COMMENTARY


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Introduction

It is a great honour to be asked to comment on Dr Tonelli’s paper ‘Integrating evidence into clinical practice, an alternative to evidence-based approaches’. Dr Tonelli has consistently been one of the more thoughtful commentators on the evidence-based medicine (EBM) debate and, in fact, published one of the first critiques of EBM from a philosophical point of view (Tonelli 1998). In this paper, I propose to explicate and critique some of the ideas found in Dr Tonelli’s paper. In addition, I hope to further the debate by questioning whether EBM and casuistry as outlined by Dr Tonelli are oriented more towards explaining or providing a basis for clinical decision making or towards the basis of a philosophy of medicine or the provision of care. I think this is an important distinction that has not yet been fully appreciated, and difficulties arise when one tries to treat them as identical pursuits.

Limitations of EBM: a reprise

Dr Tonelli’s central thesis consists of a challenge to the philosophical assumptions and arguments about the nature of medical knowledge as embraced by EBM. He correctly points out important shortcomings of EBM, particularly in his claim that EBM centres on an attempt to treat differential potential warrants for medical decision making such as empirical evidence, clinical experience and pathophysiological rationale as different in degree rather than kind. As he states:

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 particular medical decision, a method that closely resembles the casuistic or case-based approach to medical ethics advanced by Johnson and others.

I am in agreement with Dr Tonelli that proponents of EBM have not fully articulated the philosophical dimensions of EBM. There is no shortage of other thoughtful people variously tied or related to EBM who have provided such a philosophical analysis. Notable examples include the work of Tonelli (1998, 2001) himself as well as recent, quite thought-provoking papers both supportive and critical of EBM by Sehon & Stanley (2003), and Ashcroft (2004) looking at the epistemological nature of evidence. There is no doubt that considerable thought has gone into the nature of the critique of EBM as witnessed by the burgeoning set of thematic issues devoted towards EBM. The Journal of Evaluation of Clinical Practice can take pride in that it was the first journal to devote dedicated issues to the concept of EBM.

However, it may be too much for the proponents of EBM to provide such a philosophical justification. As pointed out by commentators such as Buetow

1 See for example thematic issues by such journals as Journal of Medical Ethics, and Brief Psychotherapy and Crisis Intervention.
and others (Buetow 2002; Cohen et al. 2004), EBM proponents have been unwilling or unable to embark upon a philosophical examination of the epistemological issues raised by EBM or a debate on the relative strengths and weaknesses within the doctrine. A recent paper by Haynes (2002), for example, points out the orientation of EBM as less philosophical and more pragmatic. Apologies for EBM, such as the one by Straus & McAlister (2000), simply gloss over any apparent difficulties. When a movement has been successful in such trendy practices as ‘branding’ and ‘knowledge translation’ or outright marketing, it is scarcely surprising that few among the converted have embarked on the difficult task of thinking through the root assumptions of the most cherished tenets of the creed. That EBM has transformed its self-image in an unacknowledged manner, perhaps in response to criticisms, is apparent, and several aspects of Dr Tonelli’s paper have pointed to these changes, as have others (Upshur & Tracy 2004).

Dr Tonelli argues that EBM has failed to provide explicit instructions on how to integrate evidence into clinical practice. Indeed, the very popular and influential User’s Guide to the Medical Literature ends where, some would argue, the really interesting thinking should begin. As stated in the final instalment:

Thus, knowing the tools of evidence-based practice is necessary but not sufficient for delivering the highest quality patient care. In addition to clinical expertise, the clinician requires compassion, sensitive listening skills, and broad perspectives from the humanities and social sciences. These attributes allow understanding of patients’ illnesses in the context of their experience, personalities, and cultures. The sensitive understanding of the patient links to evidence-based practice in a number of ways. For some patients, incorporation of patient values for major decisions will mean a full enumeration of the possible benefits, risks, and inconvenience associated with alternative management strategies that are relevant to the particular patient. For some of these patients and problems, this discussion should involve the patients’ family. For other problems – the discussion of screening with prostate-specific antigen with older male patients, for instance – attempts to involve other family members might violate strong cultural norms (Guyatt et al. 2000).

It is striking that EBM is completely silent on techniques and tips on how to achieve these important goals, and seems relatively perplexed about how to proceed. As Haynes (2002) wrote recently:

Furthermore, the issue of when a research finding is ready for clinical application remains mired in the lack of a satisfactory resolution of how findings from groups can be applied to individuals. For one thing, our understanding of how to determine what patients want is primitive. Also problematic, the circumstances in which patients are treated can vary widely from location to location (including locations that are right across the street from one another): the resources, expertise and patients are often quite different and the same research evidence cannot be applied in the same way, or not at all.

