HRM 751 OBSERVATIONAL RESEARCH METHODS

2023

Course Coordinator: Andrew Mente
Instructors: Andrew Mente, Wael Abdelkader
TA: Wael Abdelkader
Time: Monday mornings 9:00 am to 12:00 pm
Locations: **Large group lecture:** **MDCL room TBA**

DATE	FORMAT	TIME	LECTURER	CLASS TOPIC
Sept. 11	Lecture Tutorial	9-10 10-12	AM	1. Course introduction. Overview of Observational Studies
Sept. 18	Lecture Tutorial	9-10 10-12	AM	2. The Research Question & Theoretical Frameworks
Sept. 25	Lecture Tutorial	9-10 10-12	AM	3. Study designs for epidemiology – I
Oct. 2	Lecture Tutorial	9-10 10-12	AM	4. Study designs for epidemiology - II
Oct. 9				
Oct. 16	Lecture Tutorial	9-10 10-12	AM	5. Survey methods, questionnaire design and implementation **PROTOCOL ABSTRACT DUE**
Oct. 23	Lecture Tutorial	9-10 10-12	AM	6. Conceptualization and measurement
Oct. 30	Lecture Tutorial	9-10 10-12	AM	7. Sampling, sample size and power
Nov. 6	**STUDENTS PRESENT / DISCUSS**	9-12	----	8. Student Protocol Presentations / discussion (protocols & course content)
Nov. 13	Lecture Tutorial	9-10 10-12	AM	9. Analysis of discrete (categorical) outcomes
Nov. 20	Lecture Tutorial	9-10 10-12	AM	10. Analysis of continuous outcomes
Nov. 27	**TEST** Tutorial	9-10 10-12	AM	11. In class test and protocol development
Dec. 4	Tutorial	9-12	----	12. Final protocol reviews
Dec. 11	---	---	---	13. **FINAL COURSE PAPER DUE**

OBJECTIVES

The course introduces students to basic concepts and methods used in observational (non-experimental) studies to conduct needs assessments (e.g., prevalence of disease or disorder), to understand the determinants of health (e.g., association between independent/exposure variables and dependent/outcome variables in analytic research) and to assess the impact of interventions implemented to improve health or alter life quality (e.g., non-experimental program evaluations). The topics will focus on three broad areas: (1) the formulation of research questions and use of theory to explicate the relationships among the core variables of interest; (2) the basic elements and options for research studies: sampling, measurement and analysis; and (3) the identification and control of error.

COURSE CONTENT

The readings for the course draw from primary literature and electronic text books available through the McMaster library subscriptions. References and links to the weekly required readings are provided on Avenue. Each week, supplementary readings that provide additional explanations of concepts, or expand on topics in the required readings will be listed under the heading "Optional Readings."

EDUCATIONAL METHODS

(1) There will be 10 lectures that present core concepts and issues to all students. The lectures will be about 50-60 minutes each, at fixed times throughout the course in a central location. Some time will be set aside for large-group questions/discussions. (2) There will be a large group tutorial to expand on/explore the material presented during the lectures. Students are expected to read the book chapters/articles identified for each unit and to identify questions and issues for discussion. It is anticipated that from 25-50% of tutorial time will be taken up with student-initiated material. Each tutorial will also have 1-3 assignments. It is anticipated that the presentation and discussion of each assignment should take about 20-30 minutes each. (3) Each student will develop a research protocol in the general form of a written grant application to conduct an observational (non-experimental) study. The study will address a research question of interest to the student and include: a problem statement/formulation; brief review of relevant literature with special emphasis on theoretical framework and presumed mechanisms of effect; a description of the research design, including sampling, measurement, data collection and analysis; discussion of the threats to validity, strategies to control error, risks to subjects and ethics. By Class #5 (October 16, 2023), students will choose the question they wish to address and e-mail a half-page (not longer) description of the question to their tutor for clearance. Class #8 will be devoted to student presentations and discussions of their protocols. The idea is to present the protocol in point form (5-10 minutes), allowing 10-15 minutes discussion to identify and resolve methodological issues associated with the proposal. One student selected at random will serve as respondent and lead the discussion.

EVALUATION OF STUDENTS

The evaluation of students (grades) will be divided into 4 components:

(1) Written protocol. Described in the previous paragraph, the written protocol will constitute 60% of the grade and will be marked by your tutor. The protocol will be from 15-20 (maximum) pages, double spaced, excluding references, figures, tables, and should take the general form of an operating grant application to CIHR. Please use Times Roman 12 point or Arial 11 point, with 2 cm margins.

(2) Tutorial: There are two ratings: i) participation/contribution (Seeks clarification, asks good questions, facilitates participation of others, etc.) and ii) Comprehension (Understanding of key methodologic principles and concepts). Both components are rated on a 7-point likert scale. We feel that we will obtain a better assessment of your participation/contribution and comprehension by having each faculty member rate your weekly participation. The tutors will rate your participation each week. The in-class participation/contribution and comprehension ratings will constitute 10% of the final HRM 751 grade.

Scoring Scheme: The two components (Participation/Contribution and Comprehension) will carry equal weight. The first rating bears on your attendance and (appropriate) level of contributions to class discussion. The second rating bears on levels of understanding and knowledge inferred by the tutor from your verbal contribution to class discussions. Each component is scored out of 7, so your highest

participating rating in a given week is 14. For example, if you receive a 6 (out of 7) for participation/contribution and a 7 (out of 7) for comprehension, your mark for that week would be 13. The same rating system is used every week. Your final participation mark is simply the sum of all your weekly participation marks divided by the highest possible participation marks one can achieve in those weeks. For example, a student attends the 11 weekly tutorials and gets the following weekly ratings (each out of 14): 13, 12, 13, 14, 10, 11, 14, 9, 13, 12, and 14. The sum of these ratings is 135. The highest possible rating is 14 marks x 11 wks= 154. Thus, this student's participation is 135/154 = 87.7%. Because participation accounts for 10% of your grade, this student's final participation mark is 8.8 out of 10.

