

**PHCY 5144**  
**Patient Reported Outcomes**  
**2 Credit Hours**  
**Online Course**  
**Spring 2020**  
**April 5 through May 10**

**Background**

Patient-reported outcomes (PROs) refer to various methods used to capture the patient perspective, and may include symptoms, functioning, health-related quality of life (HRQOL), or patient-perceived health status. These measures provide important information that is increasingly being used to inform health care decision-making.

**Course Description**

This course is designed to provide an overview of methods pertaining to the development and evaluation of PROs and the role they play in regulatory, reimbursement, and market access decisions.

**Place and Time of Class Sessions**

This course will be taught primarily in a synchronous fashion. Virtual classroom sessions will be held live each week on Sunday afternoon from 3:00pm to 5:00pm Wyoming time, unless other date/time arrangements are made (see below). Students will be responsible for completing course materials as their time permits, each week, with quizzes and exams being administered on weekends. Discussion board sessions will be held around the clock during the course. Students are expected to actively participate in discussion board on a regular basis. Questions regarding course content should be posted to the discussion board to allow access by all students to the discussion of this course material.

**Course Faculty and Office Hours*****Course Coordinator:***

Kristin Khalaf Gillard, PharmD, PhD

Email: [kkhalaf@uwyo.edu](mailto:kkhalaf@uwyo.edu)

Office Hours: by appointment

**Student Learning Outcomes**

Upon successful completion of this course, the student will be able to:

1. Understand how PROs fit into the context of clinical outcome assessments (COAs) from a regulatory perspective
2. List and define the different types of PROs, and select the most appropriate PRO to use for different research objectives
3. Describe the standard process by which PRO measures are developed and evaluated, and critically evaluate the measurement properties of a PRO
4. Understand the concept of utility, methods to elicit patient preferences, and the role of preference indices in health technology assessment
5. Describe the steps involved in cross-culturally adapting existing PRO measures
6. Interpret and critically analyze published outcomes research

### Course Learning Resources:

- Required textbook:
  - Streiner David L, Norman Geoffery R, Cairney J. Health Measurement Scales: A Practical Guide to Their Development and Use. 5<sup>th</sup> Edition. Oxford University Press, 2015.
- Additional assigned reading material (reading and/or video) will be provided on a weekly basis
- Additional recommended textbook (not required; will post individual chapters online as per reading list):
  - DeVellis RF. Scale Development: Theory and Applications. Fourth Edition. Sage Publications, Los Angeles CA, 2017.

### Course Structure & Outline

Live online virtual classes will be held each week using the virtual classroom (via Zoom). Class will be held on April 7 (week 1), April 14 (week 2 \*3 hour class), April 21 (week 3), May 6 (week 4), and May 12 (week 5 \*3 hour class). Class attendance is mandatory. Homework will be assigned following weeks 1, 3, and 5. A midterm examination will be administered following week 4. The final exam will be due on May 14 by midnight.

### Evaluation Techniques:

Class participation (including discussion boards)	30 points
Homework Assignment 1	10 points
Homework Assignment 2	10 points
Homework Assignment 3	10 points
Midterm Exam	30 points
Final Exam	<u>50 points</u>
<b>Total Points</b>	<b>140 points</b>

### Grading:

A:	90.0 – 100.0
B:	80.0 – 89.9
C:	70.0 – 79.9
D:	60.0 – 69.9
F:	<60.0

### Class Attendance Policy

Students must attend all six (6) classes, and productively participate in discussion board. Each student is expected to initiate one original thread per week and one responsive thread that follows the original thread posted by another student. All threads, whether original or responsive, must relate directly to the course material for that week, and must indicate reflective consideration of the material. Please refer to the discussion board/class participation grading rubric below:

### Discussion Board / Class Participation Grading Rubric (~20% of grade)

	Excellent (5 points)	Good (3-4 points)	Inadequate (1-2 points)
<b>Contributions</b>	Consistently initiates useful and relevant ideas when participating in the discussion	Usually provides useful ideas when participating in classroom discussion board. A strong	Inconsistent in providing relevant comments on discussion board. Fails to

	board. A definite leader who contributes major effort and who makes class discussions better.	student who tries hard but is more of a follower than a leader in discussions.	initiate new threads that stimulate participation by other students.
<b>Attitude</b>	Always respectful of others; has a positive attitude, and does not rudely criticize anyone else's ideas or work. Other students feel safe responding to this student's posts.	Occasionally becomes impatient with ideas or work of others. Usually has a positive attitude toward discussions. Usually treats others and self with respect.	On more than one occasion becomes disrespectful of ideas expressed by others, using insults rather than evidence to express contrary views.
<b>Preparedness &amp; Focus</b>	Consistently stays focused on subject matter assigned for discussion board and achieves identified outcomes. Self-directed and highly motivated. Postings help with understanding of assigned materials.	Usually posts comments that are related to course materials, but occasionally rambles about subjects that are not relevant to the course.	Postings to discussion board are based on general knowledge and common sense, rather than on materials assigned for course.
<b>Quality of Work</b>	Provides work of the highest insight that motivates other students to achieve at a high level.	Provides quality work that is interesting but not consistently insightful.	Does work that reflects little understanding of the course material.

