studies that examine outcomes in large groups of people who receive an intervention of interest, comparing them with outcomes in a similar, control group. This basic study approach—examining the relationships between potential causal factors and health effects in populations of patients—comes from epidemiology. As we have seen, the roots of EBM lie in an earlier movement called clinical epidemiology (Feinstein, 1985; Sackett et al., 1985), which explicitly aimed to use the techniques of epidemiology in clinical research.

Yet there are important differences between epidemiology and clinical research. First, clinical research tends to focus specifically on one cause, the intervention being tested, while epidemiology takes into account the effects of a number of different factors on disease outcomes. Second, epidemiology is closely related to public health, which aims to improve outcomes in populations, rather than in individuals, while clinical research is intended to inform decision-making in the care of individual patients. Because of this, Last (1988) claims that "clinical epidemiology" is an oxymoron.

Philosophical discussions of epidemiology, therefore, share some issues with discussions of clinical research, but also address distinct questions. Alex Broadbent's chapter in this volume surveys current work in philosophy of epidemiology, suggesting that a central issue for both philosophers and epidemiologists themselves involves questions about

causation. He also notes that epidemiology is highly unusual among the sciences, because it does not develop a body of theory. While epidemiology may draw heavily on theories relevant to a specific condition or question being investigated, it operates via a piecemeal approach, helping itself to whichever theoretical background is relevant to the problem at hand. So instead of being defined by its specific body of theory, the defining features of this young science are to be found in its methods.

Given that so much work in the philosophy of science concerns theory development, developing a philosophical account of epidemiology raises specific and interesting challenges for philosophy. Broadbent also notes that epidemiology has limitations, that "having identified a disease 'vector' or an exposure of interest, epidemiology needs to hand over to laboratory sciences which can tell us more about how exactly the exposure works." This suggests that epidemiology is a purely empiricist approach to medicine, with no interest in understanding physiological mechanisms. But because epidemiology does draw on work from other sciences, it incorporates the knowledge obtained from a rationalist approach, as well. For example, epidemiological studies may examine the effects of sex/gender, age, socioeconomic status, comorbidities, or genetic/genomic make up on health outcomes. All of these characteristics presumably are linked to differences in the underlying physiological mechanisms, though we can recognize the influence of the characteristics even without understanding the mechanisms themselves. It is worth noting that the interaction with rationalist research is another characteristic that distinguishes epidemiology from EBM, at least when it comes to research on the effects of treatment. Since EBM focuses on differences between average outcomes in treatment and in control groups, and does not tend to address questions about the effects of social, demographic, or biological characteristics on outcomes within study groups, EBM can be characterized as a shallow form of empiricism, compared

with a deeper form of empiricism that uses knowledge of mechanisms to help to understand the sources of variability in outcomes.

In fact, there are areas of medical research that are defined by the specific health-related factors on which they focus; two chapters in this volume look more closely at specific factors that are relevant to health. Tania Gergel (in Chapter 10) examines gender medicine and Marianne Boenink (in Chapter 3) assesses personalized medicine. Gender medicine has recently become an area of great interest among medical researchers. It was inspired in part by the recognition that much of the research being done in biomedicine used only male subjects. While clinical trials have been required to enrol both women and men for some time now, these studies still do not always investigate whether there are differences in treatment outcomes for the two groups. Personalized medicine aims toward an ideal in which knowledge about individual genetic/genomic characteristics and differences in molecular biology permit the refinement of estimates of health risks and prognosis, and the tailoring of treatment to an individual's biological characteristics. While both Gergel and Boenink raise important questions about the assumptions that underlie their respective topics, as well as their potential implications for health and medicine, from the perspective of Wulff et al. (1990), gender medicine and personalized medicine both have promise as approaches that represent "realism under empirical control." Both areas of research take into account knowledge of physiological differences, and their effects on outcomes.

Another area of recent interest in biomedical research, one that focuses mainly on population-level explanations, is evolutionary or Darwinian medicine. Evolutionary medicine draws on evolutionary biology to understand human health and disease. Its central tenet is that pathophysiology and the vulnerability to disease should be understood in terms of trade-offs that secured other evolutionary advantages. Moreover, it claims that contemporary health problems are often the result of changes in our environment and lifestyles, which of course

change much more rapidly than our genome, so that there is a mismatch between the environment to which the human genome was adapted and the one in which it currently functions.

