Evidenced-Based Medicine and the Practice-Based Learning and Improvement Competency

Michael Brown MD – Grand Rapids MERC/Michigan State University

Panel:

James Jones MD – Indiana University

Jeffrey Jones MD – Grand Rapids MERC/MSU

Steve Hayden MD- University of California, San Diego

1. Locate, appraise and utilize scientific evidence related to your patient’s health problems and the larger population from which they are drawn.

2. Apply knowledge of study design and statistical methods to critically appraise medical literature.

3. Utilize information technology to enhance your education and improve patient care.
This virtual library and workstation has been put together assembling links to Web Pages on various aspects of Clinical Research and EBM. These links correspond to the Research Workbook used by residents in the Grand Rapids MERC/Michigan State University Program in EM (http://msugrem.org/ebm/).

**MENU**

Course Introduction

July—EBM Basic Concepts

August—Using Biomedical Research to Answer Clinical Questions

September—EBM: Intermediate Concepts

October—Research: Getting Started

November—Study Design

December—Writing the Research protocol

January—Research Ethics

February—Statistical Concepts and Epidemiology

March—Fine-tuning the Research Protocol

April—EBM: Advanced Concepts

May—Peer-review/Publication Bias

June—Evidence-Based Medicine and the Internet

Related Links
CURRICULUM OBJECTIVES & ASSIGNMENTS:

July

**EBM Basic Concepts**
Reading: *User's Guides to the Medical Literature*, pp 49-108, 121-173
- Therapy and Harm: An Introduction
- Therapy
- Harm
- The Process of Diagnosis
- Diagnostic Tests
- Prognosis
- Summarizing the Evidence

Seven Alternatives to Evidence Based Medicine. *BMJ* 1999;319:1618
Handout: EBM Worksheets

Written assignment: Critique of articles (therapy, harm, diagnosis, prognosis, and meta-analysis) using the User Guidelines/Worksheets.

Special project: Lead discussion during journal club during yr.

Small-group discussion: Philosophy of EBM, fundamental principles, criticisms of EBM, answer questions on written assignment, Internet web sites

**Monthly Objectives for EBM Basic Concepts:**
1. Demonstrate an understanding of the basics of EBM and how to critique an article on therapy, harm, diagnosis, prognosis, and meta-analysis using the User Guidelines.
2. Understand the philosophy of EBM, it’s fundamental principles and criticisms

August

**Using Biomedical Research to Answer Clinical Questions**
Reading: *User's Guides to the Medical Literature*, pp 13-47, 175-222, 567-582
- Finding the Evidence
- Moving From Evidence to Action
- Incorporating Patient Values
  - Decision Analysis
  - The Likelihood of Being Helped vs Harmed

Handouts: How to choose the best article

Written assignment: CAT summary, submit CAT to EBM web site. Residents on off-service rotation may turn in the CAT next month.

Special project: Watch *Lorenzo's Oil* video and answer question sheet

Small-group discussion: Ways of using the medical literature, framing the question, searching the online literature, CAT summaries, question and answer period.
**Monthly Objectives for Using Biomedical Research to Answer Clinical Questions:**
1. Demonstrate an understanding on how to apply the biomedical literature to your patients.
2. Prepare and publish online a CAT summary.
3. Demonstrate the steps involved in developing a recommendation.
4. Understand how to evaluate practice guidelines.
5. Understand the basic strategies for incorporating patient values.

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**September**  
**EBM: Intermediate Concepts**

Reading: *User's Guides to the Medical Literature*, pp 223-231, 247-290, 309-391

- Therapy and Harm
- Therapy: Validity
  - Surprising Results of Randomized Controlled Trials
  - The Principle of Intention-to-Treat
  - N of 1 Randomized Controlled Trials
- Therapy: Understanding the Results
  - Quality of Life
  - Hypothesis Testing
  - Confidence Intervals
  - Measures of Association
- Therapy: Applying the Results
  - Applying Results to Individual Patients
  - Example Numbers Needed to Treat

Written assignment: EBM problem set (off-service residents may complete this next month)

Special project: Watch *Awakenings* video and answer question sheet

Small-group discussion: Bias and random error, internal versus external validity, NNT, measures of association, review problem sheets, discuss video, question and answer period.

