MED:8101-8104
Clinical Epidemiology

Objective and Requirements

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Epidemiology Schedule 2016-17

<table>
<thead>
<tr>
<th>Biweekly/Weekly Topic</th>
<th>Topic</th>
<th>Fargo</th>
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<tbody>
<tr>
<td>Thursday, August 18, 9am-11am CST</td>
<td>Lecture: Project Requirements; Part I. Steps in Clinical Research &amp; Developing a Research Question</td>
<td>Thursday, August 18, 9am-11am CST</td>
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<tr>
<td>Monday, October 3</td>
<td>Assignment Due: Research Questions - No Class</td>
<td>Monday, October 3</td>
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<tr>
<td>Thursday, October 20</td>
<td>*Group Meeting 1: Research Question &amp; Topic Feasibility</td>
<td>Friday, October 21</td>
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<tr>
<td>Monday, November 28</td>
<td>Assignment Due: IRB Forms/Protocol - No Class</td>
<td>Monday, November 28</td>
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<tr>
<td>Thursday, December 8</td>
<td>*Group Meeting 2: IRB Forms</td>
<td>Friday, December 9</td>
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<tr>
<td>Thursday, February 16</td>
<td>*Group Meeting 3: Status/Data</td>
<td>Friday, February 17</td>
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<tr>
<td>Thursday, March 2</td>
<td>Research &amp; Writing a Research paper</td>
<td>Thursday, March 2</td>
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<tr>
<td>Thursday, April 27, 9am-4pm</td>
<td>Presentations and Paper</td>
<td>Friday, April 28, 9am-4pm</td>
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<tr>
<td>Monday, May 15</td>
<td>Paper Due</td>
<td>Monday, May 15</td>
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Epidemiology Lectures & Presentations
9-11am CST 9am-4pm CST

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<tr>
<td>Thursday, August 18, 2016</td>
<td>Lecture: Project Requirements; Research in Clinical Epidemiology; Hypotheses &amp; Topic Selection</td>
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<tr>
<td>Thursday, November 10, 2016</td>
<td>Lecture: Methods-Protocol Institutional Review Board</td>
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<tr>
<td>Thursday, March 2, 2017</td>
<td>Lecture: Results &amp; Writing a Research paper</td>
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<tr>
<td>Thursday, April 27, 2017, 9am-4pm</td>
<td>Presentations 9am-4pm</td>
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Epidemiology Group Meetings
9am-5pm CST; 20-30 minutes/group

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<td>*Group Meetings 1: Research Question Topic Feasibility</td>
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Epidemiology Assignments—No Class
E-mail to Dr. Beal: james.beal@med.und.edu

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<td>Friday, April 28, 2016</td>
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<tr>
<td>Monday, May 15@ 5pm CST</td>
<td>Paper</td>
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“*Add last name of group members top file names**

Educational Goal
• Develop an Understanding of Clinical Research
Course Learning Objectives

On completion of this course and its assignments, the student should be able to:

• Formulate a research question
• Identify and evaluate basic study designs (e.g., descriptive, cross-sectional, case-control, cohort) used in observational epidemiology
• Design an observational epidemiology study
• Understand the Institutional Review Board (Human Subjects Review) process
• Understand and utilize CDC national secondary datasets
• Recognize appropriate analysis and interpret results to answer a research question
• Present research findings in a useful and readable manner, including clear and concise tables
• Write a research manuscript

Course Activities:

Students will:

• Formulate a research question on a topic of personal interest and curiosity
• Conceptualize and design a chart review-based clinical research project to answer the research question
• Complete the CITI on-line IRB education/research ethics course
• Obtain UND Institutional Review Board approval
• Utilize the CDC’s National Center for Health Statistics National Ambulatory Medical Care Survey (NAMCS) or the National Hospital Ambulatory Medical Care Survey (NHAMCS) for data collection
• Use appropriate statistical analysis output of data to determine the findings of the study
• Develop a 15-minute presentation of the study to be given to the class
• Write a manuscript of the study in IMRAD format

3rd-year Research Project?