Pierre Méthot (2011, 2015) distinguishes between (a broad conception of) evolutionary medicine and a narrower Darwinian medicine. He describes the former as a "forward looking" attempt to predict the effects of evolutionary processes on human health; it considers not just human evolutionary history but ongoing evolutionary changes in microorganisms that are relevant to infectious disease and antibiotic resistance. This approach overlaps in interest with epidemiology, since it examines current patterns of disease. By contrast, Darwinian medicine is "backwards looking" in that it "applies evolutionary principles from the vantage point of humans' distant biological past in order to assess present states of health and disease" (Méthot, 2015, pp. 587-8).

Although evolutionary medicine looks at populations and at variability in outcomes, it also has an interest in explaining how these outcomes came about. It therefore has some rationalist and some empiricist tendencies. But instead of seeking the specific causes of an outcome at a physiological level, it focuses on processes that underlie evolutionary change in general. Darwinian medicine, as the name suggests, focuses primarily on the processes of adaptation and natural selection. Valles (2012) has criticized the focus on adaptation, arguing that it distorts research in the field (see also Cournoyea, 2013). Evolutionary medicine, by contrast, considers a wider range of biological processes relevant to evolution, including symbiosis and epigenetics (Méthot, 2015). It may therefore not be subject to these criticisms.[xi]

This section has surveyed a number of important areas of biomedical research and has briefly discussed some of the philosophical questions they raise. Two key aspects of the

discussion have been that (1) biomedical research tends to focus on either health outcomes in populations or on the physiological mechanisms that produce these outcomes; and (2) there are two distinct orientations to medicine: empiricist and rationalist. While these are, at least to some extent, naturally allied with one of the two broad approaches to research (empiricism with population level research, and rationalism with research on physiological mechanisms), we have suggested that most areas of biomedical research do (and should) incorporate some aspects of both rationalism and empiricism.

Philosophy of science and philosophy of medicine

The previous section discussed a number of current trends in medical research, addressing some of the philosophical questions they raise and pointing out their philosophical commitments. In this section, we turn to developments within philosophy itself, in particular to the ways in which recent work in philosophy of science is beginning to be used in philosophy of medicine.

Over the past decade or so, there has been a resurgence of interest in medicine among philosophers of science. We outline briefly several areas of research in philosophy of science that are particularly relevant to philosophy of medicine. These include both traditional questions (including the nature of scientific theories, the confirmation of theories by evidence, and the establishment of causal relationships) which are relevant to assessing biomedical research, regardless of its specific methods or discipline. In addition, there are some areas of philosophy of science that have developed more recently and that are relevant to medicine, specifically the focus on scientific pluralism and questions about the nature and roles of values in science.

The distinction between population-level research and research on physiological mechanisms is relevant in philosophy of science, as well as in medical research itself. We noted above that the philosophy of science has traditionally been centrally concerned with theories. While this is true, it is an oversimplification, as there are a variety of approaches to understanding what a theory is, and how theories are related to other concepts, such as laws of nature, or models. The syntactic view of theories, which dates back to logical empiricism, views theories as a set of statements (many of which represent laws of nature), while the semantic view sees theories as a set of models. A more recent development is the focus on mechanisms, which are usually described as explanations, rather than as theories (Craver, 2002). The basic idea underlying this approach is that scientists working in the life sciences do not primarily attempt to develop theories, but rather to elucidate physiological mechanisms.

Although there are a number of ways of describing what a mechanism is, one prominent view (the MDC view) is that "[m]echanisms are entities and activities organized such that they are productive of regular changes from start or set-up to finish or termination conditions" (Machamer et al., 2000, p. 3). Another important feature of mechanistic explanations is that they are inherently multilevel. The entities that make up one level of the mechanism are themselves composed of other entities, which work together in a mechanism to allow the higher-level entity to contribute to the function of the higher-level mechanism. That is, an entity itself can be viewed as a mechanism, the output of which is the activity of the higher level entity. For example, a cell is composed of a number of molecular components that contribute to the activity of the cell, allowing it to take its place in a mechanism.

