

Viewpoint: Moving Beyond Evidence-Based Medicine

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Abstract

The evidence-based medicine movement has remained both well known and controversial since its inception. The authors reframe the evidence-based medicine debate by pointing out an underappreciated epistemological deficiency: evidence-based medicine as currently conceptualized cannot accommodate concepts that resist quantitative analysis and therefore cannot logically differentiate human beings from complex machines. The authors use Michael Polanyi's philosophy of tacit knowing (which refers to the taken-for-granted knowledge at the

periphery of attention that allows persons to understand the world and discern meaning in it) as a starting point for rectifying this deficiency and for working towards an improved, person-centered epistemology of medical practice. The authors demonstrate that not only evidence-based medicine but also most traditional theories of medical practice need a concept such as tacit knowing to account for the kinds of knowledge human beings actually use. Polanyi's philosophy of tacit knowing is defined and briefly explained. A medical epistemology that can account for the

tacit dimension of human knowledge and recognize physicians and patients as persons requires a revised conception of medical uncertainty and a recognition that clinician-patient interactions are central to medicine. The authors discuss practical implications of tacit knowing for medical practice, education, research, and health care policy and suggest ways for moving beyond evidence-based medicine towards a comprehensive epistemology of medical practice.

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In this article we seek to reframe the evidence-based medicine debate by focusing on an underappreciated epistemological deficiency: as currently conceptualized, evidence-based medicine cannot adequately accommodate concepts that resist quantitative analysis and therefore cannot logically differentiate human beings from complex machines. We argue that medicine needs a more robust epistemology capable of recognizing patients and clinicians as persons, and we use the concept of *tacit knowing* as a starting point for this project. A truly person-centered medical epistemology requires a revised

conception of medical uncertainty and a recognition that clinician-patient interactions are central to medicine. We discuss practical implications of these conclusions for medical practice, education, research, and health care policy and suggest ways for moving beyond evidence-based medicine towards a comprehensive epistemology of medical practice.

The Rise of Evidence-Based Medicine

Few phrases have percolated so quickly and pervasively into the jargon of academic medicine as has *evidence-based medicine*. Prominent medical journals introduced and promoted this movement in the mid-1990s,^{1,2} and a detailed study of its development from clinical epidemiology has been published.³ Evidence-based medicine comprises a set of rules and techniques designed to promote basic epidemiological and statistical principles, to help clinicians read the medical literature more effectively, and to encourage clinical management decisions based on randomized clinical trials and other well-designed studies rather than on "opinion, unsystematic clinical experience, or pathophysiologic rationale."¹

The lynchpin of the evidence-based medicine movement as described by the two authoritative books on the subject, *Users' Guides to the Medical Literature*⁴ and *Evidence-Based Medicine*,⁵ is the premise that the results of well-designed studies, especially randomized clinical trials, should govern medical decisions. Clinicians should follow a hierarchy of research methods (Table 1) so that the least biased evidence is given priority when making clinical decisions. The evidence-based medicine paradigm admits pathophysiologic reasoning or clinical experience as evidence only when information from more highly ranked methods is not available.⁴ Despite its popularity, the movement has attracted vocal critics who argue that evidence-based medicine's general acceptance has outrun careful consideration of its implications and limitations (List 1).^{6,7}

The large-scale clinical trials and epidemiological studies evidence-based medicine promotes are important tools for improving medical care; we did not write this article to devalue the insights these tools have made possible or to dispute that clinicians should be trained to evaluate and apply the information these tools produce. We maintain, nevertheless, that evidence-based medicine takes for granted incorrect presuppositions about medical

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Table 1

Evidence-Based Medicine's Hierarchy of Evidence*

Level	Type of evidence
1 (strongest)	Randomized clinical trial with an N of 1
2	Systematic review of randomized clinical trials
3	Randomized, placebo-controlled trial
4	Systematic review of observational outcomes research
5	Observational outcomes research
6	Physiologic studies
7 (weakest)	Unsystematic clinical observations

