



PHCY 5141 PRINCIPLES OF HEALTH ECONOMICS AND OUTCOMES

COURSE INTRODUCTION

A NEW START IN HEALTH TECHNOLOGY ASSESSMENT 2023/2024

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Welcome to the Fall 2023 *Principles of Health Economics and Outcomes (PHCY 5141)* course *A New Start in Health Technology Assessment* – a three credit hour course for PharmD and MS level students. This 7-Module course is designed to provide a theoretical and practical foundation for the appropriate methods and application of techniques in health technology assessment (HTA); ones that meet the standards of normal science and fundamental measurement. Meeting the evidence needs of formulary committees, practitioners, patients and other health system decisionmakers is critical for effective health care delivery and the meaningful assessment of pharmaceutical products and devices.

PHCY 5141 makes the case that the commitment to assumption driven modelled simulation to support cost-effectiveness claims is an analytical dead end. It meets neither the standards for normal science not the required measurement standards. The new start delivers a comprehensive

package to support formulary submissions, prospective research courses to discover new facts for therapy response as well as the necessary inputs for outcomes-based contracting.

The focus of this course is to examine the appropriate theoretical and practical foundation for the methods and application of techniques in health technology assessment (HTA) that meet the standards of normal science and fundamental measurement. This involves meeting the evidence needs of formulary committees, practitioners, patients and other health system decision makers and is critical for effective health care delivery, together with the meaningful assessment of pharmaceutical products and devices by pharmacists in everyday practice. At the same time, we require disease specific single attribute and direct patient centric measures of the benefit of a new therapy to patients and caregivers. This can be achieved by the latent construct of need-fulfillment to produce unidimensional, linear and interval measures applying the Rasch model of instrument development.

The course aims to make the case for rejecting 30 years of much misplaced and wasted effort in HTA. In the early 1990s the decision was made that in order to make the case for new pharmaceutical products at product launch, hypothesis testing was to be abandoned in favor of creating assumption driven modeled approximate information to support formulary decisions. This was uncritically accepted by leaders in the field and detailed in textbooks and practice guidelines. It was also uncritically accepted by academic centers, government agencies and analysts despite warnings to the contrary. The result was the acceptance for publication of thousands of cost per quality of life (QALY) assumption driven imaginary claims which fail to meet the standards of normal science and fundamental measurement and their continued application by groups such as the Institute for Clinical and Economic Review (ICER). At the same time this acceptance of assumption driven modelled claims is open to abuse and bias . We are still locked into this belief system with the recent publication of the CHEERS 2022 guidance for submitting imaginary modeled claims to academic journals.

The new start paradigm provides a theoretical and practical foundation for the appropriate methods and application of techniques in HTA that meet the standards of normal science and fundamental measurement. Meeting the evidence needs, including outcomes contracting, of formulary committees, practitioners, patients and other health system decisionmakers, including minimizing bias, is critical for effective health care delivery and the meaningful assessment of pharmaceutical products and devices. This course proposes a new start in HTA to meet the needs of health system decision makers; a framework of analysis that is not only consistent with the standards of normal science and Rasch or modern measurement theory, but one that focuses on capturing needs-fulfillment quality of life of patients and caregivers. The importance of rejecting non-evaluable value claims for conducting and assessing outcomes research will be emphasized. This rejection provides a firm empirical basis for evaluating long-term clinical, quality of life and resource utilization outcomes, including engaging with health systems to identify and even contract for key value claims as part of disease area and therapeutic class reviews.

COURSE STRUCTURE

PHCY 5141 in two parts: Part I (Modules 1,2 3 and 4) provides a summary of the required standards for value claims in health technology assessment together with a critique of the existing

standards for creating imaginary modeled value claims while Part II (Modules 5, 6 and 7) provide the framework for a new start in HTA.

ASSESSMENT

There will be three literature critiques (25 points each), a mid-term and final written short answer examination (50 points each) and an assessment of up to 50 points for class participation.

Total score out of 225 will be translated to the following grades (corrected by 0.44):

A: 90.0 -100.0

B: 80.0 – 89.9

C: 70.0 – 79.9

D: 60.0 – 69.9

F <60.0.

LITERATURE CRITIQUE

Your critique should comprise four sections: (i) Introduction; (ii) Summary; (iii) Critique; and (iv) Conclusions. Maximum 1500 words Use DOCX format, Times New Roman (12) with reference numbers in text and references included at end.

Remember, the literature critique should reflect the course content and objectives: Is the stated purpose of the paper/commentary and the arguments presented relevant to the claim in this course that current standards of health technology assessment are at an analytical dead end?

Issues you should consider are:

- Is the purpose of the paper/commentary clearly stated?
- Have the author(s) indicated what motivated them?
- Does the paper/commentary provide context for their arguments?
- How convincing do you find their stated purpose?
- How convincing do you find the arguments?