“Tell me and I’ll forget;
show me and I may remember;
involve me and I’ll understand.”
General Requirements

• Student(s) must be primary investigator
• Pick a partner to complete the project
  • No 3+ member teams
• Discussion/approval of your project with Dr. Beal
• Define a need for new or continued research in an area of interest
  • Develop a question(s) that a study may answer

General Requirements

• Obtain UND IRB Approval-if necessary

• Utilize the CDC National Center for Health Statistics secondary datasets:
  • 2013 National Ambulatory Medical Care Survey (NAMCS)
  • 2011 National Hospital Ambulatory Medical Care Survey (NHAMCS)
• No Chart Reviews
• No other Databases
• REMS students-can’t use previous data and should be a new idea

National Ambulatory Medical Care Survey (NAMCS)

• National survey of ambulatory medical care services in the United States.
• Sample of visits to non-federal, office-based physicians who are primarily engaged in direct patient care.
• Excludes: Anesthesiology, pathology, and radiology physicians.
National Hospital Ambulatory Medical Care Survey (NHAMCS)

- Data on the utilization and provision of ambulatory care services in hospital:
  - Emergency departments
  - Outpatient departments
  - Ambulatory surgery centers.
- National sample of visits to emergency and outpatient departments and to ambulatory surgery facilities in noninstitutional general and short-stay hospitals

General Requirements

- Presentation of findings to class and faculty
  - 15 Minutes
  - 10-12 presentation
  - 3-5 minutes for questions

General Requirements

- Complete a concise, well-written report:
  - Approximately 2,000-2,500 words not including Abstract & References
  - Abstract- 250 words
  - Medical journal format
    - Introduction, Methods, Results, and Discussion
    - References- numbered in order of appearance
  - Adequate citations to thoroughly explore topic-min 10 References
General Requirements

• Email all assignments, presentations, and paper to Dr. Beal-
  james.beal@med.und.edu
  ♦ Preferably in Microsoft Word
  ♦ Tables, Figures, and/or graphs on separate page
  ♦ Put your names in the document
  ♦ Add Last Name of Group Members to file name
    • Ex: Beal-Sahmoun homework question.docx

General Requirements

• All Abstracts will be published on the DFCM website
  ♦ Manuscripts available upon request, unless written notification is given stating that you do not wish your manuscript to be shared.

Assignments Due Dates:

• Monday, October 3, 2016:
  Research Question Homework
• Monday, November 28, 2016:
  IRB Forms/Protocol
• Presentations : Email copy to Dr. Beal
  – Bismarck/Minot: Thursday, April 27, 2017
  – Fargo/GF: Friday, April 28, 2017
• Monday, May 15:
  Paper
Grading Components
• Research Paper – 70%
• Presentation – 25%
• Homework – 5%

Grading
• Epidemiology Course
  • Honors; 90% and 90 percentile
  • Satisfactory; 70-89%
  • Unsatisfactory; <70%
• Course Final Percentage
  • Factored into Class Rank with other Clerkship scores

Research Paper
• Definition of Problem and Development of Hypothesis (10 pts)
• Literature Review (currency, breadth, and depth -10 pts)
• Adequacy of Methods including Data Collection and Selection/Use of Research Tools(20 pts)
• Analysis of Data/Adequacy of Reported Results (including tables/figures - 20 pts)
• Adequacy of conclusions with respect to data (20 pts)
• Limitations/Recommendations for Future Study(10 pts)
• General Organization, Format, & Writing Skills(10 pts)
Presentation

- Title and introduction adequately described problem/topic (10 pts)
- Adequacy and suitability of methods (10 pts)
- Adequacy and suitability of data analysis/reported results (10 pts)
- Clarity of graphs and/or tables (10 pts)
- Adequacy of conclusions drawn data with respect data (10 pts)
- Overall quality of presentation- Clear, concise organization; easy to follow (10 pts)

Grading - Example

- **Research Paper-70%:**
  
  92/100 or 64.4/70%;

- **Presentation- 25%:**
  
  59/60 or 98.3%*25 = 24.6 /25%

- **Homework-5%:**
  
  5/5-

- **Overall Research Project Grade: 94.0%**
  
  *Epidemiology Course – Honors
  
  » 90th percentile = 91.0

Epidemiology Web-based Manual

- **UNDSMHS Homepage**
  
  - Education
  - Degree Programs
  - MD Program-Doctor of Medicine (MD)
  - Clinical Epidemiology

- **http://www.med.und.edu/education-resources/epidemiology/index.cfm**
Epidemiology

Epidemiology is the study of the distribution and determinants of disease within human populations

— Medical Epidemiology 3rd ed.

