McMaster University **School of Graduate Studies**

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June 8, 2009

To : Members of the Faculty of Health Sciences Graduate Policy and Curriculum Committee

From : Medy Espiritu
Assistant Secretary and SynApps System Administrator

The next meeting of the Faculty of Health Sciences Graduate Policy and Curriculum Committee will be held on **Wednesday, June 10, 2009** at **2:00 p.m.** in **MUMC-1J8**.

Listed below are the agenda items for discussion.

If you are unable to attend the meeting, please call extension 24204 or email espiritu@mcmaster.ca.

A G E N D A

A. Curriculum Revisions

Health Research Methodology

New online courses:
*771 – Fundamentals of Health Research and Evaluation Methods
*772 – Introduction to Research Methods for Randomized Controlled Trials
*773 – Systematic Review Methods

Change in course description: *791 – Topics in Advanced Health Economics

Medical Sciences
*733 – Vascular Diseases, Hemostasis and Thrombosis II – change in method of evaluation and course content

Health Policy Analysis
- Changes to the Ph.D. comprehensive examination procedures – Dr. M. Giacomini

B. Graduate Expansion Update – Dr. A. Sekuler

McMaster University

SCHOOL OF GRADUATE STUDIES

RECOMMENDATION FOR CHANGE IN GRADUATE CURRICULUM - FOR CHANGE(S) INVOLVING COURSES

PLEASE READ THE FOLLOWING NOTES BEFORE COMPLETING THIS FORM:

1. This form must be completed for **ALL** course changes. All sections of this form **must** be completed.
2. An electronic version of this form must be emailed to the Assistant Secretary and SynApps System Administrator (Email: *espiritu@mcmaster.ca*).
3. A representative from the department is required to attend the Faculty Curriculum and Policy Committee meeting during which this recommendation for change in graduate curriculum will be discussed.

DEPARTMENT/PROGRAM	Health Research Methodology Program
COURSE TITLE	Fundamentals of Health Research and Evaluation Methods (Online)

		COURSE CREDIT		
COURSE NUMBER	*771	**FULL COURSE ( )**	**HALF COURSE (x)**	**QUARTER (MODULE) ( )**
INSTRUCTOR(S)	Mitch Levine			
PREREQUISITE(S)	SGS minimum requirements and permission from instructor; antirequisite HRM *721			

NATURE OF RECOMMENDATION ***(PLEASE CHECK APPROPRIATE BOX)***

NEW COURSE	X	**DATE TO BE OFFERED:** September 2009	**WAS THE PROPOSED COURSE OFFERED ON DEAN'S APPROVAL? IF YES, PROVIDE THE DATE:**

WILL THE COURSE BE CROSS-LISTED WITH ANOTHER DEPARTMENT? IF YES, ATTACH TO THIS FORM ANY RELEVANT CORRESPONDENCE WITH THE OTHER DEPARTMENT(S). NOTE: CROSS-LISTING OF COURSES REQUIRES APPROVAL FROM EACH DEPARTMENT AND FACULTY CONCERNED.

CHANGE IN COURSE TITLE		**PROVIDE THE CURRENT COURSE TITLE:**				
CHANGE IN COURSE DESCRIPTION		**600-LEVEL COURSE** ***(Undergraduate course for graduate credit)*** ***Please see #4 on page 2 of this form***				
CHANGE TO FULL COURSE		**CHANGE TO HALF COURSE**		**CHANGE TO QUARTER COURSE**		
COURSE CANCELLATION		**PROVIDE THE REASON FOR COURSE CANCELLATION:**				
OTHER	X	**EXPLAIN:** Same as HRM *721 but delivered 100% online (HRM*721 will continue to be offered in-class). The method of presentation and method of evaluation has been changed for the online course.				

BRIEF DESCRIPTION FOR CALENDAR - Provide a brief description *(maximum 6 lines)* to be included in the Graduate Calendar.

This online course covers the major components of research activities, including concepts of health, formulation of research questions, literature reviews, study designs, selection of study populations, choice of measuring instruments, and study interpretation issues such as determination of causality and the effectiveness of clinical and community interventions.

CONTENT/RATIONALE - Provide a brief description, i.e., outline the topics or major sub-topics, and indicate the principal texts to be used.

This course introduces students to the major components of research activities, including: concept of health, formulation of research questions, literature reviews, study designs, selection of study populations, choice of measuring instruments, and study interpretation issues such as determination of causality and the effectiveness of clinical and community interventions. This course is designed to introduce methodological issues to help students identify further learning objectives related to in-depth study of specific research methods.

This online course has the same readings as the oncampus course HRM721; Session Topics:

1. Introduction & Posing the Research Question; 2. Measures of Health and Disease Frequency; 3. Measurement & Analysis
4. Sampling; 5. Causation; 6. Qualitative Research; 7. Therapy; 8. Diagnosis; 9. Systematic Reviews; 10. HTA and Economic
11. Research Ethics; 12. Knowledge Translation

Required Material: Custom courseware PLUS

Hulley SR, Cummings SR, Browner WS, Grady SG, Newman TB. Designing Clinical Research. 3rd edition. Wolters Kluwer/Lippincott Williams and Wilkins. Philadelphia. 2007.

AND: The Evidence Based-Medicine Working Group. Guyatt G, ed

OR

DiCenso D, Guyatt G, Ciliska D. Evidence-Based Nursing: A Guide to Clinical Practice. Sigma Theta Tau Honor Society of Nursing. Elsevier Mosby. Philadelphia. 2005.

1. STATEMENT OF PURPOSE (How does the course fit into the department's program?)

The online format of this introductory course allows students to further their studies even while working full-time or living at a distance from the University. This course is also a prerequisite for most upper-level graduate courses in the HRM program, it introduces students to a wide range of perspectives and research methodologies that are relevant to the study of health phenomena. This course is designed to help students to identify further learning objectives related to in-depth study of specific research methods

2. EXPECTED ENROLMENT:

15-25 Students

3. DESCRIBE IN DETAIL THE METHOD OF PRESENTATION OF COURSE MATERIAL (i.e., lectures, seminars):

This online course consists of 12 units (a new unit is posted every week). Each unit consists of a video-captured lecture, required readings, an assignment, discussion and a tutorial session. Participation in the discussion boards is monitored and evaluated. Tutorials will be held at the end of the week via a web conferencing tool (Elluminate LIVE). Live participation in the tutorial sessions is optional although individuals who cannot attend are expected to review the archived session materials.

4. DESCRIBE IN DETAIL THE METHOD OF EVALUATION: (For 600-level course, indicate the Extra Work to be required of graduate students, i.e., exams, essays, etc.)

60% = quizzes (4 x 15%)
20% = Final paper/research proposal
10% = Participation in discussion forums
10% = Discussion facilitation and summary document

5. TO PREVENT OVERLAP, IS A COURSE IN THE SAME OR A RELATED AREA OFFERED IN ANOTHER DEPARTMENT? IF YES, PLEASE ATTACH TO THIS FORM ANY RELEVANT CORRESPONDENCE WITH THE OTHER DEPARTMENT(S).

N/A

6. IF THE COURSE IS INTENDED PRIMARILY FOR STUDENTS OUTSIDE YOUR DEPARTMENT, DO YOU HAVE THE SUPPORT OF THE DEPARTMENT/PROGRAM CONCERNED?

PLEASE PROVIDE THE CONTACT INFORMATION FOR THE RECOMMENDED CHANGE:

Name: Mitchell Levine Email: levinem@mcmaster.ca Extension:

If you have any questions regarding this form, please contact the Assistant Secretary and SynApps System Administrator, School of Graduate Studies, extension 24204.

SGS/December 2006

HRM Course Outline

Course Number & Title:	HRM *771: Fundamentals of Health Research and Evaluation Methods (Online)
Course Co-ordinator:	Mitch Levine
Additional Faculty/Support:	

Course Description

This online course utilizes video-captured lectures, required readings, discussion boards, tutorials, quizzes and assignments to introduce students to the major components of research activities, including: concept of health, formulation of research questions, literature reviews, study designs, selection of study populations, choice of measuring instruments, and study interpretation issues such as determination of causality and the effectiveness of clinical and community interventions.

Course Objectives

1. To examine quantitative and qualitative research approaches to understand their strengths and limitations
2. To learn how to apply these research approaches and methods by completing weekly assignments and preparing a research protocol in your own area of interest

Educational Methods/Course Format

This course will have the same required readings and delivered content as the on-campus course, HRM721. Each week students will be expected to complete a learning package that involves: doing the required readings, completing the online module, completing the weekly assignment and participating in discussions on the discussion boards. Students will be assigned each week to facilitating and summarizing the discussions. At the end of each week, the online instructor will hold a 'tutorial' session where the instructor will respond to any outstanding issues and answer any specific questions that students have.

Course Text/Materials

Required texts: Hulley SR, Cummings SR, Browner WS, Grady SG, Newman TB. Designing Clinical Research. 3rd edition. Wolters Kluwer/Lippincott Williams and Wilkins. Philadelphia. 2007. Plus at least one of the following: 1. The Evidence Based-Medicine Working Group. Guyatt G, ed. Users' Guides to the Medical Literature. 2nd edition. McGraw Hill. Chicago. 2008. 2. DiCenso D, Guyatt G, Ciliska D. Evidence-Based Nursing: A Guide to Clinical Practice. Sigma Theta Tau Honor Society of Nursing. Elsevier Mosby. Philadelphia. 2005.
Students are also required to purchase a courseware package and access readings online (as outlined weekly).

Prerequisites:	Students must meet SGS minimum requirements and must be approved by the instructor *antirequisite: HRM *721*

Session	Topic
Week 1	Posing the Research Question
Week 2	Measures of Health, Illness and Disease Frequency
Week 3	Measurement and Analysis
Week 4	Sampling
Week 5	Determining Causation
Week 6	Qualitative Study Design
Week 7	Therapeutic Trials – The Tactics of Performing Therapeutic Trials
Week 8	Evaluating the Accuracy of Screening and Diagnostic Tests
Week 9	Systematic Reviews
Week 10	Economics: Introduction to Health Technology Assessment (HTA)
Week 11	Knowledge Translation
Week 12	Ethics in Research
Week 13	

Evaluation of Student Performance

60% = 4 x midterm exams (multiple choice/short answer)
20% = final paper
10% = Participation in discussion forums
10% = Discussion facilitation and summary document

Course Syllabus

HRM *771: Fall 2009

Fundamentals of Health Research and Evaluation Methods (Online)

1. Course Overview

1.1 Brief Description

This online course utilizes video-captured lectures, required readings, discussion boards, tutorials, quizzes and assignments to introduce students to the major components of research activities, including: concept of health, formulation of research questions, literature reviews, study designs, selection of study populations, choice of measuring instruments, and study interpretation issues such as determination of causality and the effectiveness of clinical and community interventions. This course is designed to introduce methodological issues to help students identify further learning objectives related to in-depth study of specific research methods.

1.2 Course Objectives

- To examine quantitative and qualitative research approaches to understand their strengths and limitations
- To learn how to apply these research approaches and methods by completing weekly assignments and preparing a research protocol in your own area of interest

1.3 Prerequisites

Students must meet McMaster's School of Graduate Studies' minimum requirements (see: http://www.mcmaster.ca/graduate/grad_calendar.pdf *section 2.1.5, page 5*).

1.4 Required Materials

Required texts:
Hulley SR, Cummings SR, Browner WS, Grady SG, Newman TB. Designing Clinical Research. 3rd edition. Wolters Kluwer/Lippincott Williams and Wilkins. Philadelphia. 2007.

Plus at least one of the following:
The Evidence Based-Medicine Working Group. Guyatt G, ed. Users' Guides to the Medical Literature. 2nd edition. McGraw Hill. Chicago. 2008.

DiCenso D, Guyatt G, Ciliska D. Evidence-Based Nursing: A Guide to Clinical Practice. Sigma Theta Tau Honor Society of Nursing. Elsevier Mosby. Philadelphia. 2005.

Custom courseware and additional materials:

McMaster University

SCHOOL OF GRADUATE STUDIES

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3. A representative from the department is required to attend the Faculty Curriculum and Policy Committee meeting during which this recommendation for change in graduate curriculum will be discussed.

DEPARTMENT/PROGRAM	Health Research Methodology			
COURSE TITLE	Introduction to Research Methods for Randomized Controlled Trials (Online)			
COURSE NUMBER	*772	**COURSE CREDIT**		
		FULL COURSE ( )	**HALF COURSE (X)**	**QUARTER (MODULE) ( )**
INSTRUCTOR(S)	PJ Devereaux			
PREREQUISITE(S)	HRM *721 (or equivalent) OR approval of the instructor; antirequisite HRM *730			

NATURE OF RECOMMENDATION ***(PLEASE CHECK APPROPRIATE BOX)***

NEW COURSE	X	**DATE TO BE OFFERED:** September 2009	**WAS THE PROPOSED COURSE OFFERED ON DEAN'S APPROVAL?** **IF YES, PROVIDE THE DATE:**

WILL THE COURSE BE CROSS-LISTED WITH ANOTHER DEPARTMENT? **IF YES, ATTACH TO THIS FORM ANY RELEVANT CORRESPONDENCE WITH THE OTHER DEPARTMENT(S).** **NOTE: CROSS-LISTING OF COURSES REQUIRES APPROVAL FROM EACH DEPARTMENT AND FACULTY CONCERNED.**

CHANGE IN COURSE TITLE		**PROVIDE THE CURRENT COURSE TITLE:**				
CHANGE IN COURSE DESCRIPTION		**600-LEVEL COURSE** ***(Undergraduate course for graduate credit)*** ***Please see #4 on page 2 of this form***				
CHANGE TO FULL COURSE		**CHANGE TO HALF COURSE**		**CHANGE TO QUARTER COURSE**		
COURSE CANCELLATION		**PROVIDE THE REASON FOR COURSE CANCELLATION:**				
OTHER	X	**EXPLAIN:** Same as HRM*730 but delivered 100% online (HRM*730 will continue to be offered in-class). The method of presentation and method of evaluation has been changed for the online course.				

BRIEF DESCRIPTION FOR CALENDAR - Provide a brief description *(maximum 6 lines)* to be included in the Graduate Calendar.

This online course utilizes interactive learning modules, required readings, discussion boards, tutorials and assignments to introduce students to the main elements of clinical trial design, execution and analysis. The course is structured around the steps of designing and writing a clinical trials protocol. Students are expected to apply the knowledge they gain on an ongoing basis to complete their proposal by the end of the course. After completing this course successful students should have a firm grasp of clinical trial methodology that allows them to prepare successful grant applications.

CONTENT/RATIONALE - Provide a brief description, i.e., outline the topics or major sub-topics, and indicate the principal texts to be used.

This course will introduce students to the main elements of clinical trial design, execution and analysis. At the end of this course, students should have a firm grasp of clinical trial methodology that allows them to prepare successful grant applications. This online course has the same readings and learning materials presented in the on-campus course, HRM 730.

Session topics:

Introduction, Study Designs, General Measurement Issues, The Population, Randomization, Intervention, Outcome Events, The Analysis Plan, Part I (Scientific Decisions), The Analysis Plan, Part II (Basic and Advanced Statistical Methods), Trial Organization, Administration and Finance, Trial Management and Quality Control

Required text

Haynes RB, Sackett DL, Guyatt GH and Tugwell P. Clinical Epidemiology: How to do clinical practice research. Philadelphia: Lippincott, Williams & Wilkins. 2006.

Additional materials:

Students are required to purchase a custom courseware package and obtain readings online (as listed each week).

1. STATEMENT OF PURPOSE (How does the course fit into the department's program?)

For aspiring clinical trial researchers, this is an essential introductory course which deals with the formulation of appropriate research questions and trial designs, for funding purposes. The flexibility of the course format makes this course suitable for individuals with both time and geographical contraints.

2. EXPECTED ENROLMENT:

20-25 students

3. DESCRIBE IN DETAIL THE METHOD OF PRESENTATION OF COURSE MATERIAL (i.e., lectures, seminars):

The course will be offered online using the ELM learning content management system. The course consists of 11 units (a new unit is posted every week). Each unit consists of an interactive learning module (with audio-narrated slides), required readings, an assignment, discussion and a tutorial session. Participation in the discussion boards is monitored and evaluated. Tutorials will be held at the end of the week via a web conferencing tool (Elluminate LIVE). Live participation in the tutorial sessions is optional although individuals who cannot attend are expected to review the archived session materials.

4. DESCRIBE IN DETAIL THE METHOD OF EVALUATION: (For 600-level course, indicate the Extra Work to be required of graduate students, i.e., exams, essays, etc.)

40% = Final research protocol
25% = Written review of a fellow student's research protocol
20% = 2 multiple choice question tests
15% = Participation in discussion forums

5. TO PREVENT OVERLAP, IS A COURSE IN THE SAME OR A RELATED AREA OFFERED IN ANOTHER DEPARTMENT? IF YES, PLEASE ATTACH TO THIS FORM ANY RELEVANT CORRESPONDENCE WITH THE OTHER DEPARTMENT(S).

N/A

6. IF THE COURSE IS INTENDED PRIMARILY FOR STUDENTS OUTSIDE YOUR DEPARTMENT, DO YOU HAVE THE SUPPORT OF THE DEPARTMENT/PROGRAM CONCERNED?

N/A

PLEASE PROVIDE THE CONTACT INFORMATION FOR THE RECOMMENDED CHANGE:

Name: PJ Devereaux Email: philipj@mcmaster.ca Extension: 22063

If you have any questions regarding this form, please contact the Assistant Secretary and SynApps System Administrator, School of Graduate Studies, extension 24204.

SGS/December 2006

HRM Course Outline

Course Number & Title:	HRM *772: Introduction to Research Methods for Randomized Controlled Trials (Online)
Course Co-ordinator:	PJ Devereaux
Additional Faculty/Support:	

Course Description

This online course utilizes interactive learning modules, required readings, discussion boards, tutorials and assignments to introduce students to the main elements of clinical trial design, execution and analysis. The course is structured around the steps of designing and writing a clinical trials protocol. Students are expected to apply the knowledge they gain on an ongoing basis to complete their proposal by the end of the course. After completing this course successful students should have a firm grasp of clinical trial methodology at a level that would allow them to prepare successful grant applications.

Course Objectives

The primary objective of this course is to introduce students to the main elements of clinical trial design, execution and analysis. The secondary objective is to guide students in the design and presentation of a clinical trials protocol. After completing this course successful students should have a firm grasp of clinical trial methodology at a level that would allow them to prepare successful grant applications.

Educational Methods/Course Format

This course will have the same required readings and delivered content as the on-campus course, HRM730. Weekly lectures will be presented in an online module format, integrating in opportunities for self-evaluation and reflection on the materials being presented. Students will be evaluated on their participation in discussions on the discussion board, 2 multiple choice tests, their final paper and the review of a fellow student's paper.

Course Text/Materials

Required text:
Haynes, RB, Sackett, DL, Guyatt, GH, and Tugwell, P. Clinical Epidemiology: How to do clinical practice research. Philadelphia: Lippincott, Williams & Wilkins. 2006.
Additional materials:
Students are also required to purchase custom courseware and access readings online (as listed each week).

Prerequisites:	HRM *721 (or equivalent) OR approval of the instructor; *antirequisite HRM *730*
Session	**Topic**
Week 1	Introduction
Week 2	Study Designs
Week 3	General Measurement Issues
Week 4	The Population
Week 5	Randomization
Week 6	Intervention
Week 7	Outcome Events
Week 8	The Analysis Plan, Part I (Scientific Decisions)
Week 9	The Analysis Plan, Part II (Basic and Advanced Statistical Methods)
Week 10	Trial Organization, Administration and Finance
Week 11	Trial Management and Quality Control
Week 12	
Week 13	

Evaluation of Student Performance
40% = Final research protocol 25% = Written review of a fellow student's research protocol 20% = 2 multiple choice question tests 15% = Participation in discussion forums

Course Syllabus

HRM *772: Fall 2009
Introduction to Research Methods for Randomized Controlled Trials (Online)

1. Course Information

1.1 Brief Description

This online course utilizes interactive learning modules, required readings, discussion boards, tutorials and assignments to introduce students to the main elements of clinical trial design, execution and analysis. For aspiring clinical trial researchers, this is an essential introductory course which deals with the formulation of appropriate research questions and trial designs, for funding purposes.

1.2 Course Objectives

The objective of this course is to introduce and discuss the main elements of clinical trial design, execution and analysis. At the end of the course, students should have a firm grasp of clinical trial methodology at a level that would allow them to prepare successful grant applications.

1.3 Prerequisites

Students must:

- meet McMaster's School of Graduate Studies admission criteria, see School of Graduate Studies graduate calendar, section "2. General Regulations of the Graduate School - - Admissions Requirements": http://www.mcmaster.ca/graduate/grad_calendar.pdf
- have taken an introductory course in research methods (equivalent to the Health Research Methodology's graduate courses: HRM721; see http://www.fhs.mcmaster.ca/grad/hrm/course_list.html for additional information) OR receive permission from the instructor

1.4 Required Materials

Required text:

Haynes RB, Sackett DL, Guyatt GH and Tugwell P. Clinical Epidemiology: How to do clinical practice research. Philadelphia: Lippincott, Williams & Wilkins. 2006.

Additional materials:
Students are required to purchase a custom courseware (which includes readings not available electronically) and access online readings online, as outlined weekly.

Availability:
Custom courseware and textbooks can be purchased online from the McMaster Health Sciences Bookstore (http://titles.mcmaster.ca/mediashop)**

Textbooks are also available online through stores such as: www.amazon.ca

** Custom courseware must be ordered by the end of July – early August to ensure delivery before the start of the course

Other helpful resources:

McFadden, E. (2007). Management of data in clinical trials. (2nd Edition)
http://ca.wiley.com/WileyCDA/WileyTitle/productCd-0470046082.html

Lawrence, M. (1998). Fundamentals of clinical trials (3rd Edition)
http://www.springer.com/statistics/stats+life+sci/book/978-0-387-98586-2

Shein-Chung, C (2003). Design and analysis of clinical trials: concept and methodologies. (2nd Edition)
http://ca.wiley.com/WileyCDA/WileyTitle/productCd-0471249858,subjectCd-LSZ0,descCd-tableOfContents.html

Spilker, B. (1991). Guide to clinical trials.
http://www.amazon.com/Guide-Clinical-Trials-Bert-Spilker/dp/0881677671

Jadad, A. (2007). Randomised controlled trials: Questions, answers and musings (2nd Edition)
http://ca.wiley.com/WileyCDA/WileyTitle/productCd-1405132663.html

1.5 Brief Outline

Unit	Topic (Module Author)
1	Introduction
2	Study designs
3	General measurement issues
4	The population
5	Randomization
6	Intervention
7	Outcome events
8	The analysis plan, part I (Scientific decisions)
9	The analysis plan, part II (Basic and advanced statistical methods)
10	Trial organization/administration/finance

2. Contact Information

Distance Education Coordinator:

Soo Chan Carusone, PhD
Clinical Epidemiology & Biostatistics
Email: chan.carusone@mcmaster.ca

Course Coordinator:

PJ Devereaux, MD, FRCPC, PhD
Assistant Professor, Department of Clinical Epidemiology & Biostatistics
Email: philipj@mcmaster.ca

3. Course Format

HRM 772 consists of 11 units (a new unit is posted every week). Each unit consists of an interactive learning module (with audio-narrated slides on the topic), required readings, activities, discussion and a tutorial session. Participation in the discussion boards is monitored and evaluated. Each week students will be assigned to facilitate discussions. Student facilitators will be evaluated on their facilitation and their written summary of the discussion. Live participation in the tutorial sessions is optional although individuals who cannot attend are expected to review the archived session materials. Tutorials will be held at the end of the week via a web conferencing tool (Elluminate LIVE). The agenda for the tutorials will be directed by the unresolved issues and questions raised in the discussion forums. Students will also have the opportunity to post additional questions directly to the instructor in advance of the tutorial sessions (if they cannot attend).

To facilitate retention, this course has been designed to give students a variety of opportunities to apply the knowledge they gain.

Students are expected to:

- Complete session modules including the self-assessment questions
- Complete the weekly assignments and compare them to answer keys
- Participate in weekly discussions with the instructor and fellow students on key issues in each unit
- Complete 2 short multiple choice question tests
- Consolidate issues and topics covered throughout the term and write a brief research proposal on a topic of your choice

4. Student Evaluation

Students are given many opportunities to demonstrate their mastery of the course material. Final course marks will be calculated as follows:

40% = Final research protocol & response to reviewer's comments

25% = Written review of a fellow student's protocol

20% = 2 multiple choice question tests

15% = Participation in discussion forums

Final paper

The final paper is structured as a grant proposal on a research topic of your choice. The paper should be a maximum of 20 pages, excluding references, charts or diagrams (double-spaced, 12 point font, 2.5 cm margins). See the course website for additional instructions and a sample paper. You will receive your evaluation and comments on your paper 7 days after it is submitted. You will then have 4 days to respond to the reviewer's comments. You may want to structure this document like a response to reviewer's comments on a journal submission (indicating how the original text could be modified). This document should not exceed 4 pages, double-spaced.

