Lab 3:

Medical Literature Overview:
Study Design & "Hierarchy of Evidence"

Objectives:

- Identify at least five characteristics of biomedical literature that determine the quality of the published item
- Identify five key clinical research study designs
- Explain the strengths and limitations of key clinical research study designs
- Explain when and why specific clinical study designs are used as evidence for clinical decisions.

Resources:

- **The following can be accessed on CygNET**
  - Vancouver Citation Style Guide
  - JTASS: Determine the Quality of Biomedical Literature Guide
  - JTASS: Lab and Worksheet (blank)

References:

- Center for Evidence Based Medicine www.cebm.net EBM Tools: Study Design accessed December 12, 2007.
- Greenhalgh T How to read a paper: the basics of evidence-based medicine (2nd Ed). London: BMJ Books, 2001.
- Strauss SE, Richardson W S, Glasziou P, Haynes RB. Evidence-based Medicine: How to practice and teach EBM (3rd ed.). Edinburgh New York: Elsevier/Churchill Livingstone, 2005.

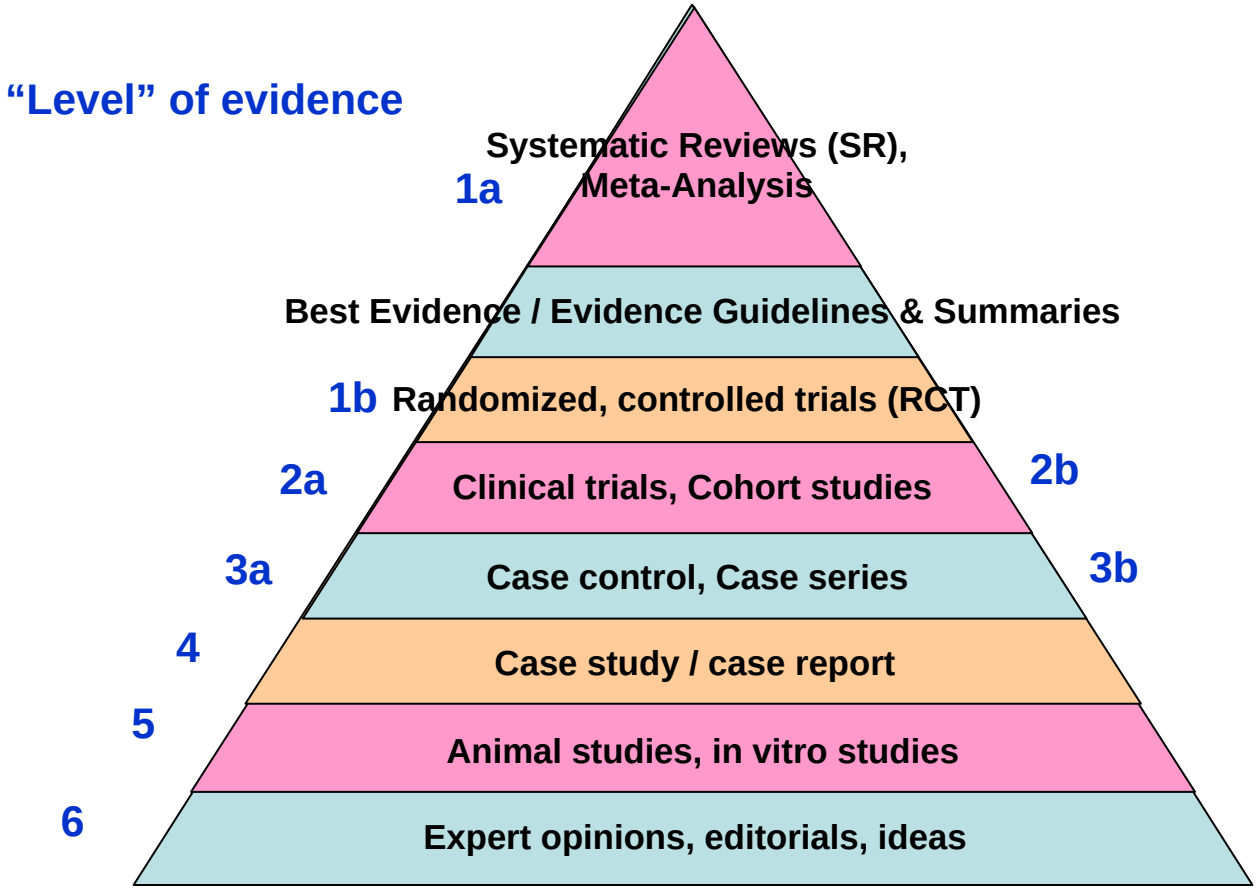
Directions:

1. **Complete the "Defining Study Designs Form"**
    a. Obtain a hard-copy "Defining Study Designs Form" from the lab packet
    b. Review the Clinical Research Study Designs Overview in the lecture notes
    c. Fill out the form as a group based on what you learned during the lecture
    d. Turn in the "Defining Study Designs Form" by submitting a hard copy to an instructor

2. **Complete the JTASS Form**
    a. Obtain an Abstract/Article from your professor
    b. Obtain the "JTASS" Form (through CygNET or in this lab section)
    c. Fill out the form as a group based on what you learned during the lecture, and from notes in this lab section.
    d. Turn in the "JTASS Form" by submitting a hard copy to an instructor

Hierarchy of Study Designs

Utilized as Clinical Evidence



Defining Study Designs

Understanding the Hierarchy of Evidence

For the following three (3) sections:

1. **Determine the type of study design → check the appropriate box**
2. **Discuss the use and value of the study design**
    a. **What is the best use –** to support clinical decisions with evidence, provide the foundation for further research, or to provide high quality information, etc.
    b. **Explain your answer –** List strengths and limitations of this study design regarding the use as clinical evidence.

Paper 1 Method:

Totals of 175 chronic LBP and 33 chronic neck pain patients completed the Multidimensional Fatigue Inventory (MFI), Neuropathic Pain Scale (NPS), and Beck Depression Inventory rating scales on admission. In addition, an information tool was completed on each CPP and contained the following information: demographics, primary and secondary pain diagnoses, DSM-IV psychiatric diagnoses assigned, pain location, pain precipitating event, type of injury, years in pain, number of surgeries, types of surgery, type of pain pattern, opioids consumed per day in morphine equivalents, workers' compensation status, and whether, according to the clinical examination, the pain did or did not have a neuropathic component. Scores on the MFI were then compared with published norms for controls (nonpatients) via chi-squared tests. Bivariate analyses were conducted between the MFI subscales and the variables selected for analysis. Pearson correlations, analyses of variance, and t-tests were used to test for relationships between MFI scale scores and the appropriate variables. In the next step of the analysis, stepwise regression analyses were used to predict each of the MFI subscale scores using the variables that were found to be significantly ($P < 0.05$) related to fatigue by the preceding analysis. In the final analysis, the variables that were significant predictors of the fatigue subscales were controlled for as covariates in an analysis of variance in order to determine if chronic LBP patients had scores on the MFI subscales that were significantly different from those of chronic neck pain patients.

☐ Systematic Review ☐ Meta-Analysis ☐ Randomized Controlled Trials ☐ Cohort Study

☐ Case Series ☐ Case Study ☐ Animal Study ☐ Opinion

Discuss the use and value of the study design (based on direction #2 questions)

Paper 2 Method:

A 71-year-old female with low back pain sought *chiropractic* care. Her initial score on the Beck *Depression* Inventory (BDI) was 8. Intervention and outcome: The patient was treated with flexion-distraction *chiropractic* technique, moist hot packs, and interferential current to the lumbar spine a total of 11 times over 11 weeks. The BDI was administered at baseline and again three times during care. Her scores went from 8 (indicated moderate *depression*) to 4 (indicating no or minimal *depression*) to 0 during her care.

