

Evidence-Based Medicine

Ibrahim Mansoor, MBBS.

ABSTRACT

Evidence-based medicine is one of the recently born explosively growing important issues, whose philosophical origins extend back to mid-19th century and remains a hot topic for clinicians, public health practitioners, purchasers, planners, and the public. Evidence-based health care has extended the application of the principles of evidence-based medicine to all professions associated with health care, including purchasing and management. So it is important for the up and coming young doctors and clinicians, and even other health care professions, to gain knowledge of critical appraisal and experience in the practice of evidence-based health care. This article gives a brief description of what evidence-based medicine is and how to practice evidence-based medicine and enlists some useful Internet sites that can provide assistance in understanding the subject in even greater detail.

Keywords: Evidence-Based Medicine, Evidence-Based Health Care, Critically Appraised Topics.

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Evidence-Based Medicine (EBM) is a newly evolved, rapidly growing discipline for learners and researchers, which has extended the application of its principles to all professions associated with health care, including purchasing and management. It is defined as "the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The practice of EBM means integrating individual clinical expertise with the best available external clinical evidence from systematic research."^{1-4,10} Evidence-based medicine has become a very renowned and hot topic and many centers for EB practice have been established in Europe, it is also planned in adult medicine, child health, surgery, pathology, pharmacotherapy, nursing, general practice, and dentistry; some centers for Review and Dissemination are providing systematic reviews of the effects of health care; as well, new EB practice journals are constantly being launched, so it has become a common topic in the lay media.⁴

What is EBM? Two million papers are published each year.¹⁰ Patients may benefit directly from a small fraction of these papers. The problem is how to find them? What principles should be applied

to find this, to the point, useful information? The solution is provided by EBM. A partial solution can be provided if searchers scan 50 journals trained in spotting papers that have a direct message for practice in patient care. Summaries of these are then published in EBM journals. Questions which are usually used to evaluate papers¹⁰ 1. Are the results valid? (Randomized? Blinded? Were all patients accounted for who entered the trial? Was follow-up complete? Were groups similar at the start? Were the groups treated equally, apart from the experimental intervention?). 2. What are the results? (How large was the treatment effect? How precise was the treatment effect?) 3. Will the results help my patients (cost-benefit sum).^{5,6} In this way the EBM provides a summary of to the point useful information to the busy clinicians, saving their time and proving them the maximum and best useful knowledge for patient care.¹⁰ The practice of EBM means integrating individual clinical expertise with the best available external clinical evidence from systematic research. By individual clinical expertise we mean the proficiency and judgement that individual clinicians acquire through clinical

From the Department of Histopathology, King Abdul Aziz University Hospital, Jeddah, Kingdom of Saudi Arabia.

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Address correspondence and reprint request to: Dr. Ibrahim Mansoor, c/o Mansoor Ali, PO Box 1432, Jeddah 21431, Kingdom of Saudi Arabia. Fax. +966 (2) 6613164. E-mail: ibm979@hotmail.com

experience and clinical practice. Increased expertise is reflected in many ways, but especially in more effective and efficient diagnosis and in the more thoughtful identification and compassionate use of individual patients' predicaments, rights and preferences in making clinical decisions about their care. By best available external clinical evidence, we mean clinically relevant research into the accuracy and precision of diagnostic tests (including the clinical examination), the power of prognostic markers, and the efficacy and safety of therapeutic, rehabilitative and preventive regimens. External clinical evidence both invalidates previously accepted diagnostic tests and treatments and replaces them with new ones that are more powerful, more accurate, more efficacious and safer.^{1,4} Good doctors use both individual clinical expertise and the best available external evidence, and neither alone is enough. Without clinical expertise, practice risks becoming oppressed by evidence, for even excellent external evidence may be inapplicable to, or inappropriate for an individual patient. Without current best evidence, practice risks become rapidly out of date, to the detriment of patients.⁴ Evidence-based medicine is not restricted to randomized trials and meta-analyses. It involves tracking down the best external evidence with which to answer clinical questions. To find out the accuracy of a diagnostic test, we need to find proper cross-sectional studies of patients clinically suspected of harboring the relevant disorder, not a randomized trial. For a question on prognosis, we need proper follow-up studies of patients assembled at a uniform, early point in the clinical course of their disease. Sometimes the evidence we need will come from the basic sciences such as genetics or immunology. It is when asking questions on therapy that we should try to avoid the non-experimental approaches, since these routinely lead to false-positive conclusions regarding efficacy. As the randomized trial and especially the systematic review of several randomized trials, is so much more likely to inform us and so much less likely to mislead us, it has become the "gold standard" for judging whether a treatment does more good than harm. However, some questions on therapy do not require randomized trials (successful interventions for otherwise fatal conditions) or cannot wait for the trials to be conducted. If no randomized trial has been carried out for our patient's predicament, we follow the trail to the next best external evidence and work from there.⁴ Despite its ancient origins, EBM remains a relatively young discipline whose positive impacts are just beginning to be validated⁷⁻⁹ and it will continue to evolve. This evolution will be enhanced as several undergraduate, post-graduate and continuing medical education programs adopt and adapt it to their learners' needs. These programs and their evaluation, will provide further information and understanding about what EBM is and what it is not.

