2015

HECO 471 Introduction to Health Economic and Clinical Outcomes Research

Candance Gunnarsson

HECO471: Introduction to Health Economic and Clinical Outcomes Research
Fall 2015

Department of Health Services Administration
College of Social Sciences, Health, and Education
Xavier University

Schedule:	Tuesday 5:45-815pm
Classroom:	Conaton Learning Center 309
Credit Hours:	3 Undergraduate Credit Hours
Prerequisites:	None
Other requirements:	Permission of HECOR Program Director
Faculty:	Candace Gunnarsson, EdD
	Adjunct Professor, Health Services Administration
Office:	Schott Hall, Room 411
Office Hours*:*	By appointment
	Administrative Assistant: Amanda Coleman acoleman@ctifacts.com
Office Phone:	(513) 543-5311
E-mail:	cgunnarsson@ctifacts.com

Program Director: Eileen S. Alexander, PhD; Assistant Professor, Health Services Administration
Alexandere2@xavier.edu (513)745 4957 www.xavier.edu/hecor
Administrative Assistance: Schott Hall 404

ACCOMMODATIONS
If you have a disability for which you require accommodation in order to give your best academic performance in this course, please notify the instructor. You should consult or register with the Learning Assistance Center (513-745-3280) so that together you can work to develop methods of addressing needed accommodations in this class.

HECOR is an experiential learning program and we gratefully acknowledge the contributions of our internal and external partners:
Health Services Administration Librarian: Ms. Marty Ferrell Ferrell@xavier.edu
Xavier Writing Center: Conaton Learning Center
XU Information Technology
CTI
Primary Health Solutions
Johnson & Johnson

HECO471: Course Description:
This course is intended for fourth year undergraduate students seeking an elective in economics, statistics, health services or epidemiology. It exposes students to a general overview of health economics and clinical outcomes research. Contemporary approaches to comparative effectiveness research will be introduced. The topics represent a broad selection of major themes in the field and each topic provides students with opportunities to develop their understanding of the field, as well as learn how economists, epidemiologists and statisticians think about and conduct research. Each topic presented could be a full course in and of itself.

HSA DEPARTMENT LEVEL Mission Statement (2011): **Please see XU HSA Student Handbook**
In keeping with its Catholic, Jesuit tradition, the mission of the Department of Health Services Administration at Xavier University is to educate knowledgeable, highly skilled, values-oriented future leaders who will contribute to the health of society by continuously improving the management of health related organizations. HSA will accomplish its mission through:

- Challenging students in the classroom and in applied field experiences including internships and administrative residencies
- Developing internal and external collaborative relationships with academicians and with health care practitioners which lead to innovations in teaching as well as in the delivery of health services
- Incorporating research, scholarship, and collaborative projects into the classroom experiences and field work.

UNIVERSITY LEVEL UNDERGRADUATE POLICIES:
http://catalog.xavier.edu/content.php?catoid=17&navoid=832

HOT TOPIC! Academic Honesty: Read this section in the XU Catalogue, linked above.
Please ask if you have questions regarding intellectual property rights.

Canvas:
Supplemental articles/chapters outside of the class, assignment descriptions and the syllabus will be available via Canvas. Reports must pass the Turnitin feature of Canvas.

HOT TOPIC! Attendance: Read the XU Catalog, linked above
Note: Reasonable attendance at all class meetings is expected. If a student is unable to attend a class, **the responsibility of missed class content is the sole responsibility of the student.** Tests and written assignments include assigned readings, media, class content and discussions.

Statistical Platforms: SAS® (Cary, NC) will be used to analyze data. SAS® is available without charge to Xavier students, faculty and staff.

HECOR PROGRAM LEVEL POLICIES: Please see HECOR Program Level Outcomes in the HSA Student Handbook
Relation to Xavier's Mission:
The M.S. in Health Economic and Clinical Outcomes Research furthers the mission of Xavier University by educating each student intellectually, morally and spiritually. This program provides a challenging and comprehensive learning opportunity for individuals who desire to expand upon their undergraduate degree and develop advanced skills in data analysis, economic and clinical quality improvement to support organizational decision making. Experiences include ethical issues inherent in the growing area of health outcomes research. Interdisciplinary classroom experiences include work with real clinical and economic data. Didactic work combined with service learning, a mentored practicum and optional internship helps students cultivate lives of reflection, compassion and informed action.

HOT TOPIC! Attendance: HECOR Program Policies:
Note: Reasonable attendance at all class meetings is expected. If a student is unable to attend a class, **the responsibility of missed class content is the sole responsibility of the student.** Tests and written assignments include assigned readings, media, class content and discussions.