Written review of a fellow student's protocol

This assignment is designed to give you the opportunity to critically appraise a peer's research protocol (the review does not contribute to the author's grade). Reviews should be typed and double-spaced, with a maximum length of 4 pages. You should outline the strength and weaknesses of the research proposal, focusing on the following:

1. The appropriateness of the research plan, focus on design, methodological issues, and feasibility (not on the clinical relevance of the question)
2. The clarity of writing

Multiple Choice Question Tests

To encourage review and consolidation of the information presented in this course, your mastery of the materials will be evaluated by multiple choice question tests twice during the term. These tests will be administered **online**. You will have a 12-hour window in which to access the tests but only one hour to complete it once opened.

Participation in discussion forums:

Participation in discussions with fellow students and instructors is known to be critical to developing a successful and effective learning environment. Student participation will be evaluated based on a minimum quantity, quality and timeliness. Each week you are expected to post one original post and

respond to at least 2 threads initiated by others. Posting more than this will not automatically equate to greater participation marks. To allow significant time for discussion each week the time of a student's post will also be considered in evaluations (that is, you should not post your comments Friday morning every week, right before the tutorial session). For detailed guidelines and marking rubrics for participation see the course website in ELM (XXXXXX).

**Weekly assignments are designed to ensure that you understand the core concepts covered in each unit and are applying them in an on-going manner to your final project. You are expected to complete the assignments in a timely fashion to ensure adequate time for discussion - assignments will not be marked directly but quality, timing and quantity of participation in discussions will be evaluated.

Student opportunities to evaluate the course and the instructors

Completion of course evaluation forms

Every week students will be asked to evaluate the current unit (the module, the assignment, etc). This information is important to course coordinators, tutors and the department administrators and is used to improve course content and delivery. We value your input and the quality of the course depends on it, so please remember to fill these out on a regular basis.

Feedback Forum

In addition, to the weekly evaluation forms (which are done completely anonymously and are read and analyzed only at the end of the course), there is a 'Feedback Forum' threaded discussion area where you can post anonymous suggestions for improving the organization and running of the course. This will give students' an opportunity to discuss with others the pros and cons of specific recommendations as well as allowing, where possible, the instructor to make immediate modifications to the current course (for example, the addition of a discussion forum or a student-created resource library).

5. Course Calendar

This is a tentative calendar. You will be notified as soon as possible if any changes need to be made. Further details of the weekly objectives, activities and readings are found below in section 6: 'Detailed Course Outline'.

Unit (Dates)	Topic (Date Posted)	Activities
UNIT 0: **Sept. 14 – 20**	Orientation	Welcome Session – Sept. 18 (TIME)
UNIT 1:	Introduction	Discussion – DATES

Sept. 21 – 27		Tutorial – DATE & TIME
UNIT 2: **Sept. 28 – Oct. 4**	Study Designs	Discussion – DATES Tutorial – DATE & TIME
UNIT 3: **Oct. 5 – 11**	General Measurement Issues	Discussion – DATES Tutorial – DATE & TIME
UNIT 4: **Oct. 12 – 18**	The Population	Discussion – DATES Tutorial – DATE & TIME **October 18th (11:59PM EST) - DUE: Research Question**
UNIT 5: **Oct. 19 – 25**	Randomization	Discussion – DATES Tutorial – DATE & TIME
UNIT 6: **Oct. 26 – Nov. 1**	Intervention	Discussion – DATES Tutorial – DATE & TIME
UNIT 7: **Nov. 2 – 8**	Outcome Events	Discussion – DATES Tutorial – DATE & TIME
UNIT 8: **Nov. 9 – 15**	The Analysis Plan, Part I (Scientific Decisions)	Discussion – DATES Tutorial – DATE & TIME
UNIT 9: **Nov. 16 – 22**	The Analysis Plan, Part II (Basic & Advanced Statistical Methods)	Discussion – DATES Tutorial – DATE & TIME
UNIT 10: **Nov. 23 – 29**	Trial Organization/ Administration/ Finance	Discussion – DATES Tutorial – DATE & TIME
UNIT 11: **Nov. 30 – Dec. 6**	Trial Management & Quality Control	Discussion – DATES Tutorial – DATE & TIME
Dec. 7 – 9	- NO MODULE - Protocol Discussion Question & Answer Session	Q&A Session – December 7, TIME
December 9th	Final Protocol Submission	**DUE: December 9th, 11:59 PM (EST)**

December 16th	Final Protocol Partner Review	**DUE: December 16th, 11:59 PM (EST)**
December 20th	Response to reviewer's comments submission	**DUE: December 20th, 11:59 PM (EST)**

Other Important Dates:

Monday October 12, 2009: Canadian Thanksgiving

Thursday, November 26, 2009: American Thanksgiving

6. Detailed Course Outline

Below you will find a unit-by-unit overview for the course including objectives, readings and assignments. You are expected to complete all the activities within the week dedicated to that unit (as outlined in the schedule). In general, it is best to complete the readings before viewing the learning module although in some cases you might find it beneficial to refer back to the readings while, or after, viewing the module as well. You are expected to contribute a post to the discussion board by **WEDNESDAY** of every week and continue to read and participate until the end of the Unit (Sunday night). Good luck and enjoy!

UNIT 0: Orientation

Introduction:

Some of you may be new to the online learning environment and all of us our new to McMaster's new Learning Management System (LMS) – ELM (E-Learning @ McMaster), so we have decided not to present a learning module for this week. However, we have lots for you to do!

Objectives:

At the conclusion of this session you should:

- Understand the course format, assignments and evaluation methods.
- Know something about your peers and your instructor
- Know where to find help

To Do:

- ✓ Confirm that you meet the computer software and system requirements, please review the E-Learn @ Mac (ELM) information posted on the Learning Technology Resource Centre's website for specific requirements: http://www.ltrc.mcmaster.ca/elm/launch/index.php
- ✓ Confirm that you have a McMaster MAC ID Eg., John Smith smithj@mcmaster.ca & MAC ID is 'smithj'. Click on website for information on how to activate your MAC ID: http://www.ltrc.mcmaster.ca/webct/index.shtml
- ✓ Confirm that you can access the HRM 772 course on ELM: http://www.ltrc.mcmaster.ca/implementation/
- ✓ **Carefully** read over the entire course syllabus and post any questions in the 'open discussion forum'.
- ✓ Prepare a bio-blurb (1-3 paragraphs), including a brief description of your background, reason(s) for taking this course, list what you hope to obtain by completing this course and some interesting information about you – pictures are also welcome!
- ✓ Post your bio-blurb on the HRM 772 'introductions' discussion board (*N.B. the discussion board is not private – all registered HRM 772 students can view your posting)* and comment on some of your peers' posts.
- ✓ Know where to go to for help:
    - ELM technical help: LTRC contact
    - CE&B/HRM Distance Education help: Soo Chan Carusone
    - HRM 772 help: PJ Devereaux

UNIT 1: Introduction

Introduction:

The first step to any research project is to pose an appropriate question. The goal of this unit is for you to understand the key components of a good clinical research question. Unit 1 also gives you a brief introduction to randomized controlled trials.

Objectives:

At the conclusion of the session, you should be able to:

- Generate a clinical research question.

- Understand the components and importance of a well-built clinical question.
- Understand and describe PICOT.
- Understand the history of clinical trials.
- Describe common themes in clinical research: bias avoidance, feasibility and ethics.

Readings:

1. Sackett, D.L. (2005). Chapter 4: An introduction to performing therapeutic trials. In Haynes, R.B., Sackett, D.L., Guyatt, G.H., & Tugwell, P. (Eds)., *Clinical Epidemiology: How to do Clinical Practice Research*, (3rd Ed.), pp 59-65. Philadelphia: Lippincott Williams & Wilkins.

2. Devereaux, P.J., & Yusuf, S. (2004). The evolution of the randomized controlled trial and its role in evidence-based decision making. *Journal of Internal Medicine*, 254(1), 105-113. http://libaccess.mcmaster.ca/login?url=http://www.blackwell-synergy.com/doi/pdf/10.1046/j.1365-2796.2003.01201.x?cookieSet=1

3. Haynes, R.B. (2005). Chapter 1: Forming Research Questions. In Haynes, R.B., Sackett, D.L., Guyatt, G.H., & Tugwell, P. (Eds)., *Clinical Epidemiology: How to do Clinical Practice Research*, (3rd Ed.), pp 3-14. Philadelphia: Lippincott Williams & Wilkins.

4. POISE Study Group. (2008). Effects of extended-release metoprolol succinate in patients undergoing non-cardiac surgery (POISE trial): a randomized controlled trial. *The Lancet*, 371(9627), May 31. *http://libaccess.mcmaster.ca/login?url=http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6T1B-4SGXYN6-1&_user=1067350&_rdoc=1&_fmt=&_orig=search&_sort=d&view=c&_acct=C000051241&_version=1&_urlVersion=0&_userid=1067350&md5=1a151334477b98ceab99e194382f4c25*

5. Editorial Commentary (2007). Fair tests of treatments in health care. The James Lind Library (www.jameslindlibrary.org): http://www.jameslindlibrary.org/essays/fair_tests/fair-tests-of-treatments-in-health-care.pdf

Optional Readings

1. Sackett, D.L. (2005). Chapter 5.2: The Research Question. In Haynes, R.B., Sackett, D.L., Guyatt, G.H., & Tugwell, P. (Eds)., *Clinical Epidemiology: How to do Clinical Practice Research*, (3rd Ed.), pp 69-74. Philadelphia: Lippincott Williams & Wilkins.

2. Sackett, D.L. (2005). Chapter 5.9: Special ethical issues in randomized controlled trials. In Haynes, R.B., Sackett, D.L., Guyatt, G.H., & Tugwell, P. (Eds)., *Clinical Epidemiology: How to do Clinical Practice Research*, (3rd Ed.), pp 146-158. Philadelphia: Lippincott Williams & Wilkins.

3. Sackett, D.L. (2005). Chapter 6.7: The uncertainty principle and equipoise. In Haynes, R.B., Sackett, D.L., Guyatt, G.H., & Tugwell, P. (Eds)., *Clinical Epidemiology: How to do Clinical Practice Research*, (3rd Ed.), pp 217-220. Philadelphia: Lippincott Williams & Wilkins.

4. Sackett, D.L. (2005). Chapter 6.9: Special issues in non-drug trials. In Haynes, R.B., Sackett, D.L., Guyatt, G.H., & Tugwell, P. (Eds)., *Clinical Epidemiology: How to do Clinical Practice Research*, (3rd Ed.), pp 224-229. Philadelphia: Lippincott Williams & Wilkins.

Assignment:

Generate a clinical research question in an area of health that is important to you and post it on Blackboard to discuss with the rest of your group – also discuss research questions from other students. Make sure that your research question defines the patient/population, intervention/exposure, comparison group and outcome as in Chapter 1 (Haynes et al, 2005).

UNIT 2: Study Designs

Introduction:

Determining which study design is most appropriate to use for your research question is a key decision to be made for your protocol. The readings and lecture slides will help you determine which design is most appropriate.

Objectives:

By the end of this unit the successful student will be able to:

- Identify, discuss and highlight the following study designs:
    - Parallel
    - Cross-over
    - Factorial
    - Cluster
    - Expertise-based
    - Non-inferiority
    - Equivalency

REQUIRED READINGS:

1. Friedman, L.M., Furberg, C.D., & DeMets, D.L. (1998). Chapter 4: Basic Study Designs. In Friedman, L.M., Furberg, C.D., & DeMets, D.L. (Eds)., *Fundamentals of Clinical Trials*, (3rd Ed.), pp 41-56. New York: Springer-Verlag.

2. Pocock, S.J. (1983). Chapter 9.5: The Number of Treatments and Factorial Designs. In Pocock, S.J. (Eds)., *Clinical Trials: A Practical Approach*, pp 138-141. Toronto: John Wiley & Sons.

3. McAlister, F.A., Straus, S.E., Sackett, D.L., & Altman, D.G. (2003). Analysis of reporting of factorial trials: A systematic review. *Journal of the American Medical Association*, 289(19), 2545-2553. http://libaccess.mcmaster.ca/login?url=http://jama.ama-assn.org/cgi/reprint/289/19/2545.pdf

4. Klar, N., & Donner, A. (2001). Current and future challenges in the design and analysis of cluster randomization trials. *Statistics in Medicine,* 20(24), 3729-3740. http://www3.interscience.wiley.com/cgi-bin/fulltext/89011313/PDFSTART

5. Campbell, M.K., Elbourne, D.R., Altman, D.G., for the CONSORT Group. (2004). CONSORT statement: Extension to cluster randomized trials. *British Medical Journal*, 328(1), 702-708. http://libaccess.mcmaster.ca/login?url=http://www.bmj.com/cgi/reprint/328/7441/702.pdf

6. Griffiths, C., Sturdy, P., Brewin, P., Bothamley, G., Eldridge, S., et al. (2007). Educational outreach to promote screening for tuberculosis in primary care: A cluster randomised controlled trial. *The Lancet*, 369(9572), 1528-1534. http://www.ncbi.nlm.nih.gov/pubmed/17482983

7. Devereaux, P.J., Bhandari, M., Clarke, M., Montori, V.M., Cook, D.J., Yusuf, S., et al. (2005). The need for expertise-based randomised controlled trials. *British Medical Journal*, 330, 88-92. http://libaccess.mcmaster.ca/login?url=http://www.bmj.com/cgi/reprint/330/7482/88.pdf

8. Sackett, D.L. (2005). Chapter 6.5: Superiority, equivalence and non-inferiority trials. In Haynes, R.B., Sackett, D.L., Guyatt, G.H., & Tugwell, P. (Eds)., *Clinical Epidemiology: How to do Clinical Practice Research*, (3rd Ed.), pp 188-201. Philadelphia: Lippincott Williams & Wilkins.

9. Piaggio, G., Elbourne, D.R., Altman, D.G., Pocock, S.J., Evans, S.J.W., for the CONSORT Group. (2006). Reporting of non-inferiority and equivalence randomized trials: An extension of the CONSORT statement. *Journal of the American Medical Association,* 295(10), 1152-1160. http://libaccess.mcmaster.ca/login?url=http://jama.ama-assn.org/cgi/reprint/295/10/1152.pdf

Assignment:

Determine which study design is most appropriate to answer your research question and outline possible issues that may arise – post this on the discussion board. In addition to providing a description of your study design, review and provide comments on at least 2 student's postings.

UNIT 3: General Measurement Issues

Introduction:

What do we measure? Understand how to identify the variables to be measured in a clinical trial.

BASELINE: Subject Characteristics (descriptive)
Prognostic Factors

FOLLOW UP: Efficacy/Effectiveness: Primary and Secondary
Covariates
Safety

How do we measure it? Know how to select the most appropriate instruments or methods for measuring the variables of interest.

MEASUREMENT PROPERTIES: Reliability
Responsiveness
Validity
Interpretability

Objectives:
By the end of this unit, the successful student will be able to explain each item and answer each question/item for their specific research project:

1. What is the unit of measurement (patient, practice, community, etc)?
2. What to measure (baseline, process and outcome measures)
3. Rationale for measures.
4. Who should measure it?
5. When should it be measured?
6. How should it be measured?
7. Selecting the "best" outcome measure
8. Quantitative measures into event outcomes
9. Avoiding measurement bias
10. Adjudication committees
11. Reliability and validity
12. Ethical issues in measurement

REQUIRED READINGS:

1. Norman, G.R. (1989). Issues in the use of change scores in randomized trials. *Journal of Clinical Epidemiology*, 42(11), 1097-1105. http://www.ncbi.nlm.nih.gov/pubmed/2809664

2. Tugwell, P., & Guyatt, G.H. (2005). Chapter 11: Generating outcome measurements, especially for quality of life. In Haynes, R.B., Sackett, D.L., Guyatt, G.H., & Tugwell, P. (Eds)., *Clinical Epidemiology: How to do Clinical Practice Research*, (3rd Ed.), pp 388-412. Philadelphia: Lippincott Williams & Wilkins.

3. Berk, R.A. (1979). The construction of rating instruments for faculty evaluation. *Journal of Higher Education*, 50, 651-659.

4. Streiner, D.L., & Norman, G.R. (2007). Chapter 2: Basic Concepts. In Streiner, D.L., & Norman, G.R. (Eds)., Health Measurement Scales: A practical guide to their development and use, pp 5-15. Oxford: Oxford University Press.

5. Streiner, D.L., & Norman, G.R. (2007). Chapter 8: Reliability. In Streiner, D.L., & Norman, G.R. (Eds)., Health Measurement Scales: A practical guide to their development and use, pp 167-207. Oxford: Oxford University Press.

6. Streiner, D.L., & Norman, G.R. (2007). Chapter 10: Validity. In Streiner, D.L., & Norman, G.R. (Eds)., Health Measurement Scales: A practical guide to their development and use, pp 247-265. Oxford: Oxford University Press.

7. Pocock, S.J. (1983). Chapter 3.5: Evaluation of Patient Response. In Pocock, S.J. (Eds)., *Clinical Trials: A Practical Approach*, pp 41-49. Toronto: John Wiley & Sons.

Assignment:

Identify 2-3 possible measurement issues with your research project and post this on the discussion board. Review and comment on 2 student's postings (*not the same 2 students who you reviewed for Unit 2).*

UNIT 4: The Population

Introduction:

You have already identified the study population in your PICO research question. In this unit, you will have an opportunity to clarify the following: inclusion/exclusion criteria, subgroups (if applicable), ethical issues and efficacy/effectiveness.

Objectives:

By the end of this unit the successful student will be able to explain each item and identify how it relates to their specific research project:

1. Inclusion criteria (definition of the disease of interest)
2. Exclusion criteria (unsuitable patients with the disease)
3. Efficacy → effectiveness spectrum
4. Patient logs
5. Large simple trials
6. Principle of uncertainty
7. Subgroup analysis

REQUIRED READINGS:

1. Friedman, L.M., Furberg, C.D., DeMets, D.L. (1998). Chapter 3: Study Population. In Friedman, L.M., Furberg, C.D., DeMets, D.L. (Eds)., *Fundamentals of Clinical Trials*, (3rd Ed.)., pp 30-39. Littleton: PSG Publishing Co.

2. Pocock, S.J. (1983). Chapter 3.3: Selection of Patients. In Pocock, S.J. (Eds)., *Clinical Trials: A Practical Approach*, pp 35-38. Toronto: John Wiley & Sons.

3. Yusuf, S., Held, P., Teo, K.K., & Toretsky, E.R. (1990). Selection of patients for controlled trials: Implications of wide or narrow eligibility criteria. *Statistics in Medicine*, 9(1-2), 83-86.

4. Yusuf, S., Wittes, J., Probstfield, J., & Tyroler, H.A. (1991). Analysis and interpretation of treatment effects in subgroups of patients in randomized clinical trials. *Journal of the American Medical Association*, 266(1), 93-98.

5. Yusuf, S., Collins, R., & Peto, R. (1984). Why do we need some large, simple randomized trials? (1984). *Statistics in Medicine*, 3(4), 409-420.

6. Pocock, S.J. (1983). Chapter 7: Ethical Issues. In Pocock, S.J. (Eds)., *Clinical Trials: A Practical Approach*, pp 100-109. Toronto: John Wiley & Sons.

7. Schafer, A. (1982). The ethics of the randomized clinical trial. *The New England Journal of Medicine*, 307(12), 719-725.

8. Assman, S.F., Pocock, S.J., Enos, L.E., & Kasten, L.E. (2000). Subgroup analysis and other (mis)uses of baseline data in clinical trials. *The Lancet*, 355(9209), 1064-1069. http://libaccess.mcmaster.ca/login?url=http://scholarsportal.info/pdflinks/07061108501024381.pdf

9. Oxman, A., & Guyatt, G.H. (2008). Chapter 20.4: Summarizing the evidence - When to believe a subgroup analysis. In Guyatt GH, Rennie, D., Meade, MO, & Cook, DJ (editors) *Users' Guides to the Medical Literature: A Manual for Evidence-Based Clinical Practice* (2nd Ed.), pp 571-587. US: McGraw Hill.

Optional Readings

1. Sackett, D.L . (2005). Chapter 6.4: Explanatory versus management trials. In Haynes, R.B., Sackett, D.L., Guyatt, G.H., & Tugwell, P. (Eds)., *Clinical Epidemiology: How to do Clinical Practice Research*, (3rd Ed.), pp 183-188. Philadelphia: Lippincott Williams & Wilkins.

2. Sackett, D.L . (2005). Chapter 5.3: Participant Selection. In Haynes, R.B., Sackett, D.L., Guyatt, G.H., & Tugwell, P. (Eds)., *Clinical Epidemiology: How to do Clinical Practice Research*, (3rd Ed.), pp 74-85. Philadelphia: Lippincott Williams & Wilkins.

3. Sackett, D.L . (2005). Chapter 6.11: Large, simple trials and Chapter 6.12: Small trials. In Haynes, R.B., Sackett, D.L., Guyatt, G.H., & Tugwell, P. (Eds)., *Clinical Epidemiology: How to do Clinical Practice Research*, (3rd Ed.), pp 234-238. Philadelphia: Lippincott Williams & Wilkins.

4. Sackett, D.L . (2005). Chapter 6.6: Physiological statistics. In Haynes, R.B., Sackett, D.L., Guyatt, G.H., & Tugwell, P. (Eds)., *Clinical Epidemiology: How to do Clinical Practice Research*, (3rd Ed.), pp 201-217. Philadelphia: Lippincott Williams & Wilkins.

Assignment:

Read the required materials and upload your research question and 1-pager to the blackboard assignment submission for approval.

UNIT 5: Randomization

Introduction:

1. Why Randomize?

-Randomization is a design mechanism used to avoid systematic bias. It produces groups that differ only by chance on all known and unknown prognostic factors.
- On average it provides balance in baseline prognostic factors. However, randomization does not guarantee balance.
- Provides the basis for statistical testing. Do outcomes between treatment groups differ by more than could be expected by chance alone?

2. How to Randomize?

I. Generation of Schedule
-Must really be random: from a list of random numbers, random permutations of a list of numbers, computer-based pseudo-random number generator.
-***Must be reproducible***
-Generation must be well documented
-Adaptive and Fixed randomization: Refers to the probability of assignment to each treatment group.

-Adaptive: the probability of being assigned to a treatment group changes as a function of the imbalance in numbers assigned to each group, baseline characteristics, or observed outcomes.
- Also known as minimization and good with if several stratification factors are necessary
-Good way of achieving balanced groups for treatment allocation and patient

characteristics

-Possible problem with prediction next treatment to be assigned but a random element can be added

-Fixed:

-Allocation ratio is odds of randomization to each treatment groups eg. equal (1:1) or unequal (2:1)

-Stratification: to reduce variation in outcomes due to a baseline prognostic factor. Prognostic factor should be predictive of outcome and occur relatively frequently. Need a separate randomization schedule for each combination of strata. Frequently treat clinic as a strata to control for differences in environment, social, demographic, or other factors.

-Block Size: Number of allocations to each treatment group is equal every *n* allocations. Block randomization list to ensure balance of treatment groups over time. Participant characteristics may change over time or RCT may end early due to lack of recruitment or interim stopping. For open trials use a random block size to ensure concealment of allocation for the next participant randomized. Minimum block size is equal to sum of the allocation ratio.

II. Administration of Randomization

-Randomize as close as possible to time of treatment administration to avoid participant withdrawal

-Conceal randomization schedule from investigators to avoid patient selection bias e.g. making sure the sickest participant are assigned to the new treatment

-Use (a) secure sequentially numbered, opaque, sealed envelopes, (b) sequential pre-packaged kits, (c) pharmacy controlled, (d) central randomization by telephone, fax or email.

-Beware the dangers of any non-central randomization system.

-Keep block size confidential

-Always record participant identifiers at the time of randomization to prevent treatment mix-ups (either intentional or unintentional) and produce an audit trail which can be inspected at any time. Also, good for doing a last minute check for participant eligibility.

III. Unit of Randomization – individual or organizations (clusters)

-Is the intervention implemented at the organization or the group level?

-Is contamination an issue?

-Randomization of organizations has implications for sample size and analysis

IV. Software for Randomization (free and otherwise):

www-users.york.ac.uk/~mb55/guide/randsery.htm

www-users.york.ac.uk/~mb55/guide/minim.htm (for minimization software)

Objectives:

By the end of this unit the successful student will be able to answer:

1. Why do we randomize, what does it accomplish?
2. Is stratification (by center, patient characteristics) needed?
3. How do you produce a randomization schedule (random number tables, blocking within strata)?
4. How will you deliver the randomization schedule (central call-in, envelopes, packaged meds)?

