

Foundations and history of evidence-based practice

It isn't what we don't know that gives us trouble, it's what we know that ain't so.
 Will Rogers

This chapter will locate systematic science and evidence-based medicine against the background of biomedical research in the second half of the twentieth century. The growth of this research paralleled and in some ways forced the evolution of current standards for communicating the results of scientific inquiry (i.e., the emergence of peer review and the expansion of the number of research programs, journals, books, etc.). The research raises interesting issues about the role and nature of expertise and medical knowledge, and it has led to a vast tableau of practice guidelines, critical pathways, consensus statements, and assorted other scientifically based imperatives for the care of individual patients. These imperatives are increasingly linked to physician and institution reimbursement. Where the stakes are highest, as in clinical medicine and public health, these forces assume special importance for ethics and public policy.

Before it became a movement, or a cause, evidence-based medicine (EBM) was a kind of cognitive itch: a troublesome doubt that follows from the realizations that humans are fallible, that scientific knowledge increases and that medical decisions sometimes have very high stakes. If you make a mistake, your patient might die. Less ominous, even if they do not die, patients are often paying for physicians' services, either through taxes or by putting cash on the barrel in one way or another. Failure to know what one is doing then becomes a kind of rip-off or scam. These realizations tend to focus the attention of most clinicians.

Patients die or otherwise come to grief all the time, of course. A bad or unhappy outcome can be the result of any of a large ensemble of causes:

- Ignorance, carelessness or inattention (individual)
- Ignorance, carelessness or inattention (collective)
- Futility
- Incompetence

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- Conflict of interest
- Deception (by a patient)
- Malign intent

There may be others, but we are concerned in any case with the first two. (Note that the first two are cognate with the increasingly important work on medical *error* or mistakes, in which various forms of inattention and failures of institutional process are identified as responsible for mistakes and consequent harms (see Bosk 1981, the locus classicus; and Kohn, Corrigan, and Donaldson 2000). We shall return to error at the end of the chapter.)

To have evidence is to have some conceptual warrant for a belief or action. This says nothing so far about the *quality* of the evidence and hence the strength of the warrant. To be in a state of ignorance is to have false beliefs or to lack beliefs one way or another about the way the world works. If I do not have the belief that germs cause disease, and if germs do cause disease, then I am ignorant of the fact that germs cause disease. Now, this would be a grave shortcoming in a twenty-first century physician, but not in one practicing in the fourth century BC, say. This is because my twenty-first century ignorance is individual and my fourth century ignorance is collective. Twenty-five centuries ago no-one knew that germs cause disease; now, everyone (at least everyone who is practicing medicine) does, or should.

At any rate, the demand that clinicians know what they are doing, more or less, is an ancient one and it has, from the beginning, been couched as a *moral* imperative. The Hippocratic Oath (likely *not* written by Hippocrates) may be read as a celebration of teachers and education at least as much as an itemization of duties and virtues. When the oath-taker vows to “regard him who has taught me this technē as equal to my parents,” she is celebrating the transmission of knowledge; when she promises not to “cut, and certainly not those suffering from stone, but I will cede [this] to men [who are] practitioners of this activity,” it is a vow not to practice beyond one’s knowledge or capacity (translation by Von Staden 1996).

The Oath of Maimonides, after the twelfth century physician, rabbi, and philosopher Moses Maimonides, entreats, “Grant me the strength, time and opportunity always to correct what I have acquired, always to extend its domain; for knowledge is immense and the spirit of man can extend indefinitely to enrich itself daily with new requirements” (translation by Friedenwald 1917). Surely this should be read as a plea not to fall too far behind in monitoring the shifting landscape of medical evidence, a medie-

val anticipation of the importance – the *moral* importance – of continuing medical education.

