Eastern Journal of Medicine 15 (2010) 43-47

Review

Evidence based decision making in pediatric practice

Madhumita Nandi*, Rakesh Mondal

Department of Pediatric Medicine, Institute of Post-graduate Medical Education and Research, SSKM Hospital, Kolkata, India

Abstract. Evidence Based Medicine (EBM) is integrating individual clinical expertise with the best available external evidence from systematic research. It has made rapid strides in the last ten years with an increase in the number of EBM centers, books and agencies. The supporters of EBM claim that it is the best and most objective system of medicine. Its opponents criticize it for many reasons referring to EBM as 'cook-book' medicine and the fad of epidemiologists etc. Though EBM centers are coming up at a fast rate in the western world, our part of the world has not yet fully aligned with this initiative. The purpose of this communication is to introduce EBM to pediatricians. Provided herein, is a brief introduction followed by brief history, how to incorporate evidence-based practice into the clinical setting and the main criticisms against it.

Key words: Evidence based medicine (EBM), evidence based child-health

1. Introduction

In this era of rapidly expanding medical information, it is really difficult to keep oneself up-to-date with all the latest developments. It has been calculated that a clinician would have to read at least 19 articles a day, 365 days a year just to keep abreast of the latest developments. For a pediatrician, this figure is 1694 articles a year or at least 5 articles a day. So to make this task somewhat easier, the system of Evidence Based Medicine (EBM) has gradually evolved over the past few decades which can give scientifically validated medical information in a short time and which is also easily retrievable and reproducible. This approach aids a busy clinician in retrieve and reviewing information in a way that minimizes reading time to access maximum possible, selective and patient-driven medical information (1-5).

EBM was defined for the first time by DL Sackett and his colleagues, the pioneers in this field 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).

*Correspondence: Dr. Madhumita Nandi
6/6,Naren Sarkar Road, Barisha, Kolkata, 700008,West Bengal, INDIA
Phone: +919433166790
E-mail: madhumitabanik@rediffmail.com

2. History

Philosophical origins of EBM date back to the mid 19th century Paris when clinicians like Pierre Louis rejected pronouncements of authorities and sought the truth in systematic observation of patients (6). Ancient Chinese medicine also practiced EBM in some way (7). In modern times, the clamor to shift to EBM started about 25 years back with its proponents insisting that it was improper to practice medicine in any other form. Rapid strides in the past ten years resulted in the launching of many Evidence Based Centres, books and agencies. The name Evidence Based Medicine was given in 1992 by a group led by Gordon Guyatt at McMaster University in Canada. But, before that in 1987, the Health Information Research Unit (HIRU) was established in the Department of Clinical Epidemiology and Biostatistics at McMaster University as the first informatics research unit in the Canadian faculty of Health Sciences. The idea of such a unit sprang from the observation that the transfer of health research (evidence) into (clinical) practice appeared to be lost in the maze of information generation. HIRU's main goal is to study the problems of research transfer and to develop and test innovations based on information technology (informatics) that will improve the transfer of evidence into practice. HIRU is promoting what could be described as "Evidence Based Health Informatics" (3). HIRU hosts the editorial office of three international EBM publications: ACP journal club (online-http://www. acpjc. org/ and http://www. ovid. com/), Evidence Based Medicine (http://www.

bmjupdates.com) and Evidence Based Nursing (http://www. evidencebasednursing. com).

When the EBM journal was launched jointly by the BMJ and The Annals of Internal Medicine in 1995, the editors of the journal wrote- 'the new journal's mission was to publish the gold that intellectually intense processes will mine from the ore of 100 of the world's top journals. So it seemed that the 'other journals' which published the 'ores' were apparently unaware of the 'gold' in their pages awaiting discovery by the intellectual processes (5)!! HIRU has also launched a project called GUIDE Project- Gaining a better Understanding of the role of the Internet on Decision based on Evidence.

