

Course Title: *Introduction to Outcomes Research, Fall 2019*

Course Number: *EPID 0563*

Course Prerequisite(s): *PHCO 0502 & PHCO 0504 (B and above)*

Course Location: *SPH Building, 683 Hoes Ln W, Piscataway, NJ 08854, Room 334*

Course Date & Time: *Mondays 6:10 pm to 8:00 pm*

Course Instructor: *Jing Yuan, PhD, BPharm*

*Center for Health Outcomes, Policy, and Economics (HOPE), Ernest
Mario School of Pharmacy,*

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Office Hours: *By Appointment Only*

Course Assistant: *None*

Course Website: <https://rutgers.instructure.com/courses/28607>

Required Course Text: *None*

Additional/Supplemental Readings/Resources:

1. *Kane RL and Radosevich DM. Conducting health outcomes research. Jones & Bartlett Publishers, 2010.*
2. *Velentgas P, et al. Developing a protocol for observational comparative effectiveness research: a user's guide. Government Printing Office, 2013. Link: <https://www.ncbi.nlm.nih.gov/books/NBK126190/>*

Course Description: *During the past few years, there has been an explosion of interest in measuring the outcomes of medical care. The science of measuring outcomes and of integrating that process into the routine care of patients has come to be known as outcomes research. Public health practitioners are expected to play a major role in evaluating the outcomes of medical care as the nation's health care system is rapidly changing and as the "Affordable Care Act" is being implemented. This course is designed to introduce students to the principles of health outcomes research and to practical applications of these principles.*

Competencies Addressed: The following competencies are addressed in this course for the MPH degree in Epidemiology and MS degree in HOPE.

1. Design, evaluate, interpret, and communicate the results of non-randomized, observational research for applications in health outcomes, health economics, and health policy research
2. Select quantitative and qualitative data collection methods appropriate for a given public health context
3. Evaluate the reliability, validity, and generalizability of individual biomedical research studies

4. Synthesize evidence for health policy decision makers to facilitate translation of interventions, applications, or programs
5. Apply epidemiological methods to the breadth of settings and situations in public health practice
6. Work independently and as part of a team to conduct health outcomes research projects

Course Objectives: By the completion of this course, students will be able to:

- a. Discuss the concepts of clinical outcomes, economic outcomes, patient satisfaction and quality of life issues.
- b. Identify sources of data for health outcomes research that are feasible to collect and minimize bias.
- c. Evaluate alternative study designs for conducting health outcomes research.
- d. Discuss the utility of emerging research methods in outcomes research.
- e. Discuss the concepts of quality of health care organizations and value-based care.
- f. Demonstrate an understanding of the process of manuscript development and evidence communication.
- g. Evaluate the efficacy of newly introduced medical technologies through meta-analytic techniques.
- h. Apply decision analysis techniques to evaluate the usefulness of alternative clinical and public health interventions.
- i. Design and conduct a study using health outcomes research methodology to inform decision-making

Course Requirements and Grading:

- *Students' final grade will be computed using a combination of the following assessments:*
 1. *Article critique assignment* 20 pts.
 2. *Midterm* 30 pts.
 3. *Class Project* 40 pts.
 4. *Class Participation* 10 pts.
 - Total:* 100 pts.
- *Class Participation:* *Students are expected to attend class and to actively participate in class discussions. Attendance will be taken using a paper sign-in sheet. Attendance will be taken for each session, for all sessions except on the dates of Mid-term exam and project presentation. Students will only be considered to have an excused absence if they contact Dr. Yuan prior to the class that will be missed. Students will be granted a maximum of **two (2)** unexcused absences. After that, points will be deducted as follows:*
 - *3rd unexcused absence: 1.5 attendance points lost*
 - *4th unexcused absence: all attendance points lost*
- *Assigned readings:* *Course readings will be available through the course's website (<https://rutgers.instructure.com/courses/28607>). Readings are organized by lecture sessions. **Students are expected to complete readings prior to class.***
- *Online 30 will include the following activities*

