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Integrating evidence into clinical practice: an alternative to evidence-based approaches

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Abstract

Evidence-based medicine (EBM) has thus far failed to adequately account for the appropriate incorporation of other potential warrants for medical decision making into clinical practice. In particular, EBM has struggled with the value and integration of other kinds of medical knowledge, such as those derived from clinical experience or based on pathophysiologic rationale. The general priority given to empirical evidence derived from clinical research in all EBM approaches is not epistemically tenable. A casuistic alternative to EBM approaches recognizes that five distinct topics, 1) empirical evidence, 2) experiential evidence, 3) pathophysiologic rationale, 4) patient goals and values, and 5) system features are potentially relevant to any clinical decision. No single topic has a general priority over any other and the relative importance of a topic will depend upon the circumstances of the particular case. The skilled clinician must weigh these potentially conflicting evidentiary and non-evidentiary warrants for action, employing both practical and theoretical reasoning, in order to arrive at the best choice for an individual patient.

Introduction

Evidence-based medicine (EBM) has been championed as a 'new paradigm' for medical education and practice (The Evidence-Based Medicine Working Group 1992). Nowhere has the impact of EBM been as prominent as that in the academic medical centre. Advocates of EBM have consistently noted the importance of learning EBM during the formative period of residency training (Rosenberg & Sackett 1996). Despite the lack of good evidence that teaching EBM improves the quality of medical education or the subsequent care of patients (Parkes *et al*. 2001; Hatala & Guyatt 2002), the vast majority of internal medicine programmes in the United States now incorporate some aspect of EBM into residency training and a third have a free standing curriculum in EBM (Green 2000). Other residency training programmes have also embraced EBM into their curricula. (Green 1999). Such a widespread adoption of EBM into graduate medical education promises to alter the way that the next generation of doctors practise clinical medicine, yet it is not clear whether such a change will ultimately benefit patients.

Although the bulk of the literature of EBM focuses on the practical issues related to the development, acquisition, interpretation and incorporation of the results of clinical research into clinical practice, EBM rests on certain philosophical assumptions and arguments about the nature of medical knowledge that have not been as fully elucidated (Miles *et al*. 2004). Though now acknowledging the need to integrate various kinds of medical and non-medical knowledge, proponents of EBM have said very little about how such integration should actually take place. Interestingly, this application of evidence to clinical decision making is also the component of EBM that is least likely to be dealt with in EBM edu-

cational curricula (Green 2000). It remains unclear by what process clinicians are to balance what may be conflicting warrants for action coming from not only published clinical research but also personal experience, pathophysiologic understanding of disease, the preferences of individual patients or other 'non-evidentiary' sources.

Here I will argue that, to date, the few attempts by proponents of EBM to describe a method for integrating various kinds of medical knowledge and reasoning into clinical decision making have been unsatisfactory. The failure of the EBM approach centres on its attempt to treat different potential warrants for medical decision making, such as empiric evidence, clinical experience and pathophysiologic rationale, as different in degree, rather than different in kind. Under such an understanding, one form of medical knowledge, specifically that derived from clinical research, can be said to be superior to the others. I will argue that this approach is philosophically untenable and that various potential warrants for medical decision making differ in kind from one another. Such an understanding of the nature of medical knowledge requires an alternative method for integrating various warrants into a particular medical decision, a method that closely resembles the casuistic, or case-based, approach to medical ethics advanced by Jonsen and others (Jonsen *et al*. 1992). Ultimately, this understanding of medical epistemology can provide for an explicit defence of a more 'common-sense' practice of medicine desired by many clinicians (Porta 2004).

Integrating the evidence: EBM approaches

EBM began by stating a clear and explicit preference for empirical evidence, defined as evidence derived from formal and systematic clinical research, over alternate kinds of medical knowledge, specifically individual clinical experience, expert opinion and pathophysiologic rationale, as grounds for clinical decision making (The Evidence-Based Medicine Working Group 1992). 'Non-evidentiary' kinds of knowledge were not completely dismissed, but were deemed useful only attributed to 'the dearth of adequate evidence' (The Evidence-Based Medicine Working Group 1992).

