



Philosophy of Evidence-Based Medicine

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Introduction

Since its introduction just over two decades ago, evidence-based medicine (EBM) has come to dominate medical practice, teaching, and policy. There are a growing number of textbooks, journals, and websites dedicated to EBM research, teaching, and evidence dissemination. EBM was most recently defined as a method that integrates best research evidence with clinical expertise and patient values and circumstances in the treatment of patients. There have been debates throughout the early 21st century about what counts as good research evidence between EBM proponents and philosophical critics and even within the EBM community itself. Similar controversy arises about the relative worth of patient values and clinical expertise (and how these can be integrated). EBM has also evolved in ways that have come under scrutiny. Specifically, policymakers have used EBM research methodology to increase the relative importance of clinical guidelines that some clinicians have argued are tyrannical. Philosophers have addressed all of these controversies, and with very few exceptions have been critical of EBM. In addition most philosophical attention has been on the epistemic role of Randomization and evidence hierarchies, with relatively little attention being paid to the role of Diagnosis, expertise, patient values, and Systematic Reviews within EBM.

General Overviews

Great places to start for concise overviews of many philosophical issues surrounding evidence-based medicine (EBM) are Bluhm and Borgerson 2011 and Ashcroft 2004. Worrall 2002 arguably sparked more widespread philosophical interest in EBM although it focuses specifically on randomization. Howick 2011 provides a more comprehensive overview that is critical but supportive of EBM. Sehon and Stanley 2003 considers (among other things) the issue of whether EBM is a new Kuhnian paradigm.

Ashcroft, Richard. "Current Epistemological Problems in Evidence-Based Medicine." *Journal of Medical Ethics* 30.2 (2004): 131–135.

This paper covers various epistemological issues raised by evidence-based medicine and provides a balanced critique of its current practice. The author thus establishes a good starting point for future discussion of the nature of clinical evidence.

Bluhm, Robyn, and Kirstin Borgerson. "Evidence-Based Medicine." In *The Philosophy of Medicine*. Edited by Dov M. Gabbay, Paul Thagard, John Woods, and Fred Gifford, 203–238. *Handbook of the Philosophy of Science* 16. Boston: Kluwer Academic, 2011.

A fantastic philosophical/historical overview.

Howick, Jeremy. *The Philosophy of Evidence-Based Medicine*. Chichester, UK: Wiley-Blackwell, 2011.

Howick defends many aspects of evidence-based medicine, including the use of Systematic Reviews and the superiority of comparative clinical studies (including observational studies and randomized trials) over pathophysiologic rationale and expert judgment.

Sehon, Scott R., and Donald E. Stanley. "A Philosophical Analysis of the Evidence-Based Medicine Debate." *BMC Health Services Research* 3.1 (2003): 3–14.

Examines various philosophical issues that arise in EBM, including whether EBM is a new Kuhnian paradigm.

Worrall, John. "What Evidence in Evidence-Based Medicine?" *Philosophy of Science* 69.Part 3 supp (2002): S316–S330.

Taking the evidence-based medicine view of such evidence as involving primarily the view that Randomization provides better evidence than observational studies, Worrall attacks evidence-based medicine from a Bayesian perspective.

Anthologies and Special Issues

The number of anthologies and special issues reflects the philosophical interest in EBM. A variety of special issues dedicated to EBM have been published. These have all featured almost exclusively articles that are critical of EBM. Loughlin, et al. 2010; Loughlin, et al. 2011; Loughlin, et al. 2012; and Loughlin, et al. 2013 argue that, contrary to what some medical researchers have claimed, philosophy is important for critically appraising EBM itself. They contain interesting critiques of EBM as well as some specific suggestions for how philosophy might be brought to bear on EBM, with each issue having a different theme. Goldenberg, et al. 2009 contains an interesting series of articles that focus on critiques of EBM, with an emphasis on its sociological consequences. Jutel and Nettleton 2011 is an argument that Diagnosis receives less attention than it deserves and contains interesting articles about both diagnosis and the social science of diagnosis.

Goldenberg, Maya, Kirstin Borgerson, and Robyn Bluhm. "The Nature of Evidence in Evidence-Based Medicine." In *Special issue: Evidence-Based Medicine*. Edited by Maya Goldenberg, Kirstin Borgerson, and Robyn Blum. *Perspectives in Biology and Medicine* 52.2 (2009): 164–167.

An excellent special issue where many philosophical critiques of EBM can be found.

Jutel, Annemarie, and Sarah Nettleton. "Toward a Sociology of Diagnosis: Reflections and Opportunities." In *Special Issue: Social Science and Medicine* 73.6 (2011): 793–944.

A special issue on the sociology of Diagnosis. Explores issues at the boundaries of EBM and questions whether or not all diagnoses must be based on "evidence."

Loughlin, Michael, Ross E. G. Upshur, Maya J. Goldenberg, Robyn Bluhm, and Kirstin Borgerson. "Philosophy, Ethics, Medicine and Health Care: The Urgent Need for Critical Practice." In *Special Issue: Evidence-Based Medicine*. Edited by Michael Loughlin, Ross E. G. Upshur, Maya J. Goldenberg, Robyn Bluhm, and Kirstin Borgerson. *Journal of Evaluation and Clinical Practice* 16.2 (2010): 249–259.

The opening of this special philosophy thematic edition, devoted to evidence-based medicine and healthcare.

Loughlin, Michael, Robyn Bluhm, Stephen Buetow, et al. "Virtue, Progress, and Practice." In *Special Issue: Philosophy of Evidence-Based Medicine*. Edited by Michael Loughlin, Robyn Bluhm, Stephen Buetow, et al. *Journal of Evaluation and Clinical Practice* 17.5 (2011): 839–846.

Editorial article for a special philosophy-related thematic issue incorporating sections on the relationship between evidence-based medicine and the philosophy of science, the epistemic arguments of homeopathy, and the ethics of abortion.