- *Article critique assignment: Students will prepare critical evaluations of assigned articles using literature review rubrics (**Appendix B**). **Five (5)** articles will be assigned by instructor. Each assignment will be worth a maximum of 4 points. The student is expected to critically evaluate the strengths and limitations of the data sources, study design, outcome measures, and analytic approach for answering the main study question. Each session will open on a Monday AM; the assignment is due in two weeks. All assignments should be submitted through course website by **11:59pm**. Late submissions will receive 1.5 assignment points lost, unless excused by Dr. Yuan.*
- *Group project activities: For most weeks, students will work with his/her team on specific sections of their class project. This assignment will foster students' abilities to work in teams and cultivate oral and written communication skills.*
- *Mid-term exam: Questions will be multiple choice, short answer, and (potentially) essay questions. The focus of the exams will be on the application of concepts discussed in class rather than memorization of covered course material. The Instructor will distribute a brief study guide one week before exam. The study guide is intended to help students focus their studying efforts, and will specify test format (i.e., number and general types of questions). The tests will include lecture material as well as any readings covered in the article critique exercises.*
- *Class Project: In a group of **four(4)** students each, students are expected to choose one project area from the list of topics covered during the course. Students will be required to identify a data source on the research topic and are encouraged to start thinking about a specific research question in their research area of choice early during the semester. Students should make a decision on their topic by **October 30th** and submit a one-page description of their proposed project plan. At the end of the semester, each group is expected to make a 15minute podium presentation of their final projects as well as submit an independent final report. The report should be a maximum of 20 double-spaced pages and contain the following sections: Introduction and Background, Specific Aims, Methodology, Results and Discussion. The report should be submitted through course website by **December 16th at 11:59pm**. Late submissions will receive 15 project points lost, unless excused by Dr. Yuan.*

Competency	Course Objectives(s)	Lessons	Assessment(s)
1	a, b, d, c, f, i	1, 2, 3, 4, 6	Reading 1-6, Mid-term, and class project
2	a, b, d	1, 5	Reading 1-4 and Mid-term
3	c, g	8, 11, 12, 14	Reading 7 and critique 1-5
4	g, h	9, 10	Reading 8, 9
5	e, g, h, i	11, 12, 13, 14	Reading 10-13
6	i	1, 2, 3, 4, 5, 6	Class project

- Grading Policy:

94 – 100 A
 90 – <94 A-
 87 – <90 B+

84 – <87 B
 80 – <84 B-
 77 – <80 C+
 70 – <77 C
 <70 F

Course Schedule:

Week	Date	Course Topic	Assigned Reading Due	Online 30	Assignment Due
1	Sept 9	Overview of outcomes research Jing Yuan, PhD, BPharm Assistant Research Professor, Center for Health Outcomes, Policy, and Economics (HOPE), Ernest Mario School of Pharmacy	Reading 1-Sept 9	Critique 1	Critique 1-Sept 23
2	Sept 16	Humanistic Outcomes Laura T. Pizzi, PharmD, MPH Professor and Director, Center for Health Outcomes, Policy, and Economics (HOPE), Ernest Mario School of Pharmacy	Reading 2-Sept 16	Critique 2	Critique 2-Sept 30
3	Sept 23	Clinical outcomes measures Devender Dhanda, PhD, MBA, MS Associate Director, Economic & Predictive Modelling Lead, WWHEOR, Bristol-Myers Squibb	Reading 3-Sept 23	Critique 3	Critique 3-Oct 7
4	Sept 30	Value-based outcomes research Akshay Kharat, PhD Manager, Real World Value & Evidence, Janssen Inc	Reading 4-Sept 30	Critique 4	Critique 4-Oct 14
5	Oct 7	Emerging outcome research design and methods Neeraj Iyer, PhD, BPharm Director, Value Evidence & Outcomes, Novo Nordisk	Reading 5-Oct 7	Critique 5	Critique 5-Oct 21
6	Oct 14	Project management and evidence communication Mike Durkin, MPH Director, Health Economics & Outcomes Research, Johnson & Johnson Manuscript development & publishing Lyn Beamesderfer, MS Associate Director, Publications & Communications, ISPOR	Reading 6-Oct 14	Class project	N/A
7	Oct 21	Midterm exam Jing Yuan, PhD, BPharm Assistant Research Professor, Center for Health Outcomes, Policy, and Economics (HOPE), Ernest Mario School of Pharmacy	N/A	N/A	N/A