Although the new mechanism has been very influential in philosophy of science, relatively little work on mechanisms has been done to date in the philosophy of medicine

itself. One question has to do with the nature of mechanisms of disease: for example, Mauro Nervi (2010) has argued that these should be considered as distinct mechanisms, while Sara Moghaddam-Taheri (2011) has argued that pathological mechanisms should be understood as broken normal mechanisms. This question is still not entirely settled. One interesting way that the question might be answered is by linking discussion of physiological mechanisms to other questions in philosophy of science/philosophy of medicine. For example, Justin Garson (2013) has drawn on work in philosophy of biology that examines biological functions in evolutionary terms; the idea is that a mechanism has a normal function in virtue of its evolutionary history. This suggestion seems to weigh in favour of the broken normal view.

To date, however, most of the discussion of mechanisms in philosophy of medicine has been influenced by work on EBM, and has addressed the question of the extent to which physiological research on mechanisms (which is near the bottom of the hierarchy of evidence) can inform treatment decisions, whether instead of, or as a supplement to, clinical trials (Anderson, 2012; Bluhm, 2013; Howick, 2011; Howick et al., 2013). Recall that EBM, with its focus on RCTs and meta-analyses, is an empiricist approach to medicine, while the elucidation of physiological mechanisms is rationalist. Contemporary rationalism is not like the theory-heavy, armchair speculative realism criticized by Wulff et al. (1990). Rather, it is based on experimentation and careful observation. Yet, it is still not clear what kind or amount of physiological knowledge is required to support predictions of clinical outcomes.

The question of predicting outcomes is related to the question of what kind of research evidence is necessary to establish causal claims in medicine. The ability to make claims about causality is important in all areas of science. As we described above, physiological research focuses primarily on understanding the causes of disease in terms of the mechanisms that lead to the signs and symptoms of disease (and, to a lesser extent, on elucidating the mechanism of action of treatments). Epidemiological studies examine the influence of potential risk factors

(i.e. causes) on disease occurrence. And, using similar methods, clinical trials aim to determine whether a therapeutic intervention causes improvement in patient outcomes. Philosophical discussions about causality in medicine have attempted to clarify the contributions that each of these kinds of research can make to our knowledge of causes.

One debate centers on whether RCTs can provide any information about causes. Proponents argue that RCTs, as opposed to observational studies, are necessary to show that a treatment causes an outcome of interest, because only RCTs can control appropriately for the influence of confounding factors. Cartwright argues, however, that RCTs can only support causal claims if we build knowledge of causes (or assumptions about what causal factors are relevant) into our experimental design, and that mere statistical associations can only be taken to be evidence of causal relations if we already have some idea of what the causal relationships are (e.g. Cartwright and Hardie, 2012).

Recent discussions have been strongly influenced by what has come to be known as the "Russo-Williamson thesis"—after the arguments presented in Russo and Williamson (2007)—which claims that both knowledge of mechanisms and knowledge of the statistical relationship between risk factors/interventions and outcomes are necessary to obtain causal knowledge in the health sciences. Statistical evidence linking causes and effects is required to show that the occurrence of an effect does depend on the presence of the cause. Mechanisms give us knowledge that a statistical relationship observed in a study sample is not merely limited to that sample, or to the specific circumstances in which the statistical relationship was observed.

In addition, it is important to realize that, to some extent, causal claims are always limited to specific circumstances. This fact has important implications for the use of biomedical and clinical research to inform policy and practice. Scientific research is designed

to isolate specific causal factors of interest, whether in the carefully controlled conditions of a laboratory, or in social science and epidemiological research that uses statistical controls. This research does not, however, give sufficient information to predict how these causes operate in the very different contexts in which the policy is implemented. Cartwright, for example, cautions that while scientific studies can show that a policy "works somewhere," much more information is needed to warrant the claim that the policy also "works here" (Cartwright and Hardie, 2012).

Pluralism, science, and values

Ultimately, the sciences described above claim that they can contribute to improved health, whether by directly influencing patient care and/or by contributing to the development of public health policies. But within each of these sciences, as we have shown, there are disagreements and controversies. These issues take on additional complexity when we look at all of the sciences together, since they use very different methods and focus on distinct aspects of biology or medical intervention. One of the most pressing problems in contemporary philosophy of science is understanding how to integrate the findings of different sciences and scientific approaches.

