Evidence-based Medicine

Dr. Vaibhavkumar B. Patel
Professor

848801

4th Year Pharm D

Evidence-based Medicine

Evidence-based medicine (EBM) is about systematically reviewing, appraising, and using clinical research findings to aid the delivery of optimum clinical care to patients.

Patient knowledge of EBM is important because it enables them to make more informed decisions about disease management and treatment.

It also gives patients a more accurate perception of risk, encourages appropriate use of elective procedures, and supports evidence-based doctor/patient decision-making.

Evidence-based Medicine

Evidence-based medicine is a combination of principles and methods. When put into action, these ensure that medical decisions, guidelines, and policies are based on the **current best evidence** about the effects of different forms of treatment and healthcare in general. With respect to medicines, it draws heavily on information from the benefit and risk (efficacy and safety) evaluation.

Clinical Experience

- The decision-maker needs to look at knowledge from their own clinical experience along with the best evidence from controlled studies and research.
- Combining clinical experience and controlled studies in the decision-making process is important.
- Without clinical experience, the risk related to a given treatment may end up causing unwanted effects.

5-Step Model of Evidence-Based Medicine

One approach to evidence-based medicine is based on a **5** step model:

- Step 1 - defining a clinically relevant question - doctor searches for information to find correct diagnosis;
- Step 2 - searching for the best evidence - doctor searches for evidence to support the findings from step 1;
- Step 3 - assessing the quality of the evidence - doctor ensures that quality and reliability is high;

5-Step Model of Evidence-Based Medicine

- Step 4 - acting on the evidence to form a clinical decision - based on Steps 1-3, patient and doctor jointly make an informed treatment decision;
- Step 5 - evaluating the process - doctor and patient assess if the intended outcome is achieved and adjust treatment decisions accordingly if needed.

