Values in doing assessments of healthcare technologies (VALIDATE)

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Friday 7th of December, 2018, HTAi Ethics IG Meeting, Amsterdam

Radboudumc

Content

- Description of the project and intended activities (Bart)
- The task for HTA (Gert Jan)
- Discussion (Gert Jan)

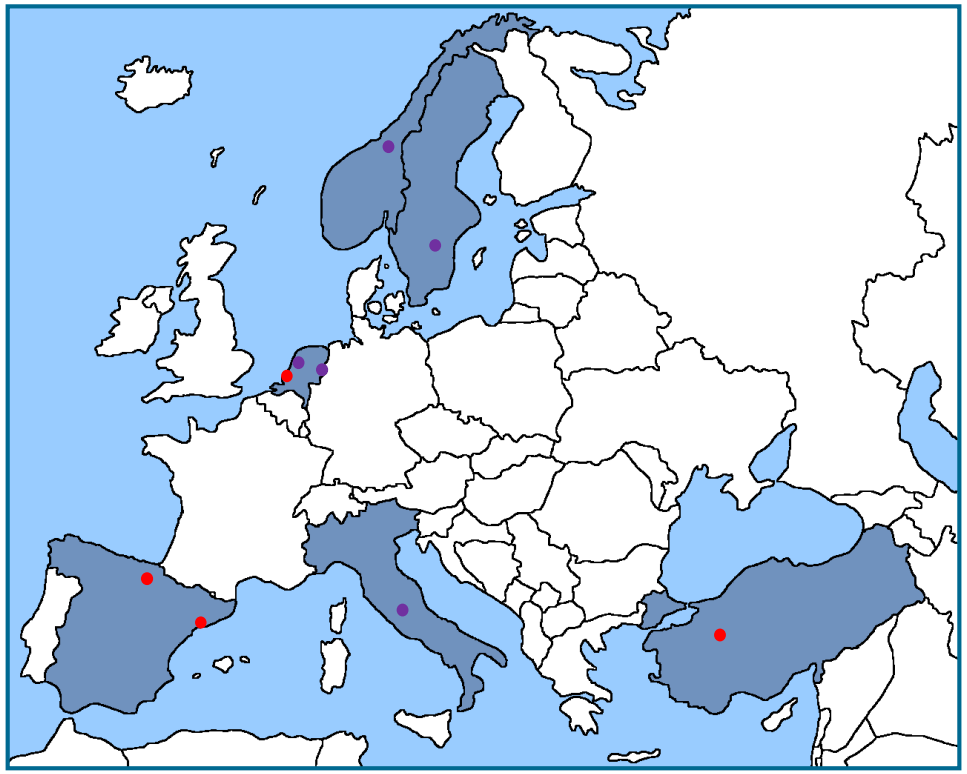
Values in doing assessments of healthcare technologies (VALIDATE)

- EU Erasmus+ Call Strategic Partnerships Higher Education

- Objectives:
  - Develop a consensus statement on skills and knowledge needed to conduct an integrative HTA
  - E-learning module + handbook
  - Invite students to conduct an internship project
  - Academic paper on critical factors for adopting novel approaches to HTA

- www.validatehta.eu

VALIDATE consortium



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LINKÖPINGS UNIVERSITET

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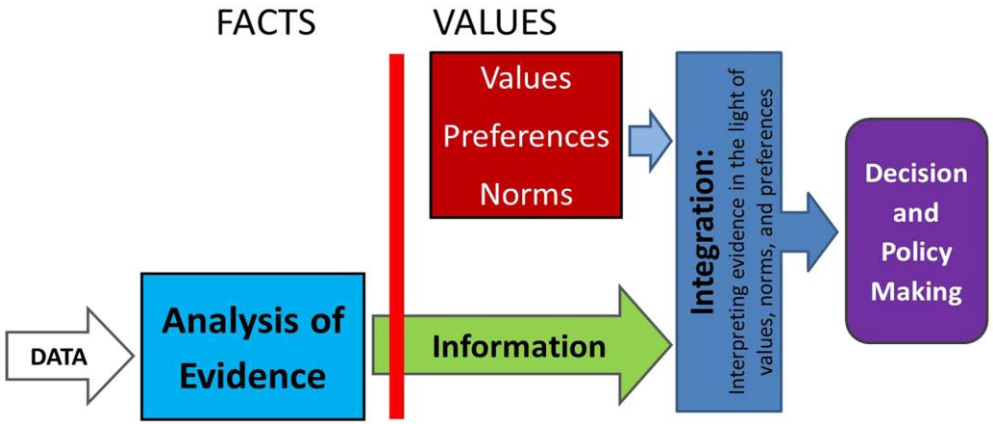
ANHTA

