Introduction to Outcomes Research EPID 0563

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COURSE BASICS

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

Course Instructor: Artem Boltyenkov, PhD, MBA, MS, Adjunct Faculty, Rutgers School of Public Health Contact Information: artem.boltyenkov@rutgers.edu Office Hours: by appointment

Course location: Rutgers School of Public Health (683 Hoes Ln W, Piscataway, NJ 08854), classroom 2A, located on the second floor.

Course Assistants: *None* **Contact Information:** *NA*

Course Website: Access course via <u>canvas.rutgers.edu</u> using NetId and Password

Required Course Textbook: *Kane, R. L., & Radosevich, D. M. (2010). Conducting health outcomes research. Jones & Bartlett Publishers*

Additional/Supplemental Readings/Resources: Robertson, J.D., Russell, S.W., & Morrison, D.C. (2019). The grant application writer's workbook: National Institutes of Health Version. Buellton, CA: Grant Central, LLC. Assigned chapters will be uploaded in Canvas.

Course Description: During the past few years, there has been an explosion of interest in measuring the outcomes of medical care. This has been called the outcomes movement. 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 from fee-forservice to managed care environment. This course introduces students to the principles of health outcomes research and to practical applications of these principles.

COURSE COMPETENCIES

The competencies addressed in this course for the MPH:

MPH Degree in Epidemiology:

- 1 Formulate a specific hypothesis and determine an appropriate study design and analysis plan
- 2 Design, implement, and assess ordinary data collection systems for public health research
- 3 Communicate and present study findings to professional audiences

MS Degree in HOPE:

- 4 Design, evaluate, interpret, and communicate the results of non-randomized, observational research for applications in health outcomes, health economics, and health policy research
- 5 Evaluate the reliability, validity, and generalizability of individual biomedical research studies
- 6 Synthesize evidence for health policy decision makers to facilitate translation of interventions, applications, or programs

Please visit the Concentration webpages on the School of Public Health's website at <u>sph.rutgers.edu</u> for more information about the curriculum and competencies for our degrees and concentrations.

Course Objectives: *Provide a bulleted list of the objectives of the course (do not present as a paragraph). Begin this section with the following statement:* 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

This table lists the competencies, objectives along with the lessons and assessments where they are met			
COMPETENCY	COURSE OBJECTIVES	LESSONS	ASSESSMENTS
1	 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. F Demonstrate an understanding of the process of manuscript development and evidence communication. I Design and conduct a study using health outcomes research methodology to inform decision-making 	Weeks 1-8	1, 2, 3.a, 3.b, 3.c, 3.d
2	 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. D Discuss the utility of emerging research methods in outcomes research. 	Weeks 1-8	1, 2, 3.a, 3.b, 3.c, 3.d
3	 C Evaluate alternative study designs for conducting health outcomes research. G Evaluate the efficacy of newly introduced medical technologies through meta-analytic techniques. 	Weeks 1- 8, 10-12	1, 3.c, 3.d

4	 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.
5	 E Discuss the concepts of quality of health care organizations and value-based care. 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
6	• I Design and conduct a study using health outcomes research methodology to inform decision-making Weeks 1- 13 1, 2, 3.a, 3.b, 3.c, 3.d

COURSE REQUIREMENTS

Course Requirements and Grading:

This table contain required activities and their grade value

ACTIVITY	GRADE VALUE
Reflections on Guest Speakers	15 pts
Midterm (online)	30 pts

Final Project – "Research Grant Proposal"	
a. Draft Aims Pageb. Draft Approach Section	5 pts
c. Presentation (via "My Kaltura Media/Canvas) or in-person. TBD	5 pts
d. Final Proposal (Aims, Significance, Innovation and	15 pts
Approach)	20 pts
Class Participation (Online30 & Attendance)	10 pts
Total	100 pts

Grading Policy (%)*

This table contains			
	numerical and letter		
gra	des		
Numeric	Letter		
Value	Value		
94 -100	А		
90 - <94	A-		
87 - <90	B+		
84 - <87	В		
80 - <84	В-		
77 - <80	C+		
70 - <77	С		
<70	F		

*Grades will not be rounded.

