Seven characteristics of medical evidence

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Abstract
This paper outlines seven essential characteristics of medical evidence and describes the implications of these for both the theory of evidence-based medicine and clinical practice. The seven characteristics are: (1) Provisional; (2) Defeasible; (3) Emergent; (4) Incomplete; (5) Constrained; (6) Collective and (7) Asymmetric. It is argued that the epistemological theory that best fits medical evidence is that of fallibilism.

Characteristics of medical evidence
In general medical evidence has the following features:
- Provisional
- Defeasible
- Emergent
- Incomplete
- Constrained
- Collective
- Asymmetric

Evidence from health care research, particularly clinical and epidemiological studies is provisional and defeasible. This means that it rarely attains...
absolute certainty and can be revised in light of new evidence. Consequently the occurrence of definitive studies is comparatively rare. This is a common feature encountered in the interpretation of health information.

An excellent example of the provisional nature of medical evidence is provided by peptic ulcer disease. In three decades the understanding of the etiology and management of this disease has undergone dramatic and profound changes. In the 1970s, textbooks proclaimed the need for white diets and postulated stress as an important element of causation. In the 1980s, with the introduction of cimetidine, hypersecretion and the use of H2 blockers were the cause and treatment. In the late 1990s, *Helicobacter pylori* is the favoured etiologic agent and eradication with triple therapy the preferred treatment.

This is but one example of how new research findings have dramatically altered the manner in which a disease entity is understood with major consequences for diagnosis, treatment and patient education. This is not to argue for the existence of paradigm shifts, but rather to assert that there is something inherently protean about scientific research. If evidence were not defeasible, that is, revisable in light of new information, new findings could not be accommodated with prior beliefs. Hence, one salient feature of medical evidence is its inherently provisional nature. Research evidence is neither eternal truth nor a constant (outside of certain basic biologic laws). This is a major barrier to both the public and professional dissemination of research evidence as there seems to be a dissonance between the actual evolution of scientific knowledge and the public’s preconceptions about what medical science can provide. The dynamic nature of medical science in particular is a barrier to the straightforward dissemination of research evidence into practice. Indeed, the conservatism and reluctance to change practice on the part of clinicians, so much bemoaned by the advocates of EBM, may be understandable given the contrariness that seems apparent in much research evidence.

This contrariness occurs because evidence is emergent and therefore is expected to change with time. There is always the possibility that even the best evidence can be overturned in the course of time. Excellent evidence-based therapies can be superseded by newer ones, but more importantly, some evidence-based therapies should be replaced. For example, isoniazid (INH) is used for the prophylaxis of tuberculosis infection. There are several excellent randomized trials that unequivocally establish its effectiveness in the prevention of active tuberculosis. It is granted a Grade A recommendation in The Canadian Guide to Clinical Preventive Health Care (1994) indicating the highest form of endorsement. However, compliance with this medication is poor, largely for two reasons. The duration of therapy is long (6–12 months) and there are potential side-effects. Clinically ill people are poorly compliant so it is no surprise that clinically well people are similarly non-compliant. Consequently, despite impeccable status as an evidence-based intervention, INH prophylaxis stands in need of improvement. Therefore, excellent evidence does not necessarily translate into excellent or successful therapy. Diagnostic and screening tests likewise can be superseded. For this reason, despite the existence of good evidence, research will continue and standards of best evidence will change with time.

The emergent nature of evidence is also illustrated by the fact that the production of evidence may not be consonant with policy and planning. Prostate-specific antigen (PSA) testing is an excellent example. There is sufficient scientific, clinical and consumer interest to proceed with trials to determine the effectiveness of PSA screening. The crucial point to be made here is that, in the time frame it has taken for PSA testing to be developed, disseminated, incorporated (appropriately or inappropriately) into practice, for policies to be created for its use and for large scale international trials to be undertaken, a new potential screening test has emerged: % free PSA. By the time it is clear whether PSA is effective or not, the process will probably need to be revisited for the next screening test. Similar conundrums occur for other screening modalities such as colorectal cancer; for therapeutics, as evidenced in for example, proton pump inhibitors (PPI’s) vs. H2 blockers, the vast range of anti-hypertensive agents and diagnostic tests. This is because there are few diagnostic and screening tests that are 100% sensitive and specific and few medications with a NNT (number needed to treat) of 1. There is always need for innovation and improvement and research is necessary to achieve this. Research, though, is largely unregulated and
medical science is not conducted with an overarching unity of purpose. There is a certain perverse intractability to the manner in which the creation of evidence outpaces clinical application and particularly policy and guideline setting.

There are also constraints on the amount and type of evidence we can expect to receive as consumers or clinicians. The existence of constraints means that there are some forms of evidence that are unlikely to be forthcoming. This means that evidence will always be incomplete.

In general there are three general constraints which lead to incompleteness:

1 **Ethical** There are some types of evidence we will not possess so long as current ethical standards prevail. Randomization of patients to hazardous substances is regarded as unethical. This constraint can be overcome only if society markedly changes its views with respect to the nature of experimentation on humans.

2 **Economic resources** Some may regard this constraint as capable of being overcome in principle. However, it is well known that sufficient resources do not exist to deliver all health care (evidence-based or otherwise) to all persons who need or desire it. Some promising therapies are not economically generalizable to all populations that could reasonably benefit from them. (for example complex antiviral combinations for HIV infections). Consequently allocation decisions must be made. Evidence may be put forth as a candidate as a criterion of resource allocation.

