

CME Article

What is this thing called EBM?

K H Pwee

You have probably heard of “EBM”. It stands for “Evidence-Based Medicine” and is a convenient abbreviation for a phenomenon that has swept through the practice of medicine in the past ten years or so. Nowadays, one cannot open a general medical journal without finding something or other that is described as being evidence-based, or not evidence-based, as the case may be. There is evidence-based practice, evidence-based healthcare, evidence-based prescribing, and so on. “Evidence” is a buzzword and is the “in” thing to be evidence-based. But what is this thing called EBM anyway? Is it old wine in a new skin? Or just common sense?

A BRIEF HISTORY

The beginning of EBM can be traced to the early 1990s, when a group of doctors at the McMaster University in Canada, the evidence-based medicine working group, published an article in the Journal of the American Medical Association in 1992. They described a new approach to teaching the practice of medicine. They advocated a new paradigm in which clinical decisions should be made on systematic observation and with decreased emphasis on authority⁽¹⁾.

The philosophical roots of EBM can be traced back even further, to 19th century Paris⁽²⁾ and the work of renowned physicians such as Magendie, Bichat and Louis. Pierre Charles Alexandre Louis, for instance, was the founder of the “numerical method” in medicine, basing choice of treatment on careful observation and collection of data. A more recent antecedent is clinical epidemiology. As Jenicek observed, in contrast to classical epidemiology where observations in individuals are extrapolated to disease at the population level, clinical epidemiology reverses the direction of reasoning, and information acquired from groups of subjects are used to make decisions concerning individual patients and groups of patients⁽³⁾. The methods of clinical epidemiology are the methods of EBM.

The antiquity of its historical antecedents notwithstanding, EBM is not old hat. A key distinguishing

feature of EBM is its requirement for explicit and systematic use of clinical evidence.

EBM: A DEFINITION

A commonly quoted definition of EBM comes from Sackett et al (1996): “Evidence-based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients”⁽²⁾.

A punchier description comes from the latest edition of Sackett et al’s little blue book (a little red book in its first edition) on how to practice and teach EBM: “Evidence-based medicine is the integration of best research evidence with clinical expertise and patient values”⁽⁴⁾.

The essential components are: (1) the evidence, (2) clinical experience and (3) the patient. In short, EBM is a philosophy about how to decide what appropriate treatment for a patient is. This philosophy is fundamentally utilitarian and empirical. It requires that the physician knows what treatments have been shown to work, and then integrate this knowledge with his/her own expertise and the patient’s circumstances, in order to recommend a course of action most likely to benefit the patient.

How are treatments shown to work? This is a matter of numbers – the treatment must have been tried on others and the results thereof carefully observed. While intellectually satisfying (and of course useful in other ways, such as developing further hypotheses) to know the theories behind why a treatment might work, the bottom-line is that if it works, it works; and if it doesn’t, it doesn’t.

While EBM focuses on the individual patient, the term “evidence-based healthcare” is sometimes used to describe the application of evidence-based approaches at the population level. Muir Gray has pointed out that decisions about groups of patients or populations are based on a combination of three factors:

1. Evidence
2. Values
3. Resources

Health Service
Development
Division
Ministry of Health
College of Medicine
Building
16 College Road
Singapore 169854

K H Pwee, MBBS,
MMed, FAMS
Assistant Director
Clinical Standards &
Technology
Assessment

Correspondence to:
Dr Pwee Keng Ho
Tel: (65) 6325 9251
Fax: (65) 6325 9211
Email: pwee_keng_ho
@moh.gov.sg

He describes opinion-based decision-making where little attention is given to evidence derived from research. However, as the pressure on resources available for healthcare increases, decisions will have to be made explicitly and openly, thereby leading to a transition from opinion-based decision-making to evidence-based decision making⁽⁵⁾. This is the milieu in which evidence-based healthcare would be necessary.

THE HIERARCHY OF EVIDENCE

What constitutes evidence? Evidence is information from research – the “truth” as demonstrated objectively through scientific studies. However, evidence also encompasses expert opinion and consensus. It is assumed that experts base their opinions on their wide knowledge of their field, as well as their own personal clinical experience. This means there are many kinds of evidence; and all these kinds of evidence may be used to support assertions of what the “truth” is.

There exists a hierarchy of evidence, and higher levels of evidence are held to have a greater likelihood of reflecting the “truth” than lower levels. Scientific studies are taken to be of a higher level of evidence than expert opinion because we can (potentially, at least) see the results for ourselves, follow the process of reasoning, and examine each step of the research methodology. This is something not readily accessible from the subjective black box of opinion and consensus, if it is not based on scientific studies. Experimental studies are felt to provide evidence of a higher level than observational studies because properly conducted experiments can control for biases and confounding factors more effectively than observational studies.

