

# PopMed Statistical Methods and Critical Evaluation of the Literature

Course outline – Fall 2011

## Co-coordinator:

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## Class schedule:

Tuesdays, 1:30 – 3:00 pm

Thursdays, 1:30 – 3:00 pm

**Description:** This is a 0.5 credit introductory graduate course that will focus on critical appraisal of the literature and basic statistical methods for epidemiological studies.

## Objectives:

Students who complete this course should be able to:

- Formulate a research question and design a study to respond to this question
- Critically appraise research papers and provide a constructive argument to explain the strengths and weaknesses of the paper and how the study could have been improved
- Complete a critical review of a group of scientific papers on one topic
- Complete a research proposal
- Conduct basic statistical analyses of epidemiological data

## Course approach:

This course will consist of two 80 minute sessions per week. Prior to class, students are expected to read the background readings and the scientific paper for the critical evaluation. Students are expected to come to the tutorial prepared to engage in the critical evaluation of the paper. Students will individually select research papers for review and are expected to lead the discussions. Students are expected to read the chapters in the statistics textbook prior to the computer laboratory sessions. The laboratory sessions are provided to review the major points in the chapters and provide students with an opportunity to apply the skills they have learned from the textbook and a brief review in the laboratory.

## Pre-requisites:

There are no specific pre-requisites for this course.

## Course topics:

Class	Date	Instructor	Topic	Room
TH	Sep 8	Dewey	Introduction to course	101 Clin Research
TU	13	Dewey	research hypotheses, study design	101 Clin Research
TH	15	Dewey	Study design and causation	101 Clin Research
TU	20	Student	Critical evaluation of literature	101 Clin Research
TH	22	Pritchard	Searching the literature	2500 Computer lab
TU	27	Pritchard	Reference management	2500 Computer lab
TH	29	Dewey	Critical evaluation	101 Clin Research
TU	Oct 4	Student	Critical evaluation	101 Clin Research
TH	6	Student	Critical evaluation	101 Clin Research
TU	11	Student	Critical evaluation	101 Clin Research
TH	13	Auld	Ethical approval	1715 LLC
TU	18	Student	Critical evaluation	101 Clin Research
TH	20	Dewey	Variability and descriptive stats	2500 Computer lab
TU	25	Dewey	Lab 1	2500 Computer lab
TH	27	Dewey	Continuous variables, t-tests, anova	2500 Computer lab
TU	Nov 1	Dewey	Lab 2	2500 Computer lab
TH	Nov 3	Dewey	Categorical – chi-square	2500 Computer lab
TU	8	Dewey	Lab 3	2500 Computer lab
TH	10	Sargeant	Non-parametric	2500 Computer lab
TU	15	Sargeant	Lab 4	2500 Computer lab
TH	17	Sargeant	Regression	2500 Computer lab
TU	22	Sargeant	Lab 5	2500 Computer lab
TH	24	Sargeant	Statistics review	2500 Computer lab
TU	29	Poljak	Data management	2500 Computer lab
FINAL EXAM	Dec 9			2500 Computer lab

## Evaluation and Grading:

Leading discussion on critical review	10
Critical review of 3 research papers	10
Statistics assignments	15
Research proposal	30
Final examination in statistics	35
Total points	100

**Pre-class preparation:** To enhance learning during classroom sessions, pre-class readings (or other preparation) have been assigned. Textbooks for chapter readings are available on 2-hour reserve from the OVC Learning Commons.

You are expected to complete the readings for each class prior to the class. The lectures will not necessarily cover all of the material in the lectures that you will be responsible for in assignments, and you will get much more out of the lectures having completed the pre-class readings.

**Assignments:** Assignments are due prior to the start of the class session on the due date. Assignments 1-3 should be submitted to Dr. Dewey at [cdewey@uoguelph.ca](mailto:cdewey@uoguelph.ca). Statistics assignments should be submitted to the instructor of the associated class session. Late assignments will be

penalized by 1 mark (out of 5) if received after the start of the class session and by 1 mark (out of 5) for each late day thereafter. Assignment due dates are as follows:

### Evaluation and Grading:

Leading discussion on critical review	5
Critical review of 3 research papers	10
Statistics assignments	15
Research proposal (see outline below)	35
Final examination in statistics	35
Total points	100

	Date due	Marks
Assignment 1: Research question and hypotheses (Q1-4)	Sep 22nd	5
Assignment 2: Definition of dependent and independent variables and sample size (Q 7 – 11)	Oct 6th	10
Assignment 3: Study design and methodology for collection of samples (Q5,6 & 12-14)	Oct 20th	10
Assignment 4: submit peer evaluation marks for leading critical review of paper	Oct 20th	5
Assignment 5: Critical review of 3 scientific papers	Oct 27th	10
Assignment 6: Statistics 1	Nov 8th	5
Assignment 7: Statistics 2	Nov 15th	5
Assignment 8: Statistics 3	Nov 22nd	5
Assignment 9: Complete research proposal (Q1 – 15)	Dec 1st	10