The notion of a general priority of empirical evidence was challenged by doctors and other commentators, many of whom pointed out the inherent limitations of attempting to apply knowledge gained from population studies to the care of individual patients (Tanenbaum 1993; Tanenbaum 1994; Horwitz 1996; Feinstein & Horwitz 1997). The response to this critique was a subsequent semantic switch on the part of EBM proponents. Rather than 'de-emphasizing' non-evidentiary kinds of medical knowledge, EBM began to call for the 'integration' of some alternate kinds of medical knowledge as well as patient goals and values into clinical decision making (Sackett *et al*. 1996). The approach has evolved over the decade since the introduction of EBM. Initial calls for integration of alternate kinds of medical knowledge focused on personal clinical experience (Sackett 1997), the devaluing of which was not coincidentally the primary objection of many clinicians to EBM. Still, little was said about how to actually go about integrating evidence with clinical experience, other than that it should be performed in a 'conscientious, explicit and judicious' fashion (Sackett 1997). Subsequently, pathophysiologic rationale was added by some to the list of non-evidentiary kinds of medical knowledge that needed to be integrated with the evidence (Ellrodt *et al*. 1997). Of note, expert opinion as a grounds for clinical decision making has not experienced a similar rehabilitation (Tonelli 1999). Throughout this initial broadening of perspective, EBM recognized clinical experience and pathophysiologic rationale as different in kind from empirical evidence (Canadian Task Force on the Periodic Health Examination 1979; Hadorn *et al*. 1996).

This recognition of the value of alternate kinds of medical knowledge, however, presents a problem for EBM. If non-evidentiary forms of medical knowledge are given equal status to empirical evidence, then the primary axiom of EBM, which identifies research-derived evidence as the 'best evidence' to guide clinical decision making, is undermined. That is, if non-evidentiary knowledge is allowed to trump empirical evidence, then the clinician who knows and understands the clinical research relevant to a particular condition but chooses to treat patients with that condition in a manner not supported by the empirical evidence can still claim to be practising 'EBM', as she

is simply integrating clinical experience in a conscientious, explicit and judicious fashion that happens to give priority to that experience. EBM, to avoid becoming simply a meaningless appellation to which anyone could claim allegiance despite radically different approaches to clinical medicine, needs to be able to preserve at least a general preference for the use of empirical evidence while simultaneously recognizing some value of at least particular kinds of non-evidentiary forms of medical knowledge to clinical practice.

The most recent attempt to resolve this problem involves the co-opting of kinds of medical knowledge previously viewed as non-evidentiary in nature under the umbrella of 'evidence'. Specifically, personal clinical experience and physiologic understanding are currently defined by some proponents of EBM as forms of medical 'evidence' that differ in degree, but not in kind from empirical evidence derived from clinical research (Guyatt & Rennie 2002). This epistemic shift is clear in the change in the hierarchies of evidence that have been advanced since the formal introduction of EBM (Table 1). Classification of clinical experience and physiologic understanding as forms of 'evidence' allows EBM to make two claims. First, a doctor relying on clinical experience or physiologic reasoning for making a clinical decision in the absence of empirical evidence derived from clinical research can still be said to be practising EBM. More importantly, by classifying clinical experience and physiologic understanding as forms of evidence, proponents of EBM can structure hierarchies of evidence that place evidence derived from clinical research higher than experiential or physiologic 'evidence'. In this way, EBM maintains a general priority of empirical evidence as 'best evidence' while recognizing some value of previously non-evidentiary kinds of knowledge. The hierarchy implies that empirical evidence, especially when of high quality, should be viewed as so compelling as to obviate the need to consider clinical experience or physiologic understanding in a clinical decision.

Both the decision to include clinical experience and physiologic understanding under the umbrella of 'evidence' and the subsequent assignment of these kinds of knowledge to the lower rungs of the hierarchy of evidence are, of course, not themselves evidence-based, but rather represent philosophical (more precisely, epistemological) assertions. Both assertions, I will argue, are incorrect.