* Adapted from Guyatt G, Rennie D, eds. *Users' Guides to the Medical Literature: A Manual for Evidence-Based Clinical Practice*. Chicago: Ill: AMA Press; 2002:7. Used with permission.

knowledge and practice that render its current conceptualization incapable of being the overriding paradigm for patient-centered medical care. Most importantly, evidence-based medicine cannot accommodate concepts that resist quantitative analysis and thus reinforces and formalizes clinicians' tendency to dismiss concepts that resist explicit analysis as unimportant or inscrutable.

Previous authors have asserted that Michael Polanyi's philosophy of *tacit knowing* demonstrates the need to move beyond evidence-based medicine^{8,9} and provides a starting point for building an accurate theory of medical knowledge.^{10,11} We build on these assertions by demonstrating that medical epistemology needs a component such as Polanyi's philosophy, briefly explaining this philosophy, and exploring the practical implications of tacit knowing for medical education, practice, research, and policy. These arguments make an important contribution towards the development of an adequate epistemology of medical practice that retains evidence-based medicine's valuable insights without its faulty precepts.

Identifying Epistemological Shortcomings

The term *evidence-based medicine* is used in so many different ways that any productive discussion must commence with a clear definition. As described above, we use the term to denote the belief that certain rules for evaluating findings from specific types of population-level research (listed in Table 1) should be the principal grounds for clinical decision making. In this article, *evidence-based medicine* does not signify

the general prescription that medical decisions should be based on the best, most current information available; that idea is neither controversial nor original to evidence-based medicine.

Proponents of evidence-based medicine sometimes redefine the movement as "the integration of best research evidence with clinical expertise and patient values."⁹ However, they admit that a method for integrating evidence with patients' values and preferences "has not been clearly stated, except that 'clinical judgment and expertise' are viewed as essential for success."¹² Despite such attempts to develop more nuanced definitions, in everyday speech evidence-based medicine connotes adherence to the hierarchy of evidence and is considered separate from or even antithetical to reliance on clinical expertise or patient values.¹³

Evidence-based medicine is controversial not because people disagree about whether medical decisions ought to incorporate the best available evidence, but because they disagree about how narrowly evidence should be defined.¹⁴ Neither advocates nor opponents of evidence-based medicine consistently differentiate between the everyday meaning of *evidence* and the *evidence of* evidence-based medicine that refers only to the results of particular types of research.^{12,15} This persistent confusion makes the label *evidence-based medicine* divisive, and authors on both sides of the debate have suggested that it be discarded or replaced.^{6,14,16}

Disagreement has also persisted because the *evidence of* evidence-based medicine is incomprehensible unless one invokes the kind of unsystematic knowledge that

the movement was designed to avoid in the first place. The *Users' Guides*⁴ define *evidence* as the available information that ranks highest on the hierarchy of evidence, but evidence-based medicine cannot provide rules for determining which information should be considered valid for any particular clinical scenario: How much bias makes a clinical trial less valid than an observational study? How do clinicians choose among evenly ranked, conflicting sources of evidence? How much of what kind of evidence is sufficient to alter clinical management? The *Users' Guides* give no rules governing when its hierarchy should shift, except that answering these difficult questions requires "deep understanding of the evidence."⁴ (p217) The authors do not explain what this means.

Proponents of evidence-based medicine founder on similarly difficult concepts when they attempt to develop rules or algorithms for medical practice. They acknowledge that clinical judgment and expertise are necessary for making diagnoses, but they describe these qualities in vague, almost mystical terms: "a gift for intuitive diagnosis, a talent for precise observation, and excellent judgment in making difficult management decisions."¹ Here again, they appeal to the type of knowledge they hoped evidence-based medicine would supersede.