It could not be otherwise. The intersection of knowledge and health points to a moral imperative because idiosyncratic ignorance causes or allows people to be harmed. An individual clinician's ignorance becomes blameworthy in part because his or her patients would have fared better elsewhere, in the hands of another whose greater knowledge (or lesser ignorance) would have saved the day. Now, this raises interesting questions about how far behind one might lapse without blame, and we will return to them later. The notion is important to us now because we want to distinguish idiosyncratic ignorance from community or collective ignorance.

What physicians don't know¹

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

The demand that clinicians make the most of evidence – or even high-quality scientific evidence – in patient care is a demand that catches our attention only if it can be shown that they were not doing so already. One might try a little experiment with a friend or family member whose work is wholly outside health care . . . mention that evidence-based medicine has become a profession-wide movement to try to get doctors to practice in accord with, well, the evidence. The hypothesis is that you will be met by confusion if not outright incomprehension: “What were they basing their decisions on before all this?” Well, what indeed? In fact, of course, the healing professions have always, albeit in one degree or another, been based on evidence. It is just that there has been precious little of it, and it hasn't been any good. In some (but not all) cases, it has been just enough to distinguish physicians from shamans.

Thomas Beddoes and Pierre Louis

The likely true but undersupported supposition at the core of evidence-based medicine is that most health care is (or, until comparatively recently, was) not evidence based. This means either of two things: (1) There is no (adequate) evidence available to support clinical inferences, or there is, somewhere, but clinicians have no access to it; (2) the truth may be out

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there, but it doesn't matter if we cannot lay our hands on it. The latter is among the targets of post-Enlightenment medical epistemology and a celebration of human experience and open communication. We can probably trace the intellectual birth of evidence-based practice to Thomas Beddoes (1760–1808), the English physician known in part for his “Pneumatic Institution” for the study of the medical use of gases² and, perhaps more importantly, for his criticism of turn-of-the-century medical practice.

Beddoes argued that eighteenth century medicine had become hide-bound, stagnant, and secretive (Porter 1992). Here is how the medical historian Roy Porter summarizes the points Beddoes makes in his 1808 “Letter to the Right Honourable Sir Joseph Banks . . . on the Causes and Removal of the Prevailing Discontents, Imperfections, and Abuses, in Medicine”:

Beddoes proposed two solutions. First, systematic collection and indexing of medical facts. “Why should not reports be transmitted at fixed periods from all the hospitals and medical charities in the kingdom to a central board?” Other “charitable establishments for the relief of the indigent sick” must also supply information, as should physicians at large. Data should be processed by a paid clerical staff, and made freely available. Seminars should be held. The stimulus to comparison and criticisms would sift good practice from bad. “What would be the effect”, Beddoes mused, of “register offices, not exactly for receiving votive tablets, like certain ancient temples, but in which attestations, both of the good and of the evil, that appears to be done by practitioners of medicine, should be deposited?” Without effective information storage, retrieval and dissemination, medicine would never take its place amongst the progressive sciences. “To lose a single fact may be to lose many lives. Yet ten thousand, perhaps, are lost for one that is preserved; and all for want of a system among our theatres of disease, combined with the establishment of a national bank of medical wealth, where each individual practitioner may deposit his grains of knowledge, and draw out, in return, the stock, accumulated by all his brethren.” . . . Second, to complement his medical bank, Beddoes urged his fellows to publish more . . . (Porter 1992: 10, notes omitted)

Data sharing . . . collecting and archiving . . . analysis and reporting . . . publishing . . . It seems that the good Dr. Beddoes was calling for a comprehensive system of medical information management. Moreover, he was calling for such a system because he believed, with good warrant, that the medical science of his day was shortchanging – was harming – patients, and that it could be better. Information becomes evidence when it applies to, bears on, or constitutes a reason for (dis)believing the truth of a proposition. If we are talking about propositions related to life, death, pain, disability, and so

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forth, then it is just a few short steps until we identify a *duty* to collect and share information that bears on those propositions.

