GMS 6812: Health Outcomes Research in Cancer
Department of Health Outcomes and Policy
College of Medicine
University of Florida

Semester: Fall 2018
Time: TBD
Location: TBD
Credits: 3
Instructors:

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Office Hours: TBD

COURSE DESCRIPTION

Understanding and measuring outcomes of health care has become increasingly important with a continued and growing focus on comparative effectiveness research, patient reported outcomes, quality of care and value-based purchasing for health care. This course is designed to focus on assessing cancer-related health outcomes particularly within the context of delivering high quality cancer care. Outcomes research is broad and includes clinical endpoints such as toxic effects of drugs, clinical progression of disease and others. But it also includes functioning, health related quality of life (HRQOL), and patient reported outcomes. Examining outcomes across the cancer care continuum is critical and includes addressing outcomes associated with preventive care, treatment phases, survivorship, palliative and end-of-life care.

This course provides a framework for assessing cancer-related outcomes and for applying this framework to clinical and community-based research. Because outcomes research is rooted across the cancer continuum from prevention to end of life care, this continuum will be included in the discussions of outcomes measure. In addition, cancer-related outcomes are measured in controlled clinical environments but also in real-world clinical and community settings. Therefore, the course will also address measurement challenges in pragmatic and community based settings. As part of this course, students will be required to develop a protocol addressing a critical issue in cancer care with a focus on identifying key outcomes, how they were selected, how the data will be collected, and how the measures will be assessed.

AUDIENCE

The course is designed for advanced masters-level and doctoral-level students in health outcomes, biomedical informatics, medicine, public health, and other health professions, as well as advanced students in public policy, sociology, psychology or other social sciences with plans for a career in health research. Prerequisites are GMS xxx Measurement and Health Outcomes and/or permission of instructor.

COURSE OBJECTIVES

The primary goals of this course are to enhance students': (1) cancer outcomes research; (2) ability to critically evaluate the cancer care continuum and outcomes that may be used; and (3) experience in designing a protocol with an emphasis on the identification and analysis of cancer-related outcomes. More specifically, students who successfully complete the course will be able to:

1. Describe the different stages in the continuum of cancer care;
2. Describe conceptual models used to conduct health outcomes assessment in cancer;
3. Demonstrate familiarity with the range of measures that are used to assess cancer health outcomes and explain the strengths and limitations of those measures;
4. Evaluate the applicability of different outcomes assessment instruments in the different stages of the cancer care continuum;
5. Identify methodological challenges associated with assessing cancer care outcomes across the continuum of care and strategies for overcoming those challenges;
6. Compare and contrast measurement issues and methodological approaches for assessing health outcomes for pediatric versus adult cancer patients; and
7. Critically evaluate specific cancer health outcomes assessment studies for their potential to inform clinical practice, cancer population science, and health care policy.

COURSE EVALUATION

Students are expected to provide feedback on the quality of instruction in this course by completing online evaluations at https://evaluations.ufl.edu. Evaluations are typically open during the last two or three weeks of the semester, but students will be given specific times when they are open. Summary results of these assessments are available to students at https://evaluations.ufl.edu/results/.

METHODS OF INSTRUCTION

We will operate as an advanced graduate seminar, with students taking an active role in initiating and leading discussions and presenting their cancer outcomes measurement protocol progress. Attendance and active participation in all class discussions is required, and will be evaluated as part of the student's grade for the course. Students must read the required readings prior to each class session.

TESTS

No exams will be given in this graduate-level seminar course.

TERM PAPER/PROTOCOL DEVELOPMENT (SEE ADDITIONAL INFORMATION AT THE END OF THE SYLLABUS)

As described in the course introduction, students will develop a study protocol to assess cancer-related outcomes. The protocol can focus on any stage in the cancer care continuum. The protocol will contain the following sections:

1) **Specific Aims** – What is the critical cancer prevention, clinical, palliative care or end-of-life care issue, the setting and the patient population? What evidence-based intervention for this issue will be the focus of your study? What are the key outcomes

that will be measured to address the critical issue? Why have you selected these outcomes? What **impact** would this study have on improving patient outcomes (clinical, health related quality of life)? Costs? Clinician and patient satisfaction and engagement?

