EVIDENCE BASED MEDICINE

M.ASHOKKUMAR
DEPT OF PHARMACY PRACTICE
SRM COLLEGE OF PHARMACY
SRM UNIVERSITY
What is evidence based medicine (EBM)?

- “the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients.”
  - The integration of individual clinical expertise with the best available external clinical evidence from systematic research.
  - Initially proposed by Dr. David Sackett and colleagues at McMasters University in Ontario, Canada.

What is EBM?

“Evidenced-based medicine is the concept of formalizing the scientific approach to the practice of medicine for identification of “evidence” to support our clinical decisions. It requires an understanding of critical appraisal and the basic epidemiologic principles of study design, point estimates, relative risk, odds ratios, confidence intervals, bias, and confounding. By using this information, clinicians can categorize evidence, assess causality, and make evidence-based recommendations. Evidence-based medicine allows analysis of complicated material so that we can make the best possible clinical decisions for the populations we serve.”

Why is EBM important?

- New types of evidence are being generated which can create changes in the way patients are treated
  - How much is actually being applied to patient care?

- Although evidence is needed on a daily basis, usually physicians don’t get it.
  1. lack of time
  2. out-of-date textbooks, and
  3. the disorganization of the up-to-date journals

Why is EBM important?

- Up-to-date knowledge and clinical performance can deteriorate with time
  - There is a statistically and clinically significant negative correlation between a physician’s knowledge of up to date care and the years that have elapsed since graduation from medical school.

- Traditional continuing medical education programs have not been shown to improve clinical performance
  - Systematic reviews of the relevant randomized trials have shown that traditional, instructional CME fails to modify clinical performance and is ineffective in improving the health outcomes of patients.

Why is EBM important?

- Knowledge translation – increasing the uptake of the best available evidence into practice – has always been a challenge
  - Scurvy: use of citrus was proven to prevent and cure scurvy in 1754, but it was almost 50 years after the data was published before lemon juice was added to British ships

<table>
<thead>
<tr>
<th>Additive to diet (n=2 in each group)</th>
<th>Observed effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quart of cider</td>
<td>Minor improvement</td>
</tr>
<tr>
<td>Unspecified elixir t.d.s</td>
<td>No change</td>
</tr>
<tr>
<td>Seawater</td>
<td>No change</td>
</tr>
<tr>
<td>Garlic, mustard and horseradish</td>
<td>No change</td>
</tr>
<tr>
<td>Spoonfuls of vinegar</td>
<td>No change</td>
</tr>
<tr>
<td>Two oranges and a lemon</td>
<td>Dramatic recovery</td>
</tr>
</tbody>
</table>

Table 1. Lind’s study on scurvy:1747

CORTICOSTEROIDS FOR PRETERM BIRTH

1972
A RCT was reported showing improved outcomes for preterm babies when mothers were given a short course of corticosteroid before the birth.

1972–89
Six more RCTs were published which all confirmed 1972 findings. During this time, most obstetricians were still unaware that corticosteroid treatment was so effective and so did not treat women about to give birth early with corticosteroids.

1989
First systematic review published.

1989–91
Seven more studies reported.

Corticosteroid treatment reduces the odds of babies dying from complications of immaturity by 30 to 50% but thousands of babies have died or suffered unnecessarily since 1972 because doctors did not know about the effectiveness of the treatment.
Finding the high quality evidence is like trying to sip pure water from a water hose pumping dirty water, or looking for ‘rare pearls’.

Information gathering

There are two ways in which we all get information: ‘push’ and ‘pull’.

Push’ new relevant and valid results
The ‘push’ method of getting our information is when we extract information from the variety of sources that we receive, across a wide spectrum of topics that may interest us. This is sometimes called ‘just in case’ learning.

Evidence-Based Medicine — a journal containing information from clinicians around the world who spot articles that pass rigorous validity criteria and are important to clinical practice. The journal is published every two months and has no original articles but it gives a condensed version of the original paper.

‘Pull’ answers in less then two minutes
We focus on how to formulate questions and ‘pull’ answers out of the literature in less than two minutes!

Also available on the internet at: http://www.evidence-basedmedicine.com & www.clinicalevidence.com
Ex of an evidence-based case

Case study: painful shoulder

A 68-year-old male complained of a painful left shoulder for several weeks. His GP had often used cortisone injections for such shoulder pain, but was now not sure if this was a good idea because she had seen a recent trial of cortisone injection for tennis elbow which showed good short-term improvement but the long-term outcomes were worse than with watchful-waiting or physiotherapy. A search of the Cochrane Library found a systematic review of randomised trials of several treatments for shoulder pain, which was last updated in 1999.

Based on two small trials (with a total of 90 patients), the authors concluded that subacromial steroid injection showed some short-term benefit over placebo. A further search of the Clinical Trials Registry identified a more recent trial that compared physiotherapy, manipulation and corticosteroid injections in a total of 172 patients. It showed that corticosteroid injections had short-term benefits (up to 1 year) with a 50% absolute increase in ‘cure’ at 11 weeks. However, when long-term outcomes were measured (2-3 years), about half the patients had some recurrence and there was no difference between the three groups.
How did EBM help?

The search revealed studies that answered the GP’s question and provided useful information for the patient. The GP was able to advise her patient of three things:

• he would probably improve even without treatment

• a steroid injection would help to relieve pain in the short-term (up to 1 year)

• a steroid injection would make no difference in the long term (2-3 years).

Based on this information, the patient was able to make an informed decision about whether to have the injection or not.
Summary of case studies

The case studies show that EBM has several advantages:

• Medical practitioners, especially GPs, can’t know everything. EBM helps doctors keep up to date across a very wide spectrum of information.