Various factors influence the likelihood that what we see from a study is the “truth”. The number of the subjects in a study is one – the larger the study size, the less likely that any results observed are the result of statistical fluctuation. Having a control in a study is another factor – the control being the same, as far as possible, as a study subject, except for the item of interest under study (e.g. a risk factor or an intervention). One of the most powerful factors is that of randomisation of study subjects into either a control arm or an interventional arm of a clinical trial. Whereas selecting study subjects to be as similar as possible can control for known confounding factors, randomisation has the added property of controlling for confounding factors that are unknown to the investigators. Given a large enough study population and an adequate randomisation procedure, even in the presence of

confounding factors, such confounding factors should be evenly distributed between the control and the interventional arms.

An illustration of how the type of study can impact on the evidence is the case of hormone replacement therapy. Until recently, the received view of hormone replacement therapy was that in addition to its improvement of menopausal symptoms, there were other potential salutary effects, including protection against coronary heart disease. This was based on several observational studies with large numbers of subjects over a long period of time⁽⁶⁾. In 2002, the results of the Women’s Health Initiative study, a large randomised controlled trial of the effect of oestrogen and progestin therapy in postmenopausal women, were published, demonstrating that overall health risks exceeded benefits and this greatly changing the thinking on hormone replacement therapy⁽⁷⁾. Now, the recommended use of hormone replacement therapy is only for symptomatic relief of menopausal symptoms⁽⁸⁾. What was the reason for the difference in results between the earlier observational studies and the randomised controlled trial? Some explanations proposed include: that more healthy women could be motivated to be on hormone replacement therapy and that observational studies on chronic interventions like hormone replacement therapy are intrinsically biased in favour of successful long-term users of the intervention^(9,10).

What happens when we have two or more similar studies that came up with different results? Which one is closer to the “truth”? Is it sufficient to just find one study that supports the conclusion you had hoped for in the first place? This is where the systematic review and meta-analysis can help. Critically appraising all relevant studies and statistically combining the results, where appropriate, can be a useful method to make sense of information from different studies. However, it is necessary to exercise caution in interpreting the results – a meta-analysis is only as good as the studies it combines.

In the hierarchy of evidence, evidence from randomised controlled trials is placed at the top. This would be followed by controlled trials without randomisation, and other prospective experimental trials. Observational studies follow and prospective cohort studies are the best of these, then case-control studies, and then case series. Expert opinion and consensus bring up the rear. At all levels, a systematic review of the existing studies, with meta-analysis where applicable, is to be preferred.

It must be reiterated: such a hierarchy only tells us the likelihood that the evidence reflects the “truth”. The hierarchy only exists as convenient

shorthand for evaluating the strength of evidence – it does not do away with the need to critically appraise individual studies. Although expert opinion in the absence of higher evidence may sit lowly in this hierarchy, this is not a repudiation of the utility of expert opinion. Consensus is often an essential part of having clinical practices implemented.

HOW DOES ONE PRACTICE EBM?

The practice of EBM involves a five-step approach^(4,11).

Steps in the practice of EBM

1. Define the problem
2. Find the information you need
3. Critically appraise the information
4. Apply the evidence to the patient
5. Evaluate how useful it was

Step 1 – Define the problem

Before getting an answer to a question, one will need to know what the question is. Framing the right question that fits your patient's circumstances means that the answer one comes up with is likely to help your patient. Sackett et al distinguish between “background” questions that ask for general knowledge about a disorder, and “foreground” questions that ask for specific knowledge about managing patients with a disorder. For such foreground questions, the PICO model is a useful way to define the question: it requires that you know about the Patient and/or his problem, the Intervention being considered for the patient, the Comparators for that intervention, and the clinical Outcomes of interest⁽⁴⁾. Examples of questions one might ask are: “In a 56-year-old man with type 2 diabetes mellitus and untreated hypertension, does “tight” blood pressure control reduce subsequent morbidity and mortality?”, or “In a 46-year-old woman with a 7-year history of extensive ulcerative colitis, what is the risk for developing bowel cancer?”⁽⁴⁾.

Make sure your clinical questions have the **PICO** elements:

- Which **P**atients are involved?
- What is the **I**ntervention?
- What are the **C**omparators?
- What are the **O**utcomes of interest?