COURSE SCHEDULE

This table list the topics, assessments and the competencies linked to them

WEEK/DA'	TE WEEKLY TOPICS AND ASSIGNED READING	ASSIGNMENTS AND ONLINE 30
	Introduction to Outcomes Research Midterm prep:	Obtain course text (Due 9/12)
1 - 9/12	 Read Syllabus & Kane (2011, Chap. 1) Final project: Read "How to develop a novel and compelling idea." Explore interests through searching Google, GoogleScholar, PubMed, and Rutgers Library. 	Online 30 (Due 9/18): • Introduce yourselves via discussion board & review requirements for final project.
2 - 9/19	 <u>Causal Thinking & Study Design</u> <u>Midterm prep:</u> Kane (2011, Chap. 2 & 3) <u>Final project:</u> Read "Specific aims section: conceptual framework for creating a bulleted outline." Continue to explore interests through searching Google, GoogleScholar, PubMed, and Rutgers Library. 	 Online 30 (Due 9/25): Review and respond to classmate introductions (minimum of 3 reviews). Post a scholarly/peerreview article related to outcomes research that interests you.
3 - 9/26	 Scientific Measurement Midterm prep: Kane (2011, Chap.4) Final project: Read "Writing the specific aims section." Review examples of specific aims sections available 	 Online 30 (Due 10/2): Review/respond to classmate posts on scholarly/peer-review articles. Post you initial ideas/brainstorm for the
4 - 10/3	via Canvas. <u>Generic Outcomes Measures</u> <u>Midterm prep:</u> • Kane (2011, Chap.5) <u>Final project:</u> • Use "Specific aims section a bulleted outline" to outline your aims page.	final project. Online 30 (Due 10/9): • Read/respond to classmates' initial ideas/brainstorm for the final project. • Ask questions or explain material we have covered.
5 - 10/10	Humanistic Outcomes Measures (Quality of Life & Patient Satisfaction) Midterm prep: • Develop study guide Speaker Reflections: • Dhanda readings available via Canvas.	Online 30 (Due 10/15): • Read/respond to explanations/questions from classmates on the material covered • Post initial questions

	Final project:	for Dr. Dhanda (next
	Collect references for your aims page.	week's lecture)
6 - 10/17	Clinical OutcomesDevender Dhanda, PhD, MBA, MSAssociate Director, Economic & Predictive ModellingLead, WWHEOR, Bristol-Myers SquibbMidterm prep:• Develop study guideSpeaker Reflections:• Ngorsuraches readings available via CanvasFinal project:• Read "Research strategy section: significance and	First Draft Aims Page (Due 10/17) Online 30 (Due 10/23): • Review and Respond to Classmate Posts on questions for Dr. Dhanda • Post initial questions
	innovation" • Review examples of significance and innovation sections provided via Canvas	for Dr. Ngorsuraches (next week's lecture)
7 - 10/24	Discrete Choice ExperimentSurachat Ngorsuraches, PhD, MSAssociate Professor, Health Outcomes Research andPolicy, Harrison College of Pharmacy, AuburnUniversityMidterm prep:• Complete/review study guideSpeaker Reflections:• Mearns readings available via CanvasFinal project:• Read "Research strategy section: approachsubsection"• Review Examples of approach sections provided via Canvas	Online 30 (Due 10/30): • Review/respond to classmate posts on questions Dr. Ngorsuraches • Post initial questions for Dr. Mearns (next week's lecture)
8 - 10/31	Systematic Review and Meta-Analysis Elizabeth Mearns, Pharmd Senior Manager, US HEOR, Hematology/Oncology,Celgene Midterm prep: • Complete/review study guide	Guest Speaker Reflection I (Due 10/30) Online 30 (Due 11/5) • Review/respond to classmate posts on questions for Dr. Mearns
9 - 11/7	MIDTERM EXAM (Delivered through Canvas) • Content: Kane, Chapters 1-5. Final Project: • Outline significance and innovation sections Speaker Reflections: • Iyer readings available via Canvas	MIDTERM EXAM Available only on 11/7, within 6pm-8pm ET window) • Delivered through Canvas Online 30 (Due 11/13):

		• Post initial questions for Dr. Iyer (next week's lecture)
10 11/14 11 11/21	Emerging Outcome Research Design and MethodsNeeraj Iyer, Phd, BpharmDirector, Value Evidence & Outcomes, Novo NordiskSpeaker Reflections:• Tak Piech readings available via CanvasFinal Project:• Work on approach sectionGlobal 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 Speaker Reflections:• TBD readings available via Canvas	Online 30 (Due 11/20): • Review/respond to classmate posts on questions for Dr. Iyer • Post initial questions for Ms. Tak Piech (next week's lecture) First Draft Approach Section (Due 11/22) Online 30 (Due 11/27) : • Review/respond to classmate posts on questions for Ms. Tak Piech • Post initial questions
12 11/28	Real World Evidence to Support Regulatory Decision Making TBD Speaker Reflections: • Beamesderfer readings available via Canvas	for Ms. TBD (next week's lecture) Guest Speaker Reflection II (Due 11/29) Online 30 (Due 12/4): • Review/respond to classmate posts on questions for Ms. TBD • Post initial questions for Ms. Beamesderfer (next week's lecture)
13 12/5	Outcomes Research Manuscript Development & <u>Publishing</u> Lyn Beamesderfer, MS Associate Director, Publications & Communications, ISPOR Final Project: • Complete proposal and presentations	Online 30 (12/11): • Review/respond to classmate posts on questions for
14 12/12	Course Wrap-up I	Upload Student Presentations to Canvas Guest Speaker Reflection III (Due 12/18)

