EVIDENCE BASED CHILD HEALTH 1

Principles of evidence based medicine

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Health care professionals are increasingly required to base clinical decisions on the best available evidence. Evidence based medicine (EBM) is a systematic approach to clinical problem solving which allows the integration of the best available research evidence with clinical expertise and patient values. This paper explains the concept of EBM and introduces the five step EBM model: formulation of answerable clinical questions; searching for evidence; critical appraisal; applicability of evidence; evaluation of performance. Subsequent articles will focus on the principles and critical appraisal of randomised controlled trials, systematic reviews, and meta-analyses, and provide a practical demonstration of the five step EBM model using a real life clinical scenario.

WHAT IS EVIDENCE BASED MEDICINE?

The concept of evidence based medicine (EBM), defined as the ''integration of best research evidence with clinical expertise and patient values'',[1] has been gaining popularity in the past decade. The practice of EBM involves a process of lifelong self directed learning in which caring for patients creates the need for important information about clinical and other health care issues. EBM recognises that the research literature is constantly changing.[2] What the evidence points to as the best method of practice today may change next month or next year. The task of staying current, although never easy, is made much simpler by incorporating the tools of EBM such as the ability to track down and critically appraise evidence, and incorporate it into everyday clinical practice.

The work of people in the field of paediatrics and child health centres on the problems of children and their families and carers. Questions about diagnosis, prognosis, and treatment often arise and sometimes the answers to these questions need to be sought. EBM allows the integration of good quality published evidence with clinical expertise and the opinions and values of the patients and their families or carers. Deciding on how to treat patients should not be based solely on the available evidence. Other factors such as personal experience, judgement, skills, and more importantly patient values and preferences must be considered.

The practice of EBM should therefore aim to deliver optimal patient care through the integration of current best evidence and patient preferences, and should also incorporate expertise in performing clinical history and physical examination. Figure 1 illustrates a typical flow chart of EBM, depicting how knowledge and experience may be integrated with patients' preferences and available evidence in the making of clinical decisions.

WHY EVIDENCE BASED MEDICINE?

The most important reason for practising EBM is to improve quality of care through the identification and promotion of practices that work, and the elimination of those that are ineffective or harmful.[4] EBM promotes critical thinking. It demands that the effectiveness of clinical interventions, the accuracy and precision of diagnostic tests, and the power of prognostic markers should be scrutinised and their usefulness proven. It requires clinicians to be open minded and look for and try new methods that are scientifically proven to be effective and to discard methods shown to be ineffective or harmful.

It is important that health care professionals develop key EBM skills including the ability to find, critically appraise, and incorporate sound scientific evidence into their own practice.

THE FIVE STEP EBM MODEL

The practice of EBM involves five essential steps[3 5]: first, converting information needs into answerable questions; second, finding the best evidence with which to answer the questions; third, critically appraising the evidence for its validity and usefulness; fourth, applying the results of the appraisal into clinical practice; and fifth, evaluating performance.

Step 1: Formulating answerable clinical questions

One of the difficult steps in practising EBM may be the translation of a clinical problem into an answerable question.[6] When we come across a patient with a particular problem, various questions may arise for which we would like answers. These questions are frequently unstructured and complex, and may not be clear in our minds. The practice of EBM should begin with a well formulated clinical question. This means that we should develop the skill to convert our information needs into answerable questions. Good clinical questions should be clear, directly focused on the problem at hand, and answerable by searching the medical literature.[7]

A useful framework for making clinical questions more focused and relevant has been suggested by Sackett *et al*.[1] They proposed that

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Abbreviations: EBM, evidence based medicine; CASP, critical appraisal skills programme

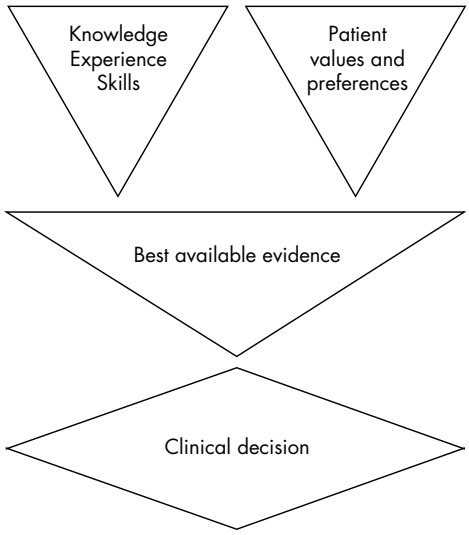

Figure 1 Flow chart of evidence based medicine.[3]

a good clinical question should have four (or sometimes three) essential components:

- the patient or problem in question;
- the intervention, test, or exposure of interest;
- comparison interventions (if relevant);
- the outcome, or outcomes, of interest.