(3) Protocol abstract: The protocol abstract will constitute 10% of the grade and will be marked by your tutor. The abstract includes a brief background and a well framed question (PICOT). The research question specified in their PICOT will be the focus of their full study protocol for the course. The length is fairly brief - typically about a half page single spaced, although it can be a bit longer if you choose to include a more detailed background section. Certainly it should not exceed a full page single spaced.

(4) In-class test. There will be one in-class test that will consist of multiple choice and/or short response questions. This will take place in late November. The test will constitute 20% of the grade.

EVALUATION OF COURSE AND TUTORS

This course has been revised substantially from earlier years, and it will be necessary for students and tutors to evaluate the course and unit objectives, along with the usefulness of the lectures, readings, assignments and tests for achieving these objectives. At the end of each class, 5-10 minutes will be set aside for students to make verbal recommendations for changing the unit. Evaluation forms (multiple choice ratings, with a space for comments) will be completed on avenue. These will be completed anonymously, collated/analysed at the end of the course.

SCHEDULING AND TOPICS

Class	Date	Topic
Class 1	Sept 11, 2023	Course introduction, Overview of Observational studies
Class 2	Sept 18, 2023	The Research Question & Theoretical Frameworks
Class 3	Sept 25, 2023	Study designs for epidemiology–I Cohort and case-control studies
Class 4	Oct 2, 2023	Study designs for epidemiology–II Cross-sectional surveys, ecological & hybrid studies
Class 5	Oct 16, 2023	Survey methods, questionnaire design and implementation **Protocol abstract due**
Class 6	Oct 23, 2023	Conceptualization and measurement
Class 7	Oct 30, 2023	Sampling, sample size and power
Class 8	Nov 6, 2023	**Student protocol presentations**
Class 9	Nov 13, 2023	Analysis of discrete (categorical) outcomes
Class 10	Nov 20, 2023	Analysis of continuous outcomes
Class 11	Nov 27, 2023	Protocol development and critical review of a research proposal **In-class test**
Class 12	Dec 4, 2023	Final protocol critiques and reviews
No class	Dec 11, 2023	**Final protocol due**

CLASS 1: Sept 11, 2023, INTRODUCTION: OVERVIEW OF OBSERVATIONAL STUDIES & CONCEPTS

Lecture: **9:00 am - 10:00 am – MDCL room TBA**
COURSE INTRODUCTION, LOGIC OF INQUIRY: THEORY, CAUSATION, MEDIATORS AND MODERATORS

To Learn About
1. Objectives for observational studies
2. The attributes of answerable questions/hypotheses
3. Concepts of causality and causal relationships
4. Basic types of observational studies
5. Briefly review confounding and bias

Key Concepts
Descriptive studies
Analytic studies
Study question
Hypothesis testing
Independent variables
Dependent variables
Confounding variables
Research design
Correlation vs. causation
Validity
Bias

Required Readings

1. Ahrens W, Kirckberg K, Pigeot I. (2005). An Introduction to Epidemiology (pages 1-6). In Ahrens W, Pigeot I (Eds.) Handbook of Epidemiology. Germany: Springer. http://libaccess.mcmaster.ca/login?url=http://dx.doi.org/10.1007/b137839

2. Mann CJ. Observational research methods. Research design II: cohort, cross-sectional, and case-control studies. Emerg Med J. 2003;20:45-60. http://libaccess.mcmaster.ca/login?url=http://www.ncbi.nlm.nih.gov.libaccess.lib.mcmaster.ca/pubmed/12533370

3. Grimes, D.A., & Schulz, K.F. (2002). Bias and causal associations in observational research. The Lancet, 359, January 19, 248-252. http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6T1B-44YNWKY-17&_user=1067350&_rdoc=1&_fmt=&_orig=search&_sort=d&_docanchor=&view=c&_searchStrId=997284537&_rerunOrigin=scholar.google&_acct=C000051241&_version=1&_urlVersion=0&_userid=1067350&md5=977601063698cfaa64ca72265d5a4a84

4. Course handout "Confounders and Mediators example"

Optional Readings
Course handout "Common Priority Areas for Funding Agencies"

Wild P. (2005). Design and Planning of Epidemiological Studies (pages 465-469). In Ahrens W, Pigeot I (Eds.) Handbook of Epidemiology. Germany: Springer. http://libaccess.mcmaster.ca/login?url=http://dx.doi.org/10.1007/b137839

Pearce N, Greenland S. Confounding and Interaction (pages 371-398). In Ahrens W, Pigeot I (Eds.) Handbook of Epidemiology. Germany: Springer.

http://libaccess.mcmaster.ca/login?url=http://dx.doi.org/10.1007/b137839

Kestenbaum A. (2009). Chapter 11: Effect Modification (pages 113-120). In Adeney KL, Weiss NS (Eds), Epidemiology and Biostatistics: An introduction to Clinical Research. Seattle: Springer. http://libaccess.mcmaster.ca/login?url=http://dx.doi.org/10.1007/978-0-387-88433-2

For the tutorial: **10:00 am - 12:00 pm**
MDCL room TBA

1. Class discussion: issues/questions arising from the readings

2. Please think of a question which can be answered using observational methods, and which you are contemplating for this course. To help focus your question, it may be helpful to review the following two websites:

http://www.hsl.unc.edu/Services/Tutorials/EBM/Question.htm

http://www.uic.edu/depts/lib/lhsp/resources/pico.shtml

Note that the above approach works best for phrasing a clinical question, and that you are free to choose a non-clinical question (as long as it is relevant to health). Be prepared to identify the patient/population, intervention/exposure, comparison, and outcome components of your question (eg, apply the PICOT method).

3. Consider which observational study design would be best suited for your question. In doing so, provide specific reasons why alternative designs are not suitable.

4. Consider in what circumstances observational studies are done in preference to randomized clinical trials.

CLASS 2: Sept. 18, 2023, THE RESEARCH QUESTION & THEORETICAL FRAMEWORKS

To Learn About

1. Identifying and framing a good research question.
2. Various theoretical frameworks and mechanisms of effect.
3. The use of theoretical frameworks to help guide data analysis.