Thomas Beddoes is suggesting a moral link between information management and medical practice. He is proposing outcomes research and fantasizing about systematic reviews; demanding databases and hoping for data mining; insisting on broader dissemination, and doing so two centuries ago, or before the World Wide Web would, at least in principle, put every publication on every desktop.

Somewhat after Beddoes, in 1834, Pierre Charles Alexandre Louis (1787–1872), published his *Essay on Clinical Instruction*. The foundation of what was for a while called the “Numerical Method,” it, along with his other works, also constituted a cornerstone in the history of clinical evaluation. Louis apparently performed the first chart reviews (“outcomes research” if you like) and thereby produced evidence to undermine beliefs about blood-letting, not least the notion that bleeding cured cholera³ (Porter 1996; Weatherall 1996):

As to different methods of treatment, it is possible for us to assure ourselves of the superiority of one or other . . . by enquiring if the greater number of individuals have been cured by one means than another. Here it is necessary to count. And it is, in great part at least, because hitherto this method has not at all, or rarely been employed, that the science of therapeutics is so uncertain. (Louis 1834: 26–28)

It is simple arithmetic, but it is systematic enough to be credited as an intellectual parent by Osler (1985 [1897]) and as a key antecedent of evidence-based practice in a major text and exposition (Sackett et al. 2000). Indeed, it might be possible to blame Osler for contributing to, if not originating, the belief that the acquisition of evidence is a simple matter:

Louis introduced what is known as the Numerical Method, a plan which we use every day, though the phrase is not now very often on our lips. The guiding motto of his life was “*Ars medica tota in observationibus*”, in carefully observing facts, carefully collating them, carefully analysing them. To get an accurate knowledge of any disease it is necessary to study a large series of cases and to go into all the particulars – the conditions under which it is met, the subjects specially liable, the various symptoms, the pathological changes, the effects of drugs. This method, so simple, so self-evident, we owe largely to Louis. (Osler 1985 [1897]: 193)

We see at any rate the several forces at work as medical science moved from innocence to awareness of the varied and gorgeously useful data to be teased from clinical experience.

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From Beddoes and Louis to Cochrane

What followed, albeit as a result of a number of forces disconnected from Beddoes and his dicta and Louis and his data, was an industry that published the cases and observations of clinicians, often in journals linked to professional societies (Bynum and Wilson 1992). Still, it took until the middle of the twentieth century before medical science was to evolve the tool we call the randomized clinical trial and which we tend to regard as the gold standard for generating the information which we then turn into evidence (British Medical Journal 1998).⁴ But what had failed to evolve was a system for making the information-evidence alchemy reliable and broadly available. The failure was frank and unavoidable: Clinicians needed help in muddling through the vast and often contradictory mess of information that might or might not drift across the transom.

What has emerged over the past quarter-century is a series of pronouncements about the percentage of health care that is based on (high-quality or even gold standard) evidence. This percentage is always very low – it ranges from 10% to 25% of medical decisions. The numbers leave us slack-jawed. If clinicians' decisions are based on (high-quality) evidence only 10% or 25% or even 50% of the time, then what on earth is guiding the rest of the decisions in which pain, suffering, disability, and life hang in the balance?

The numbers matter, because if they are wrong we have less to worry about, and if they are right we had better get moving.

The origin of the numbers is obscure. At a delightful and illuminating UK-based website, "What proportion of healthcare is evidence based?", the question elicits pointers to a broad variety of sources that try to establish the percentage with some degree of, well, evidence. The origin of the minimal-evidence claim is worth savoring:

"The 10–25% of medical decisions are evidence-based" comes from a series of conjectures, many of them humorous, starting back in the 70's. For example, in an exchange between giants of epidemiology, Kerr White . . . and Archie Cochrane . . . in Wellington, NZ, Kerr had just suggested that "only about 15–20% of physicians' interventions were supported by objective evidence that they did more good than harm" when Archie interrupted him with: "Kerr, you're a damned liar! [Y]ou know it isn't more than 10%." (Booth et al. 1999)