Tonelli notes the tenuous position of EBM being on the verge of becoming, as he says, ‘simply a meaningless appellation to which anyone can claim allegiance’. ‘Evidence-based’ is something most reasonably rational individuals would like to have associated with their professional practices. The difficulties associated with the restrictive definition of evidence employed by EBM have been discussed elsewhere (Feinstein & Horwitz 1997; Malterud 2002; Upshur & Colak 2003). Whereas Dr Tonelli believes that the concept of an evidence hierarchy is relatively well agreed upon, in my estimation, this is not the case. There has been a proliferation of evidence hierarchies that are disparate in their constructions and rating of evidence, some giving higher priority to some forms of study, and some to others (Upshur 2003). It becomes more complex when the concept of a recommendation is integrated into this concept of evidence. Which hierarchy is correct? What animates the desire for such a hierarchy? The idea of an evidence hierarchy has been challenged, and some have argued that a hierarchy cannot do the work it is meant to do, and that the concept of evidence as a hierarchically ordered set of warrants based on the robustness of study design is likely to be a faulted strategy, particularly when one regards clinical research evidence as but one of many war-
rants available to justify decisions or provide care (Upshur et al. 2001; Upshur & Colak 2003).

Dr Tonelli also correctly points out how EBM is founded on a form of empiricism and was built on the explicit rejection of rationalism. The problem with a purely research-derived conception of evidence that privileges randomized designs is that it leads to contradictions that serve as its own ultimate reductio ad absurdum. For example, one cannot use theory or physical law to reject an evidence derived from clinical research, no matter how absurd the conclusions. A notable example of this is the problematic meta-analyses of homeopathy, published in the Lancet, which concluded that homeopathy is effective. (Linde et al. 1997). Two commentaries (Langman 1997; Vandenburgoucke 1997) that accompanied the study rejected the findings of the study: one on the ground that homeopathy cannot be true because it violates established physical laws; the other on the ground that even if it were true, it would not be worth pursuing on ground of resource allocation. Neither objection is available to supporters of EBM. That homeopathy flies in the face of physical laws is not an objection that an EBM advocate can employ with security, as arguments from theory come from lower on the hierarchy than a meta-analysis, which rests at the pinnacle, regardless of the outcome. Similarly, arguments from a moral perspective have no weight at all in the EBM hierarchy, no matter how cogent or compelling. The only objections that can be raised are methodological, so one is left with the usual quibbles about the adequacy and quality of the individual study designs within the meta-analysis, publication bias, and so on, which is no different from any other meta-analysis, Cochrane or otherwise. One must be mindful that from the perspective of probability theory, a meta-analysis can be ‘positive’ by chance alone, and the entire edifice of EBM provides no tools to diagnose this possibility that are consistent with its own tenets.

Is the casuistic approach a departure from EBM?

The heart of Dr Tonelli’s approach is to integrate evidence through a casuistic approach, drawing on Jonsen & Toulmin’s (1988) landmark book. He draws the analogy between a casuistic approach in ethical thinking and casuistic understanding in clinical decision making. I think this is a fruitful application, and his highlighting the need for prudence or phronesis is an important insight.2 The refined judgement of a clinician entails far more than the application of the rules of critical appraisal to studies, and then applying those studies to patients. The casuistic model of clinical decision making consists of five elements as outlined by Dr Tonelli. These include empirical evidence, experiential evidence, pathophysiologic rationale, patient values and preferences, and system features.

Tonelli argues that clinical research can provide a paradigmatic case, but does not tell us how to bridge the gap between the studies and the patient at hand. As he writes: ‘the clinician must decide whether the patient at hand resembles the average patient provided by clinical research closely enough to warrant incorporating in the conclusions of that research into the 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’, and he further adds ‘how closely the patient at hand resembles the average patient in the study will determine how much weight to give to the results.

But does the casuistic approach provide guidance to clinicians on how to integrate research evidence into practice? The question is precisely how to go about determining what is best for a patient. Is it necessary then to look at all possible studies, especially the inclusion and exclusion criteria, to determine if a study applies to a patient? EBM itself has largely abandoned this strategy as a desirable way to practice medicine3 And is such an integration of clinical research evidence into decision making the overarching imperative of clinical medicine? If casuistry is a

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2 It has been pointed out that the concept of being a good clinician involves the development of good judgement or clinical wisdom, an area that was at the centre of the work of Alvin Feinstein, who devoted considerable energy to the study of what constitutes good clinical judgement. His book Clinical Judgement stands as a counterpoint to EBM.