### Textbooks:

REQUIRED; Norman, G. and Streiner, D. (2008) Biostatistics: The Bare Essentials, 3<sup>rd</sup> Edition. People's Medical Publishing House, ISBN: 978-1-55009-347-6

The following textbooks are recommended or required for the course. Students can access the list of reserve books as well as links to online reserves via Ares and D2L. Ares can be accessed at: <https://ares.lib.uoguelph.ca/ares/> ). Please note that only reserve items are located at the OVC Learning Commons; all other publications are now housed at the Main Library.

These texts are recommended for the survey designed and proposal component of the course:  
Rea, LM and Parker, RA. Designing and conducting survey research: A comprehensive guide. 3<sup>rd</sup> Edition. Jossey-Bass, a Wiley Imprint. 2005.

Hulley SB, Cummings SR, Browner WS, Grady D, Newman TB. Designing Clinical Research, 3<sup>rd</sup> edition. Lippincott Williams & Wilkins, 2007.

For the statistics component of the course, the following are useful general textbooks. However there are many other introductory textbooks that may also be of use!

Petrie, A. and Watson, P. (2006) Statistics for Veterinary and Animal Science, 2nd Edition. Wiley-Blackwell, ISBN: 978-1-4051-2781-3

Campbell, M.J., Machin, D. and Walters, S. (2007) Medical Statistics: A Textbook for the Health Sciences, 4th Edition. Wiley- Blackwell, ISBN: 978-0-470-02519-2

**Software:**

The program Statistix will be used for the statistics portion of the class. It is installed on the computers in the PopMed computer room, but students are encouraged to purchase a copy (it is only available for PCs).

**Students with Special Needs/Learning Disabilities:** If you have a documented disability and require accommodations to obtain equal access to this course, please meet with Dr. Sargeant at the beginning of the semester, or as soon as possible thereafter.

If you suspect you may have a learning disability, you are strongly encouraged to consult the Centre for Students with Disabilities (<http://www.slcs.uoguelph.ca/csd/docforLD.cfm>)

**Academic Misconduct:** The university has a policy on academic misconduct that ***will be supported AND enforced by all instructors in this course:***

[http://www.uoguelph.ca/registrar/calendars/graduate/current/genreg/sec\\_d0e1340.shtml](http://www.uoguelph.ca/registrar/calendars/graduate/current/genreg/sec_d0e1340.shtml)

Academic misconduct takes many forms and includes, but is not limited to: copying, plagiarism, submitting a product prepared in whole or by another person, buying or selling academic work, submitting the same piece of work twice for academic credit. Also note that aiding/abetting academic misconduct is itself academic misconduct.

**It is the responsibility of each student to read and understand the policy.** All students, particularly those on their first course of study at the University of Guelph, are **strongly encouraged** to consult the University's Academic Integrity tutorial, a short but highly useful online tutorial to help inform and clear common misconceptions regarding academic misconduct:

<http://www.academicintegrity.uoguelph.ca/>

If you need further clarification, make an appointment with someone in the Learning Commons.

## Please use the following outline when you are writing the research proposal

1. What is the title of your project?
2. What is the overall object of the research?
3. Why is this research work important? (you do not need to write a literature review for this assignment, please just state in one or two sentences why it is important)
4. What are the null and alternate hypotheses?
5. What study design will you use?
6. What sampling frame will you use? (What is the population of animals from which you will select those in your study?)
7. What is the primary dependent (outcome) variable? How will this variable be measured?
8. What (if any) are the secondary dependent variables? How will they be measured?
9. What is the primary independent variable? How will this be measured?
10. What other variables are important to measure and include in the study, either as secondary independent variables, covariates or potential confounding variables?
11. What is the required sample size? (please show your calculations)
12. How will you select your sample? (eg randomly or simple random sample or everyone who fits the criteria over a certain time period etc) (please describe this in sufficient detail so that someone reading the proposal can do this without asking additional questions)
13. What will you use as the selection criteria?
14. Who (if anyone) will you exclude from the sample?
15. What statistical test will you use to test the association between the primary dependent variable and the primary independent variable?