FUNDACIÓ CLÍNIC BARCELONA

VALIDATE

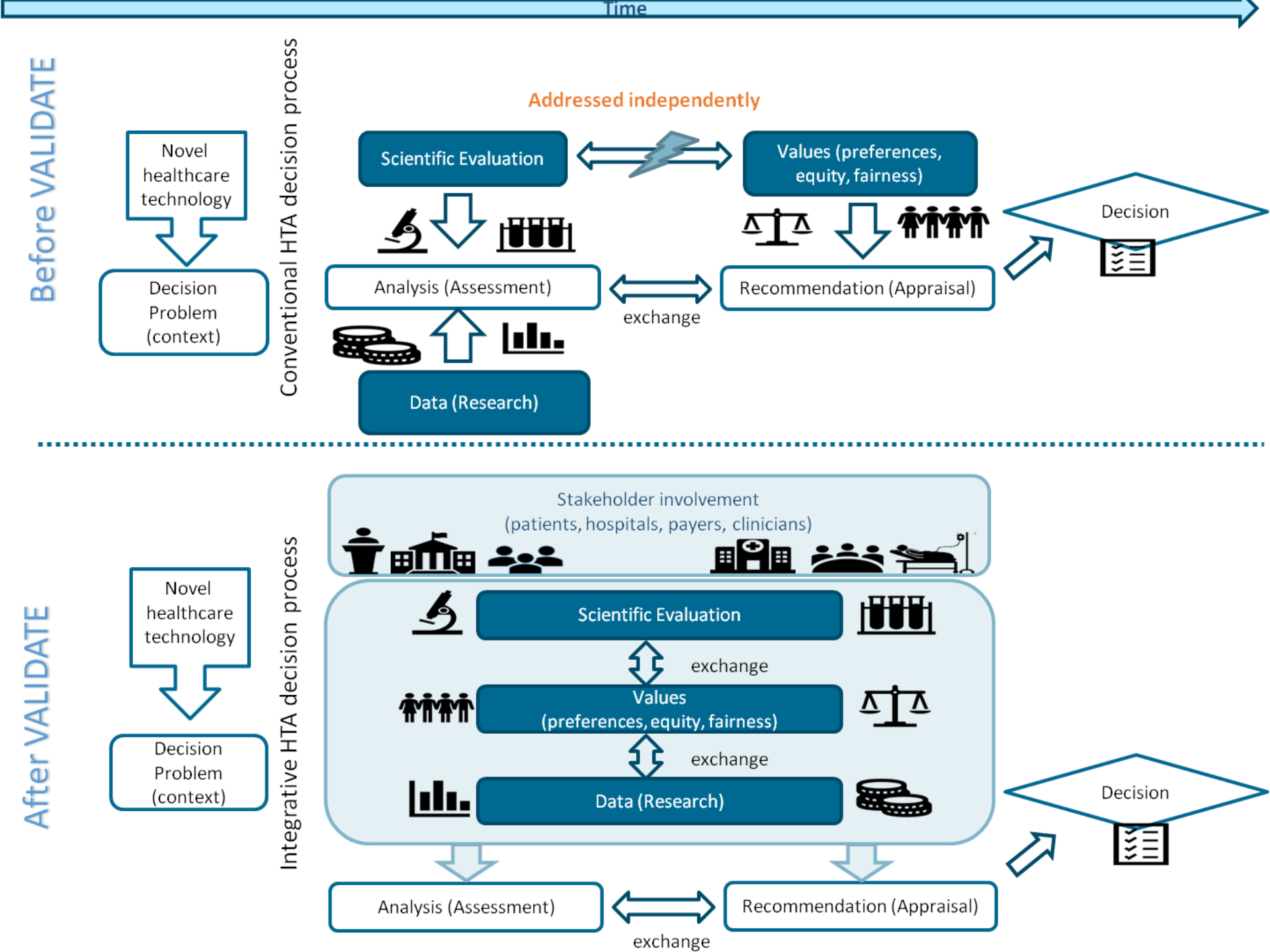
- Aspects of HTA:
  - Safety
  - Effectiveness
  - Cost-effectiveness
  - *Social and ethical aspects*