3 Instead, it has enshrined the authority of EBM behind the veil of pre-appraised evidence sources and the creation of a legion of evidence users as opposed to evidence-based practitioners.
guide to the integration of research evidence into practice, it may be argued that casuistry serves as an extension of, rather than alternative to, EBM. Even if we accept that warrants are different in kind, we are still left with a host of difficulties on how to proceed both when there is and, when there is not research evidence upon which to guide care. Doctors rarely have an intimate understanding of such inclusion and exclusion criteria. They are poorly represented in meta-analyses unless one reads an entire Cochrane Review, and are not at hand in terms of approaches such as Clinical Evidence, or other forms of pre-digested evidence where one simply is given the bottom line, which is an increasingly advocated method by EBM.

How then does one make this leap from understanding what is paradigmatic to what applies in a patient’s case? The casuistic model is one attempt to traverse this gap, and other such approaches have been suggested. The casuistic approach, however, does point to the importance of the particular case at hand. The importance of context in clinical decision making and clinical care is nicely highlighted in the casuistic model. Other approaches such as narrative-based, context-based and patient-centred care all take the point of departure for clinical reasoning as the clinical situation rather than the search for evidence.

Evidence-based medicine falters partly because of its problematic relationship to the patient. It exemplifies what could be termed an extract and apply model where the patient is seen as a vehicle or object from which to extract information. The clinician searches databanks for methodologically sound studies, critically appraises them and then brings them back for the application to the patient, and evaluates the outcome. Patients are almost complete bystanders to the process of EBM as originally described. As Dr Tonelli rightly points out, and is definitely true, personal preference can trump any form of evidence no matter of what quality, and this does not necessarily result in a bad clinical decision or inferior care. Quite the contrary in some circumstances.

The crux of the matter is how to traverse the grey zones of practice. As David Naylor has pointed out in his seminal essay ‘Grey zones in evidence-based practice’, there are always going to be difficulties of the application of clinical study trial evidence to an individual patient (Naylor 1995). Even proponents of EBM, as noted above, admit that this is a problem for which they have no solution.⁴

This thorny issue has been nicely examined by Richard Horton (2000) In his paper ‘Common sense and figures: the rhetoric of validity’, he points out the problems with various strategies of applying research evidence in clinical care. Whereas Dr Tonelli does not provide a worked example of casuistry which would have strengthened his arguments for its utility considerably, Horton provides an analysis of the ambiguities of commonly used terms such as generalizability, external validity and applicability. Suggesting that what doctors are most interested in is applicability, he examines reasons why evidence-based approaches are bound to fall short of being compelling to clinicians. Using the example of coronary artery stents, he quickly shows that approaches relying solely upon randomized control trials (RCT) will founder when faced by markets flooded with a wide range of permutations and combinations of different stents, materials, clinical practice styles and techniques to apply them. Instead, he argues for consideration of a strategy of inference derived from the philosophy of Charles Saunders Peirce’s abductive reasoning. One uses the widest range of possible considerations as having standing in deliberation and rigorously tests them in practice. Horton then proposes a strategy, based on an interpretive framework for decision making. Horton’s strategy is to pose five questions. These questions are, in the context of an intervention:

1. what evidence is available for us to favour intervention;
2. what evidence is available to us to refute the use of intervention;
3. what evidence is lacking;
4. what is an acceptable range of interpretations of the available evidence; and
5. what circumstances and according to what rules is this evidence being presented and described.

Significantly, Horton also argues for the need for a more time-rich environment to make decisions and provide care. Interestingly, it is time pressure that has

⁴ Except of course to insist that all therapy be given in the context of an n-of-1 trial.
partially scuttled the utility of EBM as classically defined. One wonders the same for casuistry.

One other dimension that requires highlighting here is the nature of the warrant provided by clinical evidence. As Dr Tonelli argues, medical knowledge has the power to produce hypothetical imperatives of the form: If you want to maximize 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 or meaningful goal. Those who hold that there is a moral imperative to practice EBM have failed to successfully reflect upon the nature of the type of warrants provided by clinical research. At best, clinical research evidence gives a plausible direction or provisional justification for action but lacks compelling moral or epistemic force. Even if evidence provided certainty, which it does not, it can be over-ridden in light of other considerations.