The Cochrane Collaboration was launched by Archie Cochrane in 1992 for systematic review of over 600 peer reviewed journals. It was the most important milestone in the history of EBM. It is now an international body dedicated to producing systematic reviews of the effects of health care using Randomized Controlled Trials as the primary study design. The Cochrane Library, updated quarterly, is produced as a CD-ROM and is accessible on the internet (www.cochrane.uottawa.ca./). It contains high quality independent evidence from Cochrane and other systematic reviews, clinical trials and more. Cochrane reviews bring us the combined results of the world's best medical research studies and are recognized as the gold-standard in evidence based health care (4). Then the Centre for Evidence Based Child Health was established in 1995 by the Great Ormond Street Hospital Trust and Institute of Child Health, London as a part of national network of Centres for Evidence Based Health Care. This centre's activities build on the experience and expertise of the Centre of Pediatric Epidemiology and Bio-Statistics and on the clinical links with the Great Ormond Street Hospital. The overall aim of the center is to increase the provision of effective and efficient child health care through the education and research programme designed to help clinicians acquire the necessary skills to integrate the critical analyses of evidence underpinning their day to day decisions into their practice.

The United States based Agency for Health Care Research and Quality (AHRQ) launched the New England Medical Centre Evidence Based Practice Centre (EPC) in Boston around the same time (5). Another hallmark was the publication of the book- How to practice and teach Evidence Based Medicine by David l Sackett et al which is running into its fourth edition (1). Many more EBM journals, centers and agencies have come up. It remains a hot topic of discussion for clinicians, public health practitioners, purchasers, planners and also the public at large in the western world. There are now frequent workshops on how to practice and teach evidence based practice, undergraduate and postgraduate programmes are incorporating it (or wondering how to do it!) as well as the lay media is also focusing on it.

Our side of the world is yet to embrace EBM, though a few sincere efforts have already started. The Indian Academy of Pediatrics (IAP) has been collaborating with Royal College of Pediatrics and Child Health (RCPCH) and the Centre for Evidence Based medicine, London in this regard. The Indian Pediatrics (official journal of IAP) has started a column called EURECA (Evidence that is Understandable, Relevant, extendible. Current and Appraised critically) which deals with evidence based child health (8). But, for promotion and practice of EBM in a big way in all parts of the world, we need to have research data relevant and valid for child health in the context of the local population.

3. Basic Steps

Five basic steps have been described in the approach to EBM (9):

1. Framing an answerable clinical question. The key elements of a well-framed question include a description of the patient or the population, the type of intervention or exposure, the comparisons of these interventions and the clinical outcome of interest.
2. Searching for the best evidence. This is likely to involve searching electronic databases like the Medline, EMBASE, CINAHL and The Cochrane Library. These search strategies may involve the expertise of the information scientists who can adjust the search strategy to maximizing finding of all relevant studies.

Table 1. Research pyramid of study designs (9)

Systematic Review of Randomized Controlled Trials
Confirmed Randomized Controlled Clinical Trials
Single Randomized Controlled Clinical Trial
Non-Randomized Controlled Clinical Trial
Case Controlled Observational Studies
Analyses of Large Computer Databases
Case Series with Historical Controls
Case Series with Literature Controls
Uncontrolled Case Studies
Anecdotal Case Report

Table 2. Quality of evidence (16)

I: Evidence obtained from systematic reviews or meta-analyses of properly conducted randomized controlled clinical trials.
II-1: Evidence obtained from well-designed controlled clinical trials without randomization.
2: Evidence obtained from well designed cohort or case-control analytic studies preferably from more than one center or research group.
3: Evidence obtained from comparisons between time and places with or without the intervention.
III: Opinion of respected authorities, based on clinical experience, descriptive studies or reports of expert committees.

Table 3. Classification of recommendations (16)

A: There is *good* evidence to support the recommendation that the intervention be performed.
B: There is *fair* evidence to support the recommendation that the intervention be performed.
C: There is *poor* evidence regarding the value or harm of the recommendation. Recommendation may be made on other grounds.
D: There is *fair* evidence to support the recommendation that the intervention *not* be performed.
E: There is *good* evidence to support the recommendation that the intervention *not* be performed.

3. Critical appraisal of the available evidence. Tools have been developed to appraised studies evaluating diagnostic tests, prognostic markers, adverse effects and systematic overviews. A hierarchy of the various study designs have been developed keeping the most robust one at the top and the least robust one at the bottom. Table 1 provides an example. Based on the robustness of the study design, the various levels of evidence have been classified into Level I, II or III (Table2) and depending on these levels various gradations of recommendations have been developed for clinical consideration (Table3).
4. Application of the evidence to clinical practice in which clinical expertise and patient values are integrated with the best available external evidence. To do this, the clinician needs to ask two questions- Is the evidence sufficiently robust to be confident in its application and is the evidence relevant to the patient or population setting?
5. Self- evaluation of the effectiveness and efficiency in executing steps 1-4 and seeking ways to improve them for the next time.