$$n = Z_{\alpha}^2 * pq / L^2$$

$$n = [1 - (1 - a)^{1/D}] * [N - (D - 1) / 2]$$

$$n = [Z_{\alpha}(2PQ)^{1/2} - Z_{\beta}(P_e Q_e + P_c Q_c)^{1/2}]^2 / (P_e - P_c)^2$$

$$n = 2[(Z_{\alpha} - Z_{\beta})S / (X_e - X_c)]^2$$

EVALUATION OF <u>OBSERVATIONAL STUDIES (A)</u>				
		YES	?	NO
	Were the objectives of the study clearly stated?			
	Was this a data snooping/preliminary study? (Relates to multiple comparisons and interpretation of results)			
	Was the study group likely to be representative of a larger (target) population? (Only concerned with extrapolation)			
	Type of study? Case-Control ( ), Cohort ( ), Cross-Sectional ( ), Longitudinal ( ), Hybrid ( ). Is this designation correct?			
Group formation	Were exclusion/inclusion criteria well-specified?			
	Was sample size considered a priori?			
	Was the F+ (D+) group well defined?			
	Was the F- (D-) group from the same source?			
	Was the F- (D-) group well defined?			
Follow-up or Trace back	Was the follow-up (TRACE BACK) performed: (a) completely? (b) blind to F+ (D+) status?			
	Was response bias within tolerable limits?			
Outcome and Analysis	Was the outcome D+ (F+) status: (a) well defined? (b) defined independently of F+ (D+) status?			
	If testing a specific hypothesis, were confounders defined <u>a priori</u> ?			
	Was confounder control adequate?			
	Were there adequate efforts to control/explain possible biases?			
	Were appropriate analyses done?			
	Were analyses done (apparently) correctly?			
	Was power likely to be adequate?			
	If used, was multiple testing managed/explained well?			
Is there evidence of a dose-response relationship?				
Presentation and conclusions	Were the <u>Methods</u> presented clearly?			
	Were the <u>Results</u> and <u>Analysis</u> presented clearly?			
	Was the <u>Discussion</u> summarized clearly?			
	Are the authors' conclusions supported by the data?			
	Was the study design appropriate to answer the objectives?			
	The more “?’s” and “N’s”, the less valid the study			

## OUTLINE FOR CRITIQUE OF EPIDEMIOLOGIC LITERATURE (B)

### Objective or Hypothesis

- A. What are the objectives of the study or the questions to be answered?
- B. What is the population to which the investigators intend to refer their findings?

### Design of the Investigation

- A. Was the study an experiment, planned observations (prospective), or an analysis of records (retrospective)? What type of epidemiologic study design was used?
- B. How was the sample selected? Are there possible sources of selection which would make the sample atypical or nonrepresentative? If so, what provision was made to deal with this bias?
- C. What is the nature of the control group or standard of comparison?

### Observations

- A. Are there clear definitions of the terms used, including diagnostic criteria, measurements made, and criteria of outcome?
- B. Was the method of classification or of measurement consistent for all the subjects and relevant to the objectives of the investigation? Are there possible biases in measurement and, if so, what provisions were made to deal with them?
- C. Are the observations reliable and reproducible?

### Presentation of Findings

- A. Are the findings presented clearly, objectively, and in sufficient detail to enable the reader to judge them for himself?
- B. Are the findings internally consistent, i.e. do the numbers add up properly, can the different tables be reconciled?

### Analysis

- A. Are the data worthy of statistical analysis? If so, are the methods of statistical analysis appropriate to the source and nature of the data and is the analysis correctly performed and interpreted?
- B. Is there sufficient analysis to determine whether “significant differences” may in fact be due to lack of comparability of the groups in sex or age distribution, in clinical characteristics, or in other relevant variables?

### Conclusions

Which conclusions are justified by the findings? Which are not? Are the conclusions relevant to the questions posed by the investigators?

### Constructive Suggestions

Assume you are planning an investigation to answer the questions put in this study. If they have not been clearly put by the authors, frame them in an appropriate manner. Suggest a practical design, criteria for observations, and type of analysis that would provide reliable and valid information relevant to the questions under study.

## Leading discussion on critical review

Students will evaluate one another using the following criteria

Each student will provide a grade out of 5 marks for their classmates

1. Peer-reviewed, scientific paper was provided to the class one week prior to the meeting
2. Student leader recommended which outline to use when reviewing the paper
3. Student leader followed one outline (or both) completely
4. Classmates were encouraged to participate in the discussion
5. Group was able to identify strengths of the study
6. Group was able to recommend how the study could be improved

## Critical review of 3 research papers

1. One or both of the outlines was used when reviewing the papers
2. Identify the key strengths of each paper (up to 3 points per paper)
3. Identify the key weaknesses of each paper (up to 3 points per paper)
4. Identify which of the 3 papers was the strongest and which was the weakest and provide justification for these decisions
5. List which papers were strong enough to include in a literature and which papers (if any) were not. These decisions need to be justified by sections 2 and 3
6. Conclude whether the weaknesses were due to design flaws or writing the manuscript
7. Recommend one improvement you would make to each study