During the mid-twentieth century, the heyday of logical empiricism, philosophy of science was guided by the assumption that, as science progressed and provided more knowledge of the natural and social worlds, scientific theories would converge to provide a unified body of knowledge. By contrast, many contemporary philosophers of science accept some form of scientific pluralism, emphasizing the diversity (both among and within scientific disciplines) of methods, theories, scientific models, and background assumptions about the nature of the phenomenon being studied. This diversity influences both the results

of research and its interpretation, leading some philosophers to conclude that it is impossible to draw any general conclusions that transcend the myriad specific scientific contexts within which a phenomenon is investigated (Longino, 2013).

Related to this point are questions about the different sorts of value-judgement that underlie and motivate scientific research. An obvious focus for this approach in philosophy of medicine has to do with the role of commercial interests, e.g. pharmaceutical and biotech companies, in shaping medical research and its uptake in clinical practice. However, even leaving aside commercial issues, a host of social, cultural, and political values may influence medical research at numerous stages, including questions about which areas become priorities and receive research funding, about what kinds of studies are considered to provide good evidence, and about how much evidence is needed before clinical practice should be changed.

Conclusion: The search for the base or center

It seems clear then that medicine is informed by a broad variety of approaches in science, and no one methodology can claim to be definitive of the whole range of studies, theories and practices that legitimately qualify for the descriptor "medical." This is hardly surprising, given the richness and diversity of medical research and practice, and the vast range of problems we are prepared to characterise as medical. There are also well defended claims that medicine should be informed by a broader range of sources and methods than can sensibly be classified as scientific, and/or that our notion of scientific reasoning needs to be expanded to incorporate a role for the sort of human capacities and dispositions that would qualify as subjective and non-rational in the writings of the logical positivists. Several authors in this volume[xii] argue that the philosophy of medicine has been impoverished to the extent that it has failed to make a systematic study of the humanistic aspects of medical practice,

including the role of intuitive and tacit knowledge in medical epistemology and phenomenological approaches to understanding illness and associated problems of meaning, suffering and embodiment. It is therefore perhaps no greater a surprise that, as noted in our opening comments, there is a diversity of methodological approaches within the philosophy of medicine itself, and no one, unifying meta-methodology to tell us what the different approaches have in common.

Should this strike us as a problem? Apart from being various ways of thinking about medical problems, research and practices, should areas as different as the philosophy of epidemiology, medical humanities, and virtue epistemology (to name just a few of the distinct and developing areas of medical philosophy) have anything in common? If there need be no general, methodological thread linking all of these different approaches, then this does of course create a problem when it comes to distinguishing legitimate from illegitimate approaches to the subject matter. It means we need to assess each alternative approach as it comes, making up our own minds as to its validity and usefulness. We do not yet have (nor, arguably, may we ever have) a definitive set of rules that simply tell us which approaches are and are not legitimate.

It is not, however, clear that this is a problem any rational person should expect ever to be solved. Is phenomenology an intellectually respectable and practically useful way to inform and enhance our understanding of medical problems and practices? The only way to answer that question is to make a serious study of work in the area of medical phenomenology, applying one's critical faculties to form a judgement about the quality of the arguments and analyses presented. (The reader might begin by studying in detail the chapters by Fredrik Svenaeus (Chapter 8) and Tania Gergel (Chapter 10) in this volume.) To think that there must, somewhere, be a list one can consult to by-pass this process of critical engagement with the specifics of the area is to adopt a "repair manual" approach to thinking

(Loughlin, 2002, p. 4), to seek exemption from the responsibility to form one's own conclusions, and thus to opt out of the processes of reasoning.

There are, however, other problems presented by the diversity of methods in the medical philosophy. We have seen, in our discussion of the relationship between EBM, PCM, and VBP, that there are legitimate questions about the extent to which different approaches in the philosophy of medicine are complementary or embody incompatible assumptions. In that discussion, a key problem concerned the status of these approaches as distinct models of clinical practice, each claiming to be comprehensive accounts of what UP should be. The very idea that such a comprehensive account should be the goal of the philosophy of medicine may strike many readers as natural, but there are also those who question why the giving of a complete account of an area should be the goal of all and any serious theoretical enterprise. Considering the names of the three approaches mentioned in this paragraph, Ross Upshur comments that in medical philosophy: "The persistent desire to name some concept or idea as the base or the centre strikes me as misguided in some fundamental way. We have seen little attention or discussion about the near mania for appellations of this sort" (2014a, p. 989).

