Department of Epidemiology and Biostatistics

CLINICAL EPIDEMIOLOGY
EPIDEMIO 4320A/9562A

FALL 2017

Janet Martin, PharmD, MSc(HTA&M)
Associate Professor, Department of Anesthesia & Perioperative Medicine
and Department of Epidemiology & Biostatistics
Director, Centre for Medical Evidence, Decision Integrity & Clinical Impact (MEDICI),
London Health Sciences Centre, St. Josephs Health Care, Lawson Health Research Institute,
and Schulich School of Medicine & Dentistry

Monday: 12:30-2:30pm (Room FNB 2220)
Wednesday: 2:30-3:30pm (Room STVH 3101)
TA: Josh Cerasuolo (jcerasuo@uwo.ca)
TA Office hours: By appointment
TA Tutorials: By request
Office: University Hospital, Room B3-412
Email: jmarti83@uwo.ca
Tel: 519-685-8500 x34482
Office hours: By appointment

Contributing Lecturers & Curriculum Development Committee
Thanks to Dr. Philip Jones, MD, MSc, FRCPC, Associate Professor, Department of Anesthesia & Perioperative Medicine, Western University, who contributes to lectures on prognosis, diagnosis, screening, and research integrity. Other guest lecturers may contribute to case discussions, depending on their availability. Thanks too to our newly formed Clin Epi Curriculum Development Committee, comprised of alumni from the last 3 years of the course, who will contribute to refining content and cases, incorporating your feedback, and further developing tools and teaching techniques.

Course Description
Students in this course develop basic and intermediate skills required for critical evaluation of the evidence from clinical studies to support evidence-informed decision-making in health care. Through a combination of lectures, videos, and interactive case-based approaches, students will find, filter, interpret and apply evidence from the scientific literature to inform decisions about individual patients (patient-level clinical decision-making) and about groups of patients (population level health policy-making).

Using a combination of cases from the real world of clinical practice and scenarios from published studies and popular media, students will interact with each other in small-group case discussions and team-based learning. Group activities will be interjected by mini-didactics to clarify concepts from the required readings. Students will be required to complete readings, evidence explorations, and assignments before class. They will be expected to demonstrate ability to apply the concepts from the readings during class. Evaluation will be highly dependent on participation, supplemented by quizzes, and assignments.
Course Information

Undergraduate pre-requisites: Biostatistics 3100A and Epidemiology 3200A.

Unless you have either the requisites for this course or written special permission to enroll in it, you may be removed from this course and it will be deleted from your record. Undergraduate students may seek permission from the Undergraduate Chair and graduate students may do so through the Graduate Chair. This decision may not be appealed. You will receive no adjustment to your fees in the event that you are dropped from a course for failing to have the necessary prerequisites or permissions.

Course Syllabus

Learning Objectives:

Upon successful completion of this course, students will be able to:

1. Describe the role of ‘evidence’ in decision-making in health care, and define the role of uncertainty in relationship to ‘evidence’.
2. Compare and contrast evidence-informed decision-making versus other forms of decision making for individual patients and for groups of patients.
3. Define and identify different types of bias in clinical research, and describe the role of appropriate study design and analysis to reduce the risk of bias.
4. Identify and formulate different types of clinical questions and policy questions in health care (diagnosis, prognosis, screening and prevention, therapy, harm).
5. Choose the best level of evidence to address different clinical and policy questions (case series, cohort studies, case-control studies, randomized controlled trials, systematic reviews, meta-analyses, economic analyses, health technology assessments, health policy analyses).
6. Critically appraise different types of studies (prognosis, diagnosis, therapy, harm, screening and prevention, meta-analysis, systematic review, health technology assessment, and cost-effectiveness analysis).
7. Apply evidence from different study types to resolve case-based clinical questions and policy scenarios.
8. Create and apply risk of bias tables and summary of findings tables using the GRADE approach to formulate evidence-informed recommendations for clinical scenarios.
9. Describe limitations in the evidence base, and the interdisciplinary role of epidemiologists, biostatisticians, clinical epidemiologists, clinicians, and policymakers to continuously improve the evidence base and its application.
10. Describe the barriers and facilitators of getting evidence from clinical studies into real world practice (knowledge translation: from evidence to impact).

Course Materials

Required Textbook:


Note: The text will be available from the bookstore. Be careful to buy the manual for evidence-based clinical practice and NOT the “essentials” of evidence-based clinical practice (which is a shorter version, also by Gordon Guyatt).

