Evidence-Based Medicine: What's in a Name?

by Barbara Armstrong

When government committees, newspaper articles and TV programmes discuss 'complementary' and 'alternative' medicine (CAM), it doesn't take long before the term 'evidence-based medicine' (EBM) is used. And it is usually with the implication that therapies other than those provided by orthodox Western medicine just don't shape up.

EBM has been embraced by 'the powers that be' in all medical specialties, by medical schools, economists, statisticians and government policy makers.

It is important, therefore, that we understand what the term means, and what it doesn't mean. And how the term is being misused and abused, especially with reference to CAM.

While EBM has achieved the status of a politically correct movement, not all doctors are enamoured of it. Health-related journals are littered with articles from doctors and other health professionals who are concerned about the way EBM is being promulgated. Cohen et al's excellent critique of EBM summarised these concerns as having the following main themes:

"1. EBM is based on empiricism, misunderstands or misrepresents the philosophy of science, and is a poor philosophic basis for medicine.

2. The EBM definition of evidence is narrow and excludes information important to clinicians.

3. EBM is not evidence-based, that is, it does not meet its own empirical tests for efficacy.

4. The usefulness of applying EBM to individual patients is limited.

5. EBM threatens the autonomy of the doctor/patient relationship." [6]

Those who dare to criticise EBM are particularly concerned about the way that one particular tool for determining efficacy, that of randomised controlled trials, has been elevated above all other techniques, including clinical experience. [6, 16, 17, 19, 23] The randomised controlled trial (RCT) is seen as the 'gold standard' for research - the top level of the scale (rather like achieving 5 stars in a 5 star rating system). A typical 'hierarchy of evidence' scale is as follows [10]:

Hierarchy of Evidence: Therapy or Prevention

n of 1 randomised trials***

Meta-analyses of trials

Randomised controlled trials

Systematic reviews of observational studies

Observational studies

Physiologic studies

Unsystematic clinical observation

Another scale includes at the bottom levels: "grouped opinion or emergent approaches from practicing experts" and "emergent opinion from popular culture/old wives tales etc". [14]

Many opponents have asserted that with the EBM approach the value of clinical experience has been denigrated. Others have pointed out that the use of RCTs as the gold standard is misguided [20] and cite the difficulties with applying EBM (and in particular RCTs) to CAM, particularly as the underlying theory of disease and healing is often quite different. [18] Alternative approaches to obtaining proof of efficacy have been described [21] and Tonelli and Callahan have put the case that "orthodox medicine should consider abandoning demands that CAM become evidence-based, at least as 'evidence' is currently narrowly defined." [18]

As a result of the many criticisms of EBM, the original concept was altered to include the skills of the practitioner and the unique requirements and preferences of the patient.

According to the most frequently quoted article on the topic, EBM is "the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients." [13]

Using this definition, EBM is not just about using the results of research. It is an approach that

integrates the individual expertise of the practitioner with the best available external evidence from systematic research. It also takes into account the "thoughtful identification and compassionate use of individual patient's predicaments, rights, and preferences in making clinical decisions about their care." [13]

So there are three elements, each informing the other: clinical expertise, best evidence regarding safety and efficacy, and the needs and preferences of the patient.

Despite the implications of those medicos, officials and journalists who use the term, it is important to note that, using the revised definition of EBM, "evidence based medicine is not restricted to randomised trials and meta-analyses." [13] While the randomised trial is seen as the top level of the scale, EBM does allow for other levels of evidence to be considered as valid. The Royal Australian College of GPs has a position statement on EBM which refers to the need to use "the most appropriate research methods rather than considering only those which may be addressed by the use of quantitative data." [11] The EBM approach is not solely about using the highest levels of scientific validation. By implication, the College of GPs acknowledges the importance of qualitative data and research methodologies that are not '5 star'.

Five star evidence tends to 'trump' lower levels of evidence, but the practitioner's skills and judgement, plus factors relevant to the patient (for example the desire for low cost, non-invasive, low-risk alternatives with fewer side-effects) must also be taken into account. The application of EBM should not be used to reduce treatment to 'the single best option'.

One of the commonly-cited limitations of EBM is that there are difficulties in applying and extrapolating statistical evidence to the care of individuals. There can be a difference between treatments which work for the 'average many' in a research setting and treatments which work for individual patients in the real world. [6, 17] The paradox is that, "the more generalised a finding is the better regarded it is, broadly speaking, but the more generalisable a result the less applicable it is to specific populations." [14]

The issue of customer choice has been examined to see how that fits with (or is at odds with) the medical choices based on EBM. [1, 7] These studies have found that there may be a discrepancy between what the doctors perceive as beneficial based on evidence, and what treatment a patient may see as beneficial. Patients need to be able to make choices based not just on statistics, but including other key issues of importance to them such as costs, quality of life, long term effects and their personal cultural beliefs.