Evidence-based medicine's attempt to reduce medical practice to formal steps involving quantifiable phenomena reflects an underlying reductionist epistemology common to most conceptions of medicine that assumes all knowledge is theoretically amenable to comprehensive description with explicit rules or models. Every proposed set of rules, however, presupposes concepts that elude the usual methods of medical investigation. Rules for applying evidence to patients require "clinical judgment and expertise"; rules for evaluating evidence require "deep understanding"; rules for diagnosis require "a talent for precise observation." These concepts point to real, important abilities that clinicians use to provide care that accommodates the particular details of each clinical situation. Evidence-based medicine's formal rules are consistently inadequate not because they lack sufficient detail, but because many medical concepts cannot

List 1

Common Criticisms of Evidence-Based Medicine

- The term *evidence-based medicine* is trivially true and obscures real disagreement about what constitutes valid evidence in medicine.
- Evidence-based medicine provides no theoretical or logical justification for the premise that epidemiologic and statistical information is inherently superior to other types of information.
- Conclusions drawn from evidence-based medicine's population-level data have limited relevance to treatment decisions for individual patients.
- Health care managers and administrators often co-opt evidence-based medicine's methods and rhetoric to decrease costs or inappropriately restrict clinical practice.
- No logical or empirical proof has demonstrated that following the tenets of evidence-based medicine leads to better patient outcomes.
- Significant practical, ethical, and financial obstacles to implementing evidence-based medicine in clinical practice have yet to be adequately addressed.

be explained within evidence-based medicine's epistemological framework.

Several proponents of evidence-based medicine have acknowledged that the movement's initial claims were more problematic than was first suspected.^{12,15} Authors have criticized reductionism in evidence-based medicine (and in other theories of medical practice)¹⁷; no one, however, has advanced an alternative that allows rigorous, nonreductionist analysis of concepts such as "deep understanding" and "clinical judgment." Polanyi's theory of tacit knowing both accounts for this epistemological deficiency and suggests solutions to it.

Tacit Knowing and Evidence-Based Medicine

Polanyi describes tacit knowing most completely in *Personal Knowledge: Towards a Post-Critical Philosophy*.¹⁸ Tacit knowing refers to the taken-for-granted knowledge at the periphery of attention that allows people to understand the world and discern meaning in it. When a physician listens to a patient describe his or her symptoms, for example, the physician pays explicit attention to the patient's story. The physician is simultaneously aware of the patient's tone of voice, facial expressions, and choice of words, but is aware of them in a qualitatively different way. The physician appreciates these subsidiary phenomena tacitly; that is, only to the extent that they provide a background that makes the physician's explicit knowledge of the patient's story intelligible and meaningful.

Explicit awareness of one observation always depends on and presupposes tacit awareness of many others, but attempts to bring tacit or background observations into explicit focus disrupts understanding of the original event. Clinicians can understand a patient's story without recalling the patient's exact choice of words. If clinicians focus exclusively on a patient's spoken words, however, the stories themselves become unintelligible in the same way that spoken words become unintelligible if listeners shift their attention to the individual syllables that compose each word.

Polanyi points out that all human knowledge has a practical dimension rooted in the accretions of experience and memory. Infants learn to speak without structured training, children learn to ride bicycles with only cursory instruction, and medical students learn to identify diseases without memorizing diagnostic algorithms. Knowing and doing involve practical knowledge that depends on humans' ability to learn from experience. Polanyi's paradigm for tacit knowing is our awareness of our own bodies. We are generally aware of our bodies indirectly while performing intentional tasks such as walking or thinking; often, this tacit knowing is apparent only when it breaks down during bodily illness or injury. Humans can obtain and use knowledge only by interacting with their environments through their bodies, so any knowledge that humans can use necessarily has both tacit and explicit components.