Optional Textbook:


Electronic Devices:

Laptops and internet-enabled devices are recommended for in-class use, and will also be useful during group exercises and between-class group work. Access to video-recording devices is recommended for selected out-of-class assignments and for submitting vlogs.
Methods of Evaluation

40% Participation + 50% Assignments + 10% Quizzes

**Participation (40%)**

Attendance in class is expected. The professor and TA should be notified of any extenuating circumstances that preclude a student from attending class. Active participation during interactive case discussions, lectures, and group assignments is expected. In addition, active participation in team-based case preparation between classes is expected. Readings and recommended videos should be reviewed prior to class so that the student is prepared to contribute to class discussion. As appropriate, student-initiated and instructor-initiated online discussions on OWL and the voluntary submission of student teaching or reflections by vlog/blog will also be considered in the participation grade.

**Participation Rubric** (the following are typical milestones along a continuum of possible grades):

<table>
<thead>
<tr>
<th>Rubric benchmarks</th>
<th>Unsatisfactory</th>
<th>Satisfactory</th>
<th>Very Good</th>
<th>Excellent</th>
<th>Brilliant</th>
<th>Max. Mark</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attendance</td>
<td>Attends &lt; 65% of classes</td>
<td>Attends 65-75% of classes</td>
<td>Attends 75-85% of classes</td>
<td>Attends 85-95% of classes</td>
<td>Attends &gt; 95% of classes</td>
<td>4%</td>
</tr>
<tr>
<td>In-Class Participation (+/− blogs/vlogs)</td>
<td>Contributes rarely in-class or via vlogs/blogs, often with less than satisfactory content knowledge, and often shows difficulty in application to cases. Displays lack of interest in class.</td>
<td>Contributes sometimes in-class and/or via vlogs/blogs, with satisfactory display of content and often able to apply to cases. Displays interest in class.</td>
<td>Contributes regularly in-class and/or via vlogs/blogs with a very good display of content knowledge and usually able to apply to cases. Displays positive interest in class.</td>
<td>Contributes frequently in-class and/or via vlogs/blogs, with excellent discernment of content and consistently able to apply to even the most complex cases and contexts with breadth of perspective, often with brilliance. Displays keen enthusiasm in class.</td>
<td></td>
<td>20%</td>
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<tr>
<td>Team-Based Participation</td>
<td>Displays less than satisfactory group participation in content contribution, professionalism, and collaboration. Often rejects feedback. Does not consistently facilitate equal opportunity for group members. Is not well-prepared for group meetings, and/or does not attend meetings.</td>
<td>Displays tentative but generally positive group participation, and professionalism which reflects 'satisfactory' level collaboration and contribution. Often accepts feedback. Agrees with equal opportunity of group members. Is generally prepared for group meetings.</td>
<td>Displays consistently positive group engagement, leadership, and professionalism which reflects 'very good' level of collaboration and contribution. Generally accepts and incorporates feedback. Provides group members equal opportunity to excel. Displays consistently positive group meetings.</td>
<td>Displays consistently positive group engagement, leadership, and professionalism which reflects 'excellent' level of collaboration and contribution. Seamlessly accepts and incorporates feedback. Provides group members equal opportunity to excel. Displays well-prepared for group meetings.</td>
<td></td>
<td>16%</td>
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<tr>
<td>Overall Participation Mark</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>40%</td>
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</table>
Student Vlog/Blog Instructions:

Unless otherwise specified, student-initiated video blogs (vlogs) or written blogs are a voluntary contribution (not mandatory), but are highly encouraged as a learning and reflective tool. Students who contribute meaningful vlogs/blogs tend to gain a richer learning experience. Vlogs/blogs provide the opportunity for students to “teach a concept”, reflect on “surprising findings”, or other “topics that resonate with you” from class or from your group work. Vlogs/blogs can also be used as a tool to provide your own reflections or feedback to the course instructor on the interactive case-based teaching style used in this course. Vlogs/blogs are provided as an alternative or additional mode of participation for students who wish to participate more freely outside of the classroom setting in order to increase their participation contribution. Any vlogs/blogs submitted will be considered as complementary to in-class participation, and provide an opportunity to increase overall participation contribution. If you opt to submit vlogs/blogs, any submissions that you wish to be considered for your interim participation mark should be submitted at least 1 week prior to mid-term participation evaluations (week 7). Similarly, any submissions that you wish to be considered for your final participation mark should be submitted at least 1 week prior to final participation evaluations (week 14).

