Comparative Effectiveness Research (M19-5252)
Spring 2018 (01/19/18 – 5/4/18)
Fridays, 1:00-3:00pm
Location: Taylor Avenue Building 2nd floor, Richmond Room

INSTRUCTOR
Erika Waters, PhD, MPH
Division of Public Health Sciences
Department of Surgery
waterse@wustl.edu
Phone: 314-747-5705
Office Hours: By appointment

COURSE DESCRIPTION & OBJECTIVES
This course will provide a comprehensive introduction to comparative effectiveness research (CER). Topics include an overview of CER, stakeholder engagement in CER, designing CER studies, methodologic challenges in doing CER, and recent developments in PCORI and Federal policy. Students will be expected to review and evaluate comparative effectiveness studies as well as actively participate in class discussions. Nearly every class session will include a case study. Through examples, class discussion, and homework students will become familiar with CER methods. They will prepare a set of specific aims for a CER project and identify gaps in CER in their field of study.

COMPETENCIES
- Define CER and its basic tenets.
- Understand the broader context of CER
- Identify common methodologies used in CER
- Be able to identify the appropriate research design for the CER question
- Identify methodologic challenges of CER

COURSE FORMAT & EXPECTATIONS
This class is based on a diverse array of activities, including lectures, discussions, reading assignments, study critiques, and in-class case-studies. Students must come to each session prepared to be active, thoughtful, and energetic participants. This requires thoughtful and careful reading of assigned course materials prior to each class session.

All registered students are expected to attend the PCOR symposium on **Wednesday, April 25, 2018** held at WUSM in the Eric P. Neuman Educational Center (EPNEC). [http://pcor.wustl.edu/PCOR-Symposium/2018-Symposium](http://pcor.wustl.edu/PCOR-Symposium/2018-Symposium)
STUDENT RESPONSIBILITIES

✓ Attend each class.
✓ Come to class on-time, prepared, and having read all required readings.
✓ Participate in class discussions and complete in-class case studies.
✓ Complete assignments on time.
✓ Seek any necessary clarification regarding course expectations.

Any issues with attendance, deadlines, or completion of assignments should be discussed before the deadline/class with the instructor. Email is the best way to contact the instructor. Emails will be answered within two business days with the exception of weekends and holidays.

CLASSROOM ETIQUETTE

✓ Please turn all cellphones and pagers to silent or vibrate.
✓ If you need to answer a call or page, please leave the room quietly to do so.
✓ Do not use the internet, social media sites, BJC clinical sites, or check email during class time.
✓ Please be respectful of differences in viewpoints expressed during class discussion.
✓ Please keep any sensitive information that arises during discussion confidential.

EVALUATION AND GRADING

Grades will be based on class participation and assignments. Additional specific details for each assignment will be distributed at least 4 week prior to their due date.

1. Class participation (15 points): The participation portion of the course grade is based upon regular and timely attendance, as well as active, meaningful contributions to class discussion and case studies. Students are expected to read the required readings. Participation points are earned by arriving to class on time and being an active and thoughtful contributor to class discussions. More than two absences from class may result in a lowered grade. Do not enroll if you have more than two absences already planned.

2. Journal article critique and presentation (25 points): You will be required to give a 25 min journal club-style review of an article of your choice in class. The only requirement is that it be an original research article and that it be related to CER. The full citation for your selected reading must be emailed to the entire class no later than 12pm the Monday before the day you are scheduled. This allows time for the instructor to review materials and to get readings to your classmates in a timely manner.

3. Project outline (10 points): A one page Project Outline to describe key aspects of your planned CER project. Please use the provided Project Outline template on Blackboard. The project outline is due March 16, 2018 at 11:59pm.

4. Letter of Intent (30 points): Students will be asked to submit a modified PCORI Letter of Intent (LOI) 3 page limit excluding references) describing a CER study. The proposed study may be of any type of study design, as long as it meets the criteria for a CER study, as discussed in class. The LOI is due April 20, 2018 at 11:59pm.

5. Project presentation (20 points): Students will give a 15-minute PowerPoint presentation describing the CER project they proposed in the LOI. The presentations will be held either April 27 or May 4, 2018.
Grading

<table>
<thead>
<tr>
<th>Component</th>
<th>Points</th>
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<tbody>
<tr>
<td>Participation</td>
<td>15</td>
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<tr>
<td>Article critique</td>
<td>25</td>
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<tr>
<td>Project outline</td>
<td>10</td>
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<tr>
<td>Letter of intent</td>
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<tr>
<td>Project presentation</td>
<td>20</td>
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Grading scale:

- **A:** 90-100 points
- **B:** 80-89 points
- **C:** 70-79 points
- **F:** less than 69 points

Late assignments: Late assignments will result in a deduction of five points for each day late including weekends unless prior approval is obtained from the instructor or a compelling situation prevents prior approval (i.e. documented health issues or family emergencies).

