Chapter 30 Evidence-based medicine

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Introduction

Doctors and other healthcare workers must not only keep pace with the rapid changes in medical knowledge, they must assimilate new relevant and valid research into their clinical expertise, and appropriately alter their clinical practice and organisation. The practice of evidence-based medicine (EBM) is a process of lifelong, self-directed learning, in which caring for our patients gives rise to clinically important questions and information about diagnosis, therapy, prognosis and other aspects of healthcare. The methods of EBM aim to provide skills that help clinicians to rapidly assimilate new evidence and ideas and put them into practice.

We can summarise the EBM approach as a five-step process (Sackett et al 2000):

- · asking answerable clinical questions
- · searching for the best research evidence
- · critically appraising the evidence for its validity and relevance
- · applying the evidence to groups and individuals
- · evaluating your own self-education performance.

To be able to teach these well you should first reflect on your own practice. How well are you keeping up to date? How often are you finding answers to the questions that arise in your practice? If you don't currently feel proficient, then you might consider one of the many available courses in practising and/or teaching EBM (for example, see the website of the Oxford Centre for Evidence-Based Medicine).

Introductory lecture - an hour on awareness raising

Any course you will teach will need to identify the key themes and concepts — to give a road map of where we are going and why. Initial concepts include the nature of EBM (sometimes called 'evidence-based practice'), the problem of information overload, the need to discriminate between good and poor quality evidence, and how EBM can help.

Important themes

Important themes include the attempt to keep up to date and the problem of how to select from the ever-increasing world literature. Over 20 000

"Evidence based medicine is the conscientious, explicit and judicious use of the best current evidence in making decisions about the care of individual patients"

Sackett et al 2000

"Change your thought and you change your world"

Norman Vincent Peale

"My students are dismayed when I say to them 'Half of what you are taught as medical students in 10 years has been shown to be wrong. And the trouble is, none of your teachers knows which half."

Dr Sydney Burwell, Dean of Harvard Medical School "Doctors are inundated with new, often poorly evidence-based and sometimes conflicting clinical information. This is particularly serious for the generalist, with over 400 000 articles added to the biomedical literature each year"

Dave Davis

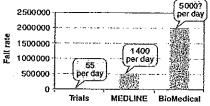


Fig. 30.1 The amount of medical research

"There is no such thing as a long piece of work, except one that you dare not start"

Charles Baudelaire

randomized controlled trials (RCTs) are published each year (with a cumulative total of over 350 000) and approximately 50 new trials are published every day (Fig. 30.1). A general practitioner would have to read one RCT every half hour, night and day, to keep up to date just with the results of trials.

You might stop and ask your learners to reflect on how they currently learn and keep up to date. You might also ask them how much time is being spent on each process. Activities usually identified include: attending lectures and conferences; reading articles in journals; tutorials; using textbooks and clinical guidelines; clinical practice; small-group learning and study groups; using electronic resources, and speaking to colleagues and specialists. There is no right or wrong way to learn, a mixture of all of these methods will be beneficial in the overall process of gathering information.

It is helpful to think of learning needs, as a process of gathering information in two different ways: 'push' and 'pull'.

The 'push' is when we extract information from the array of resources that arrive in our post or email, on a variety of topics. This type of learning can be thought of as 'just in case learning'. When information is provided that is important to clinical practice and has already been appraised for certain validity criteria it can be very useful (see for example Evidence Based Medicine and Clinical Evidence, available in print versions as well as online; see Useful links at the end of this chapter).

Although we are not advocating any one style of learning over another, in medicine and all other healthcare areas, events are rapidly changing and we need to focus more on the 'pull' strategy: information to serve our current clinical problems. The 'pull' process, which can be thought of as a 'just in time' learning method, looks at how to formulate questions and 'pull' answers out of the literature as you need them. Effective strategies can lead to answers in less than two minutes!

Evaluate your own learning strategies and your learners

- · Write down one recent patient problem.
- · What was the critical question?
- · Did you answer it? If so, how?

EBM is only one component of the many elements that go into teaching clinical practice. It supplements rather than replaces clinical expertise. It is a process of lifelong, self-directed learning in which caring for our patients creates clinically important information needs. Samples of introductory presentations are available free from the Oxford Centre for Evidence-Based Medicine website.

