Federica Lucivero – Ethical Assessments of Emerging Technologies

Bart Bloemen & Gert Jan van der Wilt

Thursday 6th of December, 2018, HTAi Ethics IG Meeting, Amsterdam

Radboudumc

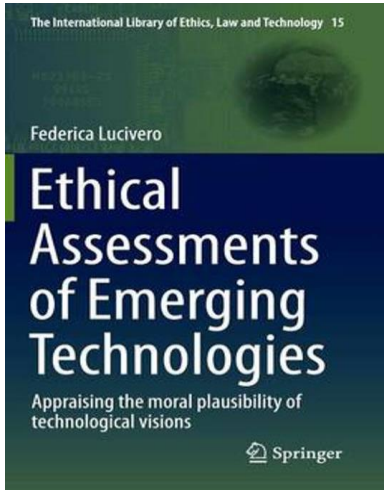
Schedule

- 15.00 – 16.00
  - Summary of Lucivero's work (Bart)
  - The task for HTA (Gert Jan)
  - Case study: NIPT (Gert Jan)
  - Questions and discussion

- 16.00 – 17.00
  - Application of the method: three groups select their own candidate health technology
    - How might the proposed approach work?
    - Advantages and limitations?
    - Suggestions for extensions of the approach?
  - Short presentation of the conclusions by the three groups
  - Wrap up

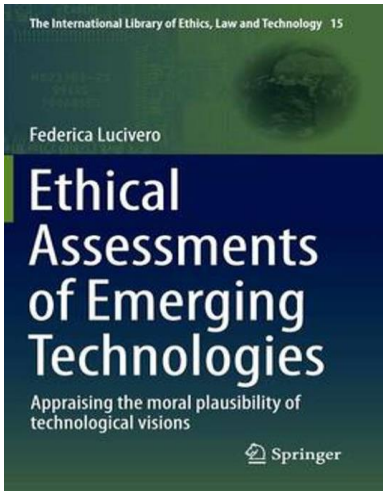
Federica Lucivero

- 2001 – 2004 BA, Philosophy, University of Pisa
- 2004 – 2007 MA, Philosophy, University of Pisa
  Thesis: *Brain-machine interfaces and persons: ontological and ethical issues*
- 2008 – 2012 PhD, University of Twente (NL)
  Thesis: *Too good to be true? Appraising expectations for ethical technology assessment*
- 2012 – 2014 Post-doctoral researcher, Tilburg University (NL)
- 2014 – 2017 Visiting postdoctoral fellow, King's College London
- 2017 Senior researcher in Data and Ethics, University of Oxford



Book: Ethical Assessments of Emerging Technologies

- Published in 2016
- This study addresses the question: '***How can the epistemological robustness of expectations on emerging technologies be assessed in view of a normative reflection of their desirability?'***
- Aim of this study: to improve the conditions for an assessment of the desirability of emerging technologies



Problem statement

- Limitations in traditions assessing technologies:
  - Normative deficit in TA → it should be recognized that TA is inherently normative:
    - The idea of shaping decision-making processes and technologies for a better societal outcome calls for a reflection on desirable goals and objectives
    - The design of TA methods has a normative dimension
  - Technological and sociological deficit in institutional ethics:
    - Promises of emerging technologies are taken at face value
    - Lack of attention to the societal context

Problem statement

- Constructive / participatory TA tend to put *empirical acceptance* before *normative acceptability*
- Institutional ethics tend to be *too speculative* concerning expectations on the technological feasibility, and societal usability, of emerging technologies
- Both TA and institutional ethics do not (fully) acknowledge the dynamic relationships between values, society and technology → claims on moral desirability are *insufficiently speculative*

Problem statement

- Expectations on emerging technologies have a rhetorical character
- These expectations rest on three interrelated types of claims:

a) Claims about the characteristics and functioning of the technology (*technological feasibility*)