In a similar vein, the Medical Council of New Zealand has produced Guidelines on Complementary, Alternative or Unconventional Medicine which allow that 'orthodox' medicine is not completely evidence based, and that, as a bicultural nation, "practitioners need to be mindful of the cultural beliefs, mores and behaviours of their patients and be respectful of these." [8] While not totally 'pro-CAM', the Guidelines do allow that "when appropriate and where there is no reason to believe such a referral would expose the patient to harm there is no barrier to making a referral to an unconventional practitioner." [8]

Originally the Medical Board of Queensland's policy on the same topic was based on that of the Medical Council of New Zealand and had similar wording. It is interesting to note, however, that the MBQ policy was re-written in December 2003 and re-labelled 'Unconventional Medical Practices', the terms 'complementary' and 'alternative' being rejected by the authors. [9] According to the policy there is only 'conventional' and 'unconventional' medicine. It eliminates any hint of apology for medical orthodoxy's credentials. Instead it states that "Medical registrants are qualified to practise conventional medicine through an accredited system of medical education and training. Conventional medical practice is scientifically based and humanely oriented." [9] (Note that there is no admission here that not all conventional treatments have been rigorously tested.) Also, doctors must "avoid referral of patients to unconventional health practitioners." [9]

The MBQ policy reflects the usual self-proclaimed superiority of Western medicine. The implication is that everything not taught in medical school is 'unconventional' and therefore unscientific and therefore 'bad'. 'Unconventional' treatments only become acceptable when they are incorporated into 'conventional practice' and are taught to medicos and therefore become treatments which are provided by them, not the CAM practitioners. In this scenario there is no niche for treatments provided by CAM practitioners.

This approach would appear to be at odds with the legal situation reported in several recent Australian articles. [2, 3, 4, 24] These articles describe some recent legal rulings, and in particular the High Court decision in Rogers v Whitaker, which have supported a patient's right to choose treatment based on information which is

meaningful and important to the patient. [12] It may therefore be the duty of doctors to advise patients of safe and effective alternative treatment options which are less invasive and may have less risk than, say, proposed 'evidence-based' surgery or medications which have the potential for debilitating side-effects. As Brophy states: "It is obvious that where a CAM option offers an outcome similar to the proposed treatment with no risks or fewer risks, this information would be significant to a hypothetical patient." [3] This would certainly be the case where the patient has expressed an interest in, or is already using CAM therapies. However, Weir points out that "The crux of the legal and ethical issue for medical practitioners is whether they are entitled or obliged to advise of CAM modalities as treatment options when their efficacy and safety may be in dispute." [24] Which brings us back to the term 'evidence-based medicine'.

What's in a name? A lot it would seem. According to Charlton and Miles' fascinating article, EBM started out under the name of 'clinical epidemiology', an approach which emphasised "the potential of epidemiological information for guiding clinical practice." [5] The term 'evidence-based medicine' was coined in 1992.

It appears that much of the problem for practitioners and proponents of CAM lies, not so much with the EBM methodology as widened and modified since its inception, but with the "almost uncritical acceptance of EBM [in its narrow sense] in powerful and influential circles." [5] (Comment in brackets added by myself.) The use of the term 'evidence-based medicine' turns it into a type of motherhood statement which is difficult to challenge. "The name itself admits to little argument. One would be pressed to admit that they practice whimsically-based, arbitrary medicine." [19] According to Charlton, "EBM effectively labelled itself as rational, objective and altruistic, while any opposition was implied to be promoting a practice that is illogical, self indulgent and opposed to the evidence." [5]

Not all medical treatments provided by doctors are supported by solid scientific evidence. [15] Homoeopaths should not be intimidated by the obvious double standard which some interests are trying to impose. However this should not make practitioners self-righteous or smug. Nor does it excuse Homoeopathic practitioners from making every effort to keep up-to-date with the latest advances in knowledge and the latest research findings, not only in their own field, but in related fields which may inform the advice and options which they give to their patients. No therapy can afford to get stuck in a 19th or 20th century time-warp. But the statements from some advocates of orthodox Western medicine which suggest that not all CAM medicines are evidence-based misunderstands the meaning of EBM – and does seem a bit like the pot calling the kettle black!

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*** "n of 1 trials" means one-patient, randomised, double-blind, controlled trials.

Such trials are a recognised way to assess the efficacy of treatment - for example to evaluate adverse effects related to medication use when the symptoms are vague and are in response to more than one medication, or the evaluation of chronic conditions. It has been suggested that this methodology could be used for the evaluation of CAM, where a CAM therapy is randomised, controlled and blinded against placebo, or against one or more standard treatment(s). (Johnston, Brad. "N-of-1 randomized controlled trials in Complementary and Alternative Medicine". 3rd Annual CAM Research Symposium". June 20, 2004)

Barbara Armstrong has qualifications in Medical Record Administration, a Graduate Diploma in Data Processing, and a Graduate Diploma in Library & Information Sciences. She has worked in the health field for over 20 years. Barbara has held positions as Manager of the Information Management Advisory Section of Victoria's Health Department, as Senior Systems Consultant for a health computing software company, ran her own medical record consulting business, and was National Quality Manager at Telstra Research Laboratories. Barbara is a lecturer in medico-legal studies for Homoeopaths and is currently National Administrator of the AHA. S