

COMPARATIVE EFFECTIVENESS RESEARCH IN HEALTH CARE

Course Description:

Comparative effectiveness research (CER) refers to the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care. The purpose of CER is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels. This course introduces the basic concept of CER, the history and current debates, the principles of CER methodology and guidelines for practice, and potential trends and directions in CER from a US and global perspective.

Course Requirements and Objectives:

This course is offered to students who have completed the introductory or intermediate level of research methods, statistics and clinical trial design and wish to acquire more advanced knowledge and skills in healthcare research, policy or pharmaceutical research and development. Textbooks and reading materials are recommended below. A large body of literature, reports, monographs, theses, lectures, presentations and training materials are available over the internet or other public media. Students are expected to actively search and preview related materials before each class and be well prepared for class discussions. Upon successful completion of the course, the students will be able to develop a general understanding of CER principles and practices, identify appropriate data sources for CER, design and conduct basic CER in a specific healthcare sector, and begin to apply CER in real world healthcare scenarios and develop publication skills in this scientific discipline.

Class Time:

6:10pm – 9:00pm every Monday

Course Evaluation:

CER is a broad subject that involves nearly all health care sectors and reflects an integrative scientific trend over activities of health technology innovation, service delivery, policy and decision making. Attainment of course objectives will be evaluated according to the demonstrated ability to internalize the basic concepts and principles of CER and to apply the acquired knowledge and skills to resolution of real world health care issues. The course will be carried out in an interactive mode between the instructor and students. Students are expected to identify relevant reading materials, prepare for active participation in class discussions,

design a CER study plan driven by a real world health care issue, and implement the study plan with an analytic project or a review paper as the final course exam. The course evaluation will be letter graded according to the stipulations of the graduate program. *The three evaluation components, including a. active participation in class discussion and team project/presentation, b. study design and synopsis for a CER project, and c. successful completion of a review paper or analytic project by end of the semester will each contribute a third to the overall course grading.* In order to successfully accomplish the course projects, students will need to work in teams for the team presentation and start to prepare for the individual review or analytic project from the beginning of the semester. For those who are preparing an analytic project instead of a review paper, it is critical to begin identification of potential data sources as early in the semester as possible. The instructor will be available to discuss with all students on the project planning throughout the course.

Course Outlines:

- Week 1:
 - Introduction - US and global perspectives on CER
 - What is comparative effectiveness research?
 - IOM priorities, CMS, AHRQ, PCORI
 - EUnetHTA, NICE, GBA, etc
 - Emerging healthcare markets

- Week 2:
 - Historical background, evolution and current trends
 - US Congressional Report
 - EU advancements in CER
 - Key debates in CER

- Week 3:
 - Healthcare systems and CER
 - Healthcare authorities
 - Healthcare policy
 - Health care financing
 - Health services delivery

- Week 4:
 - Regulatory approach to CER
 - Health technology innovations – Pharmaceutical R&D
 - Benefit risk assessments
 - Quality of evidence

- Innovative methodologies to clinical trials
- Week 5:
 - HTA approach to CER
 - Coverage and reimbursement
 - Effectiveness vs efficacy
 - Real world clinical decision making
 - Quality of care and healthcare costs
 - Value in healthcare
- Week 6:
 - Healthcare stakeholders in CER
 - Who are the healthcare stakeholders
 - Stakeholder perspectives in healthcare value
 - Parallel review in drug approval process
 - Stakeholder priorities and synergies
- Week 7:
 - Scope and key components
 - CER as a scientific discipline
 - The scope of CER as defined by healthcare priorities of key stakeholders
 - Patient centricity as the foundation of CER
 - Health outcomes, service delivery, quality and performance
- Week 8:
 - Methodology and guidelines
 - Clinical trials including pragmatic clinical trials
 - Observational or non-interventional studies
 - Systematic literature review
 - Analytic studies with pre-existing databases
 - Health services and outcomes research
 - Safety and signal detection
 - Benefit risk assessments
- Week 9:
 - CER in drug development
 - Milestones in drug development
 - Medical value in developing compounds
 - Evidence accumulation with CER
 - CER at the core of product value representation
 - Dossiers for submissions
- Week 10:
 - CER in post launch life cycle management