- Traditional view:
  - Distinction between assessment and appraisal
  - Values | Facts



- VALIDATE:
  - Value frameworks → relevance of evidence, informational requirements

Hofmann, B., Cleemput, I., Bond, K., Krones, T., Droste, S., Sacchini, D., & Oortwijn, W. (2014). REVEALING AND ACKNOWLEDGING VALUE JUDGMENTS IN HEALTH TECHNOLOGY ASSESSMENT. *International Journal of Technology Assessment in Health Care, 30*(6), 579-586.
Hofmann B, Bond K, Sandman L. Evaluating facts and facting evaluations: On the fact-value relationship in HTA. *J Eval Clin Pract*. 2018;1–9


Time
Before VALIDATE
Conventional HTA decision process
Addressed independently
Novel healthcare technology
Decision Problem (context)
Scientific Evaluation
Values (preferences, equity, fairness)
Analysis (Assessment)
exchange
Recommendation (Appraisal)
Decision
Data (Research)
After VALIDATE
Integrative HTA decision process
Stakeholder involvement
(patients, hospitals, payers, clinicians)
Novel healthcare technology
Decision Problem (context)
Scientific Evaluation
exchange
Values
(preferences, equity, fairness)
exchange
Data (Research)
Decision
Analysis (Assessment)
exchange
Recommendation (Appraisal)

Timeline

- September 2018 – December 2018:
  - Draft consensus statement
  - First project meeting (20th of December, Amsterdam)

- January 2019 – May 2019:
  - Collection and evaluation of open access teaching material
  - Second project meeting

- June 2019: HTAi panel session

- June 2019 – February 2020:
  - Students participate in the E-learning course

Timeline

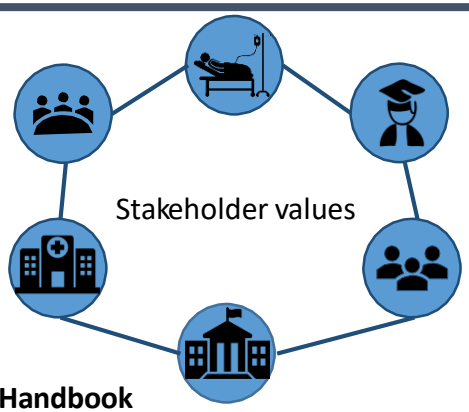
- March 2020 – February 2021:
  - Students work on internship projects at HTA agencies

- March 2021 – August 2021:
  - Write academic paper on critical factors for implementing an integrated HTA
  - Finalize consensus statement and handbook

Intellectual Outputs

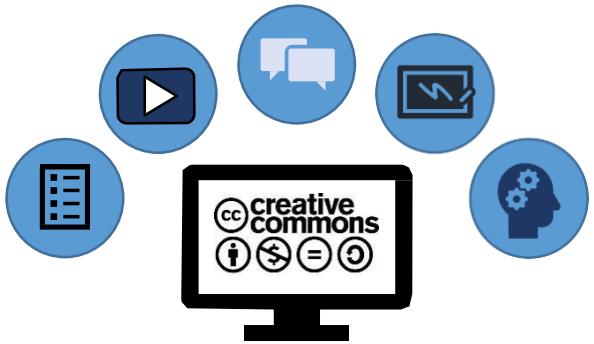
Consensus statement

- Completed HTAs and TAs
- Based on results from INTEGRATE-HTA and other FP7 funded projects
- Skills and competences needed for integrative HTA



Handbook

- Definitions
- Case studies
- Guidelines
- Expert opinions
- Value frameworks
- Skills and competences (based on **consensus statement**)



VALIDATE e-learning module

- Open-access material (based on creative commons license)
- Health technology assessment domains
- MSc level
- Web portal on project website

