Evidence-Based Medicine
Course Goals

Goals

1. Understand basic concepts of evidence-based medicine (EBM) and how EBM facilitates optimal patient care.

2. Develop a basic understanding of how clinical research studies are designed and analyzed, and how this can influence whether a study’s conclusions are valid.

3. Develop competence in the critical appraisal of common types of clinical research papers and the determination of whether the papers have drawn valid and applicable conclusions.

4. Develop competence in communicating scientific evidence to colleagues.

5. Develop competence in communicating risk and benefit of health interventions to patients.

6. Recognize the role played by physicians in population health.
Evidence-Based Medicine
Session Learning Objectives

Phase 1

Delivered In: Molecules to Medicine

**EBM Case-Control Studies**

1. Define the epidemiologic concept of case-fatality rate.
2. Discuss the strengths and limitations of case-control studies and the clinical questions best answered by this study type.
3. Describe characteristics of case-control studies, explain how these characteristics may result in bias, and recognize appropriate methods for minimizing these biases. Critically appraise a (observational) case-control study.
4. Explain the difference between risk and odds. Calculate an odds ratio. Explain the circumstances in which each is appropriate to use and how each is interpreted.
5. Recognize a population health perspective, including use of epidemiologic methods for outbreak investigation.

**EBM Cohort Studies & Testing Results**

1. Define epidemiologic concepts of incidence and prevalence.
2. Recognize differences in study design for cohort studies and randomized controlled trials. Discuss the strengths and limitations of each and the clinical questions best answered by each study type.
3. Define criteria for inferring causality from statistical associations including Hill criteria and apply to an example.
4. Describe characteristics of cohort studies, explain how these characteristics may result in bias, and recognize appropriate methods for minimizing these biases. Critically appraise an (observational) cohort study.
5. Define statistical measures commonly used in the medical literature, including sampling, normal distribution, mean, median, mode, variance, standard deviation, and range.
6. Recognize statistical methods commonly used in the medical literature, including t-tests, ANOVA, linear regression, survival analysis/Cox proportional hazards model, Kaplan-Meier curve. Understand how to interpret their results.

**EBM Cross-Sectional & Diagnostic Studies**

1. Define epidemiologic concept of prevalence.
2. Discuss the strengths and limitations of cross-sectional studies and the clinical questions best answered by this study type.
3. Describe characteristics of cross-sectional studies, explain how these characteristics may result in bias, and recognize appropriate methods for minimizing these biases.
4. Explain appropriate techniques for communicating numeric and other information from screening and diagnostic studies to colleagues and patients.
5. Calculate and apply common diagnostic/screening test information including sensitivity, specificity, and predictive values. Describe how predictive values are influenced by disease prevalence.
EBM Interpreting RCT Results & Applying RCT Results to Patients

1. Critically appraise a Randomized Control Trial (RCT).
2. Calculate and apply absolute risk. Explain the circumstances in which it is appropriate to use and how it is interpreted.
3. Calculate number needed to treat/harm (NNT/H), absolute risk reduction and relative risk reduction. Differentiate between disease-oriented outcomes and patient-oriented outcomes.
4. Describe barriers to understanding evidence and explain appropriate techniques for communicating numeric and other information to patients.
5. Identify and use summary sources, practice guidelines, pre-appraised sources, and sources of individual studies.

EBM Online Short Video Assignment 1 & 2: Observational Studies, Screening & Diagnostic Tests

1. Recognize differences in study design for both observational and experimental studies.
2. Explain how characteristics of observational studies may result in bias.
3. Describe characteristics of a screening test.
4. Calculate and apply common diagnostic/screening test information including sensitivity, specificity, and predictive values.

EBM Online Short Video Assignment 3: Interpreting Studies

1. Evaluate a study about therapy. Apply concepts that relate to validity of RCTs including randomization, concealed allocation, intention-to-treat, and blinding.

EBM Randomized Controlled Trials & Testing RCT Results

1. Differentiate between random error and bias and how these can be minimized. Define validity.
2. Describe characteristics of randomized controlled trials (RCTs) such as randomization, blinding, allocation concealment, intention-to-treat analysis (as compared with per-protocol or as-treated analyses), and follow up, and explain how these characteristics reduce bias.
3. Calculate and apply a risk ratio (also known as relative risk). Explain the circumstances in which it is appropriate to use and how it is interpreted.
4. Explain the difference between statistical significance and clinical significance. Understand type 1 and type II errors, null hypotheses, alpha level, power, p-values and confidence intervals. Accurately interpret p-values and confidence intervals in a clinical context.
5. Recognize chi-square tests. Understand how to interpret their results.
EBM Small Group: Interpreting Studies, Applying Results to Patients

1. Define criteria for inferring causality from statistical associations including Hill criteria and apply to an example.