### **Quiz/Exam Policy**

Inquiries regarding exams should be directed to the course coordinator, preferably prior to the assessment, and always within a week following the assessment.

### **Re-Grading Policy**

Requests for a re-grade of an examination, quiz, assignment, or in-class preparedness/participation points, must be requested within 2 business days of the return of the examination, quiz, or assignment. If the 2 business day period elapses and the student does not realize this, the request for a re-grade will NOT be considered. All requests for re-grading must be made in a written statement to the course coordinator and must be supported by appropriate justification (required textbooks, reading assignments, lecture citations). A request for re-grading is a re-evaluation of your work and has the potential to increase or decrease your grade when your work is reconsidered.

### **Make-up Quiz/Exam Policy**

Students who are not excused from a missed quiz or exam will receive a grade of zero on that missed assessment. Any student who misses quizzes and/or exams of a sufficient number that indicate the student has not completed enough coursework to achieve the objectives of the course will be given an incomplete (I) grade for the course.

### **Policy on Old Quizzes and Assignments**

Be advised that exams are an official University document, and not a public record, and therefore may not be communicated, copied or reproduced by any means, either in whole or in part, or shared with others in any form. Violators will be subject to discipline.

### **Academic Dishonesty Statement:**

Academic dishonesty will not be tolerated in this class. Cases of academic dishonesty will be treated in accordance with UW Regulation 2-114. The penalties for academic dishonesty can include, at the Course Coordinator's discretion, an "F" on an exam, an "F" on the class component exercise, and/or an "F" in the entire course. Academic dishonesty means anything that represents someone else's ideas as your own without attribution. It is intellectual theft – stealing - and includes (but is not limited to) unapproved assistance on examinations, plagiarism (use of any amount of another person's writings, blog posts, publications, and other materials without attributing that material to that person with citations), or fabrication of referenced information. Facilitation of another person's academic dishonesty is also considered academic dishonesty and will be treated identically

### **Disability Support Statement:**

The University of Wyoming is committed to providing equitable access to learning opportunities for all students. If you have a disability, including but not limited to physical, learning, sensory or psychological disabilities, and would like to request accommodations in this course due to your disability, , please register with and provide documentation of your disability as soon as possible to Disability Support Services (DSS), Room 128 Knight Hall. You may also contact DSS at (307) 766-3073 or [udss@uwyo.edu](mailto:udss@uwyo.edu). It is in the student's best interest to request accommodations within the first week of classes, understanding that accommodations are not retroactive. Visit the DSS website for more information at: [www.uwyo.edu/udss](http://www.uwyo.edu/udss)

### **Classroom Statement on Diversity:**

The University of Wyoming values an educational environment that is diverse, equitable, and inclusive. The diversity that students and faculty bring to class, including age, country of origin, culture, disability, economic class, ethnicity, gender identity, immigration status, linguistic, political affiliation, race, religion, sexual orientation, veteran status, worldview, and other social and cultural diversity is valued, respected, and considered a resource for learning.

### **Duty to Report:**

UW faculty are committed to supporting students and upholding the University's non-discrimination policy. Under Title IX, discrimination based upon sex and gender is prohibited. If you experience an incident of sex- or gender-based discrimination, we encourage you to report it. While you may talk to a faculty member, understand that as a "Responsible Employee" of the University, the faculty member **MUST** report information you share about the incident to the university's Title IX Coordinator (you may choose whether you or anyone involved is identified by name). If you would like to speak with someone who may be able to afford you privacy or confidentiality, there are people who can meet with you. Faculty can help direct you or you may find info about UW policy and resources at <http://www.uwyo.edu/reportit>

You do not have to go through the experience alone. Assistance and resources are available, and you are not required to make a formal complaint or participate in an investigation to access them.

### **Substantive Changes to Syllabus:**

All deadlines, requirements and course structure is subject to change if deemed necessary by the instructor. Students will be notified verbally in class, on our WyoCourses page announcement, and/or via email of these changes.