Academic paper on critical factors for the adoption of novel approaches to HTA

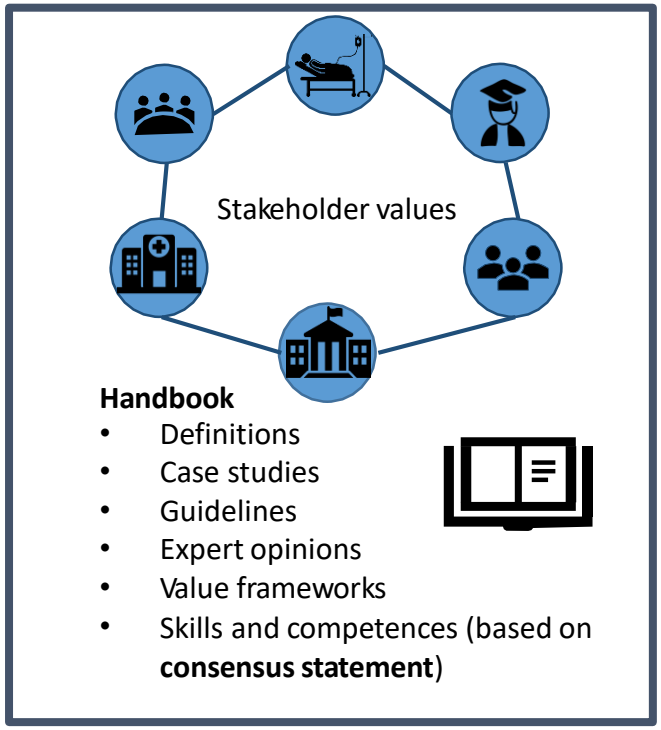
- Based on experience of HTA agencies through student internships
- Describing factors that would be critical for adoption of a comprehensive and integrative approach to HTA in the daily practice at HTA agencies

(1) Consensus statement

- Define the task for HTA
- Define the knowledge, skills and competences that students need to conduct HTA along these lines
- Define the learning goals for the E-learning course and internships
- Collect, and create, learning materials
- Evaluation:
  - Experiences of students and HTA agencies
  - Survey

(2) Handbook

- To support students
- Task for HTA
- Concepts
- Methods
- Case studies
- Open accesss, project website



(3) E-learning course

- Collection of open access teaching materials
- In line with the consensus statement
- Accessible on the project website

VALIDATE e-learning module

- Open-access material (based on creative commons license)
- Health technology assessment domains
- MSc level
- Web portal on project website

(4) Paper

- Which factors are considered critical by HTA agencies for the implementation of an integrative and comprehensive HTA into their daily routines?

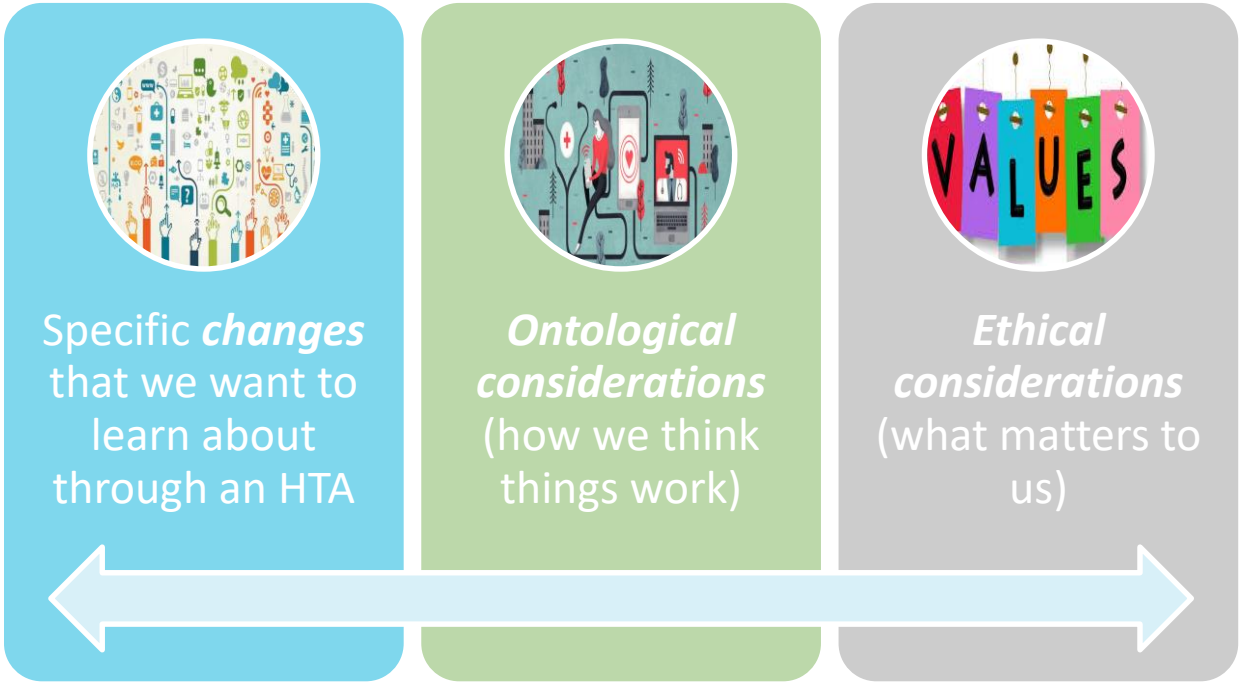
- Based on:
  - Student feedback

  - Evaluation reports


Consensus statement
Knowledge, skills, learning goals?

