Methods in Clinical Research
NUR 930
Wednesday, 1:50-4:40
Grand Rapids
Spring, 2008

Course Description:

This course will focus on a broad range of research designs and analytic issues related to the study of health status and health outcomes in individuals and populations. The discussion will center on the relative merits of choosing experimental/quasi-experimental or observational/survey designs, retrospective vs. prospective designs, and cross-sectional vs. longitudinal designs. A major theme in this discussion is how the quality of the evidence that is sought (descriptive statements, causal statements, statements that can be generalized to larger target populations) is influenced by the particular study designs chosen. Detailed analyses of published research will be used to shed light on the relationship between research design and quality of obtained evidence. A second theme involves the trade-offs between institutional constraints and human subject protection on the one hand and research design demands on the other, since clinical research occurs in institutional settings that offer researchers limited control in shaping the evidence. In line with this focus on the feasibility of research in clinical settings, the relationship between practical aspects of research implementation and quality of evidence is stressed, including issues such as: safeguarding the rights of human subjects, the trade-offs between the demands of sampling theory versus practical subject recruitment and retention, data management and quality assurance, data analysis issues in the face of ‘incomplete’ clinical data sets, etc.

Course Objectives:

At the conclusion of the course, the student will be able to:
1. Analyze the strengths and limitations of research designs used most frequently in health care research.
2. Compare major methods of probability/non-probability sampling and techniques to calculate adequate sample size.
3. Identify data analysis strategies appropriate to specific research designs.
4. Critique research designs and data analytic strategies in published research studies.
5. Understand theoretical and practical issues related to the protection of the rights of human subjects in research.
6. Formulate strategies for research implementation including the development of study timelines, subject recruitment and retention, data management plans and methods to assure data quality.
7. Develop a research proposal.

Course Faculty:
Manfred Stommel, Ph.D.
Associate Professor
W-149 Owen Graduate Center
Telephone: 355-5123
Fax: 353-9553
E-mail: stommel@msu.edu
Required Textbooks:


Required Readings:


Recommended Readings:

(Comment: Even though some of these texts are older, they have obtained the status of ‘classics’ in their field and should be consulted.)


Mulay, M. A Step by Step Guide to Clinical Trials. Boston, MA: Jones and Bartlett, 2001


Instructional method:

Seminar discussion (major emphasis!), student presentations, some lecture.

Methods of evaluation:

1. Tests (40 %) – These in-class exams will cover all course content including the assigned readings. (See separate hand-out for detailed information on the mid-term and final exams.)

2. Analysis of published research studies (30%):
   a. Each week, students will be assigned to individual class presentations.
   b. The presentations involve taking the lead in analyzing one of the assigned research articles, addressing: (1) the appropriateness of the study design in light of the stated study goals, the study implementation in the areas of (2) recruitment/sampling, (3) measurement/data collection, (4) data analysis, and (5) interpretation.

3. A research proposal covering five segments with the following content (30%):
   a. Statement of a research problem, containing research question(s), hypotheses, rationale and brief background discussion (maximum of 3 pages); particular emphasis is placed on clear identification of outcome variables and predictor/independent variables (5%).
   b. Discussion of a chosen research design (maximum 3 pages), containing a clear description of a specific design and a rationale for its choice (10%).
   c. Outline of a sampling and recruitment plan (maximum 2 pages), including both theoretical and practical rationales for particular sampling methods chosen (5%).
   d. Statement of a Study Implementation Plan (3 pages maximum) containing a list of all resources necessary for the implementation of the study, a tentative budget, and specific timelines (5%).
   e. Preparation of a UCRIHS human-subjects-approval application for the study (5%).

All research proposal segments will be presented and discussed in the seminar, after which the student will submit a modified/improved version for final evaluation.
Research Proposal Outline:

The following contains a brief outline of all the major segments in a research proposal. It should be use a guideline in the preparation of the proposal segments for the seminar.