First, the recent attempt to classify clinical experience and physiologic understanding as 'evidence' errs in asserting that these kinds of knowledge are similar enough to evidence derived from clinical research to be encompassed under a single epistemic heading. What the various kinds of knowledge do share is the potential to serve as warrants for clinical decisions, but this does not suffice to claim each is a kind of 'evidence' unless one makes the circular argument that all warrants for medical decisions constitute evidence. But proponents of EBM cannot defend that argument, as they clearly differentiate

Table 1 Evolution of hierarchies or levels of evidence in evidence-based medicine

Early hierarchy	*Current hierarchy*
1. Well-conducted randomized controlled trials	1. N-of-1 randomized controlled trial
2. Well-conducted cohort studies or case–control study (observational studies)	2. Systematic review of randomized trials
3. Poorly controlled or uncontrolled studies	3. Single randomized trial
4. Expert opinion	4. Systematic review of observational studies
	5. Single observational study
	6. Physiologic studies
	7. Unsystematic clinical observation
Adapted from Canadian Task Force (1979) and Hadorn *et al.* (1996)	Adapted from Guyatt & Rennie (2002)
Note the absence of personal clinical experience and pathophysiologic reasoning from the category of 'evidence'.	Note the addition of physiology and clinical experience to the category of 'evidence'. Expert opinion is no longer considered 'evidence'.

between clinical experience and expert opinion as well as between physiologic understanding and intuition, with explicit exclusion of expert opinion and intuition from the sphere of 'evidence' despite the fact that each may serve as a warrant for particular medical decisions. Proponents of EBM, then, must assert that clinical experience, physiologic understanding and empirical evidence share some important feature not present in excluded potential warrants, such as expert opinion. Yet clinical experience seems to be quite different from evidence derived from clinical research. The former is direct and personal, the latter indirect and general. In fact, a classic philosophical distinction exists between first-hand, primary experience and empirical evidence derived from systematic observation and experimentation, what Reed terms 'processed information'(Reed 1996). This distinction was, in fact, central to the initial claims of the superiority of EBM (The Evidence-Based Medicine Working Group 1992). Only of late has the concept of 'evidence' become so inclusive.

Likewise, the inclusion of physiologic understanding as a kind of 'evidence' is philosophically problematic. Proponents of EBM would be consistent and convincing if they limited the inclusion of physiologic understanding to evidence derived from specific physiologic experiments in humans or animals, experiments that provide no clinical outcome measures. However, doctors do not generally cite specific physiologic studies, as they do specific clinical trials, when defending particular clinical decisions. Instead, they argue from physiologic principles, from theories derived from experiments rather than from the particular experiments themselves. Reasoning from physiologic principles represents a form of rationalism in medicine, the very notion of which has been more and more vehemently rejected over the last two centuries. The new empiricism of EBM, again, was built on the explicit rejection of rationalism, recognizing the kinds of errors that have followed from this method of reasoning. Yet reliance on theory remains important in clinical medicine, rightly affecting how we interpret and value empirical evidence (Vandenbroucke & de Craen 2001).

Even if we allow that clinical experience, physiologic understanding and empirical evidence are enough alike to allow each to be considered a kind of 'evidence', the assertion that empirical evidence derived from clinical research, when present, always provides 'better evidence' to guide clinical decision making is erroneous. Each potential source of medical knowledge carries with it a different complement of strengths and weaknesses. Proponents of EBM have clearly outlined the limitations of relying on clinical experience and physiologic reasoning for medical decision making (The Evidence-Based Medicine Working Group 1992; Sackett & Rosenberg 1995), while critics have pointed to the inherent limitations of applying empirical evidence to the care of particular patients (Feinstein & Horwitz 1997; Tonelli 1998; Tanenbaum 1999). Clinical experience and/or pathophysiologic rationale may at times seem to contradict conclusions about optimal care drawn from published empirical evidence. For instance, low tidal volume ventilation has been demonstrated to be safe and to improve survival in respiratory failure from acute respiratory distress syndrome (ARDS Network 2000). Yet an individual patient may respond to the acidosis associated with this therapy with some negative physiologic response, such as cardiac arrhythmia, not otherwise described in the study. A clinician may choose to ignore this individual anomaly and continue to provide the treatment that has been demonstrated to reduce mortality, but does so here at significant risk to the individual.