The casuistic approach lends itself to a reflection upon the meaning of clinical enterprise. It is not accidental that Stephen Toulmin has a background in logic and philosophy of science. His work on argumentation theory (Toulmin 1958) has influenced writers to provide a model by which the nature of evidence is put into an argumentation framework stressing what type of a warrant clinical research evidence can be. (Dickinson 1998; Upshur & Colak 2003). As with any type of warrant for action, clinical research evidence is subject to rebuttals and counter-claims, and hence the concept of providing care or making a decision is not envisioned as a one-way stream from the well-honed cognitive domain of the doctor to the application to the patient, but is, in fact, situated within a dialogic context of shared concern. In some writing, it appears that EBM is, in essence, an approach to enhancing and sharpening the cognitive skills of doctors. The approach of EBM has been very one-sided, and its notions of truth and rationality focus more on that of the clinicians rather than seeing the fate of the doctor and the patient as intimately intertwined in some form of the unfolding of illness in the life course of a human (Upshur & Colak 2003).

This tension is also present in Dr Tonelli’s paper where he writes about EBM and casuistry providing a framework for clinical decision making as well as inconsistently using the term ‘care’. It is quite likely that care and decision making are two distinct (though related) issues, and because of this the shortcoming of EBM are most evident when one reflects upon what it means to give care, as opposed to what it means to make a clinical decision.

Consider three illustrative examples. I will refer to them as the complex, the exhausted and the personal. The complex refers to the burgeoning population of older patients. In my own clinical practice, the majority of patients I see regularly are 75 years and older, many of whom have five or six ongoing chronic illnesses such as coronary artery disease, osteoarthritis, type 2 diabetes and complex mental health issues such as depression, early and advanced dementia, insomnia and grief. As we all know, the vast majority of pharmaceutical prescribing occurs in this age group. However, most of these individuals would be excluded from any form of clinical trial, so it is hard to see how clinical research provides a paradigm for the care of these individuals. What it requires is some form of reasonable extrapolation into the hopeful in order to determine whether intervening will provide more benefit than harm. If one endorses the strategy of following guidelines as the means of securing excellent care for this population, problems also emerge. Guidelines privilege one physiological system/disease entity at the expense of others. For example, following the guidelines for the management of osteoarthritis would lead one to the consideration of a non-steroidal inflammatory treatment for pain in osteoarthritis. In the elderly, this puts one hard up against gastrointestinal complications, compromise of renal function, and increases the risk in some cases of overt heart failure or myocardial infarction. Diabetes guidelines seek to preserve renal function and keep sugar levels optimal in situations where less aggressive management may be desired. I have yet to sit back and document the many instances where guidelines are contradictory within the same patient, or where optimal compliance with all appropriate guidelines would result in a regimen more taxing than the most rigorous regimen of ascetic monks. For the most part, these recommendations will apply to a patient population excluded from the research studies that are to form the solid scientific basis for judgement. Simply put, neither is there a set of clinical research evidence available to provide direction on how to care for these individuals, nor will there ever be (at least in my lifetime!). It does require a
certain vigilance, trial and error, and a mindfulness of what patients wish and desire as they enter the late years of their life. I think the casuistic approach offers some help here, but then the question I would pose is: to which paradigms do we look for the care of these complex elderly people? It has been argued recently that neither internal medicine nor primary care has appropriate models for the provision of care for these complex individuals, and this remains a challenge to the essence of modern medicine (Whitcomb & Cohen 2004).

The exhausted refers to those individuals who have tried every form of care, evidence based or otherwise and still suffer from the initial complaint. In this regard, I think of one unfortunate patient from my experience as paradigmatic. A gentleman presented with acute herpes zoster in the T7 nerve distribution. This older man had coronary artery disease and severe chronic obstructive pulmonary disease. Being good academic doctors, my residents and I tried in sequence every treatment that had been shown in meta-analysis to be successful in the treatment of the post-herpetic neuralgia he developed. Every treatment failed, and we sent this poor gentleman to a pain clinic for a nerve block. This failed, too. The gentleman laboured in great pain with only marginal relief from large doses of narcotic analgesic before unfortunately succumbing to a myocardial infarction.

The point here is that having research evidence does not, in any way, equate with clinical success. Although on average it increases the chances of success in many cases, this does not always translate into success for individual patients. When clinical success fails to occur, a specialist always ends the consultation note, ‘I return this gentleman to your good care’. When even evidence-based approaches or any form of specialist care is exhausted, the need to be with the patient remains, even if the only ‘decision’ left is to endure together. It is not tenable to simply dismiss patients with the solace that there is nothing that we can do, and increasingly I find there are more and more conditions that prove intractable to even the most exemplary medical care. Thus, there are many contexts in which the clinical encounter does not result in making any clinical decision but are explorations into the understanding of a patient and their fate, and trying to understand mutually the struggles and challenges that a patient faces. If there is something inherently flawed in this belief, I welcome the discourse to correct the flaws in my reasoning.