Polanyi's philosophy and its application to medicine are prone to several common misunderstandings. First, tacit knowing is not merely unmeasurable knowledge and does not imply a contrast between tacit, unmeasurable knowledge and explicit, measurable knowledge. Polanyi was a chemist and physician who endorsed efforts to improve communication and standardize scientific practice, but he understood that advances in mensuration could never eliminate the tacit dimension.¹⁸ (p19–20) The tacit–explicit relationship is better understood as a functional distinction analogous to the background–foreground relationship in Gestalt psychology. When a clinician shifts his or her focus from a patient's story to a patient's words, the words come into explicit focus, but the meaning of the patient's story necessarily recedes into the background. The precise connections between tacit and explicit knowing, not the knowledge itself, are ultimately unspecifiable. A researcher observing a clinical encounter, for example, might explicitly identify many phenomena that the clinician and patient appreciate only tacitly. Tacit knowing is not some mystical ability; it is a consequence of how humans interact with reality.

Second, evidence-based medicine proponents may mistakenly identify tacit knowing with the "opinion [and] unsystematic clinical experience"¹ their movement was designed to supplant. Clinicians may choose to rely on clinical experience, evidence-based medicine, or some combination of the two, but both approaches require tacit knowing. Appeals to the "deep understanding" of evidence-based medicine and to the "intuition" of clinical experience both hint at the tacit component of medical knowledge. Formal rules can only rearrange the tacit dimensions of clinical medicine. Clinicians can neither eliminate nor directly manipulate tacit knowing because it constitutes the taken-for-granted background and tends to go unnoticed or unsuspected. Tacit knowing is certainly not infallible, and misleading tacit knowing is, by its nature, harder to recognize than faulty conclusions from clinical trials or clinical experience.

Moving Beyond Evidence-Based Medicine

Polanyi's concept of tacit knowing contributes two important insights that

help clarify the debate over evidence-based medicine. First, tacit knowing supersedes the mistaken belief in the possibility of wholly explicit, bias-free knowledge and so changes the meaning of medical uncertainty. Medical uncertainty persists not only because clinicians and patients must act on imperfect information¹⁹ but also because much medical knowledge functions tacitly. Neither evidence-based medicine nor any other medical paradigm can fully articulate or even fully recognize the exact connections between tacit and explicit knowing.

Second, human beings accrue knowledge tacitly through experience and observation and, unlike computers, make decisions that take tacit knowing into account. Thus, analyzing medical practice is not a problem akin to constructing and solving a series of mathematical equations; it is a problem akin to understanding the interactions among persons. Pathophysiology and epidemiology are necessary components of medicine, but proper understanding of medical practice and education must center on the clinical encounter. Polanyi's philosophy can contribute to the development of a patient-centered conception of medicine that is also truly person centered because it acknowledges that the tacit-explicit structure of human knowing and thinking is very different from the kind of mindless information processing that machines perform. Working out the details of this new medical epistemology will require much time and effort, but some preliminary recommendations for medical practice, research, education, and health policy are possible. These suggestions are not meant to supersede clinical trials or epidemiological research but to demonstrate how medicine can adapt to an epistemology that acknowledges tacit knowing. A comprehensive review of the developments in cognitive science, psychology, and decision science that relate to tacit knowing²⁰⁻²² is beyond the scope of this article.

Medical practice

The tacit-explicit structure of patients' and clinicians' knowledge requires that the clinical encounter remain the central element of medical practice, because clinicians can fully appreciate the innumerable explicit and tacit particulars of a patient's problem only in face-to-face

interactions. Clinicians do not *make* decisions by reckoning objective data and clinical probabilities; rather, they *reach* decisions in light of the particular tacit and explicit data they discover while encountering their patients as persons. Written reports or laboratory results may be sufficient to solve straightforward problems (e.g., diagnosing Graves' disease, treating streptococcal pharyngitis), but such impersonal data sets always simplify and omit much of the knowledge available at the bedside. For this reason, a consultant physician will withhold difficult diagnostic or therapeutic decisions until he or she has personally seen and interviewed the patient.

