



Evidence based medicine - highway to excellence in healthcare?

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In the pursuit of better health care, health authorities increasingly require clinical decisions to be based on sound clinical evidence. The development of evidence-based health service commissioning has further reinforced this trend. In the wake of this drive for excellence in healthcare, homeopathy has been criticised for its lack of supporting evidence, leading to reduction or withdrawal of funding by many primary care trusts (PCTs).

The term evidence-based medicine (EBM) is commonly used and misused. In this issue we will explore the meaning of EBM and its application to homeopathy.

EBM - Definition

The widely accepted definition of EBM is “*the conscientious, explicit and judicious use of current best medicine in making decisions about the care of individual patients*” (Sackett *et al BMJ* 1996). This laudable initiative seeks to integrate individual clinical expertise with the best available external clinical evidence from systematic research *and* the opinions and values of patients, families and carers (Guyatt *JAMA* 2000).

EBM requires four sequential processes, not always adhered to in practice; these are:

- 1) **Translating** information needs into an answerable question
- 2) **Finding** the best evidence with which to answer the questions
- 3) Critically **appraising** the evidence
- 4) **Applying** the results into clinical practice.

EBM - History

Over the last 50 years, the search for new and effective therapeutic interventions has engendered much privately and publicly funded medical research. Over that period, research protocols have been refined so as to best answer specific questions about the effectiveness or efficacy of healthcare options.

EBM evolved as a tool to help practitioners deliver best clinical practice, the term “Evidence Based Medicine” first appearing in the medical literature in 1991 (Guyatt *ACP J Club*). It was subsequently used by health policy makers to provide reliable evidence on which to base their funding priorities for public healthcare.

Thereafter, key developments in EBM have included advances in ease of accessing and understanding clinical information, and greater availability of pre-processed evidence-based information. Improvements in information technology and the development of clinical databases, e.g. MEDLINE, have facilitated the perusal of original articles.

More recently, decision support systems, incorporating best available clinical evidence at the point of care, are also evolving.

EBM - The framework

In the UK, the EBM framework categorises clinical evidence according to the strength of its freedom from bias into categories A, B, C and D. The strongest evidence for therapeutic interventions is considered to be provided by systematic reviews of randomised, double-blind, placebo-controlled trials (RCTs), involving a homogeneous patient population and medical condition (A). In contrast, patient testimonials, case reports and even “expert” opinion, represent only weak evidence, due to placebo effect, bias inherent in observation and reporting of cases, and because of difficulties of defining the term “expert”(D).

Organisations such as the Cochrane Collaboration integrate sources of high quality clinical evidence and disseminate systematic reviews of primary studies. The Cochrane Database of Systematic Reviews (CDSR) is one of several databases in the Cochrane Library, an electronic resource that regularly updates the collected work of the Cochrane Collaboration, and now contains more than 3000 systematic reviews.

To conclude the process, the National Institute for Health and Clinical Excellence (NICE) carries out assessments of the most appropriate treatment regimes for different clinical conditions.

EBM - The drawbacks

In its current form, EBM fails to achieve its aims in a number of areas.

As the 'gold standard' for evaluating clinical interventions, the RCT is the most rigorous scientific method for the evaluation of efficacy of clinical interventions. However, it requires skill to evaluate and critically appraise the quality of evidence delivered by individual RCTs, where flawed trial design and management may produce bias. Studies have shown that researchers not uncommonly employ inappropriate techniques, misinterpret results, cite literature selectively, or draw unjustified conclusions. (Groves *BMJ* 2008)

Systematic trials on which evidence is based do not necessarily represent the population at large. RCTs often use selected groups of patients, excluding those with co-morbidities, which would confound the trial design. So how can we be certain that the evidence from RCTs is applicable to the patient found in daily practice? (Hunink *BMJ* 2004)

The EBM hierarchy of evidence may be unjustified and misleading. For example, a systematic review of several small, poorly conducted RCTs is clearly not better than one large, well-executed, double blind trial. Systematic reviews may also mislead on account of absent or weak information about adverse effects.

With the increase in evidence-based policy making, there is the ever-present danger that health care managers, equating lack of evidence with lack of effectiveness, will use the former as a rationale for reducing services.

Although British general practitioners often use evidence-based guidelines or protocols generated by others, very few routinely apply the principles of EBM to individual patients in clinical practice. Indeed only a minority of medical interventions is supported by solid scientific evidence. (Smith *BMJ* 1991)

EBM and homeopathy

The necessity of an evidence base in homeopathy is clear, as public health policies need to make best use of available resources as well as protect the public from malpractice and potential fraud.

There exists presently little clinical evidence in homeopathy; relatively few trials have been performed in comparison with conventional medicine. This state of affairs has come about as homeopaths have generally tended to strive towards best practice by seeking the opinion of leaders in the field, whereas conventional medicine has embraced the RCT as the key to best practice.