15 12/19	Course Wrap-up II	Review and Comment on Student Presentations
		Due: Final Draft of Research Proposal
		Components (Due 12/19)

ASSIGNMENT STANDARDS

- <u>Late Assignments:</u> All assignments, unless otherwise indicated, must be submitted via Canvas by 11:59 PM on due date. 5% of assignment score will be deducted for each day late following the submission.
- <u>**Reflections on Guest Speakers (15% of Grade):**</u> Students will write three (3) reflections over the course of the semester. The response should include a summary the talk, how the presentation is relevant to the student's research interests or career aspirations, and what was learned. (300-500 words each).
- <u>Mid-term exam (30% of Grade)</u>: Students will be given an exam in week 9. The test will consist of multiple-choice, fill-in and short answer. (~45 questions, 120 minutes-max)
- Research Proposal (45% of Grade): Students will prepare select components for a National Institute of Health-style grant proposal: abstract (1 paragraph, 0.5 page/single-spaced/11pt font), specific aims page (1 page/single-spaced/11pt font), and research plan (significance, innovation, and approach sections, no more than 6 pages/single-spaced/11pt font). A draft of the aims page is due week 6. A draft of the approach is due week 11. The complete proposal is due at the end of semester. There is a presentation and a final draft due in the final two weeks of the semester.

<u>Class Participation (10% of Grade):</u>

1) Be Respectful. This includes interaction with guest speakers and classmates, timeliness, and communication.

2) Be Present (Physically and Mentally). Class attendance is **REQUIRED**. In the event that you must miss class for a valid reason (e.g., illness, unexpected emergency, etc.), notify the instructor as soon as possible, preferably by email and provide appropriate documentation. Any student that has more than three *unexcused* absences will receive a zero for the active participation component of their grade (i.e., the highest possible grade will be a 92). Please make every effort to come to class, even if you must arrive late. Absences may be excused on a case-by-case basis. You must notify the instructor before class begins.

3) There will be two Mondays in this course, where no in-person class takes place in the classroom 2A: zoom-only session (09/19) and a midterm exam (11/07). All other Monday in-person participation is required. If you cannot participate in-person with the instructor approval up to 2 additional sessions can be attended via zoom. Attendance via zoom is permitted only for a specific session and only for a specific student, who received the permission. No more than 2 such exceptions per course.

• Make-Up Work Policy

In cases of short-term illness or personal crises, the Instructor may grant permission to make up missed tests or assignments and/or request that the student complete a unique make-up assignment for partial credit. This will be determined on a case-by-case basis upon consultation with the Instructor and requires formal documentation (for example, a doctor's note). Prolonged absences will be addressed on a case-by-case basis in consultation with the Associate Dean for Student Affairs.

SCHOOL POLICIES

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@oit.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 (<u>sph.rutgers.edu/academics/catalog.html</u>). 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 <u>ods.rutgers.edu</u>. 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.

Student Well-Being: The School of Public Health recognizes that students may experience stressors or challenges that can impact both their academic experience and their personal wellbeing. If the source of your stressors or challenges is academic, students are encouraged to discuss these challenges and circumstances with their instructor, if they feel they may need additional support or temporary accommodations at the beginning or during this course. The course instructor may consider making reasonable temporary adjustments depending on the student's situation. For personal concerns or if additional support is needed, students may reach out to the <u>Office of Student Affairs (studentaffairs@sph.rutgers.edu</u>) or any of the appropriate referral resources listed on the <u>SPH Student Connect Canvas page</u>.

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 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. 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.

Overview of School Policies: Academic and non-academic policies and procedures, such Auditing a Course, Retaking Courses, Grade Grievance and others that cover registration, courses and grading, academic standing and progress, student rights and responsibilities, graduation and more may be found under <u>Policies</u> on the School of Public Health website. Below are select specific policies; however, students are responsible for keeping informed about academic and non-academic policies and procedures beyond those noted on this syllabus.

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 <u>Add/Drop Course Leave of Absence</u> form will receive a failing grade. Furthermore, students dropping to zero credits for the semester are considered withdrawn and must submit a completed 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: <u>sph.rutgers.edu/academics/academic-calendar.html</u>