2) **Research Strategy**
    a. Significance: Describe in more detail the issue and the evidence base selecting the issue. Describe in more detail why the outcomes you have chosen are critical. Select and describe an appropriate conceptual framework to guide your study aims and hypotheses, study design, choice of outcomes and interpretation of findings.
    b. Innovation: Explain how the application challenges and seeks to shift current research, prevention, clinical practice, and/or cancer-care paradigms
    c. **Approach**
        i. Description of the study setting
        ii. Description of the study population
        iii. Study design
        iv. Sample size considerations
        v. Specification of study variables – be specific here about how you are specifying each of the selected outcome variables and the rationale for selecting them, their reliability and validity, applicability to the topic
        vi. Intervention approach or explanation of observational approach
        vii. Data collection plan – be very specific about how you will collect your outcome information
        viii. Data analysis plan – be specific about the
    d. Strengths and limitations of the approach – be very specific here about how you will address potential barriers to collecting your outcomes of interest.
    e. Dissemination plans
3) **Literature cited**
4) **Human Subjects consideration**
    a. IRB protocol approval statement
    b. Inclusion of women, children, and minorities
5) **Data sharing plans**
6) **Data safety and monitoring plans**

Interim and Final Presentation guidelines:

You are expected to provide an interim and a final presentation of your protocol. You should prepare a well-designed set of slides in a PowerPoint file, which you will use during your presentations and will email to the entire class and the attendees (according to an attendee list that will be provided to you) at least 4 business days before your presentation. Design each visual carefully to illustrate the main points. Remember the rules for clear, easy to understand, and interesting slides: No more than 8 words per line, and no more than 8 lines on a slide; prevalent use of diagrams, charts, etc. to illustrate points; minimize the number of word-only slides; and aim for about one slide per minute.

READING ASSIGNMENTS

The following will be used to assess students' progress in achieving the course objectives:

Readings and Class Discussions. You must read the assigned readings prior to each class session and be prepared to discuss your reactions, thoughts, analysis, comments and questions on the main issues raised in the readings. Share what strikes you as new, unexpected, or particularly important. Discuss implications of that reading for your scientific work. All students are expected to participate in each class discussion. In some cases, an out-of-class discussion activity will be assigned. In the week following the lecture for which it is assigned, you are to read the article or watch the video provided and post your reactions on the course discussion board on Canvas.

EVALUATION AND GRADING

Grades will be based on attendance and participation in discussions (20%); Interim Presentation (20%); Study Protocol (40%), Final Presentation (20%). All deadlines must be met. Any assignment turned in after the deadline will receive one grade below what it would have earned had it been submitted on time. Grades will be assigned as follows:

Letter Grade	Grade Points	Grade Percentage
A	4.0	95-100
A-	3.67	90-94
B+	3.33	87-89
B	3.0	83-86
B-	2.67	80-82
C+	2.33	77-79
C	2.0	73-76
C-	1.67	70-72
D+	1.33	67-69
D	1.0	63-66
D-	.67	60-62
E	0	59 and below

For additional grading policy information, you may visit the undergraduate catalog web page at https://catalog.ufl.edu/ugrad/current/regulations/info/grades.aspx.

COURSE POLICIES

Students are expected to adhere to the following course policies.

Class Attendance

Class attendance is required. Excused absences follow the criteria of the UF Graduate Catalog (e.g., illness, serious family emergency, military obligations, religious holidays), and should be communicated to the instructor prior to the missed class day when possible. University of Florida rules require attendance during the first two course sessions, and students must attend all course sessions of student presentations for this class. Missing more than three scheduled

sessions will result in a failure. Regardless of attendance, students are responsible for all material presented in class and meeting the scheduled due dates for class assignments. Finally, students must read the assigned readings *prior to* the class meetings, and be prepared to discuss the material. For more information, please visit:
https://catalog.ufl.edu/ugrad/current/regulations/info/attendance.aspx

Class Decorum

Please: (1) be on time, (2) respect others' points of view, (3) listen quietly when others are speaking, and (4) turn off cell phones, alarms, and other such distractions.