The successful students will also understand and be able to explain the following concepts:

5. Randomization ratios (1:1, 2:1, etc)
6. Minimization
7. Adaptive Allocation

REQUIRED READINGS:

1. Meinert, C.L. (1986). Chapter 10: Randomization and the mechanics of treatment masking. In Meinert, C.L. (Eds.), *Clinical Trial Design, Conduct and Analysis*. pp 90-112. Oxford: Oxford University Press.

2. Schulz, K.F., Grimes, D.A. (2002). Allocation concealment in randomised trials: Defending against deciphering. *The Lancet*, 359(9306), 614-618. http://libaccess.mcmaster.ca/login?url=http://scholarsportal.info/pdflinks/07061111183013637.pdf

3. Okoumunne, O.C., Gulliford, M.C., Chinn, S., Sterne, J.A., Burney, P.G., & Donner, A. (1999). Methods in health service research: Evaluation of health interventions at area and organization level. *British Medical Journal*, 319(7206), 376-379. http://libaccess.mcmaster.ca/login?url=http://www.bmj.com/cgi/reprint/319/7206/376.pdf

4. Schulz, K.F., Chalmers, I., Hayes, R. J., Altman, D.G. (1995). Empirical evidence of bias: Dimensions of methodological quality associated with estimates of treatment effects in controlled trials. *Journal of the American Medical Association*, 275(5), 408-412.

5. White, S.J., & Freedman, L.S. (1978). Allocation of patients to treatment groups in a controlled clinical study. *British Journal of Cancer*, 37(5), 849-857.

6. Sackett, D.L . (2005). Chapter 5.4: Allocation of patients to treatments. In Haynes, R.B., Sackett, D.L., Guyatt, G.H., & Tugwell, P. (Eds)., *Clinical Epidemiology: How to do Clinical Practice Research*, (3rd Ed.), pp 85-98. Philadelphia: Lippincott Williams & Wilkins.

Assignment:

Read the required readings and prepare a randomization strategy for your research protocol – post this on the discussion board and discuss with the group. *(Tip! Try to review and comment on a student's protocol that you have not reviewed yet).*

UNIT 6: Intervention

Introduction:

Synopsis:

Understanding the following terms and concepts will help you to achieve the below objectives:

Blinding (masking): concealment of treatment assignment for the purpose of reducing bias.

Compliance (adherence): Adherence of patients to the assigned treatment or adherence of clinicians to the study protocol.

Co-interventions: Additional diagnostic or therapeutic maneuvers, other than the intervention under study, that are carried out differentially in experimental and control patients.

Contamination: Control patients receive experimental treatment.

Confounder: A baseline variable or intervention that is extraneous to the study question but (potentially) related to the outcome and differentially applied to the intervention and control groups.

Factorial Design: One study treatment is combined with at least one other study treatment in a trial, or multiples of a defined drug dose are used in the same trial. For example, a 2x2 factorial design would have the following four treatment assignments: A, B, Control, A+B.

Run-in period: Pre-randomization phase for gaining a stable baseline, dose-finding, or identification of poorly compliant patients.

Objectives:

By the end of this unit the successful student will be able to:

1. Understand the importance of a clear, concise but adequately comprehensive description of the intervention such that it can be replicated by other health professionals.
2. Understand how to minimize bias during the intervention period.

You should be able to :

- Specify Your Precise Experimental and Comparison Regimens
- Identify the Source and "Packaging" of Your Regimens
- Set Up a System for Distributing and Maintaining Supplies of Your Regimens
- Set Up a System for Emergency Code-Breaking (When Patients and/or Clinicians are Blind)
- Set Up a System for Maintaining Blindness (When Patients and/or Clinicians are Blind)
- Decide What to do About Monitoring (and, if Necessary, Improving) Patient Compliance

- Design Follow-up Procedures
- Set Up a System for Avoiding (and Documenting) Contamination and Cointervention
- Set Up a System for Maintaining Protocol Adherence by Your Collaborators

REQUIRED READINGS:

1. Sackett, D.L . (2005). Chapter 5.5: Intervention, follow-up and protocol adherance. In Haynes, R.B., Sackett, D.L., Guyatt, G.H., & Tugwell, P. (Eds)., *Clinical Epidemiology: How to do Clinical Practice Research*, (3rd Ed.), pp 98-107. Philadelphia: Lippincott Williams & Wilkins.

2. Rothman, K.Y., & Michels, K.B. (1994). The continuing unethical use of placebo controls. *The New England Journal of Medicine*, 331(6), 394-398. http://content.nejm.org/cgi/content/full/331/6/394

3. Sackett, D.L. (2007). Measuring the success of blinding in RCTs: Don't, must, can't or needn't? *International Journal of Epidemiology*, 36(3), 664-665. http://libaccess.mcmaster.ca/login?url=http://ije.oxfordjournals.org/cgi/reprint/36/3/664

4. Devereaux, P.J., Bhandari, M., Montori, V.M., Manns, B.J., Ghali, W.A., & Guyatt, G.H. (2002). Double-blind, you are the weakest link – Goodbye! *Evidence Based Medicine*, 7(1), 4-5. http://ebm.bmj.com/cgi/content/extract/7/1/4

5. Deans, K.J., Minneci, P.C., Eichacker, P.Q.,& Natanson, C. (2004). Defining the standard of care in randomized controlled trials of titrated therapies. *Current Opinion in Critical Care*, 10(6), 579-582. http://libaccess.mcmaster.ca/login?url=http://www.co-criticalcare.com/pt/re/cocritcare/abstract.00075198-200412000-00026.htm;jsessionid=GNQJpDVMlqLWXDrVHCwNm91pv0jLyzK3qbyw0XmtQcNhy20Sy58p!-362743511!181195628!8091!-1

6. Haynes, R.B., & Dantes, R. (1987). Patient compliance and the conduct and interpretation of therapeutic trials. *Controlled Clinical Trials*, 8(1), 12-19. http://libaccess.mcmaster.ca/login?url=http://scholarsportal.info/pdflinks/07061113123901467.pdf

7. McDonald, H.P., Garg, A.X., & Haynes, R.B. (2002). Interventions to enhance patient adherence to medication prescriptions. *Journal of the American Medical Association*, 288(22), 2868-2879. http://libaccess.mcmaster.ca/login?url=http://jama.ama-assn.org/cgi/reprint/288/22/2868.pdf

8. Devereaux, P.J., et al., (2005). Need for expertise-based randomised controlled trials. *British Medical Journal*, 330(1), 88-91. http://libaccess.mcmaster.ca/login?url=http://www.bmj.com/cgi/content/full/330/7482/88

Optional Readings

1. Sackett, D.L . (2005). Chapter 6.8: Placebos, placebo effects and placebo ethics. In Haynes, R.B., Sackett, D.L., Guyatt, G.H., & Tugwell, P. (Eds)., *Clinical Epidemiology: How to do Clinical Practice Research*, (3rd Ed.), pp 220-223. Philadelphia: Lippincott Williams & Wilkins.

Assignment:
Read the required readings and draft 2-3 paragraphs describing your intervention. Post your draft to blackboard for discussion and feedback; comment on at least 2 student's postings.

UNIT 7: Outcome Events

Introduction:
Although many research studies can express the outcome in a quantitative measure (e.g. number of inflamed joints, size of infarct, achievement tests, blood sugar, etc) some studies must inevitable deal with the phenomena that either occur or do not occur (e.g., death, infection, MI, disease recurrence, etc.). These expressions of the consequence of exposure or intervention are generally referred to as outcome events. The definition, ascertainment, and attribution of outcome events can present a formidable challenge in the design of a research project.

Objectives:
By the end of this unit the successful student will be able:

1. To appreciate some of the methodological issues associated with the selection of appropriate outcome events.
2. To consider potential problems in ascertaining whether an outcome event has occurred.
3. To consider some alternative approaches in the counting, summarization, and comparison of event data.

REQUIRED READINGS:

1. Gent, M., & Sackett, D.L. (1979). The qualification and disqualification of patients and events in long-term cardiovascular clinical trials. *Thrombosis et Diathesis Hemorragica* 41(1), 123-134.

2. Sackett, D.L., & Gent, M. (1979). Controversy in counting and attributing events in clinical trials. *The New England Journal of Medicine*, 301(26), 1410-1412.

3. The Anturane Reinfarction Trial Research Group. (1980). Sulfinpyrazone in the prevention of sudden death after myocardial infarction. *The New England Journal of Medicine*, 302(5), 250-256.

4. Temple, R., & Pledger, G.W. (1980). The FDA's critique of the anturane reinfarction trial. *The New England Journal of Medicine*, 303(25), 1487-1493.

5. Montori, V.M., Devereaux, P.J., Adhikari, N.K.J., Burns, K.E.A., Eggert, C.H., Briel, M., et al., (2005). Randomized trials stopped early for benefit: A systematic review. *Journal of the American Medical Association*, 294(17), 2203-2209. http://libaccess.mcmaster.ca/login?url=http://jama.ama-assn.org/cgi/content/abstract/294/17/2203

6. Montori, V.M., Permanyer-Miralda, G., Ferreira-Gonzalez, I., Busse, J.W., Pacheco-Huergo, V., Bryant, D., et al., (2005). Validity of composite end points in clinical trials. *British Medical Journal*, 330(1), 594-596. http://libaccess.mcmaster.ca/login?url=http://www.bmj.com/cgi/content/extract/330/7491/594

7. Freemantle, N., Calvert, M., Wood, J., Eastaugh, J., & Griffin, C. (2003). Composite outcomes in randomized trials: Greater precision but with greater uncertainty? *Journal of the American Medical Association*, 289(19), 2554-2559. http://libaccess.mcmaster.ca/login?url=http://jama.ama-assn.org/cgi/content/abstract/289/19/2554

8. Sackett, D.L . (2005). Chapter 5.6: Events. In Haynes, R.B., Sackett, D.L., Guyatt, G.H., & Tugwell, P. (Eds)., *Clinical Epidemiology: How to do Clinical Practice Research*, (3rd Ed.), pp 107-116. Philadelphia: Lippincott Williams & Wilkins.

Assignment:

Read the required readings and identify outcome events for your research protocol – post to blackboard for comments. *(Tip! Try to review and comment on a student's protocol that you have not reviewed yet).*

UNIT 8: The Analysis Plan, Part I (Scientific Decisions)

Introduction:

In this unit, you will learn how to plan your statistical analysis, including the baseline characteristics, compliance across intervention groups, primary and secondary analysis, understand the characteristics of a good analysis plan and methods to minimize bias.

Primary and Secondary analysis

Primary analysis

- Comparison to decide effectiveness of intervention
- One outcome, at one time point, using a specified statistical test
- If more than one comparison is specified, need to control type I error rate for multiple testing
- Basis of sample size or power calculation
- Try to make this the most clinically relevant outcome that you have sufficient power for.

Secondary analysis

- Evidence to support the primary comparison
- Related outcomes, different time points, different statistical tests
- Exploratory in nature
- Covariate adjustment
- Subgroups
- Safety outcomes
- Mechanistic questions

Characteristics of a Good Statistical Analysis Plan

Pre-specified comparisons so that patterns in the data will not influence which outcome is chosen as primary or secondary

Minimize bias

- Intention to Treat:
    - All outcomes for all randomized participants in the groups to which they were assigned (No exclusions, no lost to follow-up, no missing data)
    - Unbiased, most generalizable, potential to reduce study power
- Per Protocol (Valid cases, Efficacy sample, Evaluable subjects, Modified Intention to Treat)
    - Post-randomization exclusions due to ineligibility, non-compliance, lost to follow-up, competing events, missing values, and outliers
    - Open to Bias, Maximize chance to show intervention works at a mechanistic level, potential to reduce study power

Robustness of Result to statistical method used: If you had chosen another statistically valid test, would you reach the same conclusion

Maximize Precision
Adjust for frequently occurring prognostic factors correlated with outcome

Objectives:
By the end of this unit, the successful student will be able to understand and plan:

- The analysis strategy that best matches the research question
- Primary and secondary analyses
- Supporting mechanistic /explanatory analyses
- Efficacy and intention to treat analyses
- Deciding whether to adjust for baseline risk factors
- Anticipating missing data and problem cases
- Interim analysis
- Adjustment for multiple outcomes

REQUIRED READINGS:

1. Lewis, J. (1999). Statistical principles for clinical trials (ICH E9): An introductory note on an international guideline. *Statistics in Medicine*, 18(15), 1905-1907. *http://libaccess.mcmaster.ca/login?url=http://scholarsportal.info/pdflinks/07082714123127312.pdf*

2. ICH Expert Working Group. (1999). Statistical principles for clinical trials. *Statistics in Medicine*, 18(15), 1908-1942. *http://libaccess.mcmaster.ca/login?url=http://scholarsportal.info/pdflinks/07082714123127312.pdf*

3. Armitage, P. (1981). Importance of prognostic factors in the analysis of data from clinical trials. *Controlled Clinical Trials*, 1(4), 347-352. *http://libaccess.mcmaster.ca/login?url=http://www.sciencedirect.com/science?_ob=PublicationURL&_issn=01972456&_pubType=J&_acct=C000051241&_version=1&_urlVersion=0&_userid=1067350&md5=ea41a4f73829aa3c60e8cdd438b49ae3&jchunk=1#1*

4. Guyatt, G.H., Haynes, R.B., & Sackett, D.L. (2005). Chapter 15: Analyzing Data. In Haynes, R.B., Sackett, D.L., Guyatt, G.H., & Tugwell, P. (Eds)., *Clinical Epidemiology: How to do Clinical Practice Research*, (3rd Ed.), pp 446-460. Philadelphia: Lippincott Williams & Wilkins.

5. Sackett, D.L . (2005). Chapter 5.7: Analysis & Interpretation. In Haynes, R.B., Sackett, D.L., Guyatt, G.H., & Tugwell, P. (Eds)., *Clinical Epidemiology: How to do Clinical Practice Research*, (3rd Ed.), pp 117-137. Philadelphia: Lippincott Williams & Wilkins.

Assignment:
Read the required readings and identify your analysis plan – post this on the discussion board and discuss with the group. *(Tip! Try to review and comment on a student's protocol that you have not reviewed yet).*

UNIT 9: The Analysis Plan, Part II (Basic & Advanced Statistical Methods)

Introduction:

Objectives:
By the end of this unit, the successful student will be able to understand and plan:

- Baseline description and comparisons

- Differences between: quantitative, event, and time to event outcomes
- Hypothesis testing
- Estimation and confidence intervals
- Displaying results (tables and graphs)
- Sample size and power calculations
- Confounding, stratification and adjustment

REQUIRED READINGS:

1. Lenth, R.V. (2001). Some practical guidelines for effective sample-size determination. *The American Statistician*, 55(3), 187-193. *http://libaccess.mcmaster.ca/login?url=http://www.ingentaconnect.com/content/asa/tas/2001/00000055/00000003*

2. Begg, C.B. (1990). Suspended judgment: Significance tests of covariate imbalance in clinical trials. *Controlled Clinical Trials*, 11(4), 223-225. *http://libaccess.mcmaster.ca/login?url=http://www.sciencedirect.com/science/journal/01972456*

3. Lachin, J.M. (1981). Introduction to sample size determination and power analysis for clinical trials. *Controlled Clinical Trials*, 2(2), 93-113. *http://libaccess.mcmaster.ca/login?url=http://www.sciencedirect.com/science/journal/01972456*

4. Peto, R., Pike, M.C., Armitage, P., Breslow, N.E., Cox, D.R., Howard, S.V., et al., (1976). Design and analysis of randomized clinical trials requiring prolonged observation of each patient. I. Introduction and design. *British Journal of Cancer*, 34(6), 585-612.

5. Peto, R., Pike, M.C., Armitage, P., Breslow, N.E., Cox, D.R., Howard, S.V., et al., (1977). Design and analysis of randomized clinical trials requiring prolonged observation of each patient. II. Analysis and examples. *British Journal of Cancer*, 35(1), 1-39.

6. Byar, D.P. (1985). Assessing apparent treatment – covariate interactions in randomized clinical trials. *Statistics in Medicine*, 4(3), 225-263.

7. Beach, M.L., & Meier, P. (1989). Choosing covariates in the analysis of clinical trials. *Controlled Clinical Trials*, 10(4), 161S-175S. *http://libaccess.mcmaster.ca/login?url=http://www.sciencedirect.com/science/journal/01972456*

Optional Readings

1. Sackett, D.L . (2005). Chapter 5.8: Sample Size. In Haynes, R.B., Sackett, D.L., Guyatt, G.H., & Tugwell, P. (Eds)., *Clinical Epidemiology: How to do Clinical Practice Research*, (3rd Ed.), pp 137-146. Philadelphia: Lippincott Williams & Wilkins.

Assignment:

Read the required readings and prepare a sample size estimate, consider possible confounders and a plan to deal with them for your research protocol – post this on the discussion board and discuss with the group.

UNIT 10: Trial Organization/ Administration/ Finance

Introduction:

The reading material provided includes some general issues relating to the organization of multicentre studies and include details of some different models that have been used. Additional strategies will be presented in class and the pros and cons of the different models discussed. While the session is directed at large multicentre (including international) trials, scaled-down organizations can be readily developed to meet the needs of smaller trials. Some special issues in collaborative studies with industry will also be presented.

Objectives:

The objective of this session is to review some of the organizational, management, and financial aspects of multicentre clinical trials which are necessary for disciplined and unbiased study execution. The overview will be on operational strategies and tactics including the creation of appropriate committees, the use of central technical facilities, the identification of relevant external agencies, and the lines of communication and decision-making among the various components.

REQUIRED READINGS:

1. Review the "Planning a New Trial" Route Map, found at: http://www.ct-toolkit.ac.uk/route_maps.cfm (it is on the left hand side, second box in blue). Review each of the "stations".

2. Eisenstein, E.L., et al., (2008). *Clinical Trials*, 5(1), 75-84. *http://libaccess.mcmaster.ca/login?url=http://ctj.sagepub.com/cgi/content/abstract/5/1/75*

3. Granger, C.B., et al. (2008). Do we need to adjudicate major clinical events. *Clinical Trials*, 5(1), 56-60. *http://libaccess.mcmaster.ca/login?url=http://ctj.sagepub.com/cgi/content/abstract/5/1/56?rss=1*

4. Morin, K., Rakatansky, H., Riddick, F.A., Morse, L.J., O'Bannon, J.M., Goldrich, N.S., et al., (2002). Managing conflicts of interest in the conduct of clinical trials. *Journal of the American Medical Association*, 287(1), 78-84.

   http://libaccess.mcmaster.ca/login?url=http://jama.ama-assn.org/cgi/content/abstract/287/1/78

5. Ross, S., Grant, A., Counsell, C., Gillespie, W., Russell, I., & Prescott, R. (1999). Barriers to participation in randomised controlled trials: A systematic review. *Journal of Clinical Epidemiology*, 52(12), 1143-1156. http://libaccess.mcmaster.ca/login?url=http://www.sciencedirect.com/science/journal/08954356

6. Slutsky, A.S., & Lavery, J.V. (2004). Data safety and monitoring boards. *The New England Journal of Medicine*, 350(11), 1143-1147. http://libaccess.mcmaster.ca/login?url=http://content.nejm.org/cgi/content/full/350/11/1143

Assignment:
Read the required readings and outline which steps you will take to ensure that the bias in your study has been eliminated or minimized – post this on the discussion board and discuss with the group. *(Tip! Try to review and comment on a student's protocol that you have not reviewed yet).*

UNIT 11: Trial Management and Quality Control

Introduction:
A scientifically and methodologically sound study protocol, in itself, is not enough to guarantee that the rights, safety and well-being of study subjects are protected nor does it ensure disciplined study conduct, the integrity of the data or the credibility of the findings.

In September 2001, Health Canada amended the Regulations of the Food and Drug Act, Division 5: Drugs for Clinical trials Involving Human Subjects. As part of the amendments, the regulations now require that regulatory activities will include inspections and investigations by Health Canada's Inspectorate to assess compliance with the regulations. Health Canada has also adopted many of the guidelines developed by the International Conference on Harmonization (ICH) Expert Working Group, including the ICH Harmonized Tripartite Guideline for Good Clinical Practice (GCP). Indeed, parts of the GCP Guidelines are now included in the Division 5 regulations.

Objectives:
The objectives of this session are to briefly introduce:

- The regulations governing the conduct of clinical trials in Canada
- The objectives of the ICH and a review of the guidelines that have been adopted by several regulatory agencies to-date
- The emerging changes of the role and function of an institutional ethics review board
- Mechanisms to monitor study progress and data quality

After completing this unit, the successful student will be able to discuss:

- CRF design issues

- Data collection strategies
- CRF/data quality control
- Plans for data management
- Database integrity checks
- Estimating data flow and manpower requirements
- Site visits
- Data audits

REQUIRED READINGS:

De Angelis, C.D., Drazen, J.M., Frizelle, F.A., Haug, C., Hoey, J., Horton, R., et al., (2004). Clinical trial registration: A statement from the international committee of medical journal editors. *Journal of the American Medical Association*, 292(11), 1250-1251. *http://libaccess.mcmaster.ca/login?url=http://www.annals.org/cgi/content/short/0000605-200409210-00109v1*

Minister of Health (1997). Good clinical practice: Consolidated guideline. *Therapeutic products directorate guidelines ICH harmonized tripartite guidelines*. Ottawa: Health Canada.

Health Canada (). Division 5: Drugs for clinical trials involving human subjects. *Amendment to the Food and Drug Regulations (Schedule No. 1024) – Clinical Trial Framework*.

McFadden, E.T., Lopresti, F., Bailey, L.R., Clarke, E., & Wilkins, P.C. (1995). Approaches to data management. *Controlled Clinical Trials*, 16(2), 30S-65S. *http://libaccess.mcmaster.ca/login?url=http://www.sciencedirect.com/science/journal/01972456*

Baigent, C., et al. (2008). Ensuring trial validity by data quality assurance and diversification of monitoring methods. *Clinical Trials*, 5(1), 49-55. *http://libaccess.mcmaster.ca/login?url=http://ctj.sagepub.com/cgi/reprint/5/1/49*

Smith, R. (2006). Research misconduct: the poisoning of the well. *Journal of the Royal Society of Medicine*, 99(1), 232-237. *http://libaccess.mcmaster.ca/login?url=http://jrsm.rsmjournals.com/cgi/reprint/99/5/232*

Assignment:
Read the required readings and prepare a quality control strategy for your research protocol – post this on the discussion board and discuss with the group.

UNIT 12: Question & Answer Period

Introduction:
This unit provides you the opportunity to ask questions and clarify issues with Dave Sackett: http://fhs.mcmaster.ca/ceb/faculty_member_sackett.htm.

More information to come – *possible scheduling of an Elluminate session?*

Objectives:
Address any outstanding issues with your research protocol before the deadline.

REQUIRED READINGS:

None.

Students are required to purchase a custom courseware package which includes reference material not available electronically.
Students are also required to access readings online (as outlined weekly).

Availability:
Custom courseware and textbooks can be purchased online from the McMaster Health Sciences Bookstore (http://titles.mcmaster.ca/mediashop)**
Textbooks are also available online through stores such as: www.amazon.ca

** Custom courseware must be ordered by the end of August to ensure delivery before the start of the course

1.5 Brief Outline

Unit	Topic (Module Author)
1	Posing the Research Question
2	Measures of Health, Illness and Disease Frequency
3	Measurement and Analysis
4	Sampling
5	Determining Causation
6	Qualitative Study Design
7	Therapeutic Trials – The Tactics of Performing Therapeutic Trials
8	Evaluating the Accuracy of Screening and Diagnostic Tests
9	Systematic Reviews
10	Economics: Introduction to Health Technology Assessment (HTA)
11	Knowledge Translation
12	Ethics in Research

2. Contact Information

Distance Education Coordinator:

Soo Chan Carusone, Ph.D.
Clinical Epidemiology & Biostatistics
Email: chan.carusone@mcmaster.ca

Course Coordinator:

Mitchell Levine, M.D., M.Sc.
Professor, Department of Clinical Epidemiology & Biostatistics
Email: levinem@mcmaster.ca

3. Course Format

This online course consists of 12 units (a new unit is posted every week). Each unit consists of a video-captured lecture, required readings, an assignment, discussion and a tutorial session. Participation in the discussion boards is monitored and evaluated. Each week students will be assigned to facilitate discussions. Student facilitators will be evaluated on their facilitation and their written summary of the discussion. Live participation in the tutorial sessions is optional although individuals who cannot attend are expected to review the archived session materials. Tutorials will be held at the end of the week via a web conferencing tool (Elluminate LIVE). The agenda for the tutorials will be directed by the unresolved issues and questions raised in the discussion forums. Students will also have the opportunity to post additional questions directly to the instructor in advance of the tutorial sessions (if they cannot attend).

