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CTS-0152
Spring 2024

Tufts UNIVERSITY | Graduate School of Biomedical Sciences

Health Technology Assessment, CTS-0152

Term and year offered (Spring 2024)

Course Director(s):

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Course Information:
Credit(s): 2.0
Grading Option: A-F
Prerequisites: None

Course Contact Hours, Meeting Schedule, and Location:
Weekly asynchronous lecture (45 minutes), 2 live sessions (1 hour) during a weekday evening (to be selected to best accommodate everyone's schedule), weekly discussion board participation. Course duration: 14 weeks.

Brief Course Description: This course describes health technology assessment (HTA), as practiced by major agencies and other organizations in the United States and elsewhere, and introduces the processes and technical tools to engage stakeholders, review and synthesize clinical evidence, and assess the economic impact of drugs, devices, and other health interventions. For the U.S., the course reviews guidelines from the Second Panel on Cost Effectiveness Analysis in Health, and value assessment frameworks developed in the U.S., with a focus on the Institute for Clinical and Economic Review (ICER). The historical overview and current assessment of HTA in other countries focuses primarily on the National Institute for Health and Care Excellence (NICE) in the United Kingdom.

Learning Objectives:
At the conclusion of the course students should understand:

1. HTA approaches used by major organizations and agencies in the US and in other key countries.
2. How leading HTA frameworks incorporate clinical evidence, cost-effectiveness, and budget impact analysis to reach conclusions.
3. How data collected after an HTA decision or recommendation is used to monitor performance of the health technology, trigger reassessment, and support other activities.
4. The role of public input in the HTA process developed by the Institute for Clinical and Economic Review (ICER), how input from industry influences ICER, and how stakeholders can make their input more effective.
5. The advantages and limitations of HTA.

Course Texts and Materials:

- HTA 101: Introduction to health technology assessment. National Library of Medicine, 2014: https://www.nlm.nih.gov/nichsr/hta101/ta10103.html
- Neumann PJ, Cohen JT, Ollendorf DA. The Right Price: A Value-based Prescription for Drug Costs. New York: Oxford University Press, 2021. Available at:
    - https://www.amazon.com/Right-Price-Value-Based-Prescription-Costs/dp/0197512879/; or
    - https://www.barnesandnoble.com/w/the-right-price-peter-j-neumann/1138993576?ean=9780197512876; or
    - https://global.oup.com/academic/product/the-right-price-9780197512876?cc=us&lang=en& (30% off with promo code AMPROMD9);
    - Available electronically through Tufts Canvas – click on "Reading Lists" on left side of page.

We will post on Canvas lecture notes and recordings, readings for each session, and other material.

Assessments and Grading:

Class-specific readings: We will assign material from course texts and from other sources relevant to the lecture and discussion content.

Graded assignments

Assignment	**Grading weight**
Discussion board participation	25%
Industry comment critique – group presentation	25%
Debate case and rebuttal – Merits of value-based pricing	50%

Discussion board: We expect each student to submit at least one post weekly using the "Discussions" feature of the course website, starting with Session 2. The Discussion board will primarily involve professor-posted prompts, to which we ask students to respond. We will evaluate student comments based on responsiveness to the prompt, logic, and evidence, where appropriate. Written comments are due by 8:00 PM Eastern Time (ET) on the Wednesday of each week that we post a prompt.

Industry comment critique: Students will work in groups to develop a presentation that critiques biopharmaceutical industry comments on assessments conducted by the Institute for Clinical and Economic Review (ICER). We will schedule a live session during the course for these presentations (see schedule below). We expect presentations to be 5-8 minutes, with groups then responding to questions from faculty and other students.

Due dates for this assignment are:

Deliverable number	**Description**	**Due at 11:59 ET on**
1	Draft slides (bullet points and explanatory text; feedback only – ungraded)	February 23
2	Final slides and script	March 1

Groups will present their findings during a live session during the Session 8 class.

Debate case and rebuttal: Students will prepare cases (750 to 1000 words) and rebuttals (600 to 800 words) for a debate. The topic will be: *Resolved: The United States health care system should NOT use the cost-per-QALY metric to inform health expenditure resource allocation decisions.*

We will release details with Week 8 of the course.

Deliverable number	Description	Due at 11:59 ET on
1a	Case – Bullet points identifying key claims and argument points	March 20
1b	Case – First case argument	March 27
1c	Case – Full case	April 5
2a	Rebuttal – Response to first argument of opposing case	April 12
2b	Rebuttal – Full rebuttal to opposing case	April 19

Penalties for late or incomplete assignments: We will not accept late assignments unless you have requested and received advance permission from the course instructors.

