Clinical Epidemiology (EPIB 600), 3 credits

Dates: May 3 to 28, 2010
Time: 8:35 AM to 11:55 PM (Monday, Wednesday, and Friday)
Place: 3700 McTavish Street, Education Building, Room 627

Course Instructors:
Kaberi Dasgupta, MD, MSc, FRCPC(C), Assistant Professor of Medicine
Nitika Pant Pai, MD, MPH, PhD, Assistant Professor of Medicine

Office:	McGill University Health Centre, 687 Pine Avenue West, V Building.
	Dr. Dasgupta Room V 1.08
	Dr. Pai Room V2.19
	The V Building is adjacent to Allan Memorial Hospital, up the corner of Peel and Pine Avenues.
Telephone:	514-934-1934
	Dr. Dasgupta Extension 44715
	Dr. Pant Pai Extension 44729
E-mail:	Kaberi.Dasgupta@mcgill.ca
	Nitika.Pai@mcgill.ca
Office Hours:	Dr. Pant Pai Tuesday 2:30 - 4:30 PM
	Dr. Dasgupta Thursday 1:30 - 3:30 PM

Teaching Support:
Kierla Ireland, M.A. (Couns. Psych.)
Department of Epidemiology, Biostatistics and Occupational Health
McGill University
1020 Avenue Des Pins Ouest
514-398-2711
recep.eboh@mcgill.ca

Prerequisites: This course is intended for health professionals enrolled in post graduate clinical training programs. It is anticipated that these students will have been exposed to basic concepts in study design and biostatistics during their undergraduate training and that they consult the health sciences literature on a regular basis. We also expect students to revise basic concepts before attending class.

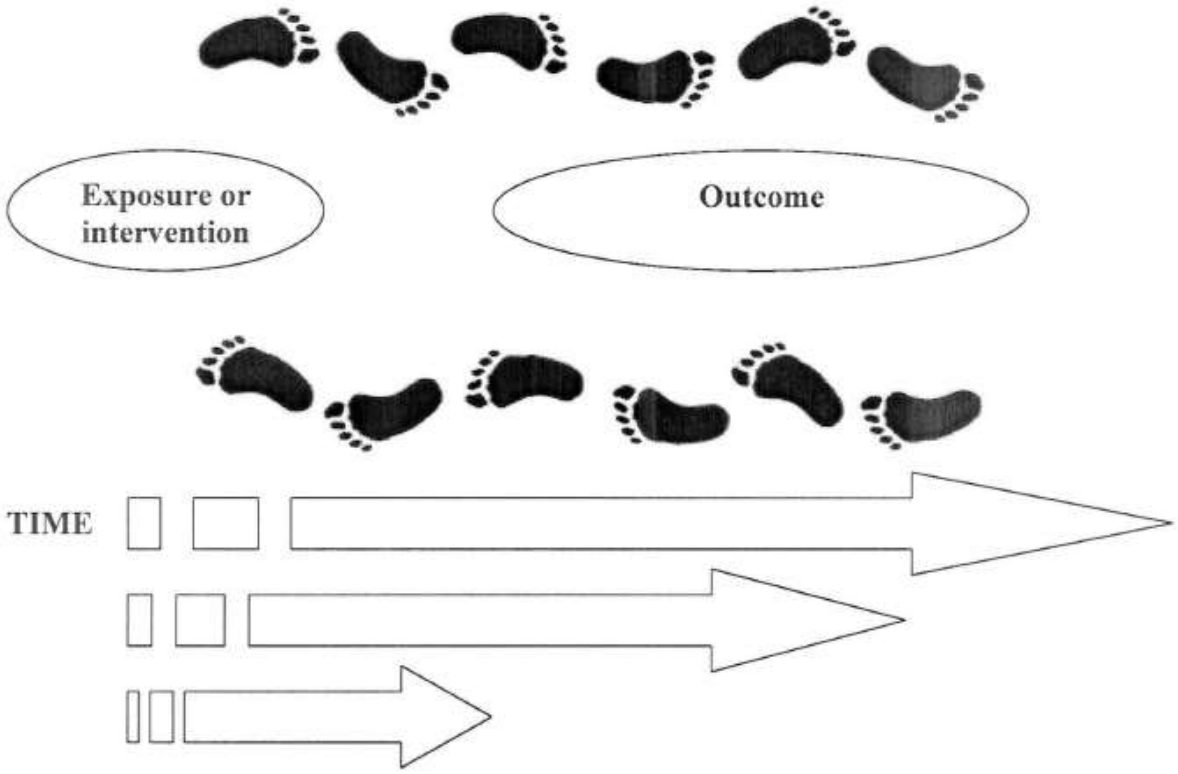
Learning Outcomes
By the end of the course students should be able to:

1. *critically evaluate* the medical literature, using not only content knowledge but integrate it with their understanding of study designs and biases.
2. *anticipate* and conceptualize the basic design and structure of a study that could be used to refute or confirm a defined research question/hypotheses
3. *create* a short research proposal that could be used to conduct a real world clinical research study.