As we noted above (cf the comments on Toulmin in the opening section), philosophy can be construed as either a body of theory or as an activity. We argued that its value, certainly in an area such as the philosophy of medicine, appears to be as an activity, an engagement with common ideas and practices in the area. The philosopher asks critical questions to expose and interrogate underlying assumptions that frame debates, with the goal of assisting the protagonists in understanding their own assumptions and considering possible alternative conceptual frameworks. In medicine this means engaging in dialogue with practitioners and patients, taking up problems that arise directly from their accounts of the problems of practice, and exploring ways of conceptualising the problems, relevant evidence,

and potential solutions. But for many theorists, the ultimate goal of such an activity must be the production of a complete body of theory, a philosophy of the area. The attraction of this idea may in part lie in a comparison with the view of scientific progress noted in the closing comments of our previous section, that theoretical unity is the ultimate goal of science.

Whatever its appeal, it explains the motivation to present an account of the "base" or "center" of all medical practice, as though explaining an entire and extremely diverse area via a single, underlying concept. But as Upshur notes:

> Basing or centring medicine on any one thing, be it evidence, persons or patients, seems to be a mistaken enterprise. I am not sure what motivates the requirement for this and why, for example, evidence, values and persons or patients cannot be seen as mutually constitutive. In some circumstances evidence, however conceived, may hold more weight than values and vice versa. There are contexts where the interests of persons or patients, always deserving of respect, may take a subordinate role to the needs of a community (2014b, pp. 214-5).

Social practices rarely come into existence because some person or group sits down, decides we need a practice called X, sets out its defining characteristics and then rounds up a group of people whose qualifications suggest they are the best qualified to create the needed practice. Practices evolve, so there is indeed something bizarre about searching retrospectively for their base or foundation. If they emerged without having to be at any point founded then why try to create a foundation, center, or unifying concept for them? It may be that theorists think that is the only way to explain or make sense of these practices, but in that case we need to examine the theorists' own assumptions about what it is to explain or make sense of a practice.

Wittgenstein's instruction: "don't think, but look!" (Wittgenstein, 1958, p. 31) sounds like the sort of anti-philosophical declaration we might expect from the blogger cited in our opening section, but it is meant to serve as a warning about philosophical methodology that may have relevance to future debates in medical philosophy. As Cooper notes in Chapter 11 to this volume, a great deal of work in the "philosophy of" medicine has been done attempting to define such key concepts as health and disease, but it is possible that no definition is ever going to capture all legitimate uses of these terms in the various contexts in which they operate. They may be what Wittgenstein calls family resemblance terms, such that understanding their meaning is a matter of tracking their uses in the range of contexts in which people employ them, understanding their contribution to the forms of life this employment facilitates. To attempt to abstract an overall, definitive meaning of the term (to stop, as it were, looking and to theorise in the sense meant in the quotation by thinking) involves taking terminology out of its specific context of use when analysing its meaning, and there are dangers associated with this.

So, a practitioner might have a very clear sense of what it means for an aspect of her practice to be patient-centered, and may be able to explain in a particular case how she has applied this idea, to the benefit of her patients. But when she fills in a management survey aimed at producing more patient-centeredness in her area or institution, via the production of general policy documents and practice guidelines, she may find that the answers she has given lead to policies and regulations that, far from facilitating her efforts in this area, actually inhibit them. This may not be because the survey's respondents are being inconsistent or "don't know what they're doing," nor need it be a result of incompetence or malice on the part of the managers attempting to base their polices on the responses. When language "goes on holiday" (Wittgenstein, 1958, p. 19), moving out of the context that gave it meaning, only to be recycled, in a different context and then fed back to practitioners as an

application of some more general insight, there can be slippages of meaning, and one role of the philosopher of medicine should be to track these possible changes and the problems they create for the communication processes in organisations.