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**Monthly Objectives for EBM Intermediate Concepts:**
1. Demonstrate an understanding of null and alternative hypotheses, the principle of intention-to-treat, and bias.
2. Demonstrate an understanding of confidence intervals, measures of association, and number needed to treat.

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**October**  
**Research: Getting Started**

Reading: *Research Workbook*, Chapters 1-4

- Research: Why Do It?
- Getting Started
- Reviewing the Literature
- Refining the Research Question
Written assignment: Turn in research worksheets for Chapters 2-4 (off-service residents may wish to turn in worksheets next month)

Special project: Begin work on research protocol (off-service residents may wish to start work on written proposal next month)

Small-group discussion: Resident research requirement, how to get started, literature search, online search engines, refining the research question, types of hypotheses, question and answer period

### Monthly Objectives for Research Getting Started:
- Demonstrate an understanding of how to begin “doing” research.
- Demonstrate an understanding of how to review the literature.
- Understand how to refine the clinical question.

#### November - Study Design

Reading: *Research Workbook*, Chapter 5
- Choosing a Research Design
- “Biomedical Bestiary: An Epidemiologic Guide to Flaws and Fallacies in the Medical Literature.”

Written assignment: Turn in research worksheet for Chapters 5 (off-service residents may wish to turn in worksheet next month), complete problem set (off-service residents may complete these problems next month), continue work on research proposal.

Special project: Each resident will be asked to develop their own “beast” which resides in neighbor of biomedical research. Examples: Significance turkey or Test bloater (see “Biomedical Bestiary”).

Small-group discussion: Study design concepts and limitations, bias, discuss resident “beasts” that were turned in, question and answer period

### Monthly Objectives for Study Design:
- Demonstrate an understanding of epidemiologic flaws common in biomedical research.
- Demonstrate an understanding of the advantages and disadvantages of various study designs, including the randomized clinical trial and case control, cohort, and cross sectional studies.

#### December - Writing the Research Protocol

Reading: *Research Workbook*, Chapters 6-9
- Writing a Protocol
- Choosing the Study Subjects
- Study Methods
- Data Management

Examples of written EM research protocols

Optional Reading: *Research Workbook*, Chapters 10-11
- Diagnostic Tests
- Interviews & Questionnaires
Written assignment: Turn in research worksheets for Chapters 6-9 (off-service residents may wish to turn in worksheets next month)

Special project: Continue work on research protocol, arrange tour of Van Andel Institute

Small-group discussion: Choosing study subjects, study methodology, data management, question and answer period, review progress on protocols, laptop demonstration of different database programs

**Monthly Objectives for Writing the Research Protocol:**
1. Demonstrate the skills necessary to write a research protocol, including selection of study subject, methodology and data management.
2. Understand how medical research is evaluated and approved by institutions.

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**January**

**Research Ethics**

Reading: *Research Workbook*: Chapter 12, Ethical Issues  
"At Your Own Risk" Time April 22, 2002; pp44-55

Written assignment: Critique examples of informed consent submitted to IRB

Special project: Watch *Mrs Evers’ Boys* video and answer question sheet; visit NIH web site and take certification test; schedule a month to attend SH IRB meeting

Small-group discussion: Discuss video, question and answer period on research ethics, history and purpose of hospital IRBs.

**Monthly Objectives for Research Ethics:**
1. Demonstrate an understanding of basic issues in consent and researchers' interactions with corporate funding sources.
2. Demonstrate an understanding of the practical and ethical ramifications of implied and non-implied consent as they apply to hospital and pre-hospital research.
3. Describe the functioning and purpose of hospital IRBs.
4. Demonstrate an understanding of basic issues in research including consent and researchers' interactions with corporate funding sources.