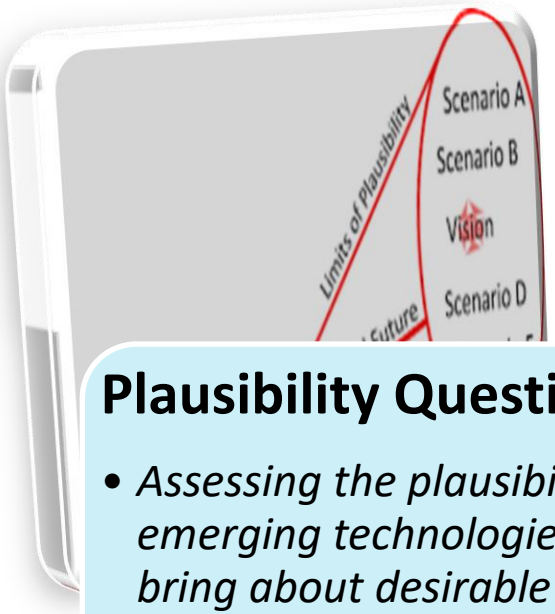
b) Claims about how the technology will be adopted by the intended users and how it will be integrated in current (medical) practice (*societal usability*)

c) Claims about how the technology will address a social problem or need (*moral desirability*)

The task for TA

- TA should integrate ethical inquiry into technology assessment with the goal of assessing the *plausibility* of expectations on emerging technologies
- This is an activity in between grounding and exploring
- We need to develop a methodological approach for analyzing and articulating the moral reasons, meanings and commitments implied in expectations concerning emerging technologies
- Such an approach is a pre-condition for *any* ethical assessment of emerging technologies

Lucivero's approach



Plausibility Question

- *Assessing the plausibility that emerging technologies will bring about desirable worlds and promote desirable social values*

Desirability Question

- *Judging the desirability of different scenarios*
- *Democratic deliberation, workshops*

The Plausibility Question

- In statements about emerging technologies a linear link is often drawn between the technology and the attainment of desirable outcomes:

  Emerging Technology (T) → Desirable Consequences (D)

- Three subquestions:
  - 1. How likely is it that the expected *artifact* will promote the expected values? (T)
  - 2. To what extent are the promised values *desirable for society*? (D)
  - 3. How likely is it that a technology will *instrumentally* bring about a desirable consequence? (→)

Case study: The Nanopil

Case study: The Nanopil

- An emerging technology exists primarily as *expectations* circulating in personal communications, funding proposals, mass media
- Promise of the Nanopil: early, cost-effective, easy and reliable screening for colorectal cancer
- Success of this promise requires that three conditions be met:

1. The Nanopil will be a functioning artifact
2. This artifact will be used in the practice of colorectal cancer screening by healthy individuals
3. The use of this device will have the desirable outcome (*Plausibility Question*)

Case study: The Nanopil

1. The Nanopil will be a functioning artifact

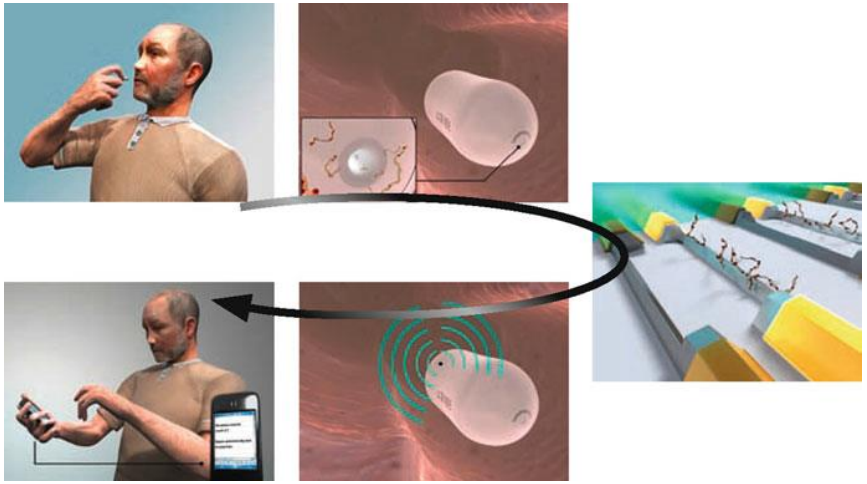
- Goal: *thicken* these expectations → add more details (alternative designs, components, conditions of its functioning)