There is no standard format for vlogs/blogs. The most advanced submissions will provide an educational “short take” or primer on a key concept related to class or from the readings, with an applied example. Other examples of advanced submissions include personal reflections on the learning from class, or the readings, or from the group work with a well-constructed overview of prior thinking versus new understanding, and remaining uncertainties that you grapple with. There is no limit to the number of blogs/vlogs you can submit. Typically, vlogs will be less than 5 minutes in length. Group vlog or blog submissions are welcome, as long as the credits briefly explain the role of the members of the group in creating the vlog content.

Please upload your vlogs to YouTube as 'Unlisted videos'. This means that only people directly provided with the link to the video will be able to view it. Please refer to the OWL course site for further instructions.

All blogs or vlogs must be submitted directly to Dr. Martin and the TA as a Message through OWL. Use the following Subject line for your submission: Subject: Student Name – Reflections Week # (example: Jane Doe – VLOG Week 3). Copy and paste the link to your video in the message body. You are responsible for making sure your link works. Please check that it does before you submit, since dead links commonly occur. If you choose to submit a written response instead of a vlog, type your response in the message body or submit it as an attachment.

Assignments (50%)

Individual or small group work assignments must be uploaded to OWL Dropbox as an attachment.

** Note: Assignments submitted after the deadline will be deducted 25% per day late.

- Assignment #1 (5%) – Critical Appraisal of Treatment Article (RCT)  
  Due: October 16 at 12:00 noon
- Assignment #2 (10%) – Critical Appraisal of Evidence Synthesis (MA)  
  Due: October 30 at 12:00 noon
- Assignment #3 (15%) – GRADE & Recommendations (GUIDELINE)  
  Due: November 20 at 12:00 noon
- Assignment #4 (20%) – Applied Cases or Teaching Vignettes  
  Due: December 8 at 11:59 pm.

• Use the following naming convention for your submissions:
  SURNAMEFirst name_Assignment# (example: MARTINJanet_Assignment1)
• Individual submissions should include the student name as a header on each page. Team submissions should include the student names of all team members as a header on each page.
• All written submissions must be either in Word Document format or PDF

Quizzes (10%)

In-class or OWL-enabled quizzes will occur at the beginning of most classes (valued at approximately 1 or 2% per quiz). Quizzes will focus on key concepts covered in the readings and discussions from prior class.
Policy on Accommodation for Medical and Non-Medical Absences

For assignments worth 10% or more, refer to Western University’s Policy on Accommodation for Medical Illness: https://studentservices.uwo.ca/secure/index.cfm.

All non-medical absences must be approved in advance. In the case of an unexpected absence on compassionate grounds, documentation may be requested. If documentation is required by the instructor for either medical or non-medical academic accommodation, then such documentation must be submitted by the student directly to the appropriate Faculty Dean’s office and not to the instructor. It will be the Dean’s office that will determine if accommodation is warranted.

Statement on Academic Offences

Scholastic offences are taken seriously and students are directed to read the appropriate policy, specifically, the definition of what constitutes a Scholastic Offence: http://www.uwo.ca/univsec/pdf/academic_policies/appeals/scholastic_discipline_undergrad.pdf.

Support Services

As part of a successful student experience at Western, we encourage students to make their health and wellness a priority. Western provides several on campus health-related services to help you achieve optimum health and engage in healthy living while pursuing your degree. For example, to support physical activity, all students, as part of their registration, receive membership in Western’s Campus Recreation Centre. Numerous cultural events are offered throughout the year. Please check out the Faculty of Music web page http://www.music.uwo.ca/ and our own McIntosh Gallery http://www.mcintoshgallery.ca/. Information regarding health- and wellness-related services available to students may be found at http://www.health.uwo.ca/

Students seeking help regarding mental health concerns are advised to speak to someone they feel comfortable confiding in, such as their faculty supervisor, their program director (graduate or undergraduate chair), or other relevant administrators in their unit. Campus mental health resources may be found at http://www.health.uwo.ca/mental_health/resources.html

To help you learn more about mental health, Western has developed an interactive mental health learning module, found here: http://www.health.uwo.ca/mental_health/module.html. This module is 30 minutes in length and provides participants with a basic understanding of mental health issues and of available campus and community resources. Topics include stress, anxiety, depression, suicide and eating disorders. After successful completion of the module, participants receive a certificate confirming their participation.

Department & Faculty Offices

The Epidemiology & Biostatistics main office is located in K201 in the Kresge Building on Main campus.

For undergraduate academic counseling assistance, students will need to speak with the Bachelor of Medical Sciences Office: http://www.schulich.uwo.ca/bmsc/general-counselling.

Technology Requirements

You are responsible for all required course materials and announcements posted to the course website on OWL. Please ensure after the first class that when you log in you are able to access the course site. A copy of the course outline will be available on both OWL and the departmental website.
Clinical Epidemiology Course Schedule – Rm FNB 2220 each Mon.; Rm STVH 3101 each Wed.