Remediation Policy: Students will ordinarily receive as much as full credit for work turned in after the original deadline if they have requested and the faculty have granted advance permission.

Course and Assignment Schedule:

Week of:	Topic	SYNOPSIS
JAN 15 SESSION 1	MARKET FAILURES AND THE NEED FOR HEALTH TECHNOLOGY ASSESSMENT (HTA)	Course overview with introduction to the need for HTA and overall concepts. (PJN)
JAN 22 SESSION 2	MEASURING VALUE	Evolution of tools to measure value of health interventions, including measurement of costs and health effects. (JTC)
JAN 29 SESSION 3	HTA IN THE US AND ABROAD – PART 1: EARLY YEARS	Discussion of history and evolution of HTA in the US and abroad, including resistance and controversies. (DAO)
FEB 5 SESSION 4	HTA IN THE US AND ABROAD – PART 2: THE RISE OF ICER AND OTHER US VALUE FRAMEWORKS	The circumstances and environment for rise of the Institute for Clinical and Economic Review as well as other frameworks for assessing value. (DAO)
FEB 12 SESSION 5	STAKEHOLDER ENGAGEMENT WITH ICER	Who participates in HTA processes and how? How does HTA support transparency, equity, and fairness in its deliberations? How can industry engage most effectively with ICER? (DAO / JTC)
FEB 19 SESSION 6	SYSTEMATIC REVIEW AND EVIDENCE SYNTHESIS	Tools and techniques for evaluating clinical evidence, including systematic literature reviews, qualitative assessment and evidence tables, and meta-analysis and other quantitative approaches. (PGS)
FEB 26 SESSION 7	CEA AND BIA FOR HTA	Use of cost-effectiveness and budget impact analysis in HTA, methods standards, and development of thresholds for decision-making. (JDC)
MAR 4 SESSION 8	CEA AND GENERIC PRICING LIVE SESSION: GROUP PRESENTATIONS ON COMMENT CRITIQUES	Life cycle pricing, including current guidance and practice, and how it influences estimates. (PJN)
MAR 11 SESSION 9	CONTEXTUAL ELEMENTS IN HTA	Considerations for HTA decisions outside of evidence synthesis or economic evaluation and the importance of multi-stakeholder deliberation. (ST)
MAR 18 SESSION 10	ROLE OF REAL-WORLD EVIDENCE	Use of observational data to inform current HTA assessments and monitor performance post-decision. (PL)
MAR 25 SESSION 11	IMPROVING MEASUREMENT	Use of the societal perspective in cost-effectiveness analysis, approaches to address uncertainty in HTA (methods and outcomes-based contracting) and the appropriate arbiters of value in the US. (JTC)
APRIL 1	EASTER – NO CLASS	
APRIL 8 SESSION 12	GETTING VALUE-BASED PRICING	Potential alternatives to value-based pricing, including cost-plus pricing, prizes and population subscription models as well as role of public research funding. Also steps payers have taken to promote value-based pricing. (JTC)
APRIL 15 SESSION 13	FUTURE OF HTA	Proposal for what a national HTA strategy in the US might look like, overview of current legislative and policy discussions for drug pricing (DAO)
APRIL 22 SESSION 14	NO LECTURE LIVE SESSION: IN-CLASS DEBATE CASE DISCUSSION	*The United States health care system should <u>NOT</u> use the cost-per-QALY metric to inform health expenditure resource allocation decisions.*

This schedule is subject to modifications at the discretion of the course director.

Instructors:

- DAO: Daniel Ollendorf
- JDC: Jon Campbell
- JTC: Joshua Cohen
- PJN: Peter Neumann
- PJS: Patricia Synnott
- PL: Pei-Jung Lin
- ST: Sean Tunis

COURSE SESSION OBJECTIVES

By the end of each lecture, students will be able to:

SESSION 1: MARKET FAILURES AND THE NEED FOR HEALTH TECHNOLOGY ASSESSMENT

- Identify factors complicating the role individuals play in selecting treatments for their own care.
- For the development and supply of medications, understand the factors complicating the role of competitive mechanisms that operate in typical markets.
- Describe factors that interfere with the intended operation of patent expirations for medications.