Loughlin, Michael, Robyn Bluhm, Stephen Buetow, et al. "Reason and Value: Making Reasoning Fit for Practice." In *Special issue: Reason and Value*. Edited by Michael Loughlin, Robyn Bluhm, Stephen Buetow, et al. *Journal of Evaluation and Clinical Practice* 18.5 (2012): 929–937.

An article introducing an insightful volume on the nature of critical thinking in the practice of medicine.

Loughlin, Michael, Robyn Bluhm, Drozdostoj S. Stoyanov, et al. "Explanation, Understanding, Objectivity, and Experience." In *Special Issue: Philosophy Thematic Issue*. Edited by Michael Loughlin, Robyn Bluhm, Drozdostoj S. Stoyanov, et al. *Journal of Evaluation and Clinical Practice* 19.3 (2013): 415–571.

A special edition on the themes outlined in this introductory editorial article.

Bibliographies

Readers seeking both evidence-based medicine and general philosophy of medicine sources will find the Mendeley Philosophy of Medicine Public Bibliography in the Philosophy of Medicine (set up by philosopher Andrew Turner) useful. The Cochrane bibliography Webliography of Resources for Evidence-Based Health Care is more comprehensive and contains books, databases, journals, news reviews, patient resources, and tutorials, as well as social media resources. Bandolier specializes in interventions that reduce pain.

Bandolier.

The Bandolier site is a bibliography of evidence for interventions intended to reduce pain. The website is an online and more comprehensive version of the Bandolier journal. The Bandolier group also develops methods for evaluating interventions to reduce pain (most recently arguing that using average pain scores is mistaken).

Mendeley Philosophy of Medicine Public Bibliography in the Philosophy of Medicine.

This bibliography set up by Andrew Turner contains a useful and comprehensive list of titles within the philosophy of medicine in general and the philosophy of evidence-based medicine in particular.

Webliography of Resources for Evidence-Based Health Care.

A useful bibliography produced by the Cochrane Collaboration.

Historical Background

Daly 2005 is a collection of interviews of founders of evidence-based medicine (EBM) and offers a useful “living” history of EBM in Anglophone countries. Cochrane 1972 provided the impetus for Enkin, et al. 1989, and subsequently the Cochrane Collaboration and contains many interesting historical anecdotes about motivations for the EBM movement. Founded by Sir Iain Chalmers, the James Lind Library contains a fantastic and growing collection of historical examples of early experiments that introduced methods to reduce bias (including alternation, randomization, blinding, and placebo controls). Marks 1997 and Wootton 2006 provide more general historical perspectives: Marks 1997 explains the rise of clinical research in the United States, and Wootton 2006 argues that medicine did more harm than good until at least 1860.

Cochrane, Archie. *Effectiveness and Efficiency: Random Reflections on Health Services*. London: Nuffield Provincial Hospitals Trust, 1972.

A must-read that outlines some early examples of Archie Cochrane’s challenges to medical practice based on expertise that he exposed as harmful. He also notes the problem of external validity: “Between the scientific measurements based on RCTs and the benefit measurements at two levels of cost in the community there is a gulf which has been much underestimated” (p. 2).

Daly, Jeanne. *Evidence-Based Medicine and the Search for a Science of Clinical Care*. Berkeley: University of California Press, 2005.

Although Daly is sympathetic with advances made in evidence-based medicine toward practicing quality healthcare in a professional manner, she recognizes its limitations in generating a science appropriate for clinical practice as a whole, in all its complexity, including the social and political contexts of health care systems and patients.

Enkin, Murray, Marc Keirse, and Iain Chalmers. *A Guide to Effective Care in Pregnancy and Childbirth*. Oxford: Oxford University Press, 1989.

This was a response to Archie Cochrane’s lamentation that there was no systematic collection of the research that had been done to date. Cochrane was especially critical of obstetricians and gynecologists.

James Lind Library.

Named after James Lind (b. 1716–d. 1794) who conducted one of the first British controlled trials to find the cure for scurvy, the aim of this collection is to document the earliest and most seminal examples of studies that used EBM principles including Randomization (and alternation), blinding, placebo controls, and other methods to reduce bias. Edited by Iain Chalmers, Ulrich Tröhler, and Mike Clarke.

Marks, Harry. *The Progress of Experiment: Science and Therapeutic Reform in the United States, 1900–1990*. Cambridge, UK: Cambridge University Press, 1997.

A book-length treatment of the history of clinical research in the United States.

McIntyre, Neil, and Karl Popper. “The Critical Attitude in Medicine: the Need for a New Ethics.” *British Medical Journal* 287.6409 (1983): 1919–1923.

This pre-evidence-based medicine article argues that overreliance on medical “authority” leads to increased medical error. The authors also advocate for self-criticism in the practice of medicine.

Wootton, David. *Bad Medicine: Doctors Doing Harm Since Hippocrates*. Oxford: Oxford University Press, 2006.

This is a wonderful history of medicine.

Wulff, Henrik, and Peter Gøtzsche. *Rational Diagnosis and Treatment: Evidence-Based Clinical Decision Making*. 3d ed. Oxford: Blackwell Science, 2000.

This classic was first published in 1976 and inspired much evidence-based thinking. It is a useful mixture of practical advice about how to practice evidence-based medicine (EBM) in the clinic, the history of EBM, EBM in relation to the humanities, and plain-English technical explanations of randomized trials and meta-analyses.

Reference Works

Critics often argue that evidence-based medicine (EBM) does not improve clinical practice, and that the (often implicit) EBM theory of evidence is flawed. EBM proponents often react by claiming that the philosophical critiques of EBM are straw man attacks. This debate has not been resolved and to make things more complicated EBM continues to evolve. In any case a good place to begin philosophizing about EBM is what EBM says about itself, and the references below are therefore “must-reads” for philosophers of EBM. The Canadian Task Force on Preventive Health Care contains an early and rudimentary “hierarchy” of evidence (recommending the use of randomized trials to reduce bias), while Evidence-Based Medicine Working Group 1992 introduced the EBM movement to the wider world (and provided an early characterization of EBM). Guyatt, et al. 2008a explains the latest and most widely used system for ranking evidence within EBM. Guyatt, et al. 2008b contains an excellent overview of general EBM methodology, while Sackett, et al. 1996 and Straus, et al. 2011 include defenses and modifications to early characterizations of EBM. Evans, et al. 2010 is an excellent plain-English explanation of EBM practice.