Asking answerable questions

Teaching the formulation of question is best done in small groups with approximately seven to eight students per tutor. If you are teaching this topic, think about recruiting some help (who is available in your department?) to guide the groups as they formulate their clinical questions. You should consider following or combining this session with searching skills.

ar librarians may have skills, unbeknownst to you, that might help in

se the PICO principle to formulate the questions:

opulation/patient - what is the disease problem? intervention/indicator - what main treatment is being considered? comparator/control – is this in relation to an alternative? Outcome - what are the main outcomes of interest to the patient?

issect the question into its component parts and then restructure it so at the components can be used to direct the search.

cenarios are useful to teach question building

or the less experienced student, you might begin with short scenarios that lend themselves to splitting the question(s) easily. For the more experienced learners, let them loose on a scenario that incorporates all the types of questions that are possible. It is relevant to think of the type of question you want to ask, as it will affect where you look for the answer and what type of research you can expect to provide it.

While it sounds easy to teach question formulation, it is more difficult to get students to carry it out in their daily clinical duties.

How you are going to integrate asking questions into your own practice?

The challenge to the teacher is to identify questions that are both problem-based and orientated to the learners' needs; at the same time you will also be identifying gaps in your own knowledge which may need to be addressed. Think of how you and your students are going to keep track of the questions and come to a clinically useful answer.

One way is to use an educational prescription (Fig. 30.2), available for download from the Oxford Centre for Evidence-Based Medicine website. Another way is to provide clinical question 'logbooks', small pocket notebooks to store questions in. If you try and achieve two questions a week and ask your group to do the same, then time spent on answering them ought to be less than an hour. This means that in your small group, including yourself, you should be generating approximately 20 clinically useful answers each week.

Remember to recognise potential questions which are clinically useful to you and your learners, decide which of the questions to focus on, guide your learners in to developing useful questions, and assess their performance in building and asking answerable questions. Once clinical questions have been formulated (step 1) it is helpful to quickly follow up by letting students loose on searching for the answers.

Searching for the evidence

Resources that you will need include:

- if available, a computer laboratory with internet access
- one terminal for every two students

Typology for question building Clinical findings: how to interpret findings from the history and examination. Aetiology: the causes of diseases.

Diagnosis: what tests are going to aid you in the diagnosis?

Prognosis: the probable course of the disease over time and the possible outcomes.

Therapy: which treatment are you going to choose, based on beneficial outcomes, harms, cost and your patient's values?

Prevention: primary and secondary risk factors which may or may not lead to an intervention.

Cost-effectiveness: is one intervention more cost-effective than another?

Quality of life: what effect does the intervention have on the quality of your patient's life?

Phenomena: the qualitative or narrative aspects of the problem.

EDUCATIONAL PRESCRIPTION

Date and Place to be presented

THE PATIENT PROBLEM

The intervention: (therapeutic, diagnostic, prognostic, causal)

Vs alternatives

The Target Outcome/s (a change in the risk or likelihood of):

The Learner:

Presentations will cover: 1. HOW you found what you found, i.e. Search Strategies;
2. WHAT you found (the bottom line);
3. the VALIDITY and APPLICABILITY of what you found (the critical appraisal);
4. How what you found will ALTER your MANAGEMENT 5. How WELL you think you DID in filling this Rx.

Fig. 30.2 Educational prescription (adapted with permission from the Centre for Evidence-Based Medicine)

- if available, data projection linked up to a computer with database access for students to view searches in action
- · internet access or access to medical research databases.

We recommend the following two databases in searching for the evidence.

- · PubMed, and
- · the Cochrane Library

Use these two databases as a starting point because they are both free to access for users in many countries. Using PubMed allows all the concepts of proficient searching to be taught. It also has the very useful 'Clinical Queries' section: a question-focused interface with filters for identifying the more appropriate studies for questions of therapy, prognosis, diagnosis and aetiology. The Cochrane Library contains a number of databases, the Cochrane Database of Systematic Reviews, the Controlled Trials Register (CENTRAL) and the Database of Abstracts of Reviews of Effectiveness (DARE).

The success of problem-based learning depends on the ability to find the current best evidence effectively

Finding answers to questions can be highly rewarding when done well with speed or can be frustrating and time consuming when done poorly. A study of 103 GPs showed that they generated about ten questions over a two-and-half-day period. They tried to find the answers for about half of them. The most critical factor influencing which questions they followed up was how long they thought it would take to obtain an answer. If they thought the answer would be available in less than a couple of minutes, they were prepared to look for it. If they thought it would take longer, they would not bother. Only two questions in the whole study (0.2%) were followed up using a proper electronic literature search (Ely et al 1999).

A similar study in 64 hospital residents (Green et al 2000) revealed they asked an average of two questions per three patients. They pursued an answer for 80 questions (29%); their reasons for not pursuing answers were lack of time and because they forgot the question. When they did answer the question, textbooks were used 31% of the time, articles 21% and they asked their consultants 17% of the time.

How are you going to maintain searching skills?