4. Caveats

EBM should not be given an easy ride. We need to prevent misinterpretations, misunderstandings and unintended affronts. As Sackett himself has said- "We should build upon rather than disparage or neglect the knowledge gained from good clinical skills and sound clinical experience. Rather, it needs a high level of clinical acumen to arrive at a sound evidence based therapeutic decision" (10-13). The following criticisms and apprehensions have often been made about the validity of EBM.

1) Bias-Even the most robustly designed double blind, placebo-controlled RCT may suffer from biases like the influence of sponsors, adamancy of experts etc. A study published in the BMJ in 2000 compared the systematic reviews and meta-analyses on asthma published by the Cochrane Collaboration with those published in various paper-based peer reviewed journals (14). Out of a total of 150 RCT's and meta-analyses which were reviewed for general characteristics, data synthesis and methodological quality- 40 reviews were judged to have serious or extensive flaws. All 6 reviews associated with the pharmaceutical industry were in this group! Most of the rigorous reviews were published in the Cochrane Database that contains reviews which are more frequently updated, rigorous and better reported. It concluded that most reviews published in the peer-reviewed journals or funded by the industry have serious methodological flaws that limit their value to guide clinical decisions.

2) Cook-Book Medicine.-Some clinicians argue that it is cook-book medicine promoted by arm-chair public health researchers and epidemiologists from their ivory-towers without any direct contact with the patients. It is troublesome if the approach to EBM emphasizes only the techniques of literature searching. To make it more useful, clinicians have to integrate the best available external evidence with their routine clinical practice (5-9).

3) Experience and skills are not important. The most frequently voiced criticism is- 'Is the clinicians experience not needed if there are sufficient data?' Many experts suggest that experience and skills of the clinician are as valuable as randomized clinical trial results when considering the execution of these findings to a particular patient. Good doctors should use both individual clinical expertise and best available external evidence- neither alone is enough. Otherwise, clinical practice risks being tyrannized by evidence that may not be aptly suited to every individual patient case (9,10-13).

4) Different patient backgrounds are not important. Another frequently voiced concern is- 'Are patient backgrounds, which may vary widely, not relevant in distinguishing the coarse of medical management?' We believe they are and that is why it is included in the patient history, a key element in patient evaluation. Errors will be made if we rely only on clinical data obtained from RCT's of patients with different ethnic, cultural and socio-economic backgrounds. A trial result based on an American or a Canadian population may not be extrapolated or applicable to an Indian patient population. To incorporate evidence based practice into medicine, we need to first have scientifically validated trial data in our patient population.

5) The practice is daunting. Some feel it is overwhelming to learn to incorporate an evidence based practice model into medicine. We have to develop new skills in information searching and critical appraisal. But newer up and coming EBM centers and journals provide clinicians with pre-appraised resources (3,4,5).

6) **Evidence based child-health is difficul**t. To some extent, this is true. Difficulties may arise in pediatric clinical practice with 'Evidence Based Child Health'. The paucity of well-designed research studies with infants and children results in less evidence available on both common and rare problems. When child health is compared to adult health care, research questions in children may have been addressed either not at all or by small poorly designed studies. Even the recent edition of Forfar and Arneil's Textbook of Pediatrics says that- When contributors were questioned about levels of evidence cited, they expressed frustration at the lack of level I evidence available for them in many different disease areas (9).

There are different reasons why it is more difficult to undertake clinical trials in children than in adults. First, obvious ethical dilemmas arise. Second, the proportion of children affected by chronic diseases is smaller than in adults. Third, even if the condition is common, the condition may be more heterogeneous and diagnostic criteria less precise like for example, childhood asthma. And last, outcome measures which have been developed and validated in adults such as quality of life measures are unlikely to be appropriate or feasible for young children and infants.

All these lead to a dearth of clinical evidence in child health. However, there are encouraging signs that these deficiencies are being identified and initiatives are being made to promote research that will meet these needs. For example, FDA in 1997 mandated that new drugs brought to the market should be tested in children unless compelling reasons exit suggesting they not be tested. In UK, the Cystic Fibrosis trust has established a clinical trials group to facilitate the conduct of high quality multi-center trials (9). Cincinnati Children's Hospital Medical Centre has also established a centre of excellence for practice of Evidence Based Pediatrics (15).

