Ethics and Evidence-Based Medicine

“At its core, evidence-based practice rests on a supposition which, while probably true, itself has unclear evidentiary support.”

A quarter-century of outcomes research, systematic reviews, and research synthesis have reshaped medicine and other health professions, even as they have been subjected to vigorous and vehement criticism. The growth of evidence-based medicine has occurred against a backdrop of health care reform, managed care, cost containment, and quality improvement, and clinicians have been urged to adopt the rigor of science while remaining true to their “clinical judgment.” This tension – between efforts to make medical practice more scientific and the suspicions of many clinicians – has caused one of the greatest practical and ethical challenges in the history of the health professions. This incisive book reviews the history and conceptual origins of evidence-based practice and discusses key ethical issues that arise in clinical practice, public health, and health policy.

Essential reading for all physicians, and practitioners in epidemiology and public health, it will also be suitable as a text in medical and public health school courses on evidence-based practice.

Kenneth W. Goodman is founder and director of the University of Miami’s Bioethics Program and its Pan-American Bioethics Initiative. He is also co-director of the University’s Program in Business, Government and Professional Ethics, and holds appointments in the Departments of Medicine, Philosophy, Epidemiology and Public Health, and the School of Nursing. He is editor of Ethics, Computing and Medicine (Cambridge, 1998), and the author of articles on bioethics, the philosophy of science and computing.
Ethics and Evidence-Based Medicine

Fallibility and Responsibility in Clinical Science

Kenneth W. Goodman
For Allison and Jacqueline
Evidence of so much that is worth believing
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Preface

It is surely one of the best – one of the most interesting and most important – questions in the history of human inquiry. It can be asked as plainly as we like, yet be disputed as fiercely as any, ever:

Why do you believe what you do, and not something else?

We can ask this question generally or specifically, grandly or trivially. It can, for instance, be about the origin of the universe or the fate of next season’s marigolds, the existence of God or the prospects for the Miami Hurricanes or the Tottenham Hotspurs, the best treatment for breast cancer or the worst way to play bridge. The question is sometimes a request for reasons or evidence or, sometimes, both (raising the further questions as to whether and when a bit of evidence is a reason . . .).

Like most good questions, the fact that it is simple to ask does not mean that it is easy to answer. This is a pity, because when we are talking about life and health and death, and not marigolds, football, or bridge, then it would have been nice if the answer were simple.

Nevertheless, and simple or not, clinicians have a bold-faced duty to answer it. The day is gone when a physician or nurse might justify a clinical decision by offering as reason (or purported reason) a story that begins in any of the following ways:

It seems to me . . .
In my experience . . .
I was taught . . .

There are a number of reasons for this change in the evidentiary standards of clinical practice. First, there is just a lot more evidence than there used to be. Second, the evidence is better than it once was. Last, it is easier to get one’s hands on this evidence than in the pre-Internet days of yore. There may be other reasons. In aggregate, they point to the thesis that motivates this book, namely that the deployment or application of scientific evidence
in the service of human health care raises ethical issues. Largest among these is that scientific uncertainty itself presents clinicians with ethical challenges and issues. This is less important when there is plenty of evidentiary warrant for clinical decisions, but at other times, it seems, we can live and die by the slenderest of epistemological threads. With very few exceptions, these issues have not been addressed in the literatures of either medicine or ethics.

The book has this structure:

After a survey of the origins of evidence-based practice (Beddoes in the eighteenth century, Louis in the nineteenth, and Cochrane in the twentieth), Chapter 1 makes a case for linking clinical and scientific knowledge on the one hand, and morality on the other; it is the core theme of the book. Along the way, we touch on some of the roles of, and relations among, information, evidence, expertise, specialization, progress, communication, and error. The project is not as grand as that might suggest, however, and the conclusion is actually quite straightforward, if not simple: Ignorance can be blameworthy.

That said, reducing ignorance is not such a simple affair. Contemporary biomedical science – including the means of reporting results, the social and professional engines that drive scientific publication, and the tools for pulling it all together – is a great and complicated affair. Chapter 2 tries to make some sense of it, and of the research synthesis revolution that has transformed the medical sciences over the past quarter-century. Such a revolution, with its systematic reviews and meta-analyses, has the goal of providing better or stronger warrant for clinical beliefs. Like other revolutions, however, partisans on all sides have an interest in making matters seem simpler than they really are.

Chapter 3 examines in greater detail the exciting and vexing problem of “evidence about evidence” (called “meta-evidence” here). From the quality of initial research and peer review to the edifices built by combining, concatenating, and otherwise melding sometimes disparate inquiries, we are faced with a practical and conceptual problem of the greatest magnitude. One solution to the problem requires that ordinary clinicians get a handle on the debates that consume investigators and scholars, if for no other reason than to have (at least the beginning of) an answer to the question, “What kind of scientific evidence is a meta-analysis or a systematic review, and how best should these tools be incorporated in research and clinical practice?”

A traditional picture of clinical investigation or human subjects research has folk in white coats moving between hospital bed and laboratory. But
information technology is changing research as it is changing all other aspects of contemporary life. Chapter 4 reviews some of these changes and attempts to locate them against the background we have grown familiar with, i.e., uncertainty, causation, and error avoidance. This chapter deals with issues including recruitment of subjects on the World Wide Web, data mining, bioinformatics (or the use of computers in genetics research and practice), and, in a field we call "emergency public health informatics," early warning systems for bioterror attacks.

Science and practice are often about discovering, recognizing, and following patterns. The growth of evidence-based practice and its new evidence has, however, engendered an opposition movement and a countervailing "new skepticism" that seeks to impeach the requirements embodied in practice guidelines and other clinical pattern-following rules. Chapter 5 has the task of making clear that the hoary confusion regarding the extent to which medicine is an art or a science is a relic of murkier times and not a useful way to think about the management of uncertainty in clinical practice. Debates over practice guidelines, especially in managed care and the law, must move beyond simple advocacy by proponents and equally facile skepticism by detractors. Evidence-based practice emerges as "an earnest and honest attempt to help clinicians do best, what they already were committed to doing well."

Chapter 6 connects the debates over evidence-based practice to issues in public policy. We use three case studies, which involve research on environmental tobacco smoke, screening mammography, and otitis media – cases chosen because of their difficulty and the controversy surrounding them. This chapter attempts to anticipate future human subjects research, especially drug discovery and genomics, in light of the needs of population-based research and the implications of such research for public policy. The by-now familiar challenge of clinical uncertainty is applied to communities and health policy.

The duties of clinicians, investigators, research synthesizers, and review boards are linked in many and various ways. Chapter 7 takes our understanding of evidence and fallibility and concludes that, as a practical matter, each of these groups does its duty when it maximizes quality, minimizes bias, and manages uncertainty. Society, too, has a duty – to provide for more and better research, as well as the means to make better sense of systematic science.

Kenneth W. Goodman
University of Miami
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