Week	Date	Course Topic	Assigned Reading Due	Online 30	Assignment Due
8	Oct 28	Systematic review and meta-analysis Elizabeth Mearns, PharmD Senior Manager, US HEOR, Hematology/Oncology, Celgene	Reading 7- Oct 28	Class project	Final report- Dec16
9	Nov 4	Global acceptance of outcomes research in market access decisions and policymaking Catherine Tak Piech, MBA VP, Value Assessment Strategy (ret.) The Janssen Pharmaceutical Companies of Johnson & Johnson	Article 8- Nov 4	Class project	Final report- Dec16
10	Nov 11	Real world evidence to support regulatory decision making Shibani Pokras, MPH Senior Director, Global Value Evidence and Outcomes, GlaxoSmithKline	Reading 9- Nov 11	Class project	Final report- Dec16
11	Nov 18	Oncology outcomes research Shuvayu Sankar Sen, PhD, BPharm Executive Director, CORE Oncology, Merck	Reading 10-Nov 18	Class project	Final report- Dec16
12	Nov 25	Diabetes outcomes research Chris Blanchette, PhD, MBA Senior Director and Head, HEOR Real World Data Analytics, Novo Nordisk	Reading 11-Nov 25	Class project	Final report- Dec16
13	Dec 2	Healthcare quality and disparity Steven Peskin, MD, MBA, FACP Senior Medical Director, Clinical Innovations, Horizon Healthcare Innovations - Horizon BlueCross Blue Shield of New Jersey	Reading 12-Dec 2	Class project	Final report- Dec16
14	Dec 9	Medical device outcomes research Arthi Chandran, PhD, MPH Vice President and Head of WW Health Economics and Outcomes Research, BD	Reading 13-Dec 9	Class project	Final report- Dec16
15	Dec16	Student presentations & final report Jing Yuan, PhD, BPharm Assistant Research Professor, Center for Health Outcomes, Policy, and Economics (HOPE), Ernest Mario School of Pharmacy	N/A	N/A	Final report- Dec16

* Schedule and topics are subject to change based on availability of instructors and guest lecturers.

Learning Management System: Canvas will be used extensively throughout the semester for course syllabus, assignments, announcements, communication and/or other course-related activities. It is the student's responsibility to familiarize themselves with Canvas and check it regularly. If you have difficulties accessing Canvas, please inform the instructor and Canvas Support (help@canvas.rutgers.edu). Canvas is accessible at canvas.rutgers.edu.

School of Public Health Honor Code: The School of Public Health Honor Code is found in the School Catalog (sph.rutgers.edu/academics/catalog.html). Each student bears a fundamental responsibility for maintaining academic integrity and intellectual honesty in his or her graduate work. For example, all students are expected to observe the generally accepted principles of scholarly work, to submit their own

rather than another's work, to refrain from falsifying data, and to refrain from receiving and/or giving aid on examinations or other assigned work requiring independent effort. In submitting written material, the writer takes full responsibility for the work as a whole and implies that, except as properly noted by use of quotation marks, footnotes, etc., both the ideas and the works used are his or her own. In addition to maintaining personal academic integrity, each student is expected to contribute to the academic integrity of the School community by not facilitating inappropriate use of her/his own work by others and by reporting acts of academic dishonesty by others to an appropriate school authority. It should be clearly understood that plagiarism, cheating, or other forms of academic dishonesty will not be tolerated and can lead to sanctions up to and including separation from the Rutgers School of Public Health.