Content

We will highlight the importance of a clearly conceptualized research question, for a well defined study population with appropriate selection of study participants in the paradigm of a right study design. Using the PICO construct- Patient/population, intervention/exposure, comparison/control group and outcomes-the three major study designs (randomized controlled trial, cohort, case control) will be understood. Further, the role of interventions, relationships between exposure and outcomes in time and appropriate design issues will be highlighted: that is, while some studies compare outcomes among those who have or have not had the exposure under consideration (cohorts), others compare exposure histories among those with and without the outcome of interest (case control) and some (randomized controlled trials, RCTs) evaluate the effect of real interventions (drugs, diagnostic tests, behavioural interventions) in select populations. The biases, pitfalls, errors, challenges and issues in the conduct of key designs will be addressed. We will also endeavour to dispel the myth that an RCT is the only valid means of answering a research question. Some basic concepts in bio-statistics will be addressed, but it should be emphasized that this is not a course in bio-statistics or statistical programming. Students will be directed to appropriate courses in bio-statistics, stat programming, advanced epidemiology, systematic reviews and meta-analyses to address any their methodological knowledge gaps.

Figure 1. Relationships between exposure, outcome, and time. In epidemiological studies, the investigator generally examines an exposure or intervention and its association with an outcome. The investigator may follow subjects forward in time from exposure to outcome (cohort studies and randomized controlled trials), depicted as footprints from exposure to outcome. Alternatively, the investigator may classify subjects in terms of presence or absence of the outcome of interest and look "backwards" in time for exposure (case control studies), depicted as footprints from outcome to exposure.



Instructional Method

The course is designed to be highly interactive. There will be some material presented by the instructors using power point presentation but it is anticipated that student presentations and discussions will constitute the bulk of in-class time. Students will be expected to complete readings and group presentation preparations between classes to optimize learning experiences.

Course Materials

It is anticipated that students will have access to the electronic resources of the McGill Health Sciences library. They will be expected to complete the preparatory readings (links to readings are posted on my Web CT). They will also be expected to select and access primary research articles through the medical library for in-class discussions and projects.

Assignments and Evaluation

It is expected that students work diligently throughout the course and apply concepts in class effectively. Evaluations will be conducted as follows:

1. Contributions to in-class discussion and in-class group exercises: 10%
2. Three weekly in-class quizzes: 30% total (i.e. 10% per quiz)
3. Group presentation and project: 25%
4. Research proposal OR final exam: 35%

In accord with McGill University's Charter of Students' Rights, students in this course have the right to submit in English or in French any written work that is to be graded. The in-class presentations and quizzes will be graded by the course instructors. McGill University values academic integrity. Therefore, all students must understand the meaning and consequences of cheating, plagiarism and other academic offences under the Code of Student Conduct and Disciplinary Procedures (http://www.mcgill.ca/students/srr/honest/)

Course Outline EPI 600 Dasgupta and Pant Pai	
3 May	**SESSION 1: Introduction to Clinical Epidemiology** *Review of course content and structure; discussion of goals; deconstructing a study in terms of population, intervention, comparison, and outcome; history of clinical epidemiology*
5 May	**SESSION 2: Measures- Learning the Lexicon** *Review and group exercises addressing risk, rate, ratios, odds, person-time, NNT, hazard ratio*
7 May	**SESSION 3: The Framingham Cohort as a Classic Cohort Study** **First in-class quiz;** *Two groups will then present two Framingham cohort study papers using the STROBE framework; Guest discussant will participate from Framingham*
10 May	**SESSION 4: Clinical vs. Statistical Significance** *Review and group exercises addressing measures of central tendency, variability, p value/confidence intervals; clinical vs. statistical significance*
12 May	**SESSION 5: Clinical Trials and the Great Debate** ***Two groups*** *will debate the design, methods, and conclusions of a clinical trial; they will use the CONSORT framework to guide their discussion; strengths and challenges of the clinical trial design will be reviewed*
14 May	**SESSION 6: Case Control Studies and a Conceptual Back Flip** **Second in-class quiz;** *Key issues in case control study design and interpretation; group exercises in case control study design*
17 May	**SESSION 7: Bias in Epidemiology; Research Using Existing Data Bases** ***Two groups*** *will present two papers that illustrate potential bias; bias will be reviewed with respect to different epidemiological study designs; Scope for using existing data sets for original research will be illustrated*
19 May	**SESSION 8: Diagnostic Studies** ***Two groups*** *will present two papers using the STARD and QUADAS checklist framework; the key elements of diagnostic studies will be reviewed; concepts of likelihood ratios and pretest/post test probability will be demonstrated through in-class exercises*
21 May	**SESSION 9: Literature Searching and Systematic Review** **Third in-class quiz;** *The methods and resources for conducting a comprehensive and narrow search will be experienced; the key components of a review and meta-analysis will be discussed*
24 May	**VICTORIA DAY HOLIDAY No Classes**
26 May	**SESSION 10: Ethical Issues in Clinical Research Studies** **Research proposal is due (option A);** *Need for Research Ethics Boards discussed; key considerations reviewed and a research proposal analyzed*
28 May	**SESSION 11: The Clinician Scientist Career Track** **Final exam (option B);** *Discussion with Clinician Scientists; The Clinician Scientist career track; the MSc program in Epidemiology; Potluck* Course feedback and evaluation