This person-centered epistemology precludes absolutely certain or inerrant knowledge; clinicians can be misled as well as enlightened by a problem's tacit (or explicit) particulars. Clinicians need to cultivate not only skepticism towards diagnostic or therapeutic certainty but also humility about the limitations of medical knowledge. Many kinds of information or methods of reasoning can be medically appropriate; no one kind or method is *a priori* superior. Investigations of medical practice have long recognized that good clinicians rely on multiple methods of reasoning and kinds of information to construct customized evidence hierarchies for each medical decision.²³

Clinicians usually fail to note the tacit component of medical reasoning because they appropriately focus on helping patients rather than on analyzing their own thought processes,²⁴ just as they focus on patients' stories rather than on patients' exact spoken words. A narrow focus on clinical epidemiology, pathophysiology, or some other reasoning system may seem sufficient for describing medical practice if one believes that knowledge can be wholly explicit, unbiased, and theory free. Reasonable clinicians who overlook tacit knowing might mistakenly conclude that understanding complicated medical decisions requires merely more elaborate models rather than a more accurate epistemology.

Medical education

Medical schools do not teach the tacit aspects of medical care directly, but they can allow for tacit learning by

maximizing face-to-face interactions at the bedside. Effective clinical education requires both explicit instruction in and tacit demonstration of medical skills and judgment; the traditional apprenticeship model of medical education provides this kind of learning through continual practice and observation. Students watching experienced clinicians at the bedside absorb both tacit and explicit features of good medical practice. Conversely, faculty cannot adequately evaluate students' and residents' clinical acumen without watching them care for real patients. If surgical residents are required to perform 60 laparoscopic procedures²⁵ before operating without close supervision, students and residents should not be expected to master physical examination or history taking without repeatedly observing and being observed performing these tasks a similar number of times.

The pace and financial pressures of contemporary U.S. medicine have induced modern medical curricula to neglect real bedside teaching and evaluation²⁶; unfortunately, traditional medical epistemologies cannot explain that textbooks, videos, and standardized patients are inadequate substitutes for learning from real patients. An epistemology that includes tacit knowing, however, provides a compelling rationale for reviving observation by and evaluation of students and residents at the bedside.

Teaching person-centered medicine also requires exposure to topics that examine persons, such as literature, history, anthropology, sociology, and psychology. The humanities and social sciences combine explicit instruction with tacit communication about the human condition in health and disease. These disciplines require different kinds of thinking and problem solving that can help students be more understanding of their patients' needs and more sensitive to the tacit dimensions of clinical practice. These topics are often justified with vague platitudes about "the art of medicine" or "clinical style" precisely because much of their value resists explicit articulation and measurement. Polanyi's insights provide a starting point for rigorously examining the optimal place and scope of the humanities and social sciences in medical curricula.

Medical research

If the clinical encounter is central to medicine, then researchers should examine the clinical encounter through, for example, real-time observational research. Observers can explicitly evaluate information that functions tacitly within the clinical encounter by focusing on how physicians and patients reach decisions rather than on what they decide. Unlike statistical analysis, human observation involves both tacit and explicit knowing and thus can capture more detailed, meaningful information about human interactions than can any collection of measurements. This kind of research does not eliminate the need for tacit knowing; it is an example of how humans' reliance on tacit information becomes an indispensable research tool within a person-centered medical epistemology.

Good descriptive work requires methods capable of analyzing interpersonal interactions. Anthropology and ethnography, for example, have developed sophisticated methods for systematically observing and characterizing human interaction that can be usefully applied to medicine. Ethnographic analysis might elucidate areas such as determinants of patient adherence, trust's effect on medical outcomes, and qualities separating superior clinicians from merely competent ones. This kind of research could expose previously unnoticed determinants of diagnostic and therapeutic reasoning; unrecognized biases could then be exposed and discarded while helpful diagnostic heuristics could be made explicit and taught to others.