**Student Resources:**

DISABILITY SUPPORT SERVICES: [udss@uwyo.edu](mailto:udss@uwyo.edu), 766-3073, 128 Knight Hall, [www.uwyo.edu/udss](http://www.uwyo.edu/udss)

COUNSELING CENTER: [uccstaff@uwyo.edu](mailto:uccstaff@uwyo.edu), 766-2187, 766-8989 (After hours), 341 Knight Hall, [www.uwyo.edu/ucc](http://www.uwyo.edu/ucc)

ACADEMIC AFFAIRS: 766-4286, 312 Old Main, [www.uwyo.edu/acadaffairs](http://www.uwyo.edu/acadaffairs)

DEAN OF STUDENTS OFFICE: [dos@uwyo.edu](mailto:dos@uwyo.edu), 766-3296, 128 Knight Hall, [www.uwyo.edu/dos](http://www.uwyo.edu/dos)

UW POLICE DEPARTMENT: [uwpd@uwyo.edu](mailto:uwpd@uwyo.edu), 766-5179, 1426 E Flint St, [www.uwyo.edu/uwpd](http://www.uwyo.edu/uwpd)

STUDENT CODE OF CONDUCT WEBSITE: [www.uwyo.edu/dos/conduct](http://www.uwyo.edu/dos/conduct)

## Course Schedule, Required Readings, and Assignments

Class will begin on April 5 and end on May 10. The final examination will be due by midnight on May 15.

Week (Date), Time	Topic and Readings	Assignment
1 (Sunday, April 5), 3:00-5:00pm	<p><b>Topics:</b></p> <ul style="list-style-type: none"> <li>• <b>Course Introduction</b></li> <li>• <b>Overview of Clinical Outcomes Assessments</b></li> <li>• <b>Patient-reported Outcomes: Basic Concepts</b></li> </ul> <p><i>Required Readings:</i></p> <ul style="list-style-type: none"> <li>– Waltman MK, et al. Clinical Outcome Assessments: Conceptual Foundation – Report of the ISPOR Clinical Outcomes Assessment – Emerging Good Practices for Outcomes Research Task Force. <i>Value in Health</i> 2015;18:741-752.</li> <li>– Streiner &amp; Norman Chapter 1-2</li> <li>– Lower SK. Part 2. The meaning of measure: accuracy and precision (pg. 11-15). Matter and measure. <a href="http://www.sfu.ca/person/lower/TUTORIALS/matmeas/">http://www.sfu.ca/person/lower/TUTORIALS/matmeas/</a></li> <li>– Chapter 8: Measurement in the Broader Research Context (p. 233-246) from DeVellis RF. <i>Scale Development: Theory and Applications. Fourth Edition.</i> Sage Publications 2017. Thousand Oaks, CA.</li> </ul> <p><i>Supplemental:</i></p> <ul style="list-style-type: none"> <li>– FDA Clinical Outcome Assessment Qualification Program. Access at: <a href="http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugDevelopmentTools/QualificationProgram/ucm284077.htm">http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugDevelopmentTools/QualificationProgram/ucm284077.htm</a>.</li> <li>– COA Compendium (Pilot Version 1). FDA, February 2016.</li> <li>– Lubaczewski S, et al. Real-world disparities between patient- and clinician-reported outcomes: Results from a disease-specific program in anxiety and depression. <i>Professional Case Management</i> 2014;19(2):63-74.</li> <li>– Dobrozi S, Panepinto J. Patient-reported outcomes in clinical practice. <i>Hematology</i> 2015: 501-506.</li> <li>– Snyder C. Use of patient-reported outcomes in clinical practice. <i>The Lancet</i> 2009(374):369-370.</li> <li>– Van Der Wees P, et al. Integrating the Use of Patient-Reported Outcomes for both Clinical Practice and Performance Measurement: Views of Experts from 3 Countries. <i>Milbank Quarterly.</i> 2014;92(4): 754-775.</li> </ul>	Homework 1 Assigned (Due April 12)

2 (April 12), 3:00-5:00pm	<p><b>Topics:</b></p> <ul style="list-style-type: none"> <li>• <b>Validity</b></li> <li>• <b>Qualitative Research Methods for Developing PROs</b></li> </ul> <p><i>Readings to be added prior to April 5.</i></p>	Homework 2 Assigned (Due April 19)
3/4 (April 19), 3:00-6:00pm	<p><b>Topics:</b></p> <ul style="list-style-type: none"> <li>• <b>Introduction to Measurement</b></li> <li>• <b>Quantitative Evaluation of PROs</b></li> </ul> <p><i>Readings to be added prior to April 5.</i></p>	Online Midterm is LIVE from Friday, April 24 @ noon until Sunday, April 26 @ 6pm
4/5 (Sunday, May 3; 3:00-6:00pm)	<p><b>Topics:</b></p> <ul style="list-style-type: none"> <li>• <b>Regulatory considerations for the use of PROs in clinical development</b></li> </ul> <p><i>Readings to be added prior to April 5.</i></p>	Homework 3 Assigned (Due May 10)
6 (Sunday, May 10): 3:00-5:00pm	<p><b>Topics:</b></p> <ul style="list-style-type: none"> <li>• <b>Electronic PROs, Special Populations (e.g., children, oncology), Translation and Cultural Adaptation;</b></li> <li>• <b>FDA Drug Development Tool Qualification Program, EMEA PRO Guidance</b></li> <li>• <b>Utilities: Preference Elicitation Methods and Applications</b></li> <li>• <b>Wrap-up</b></li> </ul> <p><i>Readings to be added prior to April 5.</i></p>	Final Exam Due May 15 (midnight)