Key Concepts

- Framing a good research question
- Sufficient cause
- Component cause
- Strength of effects
- Interaction
- Proportion of disease due to specific causes
- Induction period
- Philosophy of science
- Bradford Hill criteria for causation

Lecture: **9:00 am -10:00 am – MDCL room TBA**
THEORETICAL FRAMEWORKS

Required Readings

1. Thabane L, Thomas T, Ye C, Paul J. Posing the research question: not so simple. Can J Anaesth 2009;56:71-79.
http://libaccess.mcmaster.ca/login?url=http://www.springerlink.com/content/57642r8jt635x243/

2. Brazil K, Ozer E, Cloutier MM, et al. From theory to practice: Improving the impact of health services research. BMC Health Serv. Res. 2005;5(1):1.
http://libaccess.mcmaster.ca/login?url=http://www.ncbi.nlm.nih.gov.libaccess.lib.mcmaster.ca/pubmed/15638931

3. Rothman KJ, Greenland S. (2005). Chapters 1.1 and 1.2 (pages 45-57). Basic Concepts. In Ahrens W, Pigeot I (Eds.) Handbook of Epidemiology. Germany: Springer.
http://libaccess.mcmaster.ca/login?url=http://dx.doi.org/10.1007/b137839

Optional Readings

Brown AF, Ettner SL, Piette J, Weinberger M, Gregg E, Shapiro MF, Karter AJ, Safford M, Waitzfelder B, Prata PA, Beckles GL. Socioeconomic position and health among persons with diabetes mellitus: a conceptual framework and review of the literature. Epidemiol Rev 2004;26:63-77. (***Sample article showing development of a theoretical framework***)
http://libaccess.mcmaster.ca/login?url=http://epirev.oxfordjournals.org/cgi/reprint/26/1/63

Course handout. Causal criteria summary. (***Nice brief summary table of the Bradford Hill guidelines for assessing causation***)

***For the tutorial*: 10:00 am - 12:00 pm**
Group 1: **MDCL room TBA**

1. Class discussion: issues/questions arising from the lecture and readings.
2. Review the question you developed for session 1 and consider whether it adheres to the FINER guildeline.
3. Develop a theoretical framework related to your protocol question. Prepare a draft section explaining your theoretical framework for inclusion in your final project.

CLASS 3: Sept 25, 2023, STUDY DESIGNS FOR EPIDEMIOLOGY – I

To Learn About

1. The design of cohort and case-control studies
2. Advantages and disadvantages of each study design
3. Types of research questions that are suitable for each design

Key Concepts	Exposure status	Matching
Temporality	Outcome status	
Study population	Confounding	

Lecture: **9:00 am -10:00 am – MDCL room TBA**
COHORT AND CASE-CONTROL STUDIES

Required Readings

1.Miller AB, Goff DC, Bammann K, Wild P. (2005) Cohort Studies (pages 253-286). In Ahrens W, Pigeot I (Eds.) Handbook of Epidemiology. Germany: Springer.
http://libaccess.mcmaster.ca/login?url=http://dx.doi.org/10.1007/b137839

2. Kestenbaum A. (2009). Chapter 6: Case-control studies (pages 45-57). In Adeney KL, Weiss NS (Eds), Epidemiology and Biostatistics: An introduction to Clinical Research. Seattle: Springer.
http://libaccess.mcmaster.ca/login?url=http://dx.doi.org/10.1007/978-0-387-88433-2

3. Bland JM, Altman DG. Matching. British Medical Journal. 1994;309(6962):1128
http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2541945

Optional Readings

Grimes DA, Schulz KF. Cohort studies: marching towards outcomes. Lancet. 2002;359(9303):341-5.
http://libaccess.mcmaster.ca/login?url=http://www.ncbi.nlm.nih.gov.libaccess.lib.mcmaster.ca/pubmed/?term=cohort+marching+towards+outcomes

Schulz KF, Grimes DA. Case-control studies: research in reverse. Lancet. 2002;359(9304):431-4.
http://libaccess.mcmaster.ca/login?url=http://www.ncbi.nlm.nih.gov.libaccess.lib.mcmaster.ca/pubmed/11844534

Grimes DA, Schulz KF. Compared to what? Finding controls for case-control studies. Lancet. 2005;365(9468):1429-33.
http://libaccess.mcmaster.ca/login?url=http://www.ncbi.nlm.nih.gov.libaccess.lib.mcmaster.ca/pubmed/15836892

Grimes DA, Schulz KF. Making sense of odds and odds ratios. Obstet Gynecol. 2008;111 (2 Pt 1):423-6.
http://libaccess.mcmaster.ca/login?url=http://www.ncbi.nlm.nih.gov.libaccess.lib.mcmaster.ca/pubmed/18238982

Mamdani M, Sykora K, Li P et al. Reader's guide to critical appraisal of cohort studies: 2. Assessing

potential for confounding. BMJ. 2005; 330; 960-2.
http://libaccess.mcmaster.ca/login?url=http://www.ncbi.nlm.nih.gov.libaccess.lib.mcmaster.ca/pubmed/?term=Reader%E2%80%99s+guide+to+critical+appraisal+of+cohort+studies%3A+2.+Assessing+potential+for+confounding

Kestenbaum A. (2009). Chapter 10: Methods to Control for Confounding (pages 101-111). In Adeney KL, Weiss NS (Eds), Epidemiology and Biostatistics: An introduction to Clinical Research. Seattle: Springer.
http://libaccess.mcmaster.ca/login?url=http://dx.doi.org/10.1007/978-0-387-88433-2

Yusuf S, Hawken S, Ounpuu S, Dans T, Avezum A, Lanas F, McQueen M, Budaj A, Pais P, Varigos J, Lisheng L; INTERHEART Study Investigators. Effect of potentially modifiable risk factors associated with myocardial infarction in 52 countries (the INTERHEART study): case-control study. Lancet 2004;364:937-52. (***NOTE: Sample article of a famous case-control study***)
http://libaccess.mcmaster.ca/login?url=http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2804%2917018-9/fulltext

Kannel, W.B., Dawber, T.R., Kagan, A., Revotskie, N. & Stokes, J. (1961). Factors of risk in the development of coronary heart disease – six-year follow-up Experience. The Framingham Study. *Annals of Internal Medicine*, 55(1), 33-50. ***(NOTE: Sample article of a famous cohort study).***
http://libaccess.mcmaster.ca/login?url=http://www.ncbi.nlm.nih.gov.libaccess.lib.mcmaster.ca/pubmed/?term=Factors+of+risk+in+the+development+of+coronary+heart+disease+%E2%80%93+six-year+follow-up+Experience.+The+Framingham+Study

For the tutorial: **10:00 am - 12:00 pm**
Group 1: **MDCL room TBA**

1. Class discussion: issues/questions arising from the readings.

2. Consider your protocol question (or a different question of interest) and develop a list of advantages and disadvantages associated with developing i) a cohort study and ii) a case-control study to answer this question. Consider the issues of feasibility, cost, prevalence versus incidence, and ethics.