Historically, many trials have been performed by scientists with limited understanding of homeopathy, or by homeopaths unskilled in modern research methods. Currently the trend is towards trial designs better suited to complementary and alternative medicine (CAM), resolving the limitations of traditional RCTs. An example of this is the novel RCT trial design by C. Relton, which dispensed with the constraints placebo control while retaining high statistical validity (Relton et al *Homeopathy* 2009).

CAM-related Cochrane reviews and protocols are available in *The Cochrane Library*. Abstracts of the reviews can be viewed at no charge via the Collaboration's website, at tinyurl.com/dhvf6h. Five Cochrane reviews of homeopathic treatment have been compiled. These examine the homeopathic treatment of attention deficit hyperactivity disorder, chronic asthma, prevention and treatment of influenza and influenza-like syndromes and the induction of labour. None of these recommend the use of homeopathy. The Scottish Intercollegiate Guidelines Network (SIGN) guidelines, which investigated the management of cancer pain, lung cancer, and headache using homeopathy, also concluded that there is currently insufficient evidence to recommend homeopathy.

However, as Mathie and Fisher (*BJCP* 2007) point out, half of all homeopathic trials published have significant and positive results. They cite the positive research findings in several reviews, along with the positive evidence of cost effectiveness and safety. More specifically, systematic reviews of trials performed on children have shown positive results for the treatment of attention deficit hyperactivity disorder, diarrhoea, otitis media, stomatitis, and upper respiratory tract infections (see review by Mathie & Fisher *BJCP* 2007).

Also of significance is the fact that of the five meta-analyses of homeopathy trials published to date, four conclude in favour of the existence of a homeopathic effect. The latest study by Shang (Shang et al, *Lancet* 2005) reports negatively; however its methodology has recently been heavily criticised, and its conclusions deemed unreliable. (Lutdke & Rutten *J Clin Epidemiol* 2008, Rutten & Stolper *Homeopathy* 2008).

In response to the perceived lack of evidence, the Research Council for Complementary Medicine, in partnership with the Royal London Homoeopathic Hospital and School of Integrated Health at the University of Westminster are working to develop a specialist CAM library (see website here: tinyurl.com/d9jfbx) for the NHS National Library for Health (NLH), aiming to provide good quality information to support evidence-based decision making by patients, clinicians, managers and commissioners. Links to clinical guidelines (e.g. NICE guidelines on cancer and palliative care) are provided where there are implications for CAM.

EBM - The challenges for homeopathy

A pivotal difficulty in applying RCT designs to homeopathy is the low validity of the RCT in relation to the practice of homeopathy in the real world (Walach *JACM* 2001, Thompson *BMC Medical Research Methodology* 2004). Moreover, the introduction of placebo has an effect on the practitioner's interpretation of the remedy response. There is also the issue of the complexity of the homeopathic "package of care", as the homeopathic approach involves a potentially therapeutic, in-depth consultation (Thompson *BMC Med Res Meth* 2004).

Recognising the special place of complex interventions, the Medical Research Council (MRC) has recently acknowledged the need to revise its guidelines on designing, conducting and evaluating complex interventions in health care (Craig et al *BMJ* 2008).

The development of EBM has coincided with an increase in for-profit funding of research, and in the reporting of industry-funded research results designed to promote its products (Druss *BMJ* 2005). Yet in the UK only 0.0085% of the medical research budget is spent on CAM (*UKCRC* 2006), a significant factor in the relative lack of peer reviewed homeopathic clinical trial research, compared with that in orthodox medicine (Mathie and Fisher *BJCP* 2007).

EBM - Conclusion

EBM is used increasingly to inform health policy decision-making and individual health choices; however, for the unwary there remain pitfalls in its use. The term 'evidence-based' is applied to many recommendations and guidelines that do not incorporate systematic and critical appraisal of clinical evidence. There is perhaps a danger that unsophisticated users of medical literature will place on these more reliance than is appropriate.

Ideally, clinical evidence should remain *complementary* to clinical judgement, *including* a consideration of patients' individual predicaments, values and preferences, in making treatment decisions; even excellent evidence may be inapplicable or inappropriate for an individual patient.

EBM does not provide guidance for rare disorders, nor for patients with multiple pathologies, who are excluded from RCTs. In these cases there is evidence that the individualised approach of homeopathy can be effective (Linde et al *Lancet* 1997, Spence et al *JACM* 2005).

In the context of homeopathy, the best possible outcome of the current EBM process would be the generation of proof of the effectiveness of homeopathy. However, in its present form, EBM does not create useable templates to foster best practice in homeopathy.

A challenge facing current homeopathic practitioners is to use and expand current EBM methods to strengthen the evidence of effectiveness of homeopathy, while concurrently generating innovative research able to meaningfully compare the different trends of homeopathic practice, thus becoming a driving force for best practice in homeopathy. Currently, the greatest obstacle to this goal is a relative scarcity of funds for CAM-related research as compared to conventional medical research.

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