- Method:
  - In-depth interviews with scientists / engineers
  - Observations of their laboratory practices

Case study: The Nanopil

Technological feasibility: claims about the characteristics and functioning of the technology:

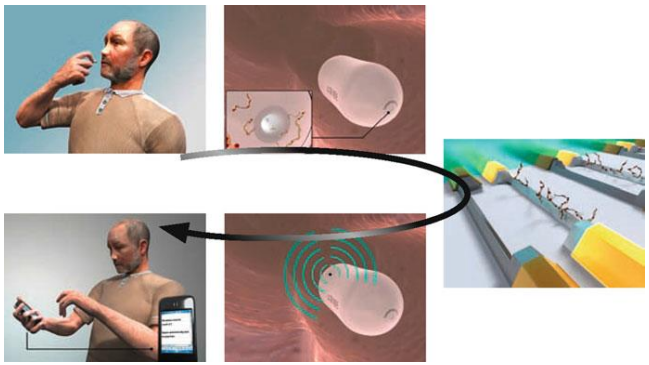
"Before a tumor is visible, it is possible to detect some changes in the DNA of the intestine cells. We can develop a pill with special nanowires to which the changing (methylated) DNA in the intestine liquid can bind. The information of the nanowires is sent to a receiver, for example a mobile phone".



Case study: The Nanopil

Technological feasibility: claims about the characteristics and functioning of the technology:

- It can be swallowed
- It can travel through the gastro-intestinal tract



- It can collect intestinal fluid
- It can purify a DNA sample

- It can detect the presence of abnormal methylation
  - *This hypermethylation is specific for colorectal cancer*

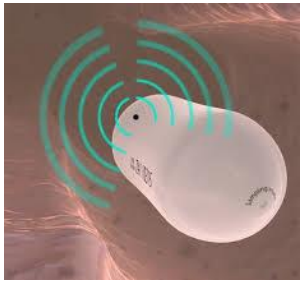
- It can communicate the results to the outside world

Lucivero, F. (2016). *Ethical Assessments of Emerging Technologies: Appraising the moral plausibility of technological visions* (Vol. 15). Springer.

Case study: The Nanopil

- Two alternative designs

“blue-dye system”



“radio-signaling system”

Case study: The Nanopil

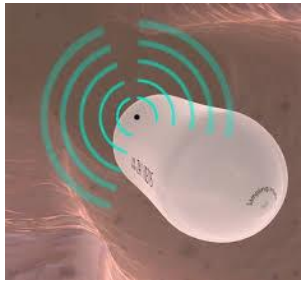
2. This artifact will be used in the practice of colorectal cancer screening by healthy individuals

- Goal: assess the plausibility of expectations on the *use* of the Nanopil
- Method:
  - Concept of a "script" (Akrich, Latour): T → (expected) use, roles
  - Semi-structured interviews engineers, "describe a world with the Nanopil" (actors, intended use, input/output) → fictive script + network of actors
  - Interviews with actors + participant observation (colonoscopy room) + document analysis (population screening programs in the Netherlands)

Case study: The Nanopil

- ***Societal usability***: claims about how the technology will be adopted by the intended users and how it will be integrated in current (clinical) practice:

The user is the only witness of the result → Self-monitoring



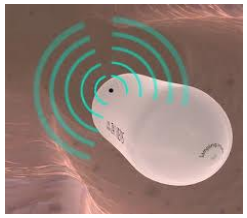
The results can be received instantaneously by other people (GP, clinician, ..) → Self-monitoring + National screening program

Lucivero, F. (2016). *Ethical Assessments of Emerging Technologies: Appraising the moral plausibility of technological visions* (Vol. 15). Springer.