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**February**

**Statistical Concepts and Epidemiology**

Reading: Reading: *User's Guides to the Medical Literature*, pp 517-528  
- Regression and Correlation  
*Research Workbook*, Chapter 13  
- Statistical Analysis

Written assignment: Turn in research worksheet for Chapter 11; statistical problem sheet (off-service residents may wish to turn in worksheets and/or problem sets next month)

Special project: Continue work on research protocol; visit sites on the internet available for teaching statistical analysis (online tutorials)
Small-group discussion: Laptop demonstration of different statistical programs, review statistical problems, question and answer period

**Monthly Objectives for Statistical Concepts and Epidemiology:**
1. Understand the differences between interval, ordinal, nominal, parametric, and non-parametric data.
2. Understand the differences between independent and dependent variables.
3. Demonstrate an understanding of methodologies and variable types analyzed by the following statistical tests: t test, analysis of variance, chi square, Fischer exact test, and non-parametric tests for interval and nominal data.
4. Demonstrate an understanding of the terms “paired” and “tailed” (one and two).
5. Demonstrate an understanding of type I and type II errors as they relate to sample size and variance.
6. Demonstrate an understanding of alpha, beta, and statistical power.
7. Demonstrate an understanding of the differences between statistical and clinical significance.
8. Define mean, median, mode, standard deviation, and variance.
9. Demonstrate an understanding of confidence intervals.
10. Describe correlation and regression to the mean.
11. Discuss the advantages of single and double blind studies.
12. Demonstrate facility with at least one computer statistical program.

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**March**

**Fine-tuning the Research Protocol**

Reading: *Research Workbook*, Chapters 14-16
- Fine-tuning the Research Protocol
- Practical Aspects of Performing Clinical Research
- Funding Strategies for EM Research

Written assignment: Turn in research worksheets for Chapters 12-13 (off-service residents may wish to turn in worksheets next month); critique example protocol as if resident was a member of IRB

Special project: Continue work research protocol (first draft due by April), download SAEM grant application suitable for your mock research proposal

Small-group discussion: Review protocol critiques, grant application, question and answer period

**Monthly Objectives for Fine-tuning the Research Protocol:**
1. Demonstrate an understanding of research funding.
2. Understand the practical aspects of performing clinical research in EM.
3. Describe potential problems in conducting research in an ED.
April  

**EBM: Advanced Concepts**

- Differential Diagnosis
- Clinical Manifestations of Disease
- Clinical Prediction Rules
- Examples of Likelihood Ratios
- Recommendations About Screening

Written assignment: EBM problem sets (off-service residents may wish to turn in problem sets next month), evaluate article on clinical manifestation of disease (this is optional for off-service residents)

Special project: Submit draft of research proposal to research office

Small-group discussion: Review progress on study protocols, discuss assigned reading, agenda for SAEM meeting next month, question and answers on EBM.

**Monthly Objectives for EBM Advanced Concepts:***
1. Demonstrate an understanding of how to evaluate articles on differential diagnosis, clinical manifestations of disease, clinical prediction rules.
2. Be able to explain how to evaluate a medical screening program.

May  

**Peer-Review & Publication Bias**

Reading: *User's Guides to the Medical Literature*, pp 529-538, *Publication Bias An Instructional Guide for Peer Reviewers of Biomedical Manuscripts*, CD-ROM

Written assignment: Critique a manuscript as if the resident was a reviewer for a medical journal using the forms provided on the CD-ROM

Special project: Attend SAEM Annual Meeting, prepare research protocols for presentation in June, final revision of research protocol due, complete any unfinished assignments to be turned in (see research checklist).

Small-group discussion: Discuss peer-review and publication issues, review published SAEM abstracts—what makes a good abstract?