Thus an answerable clinical question should be structured in the **PICO** (**P**atient or **P**roblem, **I**ntervention, **C**omparison, **O**utcome/s) or **PIO** (**P**atient or **P**roblem, **I**ntervention, **O**utcome/s) format.

To illustrate the concept of PICO/PIO, imagine that you have a four month old baby admitted to your ward with viral bronchiolitis. The child's symptoms get progressively worse and you wonder whether giving corticosteroids might help the child improve and reduce the length of stay in hospital. You decide to use ''clinical score'' as a measure of improvement. The key components of your clinical question would be:

Patient or problem: 4 month old baby with viral bronchiolitis.
Intervention: corticosteroids.
Comparison: no corticosteroids.
Outcomes: clinical score, length of hospital stay.

A four part clinical question may be formulated as follows: *In a 4 month old baby with viral bronchiolitis, does the administration of corticosteroids compared with not giving corticosteroids improve clinical score and reduce length of hospital stay?*

Step 2: Finding the evidence

Once you have formulated your clinical question, the next step is to seek relevant evidence that will help you answer the question. There are several sources of information that may be of help. Traditional sources of information such as textbooks and journals are often too disorganised or out of date.[8] You may resort to asking colleagues or ''experts'' but the quality of information obtained from this source is variable. Secondary sources of reliable summarised evidence which may help provide quick evidence based answers to specific clinical questions include *Archimedes* (http://adc.bmjjournals.com/cgi/collection/archimedes), *Clinical Evidence* (http://www.clinicalevidence.com/ceweb/conditions/index.jsp), and *BestBets* (http://www.bestbets.org/index.html).

Other important sources of evidence include the online electronic bibliographic databases, which allow thousands of articles to be searched in a relatively short period of time in an increasing number of journals. The ability to search these databases effectively is an important aspect of EBM. Effective searches aim to maximise the potential of retrieving relevant articles within the shortest possible time. Studies have shown that, even in countries where hospitals have facilities for internet access allowing health care personnel access to a number of electronic databases, many people are not familiar with the process of carrying out efficient searches and often conduct searches which result in too few or too many articles.[9 10] It is therefore important for health care professionals to undergo basic training in search skills, either through their local library services or through the attendance at formal courses.

BASIC SEARCH PRINCIPLES

Convert the clinical problem into an answerable question

The key to successful searching is to convert your clinical problem into a clear answerable question, which should ideally be framed in the PICO/PIO format as discussed above.

Generate appropriate keywords

A word list can be generated, based on keywords from the clinical question. For example, from the clinical question above, the following keywords could be used for the search: viral bronchiolitis (*patient or problem*); corticosteroids and synonyms: glucocorticoids, steroids, prednisolone, dexamethasone (*intervention*); clinical score, hospital stay (*outcomes*)

Choose a bibliographic database

Numerous online databases are available. These include the Cochrane Library databases, MEDLINE, EMBASE, and CINAHL. In day to day clinical practice, I will suggest that becoming familiar with one or two databases will suffice in most cases. I recommend the Cochrane Library databases and MEDLINE. The Cochrane Library databases—which include the Cochrane database of systematic reviews, the Database of abstracts of reviews of effectiveness, and the Cochrane controlled trials register—is maintained by the Cochrane collaboration, an international initiative which began in the early 1990s and was designed to prepare, maintain, and disseminate systematic reviews of health care interventions.[3] The Cochrane Library is updated quarterly and is available through the internet or CD-rom. There is usually a charge for