Purpose of EBM. The purpose of EBM is to alert clinicians to important advances in internal medicine, general and family practice, surgery, psychiatry, pediatrics and obstetrics and gynecology by selecting from the biomedical literature those original and review articles whose results are most likely to be both true and useful. These articles are summarized in value-added abstracts and commented on by clinical experts. The procedures which are followed to achieve this purpose are:¹¹ 1. Detecting, using prestated criteria, the best original and review articles on the cause, course, diagnosis, prevention, treatment, quality of care, or economics of disorders in the foregoing fields. 2. Introducing these articles with declarative titles and summarizing them accurately in structured abstracts that describe their objectives, methods, results and EB conclusions. 3. Adding brief, highly expert commentaries to place each of these summaries in its proper clinical and health care context. 4. Disseminating these summaries in a timely fashion to clinicians. Journals are reviewed based on the proportion of articles that meet EBM criteria and are listed in each issue. Criteria for review and selection for abstracting: 1. General: All English-language original and review articles in an issue of a candidate journal are considered for abstracting if they concern topics important to the clinical practice of internal medicine, general and family practice, surgery, psychiatry, pediatrics, or obstetrics and gynecology. Access to foreign-language journals is provided through the systematic reviews we abstract, especially those in the Cochrane Library, which summarizes articles from 800 journals in several languages. 2. Studies of prevention or treatment: random allocation of the participants to the different interventions; outcome measures of known or probable clinical importance for 80% of the participants who entered the investigation. 3. Studies of diagnosis: inclusion of a spectrum of participants, some (but not all) of whom have the disorder or derangement of interest; either an objective diagnostic standard (such as a machine-produced laboratory result) or a contemporary clinical diagnostic standard (such as a venogram for deep venous thrombosis) with demonstrable reproducible criteria for any subjectively interpreted component (such as report of better-than-chance agreement among interpreters); interpretation of the test without knowledge of the diagnostic standard result; interpretation of the diagnostic standard without knowledge of the test result. 4. Studies of prognosis: an inception cohort of persons, all initially free of the outcome of interest; follow-up of 80% of patients until the occurrence of either a major study end point or the end of the study. 5. Studies of causation: a clearly identified comparison group for those at risk for, or having, the outcome of interest (whether from randomized, quasi-randomized, or

non-randomized controlled trials; cohort analytic studies with case-by-case matching or statistical adjustment to create comparable groups; or case-control studies); masking of observers of outcomes to exposures (assumed to be met if the outcome is objective [such as, all-cause mortality or an objective test]); observers of exposures masked to outcomes for case-control studies or masking of subjects to exposure for all other study designs. 6. Studies of quality improvement and continuing education: random allocation of participants or units to comparison groups; follow-up of 80% of participants; outcome measures of known or probable clinical importance. 7. Studies of the economics of health care programs or interventions. The economic question must compare alternative courses of action in real, not hypothetical patients; the alternative diagnostic or therapeutic services or quality improvement strategies must be compared on the basis of both the outcomes they produce (effectiveness) and the resources they consume (costs); evidence of effectiveness must come from a study (or studies) that meets criteria for diagnosis, treatment, quality assurance, or review articles; results should be presented in terms of the incremental or additional costs and outcomes incurred and realized by one intervention over another; and a sensitivity analysis should be carried out. 8. Clinical prediction guides: The guide must be generated in one set of patients (training set) and validated in an independent set of real not hypothetical patients (test set) and must pertain to treatment, diagnosis, prognosis, or causation. 9. Systematic reviews: The clinical topic being reviewed must be clearly stated; there must be a description of how the evidence on this topic was tracked down, from what sources, with what inclusion and exclusion criteria, and one article included in the review must meet the above-noted criteria for treatment, diagnosis, prognosis, causation, quality improvement, or the economics of health care programs.