- Coverage with Evidence Development (CED)
 - Phase 3b and Phase 4 clinical trials
 - Product label enhancements and updates
 - Expansion of product indication
 - Accumulation of evidence through clinical practices
- Week 11:
 - Therapeutic areas and CER evidence development
 - Oncology
 - Cardiovascular disease
 - Metabolism
 - Infectious disease and internal medicine
 - Rare diseases
- Week 12:
 - Evidence-based vs value based medicine
 - Evolution of evidence based medicine
 - EBM at the cross roads
 - Value based medicine
 - EBM, VBM, translational medicine and CER
- Week 13:
 - Barriers, limitations, guidelines and compliance
 - CER – old wine in new bottle?
- Week 14:
 - Future directions – Class Discussion and Student Team Presentations

Textbooks (To be evaluated):

1. Initial National Priorities for Comparative Effectiveness Research by Committee on Comparative Effectiveness Research Prioritization Paperback \$36.00
2. Finding What Works in Health Care: Standards for Systematic Reviews by Committee on Standards for Systematic Reviews of Comparative Effectiveness Research Paperback \$61.00
3. Adaptive Methods in Clinical Studies: Clinical Development Plans and Comparative Effectiveness Research [Hardcover] \$89.95

Reading Materials - Web Links:

1. [http://www.npcnow.org/Public/Newsroom/E V I dently Today/Public/Newsroom/Go LightlyFeed/GoLightlyFeedDisplay.aspx?zbrandid=4337&zidType=CH&zid=13925452&zsubscriberId=1011944209&zbdom=http://npc.informz.net](http://www.npcnow.org/Public/Newsroom/E%20V%20I%20dently%20Today/Public/Newsroom/Go%20LightlyFeed/GoLightlyFeedDisplay.aspx?zbrandid=4337&zidType=CH&zid=13925452&zsubscriberId=1011944209&zbdom=http://npc.informz.net)
2. www.ncbi.nlm.nih.gov/pubmed/22859777/
3. content.healthaffairs.org/content/31/10/2168.abstract
4. www.iom.edu/Reports/2009/ComparativeEffectivenessResearchPriorities.aspx
5. www.pcori.org/assets/PCORI-National-Priorities-and-Research-Agenda-2012-05-21-FINAL.pdf
6. content.healthaffairs.org/content/31/10/2213.abstract
7. content.healthaffairs.org/content/31/10/2176.abstract
8. <https://www.aamc.org/newsroom/reporter/october2012/308504/pcori.html?zbrandid=4337&zidType=CH&zid=13883370&zsubscriberId=1011944209&zbdom=http://npc.informz.net>
9. <http://jco.ascopubs.org/content/early/2012/10/15/JCO.2012.42.5967>
10. <http://www.pcori.org/2012/pilot-projects-awards/>
11. <http://www.elsevierbi.com/publications/the-pink-sheet/74/43/health-technology-assessments-should-help-prioritize-cer--journal-authors>
12. <http://healthaffairs.org/blog/2012/10/09/new-health-affairs-promise-pitfalls-of-comparative-effectiveness-research/?zbrandid=4337&zidType=CH&zid=13720659&zsubscriberId=1011944209&zbdom=http://npc.informz.net>
13. <http://azhealthconnections.com/2012/10/04/real-world-evidence-answering-key-healthcarequestions/?zbrandid=4337&zidType=CH&zid=13620696&zsubscriberId=1011944209&zbdom=http://npc.informz.net>
14. <http://content.onlinejacc.org/article.aspx?articleid=1362841&zbrandid=4337&zidType=CH&zid=13620698&zsubscriberId=1011944209&zbdom=http://npc.informz.net>
15. <http://www.sciencedirect.com/science/article/pii/S0895435612001722>
16. http://www.avalerehealth.net/news/spotlight/20120925_Establishing_a_Vibrant_Evidence_Paradigm_to_Support_Innovation.pdf?zbrandid=4337&zidType=CH&zid=13491579&zsubscriberId=1011944209&zbdom=http://npc.informz.net
17. [http://www.valueinhealthjournal.com/article/S1098-3015\(12\)01610-5/abstract](http://www.valueinhealthjournal.com/article/S1098-3015(12)01610-5/abstract)