Case study: The Nanopil

- The use of this device will have the desirable outcome (*Plausibility Question*)

- 1. How likely is it that the expected *artifact* will promote the expected values? (T)
- 2. To what extent are the promised values *desirable for society*? (D)
- 3. How likely is it that a technology will *instrumentally* bring about a desirable consequence? (→)



The user is the only witness of the result → Self-monitoring → Autonomy, privacy

The results can be received instantaneously by other people (clinician, ..) → National screening program → Efficiency and quality of the care process

Case study: The Nanopil

- 1. How likely is it that the expected *artifact* will promote the expected values? (T)
- 2. To what extent are the promised values *desirable for society*? (D)
- 3. How likely is it that a technology will *instrumentally* bring about a desirable consequence? (→)
- → Problem definitions, concerns and values of stakeholders

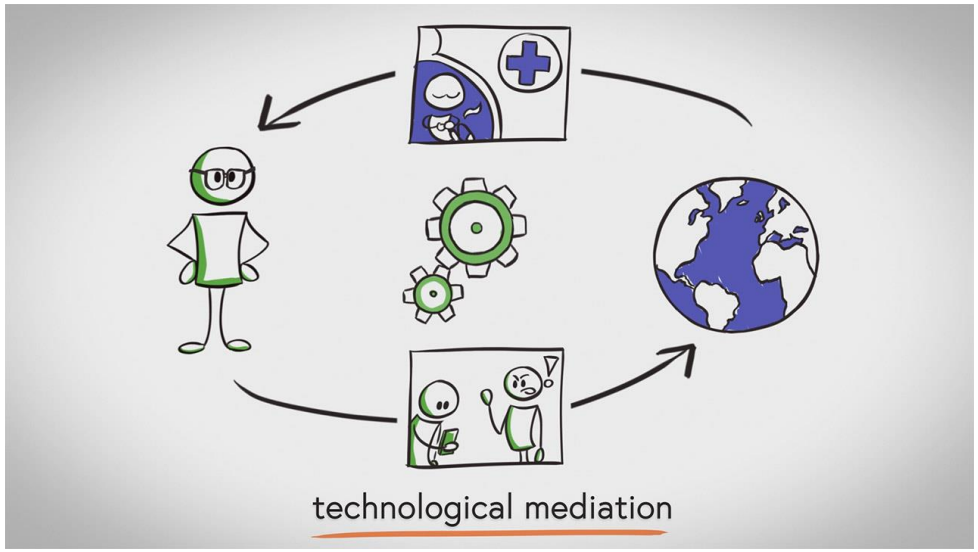
Case study: The Nanopil

- 3. How likely is it that a technology will *instrumentally* bring about a desirable consequence? (→)

- Is there a linear instrumental relation between the technology and its desirable consequences?

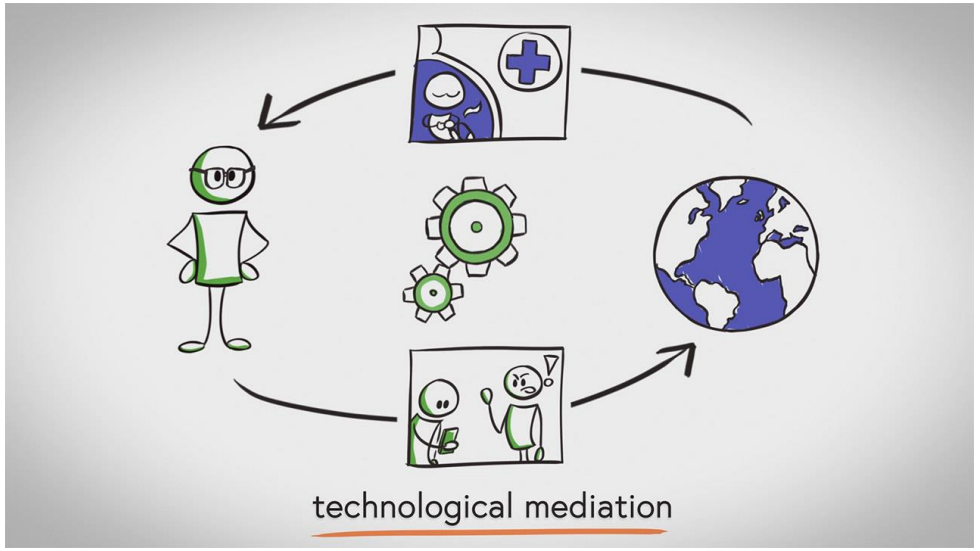
- Technology creates:
  - New ways of *experiencing and understanding* the world