The papers you are asked to critique are:

FIRST CRITIQUE: Husereau D, Drummond M, Augustovski F et al. Consolidated Health Economic Evaluation Reporting Standards 2022 (CHEERS 22) Statement: Updated reporting guidance for health economic evaluations. *ValueHealth*. 2022;25(1):3-9
<https://bmcmedicine.biomedcentral.com/articles/10.1186/s12916-021-02204-0>

SECOND CRITIQUE: Boone W, Rasch Analysis for Instrument Development: When, Why and How? CBE – Life Sciences Education. 2016; 15:rm4 1-7
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5132390/pdf/rm4.pdf>

The first critique is due 5 November (by email to the instructor at langley@maimnresearch.com and the second by 19 November.

MID COURSE AND FINAL EXAMINATION

Each examination will consist of 10 statements. You will be asked if you agree, are unsure or disagree with each statement and give the reasons for this response (max 400 words each statement response). Each examination counts 50 points. Questions for the mid-term will be distributed on 5 November and returned by 12 November. Questions for the final will be distributed on 3 December and returned by 10 December.

COURSE SCHEDULE

Classes are on Sunday from 5pm to 8pm Laramie time; there will be a 20 minute rest break at approximately 6.15 pm. Participants will be sent a Zoom link prior to each class.

Date	Module	Topic(s)
Sunday 22 October	1	The Myth of Cost-Effectiveness Claims: Science versus Non-Science in Health Technology Assessment
Sunday 29 October	2	Numbers, Measurement and Subjective Value Claims in Health Technology Assessment
Sunday 5 November	3	Assumptions, Models and Health Technology Assessment Imaginary Claims
Sunday 12 November	4	Rasch Measurement and Response to Therapy in Health Technology Assessment
Sunday 19 November	5	Truth is not Consensus in Health Technology Assessment: The Failure of Multiattribute Measures
Sunday 26 November	6	Need Fulfillment: Capturing the Patient Voice in Health Technology Assessment
Sunday 3 December	7	Formulary Submission and Product Monographs in Health Technology Assessment

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CLASS PARTICIPATION

It is important and expected that all students will be available for the 3-hour time slot on each Sunday of the course. With sufficient notice you should be able to arrange this schedule to ensure no conflicts with other activities. Each class will consider two articles which you are expected to have reviewed prior to the session (all available on-line). A series of questions will be prepared and class attendees will be expected to respond individually.

Articles
Sunday 22 October Module 1
Langley P. Nothing to Cheer About: Endorsing Imaginary Economic Evaluations and Value Claims with CHEERS 22 [version 1; peer review: 2 approved]. <i>F1000Research</i> 2022, 11:248 (https://doi.org/10.12688/f1000research.109389.1)
Husereau D, Drummond M, Augustovski F et al. Consolidated Health Economic Evaluation Reporting Standards 2022 (CHEERS 22) Statement: Updated reporting guidance for health economic evaluations. <i>ValueHealth</i> . 2022;25(1):3-9 https://www.valueinhealthjournal.com/article/S1098-3015(21)03146-6/pdf
Sunday 29 October Module 2
Wright B, Linacre J. Observations are always ordinal; measurements, however, must be interval. <i>Arch Phys Med Rehabil</i> . 1989; 70(12):857-60 https://www.researchgate.net/publication/20338407_Observations_are_always_ordinal_measurements_however_must_be_interval/link/5563b02408ae9963a11ef326/download
Langley PC and McKenna SP. Measurement, modeling and QALYs [version 1; peer review: 2 approved] <i>F1000Research</i> 2020, 9:1048 https://doi.org/10.12688/f1000research.25039.1
Sunday 5 November Module 3
Xie F, Zhou T. Industry sponsored bias in cost-effectiveness analysis: registry-based analysis. <i>BMJ</i> . 2022;377 https://www.bmj.com/content/bmj/377/bmj-2021-069573.full.pdf
Langley P. Let a Thousand Models Bloom: ICER Analytics Opens the Floodgates to Cloud Pseudoscience. <i>Inov Pharm</i> . 2021;12(1):No. 5 https://pubs.lib.umn.edu/index.php/innovations/article/view/3606/2668
Sunday 12 November Module 4
Boone W, Rasch Analysis for Instrument Development: When, Why and How? CBE – Life Sciences Education. 2016; 15:rm4 1-7 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5132390/pdf/rm4.pdf
Sunday 19 November Module 5
McKenna S, Heaney A. Composite Outcome measurement in clinical research: The triumph of illusion over reality? <i>J Med Econ</i> . 2020;23(10): 1196-1204 https://www.tandfonline.com/doi/pdf/10.1080/13696998.2020.1797755?needAccess=true