• MEDLINE and similar databases have several advantages. For medical practitioners, they are a way of finding up-to-date information that is not biased and is of good quality.

• Because the search is based on questions rather than possible answers, doctors can find information without having heard about it before. In other words, they can find information that they do not initially know they need, but which, as we have seen, is important for good clinical practice.

• The evidence can be used to quantify outcomes (empirical evidence). It allows people to assess the likelihood of benefiting from a particular treatment or activity rather than just considering the underlying mechanism.

• Patients like this empirical approach because it is easier to understand and allows them to share in decision making.

• Decision making can be shared between the doctor and patient based on empirical evidence of risks and benefits. This reduces the chances of future litigation.

• Electronic searching can reveal other useful information that is of benefit to the patient.
Steps in EBM:

1. Formulate an answerable question.
2. Track down the best evidence of outcomes available.
3. Critically appraise the evidence (ie find out how good it is).
4. Apply the evidence (integrate the results with clinical expertise and patient values).
5. Evaluate the effectiveness and efficiency of the process (to improve next time).
Developing clinical questions

“To get the right answer,
you must first ask the right question.”

EBM step 1: Formulate an answerable question
First principle
First, you must admit that you don’t know.
Questions often spring to mind in a form that makes finding answers in the medical literature a challenge. Dissecting the question into its component parts and restructuring it so that it is easy to find the answers is an essential first step in EBM. Most questions can be divided into 4 parts:

1. **The population or participants**
   Who are the relevant patients?

2. **The intervention or indicator**
   What is the management strategy, diagnostic test or exposure that you are interested in (such as a drug, food, surgical procedure, diagnostic test or exposure to a chemical)?

3. **The comparator or control**
   What is the control or alternative management strategy, test or exposure that you will be comparing the one you are interested in with?

4. **The outcome**
   What are the patient-relevant consequences of the exposure in which we are interested?

All clinical or research questions can be divided into these four components, which we call ‘P I C O’. It is important to use all four parts of the question, if possible.
Different types of questions

By far the most common type of clinical question is about how to treat a disease or condition. In EBM, treatments and therapies are called ‘interventions' and such questions are questions of INTERVENTION.

However, not all research questions are about interventions. Other types of questions that may arise are as follows:

1. What causes the problem? AETIOLOGY AND RISK FACTORS
2. What is the frequency of the problem? FREQUENCY
3. Does this person have the problem? DIAGNOSIS
4. Who will get the problem? PROGNOSIS AND PREDICTION
Interventions

Interventions cover a wide range of activities from drug treatments and other clinical therapies, to lifestyle changes (for example, diet or exercise) and social activities (such as an education program). Interventions can include individual patient care or population health activities (for example, screening for diseases such as cervical or prostate cancer).

Example 1

A 28-year-old male presents with recurrent furunculosis for past 8 months; these episodes have been treated with drainage and several courses of antibiotics but keep recurring. He asks if recurrences can be prevented.

To convert this to an answerable question, use the P I C O method as follows

Question: ‘In patients with recurrent furunculosis, do prophylactic antibiotics, compared to no treatment, reduce the recurrence rate?’
Aetiology and risk factors

Questions of aetiology and risk factors are about what causes a disease or health condition. They are the reverse of intervention questions because they deal with the harmful outcomes of an activity or exposure. Such questions commonly arise in relation to public health issues, such as whether eating certain foods increases the risk of heart disease, or being exposed to an environmental chemical increases the risk of cancer, and so on.

Example 1
George has come in to your surgery to discuss the possibility of getting a vasectomy. He says he has heard something about vasectomy causing an increase in testicular cancer later in life. You know that the risk of this is low but want to give him a more precise answer.

Question:
‘In men, does having a vasectomy (compared to not having one) increase the risk of getting testicular cancer in the future?’
Example 2
Susan is expecting her first baby in two months. She has been reading about the potential benefits and harms of giving newborn babies vitamin K injection. She is alarmed by reports that vitamin K injections in newborn babies may cause childhood leukaemia. She asks you if this is true and, if so, what the risk for her baby will be.

Develop a clinical research question using P I C O to help answer Susan’s question:

Question:
Frequency or rate

Questions of frequency (prevalence) are about how many people in the population have a disease or health problem, such as what is the frequency of hearing problems in infants or the prevalence of Alzheimer’s disease in the over 70s. If the question also includes a time period, such as for cases of influenza in winter versus summer, it becomes a question of rate (incidence).

Example 1
Mabel is a 6-week-old baby at her routine follow-up. She was born prematurely at 35 weeks. You want to tell the parents about her chances of developing hearing problems.

Question:
‘In infants born prematurely, compared to those born at full term, what will the prevalence of sensorial deafness be?’
Diagnosis questions are concerned with how accurate a diagnostic test is in various patient groups and in comparison to other available tests. Measures of test accuracy include its sensitivity and specificity.
Example 1
Julie is pregnant for the second time. She had her first baby when she was 33 and had amniocentesis to find out if the baby had Down syndrome. The test was negative but it was not a good experience as she did not get the result until she was 18 weeks pregnant. She is now 35, one month pregnant and asks if she can have a test that would give her an earlier result. The local hospital offers serum biochemistry plus nuchal translucency ultrasound screening as a first trimester test for Down syndrome. You wonder if this combination of tests is as reliable as conventional amniocentesis.

Question:
‘For pregnant women, is nuchal translucency ultrasound screening plus serum biochemistry testing in the first trimester as accurate (ie with equal or better sensitivity and specificity) as conventional amniocentesis for diagnosing Down syndrome?’