☐ Systematic Review ☐ Meta-Analysis ☐ Randomized Controlled Trials ☐ Cohort Study

☐ Case Series ☐ Case Study ☐ Animal Study ☐ Opinion

Discuss the use and value of the study design (based on direction #2 questions)

Paper 3 Method:

All new patients consulting the National College *Chiropractic* Center (NCCC) from February 1991 through mid-December 1992 with a LBP complaint episode were screened for inclusion/exclusion criteria. Screening was conducted by a staff diagnostic team independent of the attending physician. Patients who met the inclusion/exclusion criteria and our operational definition of chronic mechanical LBP were solicited for participation by a member of the research team. Patients were randomized to receive either SMT, a low force technique developed especially for this research project or a series of back lectures. Physical treatment procedures used were standardized by scheduled rehearsal with quantitative feedback on forces produced throughout the course of the study. Regardless of the group to which the patients were randomly assigned, they were scheduled for 11 visits over a two-week period. Effort was made to provide equal physician contact time for each treatment session. All treatment was administered by the attending clinician. The first follow- up occurred at the end of the two week treatment period and a second follow-up was scheduled for 2 weeks later (at the one month period). The primary outcome measures assessed at the initial visit and at both follow-up visits were: functional disability due to pain (Oswestry), perceived pain (Visual Analogue Scale), and emotional status (Modified Zung *Depression* Index).

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Discuss the use and value of the study design (based on direction #2 questions)

JTASS Guided Questions

JTASS: Journal, Title, Author(s), Site and "Summary"

Answer the following questions to determine the quality, relevance, and applicability of an article. Do not cut and paste or copy text directly from the article.

NOTE: "Summary" in this context is synonymous with "Abstract"

Journal **Understand and appraise the quality of the journal.**

Are you familiar with this journal?
(Note where and how you obtained information about the journal)

Is it peer-reviewed? Is it indexed? If indexed, where is it indexed?
(Note where and how you obtained this information)

Why is it important that journal articles be peer-reviewed and indexed?

Title **Be able to evaluate the title.**

How much information is available in the title alone?

What key words are relevant to your clinical question (PICO)?

Is it potentially interesting or possibly useful in your clinical practice?

Why or why not?

Author(s) **Make a determination regarding the quality of the authors.**

Is the track record of the authors one of careful, thoughtful work that has stood the test of time?
(Note where and how you determined the author's publication record)

What areas of expertise do the authors bring to this study? Is there any indication that methodologic and/or statistical expertise was utilized for this study?

Site **Compare the site in this study to your practice.**

Where is the site where the research was performed or from which the subjects were recruited?

Is the site considered primary, secondary, or tertiary care?

Is the site sufficiently similar to your own that results, if valid, would apply to patients in your practice?

1) Is your access to the required facilities, expertise and technology sufficient to allow you to implement the maneuver(s), therapies, diagnosis, etc described in the article?

2) Are the patients seen in the facility where the article was written likely to be similar to your patients in disease severity, treatment, age, sex, race or other key features that have an important bearing on clinical outcomes?

In areas where the site is not similar, what are the potential consequences as to how you will read the results?

Summary (Abstract) **Determine which, if any, of the results in the abstract are clinically important to you and why. Do not cut and paste or copy text from the abstract. Succinctly synthesize and summarize the key characteristics that are relevant to your clinical question (PICO) and patient.**

Team Name: _____
Date: _____

JTASS Form

JTASS stands for: Journal, Title, Author(s), Site, and Summary
Please note: Summary in this context is synonymous with "Abstract.

Do not cut and paste or copy text from the abstract.
Succinctly synthesize and summarize the key characteristics that are relevant to your clinical question (PICO) and patient.

PICO Question:

Article Citation *(Bibliographic and Static URL)***:**

J (Journal)	
T (Title)	
A (Authors)	
S (Site)	
S (Summary)	