**Monthly Objectives for Peer-review/Publication:***
1. Describe the process of peer-review in medicine.
2. Understand the steps that a manuscript must go through before publication.
3. Demonstrate the skills necessary to write a publishable manuscript.
4. Discuss the problem of publication bias.
5. Attendance at the SAEM Annual Meeting.
6. Understand how research is presented on a national level.
7. Describe what makes a good abstract, a good research presentation.
June

Evidence-Based Medicine and the Internet

Reading: *Evidence-Based Medicine and the Internet (handout)*

Written assignment: Internet assignments (this is optional for off-service residents), fill out course evaluation, turn in time sheets for the year

Special project: Present research protocols during EM residency conference

Small-group discussion: Review internet assignments, critique of research presentations, course evaluation

**Monthly Objectives for Research Presentation:**
1. Demonstrate an understanding of how to find EBM information on the internet specific to your clinical needs.
2. Understand how to “bookmark” useful web sites to develop a personal Internet library.
3. Discuss the quality of the health information on the Internet, be able to assess the information you retrieve.
Research Rotation — Assignment Checklist

July
☐ Critique of articles (therapy, harm, diagnosis, prognosis, and meta-analysis) using the User Guidelines/Worksheets
☐ Lead discussion during JC. Month assigned: __________________________

August:
☐ CAT summary completed. Topic: ________________________________
☐ Watch Lorenzo's Oil video and answer question sheet

September:
☐ EBM problem set
☐ Watch Awakenings video and answer question sheet

October:
☐ Research worksheets for Chapters 2-4
☐ Begin work on research protocol

November:
☐ Research worksheet for Chapter 5
☐ Study Design/Epidemiology problem set
☐ Written description of your own “beast” which resides in neighbor of biomedical research

December:
☐ Research worksheets for Chapters 6-9
☐ Tour of Van Andel Institute

January:
☐ Critique examples of informed consent submitted to IRB
☐ Watch Mrs Evers' Boys video and answer question sheet
☐ Visit NIH web site and take certification test
☐ Schedule month to attend SH IRB meeting (1st Tuesday each month @ 5:45pm)

February:
☐ Research worksheet for Chapter 11
☐ Statistical problem sheet
☐ Visit sites on the internet available for teaching statistical analysis (online tutorials)

March:
☐ Research worksheets for Chapters 12-13
☐ Critique example protocol as if resident was a member of IRB
☐ Download SAEM grant application suitable for your mock research proposal**

April:
☐ Evaluate article on clinical manifestation of disease
☐ Submit draft of research proposal to research office
☐ Complete EBM Problem sets**

May:
☐ Critique a manuscript as if the resident was a reviewer for a medical journal using the provided forms
☐ Final revision of research protocol due
☐ Attend SAEM annual meeting. Month attended: _______________________

June:
☐ Present research protocols during EM residency conference
☐ Internet assignments
☐ Complete course evaluation
☐ Turn in time sheets for the year
☐ Return videotapes to research office
EBM at the Bedside

How do you teach what clinical parameters are the most important ones to focus on?

At the bedside, use questions about the *history and physical exam* for teaching EBM

Take an item of history or physical exam and think of it as a “diagnostic test”

Opportunity to discuss many EBM concepts:

- Pretest probability (pre-clinical assessment)
- Test properties of clinical exam parameters
- Precision (kappa) of clinical examination
- Accuracy (likelihood ratios, PPV, NPV)
- Moving from pretest to post test probability
- Utility of diagnostic tests

Example: How *accurate* are clinical findings in chest pain patients?

- For higher level students/residents discuss how combinations of signs and symptoms can be used to risk stratify

Can this really be done in a busy ED?

- Don’t attempt to answer all possible questions for every patient
- Pick one concept relevant to current patient
- Use *knowledge gaps* you identified with Q’s
- Have a number of these “teaching bites” readily available for common ED cases
- Requires advance preparation
- Have Kappa’s, likelihood ratios with you on index cards, palm pilot, workstation, etc.
- Need rapid access to high quality evidence

How do you find articles relating to the precision and accuracy of the H&P?

Add specific terms to search strategy:

- “Physical examination”
• “Medical history taking”
• “Sensitivity” or “specificity”
• “Clinical assessment”
• “Observer variation”
• “Interrater reliability”

• JAMA Rational Clinical Examination series


**Evaluation Methods**

• Portfolio
  o JC exercise including search strategy
  o CAT summary
  o Research proposal
• Written Exam
  o Statistics
  o Methodology
• Checklist
• Live performance at bedside
• Final Senior Project: demonstrate real life application of EBM
  • Clinical question
  • Search
  • Critical appraisal
  • Application