Students with Disabilities: Rutgers University welcomes students with disabilities into all of the University's educational programs. In order to receive consideration for reasonable accommodations, a student must apply for Services by first completing a Registration Form with the Rutgers Office of Disability Services (ODS) at ods.rutgers.edu. The student will also be required to participate in an ODS intake interview and provide documentation. If reasonable accommodations are granted, ODS will provide you with a Letter of Accommodations which should be shared with your instructors as early in your courses as possible.

Commitment to Safe Learning Environment: The Rutgers School of Public Health is committed to helping create a safe learning environment for all students and for the School as a whole. Free expression in an academic community is essential to the mission of providing the highest caliber of education possible. The School encourages civil discourse, reasoned thought, sustained discussion, and constructive engagement. Provocative ideas respectfully presented are an expected result. An enlightened academic community, however, connects freedom with responsibility. The School encourages all students to disclose any situations where you may feel unsafe, discriminated against, or harassed. Harassment or discrimination of any kind will be not tolerated and violations may lead to disciplinary actions.

Reporting Discrimination or Harassment: If you experience any form of gender or sex-based discrimination or harassment, including sexual assault, sexual harassment, relationship violence, or stalking, know that help and support are available. You may report such incidents to the [RBHS Title IX Office](#) or to the School of Public Health's [Office of Student Affairs](#). Rutgers University has staff members trained to support survivors in navigating campus life, accessing health and counseling services, providing academic and housing accommodations, and more. If you experience any other form of discrimination or harassment, including racial, ethnic, religious, political, or academic, please report any such incidents to the School's [Office of Student Affairs](#). The School strongly encourages all students to report any incidents of discrimination or harassment to the School. Please be aware that all Rutgers employees (other than those designated as confidential resources such as advocates, counselors, clergy and healthcare providers as listed in Appendix A to [Policy 10.3.12](#)) are required to report information about such discrimination and harassment to the School and potentially the University. For example, if you tell a faculty or staff member about a situation of sexual harassment or sexual violence, or other related misconduct, the faculty or staff member must share that information with the [RBHS Title IX Coordinator](#). If you wish to speak to a confidential employee who does not have this reporting responsibility, you can find a list of resources in Appendix A to University [Policy 10.3.12](#). For more information about your options at Rutgers, please visit [Rutgers Violence Prevention and Victim Assistance](#).

Graduate Student Computer Policy: Students are required to possess a personal laptop, no older than approximately two years, that must meet minimum requirements which may be found online at: sph.rutgers.edu/student-life/computer-support.html

Policy Concerning Use of Recording Devices and Other Electronic Communications Systems: When personally owned communication/recording devices are used by students to record lectures and/or classroom lessons, such use must be authorized by the faculty member or instructor who must give either

oral or written permission prior to the start of the semester and identify restrictions, if any, on the use of mobile communications or recording devices.

Policy Concerning Use of Turnitin: Students agree that by taking this course all required papers may be subject to submission for textual similarity review to Turnitin.com (directly or via learning management system, i.e. Canvas) for the detection of plagiarism. All submitted papers will be included as source documents in the Turnitin.com reference database solely for the purpose of detecting plagiarism of such papers. Use of the Turnitin.com service is subject to the Usage Policy posted on the Turnitin.com site. Students who do not agree should contact the course instructor immediately.

Withdrawal/Refund Schedule: Students who stop attending their course(s) without submitting a completed [Add/Drop Course](#) form will receive a failing grade. Furthermore, students dropping to zero credits for the semester are considered withdrawn and must submit a completed [Leave of Absence](#) form from the School of Public Health's Office of Student Affairs. The School of Public Health refunds tuition only. Administrative and technology fees are non-refundable. You may find the Withdrawal/Refund Schedule on the School of Public Health website at: sph.rutgers.edu/academics/academic-calendar.html