2. Calculate number needed to treat/harm (NNT/H). Explain how it can be used to communicate risk to patients.

3. Describe barriers to understanding evidence and explain appropriate techniques for communicating numeric and other information to colleagues and patients.

4. Explain the difference between statistical significance and clinical significance. Understand p-values and confidence intervals. Accurately interpret p-values and confidence intervals in a clinical context.

5. Recognize statistical methods commonly used in the medical literature, including t-tests and chi-square tests, correlation, ANOVA, logistic regression, linear regression, survival analysis/Cox proportional hazards model, Kaplan-Meier curve, forest plot. Understand how to interpret their results.

6. Evaluate a cohort study. Apply concepts that relate to validity of cohort studies, including selection bias, selection of comparison group, exposure measurement, confounding, and loss to follow-up. Explain its relevance to patient care and clinical decision-making.

EBM Systematic Reviews & Meta-Analysis

1. Describe the evidence hierarchy. Recognize differences in study design for both observational and experimental studies including case studies; case series; cohort, case-control, and cross-sectional studies; randomized controlled trials; and systematic reviews, narrative reviews, and meta-analyses. Discuss the strengths and limitations of each and the clinical questions best answered by each study type.

2. Distinguish between narrative review articles, systematic reviews, and meta-analysis and understand issues in using them such as publication bias, forest plots, and heterogeneity.

3. Describe characteristics of a good clinical practice guideline, including a focus on clinical outcomes, use of best available evidence, and involvement of multi-professional groups and consumers in development.

EBM: Overview of Evidence-Based Medicine

1. Explain the value of evidence over opinion in making medical decisions and in the practice of life-long learning.

2. Define evidence-based medicine (EBM). Explain the EBM cycle of asking clinical questions, using appropriate resources to select high quality evidence, and applying evidence to individual patients.

3. Describe the evidence hierarchy.

Phase 2

Delivered In: Digestive, Endocrine and Metabolic Systems

EBM Resources: Applying biostatistics and epidemiology concepts to solve problems

1. Apply biostatistics and epidemiology concepts previously presented in Phase I to solve problems relevant to understanding and using the medical literature to inform patient care decision-making.

Evidence Based Medicine - EBM resources overview

1. Create a basic MEDLINE search using MESH and limits appropriately.

2. Efficiently search the medical literature in order to locate the best evidence and answer clinical questions. Identify, locate and use summary sources, practice guidelines, pre-appraised sources, and sources of individual studies.
Evidence Based Medicine- Systematic reviews, meta analysis and clinical practice guidelines

1. Distinguish between narrative review articles, systematic reviews, and meta-analysis and understand issues in using them such as publication bias, forest plots, and heterogeneity.

2. Describe characteristics of a good clinical practice guideline, including a focus on clinical outcomes, use of best available evidence, and involvement of multi-professional groups and consumers in development.

3. Evaluate a meta-analysis and apply concepts that relate to its validity, including asking a focused clinical question, specifying inclusion criteria, comprehensiveness of literature search, quality assessment of included studies, and assessment of heterogeneity. Explain its relevance to patient care and clinical decision-making.

Delivered In: Life Cycle

LC - Breast Cancer Screening: A Primary Care Perspective

1. Describe desirable attributes of screening tests.

2. Review the perils of screening tests including issues related to lead time and overdiagnosis bias.

3. Identify commonly used screening tests for breast cancer and how to optimize their use by quantifying the benefits and harms as applied to an individual patient.

4. Clarify and apply biostatistics commonly used to describe screening tests including sensitivity, specificity, predictive values, likelihood ratios, relative risk, absolute risk, risk difference, number needed to screen and number needed to harm.

5. Assess an individual patient’s risk of developing breast cancer and implement an appropriate preventive regimen including screening and chemoprevention.

6. Assess an individual patient’s risk of being a BRCA mutation carrier and when to refer for additional testing and counseling.

7. Summarize differences in breast cancer screening guidelines from professional societies and recognize the origins of those differences.

8. Discuss the potential impact of public health messaging on how patients and clinicians perceive benefits and harms of breast cancer screening.