So if PCM and EBM really do want to demonstrate their mutual compatibility (cf our discussion of these models in the section “Clinical Practice and Theory”) then they may need to moderate their claims about their own status. Instead of presenting themselves as comprehensive clinical practice models, or general theories of medicine, they might instead regard themselves as distinct ways of conceptualising practice that bring to light otherwise neglected or de-emphasised aspects, leaving it to the judgement of the informed reader of their theories to work out which approach makes sense of the specific situation she is facing. This more modest, but still important aspiration may be a more realistic goal of theory than the attempt to provide a definitive theory of any given area of practice, and it fits with the model of philosophy as an activity, a dialogue with practitioners, patients and anyone else with a stake in the practices analysed.

Such an approach might arguably be part of a solution to the crisis for EBM some of its prominent exponents have recently highlighted (Greenhalgh et al., 2014). This methodological concern might well be relevant to the developing movement for person-centered medicine, discussed at various points in this chapter. The last thing this movement needs, we suspect, is a definitive account of the meaning of the term person (which, if it is to be at all plausible, and to serve the declared purposes of the movement, must incorporate the idea of rational agency) followed by a discussion of what precisely it means for medical practices to be centered on such persons—followed swiftly by accusations that the movement risks condemning human beings that do not fit this model of personhood to the margins of medical concern and care (Loughlin, 2014). The movement’s wholly legitimate efforts to re-establish the importance of certain aspects of practice (those de-emphasised by the

approaches it condemns as “reductionist”) will not be served by its declaring itself to be the new candidate for the definitive “philosophy of” or new “foundation for” the practice of medicine. Nor does it need to make such a claim to argue that its proposals for framing discussions about medicine in future represent significant progress with regard to what has gone before.

One factor affecting which of the two alternative methodologies the philosopher of medicine adopts was touched on in the conclusion of the previous section—the values being served by research. If one sees one’s role as a philosopher as serving the needs of the policy-maker then the appeal of a new, revolutionary insight, the discovery that all of medicine is in fact based on or centered in factor X, and a complete definition of what X is, may well serve the purposes of the audience for whom one is writing. But if the purpose is to assist “a broader audience” (Loughlin, 2002 p. 151), including practitioners and the public, to make sense of a complex and challenging environment, then the more modest goal may well also be the more useful one to adopt.

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[i] David Colquhoun, self-styled “defender of science” and crusader against quackery, religious belief, and all things “unscientific.” Probably one of the few people on Earth who actually wants the Westboro Baptist Church to picket his funeral.

[ii] Why philosophy is largely ignored by science: http://www.dcscience.net/2011/10/28/why-philosophy-is-largely-ignored-by-science/ (accessed 8 May 2015).

[iii] Founder of the Westboro Baptist Church, self-styled religious controversialist and crusader against all things “ungodly.” Also of the view that critical examination of one’s underlying assumptions is a waste of time.

[iv] The issue is a central preoccupation of several chapters in this volume. See in particular Marianne Boenink (Chapter 3), Alexander Broadbent (Chapter 4), Jeremy Howick (Chapter 5), and Brendan Clarke and Federia Russo (Chapter 12).

[v] A good illustration of a much richer conception of reasoning can be found in Hillel Braude’s Chapter 13 on clinical decision-making, appealing to the Aristotelian idea of practical wisdom to give an account of what good clinical reasoning consists in.

[vi] Including some of those who, to use Toulmin’s (1982, p. 749) term, “barbarously” embraced the label “ethicists” (Loughlin, 2004).

[vii] See, http@//medicine.umontreal.ca/doc/PPS_Rapport_2011-2013.pdf (accessed 7 May 2015).

viii

Some authors, such as Jeanne Daly (2005), refer to EBM as a science of clinical practice rather than as a model, but its authors envision its role as going beyond science and offering techniques to guide actual practice.

ix

The defenders of PCM also reject the construal of the patient as the passive recipient of treatment and the practitioner as bearing sole responsibility for the decisions and outcomes of the process.

x

Jeremy Howick's Chapter 5 in this volume provides an overview of this literature and presents his own analysis.

xi

The issues in this area are taken up in much greater detail in Michael Ruse's Chapter 6 to this volume.

xii

See in particular the chapters by Alfred Tauber (Chapter 7), Lydie Fiolova (Chapter 7), Fredrik Svenaeus (Chapter 8), Andrew Miles (Chapter 9), Tania Gergel (Chapter 10), and Hillel Braude (Chapter 13).