Step 2 – Find the information you need

To look for the evidence, it helps to know where one is likely to find it. The nature of primary research evidence is that it is reported in sources such as medical journal articles rather than textbooks. Advances in information technology mean that we do not have to hand-search individual journals to seek out relevant articles as the searching can instead be done on electronic databases. One such database is MEDLINE, available freely on the Internet through PubMed (<http://www.ncbi.nlm.nih.gov/entrez/query.fcgi>). This bibliographical database lists articles published in Index Medicus journals and is an invaluable resource when literature searching. Other databases exist and should also be searched, depending on how thorough the search needs to be. A subsequent article in this series will look more closely at information sources and strategies for searching.

Step 3 – Critically appraise the information

Once one has found studies that appear to address your question, the next step is to decide if they are relevant, if the studies have been properly conducted and if the conclusions are valid. This would involve careful reading and analysis of the articles with respect to how the study was carried out (the methodology), what the results were, and whether the conclusions arrived at were reasonable. Critical appraisal is a skill that needs to be learned and developed. A future article will discuss this aspect in more detail. The reader would also find useful the series of articles on “How to read a paper” in the British Medical Journal, which are freely available on the Internet at <http://bmj.bmjournals.com/collections/read.shtml>; and the “Users Guide” articles in the Journal of the American Medical Association, which is freely available from the website of the Canadian Centre for Health Evidence at <http://www.cche.net/usersguides/main.asp>

Step 4 – Apply the evidence to the patient

Having found the evidence, it is time to apply it to the patient. This step is no less important than the others, and it is a distinct and separate step. The evidence contributes to but is not the only factor that decides what appropriate treatment for the patient is. This is where you have to apply your own clinical experience and knowledge of the particular circumstances of the patient, and respect the values and wishes of the patient.

Step 5 – Evaluate how useful it was

Having applied the first four steps, the next step is

a feedback loop in which the effectiveness and efficiency of the process is determined. In other words – how much did the process help the patient and if not much, what could be done to improve it the next time?

In a recent issue of Evidence-Based Medicine, Porzsolt et al proposed that the five-step approach should be increased to six steps. The additional step comes between step one and two, and requires the doctor to give a preliminary answer to the clinical question based on “internal evidence”. This internal evidence is the pre-existing knowledge possessed by the doctor, including clinical experience. The authors had found that in teaching the five-step approach, there was a growing hesitance to accept the strategy as students advanced in their medical training. They contended that advanced students and, to a greater extent, clinicians lose some of their ability to differentiate between scientific evidence and what seems to be evident. With the extra step, they found that students were satisfied that their pre-existing knowledge had been integrated into the evidence-based approach. In addition, it helped to clarify the distinction between internal and external evidence when integrating them to reach a clinical decision for the patient⁽¹²⁾.

A LIMITATION OF THE EVIDENCE-BASED APPROACH

Having seen the five-step approach, it should be apparent that the practice of evidence-based medicine is not an easy thing. It demands an investment in time and resources that some may feel is untenable, given the busy work lives one leads today. This concern is not casually dismissed, but may be ameliorated by accepting that it is worthwhile to make the investment, and realising that it is not quite as difficult as it seems to be. It may occur to you that the same clinical question could be asked by several doctors, and would it not be inefficient to have each doctor work through the five-step approach on their own? This is the reason why various evidence-based methods and resources have been developed to aid the busy practitioner.

Whereas clinical studies may be considered as primary sources of information, secondary resources exist that gather primary information in a systematic and reliable fashion. If you thought, “wouldn't it be nice if someone else had done the work for me?”, then you might be pleased to know that in some cases, information derived from evidence-based approaches is available. These are in the form of critically-appraised topics (CATs). These are

one-page summaries of the available evidence on common clinical questions, prepared by clinicians such as yourselves. The CAT is then made available for other doctors to use.

Locally, the Singapore Health Services (SingHealth) cluster has led the way with its repository of CATs prepared by clinicians working within SingHealth. The CATs are placed online in SingHealth's own electronic network so that its staff can access and use them. In one's own practice or professional circle, it makes sense that if one goes through the trouble of applying evidence-methodologies to help answer a question, one could share it with one's colleagues as part of continuing professional development activities. In publications, journals such as the British Medical Journal include short summaries called Patient- Oriented Evidence that Matters (POEMs) in each edition^(13,14). Secondary journals such as Evidence-Based Medicine and the ACP Journal Club contain only summaries of critically- appraised primary studies published elsewhere.