7) **Therapeutic nihilism in the absence of RCTs.** There is also concern that EBM may lead to therapeutic nihilism in the absence of evidence from randomized controlled trials. But, this is unlikely. EBM categorizes different types of clinical evidence and ranks them according to the strength of their freedom from various biases (Table1) (7). So when RCT's are not available, one can fall back on observational studies. When these are also not available, we should examine lower levels of evidence with less systematic observation and decide whether it is applicable to our patient population and the case at hand.

8) Difficult to keep track of updates. EBM may be very difficult to keep up with the pace of new research findings being reported. The best available evidence today may soon be out-of date tomorrow.

9) Danger to progress. Some fear that EBM may be a hindrance to progress. To quote a letter to the editor in the Lancet-'If Albert Einstein were to follow EBM, he would never have deduced the principles of theoretical physics which have changed our view of the world. If everything has to be double blinded, placebo-controlled, randomized and evidence based, where does that leave scope for new ideas? If evidence based medicine becomes the dominant thinking, it could impede advances in medicine (10)'.

Keeping all these things in mind, we should not be blind followers of EBM. We have to review, interpret, evaluate and master the findings of the evidence being presented and suggested rather than blindly allowing the evidence to rule us. We

have to apply the principles of EBM to extract the 'gold' from the unlimited 'ore' of medical literature. Remember that every patient is unique in his own way. We have two ears to listen, two eyes to look, two hands to examine and two hemispheres to deduce. So we should search for the best possible external evidence with our two eyes and ears, but we must use our two hands to examine the patient and our two hemispheres to deduce what we have seen, heard and felt and then develop a final decision as to what would be best for an individual patient.

References

1. Sackett DL, Straus SE, Richardson WS, Rosenberg W, Haynes RB. Evidence-Based Medicine: How to Practice and Teach EBM. Edinburgh, U.K.: Churchill Livingstone 2005.
2. Jaeschke R Guyatt GH. What is evidence-based medicine? Sem Med Practice 1999; 2: 3-7.
3. Health Information Research Unit (HIRU), Evidence Based Health informatics, Department of Clinical Epidemiology and Biostatistics, McMaster University Website. Available at: http://hiru.mcmaster.ca/hiru/Accessed September 12, 2009
4. Canadian Cochrane Centre, The Cochrane Library Website. Available at: http://www.ccnc.cochrane.org/Accessed September 12, 2009
5. Agency for Health Care Research and Quality,U.S Department of health and Human services Website. Available at: http://www.ahrq.gov/ Accessed on September 12,2009
6. Morabia A. In defense of Pierre Louis who pioneered the epidemiological approach to good medicine. J clin Epidem 2009: 62: 1-4.
7. Shea JL. Applying Evidence-Based Medicine to Traditional Chinese Medicine: Debate and Strategy. Journal of alternative and complimentary medicine 2006; 12: 255-263.
8. Mathew JL, Singh M. Evidence based child health: Fly but with feet on the ground Editorial. Indian Pediatrics 2008; 45: 95-98.
9. Smyth RL- Evidence Based Child health in Forfar and Arneil's Textbook of Pediatrics-6th Edition,Eds- McIntosh N, Helms P, Smyth RL. Churchill Livingstone 2003: pp3-10.
10. Sackett DL, Rosenberg WM, Gray JA, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. BMJ 1996; 312: 71-72.
11. Sackett D. Evidence Based Medicine: In its place; Lancet 1995; 346: 785.
12. John W. Evidence-Based Medicine in Japan. Lancet 2005; 336: 112.
13. Hadi I. Evidence Based Medicine. Why and How? KMJ200638: 1-2.
14. Jadad AR, Moher M, Browman G, et al. Systematic Reviews and meta-analyses on treatment of asthma: critical evaluation. BMJ 2000; 320: 537-540.
15. Cincinnati Children's Hospital Medical Centre.Evidence Based Care guidelines Website. Available at: http://www.cincinnatichildrens.org/svc/alpha/h/health-policy/ev-based/Accessed September 12, 2009
16. Feldman W. Evidence Based Pediatrics B.C. Decker Inc 2000.