3. Consider your protocol question and develop a list of potential confounding variables. Can you measure these variables? What methods would you consider using to control for these potential confounders?

4. If you are proposing a cohort study for your protocol, start drafting a section for your final paper that considers inclusion criteria for your cohort and how you will measure of exposure and outcome status. Give some thought to how you can maximize complete follow-up.

5. If you are proposing a case-control study for your protocol, start drafting a section for your final paper that considers how you will identify your cases and what population will serve as appropriate controls. What ratio of cases to controls will you use?

CLASS 4: Oct 2, 2023, STUDY DESIGNS FOR EPIDEMIOLOGY – II

Lecture: **9:00 am -10:00 am – MDCL room TBA**
CROSS-SECTIONAL SURVEYS, ECOLOGICAL AND HYBRID STUDIES

Required Readings

1. Kestenbaum A. (2009). Chapter 4. Cross-sectional Studies (pages 29-31). In Adeney KL, Weiss NS (Eds), Epidemiology and Biostatistics: An introduction to Clinical Research. Seattle: Springer. http://libaccess.mcmaster.ca/login?url=http://dx.doi.org/10.1007/978-0-387-88433-2

2. Kass PH, Gold EB. (2005) Modern Epidemiologic Study Designs (pages 321-333). In Ahrens W, Pigeot I (Eds.) Handbook of Epidemiology. Germany: Springer. http://libaccess.mcmaster.ca/login?url=http://dx.doi.org/10.1007/b137839

3. Parkin DM, Bray FI. (2005) Ecological Studies (pages 176-184). In Ahrens W, Pigeot I (Eds.) Handbook of Epidemiology. Germany: Springer. http://libaccess.mcmaster.ca/login?url=http://dx.doi.org/10.1007/b137839

4. London School of Economics. FAQ 8: When is it good to use a longitudinal design? Available at: http://www.lse.ac.uk/media@lse/research/EUKidsOnline/BestPracticeGuide/FAQ/FAQ-8.pdf

5. Choi, B.C., & Noseworthy, A.L. (1992). Classification, direction, and prevention of bias in epidemiologic research. Journal of Occupational Medicine. 34(3), 265-271. http://circ.ahajournals.org/cgi/content/extract/108/17/2154

Optional Readings

Cook PF. Scientific inquiry. Study designs for program evaluation: how do we know what works? J Spec Pediatr Nurs. 2009;14(1):70-72. http://onlinelibrary.wiley.com.libaccess.lib.mcmaster.ca/doi/10.1111/j.1744-6155.2008.00177.x/abstract;jsessionid=C7E26E2ED696D2C570C83A2381CFD4AC.d02t03

World Health Organization. Module 4: How to evaluate the programme. Available at http://www.who.int/roadsafety/projects/manuals/alcohol/4-How%20to.pdf

Redelmeier, D.A., & Tibshirani, R.J. (1997). Association between cellular-telephone calls and motor vehicle collisions. New England Journal of Medicine, 336, (7), 453-458.) http://content.nejm.org/cgi/content/short/336/7/453 (NOTE: Sample article of a case-crossover design)

Martinez-Sanchez JM, Blanch C, Fu M, et al. Do smoke-free policies in work and public places increase smoking in private venues? Tob Control. 2013; Apr 25 [Epub ahead of print].**[NOTE: Sample article of an ecological study]** http://libaccess.mcmaster.ca/login?url=http://dx.doi.org/10.1136/tobaccocontrol-2012-050877

Anand SS, Yusuf S, Jacobs R, Davis AD, Yi Q, Gerstein H, Montague PA, Lonn E. Risk factors, atherosclerosis, and cardiovascular disease among Aboriginal people in Canada: the Study of Health

Assessment and Risk Evaluation in Aboriginal Peoples (SHARE-AP).Lancet. 2001 ;358(9288):1147-53.
(NOTE: Sample article of a famous cross-sectional study)
http://libaccess.mcmaster.ca/login?url=http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2801%2906255-9/fulltext

For the tutorial: **10:00 am - 12:00 pm**
MDCL room TBA

1. Class discussion: issues/questions arising from the readings.

2. Consider the types of bias outlined by Choi (1992). Which types of bias are you concerned about for your study? What effect would do you expect they would have on your results? Consider how you could prevent or minimize these biases, or how you could control for them in your analysis. Draft a section for your final paper that addresses these issues.

CLASS 5: Oct 16, 2023, SURVEY METHODS, QUESTIONNAIRE DESIGN AND IMPLEMENTATION

To Learn About

1. Advantages, disadvantages and trade-offs among various survey methods.
2. Questionnaire design and implementation.
3. Approaches to maximize response rates.
4. Approaches to minimize bias.