Consensus statement: The task for HTA

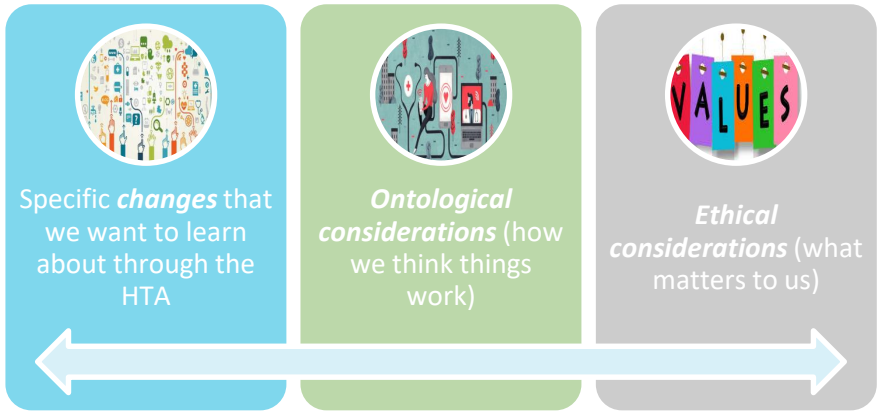
The task for HTA is to lay out, in an accessible and trustworthy way, the changes that may be anticipated to materialize following the introduction of a healthcare technology in a specific context



The task for HTA

1) What are the sort of changes that we should have in mind here?
   a) Changes that are considered *likely* → Notions of how things work (ontological considerations)
   b) Changes that are considered *relevant* → Notions of what matters to us (ethical considerations)

2) How to obtain valid knowledge of the purported changes?



The task for HTA

Assessing Plausibility

Specific ***changes*** that we want to learn about through the HTA

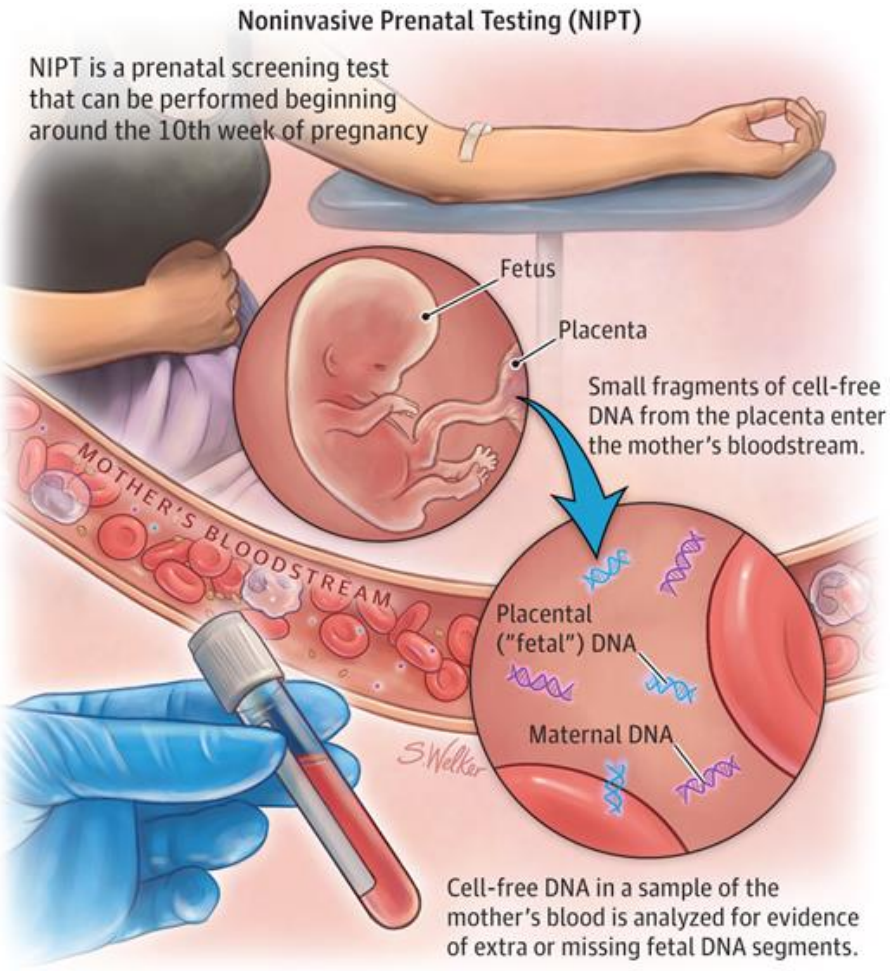
Ontological considerations (how we think things work)

