

EPID/MHCH 851 ~ Reproductive and Perinatal Epidemiology ~ Fall 2009

INSTRUCTOR: Julie L Daniels, PhD

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Office Hours by Appointment

Mailbox located in 2102, 2nd floor of McGavran-Greenberg in the Epidemiology wing.

TIME & PLACE: Tuesdays and Thursdays from 2:00-3:15 in HC0003

OBJECTIVE: This course surveys the major issues relevant to the epidemiologic study of reproductive and perinatal health and touches upon other women's and children's health issues. Most lectures focus on particular substantive topics, but cover the relevant methodological issues for interpreting the literature or conducting research on the topic.

After taking this course, students should understand the important issues in reproductive and perinatal health and appreciate the complexities of research in this area.

READING MATERIAL:

1. We have the privilege of pilot testing portions of a new book written by Dr. Allen Wilcox before it is published. A draft photocopy of the book is available at the UNC Health Affairs Bookstore, now located behind the School of Nursing at 101 North Medical Dr 962-2208. In September they will move to the main book store in the Daniels Building above the Student Union 962-4708.

2. Assigned manuscripts published in professional journals will be available through the Health Sciences Library E-Reserves Program (link to be posted on Blackboard when ready). In a few cases (noted in syllabus), the articles will posted directly on the course blackboard site.

GRADES:

Assignments - see attached for detailed description	% of Grade	Due Date
• Course Paper	55%	
Approval of the paper topic		9/10
Part 1: Two paragraphs on project topic (15%)		9/24
Part 2: Literature and methodological limitations (40%)		10/29
Part 3: Proposed research design, strengths/ limitations (40%)		12/11
Overall clarity and writing style (5%)		
• Oral presentation of course paper	25%	11/17-12/8
• Birth Certificate Project (group written paper)	15%	10/15
• <i>Active</i> participation in class discussion and group activities	5%	
This partially reflects preparation for and participation in class discussions.		

Format for Assignments

All written assignments should be submitted as a **hard copy**. (Single-spaced, 1 inch margins – Times New Roman-12 or Arial-11 point font. Double sided printing is encouraged, but not required). Electronic submissions will only be accepted under unusual circumstances that have been approved by the instructor.

All written assignments should be submitted by 5pm on the due date to Julie Daniels' mailbox (Epidemiology Dept 2102). In fairness to those who meet the assignment deadlines, late papers will be penalized 10%/day unless unusual circumstances occur and have been excused.

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Lecture schedule (See Blackboard for corresponding reading assignments)

Date	Topic	Speaker
8/25	Introduction	Julie Daniels, NC
8/27	Early Pregnancy Biology	Allen Wilcox, NIEHS
9/1	Teratology	Kathy Sulik, UNC
9/3	Infant Outcomes	Julie Daniels, UNC
9/8	Methods Discussion 1	Julie Daniels, UNC
9/10	Methods Discussion 2	Julie Daniels, UNC
9/15	Reproductive Endocrinology/Fertility	Anne Steiner, UNC
9/17	Fetal Growth & Birth weight	Allen Wilcox, NIEHS
9/22	Gestational Age, Preterm Birth	Nancy Dole, UNC
9/24	Pregnancy Cohorts	Matthew Longnecker, NIEHS
9/29	STDS & Contraception	Ward Cates, FHI
10/1	Vital Records	Robert Meyer & Sydney Evans NCDHHS
10/6	Birth Certificate Project	Students
10/8	Birth Spacing	Sian Curtis, UNC
10/13	Gene-Environment	Andy Olshan, UNC
10/15	Preeclampsia	Olga Basso
10/20	Maternal weight gain and infant outcomes	Anna Maria Siega-Riz, UNC
10/22	- No Class -	Fall Break
10/27	Cerebral Palsy	Mike O'Shea, Wake Forest
10/29	Infant Feeding Trials	Walter Rogan, NIEHS
11/3	Nutrients and Birth Outcomes	Anna Maria Siega-Riz
11/5	Birth Defects	Andy Olshan, UNC
11/10	Neurodevelopment	Julie Daniels, UNC
11/12	Asthma	Stephanie London, NIEHS
11/17	Student Presentations	Students
11/19	Student Presentations	Students
11/24	Student Presentations	Students
11/26	- No Class -	Thanksgiving
12/1	Student Presentations	Students
12/3	Student Presentations	Students
12/8	Wrap-up	

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Birth Certificate Assignment

Due: October 15, 2009

Objective: To design an epidemiological study using data from the NC birth files. The outcome should be: low birth weight or preterm birth/gestational age. The exposure is your choice.

Format:

Groups will be assigned by instructor and work together to design and write up a plan to study. You will be given one day in-class to work together. Schedule any additional meetings needed to write up the assignment at your convenience.

In Classroom:

Discuss with your group

Outcome: Low birthweight or preterm birth/gestational age

Risk Factor: One of your choosing

Study Design: Your choice

Written Assignment:

1. Study Plan: 2 single-spaced pages describing study design, including:

Specific Aims: List study aims or hypotheses

Background: 1 paragraph

Methods: describe basic study design and define variables of interest

Be sure to define key variables and justify the design choice and all related decisions.

Analysis Plan: briefly (1 paragraph) describe how you will approach statistical analysis to answer the question (power calculations not necessary)

Strengths & Limitations: Acknowledge any biases and how they might affect results and interpretation of your study. Describe any strategies taken to enhance your ability to detect associations and improve study design and results.

2. Causal Diagram – (1 page) Draw relevant etiologic pathways for key variables. Include covariates and indicate how they might confound or modify the exposure outcome relationship.