Canadian Task Force on Preventive Health Care.

The task force provides recommendations for clinical preventive services based on appraisals of evidence from Systematic Reviews and meta-analyses. Reference to CTFPHC History/Methodology was last cited 07/07 2009.

Evans, Imogen, Hazel Thornton, Iain Chalmers, and Paul Glasziou. *Testing Treatments: Better Research for Better Healthcare*. London: Pinter & Martin, 2010.

A book by prominent figures in medicine freely available online. Provides a useful survey of evidence-based practice and covers a wide range of important issues in clinical medicine.

Evidence-Based Medicine Working Group. “Evidence-Based Medicine: A New Approach to Teaching the Practice of Medicine.” *Journal of the American Medical Association* 268.17 (1992): 2420–2425.

The document that introduced evidence-based medicine to the health-care community as a new “paradigm” for medical knowledge.

Guyatt, Gordon, Andrew Oxman, Regina Kunz, et al. “GRADE: An Emerging Consensus on Rating Quality of Evidence and Strength of Recommendations” *BMJ* 336.7650 (2008a): 924–928.

Evolving out of earlier simplified and categorical hierarchies, this paper describes the most widely used system for ranking

evidence. It allows for randomized trials to be ranked lower than observational studies (and vice versa). For the GRADE Working Group.

Guyatt, Gordon, Drummond Rennie, Maureen O. Meade, and Deborah J. Cook. *Users' Guides to the Medical Literature: A Manual for Evidence-Based Clinical Practice*. 2d ed. United States: McGraw-Hill, 2008b.

Classic explanation of evidence-based medicine (EBM) methodology.

The Oxford Centre for Evidence-Based Medicine (OCEBM): Levels of Evidence.

Description by the Levels of Evidence Working Group of the Oxford Centre for evidence-based medicine revised system for ranking evidence. Unlike earlier, more simplified systems, it is not categorical and allows for randomized trials to be ranked lower than observational studies (and vice versa).

Sackett, Dave, William Rosenberg, J. A. Muir Gray, R. Brian Haynes, and W. Scott Richardson. "Evidence-Based Medicine: What It Is and What It Isn't." *BMJ* 312.71 (1996): 71–72.

A short canonical article that sets out the main claims of the evidence-based medicine movement.

Straus, Sharon, Paul Glasziou, W. Scott Richardson, and Brian Haynes. *Evidence-Based Medicine: How to Practice and Teach It*. Edinburgh: Elsevier Churchill Livingstone, 2011.

This is the fourth edition of the original evidence-based medicine textbook.

General Critiques of Evidence-Based Medicine

An early essay proposing EBM methods for diagnostic reasoning, Feinstein and Horwitz 1997, argues that EBM evidence lacks utility for making clinical decisions. Tonelli 2006 argues that EBM is too problematic to be fixed and proposes an alternative he calls "casuistic reasoning."

Feinstein, Alvan, and R. Horwitz. "Problems in the 'Evidence' of 'Evidence-Based Medicine.'" *American Journal of Medicine* 103.6 (1997): 529–535.

This early critique of evidence-based medicine preempts many points raised in the debate concerning the (external) validity of results from clinical findings, the role of judgment in health care decisions, and the clinical relevance of Mechanistic Evidence.

Tonelli, Mark R. "Integrating Evidence into Clinical Practice: An Alternative to Evidence-Based Approaches." *Journal of Evaluation in Clinical Practice* 12.3 (2006): 248–256.

Argues that the epistemic priority given by evidence-based medicine (EBM) to clinical trial evidence is untenable. This article describes Tonelli's criticism and alternative to EBM, and is a good introduction to his many other critical articles. His casuistic alternative to EBM emphasizes research evidence, pathophysiologic rationale, patient values, and system features.

Philosophy of Science and Evidence-Based Medicine

The evidence-based medicine (EBM) philosophy of evidence has been related to general themes in the philosophy of science including general epistemology (Djulbegovic, et al. 2009), Popperian falsification (Sestini 2010, Goldenberg 2010), causation (Kerry, et al. 2012), Kuhnian paradigms (Solomon 2011), and general analytic philosophy (Ashcroft 2002). See General Overviews for other resources linking EBM with other general themes within the philosophy of science.

Ashcroft, Richard. "What Is Clinical Effectiveness?" *Studies in History and Philosophy of Science Part C: Biological and Biomedical Sciences* 33.2 (2002): 219–233.

A well-written article that proposes that there is no overarching property of "clinical effectiveness," but that there are particular types of effectiveness, which are intrinsic properties.

Djulbegovic, Ben, Gordon Guyatt, and Richard Ashcroft. "Epistemologic Inquiries in Evidence-Based Medicine." *Cancer Control* 16.2 (2009): 158–168.

This paper is about the philosophy of evidence-based medicine from a nonphilosophical perspective.

Goldenberg, Maya. "From Popperian Science to Normal Science: Commentary on Sestini (2010)." In *Special Issue: Evidence-Based Medicine*. Edited by Michael Loughlin, Ross E. G. Upshur, Maya J. Goldenberg, Robyn Bluhm, and Kirstin Borgerson. *Journal of Evaluation in Clinical Practice* 16.2 (2010): 306–310.

An interesting commentary on Sestini's claim that evidence-based medicine (EBM) could be viewed as Popperian because it involves formulating clear questions and subjecting them to severe tests. Goldenberg disagrees with Sestini and denies that EBM can be classified as Popperian.

Kerry, Roger, T. E. Eriksen, Lie S. A. Noer, S. D. Mumford, and R. L. Anjum. "Causation and Evidence-Based Practice: An Ontological Review." *Journal of Evaluation in Clinical Practice* 18.5 (2012): 1006–1012.