  - New *practices*

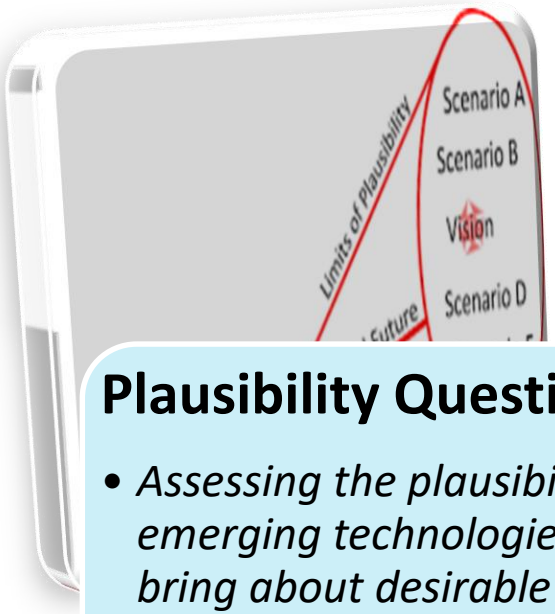


Case study: The Nanopil

- Technology creates:
  - New ways of experiencing and understanding the world
  - New practices
- The Nanopil:
  - Molecular knowledge, “the pill knows you best”
  - Self-monitoring, new responsibilities for users



Lucivero's approach



Plausibility Question

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Desirability Question

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- *Democratic deliberation, workshops*

Desirability Question

- Grounded scenarios → democratic deliberation
- Scenarios (*vignettes*) as tools to foster moral imagination
- Workshops, focus groups

“I am not gonna do this again, it’s disgusting!”

“Listen, Nya, I’m tired of this. Try to behave like an adult, you are 22 now! You know why you have to drink this laxative.”

“Yes, for the stupid pill to work.....”

“This ‘stupid’ pill is an easy way to check that everything is fine. Your dad’s family has a history of Colorectal cancer so you had to start screening early. Consider yourself lucky, 20 years ago people had to collect a sample of their stool, smear it on a sample card, compile it with their information, seal it and mail it to the lab. The pill makes this much more simple, comfortable and clean!”

“SIMPLE, COMFORTABLE, and CLEAN???? Why don’t YOU try drinking this crap? And this unbearable nausea. Blech. I feel like I have to throw up after every sip. Having to run to the toilet every half an hour is clean? Joyce wanted to go to the cinema with me, but I can’t! I have to be at home, drinking laxative, feeling sick and running to the washroom every 10 minutes. I feel like I am spending the whole day in the bathroom. I would rather spend 1 minute collecting samples and forgetting about it. But instead, I have 2 more liters of laxative to go. ARGH…”

“Hun, you are behaving like your grandma! Just drink it, the doctor said…”

“I don’t care about the doctor, I am not gonna drink it all.”

“And if the pill isn’t going to work then?”

“Even better, then they will think that I am fine and they will leave me alone.”

Contribution of this approach

- The ideal of democratic deliberation does not only entail the *inclusion* of everyone who will be affected by a technology but *also* an improvement of the *quality of discourse*

- A plausibility analysis serves the goals of ethical assessments of emerging technologies in different ways:

1) It contributes to a reduction in speculations about the desirability of implausible contexts
2) It rules out misleading assimilations to other technologies
3) It articulates invisible or hidden assumptions and expectations
4) It makes value judgments explicit
5) It enriches scenarios

→It creates the <u>preconditions</u> to engage in a normative discussion and evaluation

Room for improvement…

- Open questions:
  - What is the meaning of ‘democratic deliberation’ for assessments of emerging technologies?
  - Cultures of plausibility? How do actors with different knowledge and values regard the plausibility of the same vision?
  - How to ensure that different actors and alternatives contribute to a vision of a desirable society that is not only technology driven and focused?
  - What should an ‘ethics of promising’ look like?