Key Concepts

Questionnaire design
Types of interviews (eg. Face-to-face, telephone, etc.)
Question development and design
Steps of survey implementation
Questionnaire bias

Lecture: **9:00 am -10:00 am – MDCL room TBA**
SURVEY METHODS

Required Readings

1. Van den Broeck J, Chhagan M, Kauchali S.(2013). Chapter 18. Questionnaires (pages 357-378). In Van den Broeck J, Brestoff JR (Eds) Epidemiology: Principles and Practical Guidelines. http://libaccess.mcmaster.ca/login?url=http://dx.doi.org/10.1007/978-94-007-5989-3

2. Cordier S, Steward PA. (2005) Exposure Assessment (pages 438-445). In Ahrens W, Pigeot I (Eds.) Handbook of Epidemiology. Germany: Springer. http://libaccess.mcmaster.ca/login?url=http://dx.doi.org/10.1007/b137839

Optional Readings

Choi, B.C., & Pak, A.W. (2005). A catalog of biases in questionnaires. Preventing Chronic Diseases, 2(1), A13. http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=1323316&blobtype=pdf (***Note: Not mandatory; Read only if using a questionnaire in your study***)

Boynton, P.M., & Greenhalgh, T. (2004). Selecting, designing, and developing your questionnaire. BMJ, 328: 1312-5 http://www.bmj.com/cgi/content/full/328/7451/1312 (***Note: Nice reference; read if using a questionnaire***)

Boynton, P.M. (2004). Administering, analysing, and reporting your questionnaire. BMJ, 328: 1372-5. http://www.bmj.com/cgi/content/full/328/7452/1372 (***Note: Nice reference; read if using a questionnaire***)

Dillman, D.A.(2006). Chapter 7. Implementation Procedures (pages 149-193). In D.A. Dillman, , Internet, Mail, and Mixed-Mode Surveys: The Tailored Design Method. (2nd ed,). New York: John Wiley & Sons, Inc. http://libaccess.mcmaster.ca/login?url=http://www.MCMU.eblib.com/EBLWeb/patron?target=patron&extendedid=P_281571_0&

Dillman, D.A.(2006). Internet and Interactive Voice Response Surveys (pages 352-412). In D.A. Dillman, Internet, Mail, and Mixed-Mode Surveys: The Tailored Design Method. (2nd ed). New York: John Wiley &

Sons, Inc.
http://libaccess.mcmaster.ca/login?url=http://www.MCMU.eblib.com/EBLWeb/patron?target=patron&extendedid=P_281571_0& (***Note: Not mandatory; Read only if using an internet or interactive voice response survey in your study***)

***For the tutorial*: 10:00 am - 12:00 pm**
MDCL room TBA

**** Protocol Abstract Due****

1.Class discussion: issues/questions arising from the readings.

2. Consider whether you will need to use any form of a questionnaire for your study. If so, think about whether there is an existing questionnaire that is suitable or if you'll need to create a questionnaire. Draft a section for your final paper that addresses these issues, as well as details of survey administration and data collection. Be prepared to discuss the strengths and limitations of various survey methods (i.e. face-to-face, telephone, internet, and postal surveys) and defend your choice.

CLASS 6: Oct 23, 2023, CONCEPTUALIZATION & MEASUREMENT

To Learn About

1. Levels of measurement
2. Types, sources, and he impact of measurement error on statistical estimates and associations
3. Assessing reliability
4. Assessing validity
5. Relating measurement objectives to measurement adequacy

Key Concepts	Types of reliability (eg. Test-retest)	Types of validity (eg. Content)
Levels of measurement	Responsiveness	Statistics used for reliability and validity
Objectives of measurement	Sensitivity to change	
Measurement error		

Lecture: **9:00 am -10:00 am – MDCL room TBA**
SELECTING CONCEPTS, CHOOSING/DEVELOPING MEASURES, RELIABILITY AND VALIDITY

Required Readings

1. Streiner, D.L., & Norman, G.R. (2008). Chapter 8. Reliability. In: D.L. Streiner, G.R. Norman, Health measurement scales: a practical guide to their development and use (4th ed,). Oxford: Oxford University Press. http://libaccess.mcmaster.ca/login?url=http://dx.doi.org/10.1093/acprof:oso/9780199231881.001.0001

2. Streiner, D.L., & Norman, G.R. (2008). Chapter 10. Validity. In: D.L. Streiner, G.R. Norman, Health measurement scales: a practical guide to their development and use (4th ed,). Oxford: Oxford University Press. http://libaccess.mcmaster.ca/login?url=http://dx.doi.org/10.1093/acprof:oso/9780199231881.001.0001

3. Coggon D, Rose G, Barker DJP. 4. Measurement error and bias. In Epidemiology for the uninitiated. (4th ed). BMJ. http://www.bmj.com/about-bmj/resources-readers/publications/epidemiology-uninitiated/4-measurement-error-and-bias

Optional Readings

Taylor, R., Reeves, B., Mears, R., Keast, J., Binns, S., Ewings, P., & Khan, K. (2001). Development and validation of a questionnaire to evaluate the effectiveness of evidence-based practice teaching. Medical Education. 35(6), 544-547. http://www.ncbi.nlm.nih.gov/pubmed/11380856

For the tutorial: **10:00 am - 12:00 pm**
MDCL room TBA

1. Class discussion: issues/questions arising from the readings.

2. You have a 12-item rating scale to measure depressed mood in adults. Each item (e.g., how much of the time do you feel down in the dumps or blue?) has 5 response options (all of the time, most of the time, some of the time, a little of the time, and none of the time). You would like to use the scale for multiple purposes: estimation, measuring change, screening. Discuss some approaches to evaluating it for these purposes.

3. Consider the scales and questionnaires that will be used in your study. Has their reliability and validity been established in a population similar to yours? If not, think through what might be required to establish reliability and validity. Refer to the article: Development and validation of a questionnaire to evaluate the effectiveness of evidence-based practice teaching by R. Taylor and colleagues, *Medical Education*, 35(6), 544-547, 2001 for an example of the establishing validity and reliability

CLASS 7: Oct 30, 2023, SAMPLING, SAMPLE SIZE AND POWER

To Learn About

1. Basic approaches and concepts applicable to sampling research subjects
2. Advantages, disadvantages and trade-offs among sampling strategies in cost, complexity and accuracy
3. Choosing appropriate sampling strategies for research questions and study designs
4. Issues underlying and approaches to sampling elusive populations
5. Evaluating and adjusting for nonresponse and subject attrition in research studies
6. Methods for estimating the number of subjects needed to meet statistical power requirements to answering research questions
7. The effects on statistical power of sample loss, matching, adjustment for confounding and the assessment of effect modification