Excused absences, such as medical visits, funerals, legal proceedings, have documentation. To be excused, documentation must be received in the HSA Administrative Office **within one week of your return to classes**. EACH unexcused absence will result in a **1% reduction of your FINAL grade**. For extended needs, please make appointments to discuss with your instructor and the Director.

Participation: Active participation is expected and includes:

- Attendance
- Punctuality
- Sharing information and perspectives
- Being active in small group and team activities
- Showing respect to your classmates, guests, faculty, staff, community partners, the public
- **Planned reflection outside of class ~3-8 hours per week, i.e., homework**
- Use of XU resources in and outside of class
- Community engagement
- Business casual dress for speakers and a Thank You email to speakers afterwards

For your information: MS-HECOR Requirements:
A grade of "B-" or better is required for the MS-HECOR program. Courses in which a "C+" or lower grade is received must be repeated at the student's expense.

Grading Scale (Note: 0.55% will be rounded up):

A	93-100
A-	90-92
B+	87-89
B	83-86
B-	80-82
C+	77-79
C	73-76
C-	70-72
D+	67-69
D	60-66
F	≤59

INSTRUCTOR LEVEL and COURSE SPECIFIC POLICIES:
Late Assignment Policy:
Late assignments will accrue a penalty of 10% per day the assignment is late. An assignment is considered one day late if it is submitted past the identified due date/time. It is considered two days late if it is submitted any more than 24 hours past the identified due date/time, and so forth. This includes weekends! Once an assignment is more than 10 days late, it will become a zero and will not be accepted for credit.

If an extension for an assignment is requested, this must be received no less than 48 hours before the assigned due date/time. Extensions are not guaranteed, and are at the discretion of the instructor. Extensions may include a late penalty.

Course Level Student Learning Outcome [maps to HECOR PLO #]	**Method of assessment**

Describe comparative effectiveness research – its purpose, the process and the hurdles. [HECOR PLO 1.]	Exam; Individual reflection
Demonstrate entry level understanding of the drug and medical device development, approval and commercialization process both in and outside the United States [HECOR PLO 1.]	Exam
Be able to define in words the following methodologies and understand their differences: Retrospective Database Analyses with payer, hospital and EMR data, Systematic Review and meta-analysis, economic evaluations to include: cost effectiveness, cost burden, budget impact and cost utility. **INSTRUCTOR LEVEL and COURSE SPECIFIC POLICIES:** [HECOR PLO 2 & PLO 3.]	Exam
Present information using appropriate oral and technology skills [HECOR PLO 4.]	Team-based reflective project
Interact respectfully and effectively with team members and with teams [HECOR PLO 5.]	Team-based reflective project
Apply and present basic ethical values and principles, as well as legal, financial and policy requirements in clinical conflicts for assigned project [HECOR PLO 6.]	Team-based reflective project

Optional Textbooks:

Kane, Robert, and David Radosevich. Conducting Health Outcomes Research, 11th ed., 2010.

Instructor Note on Course Structure: The course design will be interactive with a series of current and relevant readings each week. Lecturing will be minimal. The course will mainly consist of invited speakers and either instructor or student-led discussions aimed at fostering meaningful understanding of the material. The success of this seminar depends on everyone's preparation, and everyone's preparation will depend on carefully completing the readings. Student participation will be most important. I am looking for quality discussion. Signs of good participation include: Attendance, punctuality, eagerness to participate, showing respect to others' contributions, facilitating discussion, paying careful attention to classmates' presentations, and offering constructive feedback, questions, and comments. Each student will be responsible to lead discussion fore one review-style paper or two smaller empirical papers. They will need to determine how best to accomplish this goal for the readings. As facilitators, it is not your responsibility to explain the readings to others or review the important points of each paper. Instead, your role is to provide a framework that seems sensible for discussing the topic.

