IMPORTANT. READ CAREFULLY.

TO: M-2 Epidemiology Students
FROM: Dr. Gayed
RE: Research Critique Sessions
DATE: November 2009

Between now and the end of the course, I want you to have a brief taste of critical review of the medical literature. The intent is to give you practice reading, summarizing, interpreting, and discussing medical research. If you haven't encountered such discussions already in your graduate work, later in your graduate and/or medical training you will likely be involved in "Journal Clubs," where they're the major activity. Most importantly, however, critical review of the literature is a lifelong process that will help you to keep up-to-date with progress while retaining a reasonable degree of independent clinical judgement, so that you don't fall victim to each fad that comes along.

On Tuesday, Wednesday, and Thursday of the week after Thanksgiving- December 1st, 2nd, and 3rd- I will meet with you in 7 groups of 4 students each for roughly 2 hours per group. Each of you will be assigned a recent research paper. The papers assigned to each group will include a variety of research approaches and clinical topics. The sessions will function like a journal club, with myself as moderator and sometime expert. Papers will be assigned to you and delivered to your mailbox in the CHUB by Monday, 11/16. At the session, you are responsible for having read all papers assigned to your group, and for presenting, critiquing, and stimulating discussion about the paper specifically assigned to you.

Oral Presentation
During the group sessions, 30 minutes will be devoted to each paper. Initially, the assigned person will spend 15 minutes presenting the research. This presentation should include a basic but brief summary of the objectives, study design, and results. The remainder of the presentation should be devoted to critique of the manuscript, according to guidelines described below. Each student is expected to have read in advance all papers in his/her session, so that the speaker need not spend a great deal of time recapitulating the study. The roughly 15 minutes allocated to each paper will be spent in general discussion and questioning of the speaker on issues pertaining to the planning, conduct, and analysis of the study, which are relevant to its interpretation. I will chime in as appropriate to clarify methods or points of fact, and may bring up issues that haven't been touched upon, or that need clarification.

Brief Written Critique
Each of you is also expected to prepare a brief (<1000 words) written report on your assigned paper. You will hand in this report at the start of your group session. Your written report should not include an initial summary of the research, but should be devoted entirely to a critique. Please understand that you are by no means required to trash the paper you are reviewing, or to devote your critique exclusively to problems with it. I have not selected the papers particularly to highlight problems. Many of these papers are excellent. It is permissible and even desirable to point out good aspects of the manuscripts as well as those that may be problematic.
Attendance and Grading

At the group sessions, you are expected to have read all the papers assigned to your group, not just the one you must present. The oral and written presentations will count for 20% of your individual course grade. Of this, ½ will depend on the written report, ¼ on your oral presentation and ¼ on participation in critiques of others in your session. Barring personal emergency, no credit will be given to anyone who fails to hand in the written report during the session. The nature of the critical reviews is such that, if things work right, what each person learns depends on the presentation, and contributions to discussion, of every member of the group. Therefore, barring personal emergency, attendance at the session to which you are assigned is required. UNEXCUSED ABSENCE FROM THE SESSION WILL RESULT IN A COURSE GRADE OF U IN MEDICAL EPIDEMIOLOGY.

Structure of Reviews

Your job is to summarize and evaluate the study. You must be brief. In order to be brief and thorough you must be prepared, organized, and selective. The other members of the group will learn more and enjoy it more if your presentation is also concise, though long enough to cover the relevant issues.

The reviewer has three tasks: (A) describe the essential elements of the study; (B) describe and analyze its strengths and weaknesses; (C) describe and judge its results and conclusions. The most fundamental questions pertinent to tasks (B) and (C), for virtually any study, are:

1. Do the results the investigator claims to have found depend on (explicit or implicit) comparison of different groups and, if so, did the research design include such comparison?
2. Are the results the investigator claims to have found plausibly explainable by random chance? (Issues of statistical significance and multiplicity both may be relevant to addressing this question.)
3. Are the results the investigator claims to have found plausibly explainable by bias in selecting the study subjects?
4. Are the results the investigator claims to have found plausibly explainable by bias in measuring important variables?
5. Are the results the investigator claims to have found plausibly explainable by failure to control for confounding variables?
6. If the conclusions pertain to cause and effect, does the study design provide assurance that the purported cause actually preceded the supposed outcome?

Here are some more specific questions to consider: What did the researchers want to find out? What study design was used? Don't take at face value the terms researchers use to describe their own study design, as these may be misleading. Read the Methods and look at the tables to find out. Is the population studied representative of appropriate patients? Is it representative of my patients? Are subjects in the comparison group similar to subjects in the case or experimental group in possibly confounding traits? Was randomization, statistical adjustment, or matching used appropriately and successfully? How are levels of exposure and end-points measured? Are the measures valid and reliable? Are they the same for control versus case or experimental groups? Were the correct statistical tests used? What are the results of the significance tests? What do the tables and figures say? What inferences do the authors make? Are the inferences logically correct,
or do they involve additional assumptions that go beyond what the results themselves imply. How do the various results of the study fit together, and with outside information and common sense? What inferences may be made concerning the subjects in the study, the population from which they were drawn, and other populations?

The above questions overlap considerably with the content of the material in the Evidence-Based Medicine Working Group's series in JAMA (see references below). Your textbook is also an excellent resource. You may organize your critiques using any of these guides, an appropriate selection of the questions above, or any other way you feel appropriate so long as your critique is coherent and covers the most salient issues. In the written critique you need not cover, and in some cases won't possibly be able to cover, all issues of interest in a particular study with any clarity. Pick the most important ones. If there are too many important issues to cover them well in 1000 words, briefly mention all the issues but only discuss the most critical two or three at any length.

Please note that I haven't attempted to screen out papers which use techniques of statistical analysis beyond those you've specifically been taught, any more than I've attempted to screen out papers including other aspects of clinical medicine or basic science than you already know. Reading literature that contains material beyond your preparation will be a fact of your lives from here on out. Hopefully, what you do know and your sense of what the research involves will give you some feeling as to whether the statistical methods used are reasonable, and the investigators' explanations and discussions will provide additional insight. I will be happy to help anyone having difficulty with statistical methods you haven't seen, preferably during office hours but also at other times that we can arrange. For the purpose of this exercise it is OK to assume that the correct statistical methods have been used.

Guyatt GH, Sackett DL, Cook DJ. II. How to use an article about therapy or prevention.
  A. Are the results of the study valid? JAMA 1993;270:2598-2601.
Guyatt GH, Sackett DL, Cook DJ. II. How to use an article about therapy or prevention.
  A. What are the results and will they help me in caring for my patients? JAMA 1994;271:59-63.
Laupakis A, Wells G, Richardson S, Tugwell P. V. How to use an article about prognosis.
Jaeschke R, Guyatt G, Sackett DL. III. How to use an article about a diagnostic test.
  A. Are the results of the study valid? JAMA 1994;271:389-391.
Jaeschke R, Guyatt G, Sackett DL. III. How to use an article about a diagnostic test.
  B. What are the results and will they help me in caring for my patients?
Levine M, Walter S, Lee H, Haines T, Holbrook A, Moyer V. IV. How to use an article about harm.