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

Semester: Fall 2021
Time: Tuesdays, Period 4 - 6 (10:40 AM - 1:40 PM)
Location: HMEB 423
Credits: 3
Instructors: Georges E. Khalil, MPH, PhD CTRB; gkhalil@ufl.edu
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 proposal 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 proposal 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 and prevention;
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 proposal 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.

REACTION PAPERS (SEE ADDITIONAL INFORMATION AT THE END OF THE SYLLABUS)
Students will write weekly reaction papers to review the readings of the week and present their reactions and thoughts concerning the readings. These papers must also include any implications for future research and practice.

TERM PAPER/PROPOSAL DEVELOPMENT (SEE ADDITIONAL INFORMATION AT THE END OF THE SYLLABUS)
As described in the course introduction, students will develop a study proposal to assess cancer-related outcomes. The proposal can focus on any stage in the cancer care continuum, any population of interest, and any cancer-related health issue. The proposal will contain the following sections: Specific Aims, Research Strategy, Approach, Expected Results, Implications for Future Research and Practice, and References. Please see additional information and instructions at the end of the syllabus. You will also find these in Canvas.
INTERIM AND FINAL PRESENTATION GUIDELINES:
You are expected to provide an interim and a final presentation of your proposal. 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
You must read the assigned readings prior to each class session, prepare the weekly reaction paper, 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 (10%); Interim Presentation (20%); Reaction Papers (15%), Study Proposal (35%), and 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:

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<tr>
<th>Letter Grade</th>
<th>Grade Points</th>
<th>Grade Percentage</th>
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<tr>
<td>A</td>
<td>4.0</td>
<td>95-100</td>
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<tr>
<td>A-</td>
<td>3.67</td>
<td>90-94</td>
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<tr>
<td>B+</td>
<td>3.33</td>
<td>87-89</td>
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<tr>
<td>B</td>
<td>3.0</td>
<td>83-86</td>
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<tr>
<td>B-</td>
<td>2.67</td>
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<td>C+</td>
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<td>C-</td>
<td>1.67</td>
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<td>D+</td>
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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) keep cell phones and other such distractions on silent mode.

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 for work only as a 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
This course does not include a textbook.

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. 08/23: Understanding the Cancer Care Continuum and Cancer Prevention

Class 2. 08/30: Cost Outcomes in Cancer

Class 3. 09/06: Patient Centered Communication for Cancer Treatment and Prevention

Class 4. 09/13: Patient-reported Outcomes


Class 5. 09/20: Outcomes of Integrative Cancer Therapies


Class 6. 09/27: Behavioral Outcomes of Cancer Treatment and Prevention


Class 7. 10/04: Psychosocial Outcomes of Cancer Treatment and Prevention


Class 8. 10/11: Student-led interim activities for the preparation of study proposals.
Discussion will focus on presentation 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 9. 10/18: Outcomes of Entertainment and Technology in Cancer Care and Prevention


Class 10. 10/25: Measuring Health Disparities in Cancer


Class 11. 11/01: Cancer Outcomes: Adverse Events

Class 12. 11/08: Outcomes for Special Populations with Cancer

Class 13. 11/15: Student-led interim activities for the preparation of study proposals.
   Discussion will focus on presentation topics and the revision 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 14. 11/22: Presentations of Proposals
Class 15. 11/29: Presentations of Proposals
Resources to prepare for the 7-page abbreviated proposal, Use ½ margins and Arial 11 font. You may refer to the NIH R01 Instructions in this website: http://grants1.nih.gov/grants/funding/424/index.htm

1) **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.

Key questions in the Specific Aims page: What is the critical cancer prevention, clinical, palliative care or end-of-life care issue, the setting and the patient population? What is the gap in knowledge? 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? What are your 2 or 3 aims, and what are the hypotheses to test?

2) **Research Strategy (4-6 pages):** 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. Identify the gap in knowledge. State how scientific knowledge or practice will be advanced. Describe the effect of previous studies on the concepts, methods, technologies, treatments, services or preventative interventions that drive the field.

   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, community practice, and/or cancer-care 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.
   
   c. **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.

The following outline can be helpful:

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) Data safety and monitoring plans (1/2 page)
4) Literature cited (no page limit; use AMA or APA guidelines)