3 **Computational resources** Computational constraint is an epistemological concept. It refers to the extent to which knowledge and certainty is possible. *Godelian* constraints refer to the limits of proof in open systems. Since closed axiomatic systems cannot demonstrate rigorous proof of their consistency, it is clear that any evidence provided from empirical research will fall well short of certitude. This is inherent to the process of knowing. Following from this is the existence of time constraints in the context of decision making. One can only achieve maximum information at the cost of increased time.¹ The need for decisions and actions within a specific horizon of time implies a necessary trade off between information and the time needed to procure it.

David Naylor (1995) has illustrated the clinical dimensions of computational constraint. He writes:

Another difficulty arises from the Malthusian growth of uncertainty when multiple technologies are combined into clinical strategies. Take two technologies and they can be used in two different sequences; take five and the number of possible sequences is one hundred and twenty. Furthermore the elements in a clinical strategy are usually tested in separate studies leaving few data on the chains of conditional probabilities that link sequences of tests, treatments and outcomes.

Evidence is collective. It is found in a community of inquirers. The extent and volume of current scientific evidence is too great for any one person to synthesize or comprehend. Hence there is a collective aspect to the production, dissemination, evaluation and use of evidence. Original conceptions of evidence-based practice envisioned clinicians as rational agents capable of searching and appraising the evidence required for clinical decision making. Although this may be possible in academic settings (Sackett 1998), it is cited as an impediment by clinicians to the acceptance of evidence-based practice. (Tomlin *et al.* 1999) Consequently, there has been a shift to the dissemination of digested information such as Cochrane abstracts or publications such as Evidence-based Medicine. While this is laudable in many ways, it raises important questions concerning who has the authority to create, interpret and judge evidence.

As a consequence of the above considerations, evidence as it exists today is asymmetric. There are differences in evidence access both within and between disciplines. For example the tradition of encouraging research as an important component of professional development has come comparatively late to health care disciplines such as nursing, physiotherapy and occupational therapy. For some elements of the health care system there are often no well-developed traditions in postgraduate education (for example, health inspection, health technology such as radiology technology and laboratory technology.)² Also,

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² Indeed it is unclear whether these important practices come under the rubric of evidence-based care. The academic roots are based in trade schools and polytechnics, which are not necessarily identified with a research mandate.
some issues are not sufficiently prevalent to warrant full-scale attention (rare diseases) and some lack appeal from the point of view of funding agencies (vitamins, public health interventions, e.g. restaurant inspection).

**Fallibilism and under-determination**

The provisional, defeasible and emergent properties of evidence show that the ultimate structure of medical evidence is fallibilistic. Fallibilism is the theory that most clearly describes the nature of evidence in health care. Fallibilism holds that any of our opinions or beliefs about the external world may turn out to be false and that a large cloud of uncertainty shadows our deliberations. Rather than having access to medical certainties, we must rely on probabilities and so must always leave room for the ineradicable role of error and play of chance. C.S. Peirce and Karl Popper are the philosophers of science most closely associated with fallibilism. Peirce, in particular, was aware of how the fallible nature of scientific reasoning was distressing to humans.\(^3\)

The incomplete and constrained properties of evidence show that medical evidence is under-determined. Under-determination holds that mutually incompatible, but yet internally consistent, explanations can be provided for the same evidence (Oreskes *et al.* 1994). Weed (1997) has discussed this problem extensively for observational epidemiology. The problem of under-determination is present in systematic reviews as well, otherwise neither discordant systematic reviews nor the need for guidelines for interpreting them would exist (Jadad *et al.* 1997). Consequently there is an inescapable interpretive dimension to the understanding of evidence that has hitherto been neglected by proponents of EBM, who seem to believe that an algorithm or decision tree will precisely determine the meaning and interpretation of evidence (Upshur 1999). This point underscores the importance of qualitative and narrative approaches in health care research.

The collective and historical dimensions of evidence indicate that the production, interpretation, dissemination and implementation of evidence is a social process subject to the forces and vagaries of social life. It draws attention to the importance of reflecting on the unarticulated or unacknowledged extra-evidential considerations such as values and ideological commitments that may underscore the evidence. Such issues need far more attention and reflection from the medical profession, as Callahan (1999) has recently pointed out.

Evidence itself does not recommend its own interpretation. It does not perpetuate its creation (Poovey 1998). The diseases studied, the outcomes chosen for analysis and the populations selected for study are the result of value choices. The evidence we seek to use is partly constituted by what we value and what we need to know. This does not diminish the scientific nature of medical evidence but secures its humane significance and relevance to clinicians.

Consequently, we cannot dispense with evidence, but must be keenly aware of the inherent limitations of basing clinical practice solely on evidence. Further attention must be paid to the concept of judiciousness that constitutes the process of evidence-based practice. How we learn good clinical judgement, how we impart it to trainees, how we allocate scarce resources and communicate it to our patients and the public is an essential task for future health care research.

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\(^3\) See The Scientific Attitude and Fallibilism in J.S. Buchler ed. (1940) *Philosophical Writings of Peirce*. Dover Publications, New York, p 42–59. ‘If a proposition is to be applied to action, it has to be embraced, or believed without reservation. There is no room for doubt which can only paralyse action. But the scientific spirit requires a man to be at all times ready to dump his whole cartload of beliefs, the moment experience is against them. The desire to learn forbids him to be perfectly cocksure that he knows already. Besides positive science can rest only on experience; and experience can never result in absolute certainty, exactitude, necessity or universality.’ (p. 46–47)
References