Phase 3

Delivered In: Integrated Clinicians Course 7003

Epidemiology and Biostatistics

1. Discuss the validity of a trial using a critical appraisal guide

2. Recognize the importance of intention-to-treat analyses

3. Recognize the differences between various measures of treatment effect including absolute risk difference, relative risk, relative risk difference, and number needed to treat/number needed to harm (NNT/NNH)

4. Differentiate clinically relevant endpoints from surrogate endpoints in the evaluation of treatment effects

Phase 4
Evidence-Based Medicine/Epidemiology & Biostatistics: Practice problems and critical appraisal

1. Describe the concept of validity, as it pertains to the results of clinical trials.
2. Use a critical appraisal guide to appraise the validity of a trial.
3. Explain the strengths and weaknesses of randomized controlled trials.
4. Describe the importance of intention-to-treat analyses.
5. List the differences between various measures of treatment effect including absolute risk difference, relative risk, relative risk difference, and number needed to treat/number needed to harm (NNT/NNH).
6. Define and differentiate between a point estimate and interval estimate of a treatment effect.
7. Differentiate clinically relevant endpoints from surrogate endpoints in the evaluation of treatment effects.

Thread

Delivered In: Evidence-Based Medicine: Online Journal Club 1

Online Journal Club 1 - Case 1

1. Evaluate a cohort study (including design, strengths and limitations).
2. Apply concepts that relate to validity of cohort studies, including selection bias, confounding, and follow-up.
3. Explain the study’s relevance to patient care and clinical decision-making (including establishment of causation vs. association, and communicating results to patients).

Online Journal Club 1 - Case 2

1. Evaluate a case-control study (including design, strengths and limitations).
2. Apply concepts that relate to validity of case-control studies including confounding and recall bias.
3. Recognize appropriate methods to account for confounding.
4. Explain the study’s relevance to patient care and clinical decision-making.

Online Journal Club 1 - Case 3

1. Evaluate a study about therapy (including design, strengths and limitations).
2. Apply concepts that relate to the validity of randomized controlled trials including randomization, concealed allocation, intention to treat, blinding, statistical significance, and power.
3. Explain its relevance to patient care and clinical decision-making.

Online Journal Club 1 - Case 4

1. Evaluate a study about screening (including design, strengths and limitations).
2. Apply concepts that relate to the validity of these studies including blinding, use of a gold standard, sensitivity, specificity, and negative and positive predictive value.
3. Explain its relevance to patient care and clinical decision-making.
Online Journal Club 1 - Case 5

1. Evaluate a meta-analysis based on a systematic review.
2. Apply concepts that relate to its validity, including asking a focused clinical question, specifying inclusion criteria, comprehensiveness of literature search, quality assessment of included studies, and assessment of heterogeneity.
3. Explain its relevance to patient care and clinical decision-making.

Delivered In: Evidence-Based Medicine: Online Journal Club 2

Online Journal Club 2 - Case 1

1. Evaluate a cohort study (including design, strengths and limitations).
2. Apply concepts that relate to validity of cohort studies, including selection bias, confounding, and follow-up.
3. Explain the study’s relevance to patient care and clinical decision-making (including establishment of causation vs. association, and communicating results to patients).

Online Journal Club 2 - Case 2

1. Evaluate a case-control study (including design, strengths and limitations).
2. Apply concepts that relate to validity of case-control studies including confounding and recall bias.
3. Recognize appropriate methods to account for confounding.
4. Explain the study’s relevance to patient care and clinical decision-making.

Online Journal Club 2 - Case 3

1. Evaluate a study about therapy (including design, strengths and limitations).
2. Apply concepts that relate to the validity of randomized controlled trials including randomization, concealed allocation, intention to treat, blinding, statistical significance, and power.
3. Explain its relevance to patient care and clinical decision-making.

Online Journal Club 2 - Case 4

1. Evaluate a study about screening (including design, strengths and limitations).
2. Apply concepts that relate to the validity of these studies including blinding, use of a gold standard, sensitivity, specificity, likelihood ratios, and negative and positive predictive value.
3. Explain its relevance to patient care and clinical decision-making.

Online Journal Club 2 - Case 5

1. Evaluate a meta-analysis based on a systematic review.
2. Apply concepts that relate to its validity, including asking a focused clinical question, specifying inclusion criteria, comprehensiveness of literature search, quality assessment of included studies, and assessment of heterogeneity.
3. Explain its relevance to patient care and clinical decision-making.