To facilitate retention, this course has been designed to give students a variety of opportunities to apply the knowledge they gain. Students are expected to:

- View the lectures
- Complete the weekly assignments and compare them to answer keys
- Participate in weekly discussions with the instructor and fellow students on key issues in each unit
- Complete quizzes every 3 units
- Consolidate issues and topics covered throughout the term and write a brief research proposal on a topic of the student's choice

4. Student Evaluation

Students are given many opportunities to demonstrate their mastery of the course material. Final course marks will be calculated as follows:

60% = quizzes (4 x 15%)

20% = Final paper/research proposal

10% = Participation in discussion forums

10% = Discussion facilitation and summary document

Quizzes:

Quizzes will be done after every 3 units. These are short (30-minute) exams using multiple choice or short-answer questions.

Final paper

The final paper is structured as a brief research proposal on a research topic of your choice. This is NOT intended as a grant proposal; substance counts over style. The paper should be a maximum of 10 pages (double-spaced, 12 point font, 2.5 cm margins). The paper should focus on the methodological issues of the proposed study. Extensive budgets, sample size calculations, statistical analysis, etc., are discouraged. More extensive instructions and a sample paper are found on the course website.

Participation in discussion forums:

Participation in discussions with fellow students and instructors is known to be critical to developing a successful and effective learning environment. Participation will be evaluated by both student facilitators and instructors. Each week students are expected to post one original discussion board message and respond to at least 2 threads initiated by others. To allow significant time for discussion each week the time of a student's post will also be considered in evaluations (that is, you should not post your comments Friday morning every week, right before the tutorial session). For detailed guidelines and marking rubrics for participation see the course website in ELM.

Discussion facilitation and summary document

Each week one or two students will be assigned to facilitate the weekly discussion board. This will include posting thought provoking questions early in the week to stimulate discussion, responding constructively to other's posts, and working to direct discussion to the important issues of the session. Student facilitators will also be responsible for evaluating peer participation in the weekly discussion board and creating a summary document and agenda for the tutorial session. The summary document should be presented by topic (when creating this document, think of it as an important resource for studying the key concepts!). The agenda should outline any outstanding issues and questions for the instructor that were unresolved in the discussion forum.

Weekly assignments (no marks assigned)

Weekly assignments are designed to ensure that the student understands the core concepts covered in each unit. Students are expected to complete the assignments in a timely fashion to ensure adequate time for discussion – assignments will not be marked directly but quality, timing and quantity of participation in discussions will be evaluated.

Completion of course evaluation forms (no marks assigned)

Every week students will be asked to evaluate the current unit (the module, the assignment, etc). This information is important to the course coordinator, instructors and the department administrators and is used to improve course content and delivery. We value your input and the quality of the course depends on it.

5. Course Calendar

This is a tentative calendar. You will be notified as soon as possible if any changes need to be made. Further details of the weekly objectives, activities and readings are found below in section 6: 'Detailed Course Outline'. Lectures will be posted on the first day of each Unit, Monday at 12:01 AM (EST)

Unit: Dates	Topic	Activities
UNIT 0: **Sept. 14 – 20**	Orientation	Welcome Session – DATE & TIME
UNIT 1: **Sept. 21 – 27**	Intro & posing the research question	Discussion – DATES Tutorial – DATE & TIME
UNIT 2: **Sept. 28 – Oct. 4**	Measures of health and disease frequency	Discussion – DATES Tutorial – DATE & TIME
UNIT 3: **Oct. 5 – 11**	Measurement & analysis	Discussion – DATES Tutorial – DATE & TIME
UNIT 4: **Oct. 12 – 18**	Sampling	**Midterm #1 – DATE & TIME** Discussion – DATES Tutorial – DATE & TIME
UNIT 5: **Oct. 19 – 25**	Causation	Discussion – DATES Tutorial – DATE & TIME
UNIT 6: **Oct. 26 – Nov. 1**	Qualitative research	Discussion – DATES Tutorial – DATE & TIME
UNIT 7: **Nov. 2 – 8**	Therapy	**Midterm #2 – DATE & TIME** Discussion – DATES Tutorial – DATE & TIME

UNIT 8: **Nov. 9 – 15**	Diagnosis	Discussion – DATES Tutorial – DATE & TIME
UNIT 9: **Nov. 16 – 22**	Systematic reviews	Discussion – DATES Tutorial – DATE & TIME
UNIT 10: **Nov. 23 – 29**	HTA and economic evaluation	**Midterm # 3 – DATE & TIME** Discussion – DATES Tutorial – DATE & TIME
UNIT 11: **Nov. 30 – Dec. 6**	Research ethics	Discussion – DATES Tutorial – DATE & TIME
UNIT 12: **Dec. 7 – 13**	Knowledge translation	Discussion – DATES Tutorial – DATE & TIME
December 13th	Midterm exam #4	**Midterm #4 – DATE & TIME**
December 20th	Final paper submission	**DUE: Final Paper – December 20th, 11:59 PM (EST)**

Other Important Dates:

Monday October 12, 2009: Canadian Thanksgiving

Thursday, November 26, 2009: American Thanksgiving

6. Detailed Course Outline

Background

Knowledge accumulates in many different ways. Scientific research methods constitute one "way of knowing". This approach to "knowing" is characterized by systematic study of a phenomenon of interest. Systematic implies that the research process is based on agreed upon rules and processes which are rigorously adhered to and against which the research can be evaluated.

Health researchers need to be familiar with a wide range of research methodologies and understand their strengths and limitations. Moreover, it is increasingly apparent that fields and disciplines other than the health sciences can suggest exciting new ways of thinking about how to approach a particular research problem. These insights can stimulate new methods of research which can increase our understanding of the topics we are studying. Hence, HRM 771 aims to introduce students to a wide range of perspectives and research methodologies that are relevant to the study of health and wellness

phenomena. The course emphasizes that it is more fruitful to think about a variety of research approaches, each with their own strengths and limitations rather than to think about a right or wrong way to approach a particular research problem. Your research interests and concerns will guide the choice of appropriate methods.

Health researchers also need to understand the interactive nature of the relation between theory and research. HRM 771 aims to increase participants' understanding of how theory provides guidance for research, and how research can generate, verify, modify and re-construct theory. The course balances content on how health research is designed and completed with that of acquiring skills and practice in reading and analyzing original studies and systematic reviews.

The course begins by considering the questions-based nature of research and the importance of good questions. Starting with Unit 2 we address research aspects common to all health research: ascertaining disease frequency, measurement, and sampling. Subsequently we move to address the conceptual and methodological issues relevant to specific research methods:

- causation/harm and qualitative studies (observational methods)
- therapy/interventions, and diagnosis (true experimental methods)

We next study the methods that are syntheses of existing data: systematic reviews, economics studies, and health technology assessments. We conclude with units on ethics and knowledge translation—how to translate our research findings to get them appropriately applied. The course concludes with the completion and submission of student research papers. These papers address a question of choice and how best to address that question using an appropriate research methodology.

You are expected to bring to the course the research topics of interest to you in your own field. One of the strengths of the course is that participants represent many disciplines both within and outside health. Understanding the links between your own areas of interest and discipline and the approaches to inquiry covered, is one of the main goals of the course. The course is structured to facilitate this linking process. We try to reflect this multidisciplinary strength in our choice of topics, presentation of materials and module authors.

Also, we expect that you will identify research topics and interests that you may pursue in greater depth in other courses offered in the Health Research Methodology (HRM) Programme or other graduate programs. HRM 771 should help you decide which specialized courses are most relevant to the research program you intend to pursue. Almost all of the units can be considered to be an introduction to further existing study possibilities.

Below you will find a unit by unit overview for the course including objectives, readings and assignments. You are expected to complete all the activities within the week dedicated to that unit (as outlined in the schedule). In general, it is best to complete the readings before viewing the lecture although in some cases you might find it beneficial to refer back to the readings while, or after, viewing the lecture material as well. You are expected to contribute a post to the discussion board by

WEDNESDAY of every week and continue to read and participate until the end of the Unit (Sunday night).

Good luck and enjoy!

UNIT 0: Orientation

Introduction:

Some of you may be new to the online learning environment and all of us our new to McMaster's latest Learning Management System (LMS) – ELM (E-Learning @ McMaster), so we have decided not to present a learning module for this week. Instead, we want you use this time to meet each other and ensure that everyone is comfortable navigating around the course.

Objectives:

At the conclusion of this session you should:

- Understand the course format, assignments and evaluation methods.
- Know something about your peers and your instructor
- Know where to find help

To Do:

- ✓ Confirm that you meet the computer software and system requirements, please review the E-Learn @ Mac (ELM) information posted on the Learning Technology Resource Centre's website for specific requirements: http://www.ltrc.mcmaster.ca/elm/launch/index.php
- ✓ Confirm that you have a McMaster MAC ID Eg., John Smith smithj@mcmaster.ca & MAC ID is 'smithj'. Click on website for information on how to activate your MAC ID: http://www.ltrc.mcmaster.ca/webct/index.shtml
- ✓ Confirm that you can access the 771 course on ELM: http://www.ltrc.mcmaster.ca/implementation/
- ✓ **Carefully** read over the entire course syllabus and post any questions in the 'open discussion forum'.
- ✓ Prepare a bio-blurb (1-3 paragraphs), including a brief description of your background, reason(s) for taking this course, what you hope to obtain by completing this course and some interesting information about you – pictures are welcome!

- ✓ Post your bio-blurb on the 771 'introductions' discussion board (*N.B. the discussion board is not private – all registered 771 students can view your posting)* and comment on some of your peers' posts.
- ✓ Know where to go to for help:
    - ELM technical help: LTRC contact
    - CE&B/HRM Distance Education help: Soo Chan Carusone
    - 771 help: Online Instructor

UNIT 1: Posing the research question

Introduction:

The first step to any research project is to pose an appropriate question. Unit 1 introduces you to the process of formulating a study question and gives you a brief introduction to health research methods. Unit 1 also provides an introduction to your tutorial group and the methods we will use for the course.

Learning Objective:

At the conclusion of the session, you should be able to address the following issues:

- Where do study questions come from?
- What are the key considerations in developing a study question?
- What are the components of a well-built qualitative and quantitative question?
- Be able to formulate a "researchable" question to study or evaluate a health need or issue in an area of interest to you

Required Readings:

Please note that some of the concepts in the textbook, including validity and implementation will be covered in later sessions. This session concentrates on the issue of question asking and formulation.

1. Hulley, S.B., Newman, T.B., & Cummings, S.R. (2007). Chapter 1: Getting Started: The anatomy and physiology of clinical research. In Hulley, S.B., Cummings, S.R., Browner, W.S., Grady, D.G., &

Newman, T.B. (Eds.)., Designing Clinical Research (3rd Ed.), pp 3-15. Philadelphia: Lippincott Williams & Wilkins.

2. Cummings, S.R., Browner, W.S., & Hulley, S.B. (2007). Chapter 2: Conceiving the research question. In Hulley, S.B., Cummings, S.R., Browner, W.S., Grady, D.G., & Newman, T.B. (Eds.)., Designing Clinical Research (3rd Ed.), pp 17-26. Philadelphia: Lippincott Williams & Wilkins.

3. Scott Memorial Library (2003). Evidence-based medicine: The well-built clinical question. http://jeffline.jefferson.edu/SML/helpaids/handouts/EBM_PICO.pdf

4. Mantzoukas S. (2008) Facilitating research students in formulating qualitative research questions. Nurse Education Today. 28(3):371-7. http://libaccess.mcmaster.ca/login?url=http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6WNX-4PG8H0R-2&_user=1067350&_rdoc=1&_fmt=&_orig=search&_sort=d&view=c&_acct=C000051241&_version=1&_urlVersion=0&_userid=1067350&md5=4756d719aa9108172e508ba6fc75647c

Assignment:

Generate a study question in an area of health that is important to you and come prepared to present it to your group. Make sure that your research question defines the patient/population, intervention/exposure, comparison group and outcome as in "The well-built clinical question" article or fits the criteria provided in Mantzoukas. PICO format is best for research questions of the quantitative type—how much, what, when, and where. The 5W-H format is better for asking the "why" and "how" questions—qualitative type. The rest of the course will be spent looking at research traditions and methods both quantitative and qualitative.

UNIT 2: Measures of Health, Illness and Disease Frequency

Introduction:

Frequency is concerned with the measurement of burden of illness using various measures of the occurrence of health, illness or disease. Some measures describe disease frequency in individuals (for example incidence); others include a comparator or standard (for example standardized mortality ratios).

These measures are primarily created and used by public health practitioners, epidemiologists and planners concerned about population health status. For them the issues of concern include trends

to plan health services (for example, is the incidence of melanoma or prevalence of HIV infection increasing in the community?) and to some extent the evaluation of health programs. Decision makers and funders share these interests and also have an interest in allocating resources according to need. Trend analysis can also provide clues to causes of incidence and mortality, and changes in trends within a fully functioning surveillance system, may provoke corrective action.

Clinical epidemiologists who see individual patients in their practice also need to understand frequency measures as they apply to their practice. In particular, the estimation of the likelihood of seeing patients with particular conditions depends on the frequency of its occurrence in the local community population. Individual pre-test probability of disease occurrence can be estimated using this information. In addition, clinicians can contribute to community knowledge about disease frequency through accurate reporting of diseases and deaths and through the analysis of practice patterns where appropriate.

Learning Objective:

By the end of this unit the successful student will be able to:

1. Define (in terms colleagues can comprehend) and understand the relevance to their own work of terms such as: incidence, prevalence, mortality rate, case-fatality rate, crude and standardized rates.

2. Given a dataset, sufficient time and resources, calculate (less important) and interpret (more important) different types of health/disease-related measurements.

3. Characterize a health research topic of interest using appropriate health/disease frequency.

Required Readings:

1. Gordis L. (2004). Epidemiology (3rd Edition). Philadelphia: Elsevier Saunders. Chapter 3 Measuring the Occurrence of Disease: I. Morbidity pp. 32-47.

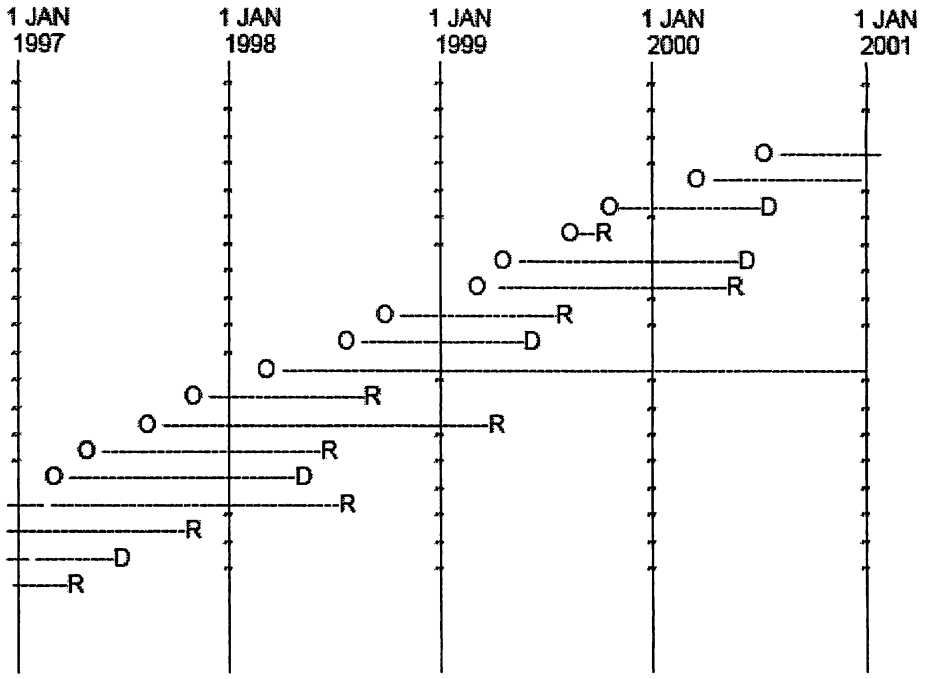
2. Gordis L. (2004). Epidemiology (3rd Edition). Philadelphia: Elsevier Saunders. Chapter 4 Measuring the Occurrence of Disease: II. Mortality pp. 48-70.

Note: These readings are not part of WebCT because of copyright restrictions. Please refer to your custom courseware package for the Gordis (2004) readings.

Assignment:

1. The following picture describes the pattern of a disease in a population of 100 people. This particular disease is an infection which you can only get once; when you get it, it either kills you or confers lifelong immunity. "O" indicates the onset of disease, and the horizontal line indicates

its clinical course. The symbol "R" indicates recovery from the disease, and the symbol "D" indicates death.



Note that all 100 people were present on January 1, 1997 and that 83 of the 100 people remained free of this disease from January 1, 1997 to January 1, 2001.

From the foregoing, calculate:

a) What was the incidence of the disease in 1997? Use the denominator population as the population size at the beginning of the year.

b) What was the incidence in 1999?

c) What was the incidence during the four year period 1997-2001?

d) What was the prevalence of the disease on January 1 of the following years: 1997? 1998 ? 1999? 2000? Use the total population alive at that point as denominator for prevalence.

e) What was the period prevalence for Jan 1 – Dec 31, 1998? Calculate using the total population alive at the beginning of the period.

f) What was the mortality rate in 1997? In 1998? In 1999? Note: Although mortality can be calculated as an incidence density, it is more commonly considered as a proportion of the population dying over a period of time.

g) What is the case-fatality rate? (Use incident cases as the denominator).

2. A Regional Trauma Centre (which encourages the surrounding hospitals to refer patients with serious injuries for expert care) is seeking additional funds from next year's health budget for more equipment and staff. A local politician (who would rather spend money on a new hospital named after his father) criticized this request for additional resources by claiming that Regional Trauma Centres do not, in fact, save lives and submits the following data to back his claim:

SEVERITY OF TRAUMA	SURROUNDING HOSPITALS		REGIONAL TRAUMA CENTRE	
	NO. OF CASES	NO. OF DEATHS	NO. OF CASES	NO. OF DEATHS
MILD	3734	37	687	3
MODERATE	1887	94	1238	37
SEVERE	1645	327	1429	172
	7266	458	3354	212
Case Fatality Rate	458/7266 = 6.3%		212/3354 = 6.3%	

You are asked for your opinion on these data. How should you respond? [Hint! The case-fatality rates presented above are crude rates. You need to find a way to adjust for the different distributions of severity of patients seen in the two locations. Key concepts here include standardized or adjusted rates.]

3. You have seen a patient with Disease X and the patient wants to know how long the disease lasts on average and how likely they are to die from the disease. You research the literature and find the following:

   Incidence rate is 75/100,000 (new cases of Disease X per population at risk per year)

   Point prevalence rate is 16/1,000 (current cases of Disease X at a particular point per population at risk)

   Mortality rate is 22/100,000 (deaths from Disease X per total population)

   a) Can you answer the patient's questions?

   b) What assumptions did you have to make in order to carry out this translation?

4. Suppose that colorectal cancer in your region is 'in somewhat equilibrium'. That is, suppose that nobody is screening for this cancer and that its incidence, prevalence, mortality and case-fatality are all in a steady state.

   Now suppose that an excellent, new gastroenterologist comes to the region and very effectively exhorts the medical community to carry out vigorous screening with the Hemoccult II slide system (in which asymptomatic patients provide fecal specimens, some of which are found to contain blood and lead to the early detection of asymptomatic colorectal cancer). Everybody starts to screen for colorectal cancer, and all sorts of early cases are detected.

   Suppose further, alas, that the treatment of colorectal cancer is no more effective when applied early than when it is applied at the usual time of diagnosis.

Assume that the screening effort is maintained over a long period of time.

For each of the following descriptions, decide which of the following measures the description applies to: Incidence, prevalence, case fatality, mortality, survival, duration.

a) No change in rate

b) The rate decreases at first and remains steady at the lower rate

c) The rate increases and then remains steady at the increased rate

d) The rate sharply increases, then decreases below the original level, before returning to steady

state at the original level.

Note that each description may apply to more than one measure.

Does this help you to understand why early diagnosis appears to improve health, even when therapy is not more effective?

UNIT 3: Measurement and Analysis

Reminder: Please complete any outstanding evaluations.

Introduction:

Unit 3 is designed to provide students with an appreciation of the measurement issues they need to consider when choosing a suitable outcome for a research question.

Learning Objective:

1. To understand reliability and validity and their components.
2. To review the meaning of objective and subjective measurement.
3. To identify the factors involved in determining what will be measured, by whom, and when, and the advantages and disadvantages of various strategies.

Required Readings:

1. Hulley, S.B., Martin, J.N., & Cummings, S.R. (2007). Chapter 4. Planning the measurements: Precision and accuracy. In Hulley, et al (Eds), Designing Clinical Research (3rd Ed), pp -37-49. Philadelphia: Lippincott Williams & Wilkins.
2. MIST Study Group. Randomised trial of efficacy and safety of inhaled zanamivir in treatment of influenza A and B infections. Lancet 1998;352:1877-81. http://libaccess.mcmaster.ca/login?url=http://www.sciencedirect.com/science?_ob=MImg&_imagekey=B6T1B-3VJ3D3V-3-1&_cdi=4886&_user=1067350&_orig=browse&_coverDate=12%2F12%2F1998&_sk=996470855&view=c&wchp=dGLbVzb-zSkzV&md5=805b70e8dcd297adca5c80926ec102d6&ie=/sdarticle.pdf
3. Townshend KH, Dorris L, McEwan MJ, Aylett SE, Brodie MJ, O'Regan M, Espie CA. Development and validation of a measure of the impact of epilepsy on a young person's quality of life: Glasgow epilepsy outcome scale for young persons (GEOS-YP). Epilepsy Behav. 2008 Jan;12(1):115-23. Epub 2007 Nov 5. http://libaccess.mcmaster.ca/login?url=http://scholarsportal.info/cgi-bin/sciserv.pl?collection=journals&journal=15255050&issue=v12i0001

Assignment:

1. After reading the Lancet article by the MIST group, identify the strengths and weaknesses of the outcomes they chose to measure in the study. How would you improve the study with respect to the measurement issues?

2. For the article by Townsend et al, did the authors and their group evaluate the following issues, and if so, how did they do this evaluation?

    - Precision
    - Test-retest ability (does a person score the same over time?)
    - Validity
        - Face validity (does it seem to make sense to those who will take it, i.e., what is the "face value" of the scale?)
        - Content validity
        - Content validity
        - Construct validity
    - Feasibility
    - Acceptability

UNIT 4: Sampling

Please complete any outstanding tutor or unit evaluations on WebCT.

Introduction:

Health research is concerned with the study of human subjects. The design of every research study includes decisions about how to select the study subjects. However, the particular approach taken will depend upon the research question asked and the methods employed to answer it.

This unit introduces you to a range of sampling strategies and allows you to examine different approaches taken in quantitative and qualitative research studies. We will NOT be studying how to estimate the number of participants that should be included in a study. This material is covered in chapters 5 and 6 of Hulley. They are better addressed in a more advanced research methods or statistics course.

Learning Objective:

1. To understand the various methods that can be used in quantitative and qualitative research to select the study subjects.

2. To understand the advantages and limitations of each method

3. To understand the terms internal and external validity in relation to sampling strategy decisions and the interpretation of study results.

Required Readings:

1. Hulley, S.B., Martin, J.N., & Cummings, S.R. (2007). Chapter 3.
2. Choosing the Study Subjects: Specification, Sampling, and Recruitment. In Hulley, et al (Eds), Designing Clinical Research (3rd Ed), pp 27-36. Philadelphia: Lippincott Williams & Wilkins.
3. Patton, MQ (1990). Qualitative Evaluation and Research Methods (2nd Edition). California: Sage Publications, pp 169-186. Available on course reserve in the HSC library. Note that this is likely the final time that you will need to do your own copying.

Assignment:

Use this week's discussion board to discuss the 3 questions on page 318 in your Hulley textbook.

1. The research question is: "What are the factors that cause people to start smoking?" The investigator decides on a cross-sectional sample of high school students, invites those in grade 11 in her suburban high school to participate, and studies those who volunteer. Discuss the suitability of this sample for the target population of interest.
2. Suppose the investigator decides to avoid the bias associated with choosing volunteers buy designing a 25% random sample of the entire 11th grade, and that the actual sample turns out to be 70% girls. It if is know that roughly equal numbers of boys and girls are enrolled in the school than the disproportion in the sex distribution represent an error in drawing the sample. Could this have occurred through random error, systematic error, or both? Be ready to explain and defend your answer.
3. The research question is, "What is the prevalence of alcohol and drug se among persons who attend rock concerts"? Classify the following sampling schemes for selecting individuals to fill out a brief questionnaire, commenting on feasibility and whether the results will be generalizable to all people who attend rock concerts.
    a) As each patron entered the theater, she is asked to throw a die. All patrons who throw a 6 are selected.
    b) As each patron entered the theatre, she is asked to throw a die. Men how threw a 1 and women who threw an even number are selected.

c) Tickets to the concert are know to e numbered serially. Each patron whose ticker number ends in 1 is selected.

d) D. After all the patrons are seated, 5 rows are chosen a random by drawing from a shuffled set of cards that has 1 card for ach theater row. All patrons in these 5 rows are selected.

e) The first 27 patrons who enter the theater are selected.

f) Some tickets are sold by mail and some were sold at the box office just before the performance. Whenever there were 3 or more people waiting in line to buy tickets at the box office, the last person in line (who had the most time available) was selected.

g) When patrons began to leave after the performance, those who seemed willing and able to answer questions were selected.