Another invaluable aid for the busy practitioner is evidence-based guidelines. The group of people who develop the guidelines do the work of searching for the evidence, appraising and synthesising it, applying it to local circumstances, and making recommendations for clinical practice based on the evidence. Since 1998, the Ministry of Health has been appointing expert workgroups to develop evidence-based clinical practice guidelines on clinical topics that have wide relevance to all practitioners. This is one of the strategies by which the Ministry seeks to promote EBM.

OTHER LIMITATIONS OF EBM

The relative youth of EBM contributes to one of its more difficult limitations: the methodologies of EBM are still developing and playing catch-up with its high ideals. For example, methods for evaluating treatments are different from evaluating diagnostic tests, which are again different from evaluating risk factors. While the steps in critical appraisal of randomised controlled trials are advanced and well-recognised, the same is not true for other study designs.

Other criticisms that have been levelled against EBM include: that it is old hat, that it is cookbook medicine, and that it is an excuse by managers to cut healthcare costs. I do not propose to delve into these issues which have been more comprehensively discussed elsewhere⁽²⁾, other than to remark that it is not unusual for a new paradigm to have both its early enthusiasts who may overstate the case for adoption,

as well as its detractors with vested interests in the old paradigm. A sensible approach is to take EBM and its methodologies as a tool, and like any tool, it is neither inherently good nor bad. It is how you use it that matters.

THIS SERIES

This article is the first in a series of articles intended to introduce the reader to EBM and its tools. Each article will focus on a particular aspect of evidence-based methods, with an emphasis on practicality. Some topics you can look forward to in subsequent articles in this series are:

- Finding the evidence
- How to read a paper
- Systematic reviews and meta-analyses
- Critically-appraised topics (CATs) and EBM journals
- Clinical practice guidelines
- Health technology assessment
- Economic evaluations

Do let us know if there are other topics in EBM you would like to see discussed. Whether you are a supporter or detractor of EBM, the proof of this pudding is in whether you can find something of use to you in these articles. I hope you find good eating here.

REFERENCES

1. Evidence-Based Medicine Working Group. Evidence-based medicine. A new approach to teaching the practice of medicine. *JAMA* 1992; 268:2420-5.
2. Sackett DL, Rosenberg WMC, Muir Gray JA, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. *Br Med J* 1996; 312:71-72.
3. Jenicek M. Foundations of Evidence-based Medicine. London: The Parthenon Publishing Group, 2003.
4. Sackett DL, Straus SE, Richardson WS, Rosenberg W, Haynes RB. Evidence-based Medicine: How to Practice and Teach EBM. 2nd ed. Edinburgh: Churchill Livingstone, 2000.
5. Muir Gray JA. Evidence-based Healthcare. Edinburgh: Churchill Livingstone, 2001.
6. Grady D, Rubin SM, Petitti DB, Fox CS, Black D, Ettinger B, et al. Hormone therapy to prevent disease and prolong life in postmenopausal women. *Ann Int Med* 1992; 117:1016-37.
7. Rossouw JE, Anderson GL, Prentice RL, LaCroix AZ, Kooperberg C, Stefanick ML, et al. Writing group for the Women's Health Initiative investigators. Risks and benefits of estrogen plus progestin in healthy postmenopausal women: principal results from the Woman's Health Initiative randomized controlled trial. *JAMA* 2002; 288:321-33.
8. MOH Clinical Practice Guidelines Workgroup on Hormone Replacement Therapy. Hormone Replacement Therapy. MOH Clinical Practice Guidelines 6/2004. Singapore: Ministry of Health, 2004.
9. Herrington DM. Hormone replacement therapy and heart disease: replacing dogma with data. *Circulation* 2003; 107:2-4.
10. Col NF, Pauker SG. The discrepancy between observational studies and randomized trials of menopausal hormone therapy: did expectations shape experience? *Ann Int Med* 2003; 139:923-9.
11. Silagy C, Weller D. 1: Evidence based practice in primary care: an introduction. In: Silagy C, Haines A, eds. Evidence Based Practice in Primary Care. London: BMJ Books, 1998; 1-10.
12. Porzolt F, Ohletz A, Thim A, Gardner D, Ruatti H, Meier H, et al. Evidence-based decision making – the six step approach. *Evidence-Based Medicine* 2003; 8:165-6.
13. Slawson DC, Shaughnessy AF. Obtaining useful information from expert based sources. *Br Med J* 1997; 314:947-9.
14. Smith R. A POEM a week for the BMJ. *Br Med J* 2002; 325:983.

EDITOR'S NOTE

The Singapore Medical Journal (SMJ) is pleased to launch a new series, Evidence-Based Medicine and Healthcare, in this issue of the journal. Dr Pwee Keng Ho, associate editor, will be in charge of coordinating this quarterly series. All articles in this series will be included in the ongoing SMJ category 3B CME programme, underlining the importance of this subject to current clinical practice and healthcare.

