

Methods for ethics in HTA

Björn Hofmann,
University College of Gjøvik, and
Centre for Medical Ethics, University of Oslo
Norway



Björn Hofmann, Section for Medical Ethics

Important questions

- What makes an issue a *moral issue* (compared to scientific issues, facts, etc)?
 - META ETHICS
- What do medical doctors think about euthanasia? Are human beings kinder to each other after they have found 50 cent on the floor?
 - DESCRIPTIVE ETHICS
- *How* should we act? What is *right*?
 - NORMATIVE ETHICS

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Key question:

- How to assess and implement a health technology in a morally acceptable manner?

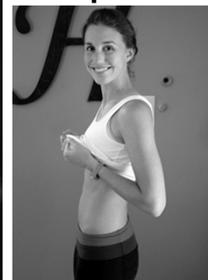
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Different methods for performing ethical analysis in HTA

- Utilitarianism (consequentialism)
- Deontological ethics
- Casuistry
- Principlism
- Coherence analysis (CA)
 - Wide reflective equilibrium (WRE);
- Interactive, participatory HTA approach (iHTA)
- Axiological approach, (Socratic approach, EUnetHTA Core model)
- Social shaping of technology (SST)
- Other special approaches (eclectic approaches):
 - AETMIS,
 - FINOHTA ,
 - Triangular method
 - Participatory and discursive approaches

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Example NIPT

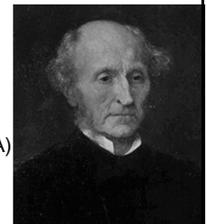


Note: The example is used in a rough way to illustrate main characteristics



Utilitarianism

- Principle: Maximise utility
 - "The greatest good for the greatest number of people" (John Stuart Mill, 1806 – 1873)
- Morally relevant: consequences of actions.
- Balance net harm and benefits
- Embedded in economic thinking (in HTA)
- Presupposes:
 - Value theory: You can estimate a comparative value of everything
 - Ranking theory: You can rank and sum values



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Utilitarianism: What do we do?

1. In a given situation, describe the alternative (action)s.
2. Identify the consequences of each alternative.
3. Estimate the values and probabilities of each alternative (both harms and benefits).
4. Estimate the net sum of harms and benefits for the various alternatives.
5. Choose the alternative that gives the highest sum.

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Utilitarianism – NIBT

- Alternatives:
 - Ultrasound and blood tests followed by invasive tests (if necessary)
 - Invasive tests (amniocentesis, chorionic villus sampling)
 - No prenatal testing

	Ultrasound and blood tests	Invasive tests	No test	NIPT
Benefits	+1	+4	0	+3
Harm	-2	-4	-2	-1
Total	-1	+0	-2	+1

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Deontological ethics



- Not only consequences are morally relevant (intentions)
- As rational human beings we have obligations towards each other.
- Which duties?
 - Relevant to all rational human beings (qualify to be a general rule).
 - Never to treat a human being as a means only, but always also an end
- Source: Immanuel Kant (1724—1804).

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Deontological ethics – NIPT

- The foetus is a potential person, and has worth (attributed).
- As abortion is the only “treatment” (=ending life).
- Cannot end the life in every case of abnormal chromosomal characteristics (i.e., make the maxim a general rule).
- The foetus is a means (to reduce the couples' anxiety and burden) and not an end in itself.
- Sex selection and (negative) selection for other traits does downgrade the worth (of people with) of certain traits.