Key Concepts

Sampling unit
Sampling frame
Types of sampling strategies (eg. Probability, quota, etc.)
Matching
Precision of estimate
Stratified/ matched sampling
Correlation
Risk
Prevalence
Incidence
Sample size and statistical power

Lecture: **9:00 am -10:00 am – MDCL room TBA**
SAMPLING: BASIC CONCEPTS

Required Readings

1. Van den Broeck J, Fossgard Sandoy I, Brestoff, JR. (2013).Chapter 9 The Recruitment, Sampling, and Enrollment Plan (pages 171-196). In Van den Broeck J, Brestoff JR (Eds) Epidemiology: Principles and Practical Guidelines. http://libaccess.mcmaster.ca/login?url=http://dx.doi.org/10.1007/978-94-007-5989-3

2. Brestoff JR, Van den Broeck. (2013). Chapter 7 Study Size Planning (pages 137-155). In Van den Broeck J, Brestoff JR (Eds) Epidemiology: Principles and Practical Guidelines. http://libaccess.mcmaster.ca/login?url=http://dx.doi.org/10.1007/978-94-007-5989-3

3. Norman G. Sample size calculations: should the emperor's clothes be off the peg or made to measure? BMJ. 2012;345:e5278. **http://libaccess.mcmaster.ca/login?url=http://dx.doi.org/10.1136/bmj.e5278**

Optional Readings

Cohen, J. (1992). A power primer. Psychological Bulletin, 112, 155-159. http://journals2.scholarsportal.info/details.xqy?uri=/00332909/v112i0001/155_app.xml

Elashoff JD, Lemeshow S. (2005) Sample Size Determination in Epidemiologic Studies (pages 559-594). In Ahrens W, Pigeot I (Eds.) Handbook of Epidemiology. Germany: Springer. [NOTE: Excellent working examples of calculations specific to study designs and analyses] http://libaccess.mcmaster.ca/login?url=http://dx.doi.org/10.1007/b137839

Hoenig JM, Heisey DM. The Abuse of Power: The Pervasive Fallacy of Power Calculation for Data Analysis. Am Stat. 2001;55(1):19-24.[NOTE: Interesting article about the pitfalls of post hoc power analyses] http://libaccess.mcmaster.ca/login?url=http://journals2.scholarsportal.info/details.xqy?uri=/00031305/v

55i0001/19_taoptpopcfda.xml

Kamangar F, Islami F. Sample Size Calculation for Epidemiologic Studies: Principles and Methods. Arch Iran Med. 2013;16(5):295-300.[NOTE: Nice overview of sample size methodology] http://libaccess.mcmaster.ca/login?url=http://www.ncbi.nlm.nih.gov/pubmed/23641744

Naing L, Winn T, Rusli BN. Practical Issues in Calculating the Sample Size for Prevalence Studies. Arch Orofac Sci. 2006;1:9-14. http://libaccess.mcmaster.ca/login?url=http://www.dental.usm.my/aos/index.html

Sample size calculations printout, from St. George's Hospital Medical School. (***NOTE: Very useful and practical guide for doing your sample size/power calculations***) http://www-users.york.ac.uk/~mb55/guide/size.htm

Schafer JL. Multiple Imputation: a primer. Stat Methods Med Res. 1999;8(1):3-15. http://libaccess.mcmaster.ca/login?url=http://www.ncbi.nlm.nih.gov.libaccess.lib.mcmaster.ca/pubmed/10347857

Useful websites and online statistical calculators

Department of Biostatistics. Vanderbilt University. PS: Power and Sample Size Calculation. http://biostat.mc.vanderbilt.edu/wiki/Main/PowerSampleSize

Lenth, RV. (2006-9). Java Applets for Power and Sample Size. http://homepage.stat.uiowa.edu/~rlenth/Power/

www.*statpages.org/*

***For the tutorial*: 10:00 am - 12:00 pm**
MDCL room TBA

1. Class discussion: issues/questions arising from the readings.

2. Draft a section for your final paper that addresses your sampling strategy and come prepared to discuss this during the tutorial. Consider how you will define the sampling frame, and the sampling unit. How will you recruit your study participants? Identify the strengths and weaknesses of your approach and consider what types of biases might be introduced.

3. In evaluating the effectiveness of some programs, it is often difficult, if not impossible, to use an experimental design. Discuss briefly the general approach to sampling (and design) that you might take to evaluate "modern" neonatal intensive care for sick newborns. How would you deal with issues of generalizability–different newborns, places and times**.**

4. Draft a section for your final paper that describes how you estimated the sample size requirements for your study and be prepared to discuss in class. To help guide you, consider the type of comparison you are proposing and whether your outcome will be measured as a continuous, dichotomous or categorical variable. Think about where you will find the parameters necessary for your calculation and whether or not these sources are appropriate to inform your sample size calculation. If you are

proposing to use matching or clustering in your design, consider how you will account for this in your sample size calculation. Finally, consider whether you will need to adjust for attrition (eg, losses to follow-up).

5. You are conducting a longitudinal study to predict stroke among a cohort of high-risk patients. At the first follow-up, 25% of patients have either refused to participate or been lost (i.e., untraced). How would you go about evaluating the effects of sample attrition over the two time points? What variables would you select to model lost-to-follow-up? What would the basis be for suspecting selective sample loss and bias? What would you do to deal with this selective loss?

CLASS 8: Nov 6, 2023, STUDENT PROTOCOL PRESENTATIONS

NOTE: NO LECTURE this week.

Presentations: **9:00 am - 12:00 pm**
MDCL room TBA

Each student will present their protocol in point form (10 minutes), divided roughly as 3 minutes for background and 6 minutes for design/measurement/analysis issues and 1 minute for summary. A 10-minute discussion will follow to identify the substantive (related to the conceptual aspects of the study) and methodological issues associated with the proposal. A student selected at random will serve as respondent and lead the discussion. Each student will serve as a respondent on one presentation. This student is to identify/summarize the major issues in point form (one page limit) and **submit the critique the following week to the tutor and student presenter**. These issues will be revisited in Session 13.

Remember that the goal of this session is to discuss areas of concern rather than to present a completed protocol. Take this opportunity to receive constructive feedback from your peers and tutor while your protocol is a work in progress.