Research and Practice

• Some physicians do research; all use research

• In everyday patient care, physicians evaluate, select, recommend, and explain new information and clinical interventions

• Research covers the entire spectrum of clinical problems as well as the organization and delivery of healthcare
Research Improves Healthcare

- Every physician should participate in the essential process of identifying and answering questions
  - that change practice
  - improve the health of our patients

Research Improves Healthcare

- Cupping
  - Ancient Chinese therapy
- Glucosamine and chondroitin sulfate
  - U.S. consumers spent $753 million in 2012
  - The American College of Rheumatology (2012) ... does not recommend for the initial treatment of osteoarthritis.
  - Mayo-“Evidence supports the use of glucosamine sulfate taken by mouth to treat knee osteoarthritis”

What makes a good clinical researcher?

- Curiosity
- Interest in the topic
- Good reasoning skills
- Patience
- Determination
- Commitment
Research Improves Healthcare

• Dr. Lind – Scurvy (1740s)
• Dr. Snow – Cholera (1860s)
• Sister Mary Joseph -- Cancer (1890-1915)

Dr. Ignaz Semmelweis- Handwashing (1841)

• Childbed fever
• 10% mortality in Division 1
  – Teaching service for medical students
• 3% mortality in Division 2
  – Midwives only
• Friend died after poked with a student's scalpel while performing an autopsy
• Cadaverous particles

Dr Alton Ochsner (1896-1981)

• Surgeon from South Dakota
• Noted a relationship between smoking and lung cancer
• Drs. Ochsner and DeBakey (1939) - First published research association between smoking and lung cancer
Research Improves Healthcare

• Fen-Phen Pills-
  ♦ 1996-$18 million prescription
  ♦ Dr. Crary

Research Question development

It is observing one’s practice and asking questions

You are always developing hypotheses - you may not always be testing them.

• It is more likely to rain after I wash the car.

• Boards part 1 has more microbiology questions than any other subject.

• More students fall asleep during Epi than any other lecture.
Moving Curiosity into Action

- Observe your surroundings
- Write down your ideas
- Read (literature searches)
- Ask Questions
- Consult
- Adapt
- Hone your general idea(s) down to an answerable question

“The best way to have a good idea is to have a lot of ideas and to throw out the bad ones.”
-- Linus Pauling, Ph.D.

FINER Criteria

F - Feasible
I - Interesting
N - Novel
E - Ethical
R - Relevant

Example

"Postpartum Weight Retention Risk Factors and Relationship to Obesity at 1 Year"
Obstet Gynecol. 2015 Jan;125(1)

Reviewed in Aug 2014 for Obstetrics & Gynecology- The Green Journal

Time and Effort

• Be honest with yourself – opportunity vs. cost
• What do you want to get out of it
• Question(s) asked
• Study design
• Advice: start simple – you can “investigate” more later

Developing Research Questions:
Common Mistakes

Identify the problem area
• Not taking a critical attitude
• Putting off selection of a problem
• Select a problem that is too vast or vague

Survey the literature-PUBMED
• Not narrowing your search terms
• Relying on textbook or review articles
• Overlooking information in Methods
• Overlooking information in Discussion
Literature Review: Where the investigation starts

Don't blindly search – map out the questions you want your literature search to answer

Literature Review: Where the investigation starts

• Ancestry Approach
• Descendency Approach
• Database Search
• "Invisible College" Approach

Literature Review: Where the investigation starts

• Why we review the literature
  • Methodological ideas – lesson learned by other investigators
  • Helps solidify terms, measurements, etc.
  • Helps bring forth questions
  • Helps put your findings into perspective
Bennet’s Classification for Reading Medical Articles

<table>
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<tr>
<th>Role</th>
<th>Description</th>
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<tbody>
<tr>
<td>Medical student</td>
<td>Reads entire article but does not understand what any of it means</td>
</tr>
<tr>
<td>Resident</td>
<td>Would like to read entire article but eats dinner instead</td>
</tr>
<tr>
<td>Junior Attending</td>
<td>Reads and analyzes entire article in order to pimp medical students</td>
</tr>
<tr>
<td>Chief resident</td>
<td>Skips articles entirely and reads the classifieds</td>
</tr>
<tr>
<td>Physician attending</td>
<td>Doesn’t buy journals in the first place but keeps an eye open for medical articles that make it into Time or Newsweek</td>
</tr>
<tr>
<td>Emeritus attending</td>
<td>Reads entire article but does not understand what any of it means</td>
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Research Question Development