One written document should be submitted per group. Attach a cover page indicating how each group member contributed to the project (1-2 sentences per person, tops). References are necessary only to credit specific statistics quoted or if they are necessary to justify the specific cutpoints for categorizing variables or other decisions you make.

Resources:

Review the readings associated with Dr. Robert Meyer's lecture on Vital Statistics.

A copy of the electronic birth certificate can be found at:

<http://www.cdc.gov/nchs/data/dvs/birth11-03final-ACC.pdf>

The NC Babybook allows you to view cross-tabulations of various maternal and infant variables such as age, race, birth order, birthweight, etc. It may be useful to determine population prevalence of various exposures or otherwise get a better feel for the population.

The "definitions" page describes how variables are defined on the birth certificate.

<http://www.schs.state.nc.us/SCHS/births/babybook/2007/>

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COURSE PAPER

Objective:

To develop the idea and strategy for a research proposal addressing a significant unresolved issue in the area of reproductive / perinatal epidemiology. Rather than focusing on the mechanics of study design and general issues in the development of research proposals (covered in other courses), the emphasis in this course is on formulation of a research question, the content of the study, and how it will add to our knowledge in reproductive epidemiology. The components of this paper are outlined below.

TOPIC FOR APPROVAL

DUE: September 10, 2009

Identify an important unresolved question about the relationship between some exposure and reproductive/perinatal health outcome (both broadly defined). Write one or two sentences about the *specific* topic you want to use for this project. Also indicate the number of papers on this *specific* topic that have appeared in *PUBMED* in the past 10 years. The purpose of this approval is to ensure the topic is relevant and that there are enough, but not too many, publications in recent years (shoot for 3-10 so that it is manageable for you). The more specific you are about the hypothesis you are studying, the easier this assignment will be.

SECTION 1

DUE: September 24, 2009

1. Description of the Problem (2 paragraphs, ≤ 1 page):

Describe the unresolved question. Include a statement about the public health importance and incidence/ prevalence of the issue.

SECTION 2 (3 pages total)

DUE: October 29, 2009

2a. Literature Review (~2 pages):

Review the pertinent literature to characterize the current state of knowledge, focusing on the limitations of previous research that leave the question unresolved.

2b. Methodological Limitations of Previous Research (~1 page):

While the literature review (2a) may acknowledge all of the relevant methodological issues, this section should focus on the one issue that has really hindered resolution of the question in previous studies. Describe how the issue has limited previous research and the implications of those limitations (e.g. type of bias and likely effect on conclusions. This issue will be what you improve upon in the study you propose.

SECTION 3 (3 pages total)

DUE: December 11, 2009

3a. Research Design (~2 pages):

Sketch out a research design to overcome the limitation described in section 2b. Even if the problem cannot be completely solved, be specific in indicating how your study represents an improvement over the past efforts and will add to our understanding. Briefly address the specifics of: study design, define the study population and selection/recruitment process, method of measuring and defining the exposure and outcome, and a brief indication of the analytical approach. Be specific and provide rationale for each decision. The aspects of the design which address the limitation you have identified should be adequately described so your solution can be evaluated.

3b. Strengths and Limitations (~1 page):

Summarize the strengths and limitations of your proposed study, include how they might affect the results and interpretation.

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PAPER PRESENTATION

November 17-December 8, 2009

Objective:

In a 10 minute presentation of your course paper, you should quickly educate the class on the topic and the methodological issues that have limited prior research. Then describe the approach you have developed to improve upon previous work.

Format:

10 minutes to present and a few additional minutes for questions.

The time limit simulates that allotted for a short presentation at a scientific meeting and will be strictly monitored.

Visual aids of some sort, preferably power point, are required. When preparing slides, remember that slides should not contain lengthy text in paragraph form. They are much more effective if only a few key points are made on each slide. Graphic displays are encouraged. Too many bells and whistles are distracting and should be used sparingly.

On the day that you are presenting, please arrive a little early to load your presentation on the classroom PC hard drive so that we can quickly transition between students.

Points to cover in the presentation:

- Primary study question or research aim
- Brief overview of literature and state of knowledge for your topic
- Main methodological issue(s) that have limited previous research
- Proposed study design, including: source of subjects, exposure and outcome measurement, assessment of important confounding or effect modifying factors, general analytic approach, and any other important design/analysis strategies.
- Summarize strengths and limitations

You must be succinct. Presenting the big picture in a summary/overview manner will help allow time to cover the main points in more detail without being too rushed. Practicing will help.

You will be graded on:

1. Knowledge of subject
2. Quality of information presented:
 - Identification of key problems and their impact
 - Study design strategy to improve upon key problem
3. Clear presentation style
 - Effective slides or visual aids
 - Smooth and practiced presentation, relaxed but not overly casual
4. Response to questions

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EPIDEMIOLOGY METHODS DISCUSSION

September 3 and 10, 2009

Each Student should review the assigned “mini-papers” posted on Blackboard before the scheduled in-class methods discussions. These mini-papers include a section of a published epidemiologic study. As you review the paper, note strengths and weaknesses with respect to:

- Overall study design
- Study population
- Measurement of exposure
- Measurement of outcome
- Potential biases
- Statistical methods
- Interpretation (if applicable)

Think about what the ideal or “gold standard” might be for answering the general research question. Consider how the features of the reviewed study relate to that standard.

In class, be prepared to:

- Briefly present the basic study question and design
- Describe the two most important strengths and limitations of the study
- Define and describe the problematic methodological issues or design features and possible alternatives.