Langley PC and McKenna SP. Measurement, modeling and QALYs [version 1; peer review: 2 approved]. *F1000Research* 2020, **9**:1048 (<https://doi.org/10.12688/f1000research.25039.1>)

Sunday 26 November Module 6

McKenna S, Doward L. The needs-based approach to quality of life assessment. *ValueHealth*. 2004; 7(5): Supp 1. S1-S40 [https://www.valueinhealthjournal.com/article/S1098-3015\(10\)60227-6/fulltext](https://www.valueinhealthjournal.com/article/S1098-3015(10)60227-6/fulltext)

McKenna S, Heaney A. COSMIN reviews: The need to consider measurement theory, modern measurement and a prospective rather than retrospective approach to evaluating patient-based measures. *J Med Econ*. 2021;24(1):860-61
<https://www.tandfonline.com/doi/pdf/10.1080/13696998.2021.1948232?needAccess=true>

Sunday 3 December Module 7

Langley P. Formulary Submissions: Value Claims, Protocols and Outcomes Based Contracting in Rare Disease. *InovPharm*. 2022;13(3): No.9
<https://pubs.lib.umn.edu/index.php/innovations/article/view/5020/3224>

Brazier J, Peasgood T, Mukuria C et al. The EQ-HWB: Overview of the development of a measure of health and wellbeing key results. *Value Health*. 2022;25(4):482-491
[https://www.valueinhealthjournal.com/article/S1098-3015\(22\)00083-3/pdf](https://www.valueinhealthjournal.com/article/S1098-3015(22)00083-3/pdf)

CLASS NOTES

A set of class notes has been prepared for each module; these are intended to give an overview of each module and to link to the reading material. This can be accessed either through PHCY 5141 on the university website or through the instructor's website www.maimonresearch.com. If the latter, you should request a password for access. The course Introduction is also posted on this website, but does not need a password.

INSTRUCTOR AVAILABILITY/CONTACT INFORMATION

Office Hours: by appointment for Zoom and via electronic mail to UW account. Responses to emails will occur within 48 hours. You can always contact the instructor on his personal email.

UNIVERSITY GENERAL REQUIREMENTS AND EXPECTATIONS

Students should obtain the required textbook and complete assigned readings prior to the live online date listed in the course calendar. Students are encouraged to participate in live class sessions.

In order for a discussion or dialogue to be successful, students must have read the assigned readings, watched any video recording and have completed some assignments **before** joining class. Assignments will be clearly indicated whether due before or after the live session.

Whether a lecture or discussion, students should feel free to ask questions during class or on-line. If you have a question, other students may have the same question.

ATTENDANCE AND ABSENCE POLICIES

Participation is defined as asking questions, providing personal experience to the class, giving recommendations, etc. Comments can be either verbal or via chat.

Attendance at scheduled online classes through zoom or another process is mandatory. However, the course coordinator will excuse students from class for valid reasons. All students are expected to participate during online class sessions by responding to or asking questions.

Since some of the projects may be started in the live sessions, missing class can make projects much more difficult. Because of the multiple available times for posting assignments as well as for taking any quizzes or examinations, the need for an excused absence would be a rare event. Only rationale accepted by the University of Wyoming as an excused absence will be accepted. Any anticipated absence from the live sessions should be discussed in advance with the instructor.

CLASSROOM BEHAVIOR POLICY

At all times, treat your presence in the classroom and your enrollment in this course as you would any professional activity. Act professionally, arrive on time, pay attention, complete your work in a timely and professional manner, and treat all deadlines seriously. All of us will be respectful of each other. Spirited debate and disagreement are to be expected in any graduate level course and all views will be heard fully, but at all times we will behave civilly and with respect towards one another. Personal attacks, offensive language, name-calling, and dismissive gestures are not warranted in a learning atmosphere. This is a safe environment and as the instructor, I have the right to dismiss anyone from the classroom, study sessions, electronic forums, and other areas where disruptive behavior occurs – there is zero tolerance on this issue.

Discrimination and harassment 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 my discretion, an “F” on an exam, an “F” on the class component exercise, and/or an “F” in the entire course. Academic dishonesty includes plagiarism, which 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.

Such conduct is described within and will result in sanctions pursuant to the following School of Pharmacy and University policy and regulations:
University of Wyoming Code of Conduct <http://www.uwyo.edu/dos/conduct/> University of Wyoming Regulations

http://www.uwyo.edu/generalcounsel/_files/docs/UW%20Reg%20Updates%202016/UW%20Reg%206-802.pdf

DUTY TO REPORT

While this is a safe environment and I want you all to feel comfortable coming to me with issues you may be struggling with or concerns you may be having, please be aware that I have some reporting obligations that are part of my faculty requirements at UW.