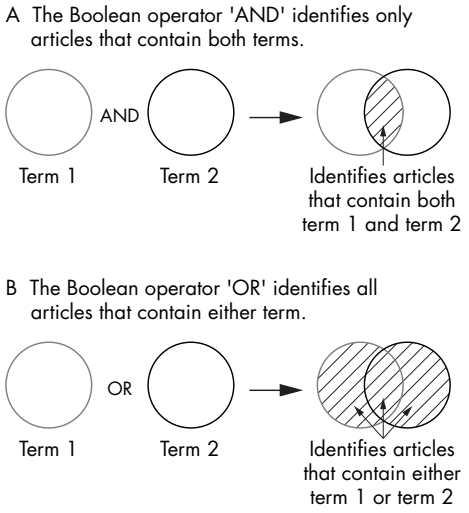

Figure 2 Venn diagram illustrating the use of Boolean operators AND and OR.

using the library, although NHS staff in the United Kingdom have free access to the service through the National Electronic Library for Health.

MEDLINE is probably the most widely used database for searching the biomedical literature.[3] It is maintained by the National Library of Medicine, USA. A version of MEDLINE (PUBMED) is freely available on the internet, is updated regularly, and is relatively user friendly.

When looking for articles on effectiveness of interventions or treatments, the first point of call should probably be the Cochrane database of systematic reviews or the other secondary sources mentioned above such as Archimedes, Clinical Evidence, and BestBets. The Cochrane controlled trials register provides an index of published randomised controlled trials. Randomised controlled trials and systematic reviews may also be searched for using MEDLINE. SUMsearch (http://sumsearch.uthscsa.edu) is a useful search engine that allows direct searches of external databases with a focus on clinical topics.

Conduct the search

Once the key words and databases have been identified, the next thing is to run the search. At the basic level, an efficient method is to combine individual words or terms using the Boolean operators ''AND'' and ''OR''.[11] If you are combining two terms, AND allows only articles containing both terms to be retrieved, while OR allows articles containing either term to be retrieved. A simple Venn diagram consisting of two overlapping circles may be used to illustrate this principle. In fig 2A, the two terms have been combined using AND, and in fig 2B, they are combined using OR.

When too many articles come up after the initial search (which is often the case), PUBMED has a feature that allows you to limit the results of your search. You can limit your search by publication type (for example, randomised controlled trials or review articles); by date of publication; by language, by study population, and so on. PubMed also has a feature called ''Clinical queries'' which provides an easy to use approach to evidence based searching within the Medline database. ''Clinical queries'' is a preprogrammed research methodology filter that helps busy practitioners access the best available evidence by providing a quick access to reliable clinical studies related to therapy, diagnosis, aetiology, or prognosis.

Example of a basic search strategy

To try to find evidence to answer the clinical question I formulated earlier, we can use the keywords generated to search the Cochrane database of systematic reviews and PUBMED, using the following search strategy:

- (1): Viral bronchiolitis
- (2): Corticosteroids OR steroids OR glucocorticoids OR prednisolone OR dexamethasone
- (3): Clinical score OR hospital stay
- (4): (1) AND (2) AND (3).

When this search strategy was used to search the Cochrane database of systematic reviews on 10 December 2004, four articles were retrieved, but only one of these was relevant.[12]

Other strategies that may be used to improve the sensitivity and specificity of literature searches have been described by Sackett *et al*.[1]

Step 3: Appraising the evidence

After you have obtained relevant articles on a subject, the next step is to appraise the evidence for its validity and clinical usefulness. Although there is a wealth of research articles available, the quality of these is variable. Putting unreliable evidence into practice could lead to harm being caused or limited resources being wasted.

Research evidence may be appraised with regard to three main areas: validity, importance, and applicability to the patient or patients of interest. Critical appraisal provides a structured but simple method for assessing research evidence in all three areas.[13] Developing critical appraisal skills involves learning how to ask a few key questions about the validity of the evidence and its relevance to a particular patient or group of patients. Such skills may be learnt within small tutorials, workshops, interactive lectures, and at the bedside.[13]

Several tools for appraising research articles are available. I like the tools developed by the Critical Appraisal Skills Programme (CASP), Oxford, UK. These include tools for appraising randomised controlled trials, systematic reviews, case–control studies, and cohort studies. The CASP tools are simple, easy to use, and freely available on the internet.[14]

A detailed discussion of the critical appraisal of randomised controlled trials and systematic reviews will be provided in the next two articles of the series.