CANVAS

Course information, readings, and grades are available on Canvas at http://lss.at.ufl.edu/. You must have a Gatorlink account to log on. *You are expected to check the web site on a regular basis* (i.e., *at least* one day prior to each class meeting).

GETTING HELP

For issues with technical difficulties for E-learning in Canvas, please contact the UF Help Desk at: learning-support@ufl.edu or by calling (352) 392-HELP - select option 2. Additional information is available at: https://lss.at.ufl.edu/help.shtml

Returned Assignments

Keep copies of all assignments that you submit and of all grades until you receive official notification of your final course grade.

Policy on Make-Up Work

Students are allowed to make up work only as the result of illness or other unanticipated circumstances. In the event of such emergency, documentation will be required in conformance with university policy. Work missed for any other reason will earn a grade of zero.

Accommodations for Students with Disabilities

Students requiring accommodations must first register with the Dean of Students' Office. The Dean of Students' Office will provide documentation to the student who must then provide this documentation to the faculty member when requesting accommodation. The College is committed to providing reasonable accommodations to assist students in their coursework.

COUNSELING & MENTAL HEALTH SERVICES

Please visit the UF counseling center website for information regarding appointments:
https://counseling.ufl.edu/ or call (352)392-1575

UF POLICE DEPARTMENT

For Campus Police, please call the UF Police Department at 352)392-1111
For **all** emergencies and medical assistance, please call 911.

TEXTBOOK

Laura Levit, Erin Balogh. Delivering High Quality Cancer Care. National Academy of Sciences.

Online Course Evaluations

Students are expected to provide feedback on the quality of instruction in this course based on 10 criteria. These evaluations are conducted online at https://evaluations.ufl.edu. Evaluations are typically open during the last two or three weeks of the semester, but students will be given specific times when they are open. Summary results of these assessments are available to students at https://evaluations.ufl.edu.

SCHEDULE OF TOPICS AND READINGS

Class 1 - Magnitude of Cancer in the U.S. and General Concepts in Cancer Health Outcomes Assessment

Readings:
Levit. Chapters 1 and 2. Introduction and The Current Cancer Care Landscape
Selected Readings related to Reliability and Validity

Class 2: Cancer Outcomes: Trust, Communication and Shared Decision Making

Protocol Topic must be selected by the start of Class 3.

Readings:
Gilligan T. Patient-Clinician Communication: American Society of Clinical Oncology Consensus Guideline. DOI: 10.1200/JCO.2017.75.2311 *Journal of Clinical Oncology* - published online before print September 11, 2017. PMID: 28892432.

Harmano J et al. Trust in Physicians, Continuity and Coordination of Care, and Quality of Death in Patients with Advanced Cancer. J Palliat Med. 2017 Jul 21. doi: 10.1089/jpm.2017.0049.

White-Means SI and Osmani AR. Racial and Ethnic Disparities in Patient-Provider Communication With Breast Cancer Patients: Evidence From 2011 MEPS and Experiences With Cancer Supplement. Inquiry. 2017 Jan 1;54:46958017727104. doi: 10.1177/0046958017727104.

Class 3: Patient Reported Outcomes

Readings:
Jeppensen MM, et al. The impact of the survivorship care plan on health care use: 2-year follow-up results of the ROGY care trial. J Cancer Surviv. 2017 Sep 5. doi: 10.1007/s11764-017-0639-7.

Kaat AJ et al. Physical function metric over measure: An illustration with the Patient-Reported Outcomes Measurement Information System (PROMIS) and the Functional Assessment of Cancer Therapy (FACT). Cancer. 2017 Sep 8. doi: 10.1002/cncr.30981.