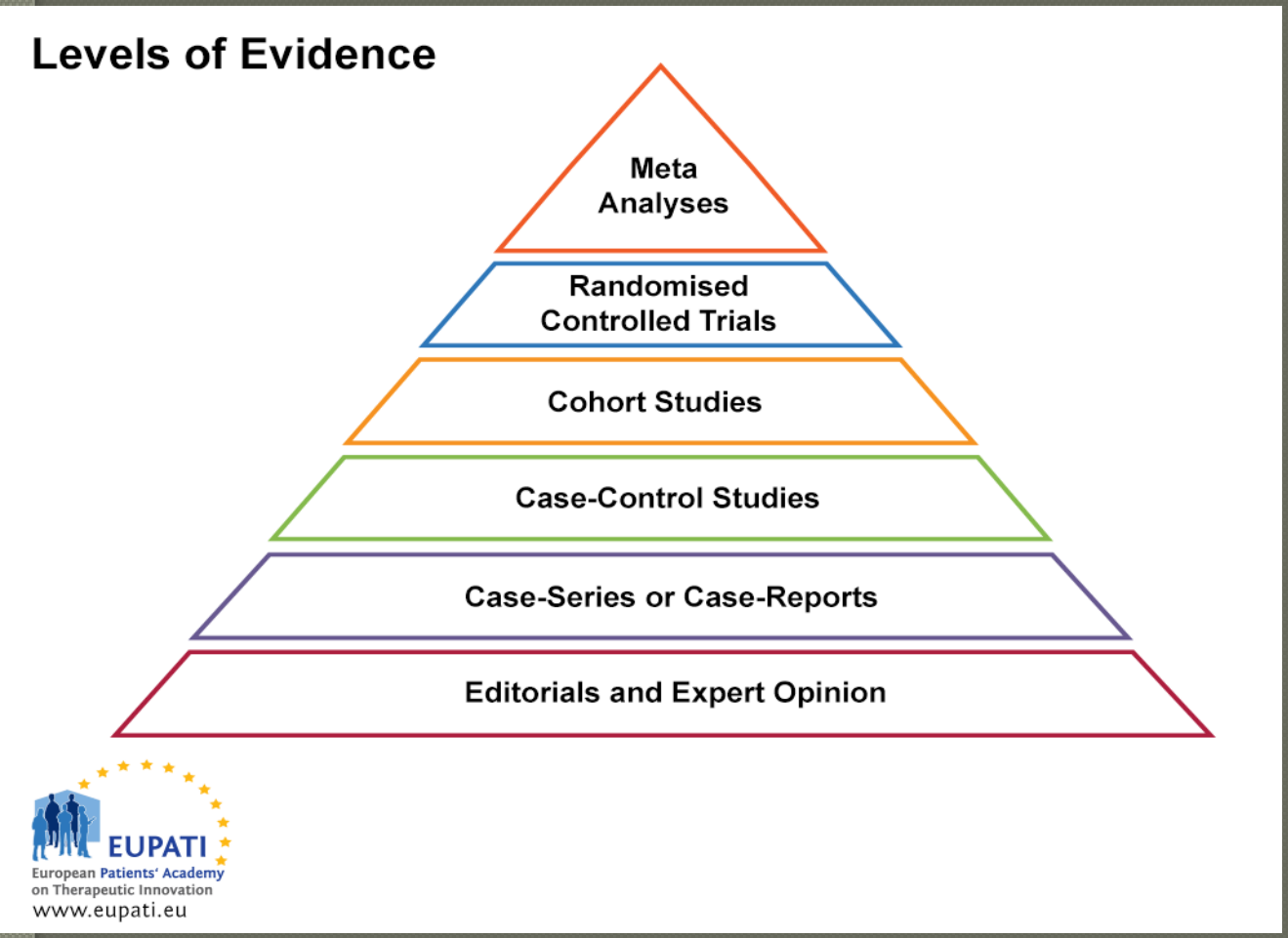
Patient Engagement

- A doctor's decision includes conscientious, explicit, and judicious use of the best evidence at the current time, including the patient's experience, when deciding how to provide the best possible medical treatment for a given patient.
- Patient engagement in decision-making processes have an important role to play in building new guidelines of treatment principles.

Patient Engagement

- This includes reading, understanding, and acting on health information, working together with clinicians to evaluate and select the right treatment options and providing feedback on outcomes.
- Patients can have an active role to play at all levels of evidence.

Levels of Evidence



Levels of Evidence

Editorials and Expert Opinions

- This is evidence based on the opinions of a panel of experts aiming to shape common medical practice.

Case-Series and Case-Reports

- Case series are descriptive studies following one small group of people. They are additions or supplements of case reports. A case report is a detailed report of the symptoms, signs, diagnosis, treatment, and follow-up of an individual patient.

Levels of Evidence

Case-Control Studies

A case-control study is an observational retrospective study (looking at historical data) that compares patients who have a disease with patients who do not have the disease.

- Outcomes such as lung cancer are generally studied by the use of case-control studies.
- A group of smokers (the exposed group) and a group of non-smokers (the unexposed group) are recruited and followed over time.

Levels of Evidence

Case-Control Studies

- The differences in the incidence of lung cancer between the groups are then documented, allowing the variable being assessed -the 'independent variable – in this case, smoking, to be isolated as the cause of the 'dependent variable' - lung cancer.
- In this example, a statistically significant increase in the incidence of lung cancer in the smoking group as compared to the non-smoking group would be considered as evidence in favour of assuming a causal relationship between smoking and lung cancer.

Levels of Evidence

Cohort Studies

- The modern definition of a 'cohort' in clinical studies is a group of people with defined characteristics who are followed in order to determine health-related outcomes.
- The Framingham Heart study is an example of the use of a cohort study to answer an epidemiological question.
- Another example of a cohort study that has been ongoing for many years is the National Child Development Study (NCDS), the most widely-researched of the British birth cohort studies.

Levels of Evidence

Randomised Clinical Trial (RCT)

- A randomised clinical trial is one that uses randomisation when allocating people to different arms of the study.
- This means that the treatment groups are chosen by chance using a formal system and each participant has an equal chance of being selected to each arm.

Levels of Evidence

Meta-analysis

- Meta-analysis is a systematic, statistics-based review of data that contrasts and combines results from different but related studies, in an attempt to identify patterns, disagreements, and other relationships across multiple studies.
- A meta-analysis can support a stronger conclusion than any individual study, but may be flawed because of publication bias.

Outcome Research

- Outcome research studies the end results of medical care – the effect of the healthcare process on the health and well-being of patients.
- Clinical outcome research seeks to monitor, understand, and improve the impact of medical treatment on a specific patient or population.
- It describes research that is concerned with the effectiveness of public-health interventions and health services - the outcomes of these services.

Outcomes Research

- Attention is frequently focused on the clinical endpoints most relevant to the patient or population. Such endpoints could be quality of life or pain level.
- Outcomes research may also focus on the effectiveness of healthcare delivery, with measures such as cost-effectiveness, health status, and disease burden (the impact of the health problem).
- The difference between EBM and outcomes research is one of focus. While the main focus of EBM is providing the best care to the patient according to clinical evidence and experience, the main focus of outcomes research is predefined endpoints.

Outcomes Research - Endpoints

- In outcomes research, the relevant endpoints are often symptoms or functional and care measures, things considered important by the patient receiving the treatment.
- When study duration is long, outcomes research studies can include the use of 'surrogate endpoints'. A surrogate endpoint is when a biomarker is used to measure an outcomes, it acts as a substitute for a clinical efficacy endpoint.
- When a surrogate endpoint is used for regulatory purposes, the marker should have previously been confirmed or validated.

Examples of Endpoints Relevant to Outcomes Research Studies

Type of endpoint	Example
Physiological measure (biomarker)	Blood pressure
Clinical	Heart pressure
Symptoms	Coughing
Functional and care	Measurement of function, for instance ability to perform tasks of everyday living, Quality of Life assessments

References

- World Health Organisation (2008). *Where are the patients in decision-making about their own care?* Retrieved 31 August, 2015, from http://www.who.int/management/general/decisionmaking/WhereArePatientsinDecisionMaking.pdf