In addition to clinical experience and pathophysiologic rationale, other features of a particular case may conspire to support a decision that would otherwise be contrary to that made in accordance with the empirical evidence only. The most obvious examples involve the refusals of patients to undergo interventions that are medically indicated and supported by excellent clinical evidence. For instance, a man post myocardial infarction may refuse beta-blocker therapy because of the side effect of impotence while fully aware of the statistical likelihood of prolonged survival provided by the drug. Recently, EBM has paid more attention to the goals and values of individual patients, though trying to quantify and process these into the form of 'patient utilities' more amenable to algorithms and decision analysis (Naglie *et al*. 1997; Man-Son-Hing *et al*. 2000). Other simple examples where high quality evidence cannot determine care centre around the availability of resources to provide care supported by empirical evidence. For

instance, the benefit of emergent angioplasty in myocardial infarction will certainly not be realized in a centre that does not have access to an advanced procedure lab and an interventional cardiologist.

The clinician, then, must contend with not only empirical evidence, but also her own experiential knowledge, an understanding of pathophysiology, the goals and values of the patient and the barriers and facilitators of care of the medical system in which she works. The relative weight to be assigned to each of these potential warrants for action depends upon the particulars of the case at hand. Recognition of this dependence on the particular case suggests that a casuistic understanding of clinical decision making may provide a more satisfactory description of optimal medical practice than that provided by EBM thus far.

Integrating the evidence: a casuistic approach

In 'The Abuse of Casuistry', Jonsen and Toulmin's examination of the history of practical moral reasoning, the authors use clinical medicine as their primary example of a 'practical' enterprise (Jonsen & Toulmin 1988). They claim that clinical decision making demands 'prudence' or *phronesis*, in addition to theoretical understanding of medicine and specific technical skills, in order to deal with particularities of individual illness. Hence, the authors argue, clinical medicine is a casuistic undertaking. Hunter also made a compelling argument for clinical medicine as casuistry 3 years before the first mention of the term 'evidence-based medicine' appeared in the medical literature (Hunter 1989). Jonsen and others have subsequently argued for and codified a casuistic approach to medical ethics by delineating the topics common to clinical situations and a method for considering each (Jonsen *et al*. 1992). Significantly less attention has been paid to delineating the relevant topics for clinical decision making itself. The topics necessary for a casuistic understanding of clinical medicine will clearly overlap with those topics central to assessing the ethical issues involved in a particular clinical decision.

As noted above, the current attempt of EBM to place multiple potential warrants for medical decision making under the umbrella of 'evidence' fails primarily because of the fact that empirical evidence, experiential evidence and pathophysiologic understanding differ *in kind* from one another, not in degree. Hence, these three kinds of medical knowledge serve as the first three topics of a casuistic model of clinical decision making. A hierarchy of value can be developed within each topic, but the importance of one topic relative to another is not fixed; clinical experience is not necessarily of less importance than empirical evidence nor more important than pathophysiologic understanding. Rather, the relative weight assigned to each topic will depend on the case at hand. A brief exposition of each of these initial three topics follows.

Empirical evidence derives from clinical research and becomes knowable to the practising doctor only through published reports. A hierarchy of empirical evidence, which ranks examples of such evidence by study design and statistical robustness, is generally agreed upon [though there is still some debate about relative strengths of particular study designs (Concato *et al*. 2000)]. Teaching how to access, interpret, and critically appraise the published reports of empirical evidence has become a major focus of Western medical education (Green 2000). The value of relying on this kind of medical knowledge is well catalogued by proponents of EBM. The major limitations of empirical evidence relate to the fact that it cannot be directly applied to any particular patient (Feinstein & Horwitz 1997; Tonelli 1998).

Experiential evidence encompasses the knowledge gained from the direct care of patients. The practising doctor may rely on personal experience or attempt to learn from the personal experience of others. With experiential knowledge, more is generally considered better than less. Hence, expert opinion, when based on extensive experience with large numbers of patients with a particular disease, may be viewed as the highest form of experiential evidence (Tonelli 1999). The major problem with experiential knowledge is that it is prone to multiple kinds of cognitive bias (Elstein & Schwarz 2002), with potentially false conclusions about causality or treatment effect being drawn.