Ethical considerations (what matters to us)

Assessing Relevance

Example: Non-Invasive Prenatal Testing (NIPT)

- Analyzes cell-free fetal DNA circulating in maternal blood in order to gain information about the fetal genotype
- Currently used to detect trisomies 13, 18, 21, and sex chromosome abnormalities



Thompson AE. Noninvasive Prenatal Testing. *JAMA.* 2015;314(2):198. doi:10.1001/jama.2015.7655

Non-Invasive Prenatal Testing

- What sort of changes should we be looking for?
  - Can NIPT be expected to result in equally or even more reliable information about the presence or absence of those fetal chromosomal anomalies?
  - Can NIPT be expected to reduce the burden associated with prenatal testing?
  - Can NIPT be expected to incur greater costs?
  - Can NIPT be expected to result in increase of pregnant women having their fetus tested for gross chromosomal anomalies, and, derivatively, in an increase in abortions?
  - ……

Non-Invasive Prenatal Testing

The specific change that we want to learn about through the HTA:	Ontological considerations (how we think things work):	Ethical considerations (what matters to us):
More reliable information?	Tests can give wrong answers; the combination test works quite differently from the NIPT; the amount of fetal cells in the maternal circulation varies from person to person and as a function of gestational age; etc etc	We want pregnant women to be able to trust the information about the status of their fetus (and the persons / organizations providing this information); we want to prevent abortion of fetuses that have no gross chromosomal abnormalities; we want to save women and their partners the distress associated with an unexpectedly adverse pregnancy outcome, etc.
Reduced burden?	Having tests during pregnancy can be stressful; many people find probabilities difficult to understand; waiting for results of confirmatory tests can be stressful; losing a baby as the result of diagnostic test procedures generally causes serious grief, etc.	We wish to avoid harm, particularly harm caused by medical intervention ('primum non nocere')
Greater costs?	Development of innovations frequently require substantial investments over prolonged periods of time; investors will only invest if there is sufficient return on investment. Also, in developed economies, increases in costs of healthcare surpass the increase in funding.	In case costs of prenatal diagnosis be borne by individual users: would tests be available to only those who can afford it, in a way that might be unfair? If costs are borne collectively: would introduction of NIPT lead to crowding out of other services, again, in a way that might be unfair?
Greater uptake of tests, higher abortion rate, decreased incidence of births of children with gross chromosomal abnormalities?	Removing barriers usually results in increased utilization of services; upon unfavorable test results, most women choose to terminate their pregnancy.	Increased control over pregnancy and pregnancy outcome is generally a good thing. Persons with serious congenital malformations have a right to life, too.

Questions

- (1) What do you think about our view on the task for HTA?
- (2) What are the skills needed to perform an HTA along these lines?
- (3) What are learning goals for educational activities that aim to develop these skills?
- (4) What are appropriate learning activities, and material, to realize these learning goals?

Thank you!

Skills needed for HTA

- Assessing plausibility
  - Be able to identify competing hypotheses
  - Be able to identify methods of inquiry and types of evidence that are needed to assess the validity of these hypotheses (what are the conditions that make a hypothesis true? → what are empirical observations that would discriminate between hypotheses?)
  - Be able to point out how concrete evidence and general theory can support each other
  - A familiarity with a broad range of types of research and an in-depth understanding of the concepts of reliability and validity

Skills needed for HTA

- Assessing relevance:
  - Be able to identify general moral values and principles that inform expectations on the desirability of health technologies
  - Be able to use ethical argumentation models
  - Be able to explain the relation between facts and values, between empirical analysis and normative inquiry
  - Be able to explain how stakeholders' commitments to underlying alues and background theories affects their initial definition of the health(care) problem and judgment of solutions for this problem