Advantages of EBM. Evidence-based medicine is important for many reasons. It will not kill off the standard medical textbooks, but book publishers would do well to recognize the new trend and adjust their thinking. More confirmation of the ease and success with which EBM techniques can be incorporated into the undergraduate curriculum will be required before students can set fire to their copies of large standard text books.⁹ The main advantages of EBM are:¹⁰ 1. It improves our reading habits. It gives us best evidence in brief summary and saves our time. 2. It leads us to ask questions, then to be skeptical of the answers. 3. As taxpayers, we should like it (wasteful practices can be abandoned). Only the required and useful information and practice is provided. 4. Evidence-based medicine presupposes that we keep up to date and make it worthwhile to

take trips around the perimeter of our knowledge. 5. Evidence-based medicine opens decision-making processes to patients.

What is a “Critically Appraised Topic” (CAT). Every encounter with a patient identifies gaps in our knowledge about the etiology, diagnosis, prognosis, or therapy of their illness. Recent research reveals that even as seasoned clinicians we can generate about 5 knowledge “needs” for every inpatient we encounter¹² and about 2 “needs” for every 3 outpatients we see.¹³ In practicing EBM^{4,15} we:^{3,4} 1. translate these needs into answerable questions; 2. track down the best evidence to answer them; 3. appraise that evidence for its validity (closeness to the truth) and applicability (usefulness in our clinical practices) [we will call the written summary of these first 3 steps a “Critically Appraised Topic” or CAT]; 4. integrate that evidence with our clinical expertise and apply it in practice; 5. evaluate our performance.

Critically appraised topics are a tactic for helping clinical learners teach themselves how to formulate clinical questions; search for the best evidence; appraise, organize and summarize this evidence; integrate it with clinical expertise; and practice EBM. When generated by clinical teams, journal clubs, or in academic half-days, their educational value is multiplied. Existing CATs can be used as starting points for seeking and appraising updates in the relevant evidence. The CAT-maker assists this process by:^{3,4} 1. Carrying out the important clinical calculations; 2. Storing appraisals (as well as the search strategies that led to them); and 3. Generating files that can be formatted with word-processors, stored and printed for other team members.

Clinical value of CATs. Once we have found the evidence and are critically appraising it, we face 3 additional barriers: we often make mistakes in carrying out important clinical calculations (especially when they involve confidence intervals); we frequently misplace our critical appraisal as soon as it is carried out! It is a hassle making copies of it for our colleagues, students and trainees. So CAT is one of the important tools of EBM and it is a draft written summary of your new observation or experience from your patient management. An example will illustrate the topic more clearly for example while managing one of your non insulin dependent diabetes mellitus (NIDDM) patients with myocardial infarction (MI) and thought that as with insulin dependent diabetes mellitus (IDDM) patients a “tight control” of blood sugar might be helpful in preventing or postponing retinopathy and neuropathy, you wondered if a more aggressive treatment of this NIDDM patient might postpone his ultimate death. On the other hand, you remembered that insulin has an atherogenic effect and how you should back off insulin doses when diabetics developed angina pectoris. So you formulated a clinical question that “Among patients with NIDDM who are having MI’s,

does tight control of their blood sugar reduce their risk of dying?" Then you made a thorough search of the literature for related evidence. Finally by applying the appropriate users' guides for evidence on therapy,¹⁷ you decided that its results and conclusions are both valid and potentially important. You generated a one-page CAT, summarizing your patient and this evidence, and add it to your file of CATs. You can use this CAT for future reference and can even provide copies to your colleagues and students.