Pathophysiologic understanding follows from the general Western understanding of illness as a perturbation of the physical self. Understanding basic biologic and physiologic principles allows doctors to both relate presenting features to a diagnosis and to

anticipate and measure response to therapy. The strength of pathophysiologic reasoning primarily depends on the strength of the underlying biologic or physiologic theory. The major limitation of reasoning from scientific principles centres on the uncertain relationship between physiologic measures and meaningful outcomes such as mortality and quality of life.

In addition to the three epistemic topics noted above, two other topics are relevant to any medical decision. Perhaps most obviously, the goals, values and preferences of the individual patient must be considered. Medical knowledge alone only has the power to produce hypothetical imperatives of the form: 'If you want to maximise the chances of A, then do B'. The incorporation of patient values is required to determine whether or not maximizing 'the chances of A' is an appropriate and meaningful goal (Tonelli 1998).

The final topic relevant to any clinical decision falls under a broad heading of 'System Features', to include the economic, logistic, legal and cultural barriers or facilitators of care. The cost, availability or legality of specific interventions may preclude use even in the setting of strong empirical and experiential evidence in support. More subtly, the very system of health care delivery, as well as professional and societal values, may influence decisions regarding the care of individuals. Not always are these considerations made explicit, nor even recognized.

The five topics relevant for any medical decision are listed in Table 2. Again, it is important to note that no topic takes general priority over any other. Any topic may prove to be determinative in a particular clinical decision. Clinical judgment, under this casuistic model of clinical medicine, can be viewed as the ability to process and weigh particular warrants for action from each topic area and arrive at a presumptive conclusion regarding the best course of action. In many cases, the clinical decision is relatively straightforward, as when the empirical evidence, experiential evidence and pathophysiologic understanding all suggest a particular treatment plan, one that is available and that the patient wishes to pursue. But in other instances, empirical evidence and experiential evidence or pathophysiologic understanding may suggest different approaches. The approach of EBM has been to give general priority to empirical evidence in such circumstances. But such an approach does not make philosophical sense. Rather, the 'conscientious and judicious' use of empirical evidence may require the clinician to set that evidence aside when individual circumstances appear to require it.

Table 2 The five topics of clinical decision making

Empirical evidence: derived from clinical research.
Experiential evidence: derived from personal clinical experience or the clinical experience of others (i.e. expert opinion).
Pathophysiologic rationale: based on underlying theories of physiology, disease and healing.
Patient values and preferences: derived from personal interaction with individual patients.
System features: including resource availability, societal and professional values, legal and cultural concerns.

Empirical evidence in isolation

Thus far, I have not specifically addressed how empirical evidence is incorporated into clinical decision making other than to argue that it does not have general priority over other kinds of medical knowledge. Another important but generally overlooked aspect of EBM deals with how doctors are to use empirical evidence in itself, rather than how that kind of medical knowledge relates to other potential warrants for medical decision making. I assert that reasoning from empirical evidence specifically also represents a form of practical or casuistic reasoning. Clinical research, and particularly the randomized controlled trial, does not generate universal and generalizable knowledge, but rather reports observations about treatment effects in populations of individuals, who share some qualities but not others, under certain specific circumstances. Thus, empirical evidence derived from clinical research does not provide us with universal truths from which we can draw deductive conclusions about the patient-at-hand, but rather with an example of a composite, 'average patient', (Feinstein & Horwitz 1997) to which we can compare the patient-at-hand.

Using Jonsen and Toulmin's description of casuistry, clinical research, when well done, provides clinicians with a 'paradigmatic' case. The clinician must

decide whether the patient-at-hand resembles the 'average' patient provided by the clinical research closely enough to warrant incorporating the conclusions of that research into that patient's care. If the patient differs from the 'average' study subject, the clinician must decide whether that difference is important enough to mean the conclusions drawn from the study are not relevant to the current decision. How closely the patient-at-hand resembles the 'average' patient in a study will determine how much weight to give the results. At times, clinicians must ask whether the patient-at-hand more closely resembles those enrolled in one study or in another that yielded a different result. This task, acknowledged as vital by proponents of EBM, is inherently casuistic. If performed correctly, this process involves not only comparisons with other potential 'paradigmatic' cases from the medical literature, but also with real cases from the clinician's personal experience and perhaps patients, individual or in aggregate, from the experience of expert colleagues. Reasoning will be in the form of analogy, with a search for cases, actual or 'average', that are most similar to the case-at-hand. Differences must be considered to see if they represent important enough distinctions to reject the provisional conclusions about the present case. Eventually, physiologic and system considerations, as well as patient goals and values, will have to be considered in order to arrive at a presumptive conclusion regarding the best course of action.