Blackboard: We will use Blackboard to manage our class and access assignment instructions. Blackboard can be accessed at [https://bb.wustl.edu/](https://bb.wustl.edu/). Log in with your WUSTL Key, and the course should appear on the homepage.

COURSE SCHEDULE

**The syllabus is subject to change at the discretion of the instructor.**

<table>
<thead>
<tr>
<th>Session</th>
<th>Date</th>
<th>Topic</th>
<th>Instructor</th>
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<tbody>
<tr>
<td>1</td>
<td>Jan 19</td>
<td>Overview of the Course and CER</td>
<td>Erika Waters</td>
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<tr>
<td>2</td>
<td>Jan 26</td>
<td>Designing Prospective Observational CER Studies</td>
<td>Siobhan Sutcliffe</td>
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<td>3</td>
<td>Feb 2</td>
<td>Consumer Engagement in CER Trials</td>
<td>Mary Politi</td>
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<td>4</td>
<td>Feb 9</td>
<td>Overview of Large Databases for Retrospective CER Studies</td>
<td>Anne Mobley Butler</td>
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<td>5</td>
<td>Feb 16</td>
<td>Stakeholder Engagement Methods</td>
<td>Goldie Komaie</td>
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<td>6</td>
<td>Feb 23</td>
<td>Patient-Reported Outcome Measures</td>
<td>Amy McQueen</td>
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<tr>
<td>7</td>
<td>Mar 2</td>
<td>CER Systematic Reviews &amp; Meta Analyses</td>
<td>Su-Hsin Chang</td>
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<td>8</td>
<td>Mar 9</td>
<td>Examples and Applications of a Pragmatic Trial in Asthma</td>
<td>Kaharu (Cajal) Sumino</td>
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<td>9</td>
<td>Mar 16</td>
<td>Examples and Applications in a Multicenter Single-Arm Feasibility Trial of Lung Cancer Survivors</td>
<td>Jamie Studts</td>
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<td>10</td>
<td>Mar 23</td>
<td>Effectiveness and Pragmatic Trials</td>
<td>Shane LaRue</td>
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<td>11</td>
<td>Mar 30</td>
<td>Examples and Applications of Patient Centered Outcomes in Anesthesia</td>
<td>Michael Avidan</td>
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<td>12</td>
<td>Apr 6</td>
<td>Examples and Applications in Thoracic Surgery</td>
<td>Varun Puri</td>
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<td>13</td>
<td>Apr 13</td>
<td>No class due to symposium</td>
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<td>14</td>
<td>Apr 20</td>
<td>No class due to symposium</td>
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<td>15</td>
<td>Apr 25</td>
<td><strong>PCOR Symposium 8 am – 4 pm, EPNEC</strong></td>
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<td>16</td>
<td>May 4</td>
<td>Student Presentations</td>
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READINGS AND RESOURCES

A schedule of required and recommended readings will be provided. Additional readings related to student presentations will be distributed a few days before each class. Below are some general resources related to our topic:

Class Background Material:

- IOM initial priorities for CER https://www.nap.edu/read/12648/chapter/1

Session 1: Overview of the Course and CER (Waters)


Session 2: Designing Prospective Observational CER Studies (Sutcliffe)

2. Berger ML, Mamdani M, Atkins D, et al. Good research practices for comparative effectiveness research:


Session 3: Consumer Engagement in CER Trials (Politi)


4. PCORI resources:

Session 4: Overview of Large Databases for Retrospective CER Studies (Butler)


4. Dreyer NA, Tunis SR, Berger M, et al. Why observational studies should be among the tools used in comparative


**Session 5: Stakeholder Engagement Methods (Komae)**


4. TBD

**Session 6: Patient-Reported Outcome Measures (McQueen)**


**Session 7: CER Systematic Reviews & Meta Analyses (Chang)**


2. AHRQ Methods guide for Effectiveness and Comparative Effectiveness Reviews: http://effectivehealthcare.ahrq.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&mp=1&productID=318

3. AHRQ also has a slide library for training for systematic reviews with their focus on comparative effectiveness:
Session 8: Examples and Applications of a Pragmatic Trial in Asthma (Sumino)

Session 9: Examples and Applications in a Multicenter Single-Arm Feasibility Trial of Lung Cancer Survivors (Studts)


3. TBD

Session 10: Effectiveness and Pragmatic Trials (LaRue)


Session 11: Examples and Applications of Patient Centered Outcomes in Anesthesia (PROMIS) (Avidan)

Session 12: Examples and Applications in Thoracic Surgery (Puri)

Session 13: No Class (time exchanged for PCOR Symposium)

Session 14: No Class (time exchanged for PCOR Symposium)

*** Special Session April 25: PCOR Symposium 8 am – 4 pm, EPNEC. Attendance is mandatory ***

Session 15: Student Presentations

Session 16: Student Presentations