UNIT 5: Determining Causation

Introduction:

Unit 5 is designed to expose the student to the circumstances when non-RCT designs are appropriate to address issues of causation, particularly when associations of harm are being evaluated.

Learning Objective:

1. To understand the role of non-experimental designs in evaluating associations.
2. To understand the issues of bias and confounding when using non-experimental designs to evaluate associations.

Required Readings:

1. Hulley, S.B., Cummings, S.R., Browner, W.S., Grady, D.G., & Newman, T.B. (editors). Designing Clinical Research (3rd Edition). Philadelphia: Lippincott Williams & Wilkins. Chapter 7, 8 and 9. pp 97-146.
2. Guyatt GH, Rennie, D., Meade, MO, & Cook, DJ (editors). User' Guides to the Medical Literature. A Manual for Evidence-Based Clinical Practice (2nd Edition). US: McGraw Hill. 2008. pp 363-381.

OR

DiCenso A, Guyatt GH, Ciliska D. Evidence-Based Nursing. A Guide to Clinical Practice. St. Louis, MO: Elsevier Mosby. 2005 Chapter 5, pages 71-86.

3. Hill AB. The environment and disease: Association of causation? Proceedings of the Royal Society of Medicine, Section of Occupational Medicine. 1965;58:295-300. http://www.edwardtufte.com/tufte/hill

4. Freudenburg WR. Perceived risk, real risk: Social science and the art of probabilistic risk assessment. Science. 1988;242:44-49. http://libaccess.mcmaster.ca/login?url=http://www.sciencemag.org/cgi/content/abstract/242/4875/44

Assignment:

1. Complete the smoking and lung cancer problem (questions 1-16).

2. Complete any outstanding unit evaluations

UNIT 6: Qualitative Study Design

Introduction:

Qualitative and quantitative research approaches are similar in some respects. However, they also differ in fundamental ways. The intent of this unit is to help the student understand how they are similar, how they are different and how the rigor of qualitative research is evaluated. The student will also be introduced to the five major traditions (or approaches) to qualitative research.

Learning Objective:

1. To familiarize the learner with:

   a) The reasons why people do qualitative research in health care

   b) the key features of qualitative research approaches or traditions

   c) how qualitative and quantitative approaches differ

   d) how qualitative and quantitative approaches may be used in a single study

   e) several qualitative approaches or traditions of inquiry

   f) how to critique a qualitative study

2. To appreciate the importance of the following key points:

   a) Qualitative approaches to research are different than quantitative research. Therefore, qualitative studies are useful in situations where quantitative studies are not.

   b) Qualitative research can draw on a range of methods, the choice and timing of which depend on the tradition of inquiry (approach) used. These include: biography, phenomenology, case study, ethnography, and grounded theory study. (There are others as well, depending on whose list you read!)

   c) Qualitative and quantitative research can be combined in a single study or in a series of studies on a single issue or topic. Some investigators do not combine them, for practical or philosophical reasons.

   d) The criteria used to judge qualitative research are different than those used to evaluate quantitative research.

Required Readings:

1. Jones, R. (1995). Why do Qualitative Research? BMJ, 311:2. http://libaccess.mcmaster.ca/login?url=http://bmj.bmjjournals.com/cgi/content/full/311/6996/2

2. Pope, C., & Mays, N. (1995). Reaching the Parts Other Methods Cannot Reach: An Introduction to Qualitative Methods in Health and Health Services Research. BMJ, 311, 42-45. http://libaccess.mcmaster.ca/login?url=http://bmj.bmjjournals.com/cgi/content/full/311/6996/42

3. Barbour, RS. (2001) Checking for improving rigour in qualitative research: A case of the tail wagging the dog? BMJ 322, 1115 http://libaccess.mcmaster.ca/login?url=http://www.bmj.com/cgi/content/full/322/7294/1115

4. Wilson, HS, Hutchinson, SA & Holzemer, WL. (2002). Reconciling incompatibilities: A grounded theory of HIV medication adherence and symptom management. Qualitative Health Research 12(10):1309-22. http://libaccess.mcmaster.ca/login?url=http://qhr.sagepub.com/cgi/reprint/12/10/1309

5. Guyatt GH, Rennie, D., Meade, MO, & Cook, DJ (editors). User' Guides to the Medical Literature. A Manual for Evidence-Based Clinical Practice (2nd Edition). US: McGraw Hill. 2008. pages 341-360.

   OR

DiCenso A, Guyatt GH, Ciliska D. Evidence-Based Nursing. A Guide to Clinical Practice. St. Louis, MO: Elsevier Mosby. 2005. Chapter 8, pp 120-136.

Assignment:

1. Apply the criteria presented in the Rowan and Huston article (use the table that has a modified version of their criteria) to the Wilson et al. article. Using this approach be prepared to discuss strengths and weaknesses of the article using those criteria plus your thoughts on grounded theory studies (based on the large group lecture).

2. Be prepared to address the following questions in the tutorial session:

   a) Why would researchers or practitioners in the health field consider using qualitative approaches?

   b) Give some examples of research questions most appropriately examined using:

      i. only quantitative research methods and/or approaches

      ii. only qualitative research methods and/or approaches

      iii. some combination or collaboration of the two sets of methods and/or approaches.

   c) What are some of the characteristics of qualitative research (regardless of which approach or tradition is used)?

   d) Identify some of the key differences between qualitative and quantitative research.

   e) How do we know that a qualitative study is well done (hint: rigour and congruence)?

   f) What would be a research question related to providing quality health care that you think would be appropriate for a grounded theory study?

UNIT 7: Therapeutic Trials - The Tactics of Performing Therapeutic Trials

Introduction:

The randomized controlled trial is an important study design commonly used to evaluate therapeutic interventions. As a new researcher, you need to know how to conduct an RCT. The purpose of this unit is to introduce you to why we need RCTs, how to design and conduct an RCT, and how to critically appraise an RCT.

Learning Objective:

At the conclusion of the session, you should be able to address the following issues:

1. What methods are available for generating an allocation sequence for patients participating in an RCT?
2. What is concealment of randomization and why is it important?
3. What is the distinction between a superiority versus a noninferiority trial?
4. When and why is blinding important?
5. Identify alternative allocation strategies. Consider strategies like cluster, cross-over, etc. When would you choose such a strategy?
6. Should you monitor for patient compliance and if yes why?
7. How do you decide on what events to capture and are there limitations to certain types of events (e.g., composite, surrogate)?
8. What are some things to avoid doing during statistical analysis and data interpretation?
9. What are some strategies to increase (effective) sample size?
10. Should you monitor your trial for RCT for safety, efficacy, and futility?
11. What strategies can be used to assess RCTs?

Required Readings:

1. Hulley, S.B. Cummings, S.R., Browner, W.S., Grady, D.G., & Newman, T.B. (eds). (2007). Designing Clinical Research, (3rd Ed). Philadelphia: Lippincott Williams & Wilkins. Chapters 10 & 11, pp 147-181.
2. Guyatt GH, Rennie, D., Meade, MO, & Cook, DJ (editors). User' Guides to the Medical Literature. A Manual for Evidence-Based Clinical Practice (2nd Edition). US: McGraw Hill. 2008. pp 67-108.

OR

Cullum, N & Guyatt, G. Health care interventions and harm: An introduction. Chapter 3 (pp 44-47) and DiCenso, A & Guyatt, G. Health care interventions. Chapter 4 (pp 48-70) DiCenso A, Guyatt GH, Ciliska D. Evidence-Based Nursing. A Guide to Clinical Practice. St. Louis, MO: Elsevier Mosby. 2005.

3. Helewa A, Goldsmith CH, Smythe HA, Lee P, Obright K & Stitt L (2007). Effect of Therapeutic Exercise and Sleeping Neck Support on Patients with Chronic Neck Pain: A Randomized Clinical Trial. The Journal of Rheumatology, 34, 151-158
http://libaccess.mcmaster.ca/login?url=http://www.jrheum.com/subscribers/07/01/151.html

Assignments:

1. Review the study published by Helewa and colleagues. Consider the issues you have reviewed about RCTs. What are the strengths and weaknesses of this work? What recommendations would you propose for its improvement?

2. One of the challenges in the health care research enterprise (or any other research area) is that producers and users of researcher can become so vigilant about critiquing a study that at the end of the day, there are no studies that are viewed as methodologically adequate because problems and strategies to improve a study can always be found. Consider what you now know about RCTs, what would you recommend as priorities for ensuring methodologically sound, good quality RCT design and implementation is achieved? What balance (if any) ought we strive toward in designing the perfect RCT and trying to implement it?

UNIT 8: Evaluating the Accuracy of Screening and Diagnostic Tests

Please complete any outstanding unit, tutor, or large group speaker evaluations.

Introduction:

The accuracy of tests used for screening and diagnosing health problems is of major concern to clinicians, researchers and other health professionals. Physicians use the term "diagnosis" while nurses apply the term "assessment". The terms are functionally identical with regard to research methods to assess the accuracy of tests and procedures to evaluate the presence and absence of diseases and conditions. This unit will increase your understanding of the concepts and methods in determining the presence and absence of disease.

Learning Objective:

1. To understand the following terms: sensitivity, specificity, and likelihood ratios.
2. To be able to use nomograms, pretest and post-test probabilities, and likelihood ratios.
3. To understand the implications of moving the cutpoints in diagnostic tests.
4. To understand and be able to apply criteria for determining the usefulness or accuracy of a diagnostic test.

Required Readings:

1. Hulley, S.B. Cummings, S.R., Browner, W.S., Grady, D.G., & Newman, T.B. (eds). (2007). Designing Clinical Research, (3rd Ed). Philadelphia: Lippincott Williams & Wilkins. Chapter 12, pp 183-205.
2. Users' Guides to the Medical Literature. http://libaccess.mcmaster.ca/login?url=http://pubs.ama-assn.org/misc/usersguides.dtl

   Richardson WS, Wilson M. The process of diagnosis. 14: pages 399-405; Richardson WS, Wilson MC, McGinn TG. Diffferential diagnosis, pages 407-416; Furukawa TA, Straus S, Bucher HC, Guyatt G. Diagnostic tests, pages 419-437.

   Or

   DiCenso A, Guyatt G, Ciliska D. Evidence Based Nursing: DiCenso A, Jull A, Guyatt G. Chapter 6. DiCenso A, Jull A, Guyatt G. Diagnosis. Pages 87-107 and Jull A, Guyatt G. Differential diagnosis. Pages 349-357.

Assignment:

1. Intimate Partner Violence—Screening Women in Primary Care

You are associated with an important local family medicine clinic—choose your role. At one of their education sessions for all the professional staff you discuss the report of a survey done by Bhandari and colleagues (Mohit is a faculty member in CE&B). This survey documents the probable need for screening for intimate partner violence by orthopedic surgeons and some of their misconceptions on intimate partner violence. Quickly read the paper by Bhandari and colleagues to review some of their findings—note how important "prevalence" is in this report.

http://www.ejbjs.org/cgi/reprint/90/7/1590

They ask you if you could find some information on what are some of the best tools that they could use to screen for intimate partner violence. They have heard of a 30-item questionnaire (Composite Abuse

Scale) and wonder if something else is faster and more efficient. You find the following article and assess its strengths and limitations using the enclosed form. Your tutor also has some other questions for you to answer before you decide if the HARK scale is one that could be used in your family medicine clinic.

http://www.biomedcentral.com/content/pdf/1471-2296-8-49.pdf

NOTE: Disregard everything about positive and negative predictive values as they change with the prevalence of the disease in populations—they are truly not useful! Concentrate more on the likelihood ratios. They function so as to apply an individual patient's situation (pre-test probability of disease) to come to an individualized estimate of that person's probability of disease.

Sohal H, Eldridge S, Feder G. The sensitivity and specificity of four questions (HARK) to identify intimate partner violence: a diagnostic accuracy study in general practice. BMC Fam Pract. 2007 Aug 29;8:49.

GUIDE	COMMENTS
ARE THE RESULTS OF THE STUDY VALID?	
1. Did participating patients present a diagnostic dilemma?	
2. Did the patient sample include an appropriate spectrum of patients to whom the test will be applied in clinical practice?	
3a. What was the gold standard test? 3b. What was the new test? 3c. Did the investigators compare the test to an appropriate, independent reference standard?	
4. Were those interpreting the test and	

reference standard blind to the other results?	
5. did investigators perform the same reference standard to all patients regardless of the results of the test under investigation?	
WHAT ARE THE REUSLTS?	
Are likelihood ratios, or the data necessary to calculate likelihood ratios, provided?	--do the calculations in the space provided.
WILL THE RESULTS HELP ME IN CARING FOR MY PATIENT?	
1. Will the reproducibility of the test results and its interpretation be satisfactory in my setting?	
2. Are the results applicable the patients in my practice?	
3. Will the results change my management strategy?	
4. Will patients be better off as a result of the test?	

The results of the study can be presented in various ways, some of which are more useful than others. Here are the data from the study taking into account whether the woman answered in 3 categories (0 points, 1-2 points, or 3-4 points). The paper presents data only in 2 categories of scores.....0 or more than 0—cutpoint of 1.

1. Calculate the likelihood ratios for these 3 cutpoints—see Users Guide for how to do this (see sections around page 427).

Score—higher more indicative of intimate partner violence (IPV)	Women who have experienced or are experiencing IPV	Women without IPV in the past year	Likelihood ratio
3-4 (out of 4)	14	0	
1-2	29	9	
0	10	170	
Total women	53	179	

2. Using the nomogram what is the post test probability for a woman with the following characteristics. The nomogram is on page 429 and you have one in the back pocket of the Users Guide textbook.

Pre-test probability—how likely is this woman to be experiencing IPV?	Score (number of "yeses"	Post-test probability calculated form the likelihood data you just calculated in question 1:	Post-test probability using data in the article (1 cutpoint at 0 vs 1 or more yes): +LR = 16 -LR = 0.1
1%	3		
1%	2		

1%	0		
5%	4		
5%	1		
5%	0		
20%	3		
20%	2		
20%	0		
50%	4		
50%	1		
50%	0		

3. Are any differences evident from this exercise? What value is there in moving to multi-level likelihood values?

Note that this assignment is not an easy one. If you have trouble ask for help. We will make sure that everyone understands this topic by the end of the tutorial session.

UNIT 9: Systematic Reviews

Introduction:

You need to know how to do systematic reviews and meta-analyses because you will have to complete them to justify any study you are thinking of conducting. Systematic reviews are considered the highest level of evidence in many evidence hierarchies. The goal of this unit is have you understand the key steps in conducting a systematic review and meta-analysis and to be able to identify and appreciate strengths and weaknesses of published systematic reviews and meta-analyses.

Learning Objectives:

At the conclusion of the session, you should be able to address the following issues:

1. What is a narrative review, systematic review, and meta-analysis?
2. What types of questions can be addressed by a systematic review?
3. What are the basic principles and processes of conducting a systematic review?
4. Do you need inclusion criteria for articles and should eligibility decisions be undertaken by one individual or two?
5. What is the difference between a fixed and random effects model of combining data across studies?
6. What is a test of heterogeneity?

Required Readings:

1. Hulley, S.B., Cummings, S.R., Browner, W.S., Grady, C.D., & Newman, T.B. (editors). (2007). Designing Clinical Research, (3rd Ed). Philadelphia: Lippincott Williams & Wilkins. Chapter 13, Utilizing Existing Databases, pp 207-220

2. **From the Second edition of UG:** Guyatt GH, Rennie, D., Meade, MO, & Cook, DJ (editors). User' Guides to the Medical Literature. A Manual for Evidence-Based Clinical Practice (2nd Edition). US: McGraw Hill. 2008. pp 523-562.

OR

From the First edition of UG: Guyatt G, Rennie DR. (eds.) Users' guides to the medical literature. United States of America; AMA Press, 2002: Chapter 1E, 155-174, and Chapter 2E, 529-565. http://libaccess.mcmaster.ca/login?url=http://pubs.ama-assn.org/misc/usersguides.dtl

OR

DiCenso A, Guyatt GH, Ciliska D. Evidence-Based Nursing. A Guide to Clinical Practice. St. Louis, MO: Elsevier Mosby. 2005. Chapter 9 : Summarizing the evidence through systematic reviews. (pp 137-153), Chapter 23: Publication Bias (pp 373- 380), & Chapter 24: Evaluating Differences in Study Results (pp 381-387).

3. DiCenso, A., Guyatt, G., William, A., & Griffith, L. (2002). Interventions to reduce unintended pregnancies among adolescents: systematic review of randomised controlled trials. BMJ, 324:1426-35. http://libaccess.mcmaster.ca/login?url=http://www.pubmedcentral.gov/picrender.fcgi?artid=115855&blobtype=pdf

Assignment:

As a health care professional, your local high school has asked you to come to a board of trustees meeting to discuss a proposed sexuality program for the students to hopefully reduce the rate of teen pregnancy. The rate of pregnancy in Canada was 48.1 per 1000 teens aged 15 to 19 in 1992 and had fallen to 33.9 in 2002. Despite this reduction in incidence, the school board wants to reduce their pregnancy rates even further. Their proposed program will feature an "abstinence program" that some individual trustees on the school board are advocating.

Read and critique the DiCenso et al review of pregnancy prevention programs in adolescents. Will you support the abstinence program for the high school? Please come prepared to discuss why or why not.

Note: Make sure that you know how to read the forest plots in the article.

UNIT 10: Economics: Introduction to Health Technology Assessment (HTA)

Introduction:

Unit 10 is designed to provide students with a basic introduction to health economic analyses and the role that health economic assessment (HTA) can play in health care evaluation.

Learning Objectives:

1. To learn about the basics of HTAs (e.g. systematic literature reviews, economic analyses/modeling, budget impact analyses)
2. To learn about different types of economic evaluations
3. To learn about finding a model type and structure (e.g. decision tree, Markov models) that is best suited for a particular disease or intervention

Required Readings:

1. Guyatt GH, Rennie, D., Meade, MO, & Cook, DJ (editors). User' Guides to the Medical Literature. A Manual for Evidence-Based Clinical Practice (2nd Edition). US: McGraw Hill. 2008. pp 619-641.

OR

DiCenso A, Guyatt GH, Ciliska D. Evidence-Based Nursing. A Guide to Clinical Practice. St. Louis, MO: Elsevier Mosby. 2005. pp156-167.

2. Kernick DP. Introduction to health economics for the medical practitioner. Postgrad Med J. 2003: 79, 147-150. http://libaccess.mcmaster.ca/login?url=http://pmj.bmj.com/cgi/content/abstract/79/929/147
3. Goeree, R. & Levin, L. Building bridges between academic research and policy formulation. The PRUFE framework – an integral part of Ontario's evidence-based HTPA process. Pharmacoeconomics, 2006; 24(11), 1143-1156. http://libaccess.mcmaster.ca/login?url=http://www.ingentaconnect.com/content/adis/pec/2006/00000024/00000011/art00010
4. Noorani, HZ, Husereau, DR., Boudreau, R. & Skidmore, B. Priority setting for health technology assessments:A systematic review of current practical approaches. International Journal of Technology Assessment in Health Care, 23:3 (2007), 310–315. http://libaccess.mcmaster.ca/login?url=http://journals.cambridge.org/download.php?file=%2FTHC%2FTHC23_03%2FS026646230707050Xa.pdf&code=ec21b1051eda5338b38b329bcd41b762
5. Sonnenberg FA, Beck JR. Markov Models in Medical Decision Making: A Practical Guide. Medical Decision Making 1993;13:322-338. Available at: http://mdm.sagepub.com/cgi/reprint/13/4/322

Optional Readings:

1. Briggs AH, O'Brien BJ. The Death of Cost-Minimization Analysis? Health Econ 2001; 10(2):179-184. http://ideas.repec.org/a/wly/hlthec/v10y2001i2p179-184.html

2. Lehoux, P, Tailliez S, Denis JL, Hivon M. Redefining health technology assessment in Canada: diversification of products and contextualization of findings. Int J Technol Assess Health Care. 2004 Summer: 20(3): 325-36. http://libaccess.mcmaster.ca/login?url=http://scholarsportal.info/cgi-bin/sciserv.pl?collection=journals&journal=02664623&issue=v20i0003&article=325_rhtaicopacof http://libaccess.mcmaster.ca/login?url=http://journals.cambridge.org/action/displayFulltext?type=1&fid=235628&jid=THC&volumeId=20&issueId=03&aid=235626

Assignment:

1. Identify a health technology that is of interest to you (e.g. a drug, a surgical intervention, or a diagnostic test, etc.) that would benefit from an economic evaluation (preferably model-based) to better understand its value. Some emerging technologies are listed at this site: http://www.euroscan.org.uk/

2. Check in the various HTA databases to see if anyone has done an HTA evaluation on your topic. Please identify an HTA report and bring its abstract to class and be prepared to briefly describe this HTA report. Some of the possible databases are:

    a) http://www.crd.york.ac.uk/crdweb/ (HTA database)

    b) http://216.194.91.140/vortal/ (index of HTA sites—lots of choice).

3. Be prepared to discuss the economic analysis in your identified HTA report. You should be able to identify which type of economic analysis it is and justify your choice. If your chosen HTA report does not have an economics section, please identify a health economics study from one of the following databases. You should be able to identify its type of analysis. Some of the economics databases follow:

    a) http://www3.interscience.wiley.com/cgi-bin/mrwhome/114130635/HOME

    b) http://www.crd.york.ac.uk/crdweb/ (NHS EED—Economics Evaluation Database)

    c) http://www.ncbi.nlm.nih.gov/sites/entrez (Pubmed has many economics studies but they are often difficult to find)

UNIT 11: Knowledge Translation

Introduction:

The knowledge production process in healthcare is vital to increasing our knowledge, evaluating advances in care, and improving well being. This course has provided an overview of some of the major methods of doing effective health research that address important health topics. We now move to look at how to get our research applied.

> "The term *knowledge translation* most readily appears in medical and health-care literature and primarily pertains to the assessment, review, and utilization of scientific research. One of the most well-known references for KT hails from the Canadian Institutes for Health Research (CIHR).
>
> CIHR defines KT as the exchange, synthesis, and ethically-sound application of knowledge—within a complex set of interactions among researchers and users—to accelerate the capture of the benefits of research for Canadians through improved health, more effective services and products, and a strengthened health care system (CIHR, 2004).
>
> For the CIHR, the primary purpose of KT is to address the gap between the large volume of research data and its systematic review and implementation by key stakeholders."
>
> From: http://www.ncddr.org/kt/products/focus/focus10/

Unless we are both a) aware of the research and knowledge that exists in our domain and others areas before we start projects and b) seriously work to "move" or integrate our findings to those who would benefit from its application, we will not be effective as researchers and educators. This unit is designed to show why KT is important, provide some of the challenges of KT, and to examine KT research and applications.

Learning Objectives:

1. To understand the basic tenets of KT
2. To come to an appreciation of the magnitude of the problem of failing to implement important advances in health research.
3. To recognize the various terms used for KT.
4. To recognize the various disciplines and stakeholder groups involved with KT.
5. To review some of the effective, and not so effective methods of KT implementation and the challenges in doing KT research.

Required Readings:

1. Woolf SH, Johnson RE. The break-even point: When medical advances are less important than improving the fidelity with which they are delivered. Annals of Family Medicine. 2005(6):545-552. http://libaccess.mcmaster.ca/login?url=http://www.annfammed.org/cgi/reprint/3/6/545

2. Lu CY, Ross-Degan D. Soumerai SB, Pearson SA. Interventions designed to improve the quality and efficiency of medication use in managed care: A critical review of the literature. BMC Health Services Research 2008;8:75. http://www.biomedcentral.com/content/pdf/1472-6963-8-75.pdf

3. 3. Wensing M, Wollersheim H, Grol R. Organizational interventions to implement improvement in patient care: A structured review of reviews. Implementation Science. 2006;1:2. http://www.implementationscience.com/content/pdf/1748-5908-1-2.pdf

4. 4. Ryan KW, Card-Higginson P, McCarthy SG, Justus MB, Thompson JW. Arkansas fights fat: Translating research into policy to combat childhood and adolescent obesity. Health Affairs. 25;(4):992-1003. http://libaccess.mcmaster.ca/login?url=http://content.healthaffairs.org/cgi/content/abstract/25/4/992

Assignment:

1. What are Woolf and Johnson's findings? How are the findings applicable to your discipline area?

2. Lu et al is a review article that analyzes reviews of the literature looking at the research that concentrates on making changes in individual clinician behaviours by concentrating on the individual. Wensing et al is a review article of individual studies assessing the effect of changes in organizational operations or structures that can contribute to improvements in patient care. Ryan et al is a case study of how changes were made at the policy level for a large geographic and political unit (US state). The science of KT addresses all 3 "levels" of care (individuals, health organizations, and a large political unit). Read the articles assessing similarities and differences in KT for the 3 levels. Be prepared to discuss what you learned and how you would/could implement programs in your own clinical/research areas.

