Department of Epidemiology and Biostatistics

CLINICAL EPIDEMIOLOGY
EPIDEMIO 4320B/9562B

Winter 2022

Joel J Gagnier, ND, MSc, PhD
Associate Professor, Department of Epidemiology & Biostatistics and
Department of Surgery, Schulich School of Medicine & Dentistry

Classes: Wednesdays, 1:30-4:30pm (Room PHFM 3015)
TA: Karina Tassiopoulos (ktassiop@uwo.ca)
TA: Jason Hallarn (jhallarn@uwo.ca)
TA Office hours: By appointment
TA Tutorials: By request
Office: PHFM Room 3123
Email: jgagnie4@uwo.ca
Tel: 519-685-8500 xTBD
Mobile: 519-999-4903
Office hours: By appointment

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 prerequisites 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.

Contributing Lecturers & Curriculum Development Committee
Guest lecturers may contribute to case discussions, depending on their availability.
Learning Outcomes

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 (&lt;65%)</th>
<th>Satisfactory (65-75%)</th>
<th>Very Good (75-85%)</th>
<th>Excellent (85-95%)</th>
<th>Brilliant (95-100%)</th>
<th>Max. Mark</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Attendance</strong></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>
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<tr>
<td><strong>In-Class Participation (+/- vlogs/blogs)</strong></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 across contexts. Displays keen enthusiasm 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 and expert level engagement in class.</td>
<td>20%</td>
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<tr>
<td><strong>Team-Based Participation</strong></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. Is well-prepared for 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. Is well-prepared for group meetings.</td>
<td>Displays consistently positive group engagement, leadership, and professionalism which reflects ‘expert’ level collaboration and contribution. Seamlessly accepts and incorporates feedback. With exceptional skill, builds up other group members to ensure they excel and facilitates a well-functioning team. Is exceptionally well-prepared for group meetings.</td>
<td>16%</td>
</tr>
</tbody>
</table>

**Overall Participation Mark**

40%

**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. Gagnier and the TAs 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: February 16 at 12:00 noon
- Assignment #2 (10%) – Critical Appraisal of Evidence Synthesis (MA)  Due: March 16 at 12:00 noon
- Assignment #3 (15%) – GRADE & Recommendations (GUIDELINE)  Due: March 30 at 12:00 noon
- Assignment #4 (20%) – Applied Cases or Teaching Vignettes  Due: April 13 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.

Absence from Course Commitments

Undergraduate Policy: Policy on Academic Consideration for Student Absences

If you are unable to meet a course requirement due to illness or other serious circumstances, you must seek approval for the absence as soon as possible. Approval can be granted either through a self-reported absence or via the Academic Counselling unit. Students have two self-reports to use throughout the academic year; absence from course commitments including tests, quizzes, presentations, labs, and assignments that are worth 30% or less
can be self-reported. Self-reported absences cover a student for 48 hours (yesterday + today or today + tomorrow). Your instructor will receive notification of your consideration; however, you should contact your instructor immediately regarding your absence. Students are expected to submit missed work within 24 hours of the end of the 48-hour period. Please review Western’s Academic Consideration for Student Absences policy for more details.

If you have used both their self-reported absences or will miss more than 48 hours of course requirements, a Student Medical Certificate (SMC) should be signed by a licensed medical or mental health practitioner and you should contact academic counselling. Academic Counselling will be operating virtually this year and can be contacted at scibmsac@uwo.ca.

Graduate Policy: 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 for either medical or non-medical academic accommodation, then such documentation must be submitted by the student to the instructor.

Special Examinations (Undergraduate Policy)

A Special Examination is any examination other than the regular examination, and it may be offered only with the permission of the Dean of the Faculty in which the student is registered, in consultation with the instructor and Department Chair. Permission to write a Special Examination may be given on the basis of compassionate or medical grounds with appropriate supporting documents. To provide an opportunity for students to recover from the circumstances resulting in a Special Examination, the University has implemented Special Examinations dates. These dates as well as other important information about examinations and academic standing can be found here.

Statement on Academic Offences

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

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

The following policies apply to all students:
All required papers may be subject to submission for textual similarity review to the commercial plagiarism detection software under license to the University for the detection of plagiarism. All papers submitted for such checking will be included as source documents in the reference database for the purpose of detecting plagiarism of papers subsequently submitted to the system. Use of the service is subject to the licensing agreement, currently between The University of Western Ontario and Turnitin.com (http://www.turnitin.com).
Computer-marked multiple-choice tests and/or exams may be subject to submission for similarity review by software that will check for unusual coincidences in answer patterns that may indicate cheating.

Copyright and Audio/Video Recording Statement

Course material produced by faculty is copyrighted and to reproduce this material for any purposes other than your own educational use contravenes Canadian Copyright Laws. You must always ask permission to record another individual and you should never share or distribute recordings.

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/.