SESSION 2: MEASURING VALUE

- Describe the origin of efforts to measure the value of life and health
- Understand different approaches for valuing life, along with their limitations
- Explain why analysts introduced cost-effectiveness analysis into HTA
- Understand standardized methods for developing health utility preference weights

SESSION 3: HTA IN THE US AND ABROAD (PART 1): EARLY YEARS

- Summarize the history of HTA and related efforts in the US
- Enumerate the major barriers and challenges to formal HTA adoption domestically
- Describe the rationale for adoption of HTA internationally and the reasons for its spread

SESSION 4: HTA IN THE US AND ABROAD (PART 2): THE RISE OF ICER AND OTHER US VALUE FRAMEWORKS

1. Summarize changes in the US drug pricing environment in the last 10 years
2. Explain how these changes increased interest in "value-based" pricing
3. Describe the increase in ICER's visibility and importance in the current context
4. Describe other value frameworks that developed during this period, how they differ from ICER's, and why they seem to be less influential.

SESSION 5: STAKEHOLDER ENGAGEMENT WITH ICER

- Understand ICER's stakeholder engagement measures and why some see ICER's role in the HTA process as problematic.
- Understand why many industry comments seem to have had a limited influence on ICER's deliberations.
- Be able to anticipate weaknesses in comments drafted in response to ICER HTAs.

SESSION 6: HTA METHODS – SYSTEMATIC REVIEW AND EVIDENCE SYNTHESIS

- Explain the PICOTS framework and other constructs for defining a systematic review's scope
- Identify the major databases used for literature searches and describe how they differ
- Understand the key elements of defining a search strategy
- Describe qualitative evidence synthesis approaches and approaches for presenting evidence (e.g., evidence tables)
- Explain the criteria for assessing whether meta-analysis is appropriate for a particular review and be able to distinguish between the major types of meta-analysis

SESSION 7: HTA METHODS – COST-EFFECTIVENESS ANALYSIS (CEA) AND BUDGET IMPACT ANALYSIS (BIA)

- Explain the use of CEA in an HTA setting, including development and deployment of a reference case
- Understand different approaches to identifying CEA value benchmarks used by HTA bodies
- Summarize the structure, data needs, and approaches for BIA, and the role of BIA in HTA
- Describe how assessment bodies conduct HTAs in settings that do not use economic evaluation (e.g., Germany)

SESSION 8: CEA AND GENERIC PRICING

- Understand what HTA guidelines say about incorporation of generic pricing into assessments, and when CEAs incorporate it in practice.
- Understand the influence on cost-effectiveness of incorporating generic pricing.
- Understand arguments for and against inclusion of generic pricing in CEAs.

SESSION 9: CONTEXTUAL ELEMENTS IN HTA

- Compare how HTA bodies account for contextual elements not reflected in quantified clinical and economic assessment
- Describe the major approaches for incorporating such considerations (e.g., qualitative approaches, MCDA, special population adjustments)
- Identify cases where contextual considerations influenced an HTA.
- Discuss approaches for considering and integrating health equity concerns into HTA.

SESSION 10: THE ROLE OF REAL-WORLD EVIDENCE

- Understand the key types of datasets that can inform HTA activities
- Describe the use of real-world evidence for evidence assessments and simulation model parameter estimation
- Explain how analysts can use real-world evidence after a technology's adoption for monitoring and to trigger downstream activities (e.g., reassessment, pricing changes)

SESSION 11: IMPROVING MEASUREMENT

- Understand what HTA guidelines say about using the societal perspective, its use, and how much it can influence CEA estimates.
- Understand limitations of how HTA bodies characterize uncertainty and to dealing with uncertainty using outcome-based risk sharing agreements.

SESSION 12: GETTING VALUE-BASED PRICING

- Understand cost-plus pricing, prize models, subscription models, government-led drug development and the prospect of using these measures to mitigate the need for value assessment.
- Understand what public and commercial payers have done to implement value-based pricing, and why those efforts have not gone further

SESSION 13: THE FUTURE OF HTA IN THE US

- Understand the current political environment for HTA and the challenges ICER faces
- Explain recently promulgated criteria for establishing a national HTA coordinating center in the US and the activities it would direct
- Describe key legislation and policy on drug pricing reform that have been discussed and debated as well as reforms recently passed and undergoing implementation
- Understand the political challenges directed at the QALY metric and the details of alternative measures that have been proposed

UNIVERSITY AND GSBS POLICY

The Tufts Graduate School of Biomedical Sciences mandates inclusion of the following language in syllabi:

Diversity, Equity, and Inclusion for all Tufts Community Members:
It is our commitment that students from all diverse backgrounds and perspectives be well served by this course, that students' learning needs be addressed, and that the diversity that students bring to this class be viewed as a resource, strength and benefit. It is our intent to present materials and activities that are respectful of diversity in all forms, including but not limited to: gender, sex, sexual orientation, disability, age, socioeconomic status, national origin, ethnicity, race, color, religion, culture, and the intersectionality of identities. Please let us know ways to improve the course for you personally or for other students or student groups. Please see the Tufts University Non-Discrimination Policy for more information.