NOTE: due to the number of presentations, a maximum of 20 minutes per presentation is allotted. Rooms are equipped with computer projection. Please bring your Powerpoint presentation in a USB drive or email to the tutorial leader at least 24 hours in advance.

Required Readings

1. Zaccai, J.H. (2003). How to assess epidemiological studies. Postgraduate Medical Journal, 80, 140-147. http://pmj.bmj.com/cgi/reprint/80/941/140.pdf

Optional Readings

STROBE (Strengthening the reporting of observational studies in epidemiology) Statement. [NOTE: Comprehensive checklists are available here to guide the reporting of various study designs].
http://www.strobe-statement.org/index.php?id=available-checklists

CLASS 9: Nov 13, 2023, ANALYSIS OF DISCRETE (CATEGORICAL) OUTCOMES

To Learn About

1. The distinction between estimation and hypothesis testing
2. The implications for analysis of the research design, sampling strategy and level of measurement in the dependent variable
3. Statistical parameters that characterize the association between independent and dependent variables

Key Concepts

Statistical association
Descriptive statistics
Confidence interval
Hypothesis testing
Type I or alpha error
Type II or beta error
Assumptions of statistical tests
p-value
Logistic regression
Chi-square test
Survival Analysis

***Lecture*: 9:00 am - 10:00 am – MDCL room TBA**
SELECTING STRATEGIES FOR ANALYSING DISCRETE OUTCOMES

Required Readings

1. Kestenbaum A. (2009). Chapter 15. Introduction to Statistical Inference (pages 29-31). In Adeney KL, Weiss NS (Eds), Epidemiology and Biostatistics: An introduction to Clinical Research. Seattle: Springer. http://libaccess.mcmaster.ca/login?url=http://dx.doi.org/10.1007/978-0-387-88433-2

2.Kestenbaum A. (2009). Chapter 16. Hypothesis Testing (pages 171-177). In Adeney KL, Weiss NS (Eds), Epidemiology and Biostatistics: An introduction to Clinical Research. Seattle: Springer. http://libaccess.mcmaster.ca/login?url=http://dx.doi.org/10.1007/978-0-387-88433-2

3. Van den Broeck J, Fadnes LT, Robberstad B, Thinkhamrop B. (2013).Chapter 24 Statistical Modeling (pages 451-454 & 459-469). In Van den Broeck J, Brestoff JR (Eds) Epidemiology: Principles and Practical Guidelines. http://libaccess.mcmaster.ca/login?url=http://dx.doi.org/10.1007/978-94-007-5989-3

4. Katz MH. Multivariable analysis: a primer for readers of medical research. Ann Intern Med. 2003;138(8):644-50. http://libaccess.mcmaster.ca/login?url=http://www.ncbi.nlm.nih.gov.libaccess.lib.mcmaster.ca/pubmed/?term=multivariable+analysis%3A+a+primer+for+readers+of+medical+research

5. Walters SJ. (2009) What is a Cox model? (2nd ed.). Hayward Medical Communitcations. http://www.medicine.ox.ac.uk/bandolier/painres/download/whatis/cox_model.pdf

Optional Readings

Kestenbaum A. (2009). Chapter 14. Summary Measures in Statistics (pages 153-162). In Adeney KL, Weiss NS (Eds), Epidemiology and Biostatistics: An introduction to Clinical Research. Seattle: Springer. http://libaccess.mcmaster.ca/login?url=http://dx.doi.org/10.1007/978-0-387-88433-2

Bagley SC, White H, Golomb BA. Logisitic regression in the medical literature: standards for use and

reporting, with particular attention to one medical domain. J Clin Epidemiol. 2001;54(10): 979-85. http://libaccess.mcmaster.ca/login?url=http://www.ncbi.nlm.nih.gov.libaccess.lib.mcmaster.ca/pubmed/?term=Logistic+regression+in+the+medical+literature%3A+Standards+for+use+and+reporting%2C+with+particular+attention+to+one+medical+domain

Kestenbaum A. (2009). Chapter 20. Survival Analysis (pages 215-228). In Adeney KL, Weiss NS (Eds), Epidemiology and Biostatistics: An introduction to Clinical Research. Seattle: Springer. http://libaccess.mcmaster.ca/login?url=http://dx.doi.org/10.1007/978-0-387-88433-2

Chan YH. Biostatistics 203. Survival Analysis. Singapore Med J. 2004;45(6):249-56. [NOTE: Simple example of survival analysis with working SPSS example]. http://www.ncbi.nlm.nih.gov.libaccess.lib.mcmaster.ca/pubmed/15181518

Agresti A. 2007. Appendix. (SAS codes for chapters 1-4) In A. Agresti, An Introduction to Categorical Data Analysis (pp 332-335). New York: Wiley. (***NOTE: Optional reading; reference material***) http://libaccess.mcmaster.ca/login?url=http://www.MCMU.eblib.com/EBLWeb/patron?target=patron&extendedid=P_290465_0&

Additional Statistical Resources

Hosmer DW, Lemeshow S. (2004) Applied Logisitic Regression.(2nd ed.). Wiley. e-book. http://libaccess.mcmaster.ca/login?url=http://www.MCMU.eblib.com/EBLWeb/patron?target=patron&extendedid=P_215160_0&

Vittinghoff E, Glidden DV, Shiboski SC, McCulloch CE. (2012). Regression methods in Biostatistics: Linear, Logistic, Survival, and Repeated Measures Models. (2nd ed.). Boston: Springer. e-book. http://libaccess.mcmaster.ca/login?url=http://dx.doi.org/10.1007/978-1-4614-1353-0

***For the tutorial*: 10:00 am - 12:00 pm**
MDCL room TBA

1. Class discussion: issues/questions arising from the readings.

2. Consider the data that you are proposing to measure/collect in your study. Identify the categorical variables and decide whether they are independent or dependent variables. Consider the appropriate descriptive statistics for your categorical variables.
3. If you identified a categorical dependent variable, consider which statistical method will be most appropriate to answer your study question. Draft a section for your final paper that addresses the statistical methods you propose to use.