This article gives an analysis of various notions of causation in evidence-based practice. It rejects interventionism, correlation, and counterfactual causation, and advocates for a dispositionalist view of causation.

Sestini, Piersante. "Epistemology and Ethics of Evidence-Based Medicine: Putting Goal-Setting in the Right Place." *Journal of Evaluation in Clinical Practice* 16.2 (2010): 301–305.

Argues that evidence-based medicine follows a Popperian method of defining a clear problem and generating the best-corroborated solution.

Solomon, Miriam. "Just a Paradigm: Evidence-Based Medicine Meets Philosophy of Science." *European Journal of Philosophy of Science* 1.3 (2011): 451–466.

Covers important historical and social background aspects of evidence-based medicine and reviews the literature debating its methods. Solomon evaluates three types of criticism directed at evidence-based medicine: it is incomplete as a philosophy of science; its methods show greater-than-expected fallibility; its procedures for producing evidence are flawed.

Sociology of Science and Evidence-Based Medicine

Initially designed as a tool to help doctors treat patients in the clinic, evidence-based medicine (EBM) has evolved in various ways, and been used by different groups in interesting ways. For example, EBM is being increasingly used to develop guidelines with which policymakers can (and do) control clinicians. Likewise, EBM was devised to protect clinicians from commercial interests but many argue it has been appropriated by industry (who have the resources to produce EBM evidence). These and other trends have been scrutinized. Nettleton 2004 and Charlton and Miles 1998 provide useful overviews of EBM as a social movement, while Bekelman, et al. 2003 and Spence 2014 provide strong evidence that industry interests have corrupted EBM. Rosenberg 2002 (cited under Diagnosis) argues that diagnosis is in part historically and socially constructed, not the fitting of illness experience into natural categories. Feminist philosophers of science have investigated EBM (both EBM evidence and EBM as a social movement) in relationship to women's health. Like other critiques of EBM these are mostly negative, and both Rogers 2004 and Goldenberg 2010 argue that EBM has had a negative impact on women's health because it ignores values and also evidence that is important to women.

Bekelman, Justin E., Y. Li, and C. P. Gross. "Scope and Impact of Financial Conflicts of Interest in Biomedical Research: A Systematic Review." *Journal of the American Medical Association* 289.4 (2003): 454–465.

Presents a comprehensive, systematic review of the literature addressing the impact of financial conflicts on biomedical research. Concludes that financial relationships among industry, scientific investigators, and academic institutions are pervasive and problematic—for example, evidence indicates that one of four researchers at academic institutions has financial ties to industry and industry-sponsored trials tend to use comparisons that favor new therapies.

Charlton, Bruce G., and Andrew Miles. "The Rise and Fall of EBM." *Quarterly Journal of Medicine* 91.5 (1998): 371–374.

Suggests a striking transition from the "clinically led" approach first advocated by the clinical epidemiology movement to a managerially led approach of evidence-based medicine, with a pronounced belief in the primary role of statistical information to enforce practices upon clinicians.

Dehue, Trudy. "A Dutch Treat: Randomized Controlled Experimentation and the Case of Heroin-Maintenance in the Netherlands." *History of the Human Sciences* 15.2 (2002): 75–98.

A fascinating paper, which questions the justifications for randomized controlled trials (RCTs) via an examination of the heroin maintenance experiment in Holland. The author concludes that, in some cases, RCTs create truth rather than establish it, and in these instances observational or "ethnographic studies" are preferable.

Goldenberg, Maya J. "Perspectives on Evidence-Based Healthcare for Women." *Journal of Women's Health* 19.7 (2010): 1235–1238.

A great paper that explores potential implications of evidence-based medicine (EBM) for improving women's health.

Lexchin, Joel, L. A. Bero, B. Djulbegovic, and O. Clark. "Pharmaceutical Industry Sponsorship and Research Outcome and Quality: Systematic Review." *BMJ* 326.7400 (2003): 1167–1170.

Via a statistical analysis, maintains that research funded by a drug company is more likely to produce results that favor the company's product. Several explanations for this finding are presented.

Nettleton, Sarah. "The Emergence of E-Scaped Medicine?" *Sociology* 38.4 (2004): 661–680.

Sets EBM within a philosophical/historical framework, emerging after "bedside medicine" (pre-1840) and "hospital medicine" (1841–EBM era).

Rogers, Wendy. "Evidence-Based Medicine and Women: Do the Principles of EBM Further Women's Health?" *Bioethics* 18.1 (2004): 50–71.

Rogers argues that evidence-based medicine can—and at times has been—used as a biased tool that undermines women's health.

Spence, Des. "Evidence-Based Medicine is Broken." *BMJ* 348 (2014): g22.

Spence argues that EBM was initially used as a defense against "Big Pharma," whose treatments did not have much EBM to support their effectiveness or that of their diagnostic tests. However Big Pharma adapted: now they produce EBM evidence (and more of it than most others because they have the resources to do so) and so can threaten healthcare professionals and policymakers with that evidence.

Hierarchies of Evidence

There is currently much discussion in the philosophical literature over whether or not medical evidence can be put into hierarchies, as is the case with evidence-based medicine. And if this is possible, there is debate over the manner of structuring those hierarchies. Rawlins 2008 argues that medical evidence does not lend itself to hierarchical categorization. Though not rejecting the idea of hierarchies of evidence entirely, Borgerson 2009 maintains that evidence-based medicine lacks justification for such hierarchical structures. La Caze 2009 contends that the current literature on evidence-based medicine hierarchies should be less ambitious in its epistemic claims. The The Oxford Centre for Evidence-Based Medicine website contains the Centre's "Levels of Evidence Table" along with explanatory documents.

Borgerson, Kirstin. "Valuing Evidence: Bias and the Evidence Hierarchy of Evidence-Based Medicine." *Perspectives in Biology and Medicine* 52.2 (2009): 218–233.