Duman-Lubberding S et al. Durable usage of patient-reported outcome measures in clinical practice to monitor health-related quality of life in head and neck cancer patients. Support Care Cancer. 2017 Jul 12. doi: 10.1007/s00520-017-3808-3.

Jefford M. Patient-reported outcomes in cancer survivors: a population-wide cross-sectional study. Support Care Cancer. 2017 Apr 22. doi: 10.1007/s00520-017-3725-5.

Jayadevappa R, Cook R, Chhatre S. Minimal important difference to infer changes in health-related quality of life-a systematic review. J Clin Epidemiol. 2017 Jul 1. pii: S0895-4356(16)30459-0. doi: 10.1016/j.jclinepi.2017.06.009.

Class 4 – Cost Outcomes

Readings:
Lao C et al. The cost-effectiveness of active surveillance compared to watchful waiting and radical prostatectomy for low risk localised prostate cancer. BMC Cancer. 2017 Aug 8;17(1):529. doi: 10.1186/s12885-017-3522-z.

Thein HH. Cost-effectiveness analysis of potentially curative and combination treatments for hepatocellular carcinoma with person-level data in a Canadian setting. Cancer Med. 2017 Sep;6(9):2017-2033. doi: 10.1002/cam4.1119. Epub 2017 Aug 8.

Van de Vrie R. Cost-effectiveness of laparoscopy as diagnostic tool before primary cytoreductive surgery in ovarian cancer. Gynecol Oncol. 2017 Sep;146(3):449-456. doi: 10.1016/j.ygyno.2017.06.019. Epub 2017 Jun 20.

McLeod M. Colorectal Cancer Screening: How Health Gains and Cost-Effectiveness Vary by Ethnic Group, the Impact on Health Inequalities, and the Optimal Age Range to Screen. Cancer Epidemiol Biomarkers Prev. 2017 Sep;26(9):1391-1400. doi: 10.1158/1055-9965.EPI-17-0150. Epub 2017 Jun 16.

Class 5 – Measuring the Quality of Cancer Care

Readings:
Teno JM et al, Challenges Of Measuring Quality Of Community-Based Programs For Seriously Ill Individuals And Their Families *Health Affairs* 36, no.7 (2017):1227-1233 doi: 10.1377/hlthaff.2017.0161

Shrujal S. et al. Overuse of Health Care Services in the Management of Cancer: A Systematic Review Medical Care. 55(7):723–733, JUL 2017

Colligan EM, Ewald E, Keating NL, et al. Two innovative cancer care programs have potential to reduce utilization and spending. *Med Care*. 2017;55:873–879.

Rocque GB, Partridge EE, Pisu M, et al. The patient care connect program: transforming health care through lay navigation. *J Oncol Pract*. 2016;12:e633–e642.

Colligan EM, Ewald E, Ruiz S, et al. Innovative oncology care models improve end-of-life quality, reduce utilization and spending. *Health Aff (Millwood)*. 2017;36:433–440.

Class 6 – Student-led interim presentations of their study protocols. Discussion will focus on topics and the selection of outcome measures**.** To aid in preparation of their final presentations, students will receive in-class feedback on their presentation topics, content, and delivery.

Class 7 - Student-led interim presentations of of their study protocols. Discussion will focus on topics and the selection of outcome measures**.** To aid in preparation of their final presentations, students will receive in-class feedback on their presentation topics, content, and delivery.

Class 8 – Outcome Measures and Community Engagement

Meet the Citizen Scientists: Citizen Scientist Panel Discussion &
Learning Health System Portal Demonstrations and Maintenance of Certification

Class 9: Measuring Health Disparities in Cancer

Readings:
Paskett E. et al. Multilevel Interventions To Address Health Disparities Show Promise In Improving Population Health. Health Aff (Millwood). 2016 Aug 1;35(8):1429-34. doi: 10.1377/hlthaff.2015.1360.