- **Introduction**: topic area and focus of the proposal plus literature review: a short summary of the substantive background issues and (if applicable) the methodological issues involved in past research.
- **Rationale for your research problem**: what problem does it address/solve, what research agenda does it advance, who would be interested in the knowledge generated by your study? etc.
- **Theoretical Modeling**: a conceptual or theoretical model, presented verbally or graphically, that specifies the relationships among MAIN concepts (and variables representing the concepts) that are part of the proposed research study.
- **A full statement of the research problem, research questions and (if applicable) research hypotheses**: the research question(s) should be clearly related to an explicit statement about the aims and purposes of the proposed study; questions or hypotheses include a clear formulation of the logical status of the variables involved, i.e., in the framework of the proposed study, do the variables simply identify foci of observations/data collection (as in some descriptive studies) or do they function as dependent, intervening, independent or confounding variables within the theoretical model?
- **(The following section is optional and may not apply:) Short description of past research efforts**: past research projects and publications that led to the current application; preparatory work in measurement or sampling; past access to relevant target populations, etc.
- **Measurement of key variables**: a precise description of the outcomes measures chosen that represent the key concepts in the proposed research (including the measurement properties of chosen scales, data collection techniques, handling of known measurement problems, such as recall bias, etc.)
- **Research design**: a detailed description of the research design with a rationale for the chosen design:
  1) is the design cross-sectional or longitudinal, how many observations on the study participants, etc.
  2) prospective or retrospective,
  3) experimental, quasi-experimental or non-experimental,
  4) relies on primary data or secondary data collection.
- **Study Sample**:
  1) a detailed description of the target population,
  2) recruitment plan and sampling procedures,
  3) determination of initial sample size in light of likely subject attrition over the course of the study and required statistical power,
  4) for intervention studies: a detailed description of subject assignment procedures, including randomization procedures,
  5) a description of procedures to minimize subject attrition.
- **Study Implementation**:
  1) a description of all major task categories involved in the implementation of the research project, including the suggested personnel for the various tasks, traveling, resource needs, etc.
  2) time table: a plan that specifies all major anticipated study phases and their likely duration.
- **Data Analysis**: an outline of an analysis plan that details suggested approaches to data analysis, statistical models employed, interpretative methods, software implementations to be used.
- **A description of procedures to safeguard the rights of human subjects.**
## Course Calendar:

<table>
<thead>
<tr>
<th>Week</th>
<th>Date</th>
<th>Topic</th>
<th>Reading/Assignment/Activity</th>
</tr>
</thead>
</table>
| 1    | 1/9  | Course introduction:  
- What is “science”?  
- Components of a research design  
- Extracting design components from published research studies  
- Asking Researchable Questions  
- Theoretical vs. practical choices | **Texts:**  
SC&C: Chapter 1;  
S&W: Chapter 2;  
H et al., Chapters 1-2. |
| 2    | 1/16 | Are nursing researchers social or natural scientists?  
- Causal inference  
- Motivational understanding  
- Human action versus human behavior  
- Criteria for “correct” causal inference  
- Criteria for “correct” interpretation of human understandings  
- Induction versus deduction  
- Internal and External Validity | **Texts:**  
SC&C: Chapter 1;  
S&W: Chapters 2, 3, 12;  
**Papers:**  
Fay & Moon, 1998;  
Hutchinson, 2001;  
Machlup, 1998;  
Sandelowski, 2001;  
Susser, 1991; |
| 3    | 1/23 | Causal inference in experimental studies I:  
- Designs with separate control groups  
- The logic of randomization  
- Threats to validity | **Texts:**  
H et al., Chapters 10;  
SC&C: Chapters 2, 8, pp. 246-266;  
S&W: Chapters 3-4;  
**Studies to be analyzed in class:**  
Clark et al., 1998;  
Dansinger et al., 2005;  
Peragallo et al., 2005. |
| 4    | 1/30 | Causal inference in experimental studies II:  
- Repeated measures and repeated treatment designs  
- Cross-over designs | **Texts:**  
H et al., Chapters 10;  
S&W: Chapters 3-4;  
SC&C: Chapter 8, pp. 266-269;  
**Studies to be analyzed in class:**  
Cohen et al., 2005;  
Henry et al., 2006;  
Faucett et al., 2007;  
**Discussion of Student Research Problems** |
<table>
<thead>
<tr>
<th>Week</th>
<th>Date</th>
<th>Topic</th>
<th>Reading/Assignment/Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>2/6</td>
<td>Causal inference in experimental studies III:</td>
<td>Texts: H et al., Chapters 11, pp. 167-169; S,C &amp; C: pp.269-278; Chapters 9, 10; S&amp;W: Chapters 5.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Practical Problems in Intervention Studies and Clinical Trials</td>
<td>Papers: Fogg &amp; Gross, 2000; Gross &amp; Fogg, 2001; Sidani et al., 2003; Stommel &amp; Wills, 2008.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Strategies to improve validity of intervention studies</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Ethics of intervention studies</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>2/13</td>
<td>Characteristics of quasi-experimental designs:</td>
<td>Texts: S&amp;W: Chapters 6-7; SC&amp;C: Chapters 4, 5, 6; Studies to be analyzed in class: Forbes et al., 2006; Metheny &amp; Stewart, 2002; Smith et al., 2006.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Non-equivalent control group designs</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Interrupted time-series designs</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Causal Inference without random assignment</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>2/20</td>
<td>Quantitative observational studies I:</td>
<td>Texts: S&amp;W: Chapters 8-9; H et al., Chapter 7; Studies to be analyzed in class: Leveatt et al., 2004; Tsubono et al. 2001; Stommel et al. 2006.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Cohort studies</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Selection Criteria</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Retrospective and prospective design</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Attrition problems</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Discussion of Student Research Designs</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>2/27</td>
<td>MIDTERM EXAM</td>
<td>Covers material through 2/20</td>
</tr>
<tr>
<td>3/3-3/7</td>
<td>SPRING BREAK</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>3/12</td>
<td>Quantitative observational studies II:</td>
<td>Texts: H et al., Chapter 8; S&amp;W: Chapters 10-11; Studies to be analyzed in class: Bremner et al., 2005; Kõlves et al., 2006; Simko et al., 2006.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Case Control studies</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Selection Criteria</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Retrospective and prospective design</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Recall bias</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>3/19</td>
<td>Quantitative observational studies III:</td>
<td>Texts and Papers: H et al., Chapter 13; S&amp;W: Chapters 12, 18; Studies to be analyzed in class: Flegal et al., 2007; Stommel et al., 2002; Stommel et al., 2004.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Survey designs:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• cross-sectional,</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• longitudinal,</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• panel studies</td>
<td></td>
</tr>
<tr>
<td>Week</td>
<td>Date</td>
<td>Topic</td>
<td>Reading/Assignment/Activity</td>
</tr>
<tr>
<td>------</td>
<td>------</td>
<td>-------</td>
<td>-----------------------------</td>
</tr>
</tbody>
</table>
| 11   | 3/26 | Measurement and Instrument Development Studies:  
• Reliability and validity in measurement  
• Sensitivity, specificity, PPV, NPV  
• Instrument development studies  
• Mixed methodology studies | Texts:  
H et al., Chapter 13;  
S&W: Chapters 13-16;  
Studies to be analyzed in class:  
Beck, 1993; Beck, 1997;  
Beck & Gable, 2000;  
Beck & Gable, 2001;  
Brener et al., 2003;  
Sandelowski, 2000;  
Stommel et al., 2004;  
Canady & Stommel, 2008. |
| 12   | 4/2  | Key concepts in sampling  
• Units of analysis and definitions of populations  
• Samples and Populations  
• Types of Sampling  
• Statistical Inference based on probability sampling  
• Statistical inference versus induction: types of generalizations  
• Meta-analysis  
• Practical Sampling Issues  
• Recruitment and retention of subjects | Texts:  
H et al., Chapters: 3, 5-6, 13;  
SC&C: Chapters 11-13;  
S&W: Chapters 19-21; pp. 273-275;  
Studies to be analyzed in class:  
Dansinger et al., 2005;  
Flegal et al., 2007;  
Stommel et al., 2006;  
Tsubono et al. 2001; |
| 13   | 4/9  | Study Implementation:  
• Pilot testing  
• Developing study procedures, interviewer training and supervision  
• Quality control in research studies  
• Preparation for data analysis: formatting, coding & cleaning data, handling missing data  
Safeguarding the rights of human subjects in research:  
• High risk subjects  
• Approaching human subjects  
• Using existing databases for recruitment purposes  
• Data management & the rights of human subjects  
• Use of secondary data and the rights of human subjects  
• Scientific integrity and the research process | Texts and papers:  
H et al.: Chapter 14 – 17;  
SC&C: Chapters 9, 10;  
S&W: Chapter 23, 24;  
Pallikkathayil et al, 1998 (Part 1&2);  
Midwest Nursing Research Society Guidelines for Scientific Integrity;  
American Psychological Association Guidelines for Ethical Conduct;  
Michigan State University Committee on Research Involving Human Subjects, website:  
MSU Procedures on Allegations  
Involving Misconduct in Research and Creative Activities, website:  
[http://www.msu.edu/dig/miscon/](http://www.msu.edu/dig/miscon/) |
<table>
<thead>
<tr>
<th>Week</th>
<th>Date</th>
<th>Topic</th>
<th>Reading/Assignment/Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>14</td>
<td>4/16</td>
<td>Presentation and Discussion of Student Research Proposals</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>4/23</td>
<td>Data analysis strategies: Overview of data analysis options and examples for interpretation II:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Analysis of experimental vs. non-experimental data</td>
<td>Texts:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Cross-sectional vs. longitudinal data (including panel studies and time series data)</td>
<td>H et al.: Chapter 17, 19; SC&amp;C: Chapters 9, 10; S&amp;W: Chapter 23, 26;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Data with continuous outcome measures</td>
<td>TBA: Special Assignments</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Data with categorical outcome measures</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Time to event/survival data</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Data with matched study samples</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Data with complex sampling designs</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Measurement models</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Principles of writing:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• A proposal</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• A journal article</td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>4/30</td>
<td><strong>FINAL EXAM</strong></td>
<td>Covers material through 4/23</td>
</tr>
</tbody>
</table>