Borgerson argues that two common justifications for evidence for evidence hierarchies (that they provide special justification for causes, and that evidence from "higher up" is less biased) fail.

La Caze, Adam. "Evidence-Based Medicine Must Be. . ." *Journal of Medicine and Philosophy* 34.5 (2009): 509–527.

In contrast to other philosophical works such as Worrall 2002 (cited under General Overviews), argues that a hierarchy of evidence can be assumed, provided it is viewed as a hierarchy of "comparative internal validity." States that such a hierarchy would provide less ambitious, more easily justified claims than the standard ones found in the literature.

The Oxford Centre for Evidence-Based Medicine.

The Oxford Centre for Evidence-Based Medicine (OCEBM) website has a variety of evidence-based medicine teaching and research tools including the OCEBM Levels of Evidence.

Rawlins, Michael. “*De Testimonio: On the Evidence for Decisions about the Use of Therapeutic Interventions.*” *The Lancet* 372.9656 (2008): 2152–2161.

This paper argues that evidence cannot be reliably placed into hierarchies. It includes a good discussion of the null hypothesis and frequentist probability.

Mechanistic Evidence

Evidence-based medicine ranks evidence from (more strictly empirical) clinical studies over evidence about mechanisms that come from the basic sciences. Bluhm 2005 criticizes this view and argues that a “network” of evidence from the basic sciences *and* evidence from clinical epidemiology would be more useful than a hierarchy. Russo and Williamson 2007 makes the point more forcefully and argues that mechanistic evidence is *required* alongside clinical evidence to support causal hypotheses about treatment effects. Pointing to numerous examples ranging from the adoption of anesthetics to aspirin, Howick 2011 (cited under General Overviews) points to dozens of cases where treatments were (justifiably) accepted without any mechanistic evidence at all. The strong view that mechanistic evidence is universally required alongside epidemiological evidence has been dropped. Philosophers have since offered clarifications of what mechanistic evidence amounts to (McKay Illari 2011). Others have insisted that while perhaps not useful for supporting efficacy, mechanistic evidence may have other important roles, such as hypothesis generation and supporting claims about generalizing (see Clarke, et al. 2013). Howick, et al. 2013 responds to these further argumentative claims by maintaining that using evidence to assist with generalizing studies is highly problematic.

Bluhm, Robyn. “*From Hierarchy to Network: A Richer View of Evidence for Evidence-Based Medicine.*” *Perspectives in Biology and Medicine* 48.4 (2005): 535–547.

Proposes a “network view” of evidence, which puts more emphasis on the relationship between epidemiological studies and mechanistic evidence as an alternative to a hierarchical view of evidence.

Clarke, Brendan, Donald Gillies, Phyllis McKay Illari, Federica Russo, and Jon Williamson. “*Mechanisms and the Evidence Hierarchy.*” *Topoi* 33.12 (2013).

In this interesting paper, the authors argue that evidence from mechanisms can complement other types of evidence, and they suggest how this can be achieved.

Howick, Jeremy, Paul Glasziou, and Jeffrey K. Aronson. “*Problems with Using Mechanisms to Solve the Problem of Extrapolation.*” *Theoretical Medicine and Bioethics* 34.4 (2013): 275–291.

Sets out the difficulties inherent in translating results from clinical research to the treatment of individual patients by relying on mechanistic evidence.

McKay Illari, Phyllis. “*Mechanistic Evidence: Disambiguating the Russo-Williamson Thesis.*” *International Studies in the Philosophy of Science* 25.2 (2011): 139–157.

This paper argues that there are problems with Russo and Williamson’s thesis in its strong form (because mechanistic evidence is not always required alongside epidemiological evidence), but that a weaker version (whereby mechanistic evidence can increase the strength of evidence) is defensible.

Russo, Federica, and Jon Williamson. "Interpreting Causality in the Health Sciences." *International Studies in the Philosophy of Science* 21.2 (2007): 157–170.

Argues that evidence from mechanisms and evidence from comparative studies are both required to support causal claims.

Expertise, Patient Values, and Circumstances

According to textbook definitions, evidence-based medicine requires integration of research evidence with patient values and circumstances as well as clinical expertise. However, it is fair to say that the vast majority of evidence-based medicine methodology has been devoted to investigating research evidence while neglecting the other allegedly essential components. Hence, it is unsurprising that a number of proposals have arisen to integrate these other features. (See General Overviews for other relevant sources.) Fulford, et al. 2012 provide a rationale and method for considering values alongside evidence, Bluhm 2009 argues that EBM fails to respect patient autonomy. Montgomery 2006 and Greenhalgh 1999 argue for the role of narratives within the clinical encounter, while Naylor 1995 and Tonelli 1998 suggest various nonevidentiary components that are important in that setting.

Bluhm, Robyn. "Evidence-Based Medicine and Patient Autonomy." *International Journal of Feminist Approaches to Bioethics* 2.2 (2009): 134–151.

Bluhm argues that the way in which patients are involved in decisions about their care (selecting from among a set group of alternatives presented by the clinician) is lacking because it does not allow the patient to consider their illness as a whole. This, she argues, undermines patient autonomy.

Fulford, K. William, Ed Peile, and Heidi Carroll. *Essential Values-Based Practice: Clinical Stories Linking Science with People*. Cambridge, UK: Cambridge University Press, 2012.

This work is not a critique of evidence-based medicine; rather it provides a methodology for combining values with evidence and asserts that "all decisions stand on two feet: evidence and values" (p. 131). In terms of theory, values-based medicine is a counterpart of evidence-based medicine.

Greenhalgh, Tricia. "Narrative-Based Medicine in an Evidence-Based World." *BMJ* 318.7179 (1999): 323–325.

Greenhalgh accuses practitioners of evidence-based medicine of merely paying lip service to the importance of expertise and patient values. She argues that patient narratives are important and demand appropriate expertise.

Montgomery, Kathryn. *How Doctors Think: Clinical Judgment and the Practice of Medicine*. New York: Oxford University Press, 2006.