Implications of the casuistic approach for EBM

A casuistic understanding of clinical medicine has at least two important implications for the current understanding of EBM. First, the current focus of EBM on teaching students and doctors how to develop, acquire and critically appraise clinical research must be acknowledged to be insufficient to encourage the provision of optimal medical care. By not acknowledging the difficulties in negotiating between evidentiary and non-evidentiary warrants, EBM runs the risk of training a generation of doctors who, while skilled in study interpretation and statistical methods, fail to recognize and develop the complex reasoning skills necessary for sound clinical judgment. While skills in the critical appraisal of reports of clinical research will remain vital to doctor education, medical training must directly address the limitations of relying primarily on empirical evidence for clinical decision making.

Second, a casuistic understanding of clinical medicine recognizes that clinical decision making is a personal and prudential undertaking and therefore clinicians may arrive at different conclusions in similar cases. This acceptance of variability runs counter to one of the stated benefits of EBM, the limiting of practice variability. By failing to explicitly acknowledge that empirical research is not prescriptive and that reasoning from empirical evidence is not deductive, EBM presumes that there is a right course of action in particular cases: the one 'supported by the evidence'. Only when the body of empirical evidence is viewed as insufficient does EBM allow for significant variability in practice, given the perceived unreliability of other kinds of medical knowledge. But clinical decisions remain presumptive not only because of a paucity of clinical research, but also because exceptions to any rule derived from such research will always exist. Excellent and copious clinical research can become compelling enough to guide care in a large number of straightforward cases, but the doctor must always remain open to the possibility that the patient-at-hand represents an exception. And EBM must not only allow but also encourage doctors to consider all potentially relevant kinds of medical knowledge in each case. To do less is to risk creating a new dogmatic kind of medical authority, one based on 'the evidence' (Feinstein & Horwitz 1997).

The casuistic approach does, however, embrace some of the core values of EBM. In particular, this approach demands that medical reasoning be rigorous and explicit. Doctors may differ in their final assessments based on the weight they give to different potential warrants, but they must be aware of and fully consider the empirical evidence available in reaching conclusions. The casuistic method outlined above offers an easily teachable and formal approach to clinical decision making that likely will facilitate the education of doctors-in-training. What might otherwise appear to be simply differences in style or opinion on the part of clinicians can be made explicit and traced back to differences in the weight given to conflicting warrants. As such, the root causes of practice variability can be made clear

and debated openly, improving the educational process.

Conclusion

The philosophical underpinnings of EBM have never been well elucidated and have shifted significantly over the last decade. A careful analysis of the kind of knowledge generated by clinical research reveals that attempts to view such knowledge as prescriptive in individual clinical decision making is in error. Rather, the clinician uses empirical research in a casuistic fashion, comparing the patient-at-hand with those paradigmatic cases provided in the medical literature. Subsequently, the clinician must then consider other potential warrants for action in order to arrive at a presumptive conclusion about the case. The five topics relevant to any particular clinical decision are (1) empirical evidence (2) experiential evidence (3) pathophysiologic understanding (4) patient goals and values and (5) system features. The skilled clinician, then, must weigh these potentially conflicting warrants for action when dealing with the patient-at-hand, employing both practical and theoretical reasoning and comparing the patient with paradigmatic cases from both the literature and experience, before coming to a presumptive conclusion regarding the appropriate course of action. This casuistic understanding of clinical medicine has important implications for medical education as well as the provision of health care. The personal and prudential nature of clinical decision making means that clinicians may reasonably differ in assessments, conclusions and recommendations regarding the care of individual patients. The optimal practice of clinical medicine, though requiring the knowledge of the results of clinical research, demands that doctors thoughtfully consider both evidentiary and non-evidentiary warrants for action in each attempt to deliver the best care to a particular individual.

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