For example, if you inform me of an issue of sexual harassment, sexual assault, or discrimination I will keep the information as private as I can, but I am required to bring it to the attention of the institution's Title IX Coordinator. If you would like to talk to those offices directly, you can contact Equal Opportunity Report and Response (Bureau of Mines Room 319, 766-5200, report-it@uwyo.edu, www.uwyo.edu/reportit). Additionally, you can also report incidents or complaints to the UW Police Department. You can also get support at the STOP Violence program (stopviolence@uwyo.edu, www.uwyo.edu/stop, 766-3296) (or SAFE Project (www.safeproject.org, campus@safeproject.org, 766-3434, 24-Hour hotline: 745-3556).

Another common example is if you are struggling with an issue that may be traumatic or unusual stress. I will likely inform the Dean of Students Office or Counseling Center. If you would like to reach out directly to them for assistance, you can contact them using the info below or going to www.uwyo.edu/dos/uwyocares.

Finally, know that if, for some reason, our interaction involves a disruptive behavior or potential violation of policy, I must inform the Dean of Students, even when you and I may have reached an informal resolution to the incident. The purpose of this is to keep the Dean apprised of any behaviors (by students or faculty) and what was done to resolve them.

SUBSTANTIVE CHANGES TO THE SYLLABUS

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

STUDENT RESOURCES

- DISABILITY SUPPORT SERVICES: udss@uwyo.edu, 766-3073, 128 Knight Hall, www.uwyo.edu/udss
- COUNSELING CENTER: uccstaff@uwyo.edu, 766-2187, 766-8989, 341 Knight Hall, www.uwyo.edu/ucc
- ACADEMIC AFFAIRS: 766-4286, 312 Old Main, www.uwyo.edu/acadaffairs
- DEAN OF STUDENTS OFFICE: dos@uwyo.edu, 766-3296, 128 Knight Hall, www.uwyo.edu/dos

UW•POLICE DEPARTMENT: uwpd@uwyo.edu, 766-5179, 1426 E Flint St, www.uwyo.edu/uwpd

•STUDENT CODE OF CONDUCT WEBSITE:www.uwyo.edu/dos/conduct

"If you have a physical, learning, sensory or psychological disability and require accommodations, please let me know as soon as possible. You will need to register with, and possibly provide documentation of your disability to Disability Support Services (DSS), room 109 Knight Hall. You may also contact DSS at (307) 766-3073 orudss@uwyo.edu. Visit their website for more information:www.uwyo.edu/udss."

COVID-19 POLICIES– while we are post pandemic, you must abide by all UW policies and public health rules put forward by the City of Laramie (or by Natrona County if at UW-Casper), the University of Wyoming and the State of Wyoming to promote the health and well-being of fellow students and your own personal self-care. The current policy is provided for review at: <https://www.uwyo.edu/alerts/campus-return/index.html>

As with other disruptive behaviors, we have the right to dismiss you from the classroom (Zoom and physical), or other class activities if you fail to abide by these COVID-19 policies. These behaviors will be referred to the Dean of Students Office using the UWYO Cares Reporting Form for Student Code of Conduct processes (https://cm.maxient.com/reportingform.php?UnivofWyoming&layout_id=5).

Syllabus Changes: I will alert you to any possible course format changes in response to UW decisions about community safety during the semester.

HYFLEX, ZOOM, BIG BLUE BUTTON AND WYOCOURSES EXPECTATIONS

As with all UW coursework, this course will be educational and useful to you. I will respond to questions, concerns, and feedback in a timely manner.

Your responsibilities:

- Give and receive feedback from me and your classmates respectfully and constructively in all interactions. This includes in Zoom chats, on WyoCourses boards, and within physical classroom spaces.
- Actively engage in civil discourse in a respectful manner. Use professional language in all course related forums.
- Communicate professionally. When ever you send class-related email or messages, please include a clear, specific subject line and use the body of the email or message to explain the purpose for the email and any attached materials. Conduct yourself professionally.
- Meet assignment deadlines. We expect that you're interacting with course material multiple times during the week.
- Ask for help when you need it. For academic assistance for this course please contact me for available resources. For Dean of Students assistance please see: <https://www.uwyo.edu/dos/student-resources/covid-19-student-resources.html>
- Please let us know if you notice another student who needs help in our (anonymous) WyoCares referral option (<https://www.uwyo.edu/dos/students-concern/index.html>).

INFORMATION TECHNOLOGY (IT) If you have any IT related challenges, please contact the UWIT Service Center:

<https://uwyo.teamdynamix.com/TDClient/1940/Portal/Requests/ServiceDet?ID=8890>

EXTERNAL UNIVERSITY CREDIT

For further information on this program for external university credit:

Elliott M Sogol PhD RPh FAPhA
Director Postgraduate and Continuing Education
School of Pharmacy
College Of Health Sciences
University of Wyoming
Email: esogol@uwyo.edu