Week (Dates)	Topic	Guest Lecturer	Assigned Readings
August 25	Syllabus and course expectations Introduction to Health Economic & Clinical Outcomes Research	Candace Gunnarsson, EdD *VP, HECOR* Sudip K. Ghosh, PhD *Associate Director, Global Health Economics and Market Access*	• Review Basics of Microeconomics (Khan Academy) • Fuchs VR. How to think about future health care spending. N *Engl J Med* 2010; 362(11):965-7 • Price-Haywood EG. Clinical comparative effectiveness research through the lens of healthcare decisionmakers. *Ochsner J* 2015; 1592): 154-61. • McDonald PA et al. The employer-led health care revolution. *Harvard Business Review* 2015; 93(7):38-50.
September 1	Drug Development and Approval: Understanding " the clinical trial" and the regulatory pathway for drug approval in the United States *Students will understand key steps in the drug development and approval process from bench to approval.*	Kathy Wekselman, PhD, RN *Senior Director, Regulatory and Scientific Affairs*	• http://www.fda.gov/Drugs/ResourcesForYou/SpecialFeatures/ucm279676.htm Frequently Asked Questions about the FDA Drug Approval Process • http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm394839.htm FDA Drug Approval Process Infographic • http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/default.htm How Drugs are Developed and Approved
September 8	Medical Devices. How is the regulatory pathway in the United States different? *Although the process is similar, students will understand the differences in bringing a medical device to market versus a drug.*	Candace Gunnarsson, EdD *VP, HECOR* Sudip K. Ghosh, PhD *Associate Director, Global Health Economics and Market Access*	• Kaplan AV *et al.* Medical device development. From prototype to regulatory approval. *Circulation* 2004;109:3068-72. • Hwang TJ *et al.* Assessment of US pathway for approving medical devices for rare conditions *BMJ.* 2014;348:g217 • Kramer DB *et al.* Regulation of Medical Devices in the United States and European Union. *N Engl J Med* 2012; 366:848-855
September 15	HECOR after a drug or device is approved-What is next? The road to commercialization in the United States. Understanding the Burden of Illness	Peter Mallow, PhD *Associate Director, Health Economics*	• Dorros G. FDA Approval Does Not Mean What you Think It Does. Accessed at http://www.hudson.org/research/7264-fda-approval-does-not-mean-what-you-think-it-does- • DeKoven et al. Hospital Providers: The Day After

	Students will understand the various stakeholders and the key steps that need to take place in order for a drug or device to be approved for payment in the United States.		FDA Approval. Biotechnol Healthc 2005;2(4):58-61. • Rice DP. Cost of Illness Studies: What is Good about them? Inj Prev 2000;6:177-179. • Currie et al. Are Cost of Injury Studies Useful? Inj Prev 2000;6:175-176. • Berndt ER & Newhouse JP. Pricing and Reimbursement in US Pharmaceutical Markets. NBER Working Paper 16297 2010. Accessed at www.nber.org/papers/16297.
September 22	Global Drug and Device Development and Commercialization *Students will understand the various stakeholders and the key steps that need to take place in order for a drug or device to be approved for payment outside the United States*	Sudip K. Ghosh, PhD *Associate Director, Global Health Economics and Market Access*	• Value Driven Drug Development. Report by the McKinsey Institute June 2012.
September 29	Assessing Value: The Role of Health Economics *Students will learn basic concepts of comparative effectiveness research and how a value is assessed for a new drug or device.*	Peter Mallow, PhD *Associate Director, Health Economics*	• Haycox A. What is Health Economics? Accessed at http://www.medicine.ox.ac.uk/bandolier/painres/download/whatis/what_is_health_econ.pdf • Drummond et al. Assessing the Added Value of Health Technologies: Reconciling Different Perspectives. 2013 Value in Health; 16:S7-S13. • Porter ME. A Strategy for Health Care Reform – Toward a Value-Based System. 2009 NEJM;361(2):109-112 • Porter ME: What is Value in Health Care? 2010 NEJM; 363(26):2477-2481. • Porter ME: What is Value in Health Care? 2010 NEJM; 363(26):2477-2481. Supplementary Appendix 1. • Porter ME: What is Value in Health Care? 2010 NEJM; 363(26):2477-2481. Supplementary Appendix 2.

October 6	Tools of the trade: Systematic Review and Meta Analyses *Students will learn the basic steps of a systematic review process with meta-analysis – This is just introducing the student to the concept. Students will learn how to actually perform these analyses later in the program.*	Erin Baker, PhD *Epidemiologist, Medical and Scientific Affairs*	• Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Medicine 6(6): e1000097. doi:10.1371/journal.pmed1000097 • Stroup DF, Berlin JA, Morton SC, et al, for the Meta-analysis Of Observational Studies in Epidemiology (MOOSE) Group. Meta-analysis of observational studies in epidemiology. A proposal for reporting. JAMA 2008; 283:2008-2012
October 13	Exam	Sudip K. Ghosh, PhD *Associate Director, Global Health Economics and Market Access*	
October 20	Tools of the trade: Retrospective Data Base Analyses	Sudip K. Ghosh, PhD *Associate Director, Global Health Economics and Market Access*	• ISPOR Taskforce report on Retrospective Database Analysis http://www.ispor.org/TaskForces/RetrospectiveDBPractices.asp • Crown WH. There's a reason they call them dummy variables: a note on the use of structural equation techniques in comparative effectiveness research. Pharmacoeconomics. 2010;28(10):947-55.
October 27	Tools of the trade: Secondary Data Collection *Students will learn about secondary data capture and when it is needed during the commercialization process. Students will learn the process that needs to be followed when these studies are undertaken: Protocol, SAP, IRB approval, value dossier, conceptualizing, creating and communicating a value message.*	Bill Irish, MSc, PhD *VP, Biostatistics & Health Outcomes Research*	TBD
November 3	Tools of the trade: Economic	Peter Mallow, PhD	• Caro et al. Modeling Good Research Practices –