Step 4: Applying the evidence

When we decide after critical appraisal that a piece of evidence is valid and important, we then have to decide whether that evidence can be applied to our individual patient or population. In deciding this we have to take into account the patient's own personal values and circumstances. The evidence regarding both efficacy and risks should be fully discussed with the patient or parents, or both, in order to allow them to make an informed decision. This approach allows a ''therapeutic alliance'' to be formed with the patient and the parents and is consistent with the fundamental principle of EBM: the integration of good evidence with clinical expertise and patient values.[15] The decision to apply evidence should also take account of costs and the availability of that particular treatment in your hospital or practice. A practical illustration of issues to consider before applying research evidence will be provided in the fourth article of the series.

Step 5. Evaluating performance

As we incorporate EBM into routine clinical practice, we need to evaluate our approach at frequent intervals and to decide whether we need to improve on any of the four steps discussed above. As Strauss and Sackett have suggested, we need to ask whether we are formulating answerable questions, finding good evidence quickly, effectively appraising the evidence, and integrating clinical expertise and patient's values with the evidence in a way that leads to a rational, acceptable management strategy.[15] Formal auditing of performance may be needed to show whether the EBM approach is improving patient care.

CONCLUSIONS

EBM aims to improve quality of care through the integration of best research evidence with clinical expertise and patient's and parents' preferences. In this article, I have explained the five essential steps for practising EBM, which are: formulating answerable clinical questions; searching for evidence; making a critical appraisal; assessing the applicability of the evidence; and evaluating performance. The principles and critical appraisal of randomised controlled trials, systematic reviews, and meta-analyses, and a practical demonstration of the five step EBM model will be explored further in later articles in this series.

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EVIDENCE BASED CHILD HEALTH 2

Understanding randomised controlled trials

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The hierarchy of evidence in assessing the effectiveness of interventions or treatments is explained, and the gold standard for evaluating the effectiveness of interventions, the randomised controlled trial, is discussed. Issues that need to be considered during the critical appraisal of randomised controlled trials, such as assessing the validity of trial methodology and the magnitude and precision of the treatment effect, and deciding on the applicability of research results, are discussed. Important terminologies such as randomisation, allocation concealment, blinding, intention to treat, p values, and confidence intervals are explained.

In the first article of the series,[1] I described evidence based medicine (EBM) as a systematic approach to clinical problem solving, which allows the integration of the best available research evidence with clinical expertise and patient values. In this article, I will explain the hierarchy of evidence in assessing the effectiveness of interventions or treatments, and discuss the randomised controlled trial, the gold standard for evaluating the effectiveness of interventions.

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HIERARCHY OF EVIDENCE

It is well recognised that some research designs are more powerful than others in their ability to answer research questions on the effectiveness of interventions. This notion has given rise to the concept of ''hierarchy of evidence''. The hierarchy provides a framework for ranking evidence that evaluates health care interventions and indicates which studies should be given most weight in an evaluation where the same question has been examined using different types of study.[2]

Figure 1 illustrates such a hierarchy. The ranking has an evolutionary order, moving from simple observational methods at the bottom, through to increasingly rigorous methodologies. The pyramid shape is used to illustrate the increasing risk of bias inherent in study designs as one goes down the pyramid.[3] The randomised controlled trial (RCT) is considered to provide the most reliable evidence on the effectiveness of interventions because the processes used during the conduct of an RCT minimise the risk of confounding factors influencing the results. Because of this, the findings generated by RCTs are likely to be closer to the true effect than the findings generated by other research methods.[4]

The hierarchy implies that when we are looking for evidence on the effectiveness of interventions or treatments, properly conducted systematic reviews of RCTs with or without meta-analysis or properly conducted RCTs will provide the most powerful form of evidence.[3] For example, if you want to know whether there is good evidence that children with meningitis should be given corticosteroids or not, the best articles to look for would be systematic reviews or RCTs.

WHAT IS A RANDOMISED CONTROLLED TRIAL?

An RCT is a type of study in which participants are randomly assigned to one of two or more clinical interventions. The RCT is the most scientifically rigorous method of hypothesis testing available,[5] and is regarded as the gold standard trial for evaluating the effectiveness of interventions.[6] The basic structure of an RCT is shown in fig 2.

Abbreviations: Abbreviations: CONSORT, consolidated standards of reporting trials; EBM, evidence based medicine; PCDAI, paediatric Crohn's disease activity index; RCT, randomised controlled trial