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CTS-0152: Health Technology Assessment
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CTS-0152: Health Technology Assessment (HTA): Philosophy, Approach, and Challenges
Fall 2021

Course Directors

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

Course Time and Location: Weekly asynchronous lecture (45 minutes), 2 live sessions (1 hour), weekly discussion board participation

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);
  - Hirsh library link – To be added.
- We will post on Canvas lecture notes and recordings, readings for each session, and other material.

Summary of Assignments and Grading:

Assignment	Grading weight
Discussion board participation	25%
Midterm group presentation	25%
Debate case and rebuttal	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 6:00 PM on the Saturday of each week that we post a prompt.

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

Midterm group presentation: 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:

- Draft slides (bullet points and explanatory text; feedback only – ungraded) – October 11 at 6:00 PM.
- Final slides and script – October 18 at 6:00 PM.
- Presentation during the course live session for the week of October 25.

Final project: Students will participate in an online, written debate. The topic will be:

> *Resolved: For pharmaceuticals, value-based pricing is the best way to improve the health of people living in the United States.*

- Students will write a case of 800 to 1,000 words negating the resolution. The case should consist of 2-3 arguments, each of which stands as an independent reason for why the resolution is false. Reasons can include but are not limited to: (1) lack of workability, (2) ethical challenges, (3) alternative approaches that obviate the need for value-based pricing. We will evaluate cases based on clarity, development of arguments that anticipate rebuttals and defend against them, and use of logic and evidence to support claims.

- Every student will receive a case from another student and write a 600-800 word point-by-point rebuttal. We will evaluate rebuttals based on coverage of the opposing arguments, clarity, logic, and use of evidence.

Cases and rebuttals may not quote *The Right Price* to support arguments, but they can quote sources cited by *The Right Price*. Word counts do not include endnotes. Endnotes should specify sources cited and page number(s) for evidence cited, and include the supporting passage.

Due dates for this assignment are:

- Case bullet points identifying key claims and argument points (feedback only – ungraded) – October 25 at 6:00 PM.
- First case contention (i.e., first main argument; feedback only – ungraded) – November 8 at 6:00 PM.
- Full case (to be graded) – November 22 at 6:00 PM.
- Rebuttal response to first argument of opponent's case (feedback only – ungraded) – November 29 at 6:00 PM.
- Full rebuttal to opponent's case (to be graded) – December 6 at 6:00 PM.

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

Special Circumstances and Accommodations for Students with Disabilities:
Students seeking accommodations must first consult with Kathryn Lange, the School's Disability Officer. Students who anticipate being absent for an extended period or unable to complete coursework in the required time frame should also speak with Dean Lange as soon as possible. Information disclosed is confidential.

University Policies:
All students are required to abide by the Tufts University Sexual Harassment Policy (http://oeo.tufts.edu/policies-and-procedures/sexual-harassment-policy) and the Information Stewardship Policy (http://uit.tufts.edu/?pid=786).

Academic Conduct:
Academic integrity, including avoiding plagiarism, is critically important. Each student is responsible for being familiar with the standards and policies outlined in the Graduate School of Biomedical Sciences Student Handbook (https://gsbs.tufts.edu/studentLife/StudentHandbook). We will sanction violations, with penalties that can include grade reduction, course failure, and dismissal from the school, depending on the infraction's nature and context.

We encourage students to discuss course assignments, but submitted work must be entirely your own (in your own words), with the exception of work we explicitly designate as having a group deliverable. For this course, only the midterm group presentation falls into this category. For any work that has involved collaboration with others, please include the names of the other students involved.

Submitting work: We ask that you upload the group presentation and final project case and rebuttal to Canvas on the dates indicated on the course schedule (below).

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Course and Assignment Schedule:

Week of:	Topic	Synopsis
Sept 6 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)
Sept 13 Session 2	Measuring value	Evolution of tools to measure value of health interventions, including measurement of costs and health effects. (JTC)
Sept 20 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)
Sept 27 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)
Oct 4 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)
Oct 11 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)
Oct 18 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)
Oct 25 Session 8	Contextual elements in HTA Live Session: Group Presentations on Comment Critiques	Considerations for HTA decisions outside of evidence synthesis or economic evaluation and the importance of multi-stakeholder deliberation. (ST)
Nov 1 Session 9	CEA and generic pricing	Life cycle pricing, including current guidance and practice, and how it influences estimates. (PJN)
Nov 8 Session 10	Role of real-world evidence	Use of observational data to inform current HTA assessments and monitor performance post-decision. (PL)
Nov 15 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)
Nov 22	Thanksgiving—no lecture or live session	
Nov 29 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)
Dec 6 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)
Dec 13 Session 14	No lecture Live Session: In-class debate	*Resolved: For pharmaceuticals, value-based pricing is the best way to improve the health of people living in the United States.*

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: 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.

SESSION 9: 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 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 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 are the subject of current debate

List of revisions since initial release (July 20, 2021)

Date	Revision
	None to date