18. http://weill.cornell.edu/news/deans/2012/09_21_12.shtml?zbrandid=4337&zidType=CH&zid=13429924&zsubscriberId=1011944209&zbdom=http://npc.informz.net
19. <http://www.ncbi.nlm.nih.gov/pubmed/22992327?dopt=Abstract&zbrandid=4337&zidType=CH&zid=13429928&zsubscriberId=1011944209&zbdom=http://npc.informz.net>
20. <http://www.pharmalot.com/2012/09/the-op-ed-a-suggestion-to-restore-faith-in-pharma-studies/>
21. <http://online.wsj.com/article/SB10000872396390443819404577633591046105150.html?zbrandid=4337&zidType=CH&zid=13385641&zsubscriberId=1011944209&zbdom=http://npc.informz.net>
22. <http://www.futuremedicine.com/doi/pdf/10.2217/cer.12.41>
23. <http://www.raps.org/focus-online/news/news-article-view/article/2217/iom-regulatory-holds-promise-of-improving-healthcare-outco/zbrandid/4337/zidtype/ch/zid/13226211/zsubscriberid/1011944209.aspx?zbdom=http://npc.informz.net>
24. <http://www.futuremedicine.com/doi/pdfplus/10.2217/cer.12.49>
25. <http://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=1236&zbrandid=4337&zidType=CH&zid=13206413&zsubscriberId=1011944209&zbdom=http://npc.informz.net>
26. <http://iom.edu/Activities/Quality/VSRT.aspx>
27. <http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=13444>
28. <http://www.elsevierbi.com/publications/the-pink-sheet/?zbrandid=4337&zidType=CH&zid=13128442&zsubscriberId=1011944209&zbdom=http://npc.informz.net>
29. <http://www.nejm.org/doi/pdf/10.1056/NEJMp1207437>
30. <http://www.healthnewsreview.org/2012/08/take-2-aspirin-thoughts-on-the-aspirinprostate-cancer-news/?zbrandid=4337&zidType=CH&zid=13102576&zsubscriberId=1011944209&zbdom=http://npc.informz.net>
31. <http://www.expert-reviews.com/doi/full/10.1586/egh.12.28?zbrandid=4337&zidType=CH&zid=13086939&zsubscriberId=1011944209&zbdom=http://npc.informz.net>
32. <http://jama.jamanetwork.com/article.aspx?articleid=1352120>
33. <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0042003>

34. http://adisonline.com/pharmaceuticalmedicine/Abstract/2012/26040/Value_Based_Pricing__Examples_of_Healthcare_System.1.aspx
35. <http://onlinelibrary.wiley.com/doi/10.1002/pst.1530/pdf>
36. http://ridigest.sanofi-aventis.com/db/attachments/pvdnews/10164/1/NICE_appraised_medicines_NHS_England_2010_2011_report.pdf
37. <http://ridigest.sanofi-aventis.com/traction?type=single&proj=PVDNews&sort=3&stickyparams=sort&rec=10144>
38. <http://ridigest.sanofi-aventis.com/traction?type=single&proj=PVDNews&sort=3&stickyparams=sort&rec=10148>
39. <http://ridigest.sanofi-aventis.com/traction?type=single&proj=PVDNews&sort=3&stickyparams=sort&rec=10138#pvdnews10138attachments>
40. <http://ridigest.sanofi-aventis.com/traction?type=single&proj=PVDNews&sort=3&stickyparams=sort&rec=10136>
41. <http://ridigest.sanofi-aventis.com/traction?type=single&proj=PVDNews&sort=3&stickyparams=sort&rec=10117>
42. <http://www.aacr.org/home/public--media/science-policy--government-affairs/science-policy--legislative-affairs-committee/2012-annual-meeting-regulatory-science--policy-track.aspx>