	Simulations *Students will be introduced to economic simulations: Markov, Discrete events, etc. Students will be able to define the most common forms of economic simulations and when they are appropriate. Students will understand the process that needs to be followed when running this type of research. Students will learn how to run these evaluations later in the program.*	*Associate Director, Health Economics*	Overview: A Report of the ISPOR-SMDM Modeling Good Research Practices Task Force-1. 2012 Medical Decis Making; 32(5):667-677. • Roberts et al. Conceptualizing a Model: A Report of the ISPOR-SMDM Modeling Good Research Practices Task Force-2. 2012 Medical Decis Making; 32(5):678-689. • Siebert et al. State-Transition Modeling: A Report of the ISPOR-SMDM Modeling Good Research Practices Task Force-3. 2012 Medical Decis Making; 32(5):690-700. • Karnon et al. Modeling Using Discrete Event Simulation: A Report of the ISPOR-SMDM Modeling Good Research Practices Task Force-4. 2012 Medical Decis Making; 32(5):701-711. • Pitman et al. Dynamic Transmission Modeling: A Report of the ISPOR-SMDM Modeling Good Research Practices Task Force-5. 2012 Medical Decis Making; 32(5):712-721. • Briggs et al. Model Parameter Estimation and Uncertainty Analysis: A Report of the ISPOR-SMDM Modeling Good Research Practices Task Force-6. 2012 Medical Decis Making; 32(5):722-732. • Eddy et al. Model Transparency and Validation: A Report of the ISPOR-SMDM Modeling Good Research Practices Task Force-7. 2012 Medical Decis Making; 32(5):733-743.
November 10	**Project Assignments** *Tools of the trade: continued*	Sudip K. Ghosh, PhD *Associate Director, Global Health Economics and Market Access*	Team and role assignments will be appropriate for undergraduate members.
November 17	What about Rare Diseases? *Students will be introduced to how the*	Laura Wright, PhD *Senior Medical Writer*	TBD

	"game" changes when you are dealing with the treatment of very rare diseases and often patient sample size is so small it prevents the researcher from employing the typical forms of outcomes research. Students will be able to explain what it means for a disease to be considered "rare" and how modified research plans need to exist when dealing with the treatment of rare diseases.		
November 24	**NO CLASS – Thanksgiving Holiday**		
December 1	Ethical Considerations *Students will understand the ethical considerations in drug and medical device commercialization. Students will understand patient de-identification. Students will have a broad understanding of what constitutes ethical research practices with secondary data.*	Sudip K. Ghosh, PhD *Associate Director, Global Health Economics and Market Access*	• Moore TJ et al. The safety risks of innovation: the FDA's expedited drug development pathway. JAMA 2012; 308(9): 869-870. • Faden RR et al. An Ethics Framework for a Learning Health Care System: *A Departure from Traditional Research Ethics and Clinical Ethics* The Hastings Center Report 2013; 43:S16-S27. • World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects
December 8	Project Presentation	Candace Gunnarsson, EdD *VP, HECOR* Sudip K. Ghosh, PhD *Associate Director, Global Health Economics and Market Access*	
December 15	Final Exam	Sudip K. Ghosh, PhD	

Assignments:
Assignments will have a description on Canvas by the assigned date at the latest. Case studies, papers, and the group project should be written utilizing APA format. The library provides a good resource on APA format via the following website: http://www.xavier.edu/library/help/apa_guide.pdf. RefWorks is a bibliographic management tool to assist you in creating in-text references and bibliographies in appropriate format, available via the library website.

Assignment Descriptions and Grading Weights

Dates	Part	Assignment	Description	Points	Percent
Continuous		Attendance		±	±
Continuous		Participation		100	10%
August 25-October 13	Part 1	Exam	Exam will be in class: closed book, multiple choice, matching, true/false or fill-in, covering assigned readings, presentations and class discussions in Part 1	300	30%
October 20-December 8	Part 2	Team Reflection	Thoughtful team-based written and oral reflection using PowerPoint (or similar platform, with approval) to demonstrate results and insights gained from coursework and assigned project. Topic, instructions and PowerPoint template will be assigned prior. Team and role assignments will be appropriate for undergraduate members.	300	30%
December 15		Exam	Exam will be in class: closed book, multiple choice, matching, true/false or fill-in, covering assigned readings, presentations and class discussions in Part 2 as well as cumulative concepts	300	30%
	Total			1000	100%