Other sources of the claim include the US Office of Technology Assessment (10–20%; Office of Technology Assessment 1978) and the Institute of

Medicine (2–25% varying by strength of evidence and consensus; Field and Lohr 1992). But we might as well trace the contemporary unease, the epistemological gap, the cognitive itch to Archie Cochrane's observation and complaint: "It is surely a great criticism of our profession that we have not organised a critical summary, by specialty or subspecialty, adapted periodically, of all relevant randomized controlled trials" (Cochrane 1979; cf. Cochrane 1972). There is a sense in which Cochrane, born in Galashiels, Scotland, in 1909, a century after Beddoes' death, has done as much as any other individual to reshape health education and practice. Since his death in 1988, his core idea has mutated from insight to tribute to movement to professional imperative.

Such a simple idea, so straightforwardly expressed, so intuitively compelling: It was a great criticism indeed that there were, two millennia after the physicians at Kos, few collective accounts or reports that what clinicians did had any demonstrable scientific traction. It is surely one of the great oversights in the history of human inquiry and applied epistemology. Indeed, even Beddoes' proposed system for rudimentary data collection and outcomes research had not been instituted in some quarters, two centuries later.

To be sure, the fact that a claim or practice is not supported by (adequate) evidence does not mean that it is false. But it does mean that practitioners have inadequate grounds for believing it to be true or effective. Put differently: The remaining 90% or 75% or whatever percentage of health care that is said not to be evidence based is not necessarily false – only that clinicians lack (adequate) justification to assert it to be true and perhaps to practice as if they knew it to be.

Efforts to warrant such assertions have, in less than 25 years, shaped everything from medical reimbursement to resource allocation to managed care to public health to individual decisions by individual clinicians – faced and challenged by vast amounts of health research and by partisan claims about how to make sense of it all.

Observe that Cochrane's complaint here is not that most individual clinicians' beliefs are not supported by evidence. It is that, for all they know, they are! It is therefore a much broader challenge: If the beliefs of clinicians can be linked to evidence, then those links need to be accessible – in an "organized, critical summary." In this sense, Archie Cochrane was not asking for more research or more evidence; he was merely observing that the evidence we already have is removed or disconnected from the people who ought to be using it to take care of sick people.

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In terms of the two kinds of ignorance we included in our earlier list of causes of bad outcomes, Cochrane is therefore talking about the first, or individual ignorance (call it “I-I”; collective ignorance will be “C-I”). Now, I-I must, if it is to make any sense, mean something like this:

A clinician is *individually ignorant* of evidence that would affect her practice if she were aware of it, if:

- such evidence has already been acquired by someone, somewhere; and
- the evidence is not secret, and has not been hidden or unpublished/unshared.

We want these two conditions to apply in order to insulate us from cases (as suggested in Chapter 2) in which, say, a discovery had been made but unreported – ignorance of such a discovery would be ignorance that (almost) everyone has and so would be no different in salient respects from collective ignorance:

A clinician is *collectively ignorant* of evidence that would affect her practice if she were aware of it, if:

- such evidence has not been acquired by anyone yet, where “acquired” may include evidence requiring either primary research or knowledge discovery as is attributed to database research, meta-analysis, etc.

In other words, the set or class of people who are collectively ignorant comprises members none of whom has evidence that would affect practice decisions if the evidence were known. Ignorance, like misery, loves company.

There are several ways in which our simple distinction does not cover all eventualities. For instance, in trying to distinguish between having and not-having some evidence, we have adopted a vague and imprecise picture of evidence. It makes no mention of the quality of the evidence, for instance. When we say “evidence that would affect her practice if she were aware of it,” we have said nothing about whether our clinician *should* alter her practice in light of it, whether it would be *rational* to do so, etc. These are important questions and we will return to them in Chapter 2. For now, it is adequate to point out that the historical thrust of evidence-based practice owes much to men who were asking for something very basic and obvious.