Smith SA. Persons Who Failed to Obtain Colorectal Cancer Screening Despite Participation in an Evidence-Based Intervention. J Community Health. 2017 Feb;42(1):30-34. doi: 10.1007/s10900-016-0221-7

Class 10 –Cancer Outcomes: Adverse Events

Readings:

Lipitz-Snyderman A Pfister D, Classen D, Atoria CL, Killen A, Epstein AS, Anderson C, Fortier E, Weingart SN. Preventable and mitigable adverse events in cancer care: Measuring risk and harm across the continuum. Cancer. 2017 Aug 17. doi: 10.1002/cncr.30916.

Basch E et al. Feasibility of Patient Reporting of Symptomatic Adverse Events via the Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) in a Chemoradiotherapy Cooperative Group Multicenter Clinical Trial. Int J Radiat Oncol Biol Phys. 2017 Jun 1;98(2):409-418. doi: 10.1016/j.ijrobp.2017.02.002. Epub 2017 Feb 10.

Lipitz-Snyderman A. et al. Performance of a Trigger Tool for Identifying Adverse Events in Oncology. DOI: 10.1200/JOP.2016.016634 *Journal of Oncology Practice* 13, no. 3 (March 2017) e223-e230. PMID: 28095173

Class 11 – Using Health Outcomes to Create a Cancer-Focused Learning Health System

Readings:

Levit - Chapters 5, 6, and 7 - The Evidence Base for High Quality Cancer Care and A Learning Health Care Information Technology System for Cancer and Translating Evidence Into Practice

Class 12 – Outcomes for Special Populations With Cancer

Kommann VNN et al. The First Year After Colorectal Surgery in the Elderly. Ann Coloproctol. 2017 Aug;33(4):134-138. doi: 10.3393/ac.2017.33.4.134. Epub 2017 Aug 31.

Rocque GB et al. Healthcare utilization, Medicare spending, and sources of patient distress identified during implementation of a lay navigation program for older patients with breast cancer. Breast Cancer Res Treat. 2017 Sep 12. doi: 10.1007/s10549-017-4498-8.

Ehrhardt MJ, et al. Neurocognitive, psychosocial, and quality-of-life outcomes in adult survivors of childhood non-Hodgkin lymphoma. Cancer. 2017 Sep 15. doi: 10.1002/cncr.31019.

Class 13 - Student Presentations of Protocols

Class 14 - Student Presentations of Protocols

Class 15 - Student Presentations of Protocols

Resources for preparation of 7-page abbreviated proposals, Use ½ margins and Arial 11 font.

Specific Aims (1 page)
State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved. List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology. Be sure to list the very *specific* few research questions or hypotheses to be tested in the proposed study.

Research Strategy (6 pages)

Significance
Briefly sketch the background leading to the present application, critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. State concisely the importance and health relevance of the research described in this application by relating the specific aims to the broad, long-term objectives. If the aims of the application are achieved, state how scientific knowledge or practice will be advanced. Describe the effect of these studies on the concepts, methods, technologies, treatments, services or preventative interventions that drive the field.

Innovation
Explain how the application challenges and seeks to shift current research or clinical practice paradigms. Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions. Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

Approach
Describe the research design, conceptual or clinical framework, outcomes selected (include their reliability and validity, applicability to your population and topic) procedures (include how you will collect the data, barriers to data collection and how you will overcome these barriers), and analyses. Describe any new methods and their advantage over existing methods. Describe any novel concepts, outcome measures, approaches, tools, or technologies for the proposed studies. Discuss how threats to validity are addressed by the design. Discuss potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. As part of this section, provide a tentative sequence or timetable for the project. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised.

Human Subjects consideration (no page limit)

a. IRB protocol approval statement

b. Inclusion of women, children, and minorities

Data Sharing and Dissemination Plans (1/2 page)

Data Safety and Monitoring Plans (no page limit)

Literature cited (no page limit; does not count toward 6 pages)

a. Use AMA or APA guidelines, be accurate and consistent

NIH R01 Instructions from website:

http://grants1.nih.gov/grants/funding/424/index.htm