Requesting Reasonable Religious or Disability-related Accommodations at Tufts University
Both university policy and Massachusetts law provides that students unable to attend classes, participate in required course or lab activities, or take a scheduled examination because of religious observance will be provided with reasonable opportunity to make up the course work without adverse effects. The University's Disability and Religious Reasonable Accommodations Policy and other policies are available at https://oeo.tufts.edu/policies-procedures/accommodation-policies/. Students requiring an accommodation should contact the course director prior to the requested dates to work out suitable accommodations.

Tufts University is also committed to providing reasonable accommodations for qualified individuals with disabilities. If you are interested in seeking accommodations in courses or in a laboratory setting, please contact Michael T. Chin: michael.chin614279@tufts.edu at GSBS. You can also request a reasonable accommodation for either a disability-related or a religious reason at https://oeo.tufts.edu/accommodations/.

Decolonization
The course director and lecturers acknowledge the damage done to BIPOC communities by generations of systemic racism within academia. The director also acknowledges that this is a particularly difficult time to be students, and that the political, medical, economic, and personal stresses that have been amplified in the past few years disproportionately affect already marginalized students. This course enthusiastically supports the University's stated anti-racist goal (https://gsbs.tufts.edu/about/diversity-equity-and-inclusion) and in pursuit of this, will abide by the following policies.

1. The director and lecturers will seek and use course resources that are inclusive of race, socio-economic standing, gender, sexuality, disability, immigration status, English language learning status, and first-generation status.
2. Microaggressions, along with any other racist remarks, actions or behaviors will not be tolerated.
3. Students experiencing challenges are encouraged to reach out to Michael T. Chin: michael.chin614279@tufts.edu or to whom they feel comfortable talking to at GSBS to discuss solutions. Students who want to file a formal complaint can do so with the Tufts Office of Equal Opportunity or through the online portal at Tufts-OEO.ethicspoint.com.

Students are encouraged to reach out to the course director with any suggestions for adjustments or further course guidelines.

Course Expectations
In addition to the course specific late work and remediation policies detailed above, students, course director and lecturers acknowledge the following:

1. The director accepts responsibility to notify students early if expectations regarding learning, attendance or participation are not being met.
2. The course director will make themselves available by multiple avenues of communication and if needed, will work with students to find mutually convenient times to meet.
3. Opportunities may be available, upon request, to retake missed or late work. If a student falls behind, the director may provide opportunities for that student to catch up. If a student is struggling to understand the material, the course director will work with the student on strategies to better understand the material.
4. Mistakes are expected and respected, and the director will make conscious efforts to prevent them from biasing their opinion of students. The director acknowledges that graduate level biological science material is

difficult, and the best way to learn it is by engaging at the limits of your knowledge. If done well, this inevitably will lead to mistakes being made.

University Policies:

- ***Sexual Misconduct Policy:*** Tufts is committed to providing an education and work environment that is free from sexual misconduct. If you or someone you know has been harassed or assaulted, please contact the Office of Equal Opportunity who can help you find appropriate resources and discuss your options before you decide if you want to formally file. Anonymous reporting is available through the third party online reporting tool called Ethicspoint which also has an option to report anonymously. Students may also obtain free confidential counseling through Talk One2One at 1-800-756-3124. Campus police may be contacted at 6-6911 in an emergency.

- ***Tufts Information Stewardship Policy*** outlines the actions all members of the Tufts community are expected to follow when working with institutional data and systems (https://it.tufts.edu/ispol).

- ***Academic Conduct:*** All students are responsible for compliance with all academic standards and policies, including plagiarism and academic integrity, as outlined in the Graduate School of Biomedical Sciences Student Handbook (https://gsbs.tufts.edu/studentLife/StudentHandbook).

- ***Disclosing Conflicts of Interest***: The course director and lecturers, including guest lecturers, are expected to disclose any significant financial interests or conflicts of interest that might undermine, appear to undermine, or have the potential to undermine the objectivity of their lecture content and assigned reading materials.

Revised August 2023