A description of how patients and clinicians reach medical decisions is an important prerequisite for working out the details of an adequate medical epistemology. Alvan Feinstein, the "godfather of evidence-based medicine,"³ repeatedly criticized physicians and researchers for analyzing medical practice using quantitative models that were not developed from clinical experience and observation.^{27,28} In contrast to theoretical models of medical decision *making*, real-time descriptive studies of medical decision *reaching* suggest that physicians and patients often reach decisions in ways that are very different from the algorithms of evidence-based medicine or

decision analysis.²⁹ Prescriptive strategies to improve the quality, safety, and value of medical care would benefit from being informed by more accurate descriptions of how clinicians and patients interact and reach decisions.

Health care policy

The treatment algorithms and practice guidelines that evidence-based medicine produces cannot incorporate tacit knowing because tacit knowing cannot be formalized. Guidelines are necessarily imperfect and incomplete; they can provide useful starting points for making treatment plans, but patients may actually be harmed when guidelines are interpreted as rigid rules rather than as heuristics.³⁰ Nor can guidelines supersede physicians' responsible judgment about the right decisions for individual patients,^{31,32} because guidelines ignore tacit (and many explicit) details of a patient's clinical problem that are usually relevant.

Uncertainty increases as clinical decisions are made further from the patient's bedside, because decisions taken outside of the clinical encounter lack the rich level of mostly tacit detail available within it. Health care payors' and administrators' tendency to co-opt "evidence-based" methods and rhetoric to control costs (see List 1) is an important concern for both proponents and critics of evidence-based medicine. Administrative decisions to limit the quality of care to reduce costs, for example, should be admitted honestly instead of pretending that "best practice" and "most cost-effective" are synonyms. Unfortunately, most current medical epistemologies do not recognize qualitative differences among clinician-patient medical decisions, health care system management decisions, health care payor decisions, and population-level public health policy decisions. Persons deciding at each of these different levels have different motivations, use different kinds of information, and rely on different domains of tacit knowing. A new epistemology of medical practice must be able to recognize these different levels and determine the motivations, kinds of information, and methods of decision *reaching* that are appropriate for each one.

Health care administrators, payors, and policy makers should be both cautious and humble about their capacity to evaluate medical decisions "from above" based on small amounts of explicit information in medical or financial records. This humility becomes especially important when their purpose is reducing variation or controlling costs rather than improving patients' welfare. Merely measuring how well physicians' practice patterns match clinical guidelines may not fully indicate quality of care. Low adherence to even seemingly straightforward guidelines can result from patients' particular circumstances rather than from poor care.³³ Novel methods of evaluating clinical practice are needed that go beyond simple measurement and allow for or at least recognize the important role of tacit knowing in medical decisions.

Conclusion

In this article, we have sought to reframe the evidence-based medicine debate by highlighting an underappreciated epistemological deficiency present in evidence-based medicine as well as most other traditional conceptions of medicine. Standard assumptions about medical practice are unable to account for or even recognize medicine as an inescapably human and uncertain undertaking. Current reductionist notions of science and medicine have survived largely unquestioned; the spectacular technical achievements of modern medicine have not given clinicians obvious reasons for questioning these presuppositions.

We suggest the need for an expanded and reworked epistemology of clinical practice that moves beyond evidence-based medicine and its current beliefs about medical knowledge. Twenty-first century person-centered medicine requires an epistemology that accommodates the human nature of medical knowledge and that recognizes medicine's inherent uncertainty without collapsing into relativism. Polanyi's philosophy of tacit knowing provides one useful starting point for building such an epistemology.

Developing a truly person-centered medical epistemology will require years of work and cooperation among clinicians, scientists, sociologists,

anthropologists, philosophers, and psychologists. The recommendations sketched here are initial explorations of this important undertaking; they lay the groundwork for understanding the clinical encounter and providing rigorous practical and conceptual justification for keeping it rhetorically and substantively at the heart of medicine. Such a properly person-centered medical epistemology will help clinicians to provide good patient care amid the complex economic, political, and social forces that buffet U.S. medicine today.

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