UNIT 12: Ethics in Research

Introduction:

Ethics is a critical aspect of good research. To be a responsible researcher it is necessary to know and be able to apply the requirements of ethical research. In this session you will learn about the policy that guides ethics in human research in Canada. Your textbook reading will give you some insights into US

ethics. The additional JAMA article provides additional broad perspectives. You will explore some of the background theory that informs this guidance and apply it to a case study. The class time will be spent working on a case study provided in class.

Learning Objectives:

1. Know how to access the Tri-Council Policy Statement: ethical conduct for research involving humans (TCPS) that "describes standards and procedures for governing research involving human subjects" http://www.pre.ethics.gc.ca/english/policystatement/goals.cfm
2. Understand some of the historical and theoretical background that informs ethical guidance for human research.
3. Understand some of the challenges of applying ethics policy to a case.

Required Readings:

1. Hulley reading: Chapter 14. Lo, Bernard. Addressing Ethical Issues. Pages 225-240.
2. Emanuel EJ, Wendler D & Grady C. (2000). What makes clinical research ethical? JAMA, 283(20), 2701-2711. http://libaccess.mcmaster.ca/login?url=http://jama.ama-assn.org/cgi/reprint/283/20/2701

Assignment:

1. COMPLETE the Introductory Tutorial for the Tri-Council Policy Statement: ethical conduct for research involving humans, http://www.pre.ethics.gc.ca/english/tutorial/
2. PRINT your certificate;
3. 3. Submit a COPY at the session.
4. Think about how Canadian and US approaches to ethical issues in clinical studies differ and are the same.

McMaster University

SCHOOL OF GRADUATE STUDIES

RECOMMENDATION FOR CHANGE IN GRADUATE CURRICULUM - FOR CHANGE(S) INVOLVING COURSES

PLEASE READ THE FOLLOWING NOTES BEFORE COMPLETING THIS FORM:

1. This form must be completed for **ALL** course changes. All sections of this form **must** be completed.
2. An electronic version of this form must be emailed to the Assistant Secretary and SynApps System Administrator (Email: *espiritu@mcmaster.ca*).
3. A representative from the department is required to attend the Faculty Curriculum and Policy Committee meeting during which this recommendation for change in graduate curriculum will be discussed.

DEPARTMENT/PROGRAM	Health Research Methodology			
COURSE TITLE	Systematic Review Methods (Online)			
COURSE NUMBER	*773	**COURSE CREDIT**		
		FULL COURSE ( )	**HALF COURSE (X)**	**QUARTER (MODULE) ( )**
INSTRUCTOR(S)	Gordon Guyatt and Deborah Cook (co-ordinators)	Antirequisite HRM 743*		
PREREQUISITE(S)	HRM *721 (or equivalent) AND HRM*702 (or equivalent) OR permission of the instructor.			

NATURE OF RECOMMENDATION ***(PLEASE CHECK APPROPRIATE BOX)***

NEW COURSE	X	**DATE TO BE OFFERED:** September, 2009	**WAS THE PROPOSED COURSE OFFERED ON DEAN'S APPROVAL? IF YES, PROVIDE THE DATE:**

WILL THE COURSE BE CROSS-LISTED WITH ANOTHER DEPARTMENT? No **IF YES, ATTACH TO THIS FORM ANY RELEVANT CORRESPONDENCE WITH THE OTHER DEPARTMENT(S). NOTE: CROSS-LISTING OF COURSES REQUIRES APPROVAL FROM EACH DEPARTMENT AND FACULTY CONCERNED.**

CHANGE IN COURSE TITLE		**PROVIDE THE CURRENT COURSE TITLE:**				
CHANGE IN COURSE DESCRIPTION		**600-LEVEL COURSE** ***(Undergraduate course for graduate credit)*** ***Please see #4 on page 2 of this form***				
CHANGE TO FULL COURSE		**CHANGE TO HALF COURSE**		**CHANGE TO QUARTER COURSE**		
COURSE CANCELLATION		**PROVIDE THE REASON FOR COURSE CANCELLATION:**				
OTHER	X	**EXPLAIN:** Same as HRM *743 but delivered 100% online (HRM*743 will continue to be offered in-class). The method of presentation and method of evaluation has been changed for the online course.				

BRIEF DESCRIPTION FOR CALENDAR - Provide a brief description *(maximum 6 lines)* to be included in the Graduate Calendar.

This online course about research synthesis focuses on comparisons between alternative interventions. Interactive learning modules, required readings, discussion boards, tutorials, and assignments will be used to highlight rigorous review methods, such as searching for potentially relevant articles, selecting primary articles using explicit, reproducible criteria, appraisal of study architecture, quantitative data synthesis and interpretation. Students enrolling in the course must first identify a suitable research question and identify a partner for their review. The course is structured around the steps of executing a systematic review and students are expected to apply the knowledge they gain on an ongoing basis to complete their review by the end of the course.

CONTENT/RATIONALE - Provide a brief description, i.e., outline the topics or major sub-topics, and indicate the principal texts to be used.

This course about research synthesis focuses on comparisons between alternative interventions. Rigorous review methods will be highlighted, such as searching for potentially relevant articles, selecting primary articles using explicit, reproducible criteria, appraisal of study architechture, quantitative data synthesis and interpretation. The course is structured around the steps of executing a systematic review and students are expected to apply the knowledge they gain on an ongoing basis to complete their review by the end of the course.

This online course has the same readings and learning materials presented in the on-campus course HRM 743.

Session topics: Introduction; Review of Reviews; Protocol Formulation and Protocol Development; Identifying and Selecting Studies; Quality of Evidence Assessments; Data Collection Forms; Combining the Findings of Independent Studies;

LAB – Measuring Disagreement/Quantitatively Combining Research Findings; Variation Between Study Findings; Summarizing and Interpreting Results

Required Materials: Custom courseware AND the following text:

Gordon Guyatt, Drummond Rennie, Maureen O. Meade, Deborah J Cook. Users' Guide to the Medical Literature: A Manual for Evidence-Based Clinical Practice. Second Edition. American Medical Association. 2008.

1. STATEMENT OF PURPOSE (How does the course fit into the department's program?)

Systematic reviews synthesize the results of multiple primary investigations using strategies that limit bias and random error; these strategies include a comprehensive search of all potentially relevant artilces, and their selection using explicit, reproducible criteria. Primary research designs and study characteristics are appraised, data are synthesized, and the results are interpreted. Systematic reviews of previous research from the backbone of grant poposals and help to highlight what is known and yet to be discovered or clarified. Systematic reviews can help practicitioners keep abreast of the medical literature by summarizing large bodies of evidence, and by helping to explain differences among several studies. Used increasingly to set clinical policy, systematic reviews may facilitate the link between best research evidence and optmal health care at the population level. Thus, this course will be of potential use and interest to many HRM students in several ways.

2. EXPECTED ENROLMENT:

15-25 Students

3. DESCRIBE IN DETAIL THE METHOD OF PRESENTATION OF COURSE MATERIAL (i.e., lectures, seminars):

This online course consists of 10 units (a new unit is posted every week). Each unit consists of an interactive learning module (with audio-narrated slides), required readings, an assignment, discussion and a tutorial session. Participation in the discussion boards is monitored and evaluated. Tutorials will be held at the end of the week via a web conferencing tool (Elluminate LIVE). Live participation in the tutorial sessions is optional although individuals who cannot attend are expected to review the archived session materials.

4. DESCRIBE IN DETAIL THE METHOD OF EVALUATION: (For 600-level course, indicate the Extra Work to be required of graduate students, i.e., exams, essays, etc.)

50% = final paper
30% = weekly assignments
10% = Written review of a fellow student's final paper
5% = Participation/contribution to discussion forums
5% = Facilitation and summary of discussion

5. TO PREVENT OVERLAP, IS A COURSE IN THE SAME OR A RELATED AREA OFFERED IN ANOTHER DEPARTMENT? IF YES, PLEASE ATTACH TO THIS FORM ANY RELEVANT CORRESPONDENCE WITH THE OTHER DEPARTMENT(S).

N/A

6. IF THE COURSE IS INTENDED PRIMARILY FOR STUDENTS OUTSIDE YOUR DEPARTMENT, DO YOU HAVE THE SUPPORT OF THE DEPARTMENT/PROGRAM CONCERNED?

N/A

PLEASE PROVIDE THE CONTACT INFORMATION FOR THE RECOMMENDED CHANGE:

Name: Gordon Guyatt & Deborah Cook Email: guyatt@mcmaster.ca Extension: 22160

If you have any questions regarding this form, please contact the Assistant Secretary and SynApps System Administrator, School of Graduate Studies, extension 24204.

SGS/December 2006

HRM Course Outline

Course Number & Title:	HRM *773: Systematic Review Methods (Online)
Course Co-ordinator:	Gordon Guyatt, Deborah Cook
Additional Faculty/Support:	

Course Description

This online course about research synthesis focuses on comparisons between alternative interventions. Interactive learning modules, required readings, discussion boards, tutorials, and assignments will be used to highlight rigorous review methods, such as searching for potentially relevant articles, selecting primary articles using explicit, reproducible criteria, appraisal of study architecture, quantitative data synthesis and interpretation. Students enrolling in the course must first identify a suitable research question and identify a partner for their review. The course is structured around the steps of executing a systematic review and students are expected to apply the knowledge they gain on an ongoing basis to complete their review by the end of the course.

Course Objectives

The primary objectives of this course are to:

1. Introduce and discuss review methods
2. Apply acquired skills in the execution of a rigorous systematic review.

Secondary objectives include:

- To familiarize students with the work of the Cochrane Collaboration and the Cochrane handbook
- To explore concepts and controversies in review methods

Educational Methods/Course Format

This course will have the same required readings and delivered content as the on-campus course, HRM743. Each week students will be expected to complete a learning package that involves: doing the required readings, completing the online module, completing the weekly assignment and participating in discussions on the discussion boards. Several students will be assigned each week to facilitate and summarize the discussions. At the end of each week, the online instructor will hold a 'tutorial' session where the instructor will respond to any outstanding issues and answer any specific questions that students have.

Course Text/Materials

Required text: Gordon Guyatt, Drummond Rennie, Maureen O. Meade, Deborah J Cook. Users' Guide to the Medical Literature: A Manual for Evidence-Based Clinical Practice. Second Edition. American Medical Association. 2008.

Students are also required to purchase a custom courseware and access additional readings online (as listed each week).

Prerequisites:	**1.** Meet SGS minimum requirements **2.** Have taken courses equivalent to HRM*721 and HRM*702 (syllabuses will be provided online) OR approval of the instructor *Antirequisite HRM *743*
Session	**Topic**
Week 1	Introduction
Week 2	Review of Reviews
Week 3	Protocol Formulation and Protocol Development
Week 4	Identifying and Selecting Studies
Week 5	Quality of Evidence Assessments
Week 6	Data Collection Forms
Week 7	Combining the Findings of Independent Studies
Week 8	LAB – Measuring Disagreement/Quantitatively Combining Research Findings
Week 9	Variation Between Study Findings

Week 10	Summarizing and Interpreting Results
Week 11	
Week 12	
Week 13	

Evaluation of Student Performance
50% = final paper 30% = weekly assignments 10% = Written review of a fellow student's final paper 5% = Facilitation and summary of discussion 5% = Participation/contribution to discussion forums

Course Syllabus

HRM *773: Fall 2009
Fundamentals of Health Research and Evaluation Methods (Online)

1. Course Overview

1.1 Brief Description

This online course about research synthesis focuses on comparisons between alternative interventions. Interactive learning modules, required readings, discussion boards, tutorials, and assignments will be used to highlight rigorous review methods, such as searching for potentially relevant articles, selecting primary articles using explicit, reproducible criteria, appraisal of study architecture, quantitative data synthesis and interpretation. Students enrolling in the course must first identify a suitable research question and identify a partner for their review. The course is structured around the steps of executing a systematic review and students are expected to apply the knowledge they gain on an ongoing basis to complete their review by the end of the course.

1.2 Course Objectives

The primary objectives of this course are to:

1. Introduce and discuss review methods
2. Apply acquired skills in the execution of a rigorous systematic review.

Secondary objectives include:

- To familiarize students with the work of the Cochrane Collaboration and the Cochrane handbook
- To explore concepts and controversies in review methods

1.3 Prerequisites

- have taken introductory courses in biostatistics and research methods (equivalent to the Health Research Methodology's graduate courses: HRM721 and HRM702; see www.XXXXXX for detailed syllabuses) OR obtain approval of the instructor
- meet McMaster's School of Graduate Studies admission criteria (see: http://www.mcmaster.ca/graduate/grad_calendar.pdf *section 2.1.5, page 5*)

1.4 Required Materials

Required text:

Gordon Guyatt, Drummond Rennie, Maureen O. Meade, Deborah J Cook. Users' Guide to the Medical Literature: A Manual for Evidence-Based Clinical Practice. Second Edition. American Medical Association. 2008.

Custom courseware and additional materials:

Students are required to purchase a custom courseware package which includes reference material not available electronically.

Students are also required to access readings online (as outlined weekly).

Availability:
Custom courseware and textbooks can be purchased online from the McMaster Health Sciences Bookstore (http://titles.mcmaster.ca/mediashop)**
Textbooks are also available online through stores such as: www.amazon.ca

** Custom courseware must be ordered by the end of August to ensure delivery before the start of the course

NOTE: This course is very resource intensive and materials necessary for final projects may incur additional costs (these are strictly the responsibility of the student). Students are **strongly encouraged** to identify library assistance (for searching and acquiring materials) at their home institution or within their community **BEFORE** the start of the course. Currently, McMaster University Libraries do not have the ability to mail books obtained through inter-library loans directly to students (these materials are available to McMaster students only through library pick-up). Articles available through McMaster Libraries only in print CAN be mailed to students, when necessary, however the student is responsible for paying for the reproduction and shipping and handling of these resources.

1.5 Brief Outline

Unit	Topic (Module Author)
1	Introduction
2	Review of Reviews
3	Protocol Formulation and Protocol Development
4	Identifying and Selecting Studies
5	Quality of Evidence Assessments
6	Data Collection Forms
7	Combining the Findings of Independent Studies
8	LAB – Measuring Disagreement/Quantitatively Combining Research Findings
9	Variation Between Study Findings
10	Summarizing and Interpreting Results

2. Contact Information

Distance Education Coordinator:

Soo Chan Carusone, Ph.D.
Clinical Epidemiology & Biostatistics
Email: chan.carusone@mcmaster.ca

Course Coordinators:

Gordon Guyatt, M.D., M.Sc.
Professor, Department of Clinical Epidemiology & Biostatistics
Email: guyatt@mcmaster.ca

Deborah Cook, M.D., M.Sc.
Professor, Department of Medicine & Dept. of Clinical Epidemiology & Biostatistics
Email: debcook@mcmaster.ca

3. Course Format

This is an advanced graduate-level course designed to highlight rigorous review methods while students complete a systematic review on a topic of their choice. This online course consists of 10 units (a new unit is posted every week). Each unit consists of an interactive learning module (with audio-narrated slides and self-assessment questions designed by a faculty member with expertise on the topic), required readings, an assignment, discussion and a tutorial session. Participation in the discussion boards is monitored and evaluated. Each week students will be assigned to facilitate discussions. Student facilitators will be evaluated on their facilitation and their written summary of the discussion. Live participation in the tutorial sessions is optional, although individuals who cannot attend are expected to review the archived session materials. Tutorials will be held at the end of the week via a web conferencing tool (Elluminate LIVE). The agenda for the tutorials will be directed by the unresolved issues and questions raised in the discussion forums. Students will also have the opportunity to post additional questions directly to the instructor in advance of the tutorial sessions (if they cannot attend).

To facilitate retention, this course has been designed to give students a variety of opportunities to apply the knowledge they gain. Students are expected to:

- Complete session modules including the self-assessment questions
- Complete the weekly assignments
- Participate in weekly discussions with the instructor and fellow students on key issues in each unit
- Consolidate issues and topics covered every week in the preparation of a systematic review, to be submitted at the end of the term, on a topic of their choice

4. Student Evaluation

Students are given many opportunities to demonstrate their mastery of the course material. Final course marks will be calculated as follows:

50% = final paper

30% = weekly assignments

10% = Written review of a fellow student's final paper

5% = Participation/contribution to discussion forums

5% = Facilitation and summary of discussion

Final paper

The final paper is a systematic review on a topic of the student's choice. The research question must be submitted (and approved) before the start of the course. The research and presentation of this work should be of a level suitable for publishing in a peer-reviewed journal. Sample papers and structured evaluation forms used in grading the final papers are available in the folder labeled 'XXXXXXXXXXXXXXXXXXXX'.

Weekly assignments:

Weekly assignments will be posted with each module. These assignments are designed to guide students in the production of their systematic review. Assignments will be due at the end of each week (Saturday, at midnight). Assignments will be graded by the instructor and returned within 7 days.

Written review of a fellow student's final paper:

This assignment is designed to give students the opportunity to critically appraise a peer's systematic review (the review does not contribute to the author's grade). Reviews should be typed and double-spaced, with a maximum length of 4 pages. Use the evaluation form posted to guide your review. Students' should outline the strength and weaknesses of the systematic review paper: focus on methodological issues and presentation of the findings (and not on the clinical relevance of the question).

Participation in discussion forums:

Participation in discussions with fellow students and instructors is known to be critical to developing a successful and effective learning environment. Discussion forums will be set-up every unit to discuss three questions presented by the lecturer and any ongoing issues related to your project or other course content. Participation will be evaluated by the instructor. Each week students are expected to post one original post and respond to at least 2 threads initiated by others. To allow significant time for discussion each week the time of a student's post will also be considered in evaluations (that is, you should not post your comments Friday morning every week, right before the tutorial session). For

detailed guidelines and marking rubrics for participation see the 'XXXXXXX' document posted in XXXXXXXXXXXX.

Discussion facilitation and summary document

Each week several students will be assigned to facilitate the weekly discussion board. This will include posting thought provoking questions early in the week to stimulate discussion, responding constructively to other's posts, and working to direct discussion to the important issues of the session. Student facilitators will also be responsible for evaluating peer participation in the weekly discussion board (although this will not contribute directly to the marks allocated to the students) and creating a summary document and agenda for the tutorial session. The summary document should be presented by topic (when creating this document, think of it as an important resource for studying the key concepts!). The agenda should outline any outstanding issues and questions for the instructor that were unresolved in the discussion forum.

5. Course Calendar

Unit/Dates	Topic (Date Posted)	Activities
Sept. 14		**DUE: Research question** **DUE: Submit name of review partner**
UNIT 0: **Sept. 14 – 20**	Orientation	Welcome – Sept. 18 (TIME)
UNIT 1: **Sept. 21 – 27**	Introduction	Discussion – DATES Tutorial – DATE & TIME
UNIT 2: **Sept. 28 – Oct. 4**	Review of reviews	Discussion – DATES Tutorial – DATE & TIME
UNIT 3: **Oct. 5 – 11**	Protocol formulation and protocol development	Discussion – DATES Tutorial – DATE & TIME
UNIT 4: **Oct. 12 – 18**	Identifying and selecting studies	Discussion - DATES Tutorial – DATE & TIME
UNIT 5: **Oct. 19 – 25**	Quality of evidence assessments	Discussion – DATES Tutorial – DATE & TIME
UNIT 6: **Oct. 26 – Nov. 1**	Data collection forms	Discussion – DATES Tutorial – DATE & TIME

UNIT 7: **Nov. 2 – 8**	Combining the findings of independent studies	Discussion - DATES Tutorial – DATE & TIME
UNIT 8: **Nov. 9 – 15**	Measuring disagreement/quantitatively combining research findings	Discussion – DATES Tutorial – DATE & TIME
UNIT 9: **Nov. 16 – 22**	Variation between study findings	Discussion – DATES Tutorial – DATE & TIME
UNIT 10: **Nov. 23 – 29**	Summarizing and interpreting results	Discussion – DATES Tutorial – DATE & TIME
November 30 – December 12	- NO MODULE – Discussion on final papers	Discussion - Nov 30 – Dec 12 Tutorial – December 4 (TIME)
December 13th	- NO MODULE -	**DUE: Final paper (11:59pm EST)** Peer reviews assigned
December 20th	- NO MODULE -	**DUE: Peer reviews (11:59pm EST)**

Other Important Dates:

6. Detailed Course Outline

Background

Systematic reviews synthesize the results of multiple primary investigations using strategies that limit bias and random error; these strategies include a comprehensive search of all potentially relevant articles, and their selection using explicit, reproducible criteria. Primary research designs and study characteristics are appraised, data are synthesized, and the results are interpreted. Systematic reviews of previous research form the backbone of grant proposals and help to highlight what is known and yet to be discovered or clarified. Systematic reviews can help practitioners keep abreast of the medical literature by summarizing large bodies of evidence and by helping to explain differences among several studies. Used increasingly to set clinical policy, systematic reviews may facilitate the link between best research evidence and optimal health care at the population level. Thus, this course will be of potential use and interest to a broad student base.

UNIT 1: Introduction

Introduction:

The first step to any research project is to pose an appropriate question. The goal of this unit is have you understand the key components of a good study question.

Learning Objectives:

1. To review the course content, format and evaluation system.
2. To understand the differences between systematic reviews, narrative reviews and meta-analyses.
3. To confirm your choice of your question, partners, and the resources you will need to complete your review.
4. To achieve an initial understanding of when it is advisable to aggregate across studies to generate a single estimate, and when it is not.
5. To identify the importance of a priori hypotheses to drive sub-group analyses.

To do:

1. Review and refine the formulation of the question for your systematic review
2. Decide if you are going to be able to conduct a meta-analysis. If yes, across what range of patients, interventions, and outcomes? What will be your a priori hypotheses to explain heterogeneity?
3. Prepare a draft of the section of your overview which relates to this session.

Required Readings:

1. Users' Guides to the Medical Literature: A Manual for Evidence-Based Clinical Practice. 2nd Edition. Gordon Guyatt, Drummond Rennie, Maureen O. Meade, Deborah J. 2008. American Medical Association. Chapter 19 "Summarizing the Evidence" p. 523-542.
2. Cochrane Handbook, Chapter 5. Defining the Review Question and Developing Criteria for including studies.sections 5.2, 5.3, 5.6. http://www.cochrane-handbook.org/
3. Cook DJ, Sackett DL, Spitzer WO. Methodological guidelines for systematic reviews of randomized control trials in health care from the Potsdam Consultation on Meta-analysis. J Clin Epidemiol 1995; 48(1):167-171.

http://libaccess.mcmaster.ca/login?url=http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6T84-3YVD10R-6J&_user=1067350&_rdoc=1&_fmt=&_orig=search&_sort=d&view=c&_acct=C000051241&_version=1&_urlVersion=0&_userid=1067350&md5=ade0f38bcde8fe1bbc4cdb6bd3eed41f

UNIT 2: Review of Reviews

Introduction:

Before commencing your own review, you need to be aware of relevant prior reviews. In this unit you will be introduced to criteria to judge the quality of a literature review, and to the GRADE approach to creating a systematic review. The GRADE approach will be emphasized throughout the course.

Learning Objectives:

By the end of this unit the successful student will be able to:

1. Systematically review prior reviews on the same topic as your review.
2. Clarify the rationale for your review.
3. Develop an initial understanding of what makes a systematic review high quality
4. Develop an initial understanding of the GRADE approach to creating a systematic review.

Required Readings:

1. Summary of Findings tables
2. Guyatt GH, Oxman AD, Vist GE, Kunz R, Falck-Ytter Y, Alonso-Coello P, Schunemann HJ. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ 2008; 336:924-926. http://libaccess.mcmaster.ca/login?url=http://www.bmj.com/cgi/content/extract/336/7650/924
3. Oxman AD, Guyatt GH, Singer J et al. Agreement among reviewers of review articles. J Clin Epidemiol 1991;44:91-98. http://libaccess.mcmaster.ca/login?url=http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6T84-4CT0VF6-2W&_user=1067350&_rdoc=1&_fmt=&_orig=search&_sort=d&view=c&_acct=C000051241&_version=1&_urlVersion=0&_userid=1067350&md5=5c1bb343a7711ba2acd1559bff381e97

To do:

1. Identify all the relevant patient important outcomes for your review.
2. Search for review articles on the specific question or general topic you intend to review.
3. Critically appraise the relevant reviews you find using the course evaluation form.
4. Write a paragraph or two summarizing your review of reviews.
5. Be prepared to discuss:
   a) the search methods you used and the yield
   b) the criteria you used to assess the quality of the reviews
   c) your findings and, in particular
   d) why you should write yet another review on the same topic
6. If you have found a prior review addressing your question, see if you can complete a "summary of findings table" similar to the one of those in the required reading. The Schunemann et. al. paper will help you with this task.
7. Prepare a draft of the section of your review which relates to this session.