Evidence-based medicine has been almost pathological in its avoidance of the nature of relationship in the provision of care. A focus on decision making places undue weight on the cognitive structure of a doctor at the expense of looking at how to optimize the determinants of good care and understand the needs of those seeking our care. Issues like trust, care, therapeutic alliance, being with, and if one wants to even expand into the role of healing, are avoided in this kind of empiricist mode of conceptualizing medicine. I think casuistry has a chance to move this forward by realizing that the clinical encounter between a patient and doctor is embedded into distinct life courses in an evolving temporal horizon. The expectation that an answer is there, or that a solution exists to all problems, is likely an unfounded one. Hence, those of us in primary care are often in the situation of providing care, support and lending a helpful ear to those who face intractable and often fatal problems. The provision of research evidence and the existence of RCTs and meta-analysis are irrelevant in some of these circumstances.

Finally, I am led to a speculation. I wonder what the generation of evidence-based trained doctors will look for when it comes to the provision of their own and their family’s medical care. As the cohort of doctors ages, will they look for a doctor who is skilled in the searching and appraising of literature, or will they look for someone who has exemplary diagnostic clinical skills and a humane, compassionate presence?

There is a small literature relating to the application of evidence-based care to doctors themselves. I think notably of the article by Chris del Mar in the British Medical Journal. This is an amusing but cautionary tale: while sitting in for an objective structured clinical examination (OSCE), he realized that there was no urine to be dipped, so he provided his own urine at the OSCE station. He was found to have trace haemoglobin in his urine. This led him on an interesting odyssey where he tried to determine what the best strategy to follow up for his asymptomatic haematuria would be. He
consulted his clinical colleagues, he looked at the literature, and again was faced with what is the most pressing issue not addressed by EBM, and this is uncertainty.

These steps are not easy. Searching the published reports is still awkward and time consuming. Some answers are difficult to find. How long, for example, should we carry on looking before concluding that there seems to be no published work to guide us? We also need a forum of peers and those skilled at evidence based medicine in which to test out our ideas so that we can reassure ourselves that we are not completely off course. If health authorities are serious about promoting evidence based medicine in clinical practice, they may have to consider providing a service (perhaps like pathology, radiology, or referred specialist opinions) to help clinicians to take these steps (Del March 2000, p. 165).

Quite often there is no clear, certain path. This is not a failure in EBM, but, as others have commented, is inherent in the process of medical care itself (Mike 1999).

I think of my own example. At a relatively young age, I started to experience generalized muscle fasciculations and leg weakness. After finally heeding good (spousal) advice to actually see a doctor, it was determined that I had a cervical myelopathy. In this case, I decided to search the literature for what the best choice of future therapy would be: medical, physical or surgical. To say that the literature was confusing and not reassuring is to understate the problem. Taking a purely evidence-based approach and looking at randomized trials, there are few that look at the appropriate management of cervical myopathy and compare conservative and operative approaches. Most patients are older, and the length of follow-up is limited to three to five years. Facing an uncertain future of a worsening spasticity and leg weakness, being told by a colleague that a mere tap from a rear-end accident would be enough to send my cervical disc through my spinal cord, and finding inconsistent results in the literature, none of which could answer the question of what it really means to have titanium plates in your cervical spine for three or four decades, I hope, of life expectancy, I came up with a process that included discussions with my family and consulting trusted colleagues. I eventually opted for surgical decompression and, to my great pleasure, all signs and symptoms resolved, for now. The reality was that the evidence was unclear and did not direct me to an unequivocal answer, and many uncertainties remain and will become clear only in the fullness of time. There is, to borrow from Kierkegaard, a certain leap of faith required in making some decisions.

In conclusion, the casuistic model proposed by Tonelli is a fruitful one, and he is to be commended for his ongoing thoughtful and stimulating critiques of EBM. The challenges he raises are as much epistemic as they are existential and moral. I think that Tonelli, following Toulmin and Jonsen, has opened up a fruitful avenue for future discussion.

Evidence-based medicine arose in the 1990s as an iconoclastic movement. One could see them pushing the pendulum far in one direction towards the need to consider clinical research evidence as central to the delivery of good health care. I think there has been some good associated with this. The iconoclasm has certainly caused a reaction, and part of this reaction has been the focusing and sharpening of reflection upon what the actual nature of medicine is, or could be. If there are good outcomes from EBM, one, I would argue is the thoughtful and reflective writing exemplified by Dr Tonelli’s paper.

References