CLASS 10: Nov 20, 2023, ANALYSIS OF CONTINUOUS OUTCOMES

To Learn About

1. The general linear model (GLM)
2. The use of regression analysis to understand the form and strength of association between independent and dependent variables
3. Statistical adjustments for confounder variables
4. Tests for moderator and mediator variables
5. Approaches to developing multivariable models
6. Introduction to multilevel models

Key Concepts	Single variable model	Residual error
General Linear Model (GLM)	Multi-variable model	Analysis of covariance
Linear Regression analysis	Beta coefficient	

Lecture: **9:00 am - 10:00 am – MDCL room TBA**
SELECTING STRATEGIES FOR ANALYSING CONTINUOUS OUTCOMES

Required Readings

1. Kestenbaum A. (2009). Chapter 18. Linear Regression (pages 189-205). In Adeney KL, Weiss NS (Eds), Epidemiology and Biostatistics: An introduction to Clinical Research. Seattle: Springer. http://libaccess.mcmaster.ca/login?url=http://dx.doi.org/10.1007/978-0-387-88433-2

2.Austin, P.C., Goel, V., & van Walraven, C. (2001). An introduction to multilevel regression models. Canadian Journal of Public Health, 92, 150-154. http://journal.cpha.ca/index.php/cjph/article/viewArticle/76

Optional Readings

Killip S, Mahfoud Z, Pearce K. What is an intracluster correlation coefficient? Crucial concepts for primary care researchers. Ann Fam Med 2004;2:204-8. http://libaccess.mcmaster.ca/login?url=http://www.annfammed.org/cgi/reprint/2/3/204

Adewale AJ, Hayduk L, Estabrooks CA, et al. Understanding hierarchical linear models: applications in nursing research. Nurs Res. 2007;56(4 Suppl):S40-6. http://libaccess.mcmaster.ca/login?url=http://www.ncbi.nlm.nih.gov.libaccess.lib.mcmaster.ca/pubmed/17625473

Hubbard AE, Ahern J, Fleisher NL, et al. To GEE or not to GEE: comparing population average and mixed models for estimating the associations between neighbourhood risk factors and health. Epidemiology. 2010;21(4):467-74. http://libaccess.mcmaster.ca/login?url=http://dx.doi.org/10.1097/EDE.0b013e3181caeb90

Additional Statistical Resources

Elston RC, Johnson W. (2008). Basic Biostatistics for Geneticists and Epidemiologists: A Practical Approach. Chichester: John Wiley & Sons, Lts. e-book. http://libaccess.mcmaster.ca/login?url=http://www.MCMU.eblib.com/EBLWeb/patron?target=patron&extendedid=P_406482_0&

Vittinghoff E, Glidden DV, Shiboski SC, McCulloch CE. (2012). Regression methods in Biostatistics: Linear, Logistic, Survival, and Repeated Measures Models. (2nd ed.). Boston: Springer. e-book. http://libaccess.mcmaster.ca/login?url=http://dx.doi.org/10.1007/978-1-4614-1353-0

***For the tutorial*: 10:00 am - 12:00 pm**
MDCL room TBA

1. Class discussion: issues/questions arising from the readings.

2. Identify the continuous variables that you propose to measure or collect in your study. Consider the appropriate descriptive and analytic statistical methods for these variables. Draft a section for your final paper that addresses the statistical methods you propose to use.

CLASS 11: Nov 27, 2023, PROTOCOL DEVELOPMENT AND CRITICAL REVIEW OF RESEARCH PROPOSAL

NOTE: NO LECTURE this week.
Class test: **9:00 am - 10:00 am – MDCL room TBA**

To Learn About

1. To integrate and consolidate the information presented in the preceding 10 lectures.
2. To develop a complete study protocol using an appropriate observational study design for a specific question of interest.

Key Concepts

Study problem	Sampling	Alternative explanations
Review of the literature	Measurement	Bias
Mechanisms of effect	Data collection	Random error
Theoretical framework	Analyses	Validity
Research design	Inferences	Reliability

Optional Readings

Course handout. Smieja et al, CIHR Grant Protocol for discussion

Course handout. Krueger et al, CIHR Grant Protocol

CIHR Peer Review Process - Policies And Responsibilities Of Grants Committee Members at:
http://www.cihr-irsc.gc.ca/e/4656.html

For the tutorial: **10:00 am - 12:00 pm**
MDCL room TBA

1. As you near the completion of your study protocol, consider whether the following questions have been fully addressed in your final project:
    i. What is the specific problem/issue that the study is supposed to address?
    ii. How important is this problem/issue: to our scientific understanding of some phenomena? to health and/orsocial welfare policy? to programs for people? to clinical practice?
    iii. Is there a clearly defined question that fits the PICO and FINER guidelines?
    iv. Is the theoretical basis for the study and presumed mechanisms of effect described and referenced adequately?
    v. Allowing for practical constraints, is the research design optimal for addressing the research question? Is there a better alternative (i.e., a design that would be feasible to execute and less susceptible to bias)?
    vi. Are there elements of the research design (i.e., sampling, measurement, data collection, analysis, risks to subjects) that are unclear?
    vii. Have the authors identified the major threats to validity and made effort to successfully minimize their impact on each element of the research design?
    viii. How will the anticipated results of this study inform the scientific or clinical community? What would be an appropriate future study?
2. Be prepared to discuss any methodological concerns related to your protocol that remain unresolved.

CLASS 12, Dec 4, 2023, FINAL PROTOCOL CRITIQUES AND REVIEWS

NOTE: NO LECTURE this week.

For the tutorial: **9:00 am - 12:00 pm**
MDCL room TBA

This session picks up from Session 8 Protocol Presentations and the substantive/conceptual issues identified in class. After a very brief (3-5 minute) overview of their research protocol, each student will identify and discuss the major substantive and methodological issues faced by their work. This should be a maximum of 13 minutes. In addition to newly emerging issues, all issues raised in Session 8 should be brought forward and discussed in this session. It will be the responsibility of the student reviewer from Session 8 to ensure that these latter issues are addressed. Although 20 minutes on average will be available for discussion, it is expected that the time needed will vary a little by protocol.

Final Course Paper Due: December 11, 2023.