In teaching searching skills think of the resources you have available to you. Librarians are currently changing the way they work; they often have knowledge in this area far beyond the skills of a busy clinician. They often run courses and workshops; if they aren't then consider approaching them to begin setting them up. On a personal level you should be proficient in searching; often you will be asked questions about searching strategies: 'Which database to use?' 'Why do I seem to get many articles?'

onverting your question into a search strategy

is often best to have a prepared scenario which generates a four-part diestion and leads on to demonstrating some of the key components of n effective search strategy. For example:

In a five-year-old with a fever and a red bulging tympanic membrane should I prescribe antibiotics or watch and wait?

(Clinically useful answer in the Cochrane database of systematic reviews in Glasziou et al 2004.)

A 35-year-old lady came to clinic with a fresh dog-bite and she wanted to know whether she should have some prophylactic antibiotics.

(Clinically useful answer in PubMed/Medline, in Cummings 1994.)

There are two main types of strategy for searching bibliographic databases: thesaurus searching (all articles are indexed under subject headings, so if you search for a specific heading you will pick up potentially relevant materials) and text-word searching (where you search for specific words or phrases in the studies' bibliographic record). Once the question has been broken down into its components (see Table 30.1), it can be combined using Boolean operators 'AND' and 'OR' (Fig. 30.3).

In combining terms into a search strategy, it can be useful to represent them as a Venn diagram (Fig. 30.4). Complex combinations can then be structured. Once this level of skill has been achieved, then it is time to let your students search on their own questions that they have generated.

Critically appraising the evidence for its validity and relevance

The initial steps in applying the evidence revolve around what to look out for in individual or combined trials to determine whether the results are valid and clinically useful. This process developed by epidemiologists and statisticians for assessing trials, is called 'critical appraisal'. Initially it is worth presenting in a lecture format some of the key concepts involved in appraisal, why it is important and some of the potential pitfalls. Flecainide

Table 30.1 Applying the PICO principle

Question: In a 65-year-old man with heart failure does the addition of a beta-blocker compared with usual care improve survival?

Question part

Question term

Synonyms

Patient/problem

Adult, Heart failure

Left ventricular failure, congestive heart

failure, NYHA classification

Intervention

Beta-blocker

Metoprolol, carvedilol,

Comparison

Usual care, standard therapy

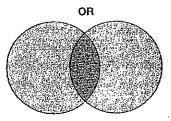
Outcome

Mortality

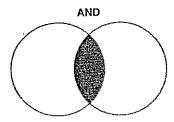
Death*, survival



searching



Retrieve all articles with either word



Retrieves articles only with both words

Fig. 30.4

use in the treatment of ventricular arrhythmias (Anderson et al 1981, Echt et al 1991) is an illustration of potential pitfalls.

If you are about to embark on teaching critical appraisal, consider how proficient you are yourself in appraisal of the following study types:

- therapy
- diagnosis
- · systematic reviews
- · harm/actiology
- prognosis
- · economic analysis optional.

If you do not feel confident, then refer back to the EBM book by Sackett and colleagues (2000) or consider attending a workshop on teaching and practising EBM (Oxford Centre for Evidence-Based Medicine).

Critical appraisal

Teaching the details of critical appraisal lends itself to small-group work. Small-group work allows generation of free discussion of these new concepts between the group leader and the participants, enabling them to gain knowledge from their peers. As with many intellectual skills, practice, discussion and feedback are helpful for faster and deeper learning.

Tutors can function in many different ways. They can identify errors in the group's interpretations of concepts and also act as a listener. The teacher's role is to set the ground rules for individual sessions. Pick out the educational needs and adapt the tutorial style accordingly (see chapter 7, Learning in small groups, and Elwyn et al 2001).

Working through critical appraisal

To help you, we suggest that you have some prepared critical appraisal worksheets to guide the process. You can design your own but there are many available which will help you. See for example:

- Oxford Centre for Evidence-Based Medicine (free downloads of critical appraisal worksheets)
- · Centre for Health Evidence, University of Alberta
- · Public Health Resource Unit
- Centre for Evidence-Based Medicine, Mount Sinai, Toronto
- Glasziou et al 2003
- Badenoch et al 1999.

Pitfalls and solutions

Small-group work can sometimes be relatively unprofitable when the individuals are not especially motivated. One useful trick here is to give the group a choice of content topics, e.g. by voting on which of several questions they wish to address. Since the appraisal process will be similar, this flexibility and choice improves engagement.

Participants may have differing levels of knowledge, resulting in time-consuming discussion about areas that some find boring. A way

"Opportunity is missed by most people because it is dressed in overalls and looks like work"

Thomas A. Edison

caling with this is to get the group to break into pairs for some periods, and allow more experienced students to help less experienced ones.