Educational value of CATs. General internal medicine fellows at McMaster University invented CATs as a means for sharpening their critical appraisal skills and improving their abilities as bedside teachers of EBM.¹⁶ At Oxford, learners generate CATs in response to the Educational Prescriptions¹⁸ they receive when they present patients recently admitted to the clinical service. Concise and portable in both concept and form, CATs have been adopted by several other institutions and incorporated into their undergraduate and postgraduate training programs. As they are patient-based, CATs appeal to clinical learners at every stage of their careers, from medical students to senior clinicians. As they are EB, they promote the acquisition and polishing of literature-searching and critical appraisal skills, as well as the integration of evidence with clinical expertise to form patient-care decisions. Far more educational value comes from creating a CAT than from just reading it 2nd hand. Thus, although CAT "banks" have been created at various sites, their value to browsers is mainly to show what can be achieved as starting points for updating CATs. Although most CATs are generated by individual learners, clinical teams or other groups (such as academic half-days for residents/trainees and "the different sort of journal club")¹⁹ have started to generate CATs as a group activity, ever member having examined the original evidence and then coming together to generate and record their "clinical bottom line" in a CAT. Critically appraised topics (and CAT - Makers!) are not limited to evidence about therapy. Evidence about diagnostic tests (including bits of the clinical history and physical examination) have been summarized in CATs, highlighting appraisal issues and calculations unique to diagnostics; so too for prognosis, causation and systematic reviews.

Limitations of CATs 1. Individual CATs can be wrong. Their emphasis on real time responses to real time clinical problems means that CATs will first appear as drafts, without peer review. These first drafts may contain inferior evidence, or errors of fact, calculation, or interpretation. This limitation can be transformed into an educational virtue by revising draft CATs in rounds and other educational events and one feature of our CAT bank in Oxford will be the opportunity for feedback, criticism and revision.

2. Individual CATs contain a single element of the relevant literature. Created in busy practices where busy clinicians decide that one piece of critically appraised evidence is better than none, CATs are based on quick searches for at least one useful article, not comprehensive explorations for all useful articles. Although many summarize systematic reviews, most are based on reports of single investigations and thus are at least incomplete and sometimes non representative of the entire body of evidence. 3. Individual CATs may have a short shelf life. They become obsolete as soon as newer, better evidence, becomes available. Unless they are updated on the basis of this newer, better evidence, their clinical bottom lines become out of date. For this reason, CAT-browsers will be wise to use them as the starting points for updated searches for newer, better evidence. To assist updating, users of the CAT maker are invited to specify their exact search strategy and also are invited to specify "sell-by" dates after which their CATs should be considered obsolete.⁴

In conclusion there is little doubt that, in any field where it is available, EBM can be better than what it is superseding. It may not have as much impact as it was hoped because gaining unimpeachable evidence is time consuming and expensive and perhaps impossible. Despite these caveats, EBM is one of the most exciting medical developments of the decade. Lets all join by subscribing to its ideals and its journals.

Useful Evidence-Based Medicine sites. Centre for Evidence-Based Medicine, Oxford, UK. <http://cebm.jr2.ox.ac.uk/> Canadian Medical Association <http://www.cma.ca/webmed/evi.htm> McMaster University, Hamilton, Ontario, CA <http://hiru.hirunet.mcmaster.ca/ebm/> Netting the Evidence:SchHARR, Sheffield, UK <http://www.shef.ac.uk/-schar/ir/netting.html> Evidence-Based on Call, Oxford, UK <http://cebm.jr2.ox.ac.uk/eboc/eboc.html>

Tools for Evaluating Evidence. Critically Appraised Topics (CAT Makers, Centre for EBM, Oxford, UK. <http://cebm.jr2.ox.ac.uk/docs/catmaker.html>

Guidelines. National Guideline Clearinghouse: <http://www.guideline.gov/> CDC-Prevention Guidelines <http://wonder.cdc.gov/wonder/prevguid/> Canadian Medical Association <http://www.cma.ca/cpgs/index.asp> Listing of Various Guideline Sites <http://www.ogh.on.ca/librarv/cpge.htm> Health Services Technology Assessment (HSTAT) <http://text.nlm.nih.gov/> UK Guideline Collection <http://www.ihs.ox.ac.uk/guidelines/index.html>

Online Evidence-Based Medicine Journals. Bandolier: Evidence-Based Health Care <http://jr2.ox.ac.uk/bandolier/> Evidence <http://www.Bangor.ac.uk/hs/evidence/> Evidence-Based Medicine <http://www.acponline.org/journals/ebm/ebmmenu.htm>

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