Via the use of clinical narratives, this book argues against the medicine-as-science view by maintaining that Clinical Reasoning differs from scientific reasoning in that it is situational reasoning with a practical end.

Naylor, C. David. "Grey Zones of Clinical Practice: Some Limits to Evidence-Based Medicine." *The Lancet* 345.8953 (1995): 840–842.

Points out the relevance of clinical judgment in health care situations that involve uncertainty (especially in the absence of

robust evidence) and, importantly, for integrating clinical decisions with patient values.

Tonelli, Mark R. "The Philosophical Limits of Evidence-Based Medicine." *Academic Medicine* 73.12 (1998): 1234–1240.

Makes the point that evidence-based medicine allegedly overlooks the "gap" between clinical research and clinical practice. Recognizes that evidence is important but, at the same time, insufficient for making well-informed clinical decisions about individual patients, which also requires taking into consideration nonevidentiary aspects.

Diagnosis

Treatment follows diagnosis in medicine, yet the philosophical attention to evidence-based medicine (EBM) has mostly been paid to EBM evidence for therapeutic interventions. The list below therefore consists primarily of texts written by medical researchers who express (albeit implicitly) epistemological views about what counts as good evidence for diagnosis. Bossuyt, et al. 2000; Brozek, et al. 2009; Ferrante di Ruffano, et al. 2012; and Lord, et al. 2006 provide a basis for critically appraising the value of diagnostic tests (arguing that randomized trials are sometimes required). Huw, et al. 2014 situates the logic of diagnosis within other theories in the philosophy of science, while Rosenberg 2002 argues for a social role in the categorization of diagnoses.

Bossuyt, Patrick M. M., Jeroen Lijmer, and Ben Mol. "Randomised Comparisons of Medical Tests: Sometimes Invalid, Not Always Efficient." *The Lancet* 356.9244 (2000): 1844–1847.

In this seminal medical paper, the authors argue that diagnostic accuracy may be insufficient for appraising the value of diagnostic tests. Instead, they propose that randomized trials are sometimes required.

Brozek, Jeffrey, E. A. Aki, Roman Jaeschke, et al. "Grading Quality of Evidence and Strength of Recommendations in Clinical Practice Guidelines: Part 2 of 3. The GRADE Approach to Grading Quality of Evidence about Diagnostic Tests and Strategies." *Allergy* 64.8 (2009): 1109–1116.

This paper for the GRADE Working Group explores the difference between diagnostic accuracy studies and randomized trials in investigating the consequences of new diagnostic tests. Written by GRADE authors, it represents the state of the art in how diagnostic tests are evaluated by evidence-based medicine practitioners.

Ferrante di Ruffano, Lavinia, Christopher J. Hyde, Kirsten J. McCaffery, Patrick M. Bossuyt, and Jonathan J. Deeks. "Assessing the Value of Diagnostic Tests: A Framework for Designing and Evaluating Trials." *BMJ* 344.7847 (2012): e686.

Updated argument that diagnostic tests need to be evaluated in clinical trials and a proposal for the design of such trials.

Huw, Llewelyn, Hock Aun Ang, Keir E. Lewis, and Anees Al-Abdullah. "Making the Diagnostic Process Evidence-Based." In *The Oxford Handbook of Clinical Diagnosis*. Edited by Llewelyn Huw, Hock Aun Ang, Keir E. Lewis, and Anees Al-Abdullah. 3d ed. Oxford: Oxford University Press, 2014.

Excellent explanation of evidence-based diagnosis in relation to other theories in the philosophy of science, including Popper's falsificationism and the problem of common causes.

Lord, Sarah, Les Irwig, and R. John Stimes. "When Is Measuring Sensitivity and Specificity Sufficient to Evaluate a Diagnostic Test, and When Do We Need Randomized Trials?" *Annals of Internal Medicine* 144.11 (2006): 850–855.

This paper follows up on the work of Bossuyt, et al. 2000 and provides a framework for when diagnostic accuracy (sensitivity and specificity) are sufficient and when we need randomized trials.

Rosenberg, Charles E. "The Tyranny of Diagnosis: Specific Entities and Individual Experience." *Milbank Quarterly* 80.2 (2002): 237–260.

Argues that we need to accept diagnosis as a social entity.

Clinical Reasoning

Clinicians and philosophers have criticized EBM for downplaying the role of nonquantitative research (Tanenbaum 1993) and informal logic (Upshur and Colak 2003) in medical practice. Such authors point out that quantitative and qualitative evidence, formal and informal logic, clinical experience, and careful consideration of patient history (Kennedy 2013) are required for adequate patient care. Furthermore, Feinstein 1985 and Feinstein 1994 argue that clinical research can be experimental and contribute to knowledge in medical practice. Murphy 1976 articulates the relationship between classical epistemology and philosophy of science with actual clinical decision making.

Feinstein, Alvan R. *Clinical Judgment*. Malabar, FL: R. E. Krieger, 1985.

Feinstein argues that the background of clinical judgment is experience, and that (good) clinicians are always doing experiments.

Feinstein, Alvan R. "Clinical Judgment Revisited: The Distraction of Quantitative Models." *Annals of Internal Medicine* 120.9 (1994): 799–805.

Revisits some of the topics in the author's original (1967) book. Specifically, Feinstein maintains that more clinical research is needed to complement the recent mathematical research contributions to medicine.

Kennedy, Ashley Graham. "Differential Diagnosis and the Suspension of Judgment." *Journal of Medicine and Philosophy* 38.5 (2013): 487–500.

Kennedy proposes a clinical reasoning methodology for approaching patient cases that lack objective evidential findings.

Murphy, Edmond A. *The Logic of Medicine*. Baltimore: Johns Hopkins University Press, 1976.

Murphy does a first-class job of describing the relationship between classical logic and the philosophy of science with actual clinical decision making.

Tanenbaum, Sandra J. "What Physicians Know." *New England Journal of Medicine* 329.17 (1993): 1268–1271.

A short opinion article on outcomes research which argues that multifaceted medical knowledge is a better basis for

clinical decision making than outcomes data.