<table>
<thead>
<tr>
<th>Wk</th>
<th>Date</th>
<th>Topic</th>
<th>Required Readings in 3rd Edition Users’ Guides to the Medical Literature – A Manual for Evidence-Based Clinical Practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Sept 11 (M)</td>
<td>Intro to Clinical Epidemiology and Evidence-Based Medicine (EBM)</td>
<td>Chapter 2, 3 See OWL course website</td>
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<tr>
<td></td>
<td>Sept 13 (W)</td>
<td>Bias &amp; Spin</td>
<td>Chapter 6, 11.1, 12.1</td>
</tr>
<tr>
<td>2</td>
<td>Sept 18 (M)</td>
<td>Study Design &amp; PICOS Critical Appraisal Framework</td>
<td>Chapter 4 See OWL course website</td>
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<tr>
<td></td>
<td>Sept 20 (W)</td>
<td>Measures of Effect</td>
<td>Chapter 9, 12.2, 12.3, 13.2, 10</td>
</tr>
<tr>
<td>3</td>
<td>Sept 25 (M)</td>
<td>Treatment &amp; Prevention #1</td>
<td>Chapter 7, 8, 11.3, 11.4, 11.5, 12.4, 13.1, 13.3, 13.4 See OWL course website</td>
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<tr>
<td></td>
<td>Sept 27 (W)</td>
<td>Treatment &amp; Prevention #2</td>
<td></td>
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<tr>
<td>4</td>
<td>Oct 2 (M)</td>
<td>Screening &amp; Diagnosis</td>
<td>Chapter 22, 23, 24, 25 See OWL course website</td>
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<td></td>
<td>Oct 4 (W)</td>
<td>Prognosis &amp; Harm</td>
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<tr>
<td>5</td>
<td>Oct 9 (M)</td>
<td>Fall Study Break</td>
<td><em>No Class</em></td>
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<tr>
<td></td>
<td>Oct 11 (W)</td>
<td></td>
<td>Chapter 14, 20</td>
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<tr>
<td>6</td>
<td>Oct 16 (M)</td>
<td>Evidence Synthesis #1</td>
<td>Chapter 16, 18, 19.1, 28.3 See OWL course website</td>
</tr>
<tr>
<td></td>
<td>Oct 18 (W)</td>
<td>Evidence Synthesis #2</td>
<td>Chapter 11.2 See OWL course website</td>
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<tr>
<td>7</td>
<td>Oct 23 (M)</td>
<td>Guidelines &amp; GRADE I</td>
<td>Chapter 28.2 See OWL course site for video series</td>
</tr>
<tr>
<td></td>
<td>Oct 25 (W)</td>
<td>Guidelines &amp; GRADE II</td>
<td>See OWL course site for video series</td>
</tr>
<tr>
<td>8</td>
<td>Oct 30 (M)</td>
<td>Economic Evaluation Health Technology Assessment Know4Go &amp; Decision-Making</td>
<td>Chapters 28.1, 26 Note: Decision trees are not part of this course, and can be ignored in the readings.</td>
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<td>Nov 1 (W)</td>
<td>Research Integrity</td>
<td>See OWL course website</td>
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<tr>
<td>9</td>
<td>Nov 6 (M)</td>
<td>Applied Case Studies</td>
<td>See OWL course website</td>
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<td>Nov 8 (W)</td>
<td>Applied Case Studies</td>
<td>See OWL course website</td>
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<td>10</td>
<td>Nov 13 (M)</td>
<td>Applied Case Studies</td>
<td>See OWL course website</td>
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<td>Nov 15 (W)</td>
<td>Applied Case Studies</td>
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<td>11</td>
<td>Nov 20 (M)</td>
<td>Applied Case Studies</td>
<td>See OWL course website</td>
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<td>Nov 22 (W)</td>
<td>Applied Case Studies</td>
<td>See OWL course website</td>
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<tr>
<td>12</td>
<td>Nov 27 (M)</td>
<td>Applied Case Studies</td>
<td>See OWL course website</td>
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<td></td>
<td>Nov 29 (W)</td>
<td>Applied Case Studies</td>
<td>See OWL course website</td>
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<tr>
<td>13</td>
<td>Dec 4 (M)</td>
<td>Applied Case Studies</td>
<td>See OWL course website</td>
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<tr>
<td></td>
<td>Dec 6 (W)</td>
<td>Applied Case Studies</td>
<td>See OWL course website</td>
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Assignment #4 is due December 8 at 11:59pm.