Registrarial Services: http://www.registrar.uwo.ca
USC Student Support Services: http://westernusc.ca/services/
Academic Support and Engagement: http://academicsupport.uwo.ca/
SGPS Life & Community web page: https://grad.uwo.ca/life_community/self/index.html

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. Health and Wellness-related information and services are available at https://www.uwo.ca/health/.

Students who are in emotional/mental distress should refer to Mental Health@Western https://www.uwo.ca/health/ for a complete list of options about how to obtain help.

Accessible Education Western (AEW)

Western is committed to achieving barrier-free accessibility for all its members, including graduate students. As part of this commitment, Western provides a variety of services devoted to promoting, advocating, and accommodating persons with disabilities in their respective graduate program. Graduate students with disabilities (for example, chronic illnesses, mental health conditions, mobility impairments) are strongly encouraged to register with Accessible Education Western (AEW), a confidential service designed to support graduate and undergraduate students through their academic program. With the appropriate documentation, the student will work with both AEW and their graduate programs (normally their Graduate Chair and/or Course instructor) to ensure that appropriate academic accommodations to program requirements are arranged. These accommodations include individual counselling, alternative formatted literature, accessible campus transportation, learning strategy instruction, writing exams and assistive technology instruction. More information and access to services is available on the AEW website: http://academicsupport.uwo.ca/accessible_education/index.html

Department & Faculty Offices

The Department of Epidemiology and Biostatistics is located on the third floor of the Western Centre for Public Health & Family Medicine (PHFM) on Western University’s Main Campus.
Undergraduate Students requiring academic counselling should contact the Science & Basic Medical Sciences Academic Counselling Office: https://www.uwo.ca/sci/counselling/.

Technology Requirements

You are responsible for all required course materials and announcements posted to the course’s OWL website. 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 (lecture dates and topics subject to change)

<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>Jan 12</td>
<td>Intro to Clinical Epidemiology and Evidence-Based Medicine (EBM); Bias &amp; Spin (J. Gagnier)</td>
<td>Chapter 2, 3 Chapter 6, 11.1, 12.1 See OWL course website</td>
</tr>
<tr>
<td>2</td>
<td>Jan 19</td>
<td>Study Design &amp; PICOS&lt;br&gt;Critical Appraisal Framework; Measures of Effect (J. Gagnier)</td>
<td>Chapter 4, 9, 12.2, 12.3, 12.4, 13.2, 10 See OWL course website</td>
</tr>
<tr>
<td>3</td>
<td>Jan 26</td>
<td>Treatment &amp; Prevention (J. Gagnier)</td>
<td>Chapter 7, 8, 11.2, 11.3, 11.4, 11.5, 13.1, 13.3, 13.4 See OWL course website</td>
</tr>
<tr>
<td>4</td>
<td>Feb 2</td>
<td>Measuring Patients’ Experience (J Gagnier); Harm (Observational Studies)</td>
<td>Chapter 12.5 See OWL course website</td>
</tr>
<tr>
<td>5</td>
<td>Feb 9</td>
<td>Applied Case Studies (K. Milne)</td>
<td>See OWL course website</td>
</tr>
<tr>
<td>6</td>
<td>Feb 16</td>
<td>Evidence Synthesis (J. Gagnier)&lt;br&gt;NOTE: Assignment #1 is due at 12:00 noon today</td>
<td>Chapter 22, 23, 24, 25 See OWL course website</td>
</tr>
<tr>
<td>7</td>
<td>Feb 23</td>
<td>Reading Week</td>
<td>No Class</td>
</tr>
<tr>
<td>8</td>
<td>March 2</td>
<td>Screening &amp; Diagnosis; Prognosis &amp; Harm (P. Jones)</td>
<td>Chapter 14, 16, 18, 19.1, 28.3 See OWL course website</td>
</tr>
<tr>
<td>9</td>
<td>March 9</td>
<td>Guidelines &amp; GRADE (J. Gagnier)&lt;br&gt;NOTE: Assignment #2 is due at 12:00 noon today</td>
<td>Chapter 11.2, 28.1, 26 See OWL course website</td>
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<td></td>
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<td>† Note: Decision trees are not part of this course, and can be ignored in the readings.</td>
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<tr>
<td>10</td>
<td>March 16</td>
<td>Applied Case Studies (K. Milne)</td>
<td>See OWL course website</td>
</tr>
<tr>
<td>11</td>
<td>March 23</td>
<td>Research Integrity (P. Jones)</td>
<td>See OWL course website</td>
</tr>
<tr>
<td>12</td>
<td>March 30th</td>
<td>Applied Case Studies, Knowledge Translation (K. Milne)&lt;br&gt;NOTE: Assignment #3 is due at 12:00 noon today</td>
<td>See OWL course website</td>
</tr>
<tr>
<td>13</td>
<td>April 6th</td>
<td>Moving from evidence to action (K. Milne)</td>
<td>See OWL course website</td>
</tr>
<tr>
<td>14</td>
<td>April 13th</td>
<td>Assignment #4 is due April 6th at 11:59pm.</td>
<td>See OWL course website</td>
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</table>