Upshur, Ross E. G., and Errol Colak. "Argumentation and Evidence." *Theoretical Medicine and Bioethics* 24.4 (2003): 283–299.

An excellent article that evaluates, via a case study, the role of informal logic in evaluating evidence in clinical reasoning.

Randomization

Philosophical critiques of evidence-based medicine arguably began (they were certainly catalysed by) Worrall 2002 questioning the role of randomization. Worrall's work, in turn, builds on earlier work by Urbach 1993. Worrall maintains that with one exception, all standard justifications for the epistemic value of randomization, fail. The one exception (again, according to Worrall) is that Randomization helps reduce selection bias. However Worrall argues that allocation concealment and blinding can achieve the same effect. Sackett, et al. 1996 denies that evidence-based medicine (EBM) can be reduced to randomized trials, while Pocock and Elbourne 2000 asserts the value of randomization against critics. Glasziou, et al. 2007 acknowledges that randomized trials are not required when effect sizes are dramatic, and Vandembroucke 2004 argues that observational studies are on a par with randomized trials for detecting adverse events. Cartwright argues that randomized trials are not the "gold standard" for evaluating causal claims. (See Blinding and Placebo Controls for other relevant references.)

Cartwright, Nancy. "Are RCTs the Gold Standard?" *Biosocieties* 2.1 (2007): 11–20.

Contends that randomized controlled trials have too low an internal validity for adequate causal inferences to be drawn from them. Suggests that methods be applied for judging causal inferences on a "case-by-case basis" and that there is no gold standard for drawing causal conclusions.

Glasziou, Paul, Iain Chalmers, Michael Rawlins, and Peter McCulloch. "When are Randomised Trials Unnecessary? Picking Signal from Noise." *BMJ* 334.7589 (2007): 349–351.

Provides some historical examples of treatments with "dramatic effects," which demonstrate an exception to the idea that without randomized trials we cannot establish effectiveness.

Pocock, Stuart, and Diana R. Elbourne. "Randomized Trials or Observational Tribulations?" *New England Journal of Medicine* 342.25 (2000): 1907–1909.

This editorial maintains that observational studies are less reliable evidence than randomized controlled trials since the design of the former is not experimental and thus allegedly open to bias.

Sackett, David L., William M. C. Rosenberg, J. A. Muir Gray, R. Brian Haynes, and W. Scott Richardson. "Evidence-Based Medicine: What It Is and What It Isn't." *BMJ* 312.7023 (1996): 71–72.

A short, canonical article that sets out the main claims of the EBM movement, and denies that evidence-based medicine can be reduced to randomized trials. The paper also argues that EBM often does apply to individual patients.

Urbach, Peter. "The Value of Randomization and Control in Clinical Trials." *Statistics in Medicine* 12.15–16 (1993):

1421–1431.

This paper affirms that the standard justifications presented for the epistemic value of randomization and control in clinical trials are not valid. Instead, Bayesian justification for trial controls is offered. Philosophers will therefore find this paper (and the issue in which it was published) interesting.

Vandenbroucke, Jan. “When Are Observational Studies As Credible As Randomized Trials?” *The Lancet* 363.9422 (2004): 1728–1731.

Vandenbroucke argues that the value of randomization lies in its usefulness for concealing allocation. Since adverse events are unpredictable (it is argued), investigators in an observational study are blinded to the possibility of patients developing adverse events. Hence for detecting adverse events observational studies are on a par with randomized trials.

Worrall, John. “What Evidence in Evidence-Based Medicine?” *Philosophy of Science* 69.Part 3 supp (2001): S316–S330.

Building on earlier work by Urbach 1993, Worrall contends that most arguments in support of randomization—especially the view that randomization controls for all known and unknown confounders—are flawed. Worrall maintains that the only benefit of randomization is that it controls for selection bias.

Blinding and Placebo Controls

There has been a lack of philosophical attention to the issue of blinding and placebo controls. This is potentially fertile philosophical ground because there has been confusion between allocation concealment (which was the reason Randomization was introduced to medical trials) and blinding as well as between the different types of blinding. There is also a dispute regarding the reason for the introduction of randomization to clinical trials. Contributors to the James Lind Library (cited under Historical Background) argued it was because of the usefulness of randomization for helping to conceal allocation (and nothing to do with frequentist statistics), while many philosophers adopted a critique of randomization from a Bayesian perspective (while also attacking randomization as a feature of frequentist statistics). Howick 2011 begins to clear up some of this confusion surrounding the term “blinding” and argues for its importance. He also argues that, contrary to what some policymakers assert, placebo-controlled trials are not methodologically superior to “active” controlled trials. Turner 2012 explains the epistemological role of placebo controls in great detail. (See Historical Background for other relevant references.)

Howick, Jeremy. *The Philosophy of Evidence-Based Medicine*. Chichester, UK: Wiley-Blackwell, 2011.

Examines empirical studies that have reported the many different ways in which the term “blinding” is used, and defends the benefits of blinding patients, doctors, and other trial personnel.

Turner, Andrew. “‘Placebos’ and the Logic of Placebo Comparison.” *Biology and Philosophy* 27.3 (2012): 419–432.

Turner argues that the logic of placebo controls implies we should drop the term “placebo” because “placebos” are not categorically different from other treatments.

Ethics and Evidence-Based Medicine

A number of authors have published critical examinations questioning the ethical imperatives for conducting clinical research according to the standards of evidence-based medicine. Particular attention has been devoted to discussing the ethical obligation to randomize patients in clinical trials. Bluhm 2010 discusses the ethical implications of conducting short-term randomized controlled trials for the treatment of chronic diseases.

Bluhm, Robyn. “The Epistemology and Ethics of Chronic Disease Research: Further Lessons from ECMO.” *Theoretical Medicine and Bioethics* 31.2 (2010): 107–122.

Argues that observational studies are better suited both ethically and epistemologically than randomized clinical trials for studying the treatment of chronic disease.