- How to make values explicit? How to evaluate ethical argumentation? Lucivero does not provide a formal method for assessing the plausibility and desirability of expectations on emerging technologies

The task for HTA

Assessing Plausibility

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

Ontological considerations (how we think things work)

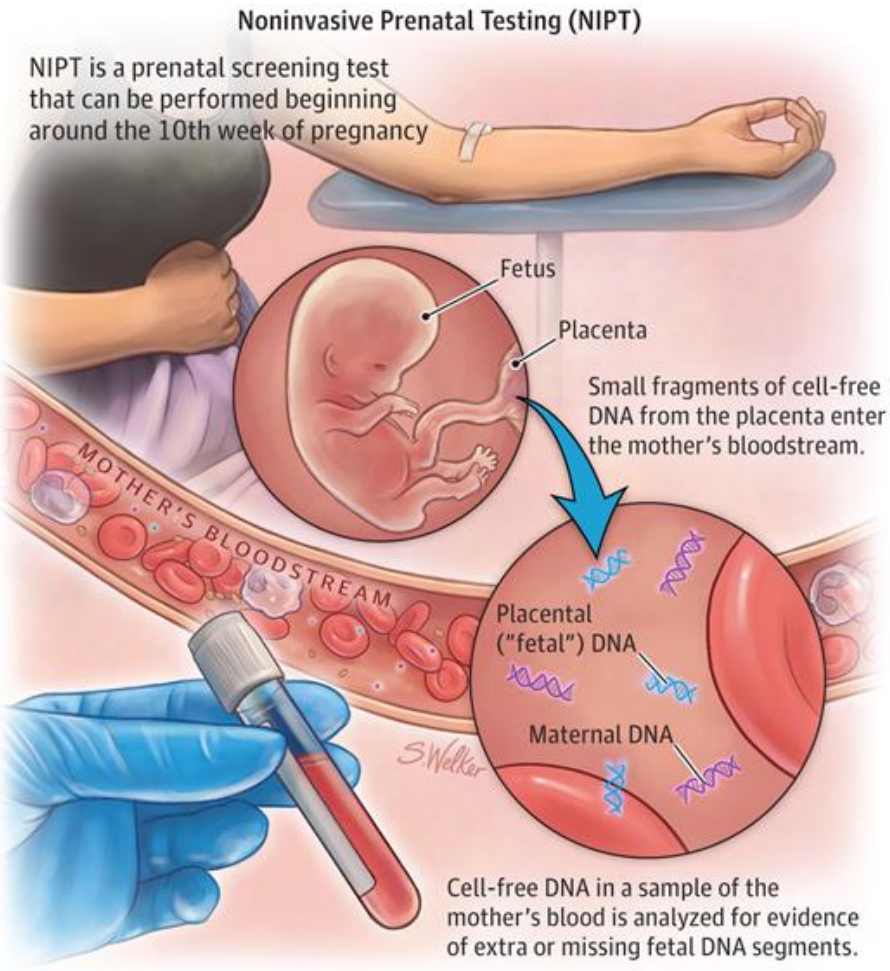
Ethical considerations (what matters to us)

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.

Schedule

- 15.00 – 16.00
  - Summary of Lucivero's work (Bart)
  - The task for HTA (Gert Jan)
  - Case study: NIPT (Gert Jan)
  - Questions and discussion

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  - Application of the method: three groups select their own candidate health technology
    - How might the proposed approach work?
    - Advantages and limitations?
    - Suggestions for extensions of the approach?
  - Short presentation of the conclusions by the three groups
  - Wrap up