It is important to set clear objectives at the outset of a discussion. This helps to avoid heading off at tangents, with participants being left confised about what they are actually trying to learn. This can occur when the agenda is too large or varied.

It is useful to evaluate your performance by taking a few minutes at the end of the session to discuss whether participants felt their needs were met by this particular style of learning. This will not always be the case, and sometimes it will be seen that a more didactic approach is needed.

Crunching the numbers

You and the learners should become proficient with most of the outcome variables that are possible in trials. Results can be expressed in many ways and you should feel comfortable in demonstrating the calculations involved, such as those for:

- relative risk
- · absolute risk reduction
- · relative risk reduction
- · number needed to treat (NNT)
- · odds ratios
- · sensitivity and specificity
- · pre-test probabilities, likelihood ratios and post-test probabilities.

Do not expect your learners to calculate all of these variables all of the time, but they should be able to calculate NNTs and relative risks; however the more complex calculations may put them off. Introduce the use of a nomogram (Fig. 30.5) to aid diagnostic decision making.

Confidence intervals and P values

This is the branch of statistical analysis that will bring fear to some of your students. Remember that most people will only need to be users of statistics not 'doers'; interpretation is vital but calculation is unnecessary. So you might explain that all studies are subject to some random error, and that the best we can do is estimate the true risk based on the sample of subjects in a trial (called the point estimate). Statistics provide two estimates of the likelihood that a result was not due to random error:

- · P values (hypothesis testing)
- · confidence intervals (estimation).

Do not go into the statistical methods of calculating the answers. Provide discussion about the relevant methods and why an intervention can only be considered useful if the 95% confidence interval (CI) includes a clinically important treatment effect. Make a distinction between statistical significance and clinical importance:

 Statistical significance relates to the size of the effect and the 95% CIs in relation to the null hypothesis.

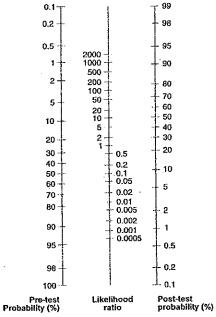


Fig. 30.5 Nomogram for converting pre-test probabilities into post-test probabilities for a diagnostic test result with a given likelihood ratio (reproduced with permission from the Oxford Centre for Evidence-Based Medicine)

"Statistics is a matter of common sense but it is a matter of ADVANCED common sense"

Stephen Senn

"Increasingly this is not good enough. There is a need for numbers, and many doctors don't feel easy with numbers. 'Can you,' asks Tze-Wey Loong, 'explain why a test with 95% sensitivity might identify only 1% of affected people in the general population?' My guess is that not one BMJ reader in a thousand could answer that question, but the numbers are in many ways the easy bit. The communication is the harder bit"

Richard Smith 2003, Editor of the BMJ

"I can live with doubt and uncertainty and not knowing. I think it is much more interesting to live not knowing than to have answers that might be wrong"

Richard Feynman

 Clinical importance relates to the size of the effect and to a minimum effect that would be considered to be sufficiently important to change practice.

Applying the evidence

The questions you should consider before you decide to apply the results of a study to your patient are:

- · Is the treatment feasible in my setting?
- · Is my patient similar to those of the study?
- · What alternatives are available?
- · Will the potential benefits outweigh the harms?
- · What does the patient value?

Communication skills and risk

You can use the final step of reading a paper as a chance for your students to practise their communication skills. If you put a scenario to your learners before the outset of your critical appraisal and ask for their opinions based on their current knowledge, it can be enlightening to see how the evidence can alter management in the light of new information. Think of how you communicate risk: it isn't easy.

Two studies illustrate the point (Gigerenzer & Edwards 2003, Hoffrage & Gigerenzer, 1998). Doctors with an average of 14 years of professional experience were asked to imagine using the Haemoccult test to screen for colorectal cancer.

The prevalence of cancer was 0.3%, the sensitivity of the test was 50%, and the false-positive rate was 3%.

The doctors were asked: "What is the probability that someone who tests positive actually has colorectal cancer?"

The correct answer is about 5%. However, the doctors' answers ranged from 1% to 99%, with about half of them estimating the probability as 50% (the sensitivity) or 47% (sensitivity minus false-positive rate). If patients knew about this degree of variability and statistical innumeracy they would be justly alarmed.

Consider getting to grips with presenting information in terms of natural frequencies; information is often presented to us in confusing language, so it is no wonder that our own patients will often be confused.

Evaluating your own performance

The most important evaluations are the ones you and your learners design and carry out yourselves. The questions you might want to ask of yourself include:

- · How many questions am I recording?
- · Am I using different databases in my search strategies?