Goldenberg, Maya J. “Evidence-Based Ethics? On Evidence-Based Practice and the ‘Empirical Turn’ from Normative Bioethics.” *BMC Medical Ethics* 6.1 (2005): 11.

In this overview, Goldberg laments the reduction of ethics to apparently neutral technical considerations.

Goodman, Kenneth W. *Ethics and Evidence-Based Medicine: Fallibility and Responsibility in Clinical Science*. New York: Cambridge University Press, 2003.

The title of Goodman’s book is deceptive because one of his main aims is to defend EBM methodology (in addition to addressing ethical questions). He contends that many critiques of evidence-based medicine are straw men and asserts that the “evidence” in evidence-based medicine is a useful and necessary tool for informing clinical judgments.

Sestini, Piersante. “Epistemology and Ethics of Evidence-Based Medicine: Putting Goal-Setting in the Right Place.” *Journal of Evaluation in Clinical Practice* 16.2 (2010): 301–305.

Argues that EBM follows a Popperian method of defining a clear problem and generating the best-corroborated solution.

Evidence-Based Policy

Several authors have identified problems with current methods of comparing and evaluating public policy proposals while arguing that evidence-based policy cannot rely on the same methodological standards as evidence-based medicine. Cartwright and Hardie 2012 suggests that existing standards of evidence must be modified since randomized controlled trials often lack sufficient external validity. What is required (they argue) is the use of evidence about mechanisms to extrapolate the results from a randomized controlled trial population to a different target population. Evans 2010 and Gray 2001 explain how evidence-based policy methodologies are actually used in practice.

Cartwright, Nancy, and Jeremy Hardie. *Evidence-Based Policy: A Practical Guide To Doing It Better*. Oxford: Oxford University Press, 2012.

Maintains that the measures of efficacy in the ideal context of a randomized controlled trial do not correspond to effectiveness in the target context.

Evans, Barbara J. “Seven Pillars of a New Evidentiary Paradigm: The Food, Drug, and Cosmetic Act Enters the Genomic Era.” *Notre Dame Law Review* 85.2 (2010): 419–524.

Assumes that evidence-based medicine is a new “paradigm” and discusses how this new paradigm has been enacted by policymakers in the United States.

Gray, J. A. Muir. *Evidence-Based Healthcare: How To Make Health Policy And Management Decisions*. 2d ed. Edinburgh: Churchill Livingstone, 2001.

A book about evidence-based policy written by an early proponent of evidence-based medicine who has successfully bridged the gap between evidence and practice.

Systematic Reviews

For judging the benefits of treatments, systematic reviews of randomized trials are usually considered to offer the best evidence within evidence-based medicine. This area has been largely ignored by philosophers of science. Howick 2011 (cited under General Overviews) adopts the view that taking all relevant evidence into account is unequivocal—while admitting that it is legitimate to debate what kind of evidence is admitted within a systematic review—but he does not go into detail. Meanwhile Stegenga 2011 attacks meta-analyses as “the platinum standard” of medicine, mostly because they suffer from the same (alleged) problems with randomized trials that other authors, especially Worrall 2002 (cited under General Overviews) and Cartwright 2007 (cited under Randomization) have pointed out. Yet there is an important distinction to be made between systematic reviews and meta-analysis. The term “meta-analysis” simply refers to the statistical pooling of a group of studies, whether or not the group of studies was gathered using some systematic method. A systematic review of studies, on the other hand, involves explicit methods for identifying a group of studies that answer a given question. Hence Higgins and Green 2010 in their *Cochrane Handbook* as well as Guyatt, et al. 2008a (cited under Reference Works) for the GRADE working group and working groups for OCEBM (also cited under Reference Works) would surely argue that Stegenga erects a straw man since systematic reviews (and not meta-analysis) are ranked as the highest quality of evidence. Meta-analyses without systematic reviews are not ranked at all highly by practitioners of evidence-based medicine. In fact, the *Cochrane Handbook* warns against meta-analysis in cases where heterogeneity is high—especially if the results of the included studies differ in terms of effect direction. According to the *Cochrane Handbook*, it therefore follows that in some cases a meta-analysis would *lower* the quality of the systematic review. In practice, some Cochrane reviews do not pool their results. Mebius 2014 maintains that most evidence-grading systems are set up in a way that precludes the possibility of combining upgraded non-randomized studies of high quality with randomized controlled trials (RCTs) of similar quality in systematic reviews and meta-analysis. The The Cochrane Library and the Centre for Reviews & Dissemination Databases contain databases of systematic reviews, with the latter also containing evidence about cost-effectiveness.

Bohlin, Ingemar. “Formalizing Syntheses of Medical Knowledge: The Rise of Meta-Analysis and Systematic Reviews.” *Perspectives on Science* 20.3 (2012): 273–309.

This article gives an historical account of the adoption of meta-analysis from the social sciences by medicine and an analysis of the formal procedures used in synthesizing clinical trial data.

Centre for Reviews & Dissemination.

Created by the University of York, this site contains databases of systematic reviews of treatment effects, cost-effectiveness, and technology assessment.

The Cochrane Library.

A library of systematic reviews. The website also includes historical information about the Cochrane Library, Cochrane colloquia, and systematic review methodology.

Higgins, Julian, and Sally Green. *The Cochrane Handbook of Systematic Reviews for Intereventions*. Chichester, UK: Wiley-Blackwell, 2010.

Handbook explaining in detail how to conduct systematic reviews. Also contains justifications and explanations.

Mebius, Alexander. "Corroborating Evidence-Based Medicine." *Journal of Evaluation in Clinical Practice* n2 (2014).

Argues that there should be cross-corroboration of evidence between randomized trials and nonrandomized studies, in which high-quality evidence from both sources is combined in systematic reviews and meta-analysis.

Stegenga, Jacob. "Is Meta-Analysis the Platinum Standard of Evidence?" *Studies in History and Philosophy of Biological and Biomedical Sciences* 42.4 (2011): 497–507.

Argues that meta-analysis is not the "platinum standard" of evidence.

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