The SMJ is indeed privileged that Professor Brian Haynes has kindly agreed to write the editorial in conjunction with the launch of this new series. Professor Haynes is widely regarded as one of the founders of the international evidence-based medicine and healthcare movement. He was the founding director of the Canadian Cochrane Network and Centre, and founding editor of a number of "evidence-based" journals, such as ACP Journal Club, Evidence-Based Medicine, Evidence-Based Mental Health and Evidence-Based Nursing. His main interests are in the methodology for healthcare research and in improving healthcare through enhancing the validation, distillation, dissemination and application of healthcare knowledge.

Professor Wilfred C G Peh
Editor
Singapore Medical Journal

SINGAPORE MEDICAL COUNCIL CATEGORY 3B CME PROGRAMME

Multiple Choice Questions (Code SMJ 200409A)

	True	False
Question 1. Evidence-based medicine:		
(a) Is the integration of best research evidence with clinical expertise and patient values.	<input type="checkbox"/>	<input type="checkbox"/>
(b) Mandates the same treatment for all patients.	<input type="checkbox"/>	<input type="checkbox"/>
(c) Requires explicit and systematic use of clinical evidence.	<input type="checkbox"/>	<input type="checkbox"/>
(d) Uses the methods of clinical epidemiology.	<input type="checkbox"/>	<input type="checkbox"/>
Question 2. Which of the following are considered evidence?		
(a) Theoretical constructs.	<input type="checkbox"/>	<input type="checkbox"/>
(b) Results of experimental studies.	<input type="checkbox"/>	<input type="checkbox"/>
(c) Information from case series.	<input type="checkbox"/>	<input type="checkbox"/>
(d) Expert opinion based on clinical experience.	<input type="checkbox"/>	<input type="checkbox"/>
Question 3. Which of these statements regarding scientific studies is true?		
(a) Observational studies control for biases better than experimental studies.	<input type="checkbox"/>	<input type="checkbox"/>
(b) Only randomised controlled trials can be used as clinical evidence.	<input type="checkbox"/>	<input type="checkbox"/>
(c) Critical appraisal of studies is an important step before applying their results.	<input type="checkbox"/>	<input type="checkbox"/>
(d) Bibliographic databases are useful tools for locating scientific studies.	<input type="checkbox"/>	<input type="checkbox"/>
Question 4. Which of these are steps in practising EBM?		
(a) Framing the clinical question to be answered in terms of Patient, Intervention, Comparators and Outcomes.	<input type="checkbox"/>	<input type="checkbox"/>
(b) Finding the evidence.	<input type="checkbox"/>	<input type="checkbox"/>
(c) Careful analysis of the evidence.	<input type="checkbox"/>	<input type="checkbox"/>
(d) Application of the evidence and your own clinical experience to your patients.	<input type="checkbox"/>	<input type="checkbox"/>
Question 5. Useful aids for the practice of EBM include:		
(a) Critically-appraised topics.	<input type="checkbox"/>	<input type="checkbox"/>
(b) Secondary journals.	<input type="checkbox"/>	<input type="checkbox"/>
(c) Clinical practice guidelines.	<input type="checkbox"/>	<input type="checkbox"/>
(d) Systematic reviews.	<input type="checkbox"/>	<input type="checkbox"/>

Doctor's particulars:

Name in full: _____

MCR number: _____ Specialty: _____

Email address: _____

Submission instructions:**A. Using this answer form**

1. Photocopy this answer form.
2. Indicate your responses by marking the "True" or "False" box
3. Fill in your professional particulars.
4. Either post the answer form to the SMJ at 2 College Road, Singapore 169850 or fax to SMJ at (65) 6224 7827.

B. Electronic submission

1. Log on at the SMJ website: URL <http://www.sma.org.sg/cme/smj>
2. Either download the answer form and submit to smj.cme@sma.org.sg or download and print out the answer form for this article and follow steps A. 2-4 (above) or complete and submit the answer form online.

Deadline for submission: (September 2004 SMJ 3B CME programme): 25 October 2004**Results:**

1. Answers will be published in the SMJ November 2004 issue.
2. The MCR numbers of successful candidates will be posted online at <http://www.sma.org.sg/cme/smj> by 20 November 2004.
3. Passing mark is 60%. No mark will be deducted for incorrect answers.
4. The SMJ editorial office will submit the list of successful candidates to the Singapore Medical Council.