UNIT 3: Protocol Formulation and Protocol Development

Introduction:

Now, it is time to get serious about your systematic review. You should be drafting your protocol, including eligibility criteria, specification of all patient-important outcomes, search strategy, methods of assessing validity, what data you want to extract, a priori hypotheses to explain heterogeneity, and an analysis plan.

Learning Objectives:

1. To frame the question which you are asking.
2. To develop your review protocol in detail.

Required Readings:

1. Cochrane Handbook, Chapter 2, Preparing a Cochrane review section 2.1 to 2.3.2 http://www.cochrane-handbook.org/

2. Cochrane Handbook, Chapter 5, Defining the Review Question and Developing Criteria for Including Studies, sections 5.1 to 5.4. http://www.cochrane-handbook.org/

3. Glasziou PP, Sanders SL. Investigating causes of heterogeneity in systematic reviews. Statistics in Medicine 2002;21:1503-1511. http:libaccess.mcmaster.ca/login?url=http://www3.interscience.wiley.com/cgi-bin/fulltext/93521073/PDFSTART

To do:

1. Prepare a detailed protocol for your review in outline form. Make note of all of the issues about which you are uncertain.

2. Develop a realistic plan for completing your review (see time chart on page 15 of the Detailed Outline for an Overview Protocol that follows). Reconsider your objectives for the course in light of your plan and the methodological issues you have identified. Browse through the rest of the course materials, if you have not already done so.

3. If it is relevant to your review (and it very likely is), decide on your a priori hypotheses to explain any heterogeneity you may find.

4. To get the most out of each future session, and to complete your review by the end of the course, your should start working ahead as much as possible; (e.g. make a rough draft of your relevance forms, validity and data extraction forms now, at the same time that you prepare your protocol).

5. Prepare a draft of the section of your overview which relates to this session.

UNIT 4: Identifying and Selecting Studies

Introduction:

Systematic reviews, by their very nature, require an exhaustive search to identify as many relevant studies as possible. There is no magic to searching the literature. It only requires an understanding of the potential sources of information, how to search each source effectively and an awareness of their limitations. Time and patience are also assets. While everyone is excited to move onto the scanning and the data extraction, it is imperative to complete this step correctly to ensure success. If your search is lacking and missing relevant studies, the rest of your review becomes irrelevant. Thus, the search must be thorough, well-designed, and reproducible.

Steps for success: The first step is to begin with a well-designed research question the review seeks to address. Not only can the question guide the scanning process, it can help in constructing the search strategy.

Learning Objectives:

1. To appraise the comprehensiveness and efficiency of various search strategies.
2. To consider alternative strategies for dealing with publication bias and other selection biases.
3. To develop and implement a plan for identifying relevant research for your review.
4. To assess alternative approaches to filing and record keeping.
5. To consider how you will deal with issues of reproducibility of study selection.

Required Readings:

1. Users' Guides to the Medical Literature: A Manual for Evidence-Based Clinical Practice Second Edition. Gordon Guyatt, Drummond Rennie, Maureen O. Meade, Deborah J. Cook. Copyright © 2008 American Medical Association. Chapter 20.1 "Reporting Bias" p. 543-554
2. Cochrane Handbook, Part 2, Chapter 6, Searching for Studies: http://www.cochrane-handbook.org/ ((direct link to chapter: http://www.mrc-bsu.cam.ac.uk/cochrane/handbook/chapter_6/6_searching_for_studies.htm)
3. Searching tips, worksheet, & links to online tutorials (below)
4. Eggar M, Juni P, Bartlett C, Holenstein F, Sterne J. How important are comprehensive literature searches and the assessment of trial quality in systematic reviews? Empirical study. Health Technology Assessment 2003;7(1):1-56. http://www.hta.ac.uk/fullmono/mon701.pdf

To do:

1. Develop a 1 page protocol for how you will identify research for your review and conduct at least one online search for research relevant to your question. How you will decide when it is unlikely that you have omitted any important research from your review?
2. Develop a (1 page) protocol for selecting studies to be included in your overview. Include a precise definition of the following criteria: population(s) of interest, the intervention(s) or exposure(s) of interest, the outcome(s) of interest, and the type of evidence (research design). You might also want to include other criteria such as language of publication and date of publication. If you plan to include indirect evidence as well as direct evidence, state criteria for selecting indirect evidence as well. Be prepared to discuss how selection bias might threaten the validity of your review and how you will protect against this. Your protocol should address the reproducibility of decisions to select studies.

3. Consider the following questions:

   a) What is the potential for publication bias in your area and what, if anything, will you do to protect against a possible publication bias?

   b) What organizations or individuals will you contact, if any to locate research?

   c) What efforts, if any, will you make to identify studies not reported in English?

   d) How will you record the search strategies used, yields, costs (including your time), personal contacts, and rejected studies?

Additional Resources:

Tips on getting started

1. Consider the issues raised on the session outline
2. Complete the worksheet to help create your search strategies (see attached)
3. Complete the online tutorials for tips on searching the databases (see attached for links)
4. Try your first attempt at the search and scan the results
5. Consider the following questions:

   a. Are you missing *known* relevant articles? If so, investigate why your search did not retrieve them.

   b. Is your search too focused thus resulting in little or no hits?

   c. Conversely, is your search too broad thus resulting in too many hits?

6. When searching for study design or research design, try searching for the term(s) in the *publication type* limit first. If the term does not appear, try searching the term as a subject heading. Finally, search the term as a keyword.
7. Go back and modify your original search strategy after reflecting on the results – remember, this is an iterative process.
8. Consider additional sources of information beyond the standard bibliographic databases.
9. Keep records of all your search strategies with clear notes of what worked and what failed

Quick link to potential health databases available at McMaster University:

http://library.mcmaster.ca/articles/results/field_subjects%3A%22Health+Sciences%22

Link to the Health Sciences Library:

http://hsl.mcmaster.ca/

Links to online tutorials

OVID

OVID Tutorials – Health Sciences Library, McMaster University

Ovid Databases: Basic Search
View Online Download file

Ovid Databases: Advanced Searching -- Focus and Explode
View Online - 19" Monitors View Online - 15" Monitors Download file

Ovid Databases: Advanced Searching -- Combining Terms and Using Subheadings
View Online Download file

Orientation to the *search screen* (tutorial from OVID)

http://www.ovid.com/site/help/tutorials_ovidsp/searchPage_demo20080208/searchPage_demo20080208_900.htm

OVID *advance search* overview (tutorial from OVID)
http://www.ovid.com/site/help/tutorials_ovidsp/advanced_demo20080305/advanced_demo20080305_900.htm

Overview of applying *limits* to search (tutorial from OVID)

http://www.ovid.com/site/help/tutorials_ovidsp/limits_demo20080529/limits_demo20080529_900.htm

Overview of *Search Fields* (tutorial from OVID)

http://www.ovid.com/site/help/tutorials_ovidsp/searchFields_demo20080322/searchFields_demo20080220_900.htm

Cochrane Library

Overview of Cochrane Library (by Wiley InterScience)

http://www.cochrane.org.au/libraryguide/

Cochrane Library – tips on advanced and MeSH searching (by Wiley InterScience; free but registration required)

http://www.brainshark.com/wiley/cochrane2

Cochrane Library –searching tips including saving strategies and creating alerts (by Wiley InterScience; free but registration required)

http://www.brainshark.com/wiley/cochrane3

Search Strategy – Worksheet
SAMPLE

Question to be answered:
Are probiotics effective in the treatment of eczema?
Bibliographic Databases to be searched: (e.g. Medline/PubMed, Embase, CINAHL, etc) [hint: list all applicable databases] Medline(PubMed), Embase, CINAHL, Cochrane Central Register of Controlled Trials, etc.
List possible search terms for the major concepts in your question: (e.g. CINAHL/Medical subject headings, keywords, synonyms, etc.)

Protiotics terms:	**Eczema terms:**
Probiotics	atopic dermatitis
Lactobacillus	atopic eczema
Bifidobacterium	Neurodermatitis
Lactococcus	neurodermatitis atopica
Saccharomyces	eczema
streptococcus thermophilus	besniers prurigo
Bacillus subtilis	etc, ...
Enterococcus faecalis	
intestinal microflora	
microbiotica	
etc, ...	

List terms for appropriate study design (evidence)

[hint: your topic will help guide on applicable terms]

RCT or Clinical Trial terms:

Randomized controlled trial

Controlled clinical trial

Double blind method

Single blind method

Clinical trial

Etc., ...

Note possible limits to add to your search, e.g. age, language, date of publication

English, 2000-2008

Construct search strategy:

1. Probiotics
2. Lactobacillus
3. Bifidobacterium
4. Lactococcus
5. Saccharomyces
6. streptococcus thermophilus
7. Bacillus subtilis
8. Enterococcus faecalis/
9. intestinal microflora
10. microbiotica
11. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10
12. atopic dermatitis
13. atopic eczema
14. Neurodermatitis
15. neurodermatitis atopica
16. eczema
17. besniers prurigo
18. 12 or 13 or 14 or 15 or 16 or 17
19. 11 and 18

Add study design filter if applicable [hint: in some databases these terms may be "publication types" limits]

20. Randomized controlled trial
21. Controlled clinical trial
22. Double blind method
23. Single blind method
24. Clinical trial

25. 20 or 21 or 22 or 23 or 24
26. 19 and 25
27. Apply limits if applicable

[note: set 27 is a combination of the major concepts and the study design with the limits added. Typically it is this set result you will work with]

Now you are ready to go online!

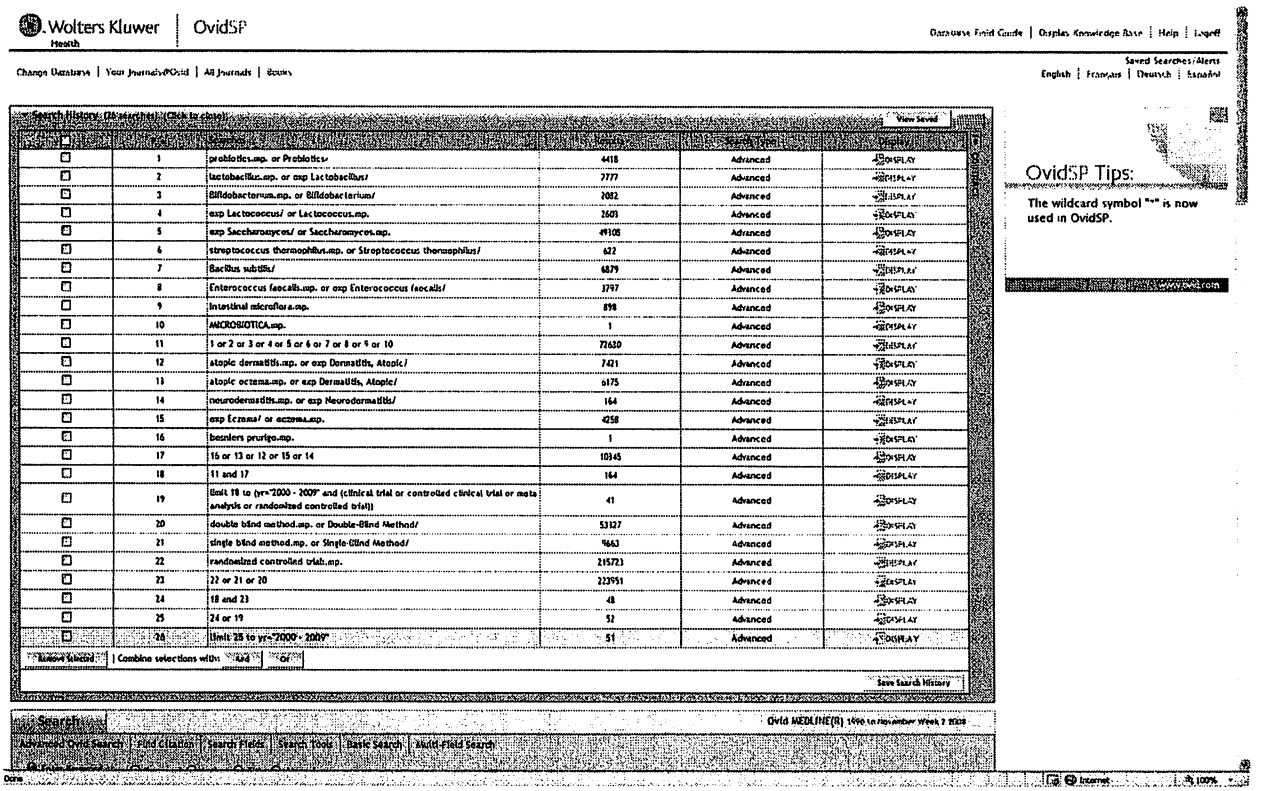
[hint: be sure to search terms both as keywords and as subject headings]

Remember each database is unique! Do not rerun the search from one database in another.

Always keep a copy of the actual search strategy used in each database for your reference and for inclusion in the systematic review.

Final reminder: searching is an iterative process. Your first attempt at the search strategy may require modifications after you review the results.

Below is a screen shot of the search strategy in OVID Medline:



UNIT 5: Quality of Evidence Assessments

Introduction:

Of the five reasons for rating down quality of evidence that GRADE has identified, this unit focuses primarily on study limitations (risk of bias). By the end of this unit, you need to have made a definitive decision regarding how you will assess risk of bias, and have your data forms ready for the exercise.

Learning Objectives:

1. To identify the major threats to the quality of evidence of the research that you are reviewing.
2. To develop an explicit set of criteria for assessing the quality of evidence of the individual studies that you are including, and of the entire body of evidence that bears on your question.
3. To develop a detailed protocol for how you intend to test the reproducibility of your quality evaluations.

Required Readings:

1. Guyatt GH, Oxman AD, Kunz R, Vist GE, Falck-Ytter Y, Schunemann HJ. Rating quality of evidence and strength of recommendations What is "quality of evidence" and why is it important to clinicians?. BMJ 2008;336:995-998 http://libaccess.mcmaster.ca/login?url= http://www.bmj.com/cgi/content/extract/336/7651/995
2. Juni P, Witschi A, Bloch R, Egger M. The hazards of scoring the quality of clinical trials for meta-analysis. JAMA 1999; 282(11):1054-60 http://libaccess.mcmaster.ca/login?url=http://jama.ama-assn.org/cgi/content/full/282/11/1054
3. Whiting P, Rutjes AWS, Reitsma JB, Bossuyt PMM, Kleijnen J. The development of QUADAS: a tool for the quality assessment of studies of diagnostic accuracy included in systematic reviews. BMC Medical Research Methodology 2003; 3: http://libaccess.mcmaster.ca/login?url=http://www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=14606960
4. Cochrane Handbook. Chapter 8, Risk of Bias, Sections 8.2 to 8.5. http://www.cochrane-handbook.org/

To do:

1. Develop a protocol/form for how you intend to evaluate the methodologic quality of the primary studies that you will include in your review. Include precise definitions of each of the criteria you will use. Describe how you will test the reproducibility of your assessments (i.e. inter-judge agreement). What criterion will you use to decide if your assessments are acceptably reproducible?

2. Decide if the GRADE criteria for summarizing the quality of evidence make sense for your review. Consider the following study limitations in direct comparison or indirect comparisons with respect to patients, interventions and outcomes.

3. Be prepared to discuss the rationale for using the criteria you intend to use, how you will summarize the quality of each study and, in particular, the face validity of the criteria; (i.e., will they make sense to readers of your review?)

UNIT 6: Data Collection Forms

Introduction:

If you haven't already done so, it is time to launch into extracting the data from your eligible studies. You need to develop your data collection forms, to clarify where there is likely to be ambiguity or problems in interpreting the form, and to create a document that clarifies any such issues.

Learning Objectives:

1. To develop data collection forms for extracting information from study reports.

2. To consider potential sources of error and bias in extracting information from research reports.

Required Readings:

1. Examples of data collection forms. – see attachment

2. Weaning systematic review data abstraction forms:

    a. general characteristics of studies

    b. data extraction for observational studies

    c. data extraction for RCTs

    d. data extraction for non-RCT=s but controlled intervention studies (CCTs)

3. Buscemi N, Hartling L, Vandermeer B, Tjosvold L, Klassen TP. Single data extraction generated more errors than double data extraction in systematic reviews. J Clin Epid 2006; 59:697-703. http://libaccess.mcmaster.ca/login?url=http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6T84-4JGJJ5K-6&_user=1067350&_rdoc=1&_fmt=&_orig=search&_sort=d&view=c&_acct=C000051241&_version=1&_urlVersion=0&_userid=1067350&md5=97222fefb7c78dc806954b15df9096a3

4. The Cochrane Handbook. Chapter 7, Selecting studies and collecting data. Sections 7.3 to 7.5. http://www.cochrane-handbook.org/

To do:

1. Evaluate the merits and demerits of each data collection form.
2. Prepare your own data collection forms.
3. Prepare a "data dictionary" for the information you will extract from the articles you are reviewing. This document should include a precise definition of each variable you will use in your analysis, and it should specify what you will do when there is missing information.
4. Be prepared to discuss the rationale for your definitions, the relevance of each item on your data collection form to the question(s) your overview addresses (i.e. , how the data will be used), and the major problems (sources of error and bias) that you anticipate relative to extracting data from articles. How will you address the possibility of errors in data abstraction?
5. *Prepare a draft of the section of your overview which relates to this session.*

UNIT 7: Combining the Findings of Independent Studies

Introduction:

In this unit, you should learn the fundamentals of meta-analysis, and the alternative strategies for summarizing the data. You should arrive at a definitive plan for your own data analysis.

Learning Objectives:

1. To consider the advantages, the disadvantages, and the underlying assumptions of alternative quantitative and non-quantitative approaches to synthesizing the findings of the research you are reviewing.
2. To determine how you are going to reach a conclusion regarding your primary question.

Required Readings:

1. Users' Guides to the Medical Literature: A Manual for Evidence-Based Clinical Practice Second Edition. Gordon Guyatt, Drummond Rennie, Maureen O. Meade, Deborah J Cook. Copyright © 2008

American Medical Association. Chapter 7 "Does Treatment Lower Risk? Understanding the Results" p.87-98.

2. Users' Guides to the Medical Literature: A Manual for Evidence-Based Clinical Practice. Second Edition. Gordon Guyatt, Drummond Rennie, Maureen O. Meade, Deborah J Cook. Copyright © 2008 American Medical Association. Chapter 20.2 "Fixed-Effects and Random-Effects Models" p. 555-562.

3. Cochrane Handbook. Analyzing data and undertaking meta-analyses. Sections 9.2.3.- 9.4.10. http://www.cochrane-handbook.org/

To do:

1. Consider the advantages and the disadvantages of different ways of synthesizing research findings relative to your question and decide which analytic approach you are going to use. Consider the following issues.

    a. Will you use a quantitative technique (meta-analysis)?

    b. What parameters will you use to summarize each study (e.g. relative risk, risk difference, odds ratio, effect size, p value, hazard ratio, likelihood ratio)?

    c. If you are going to use a statistical technique to combine the results of the studies you have reviewed, which technique will you use? Will you use a fixed or random effects model?

    d. Confirm you're a priori hypothesis to explain any heterogeneity you may find

    e. Will you test for a potential publication bias? If so, how?

2. Prepare a draft of the section of your overview which relates to this session.

UNIT 8: Measuring Disagreement/Quantitatively Combining Research Findings

Introduction:

This unit focuses on the practical aspects of conducting the analyses associated with your study. The minor part is the statistical evaluation of agreement regarding eligibility and quality assessments, the major part any meta-analyses that you will undertake.

Learning Objectives:

1. To consider and measure the reproducibility of decisions about what research to include in your review.
2. To familiarize yourself with software to calculate measures of reliability.
3. To familiarize yourself with computer programs that perform meta-analyses.
4. To consider interpretations of the results of quantitative meta-analyses.
5. To examine methods of presenting the results of meta-analyses.

Required Readings:

1. Streiner DL, Norman GR. Reliability. In: Principles and Applications of Measurement for the Health Sciences, Oxford: Oxford University Press, 1989.
2. Walter SD, Cook RJ. Documentation for PC-Agree (version 2.5): A PC Program for the Analysis of Interobserver Variation, Hamilton, Ontario: McMaster University, 1988. see attachment
3. Meade MO, Cook RJ, Guyatt GH, Groll R, Kachura JR, Bedard M, Cook DJ, Slutsky AS, Stewart TE. Interobserver variation in interpreting chest radiographs for the diagnosis of acute respiratory distress syndrome. Am J Respir Crit Care Med 2000;161:85-90. http://libaccess.mcmaster.ca/login?url=http://ajrccm.atsjournals.org/cgi/reprint/161/1/85
4. Fleiss, JL. The statistical basis of meta-analysis. Statistical Methods in Medical Research 1993;2:121-145. http://libaccess.mcmaster.ca/login?url=http://smm.sagepub.com/content/vol2/issue2/

To do:

1. Calculate kappa and phi for the observed agreement of your study results.
2. Perform meta-analyses in Review Manager, using examples of both dichotomous and continuous examples of data. Create forest plots, funnel plots and provide interpretations.

UNIT 9: Variation between Study Findings

Introduction:

You will inevitably find that there is variability in the results across the eligible studies in your review. Can this variation be explained by chance? If not, can any of your a priori hypotheses regarding heterogeneity explain the variation? If you believe that one or more hypotheses can explain the results, you have to decide just how credible these sub-group analyses are.

Learning Objectives:

1. To identify potential sources of variation among the findings of the studies you are reviewing.
2. To determine if this variation is greater than what you would expect due to chance alone.

Required Readings:

1. Users' Guides to the Medical Literature: A Manual for Evidence-Based Clinical Practice. Second Edition. Gordon Guyatt, Drummond Rennie, Maureen O. Meade, Deborah J Cook. Copyright © 2008 American Medical Association. Chapter 20.3 "Making Sense of Variability in Study Results" p 563-570.
2. Users' Guides to the Medical Literature: A Manual for Evidence-Based Clinical Practice. Second Edition. Gordon Guyatt, Drummond Rennie, Maureen O. Meade, Deborah J Cook. Copyright © 2008 American Medical Association. Chapter 20.4 "When to Believe a Subgroup Analysis" p. 571-596.
3. Thompson SG, Higgins JPT. How should meta-regression analyses be undertaken and interpreted? Stat Med 2002; 21:1559-1573. http://libaccess.mcmaster.ca/login?url=http://www3.interscience.wiley.com/cgi-bin/fulltext/93521074/PDFSTART
4. Cochrane Handbook. Analyzing data and undertaking meta-analyses. Section 9.5. http://www.cochrane-handbook.org/

To do:

1. Look back at your a priori hypotheses to explain heterogeneity. Do they indeed explain heterogeneity? In particular, do the relevant statistical tests (comparison of studies that fall into one sub-group or another, or meta-regression) suggest any compelling explanations of heterogeneity?
2. Decide if you are going to use any or all of; I2 without a confidence interval, I2 with a confidence interval, or the conventional test for heterogeneity that generates a p-value.
3. Check how well any factors that explain heterogeneity meet the seven criteria for a credible sub-group analysis.

UNIT 10: Summarizing and Interpreting Results

Introduction:

This unit focuses on creating the evidence profiles and summary of findings tables that will be the key output of your review in terms of making it optimally useful to clinical, consumer, and decision-making audiences.

Learning Objectives:

1. To consolidate your understanding of the evidence profiles, and "summary of findings" tables.
2. To evaluate the extent to which you have substantiated any inferences that you make based on your review.

Required Readings:

1. Cochrane handbook. Presenting results and 'Summary of findings' tables. Chapter 11: http://www.cochrane-handbook.org/
2. Cochrane handbook. Interpreting results and drawing conclusions. Chapter 12: http://www.cochrane-handbook.org/
3. Examples of evidence profiles and summary of findings tables. See slides

To do:

1. If your review addresses the impact of an intervention on patient important outcomes (or you make inferences about the impact on patient-important outcomes from findings on surrogate outcomes) decide on the quality of the evidence for each outcome using the GRADE system as part of your summary of findings table.
2. Prepare clear and succinct (one sentence) statements of the most important inferences (conclusions) from your overview.
3. Be prepared to discuss the strength of your inferences and the practical implications of the inferences that you make.
4. Prepare a draft of the section of your overview which relates to this session.