- Identify variables you are interested in:
  - Exposure (risk factor, protective factor, predictor variable, treatment, disease)
  - Outcome (disease/problem, event, measure)
- Compare groups of subjects with respect to the exposure and outcome

PICO Criteria: Research Questions

- Population
- Intervention (Exposure)
- Comparison
- Outcome
Research Question Development

- State the exposure to be measured as specifically as possible.
- State the health outcome as specifically as possible.

Good Ideas?

- Is there a relationship between spinal deformity (scoliosis) and body image before and after corrective surgery in adult women?
- Is there an association between breastfeeding and the pass-fail rate on the MCHAT (Autism)?
Good Ideas?

- Is there a correlation between childhood obesity and number of fast food meals consumed per week?

- Is there an association between obesity and type II diabetes among Native American vs. White adolescents?

Writing Your Research Questions

- Is there an association between... exposure... and... outcome (rate)?

- Is there a difference in... exposure... and... outcome (level/measure)?

Writing Your Research Questions

“Association”, “Relationship”

The degree to which the rate (percentage) of disease in persons with a specific exposure is either higher or lower than the rate of disease among those without that exposure.

“Is there an association between obesity and A1c control (<7) among diabetic patients.”
Writing Your Research Questions

“Difference” or “Correlation”

The degree to which the level/measure (mean) in persons with a specific exposure is either higher or lower than the level/measure among those without that exposure.

“Is there an difference between obesity and A1c levels among diabetic patients.”

Examples

• The association between cardiovascular risk factors and obstructive sleep apnea

• The association between maternal substance abuse and pregnancy outcomes

• The association between a history of preeclampsia and future development of hypertension in American Indians

Writing A Research Questions

• Two most important questions to ask:
  • Is the information available
  • Will there be a large enough sample
  • DO THE MATH!!
Homework

• Write two distinct questions, i.e., different topics, of interest with main ICD-9 codes.
• For each question list five journal articles and attach a copy of the best article/reference for each question.
• References should be single studies not reviews, guidelines, or textbooks.
• Rename Document with Last Names of Group
• Due by Monday October 3, 2016.
  e-mail to Dr. Beal: james.beal@med.und.edu

Example

• Association between Obesity and Depression in Middle-aged Women
  • Obesity= ICD-9: 278.00
  • Depression= ICD-9:311 or 296.3


Homework

• Review NAMCS and NHAMCS Documents and Website
  • 2013 National Ambulatory Medical Care Survey (NAMCS)
  • 2011 National Hospital Ambulatory Medical Care Survey (NHAMCS)
  • http://www.cdc.gov/nchs/ahcd/about_ahcd.htm
Homework

- Review ICD-9 websites and documents
  - icd9.chrisendres.com-
    http://icd9.chrisendres.com/
  - ICD9Data.com-http://www.icd9data.com/
  - Find-A-Code-

Homework

- Required Human Subjects Research Education
  - CITI Program
    Biomedical Researchers-Basic Course
    https://www.citiprogram.org
  - Epidemiology Schedule Page for Directions
    http://www.med.und.edu/medical-education/epidemiology/schedule.cfm
  - E-mail Completion Report to Dr. Beal:
    james.beal@med.und.edu

References

- IGNAZ PHILIPP SEMMELWEIS by John H. Lienhard
- Greg Holzman, M.D. “Epidemiology: Developing and Testing Hypotheses”.
- Abe Shamoun, Ph.D.
- Vancouver JB et al. (1993). Planning a Research Study. Michigan State University, Office of Medical Education Research and Development
Write two distinct questions, i.e., different topics, of interest. For each question list five journal articles and **attach a copy of the best article/reference for each question**. References should be articles and/or studies not textbooks or guidelines. Include main ICD-9 codes for primary outcomes/diseases.

Due (e-mail to Dr. Beal: james.beal@med.und.edu) by Monday October 3, 2016.

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