That something is basic or obvious, however, does not always make it easy to believe.

Health science and the growth of knowledge – the role of “experts”

Even as scientific progress entails scientific change, the reverse is not the case. Some changes are trivial, off the mark, or even destructive or regressive. Evaluating candidates for, and changes in, scientific corpora requires a broad cluster of attributes, most especially knowledge of the science in which an inquiry is conducted and in which the progress is alleged. The conflicting forces of specialized knowledge and interdisciplinary knowledge create a vast cluster of problems for those who would assess scientific change and progress. Such an assessment is precisely what evidence-based medicine demands.

On one obvious reading, the evolution of specialization in medicine has been driven by the great and rapid accumulation of information about the human organism. The effects of this accumulation force us to abandon the hope that individuals might become complete masters of particular disciplines:

In every subject of scientific study the progress of investigation and the accumulation of knowledge must reach a point where it becomes a serious task to master all its facts, or to be acquainted with all that has been written about it. When a great number of zealous observers are bending their energies in a common pursuit, it happens after a time that not the oldest and most eminent among them can possibly attain to a perfect acquaintance with all that is known about it. (Noyes 1865: 59)⁵

In the century-and-a-third since Dr. Noyes reflected thus on the heavy weight of information that increasingly attaches to the good fortune of knowledge, the situation has become somewhat more complicated. Not only has medicine progressed, it has found itself closely allied with disciplines not then imagined. All the while and as ever, going back to Plato and Aristotle, the questions of how to assess medical and other scientific claims, and of who is most fit to communicate the claims, have tended to turn to experts.⁶ Now, this could be a problem because it is probably too much to require that ordinary clinicians become experts. If evidence-based practice required this, it would be doomed to failure. It is a more democratic enterprise, requiring that all clinicians take responsibility for their own epistemic warrants. In other contexts, we would call this “education.”

Fortunately, there are a number of ways to defang calls to expertise. One is to make the case that “expertise” is akin to “narrowness” or “rigidity.”

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Another is to undermine the very idea that there is such a thing as expertise, or that it is needed for the purpose at hand.

For instance, regarding the former, the philosopher Paul Feyerabend has condemned experts “who quite naturally confound knowledge with mental rigor mortis” (Feyerabend 1975: 182; cf. Feyerabend 1978). Feyerabend is also reading “authority” for “expert” and this bit of economy links social position with (narrow) epistemological status: better to plague both houses.

Can we successfully set aside the very concept of “expert?” Or, better, does evidence-based medicine even need any expertise?⁷ Since a large part of the evidence-based engine requires the synthesis and communication of information by ordinary clinicians, we should look a little more closely at this process of evaluation.

Evaluating progress in medicine

Evidence of progress in medicine and nursing is in some respects less controversial than evidence of progress in physics, genetics, astronomy, psychology, and other sciences. Where quarks, genes, black holes, super-egos, and other entities have raised, and continue to raise, difficult problems for those who postulate their existence, structure, and function, the entities of modern medicine lend themselves somewhat less readily to philosophical scavenging. This is emphatically not to argue that medicine offers no or even only few special difficulties for the analysis of new evidence – indeed, as we will see later, scientific uncertainty poses the greatest ethical challenge to evidence-based practice – it is merely to suggest that these difficulties are in some respects harder to come by or more tractable than issues in other sciences. The observation has this to recommend it: To the extent that medicine reduces to chemistry and physics, its deepest problems will not be uniquely medical at all but rather chemical, physical, and so forth.

Still, there are fundamental difficulties in the task under analysis, namely assessing and communicating facts and allegations of progress. No matter how we join the old philosophical debate over progress in science, the question of whether there has been any of it in a given domain will be answered only or best by those who have some set of skills and/or some amount of knowledge.

Consider provisionally that an assessment of progress in a science will require knowledge of the (at least short-term) history of the science and of