McMaster University

SCHOOL OF GRADUATE STUDIES

RECOMMENDATION FOR CHANGE IN GRADUATE CURRICULUM - FOR CHANGE(S) INVOLVING COURSES

PLEASE READ THE FOLLOWING NOTES BEFORE COMPLETING THIS FORM:

1. This form must be completed for **ALL** course changes. All sections of this form **must** be completed.
2. An electronic version of this form must be emailed to the Assistant Secretary and SynApps System Administrator (Email: *espiritu@mcmaster.ca*).
3. A representative from the department is required to attend the Faculty Curriculum and Policy Committee meeting during which this recommendation for change in graduate curriculum will be discussed.

DEPARTMENT/PROGRAM	ECONOMICS / HRM			
COURSE TITLE	Topics in Advanced Health Economics			
COURSE NUMBER	791	**COURSE CREDIT**		
		FULL COURSE ( )	**HALF COURSE (X)**	**QUARTER (MODULE) ( )**
INSTRUCTOR(S)	P. Contoyannis, J. Hurley, E. Tompa, J. Tarride			
PREREQUISITE(S)				

NATURE OF RECOMMENDATION ***(PLEASE CHECK APPROPRIATE BOX)***

NEW COURSE		**DATE TO BE OFFERED:**	**WAS THE PROPOSED COURSE OFFERED ON DEAN'S APPROVAL? IF YES, PROVIDE THE DATE:**

WILL THE COURSE BE CROSS-LISTED WITH ANOTHER DEPARTMENT? IF YES, ATTACH TO THIS FORM ANY RELEVANT CORRESPONDENCE WITH THE OTHER DEPARTMENT(S). NOTE: CROSS-LISTING OF COURSES REQUIRES APPROVAL FROM EACH DEPARTMENT AND FACULTY CONCERNED.

CHANGE IN COURSE TITLE		**PROVIDE THE CURRENT COURSE TITLE:**				
CHANGE IN COURSE DESCRIPTION	X	**600-LEVEL COURSE** ***(Undergraduate course for graduate credit) Please see #4 on page 2 of this form***				
CHANGE TO FULL COURSE		**CHANGE TO HALF COURSE**		**CHANGE TO QUARTER COURSE**		
COURSE CANCELLATION		**PROVIDE THE REASON FOR COURSE CANCELLATION:**				
OTHER	X	**EXPLAIN:** Cross list with ECONOMICS 791				

BRIEF DESCRIPTION FOR CALENDAR - Provide a brief description *(maximum 6 lines)* to be included in the Graduate Calendar.

This course focuses on contemporary issues relating to the economics of health and health care. It is intended to provide a more detailed examination of selected issues from Econ/HRM 788 as well as expose students to more advanced topics and aspects of recent research in health economics. Topics may include economic evaluation, the economics of occupational health and safety, evaluation of health-care related interventions, advances in the empirical analysis of income and health inequalities, and the evolution of health from childhood to adulthood.

CONTENT/RATIONALE - Provide a brief description, i.e., outline the topics or major sub-topics, and indicate the principal texts to be used.

1. STATEMENT OF PURPOSE (How does the course fit into the department's program?)
2. EXPECTED ENROLMENT:
3. DESCRIBE IN DETAIL THE METHOD OF PRESENTATION OF COURSE MATERIAL (i.e., lectures, seminars):
4. DESCRIBE IN DETAIL THE METHOD OF EVALUATION: (For 600-level course, indicate the <u>Extra Work</u> to be required of graduate students, i.e., exams, essays, etc.)
5. TO PREVENT OVERLAP, IS A COURSE IN THE SAME OR A RELATED AREA OFFERED IN ANOTHER DEPARTMENT? IF YES, PLEASE ATTACH TO THIS FORM ANY RELEVANT CORRESPONDENCE WITH THE OTHER DEPARTMENT(S).
6. IF THE COURSE IS INTENDED PRIMARILY FOR STUDENTS OUTSIDE YOUR DEPARTMENT, DO YOU HAVE THE SUPPORT OF THE DEPARTMENT/PROGRAM CONCERNED?
PLEASE PROVIDE THE CONTACT INFORMATION FOR THE RECOMMENDED CHANGE: Name: Lonnie Magee Email: magee@mcmaster.ca Extension: 23805 Date: February 17, 2008

If you have any questions regarding this form, please contact the Assistant Secretary and SynApps System Administrator, School of Graduate Studies, extension 24204.

SGS/December 2006

McMaster University

SCHOOL OF GRADUATE STUDIES

RECOMMENDATION FOR CHANGE IN GRADUATE CURRICULUM - FOR CHANGE(S) INVOLVING COURSES

PLEASE READ THE FOLLOWING NOTES BEFORE COMPLETING THIS FORM:

1. This form must be completed for **ALL** course changes. All sections of this form **must** be completed.
2. An electronic version of this form must be emailed to the Assistant Secretary and SynApps System Administrator (Email: *espiritu@mcmaster.ca*).
3. A hard copy of this form **must be signed** by the department chair or graduate advisor and sent to the Assistant Secretary and SynApps System Administrator, School of Graduate Studies, GH-212.
4. A representative from the department is required to attend the Faculty Curriculum and Policy Committee meeting during which this recommendation for change in graduate curriculum will be discussed.

DEPARTMENT/PROGRAM	Faculty of Health Sciences, Medical Sciences Graduate Program			
COURSE TITLE	Vascular Diseases, Hemostasis and Thrombosis II			
COURSE NUMBER	MS733	**COURSE CREDIT**		
		FULL COURSE ( )	**HALF COURSE (X)**	**QUARTER (MODULE) ( )**
INSTRUCTOR(S)	Dr. Patricia Liaw, email pliaw@thrombosis.hhscr.org			
PREREQUISITE(S)	undergraduate biology, biochemistry, or equivalent			

NATURE OF RECOMMENDATION ***(PLEASE CHECK APPROPRIATE BOX)***

NEW COURSE		**DATE TO BE OFFERED:** September 2009	**WAS THE PROPOSED COURSE OFFERED ON DEAN'S APPROVAL?** No **IF YES, PROVIDE THE DATE:**

WILL THE COURSE BE CROSS-LISTED WITH ANOTHER DEPARTMENT? No **IF YES, ATTACH TO THIS FORM ANY RELEVANT CORRESPONDENCE WITH THE OTHER DEPARTMENT(S). NOTE: CROSS-LISTING OF COURSES REQUIRES APPROVAL FROM EACH DEPARTMENT AND FACULTY CONCERNED.**

CHANGE IN COURSE TITLE		**PROVIDE THE CURRENT COURSE TITLE:**			
CHANGE IN COURSE DESCRIPTION		**600-LEVEL COURSE** ***(Undergraduate course for graduate credit)*** ***Please see #3 on page 2 of this form***			
CHANGE TO FULL COURSE		**CHANGE TO HALF COURSE**		**CHANGE TO QUARTER COURSE**	
COURSE CANCELLATION		**PROVIDE THE REASON FOR COURSE CANCELLATION:**			
OTHER		**EXPLAIN:** There will be a change in the method of evaluation. There will also be a change in the course content (approximately 70% is the same as the previous course and 30% will be new material)			

BRIEF DESCRIPTION FOR CALENDAR - Provide a brief description *(maximum 6 lines)* to be included in the Graduate Calendar.

MS733 is a graduate course which is directed largely to the needs of students in the "Blood and Vasculature" area of the Medical Sciences Graduate Program, although other graduate students in Medical Sciences, Biomedical Engineering, or Biochemistry are welcome to attend. The subject areas covered in this course include evolution of the hemostatic system, the endothelium as an organ system, venous thrombosis, the microcirculation, animal models, intravital microscopy, vasculogenesis, angiogenesis, and atherosclerosis.

CONTENT/RATIONALE - Provide a brief description, i.e., outline the topics or major sub-topics, and indicate the principal texts to be used.

Primary research articles and recent peer-reviewed review articles will be used. The major sub-topics in this course are:

-The Evolution of Hemostasis
- The Endothelium as an Organ System
- The Microcirculation
-Venous Thromboembolism Overview
-Venous Thromboembolism and Cancer
-Animal models and intravital microscopy
- Vasculogenesis and Angiogenesis
- Atherosclerosis I (Diabetes)
-Atherosclerosis II (Hypertension and Dyslipidemia)

1. STATEMENT OF PURPOSE (How does the course fit into the department's program?)

The purpose of this course is to provide students with an understanding of the range of mechanisms, from the gene to the tissue level, involved in the pathogenesis of vascular diseases. This course will deal with the basic mechanisms of haemostasis which take place at the blood vessel wall with focus on the processes of blood coagulation, venous thromboembolism, atherosclerosis, and angiogenesis. The course will draw upon the expertise of faculty members within the Experimental Thrombosis and Atherosclerosis group at the Henderson Research Centre and at McMaster University.

2. EXPECTED ENROLMENT:

Minimum 4, maximum 14, MSc and PhD students

3. DESCRIBE IN DETAIL THE METHOD OF PRESENTATION OF COURSE MATERIAL (i.e., lectures, seminars):

Lectures will be given by Dr. Patricia Liaw and 5 to 6 other faculty members. Each topic will be introduced by the faculty expert lecturer (1 hour presentation). Following the faculty presentation, there will be a critical appraisal of 2-3 primary articles. Two relevant review articles and the primary articles will be distributed to the students 1 week prior to the start of each class.

4. DESCRIBE IN DETAIL THE METHOD OF EVALUATION: (For 600-level course, indicate the Extra Work to be required of graduate students, i.e., exams, essays, etc.)

Class participation (20%)
Oral presentation (30%)
Two take-home essays (25% each)

5. TO PREVENT OVERLAP, IS A COURSE IN THE SAME OR A RELATED AREA OFFERED IN ANOTHER DEPARTMENT? IF YES, PLEASE ATTACH TO THIS FORM ANY RELEVANT CORRESPONDENCE WITH THE OTHER DEPARTMENT(S).

No

6. IF THE COURSE IS INTENDED PRIMARILY FOR STUDENTS OUTSIDE YOUR DEPARTMENT, DO YOU HAVE THE SUPPORT OF THE DEPARTMENT/PROGRAM CONCERNED?

N/A

PLEASE PROVIDE THE CONTACT INFORMATION FOR THE RECOMMENDED CHANGE:

Name: Patricia Liaw Email: see above Extension: 43782

Department Chair or Graduate Advisor: _____ Date: _____
(Signature)

If you have any questions regarding this form, please contact the Assistant Secretary and SynApps System Administrator, School of Graduate Studies, extension 24204.

SGS/November 2005

MS733 Course Schedule ("Vascular Diseases, Hemostasis, and Thrombosi II")

Course Co-Ordinator: Dr. Patricia Liaw
Instructors: Drs. Lim, Linkins, Fox-Robichaud, Gross, Gyorffy, Werstuck, Rashid, Shaughnessey

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MS733 will be offered in September, 2009. This course schedule includes the titles of the twelve weekly sessions, details of the evaluation procedure and the proposed distribution of marks for student performance (i.e. a 30-min seminar, two 'take-home' essays, and class attendance/participation; see below for details), and a list of recommended reference texts. Throughout the course, Dr. Liaw will attend **all sessions** to assess student performance. In addition, she may be reached throughout the course by either telephone or e-mail (pliaw@thrombosis.hhscr.org or 905-527-2299 Ext 43782).

MS733 will be offered on **Monday afternoons (12:00 p.m. - 3:00 p.m.)** starting **September 21, 2009**. **All sessions will be held in the Henderson Research Centre 2nd Floor Conference room.** Generally, sessions throughout the course will begin with a lecture (usually 1h with 10-20 min for discussion). This will be followed by either a critical appraisal of 2 to 3 primary research papers, or by student seminars (each 20-25 min with 10-15 min for discussion).

Class topics:

Session 1 (Sept. 21)	"Control of blood loss and the evolution of hemostasis" (Liaw)
Session 2 (Sept 28)	"The endothelium as an organ system" (Liaw)

[N.B. TAKE-HOME ESSAY #1: TITLES WILL BE HANDED OUT SEPT 28, ESSAY TO BE HANDED IN OCT 26]

Session 3 (Oct. 5)	"Venous Thromboemoblism- Overview" (Lim)
October 12	NO CLASS, Thanksgiving Monday
Session 4 (Oct 19)	"Venous Thromboembolism and Cancer" (Liaw, Linkins)
Session 5 (Oct 26)	"The Microcirculation" (Fox-Robichaud)
Session 6 (Nov. 2)	"Animal Models and Intravital Microscopy" (Gross)

[N.B. TAKE-HOME ESSAY #2: TITLES WILL BE HANDED OUT NOV 2; ESSAY #2 TO BE HANDED IN NOV. 30]

Session 7 (Nov. 9)	"Vasculogenesis and Angiogenesis" (Gyorffy)
Session 8 (Nov. 16)	"Atherosclerosis and Diabetes" (Werstuck)
Session 9 (Nov. 23)	"Atherosclerosis, Hypertension, and Dyslipidemia" (Rashid)
Session 10 (Nov. 30)	"Vascular Calcification" (Shaughnessey)
Session 11 (Dec. 7)	"Hemostasis and the Immune System" (Liaw)

Seminar Presentations:

Each student will give one **20- 25-min seminar** and issue a **prepared 1-2 page handout (examples available on request)**. A photocopy of **at least one relevant recently-published paper** is provided to the student **speaker** one week before their presentation; in addition, another student will be appointed as **'discussant'** at the time of the presentation. The speaker will be expected to study the paper (and other appropriate papers as necessary) and produce a critical evaluation of the topic for presentation the following week. During the presentation, the speaker should try to present their information in their own words and NOT merely read the information on the screen! Each talk (**20 min MINIMUM; 25 min MAXIMUM**) will be uninterrupted. When the talk is finished, the **'discussant'** will be selected from the audience to lead the discussion. The discussant may give a brief (**1-2 min**) summary of his/her perceptions of the paper (not of the speaker's talk!) and will put the first question(s) to the speaker. Thereafter, the discussion/question time will be thrown open to the audience.

In addition to giving the seminar, the student speaker will prepare for each member of the class a short handout covering the principal features of the talk. The handout will consist of **no more than 2 pages** of annotated points including Figures and Tables as required.

Assessment of the speaker's performance: 1 or 2 faculty members will assess each student speaker with respect to: (a) the presentation (e.g. the quality of delivery, the slides and the handout); (b) the content of the talk and the student's understanding of the subject, including a critique, and his/her adeptness at handling questions; (c) the ability of the student to summarise the topic and to predict questions for future research. **Dr. Liaw will email the speaker (usually within 48 hours) a written assessment and a grade.**

Take-Home Essays:

Students will have 4 weeks to complete take-home essays # 1 and # 2. Each essay should consist of **no less than 5 and no more than 6 pages** of text (written in prose style, double-spaced) **excluding** references, Figures and Tables; unlimited references. Each essay will be marked by two faculty members.

For essay # 1, a choice of essay titles will be handed to you in session 2 (**September 28)** and the completed essays should be handed in during session 6 **(October 26)**. Marked essays will be returned to you as soon as they have been marked (probably by mid November). For essay # 2, a choice of titles will be handed out during session 6 **(November 2)** and completed essays should be handed in during session 10 **(November 30).** Marked essays will be returned to you in early January, 2007.

Class Participation:

Dr. Liaw will apportion marks for attendance and, particularly, **participation in class discussions (including the role of 'discussant')**.

Final Assessment:

The final mark and grade for the course will be determined as the sum of marks awarded for the two take-home essays (25% each), for the seminar (30%), and for class participation (20%). Dr. Liaw will calculate the final marks after the course has finished and inform students of their final grade by e-mail early in term 2.

Suggested Reading Materials:

A list of relevant reviews appropriate to each session (as supplied by the instructors) will be given to students registered for this course during week 1. If students have problems accessing some of these references, please contact Dr. Liaw for PDF versions of these papers. You are urged to read these papers (or other relevant reviews that you may find) before class. In addition, support materials (i.e. 'powerpoint' slides) for the lectures will also be available on 'Learnlink' at least 48h before each scheduled lecture.

To: Carl Richards
From: Mita Giacomini
Re: **Responses to GPCC queries about proposed Health Policy PhD comp exam policies**
Date: 8 June 2009

Thank you for forwarding the feedback from the last GPCC meeting. This was discussed at our last Advisory Committee meeting on May 6. I have attached a revised comprehensive examination policy for the Health Policy PhD program, and respond to specific GPCC concerns below. I look forward to attending the June 10 GPCC meeting and can clarify any additional points then.

Re: Need to specify methods for evaluation (pass, fail, pass with distinction).
We agree with these 3 proposed levels and have revised the document accordingly; see new section for each exam titled "Evaluation" (changes highlighted in blue).

Re: Clarity on relationship of topics to thesis.
Exam questions are developed by program faculty members to assess students' mastery of key program content areas. Any relationship between a given exam question and an individual student's envisioned thesis topic would be incidental. Relevance (or not) to students' thesis topics is not a criterion for either developing the questions or marking the answers.

Re: Whether this process might be too labour intensive for faculty or students.
The process follows closely on comp exam formats used in other departments (reading list load follows Sociology's standards; in-class administration and number of exams follows Economics'). The process is similar to those used in by model Health Policy programs in the U.S. (Berkeley & Harvard). We don't expect it to be more burdensome for students or faculty than, for example, HRM PhD comps. However, we will monitor this issue and consider revising the process if it seems unexpectedly onerous in practice.

Re: The procedure if a student fails any part of the exam.
The document has been revised to describe this procedure; see new section for each exam titled "Evaluation" (changes highlighted in blue). Each of the 3 exams (breadth field, methodology, and specialty field) must be passed for the student to advance to candidacy. Within the breadth and methodology exams, each of the core curriculum areas (for breadth: social org, political studies, health econ; for methods: quantitative methods, qualitative methods, and mixed/general methods) constitutes failure of that exam. In the case of failure, one opportunity for re-examination will be offered within a reasonable timeframe, and must be completed and marked before the student reaches the 24th month in the program. A second failure would entail withdrawal from the program.

Re: Rationale for no oral component:
The written exam covers core competencies. It is taken in-class, so there is no need to verify that that the student can think about the issues on his/her feet, or that the work is the student's own. Many programs across campus do not require an oral component to the doctoral comprehensive exam.Please note that, in addition to the comprehensive exam requirement, the Health Policy PhD has a separate requirement that each student formally present a dissertation proposal to the Doctoral Seminar in Health Policy in the Fall of their 3rd year. We had considered making this a formal part of the comprehensive exam process, but the SGS requirement that students complete and pass exams by the end of the 24th month means the timing wouldn't work (that is, students in their second year should not be concurrently completing their 3 comp exams, taking fulltime coursework, <u>and</u> preparing a presentable a dissertation proposal on which they would be examined).

Health Policy Ph.D. Program Comprehensive Exam Process

DRAFT, not for distribution to students – changes highlighted in blue

version of 7 June 2009

Introduction

The purpose of the comprehensive examination is to demonstrate that the student (1) has mastered and retained essential knowledge in each of the three major curriculum areas (breadth fields, methods, and specialty field), (2) is able to integrate material across these areas appropriately and effectively in this interdisciplinary field, and (3) is able to apply theory and methods to the analysis of current issues and problems in health policy.

Comprehensive examinations are completed when the student has completed all required coursework in the area being examined. All exams all should be completed by the end of the first 24 months of full-time doctoral studies. The current Graduate Calendar should be consulted for additional university-wide policies concerning comprehensive examinations.

Timing & Format of the Comprehensive Examinations

Comprehensive Examinations are normally be offered once per year in each major curricular area (breadth fields, methods, and specialty field), according to the schedule below. For each area, an alternate exam may be offered in some years as necessary to accommodate exceptional circumstances (e.g., for students who fail their first attempt, or to accommodate delayed offerings of key breadth courses).

Examination I:	**BREADTH FIELDS: SOCIAL ORGANIZATION, HEALTH ECONOMICS, AND POLITICAL STUDIES**
Who takes this exam:	All first-year students in all fields
Month and Year of regular exam [alt.]:	June Year 1 *(exception: for 2008-09 incoming cohort, December Year 2)* [December Year 2]
Preparation:	A reading list for preparation is posted the October prior to the regularly scheduled exam (~8 mos. prior) *(exception: for 2008-09 incoming cohort, reading list will be posted March 2009).*
Format of exam:	One 5 hr sit-down exam is given on campus; short answer, short essay format
Examiners:	HP Program Comps Committee, all fields (social organization, health economics, political studies)

Evaluation:	The exam will be assigned one of three marks: Pass, Pass with Distinction, or Fail Each exam is marked by two faculty members with expertise in the area examined. In the case of conflicting marks, a third examiner marks to break the tie. To pass this breadth exam, the student must receive passing marks in all 3 content areas: social organization, health economics, and political studies. In case of failure, there will be an opportunity to re-take the exam on the alternate date for that year, and before the end of the first 24 months of fulltime enrollment in the PhD program. In the case of a second failure, the student would be asked to withdraw from the program.

Examination II:	**METHODS**
Who takes this exam:	All first-year students in all fields
Month and Year of regular exam [alt.]:	February of Year 2 [April of Year 2]
Preparation:	A reading list for preparation is posted the June of the academic year prior to the regularly scheduled exam (~8 mos. prior).
Format of exam:	One 4 hr sit-down exam is given on campus; short answer, short essays format
Examiners:	HP Program Comps Committee, members representing expertise in both qualitative and quantitative methodologies
Evaluation:	The exam will be assigned one of three marks: Pass, Pass with Distinction, or Fail Each exam is marked by two faculty members with expertise in the area examined. In the case of conflicting marks, a third examiner marks to break the tie. To pass this methods exam, the student must receive passing marks in all 3 content areas: quantitative methods, qualitative methods, and mixed/general methods.

	In case of failure, there will be an opportunity to re-take the exam on the alternate date for that year, and before the end of the first 24 months of fulltime enrollment in the PhD program. In the case of a second failure, the student would be asked to withdraw from the program.
Examination III:	**SPECIALTY FIELDS: SOCIAL ORGANIZATION, HEALTH ECONOMICS, OR POLITICAL STUDIES**
Who takes this exam:	Each second-year student takes 1 exam in his/her field
Month and Year of regular exam [alt.]:	May of Year 2 [July of Year 2]
Preparation:	A reading list for preparation is posted the October prior to the regularly scheduled exam (~7 mos. prior).
Format of exam:	One 4 hr sit-down exam for each field is given on campus; short answer, short essay format
Examiners:	HP Program Comps Committee members in each specialty field (field leader + 2 HP faculty members in that field) administer each relevant field exam
Evaluation:	The exam will be assigned one of three marks: Pass, Pass with Distinction, or Fail Each exam is marked by two faculty members with expertise in the area examined. In the case of conflicting marks, a third examiner marks to break the tie. In case of failure, there will be an opportunity to re-take the exam on the alternate date for that year, and before the end of the first 24 months of fulltime enrollment in the PhD program. In the case of a second failure, the student would be asked to withdraw from the program.

Health Policy PhD Program Comprehensive Examining Committee

- The Health Policy PhD Program Comprehensive Examination Committee consists of each of the program field leaders on the Health Policy PhD Program Advisory Committee (3 fields), plus additional 2 HP faculty members who represent each field. It is possible for one faculty member (other than the field leader) to represent more than one field, depending on declared area(s) of expertise.

- Health Policy PhD Program Comprehensive Examination Committee members are appointed to serve for 3-year terms.

- Additional faculty members may be appointed as necessary to achieve at least 3 faculty members with adequate expertise in each of the 3 general methodology areas (quantitative, qualitative, and mixed or general methods).

- The Health Policy PhD Program Comprehensive Examination Committee, with input from Health Policy PhD Program faculty and the Health Policy PhD Program Advisory Committee, prepares annual comprehensive examination reading lists and exam questions, and marks the exams.

- Each exam is marked by two faculty members with expertise in the area examined. In the case of conflicting marks, a third examiner marks to break the tie.

Comprehensive Examination Reading Lists

- Reading lists for study and preparation of the *breadth field* and *specialty field* examinations are normally posted for students in October each academic year. Reading lists for the *methodology* examinations are posted in June.

- Examination questions are developed primarily from material on the reading list. Additional reading material may be presented for analysis in the context of the exam.

- The Health Policy PhD Program Comprehensive Examination Committee updates and revises the reading lists for each examination area every 1-2 years. An archive of readings in the field and relevant program courses is maintained by the program for the Committee to draw upon. All Health Policy faculty members are invited to contribute to this archive.

- Core reading lists for the Health Policy PhD Program comprehensive examinations are selective. Students are encouraged to be well-read beyond the core study list and to draw on additional material from their training, as appropriate, for the exam.

- The reading lists is comprised of the following (note: following on conventions used by other graduate programs at McMaster University, 1 unit is equivalent to 1 journal article or book chapter, and 1 book is equivalent to 5 units):

    - Breadth fields: 60 units (20 units in each of the three breadth field areas);

- Specialty field: 80 units in the student's specialty field area (20 of which would be considered core breadth readings for a non-specialist, i.e., are included in the 60 units of breadth field readings, above)

- Qualitative methods: 15 units

- Quantitative methods: 15 units

- Mixed/general/interdisciplinary empirical methods: 15 units