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Principlism

Four basic principles:

1. Respect for **autonomy** (understanding, voluntariness, decision-making capacity);
 2. **Beneficence** (balancing benefits and harm: risks/costs)
 3. **Non-maleficence** (the minimisation of harm to others)
 4. **Justice** (the distribution of benefits and burdens)
- Not absolute, but *prima facie* principles
 - Rules of infringement

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Principlism – NIPT

Four basic principles:

1. Respect for **autonomy** (understanding, voluntariness, decision-making capacity);
 2. **Beneficence** (balancing benefits and harm: risks/costs)
 3. **Non-maleficence** (the minimisation of harm to others)
 4. **Justice** (the distribution of benefits and burdens)
1. Foetuses have no autonomy, pregnant women do.
 2. The benefit appears greater than the harm.
 3. NIPT is of little harm (to the pregnant women).
 4. We do prenatal testing with other means (ultrasound, blood tests, invasive tests)

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Casuistry

- Solving morally challenging situations ("cases") by referring to relevantly similar, "paradigmatic" cases for which a solution has been found.
- Moral norms are not universal.



Casuistry – NIPT

- | | |
|---|--|
| 1. What are we perplexed about? | 1. Should we look for and eradicate certain conditions? |
| 2. What has caused the perplexity? | 2. Sorting out certain conditions. |
| 3. Comparing this case with "paradigmatic" cases. | 3. Cases <ul style="list-style-type: none"> 1. Abortion on demand. 2. Prenatal screening 3. We have eliminated other diseases |

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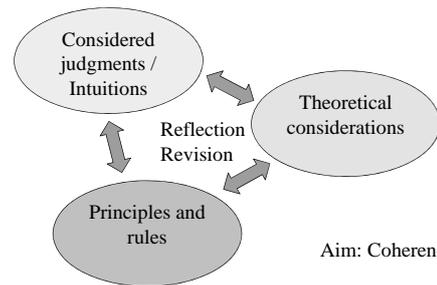
Casuistry - NIPT

- Testing and justifying the hypothesis.

- Hypothesis: it is wrong to look for and eradicate certain conditions (which people live well with).
- Only the first example supports the hypothesis.
- Hence, it is (un)reasonable to support NIPT if it is accurate and safe (depending on which example trumps).

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Wide reflective equilibrium



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John Rawls, Norman Daniels

Wide reflective equilibrium

1. Gather existing judgments about a given case
2. Find which moral principles that are at stake and that guide the judgments.
3. Find (potential) background theories supporting the ethical principles.
4. Try to obtain optimal coherence between 1-3.

Ref. John Rawls, Norman Daniels

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Wide reflective equilibrium

- | | |
|--|---|
| 1. Gather existing judgments about a given case | 1. NIPT is more accurate, increases choice, reduces spontaneous abortions, |
| 2. Find which moral principles that are at stake and that guide the judgments. | 2. Beneficence, autonomy, justice, equity, dignity/worth |
| 3. Find (potential) background theories supporting the ethical principles. | 3. Utilitarianism, deontology |
| 4. Try to obtain optimal coherence between 1-3. | 4. NIPT increases accuracy, and can replace poorer alternatives. It can reduce the number of spontaneous abortions and increase the choice of women |

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Discourse Ethics

- Valid moral decisions depend on **consensus** (the Discourse principle).
- If the consensus is reached through **rational arguments**, it is valid (and imperative) for all (the **Universality** principle).
- “The force of the better argument”

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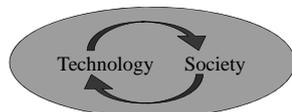
Discourse Ethics - NIPT

- By using NIPT for RhD-testing and for severe conditions early in pregnancy (<10 weeks) **consensus** is reached that the method is acceptable.
- Sceptics and critics are persuaded, as NIPT will reduce the suffering of babies born with severe diseases, reduce the number of spontaneous abortions as a result of invasive tests, and no living person with the condition will be stigmatized.

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Social Shaping of Technology

- Technology is not an independent artifact that has a certain, measurable impact.
- Technology is the product of societal processes (within the clinic, industry, governmental bodies, and society at large).
- It is formed by the conditions of its creation and use.
- We can shape technology according to our goals.



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Social Shaping of Technology - NIPT

- Have to implement NIPT in a way that it benefits pregnant women without stigmatizing persons with the conditions tested for.
- Persons with the conditions that are looked for and removed have to take part in the implementation of NIPT (if possible).

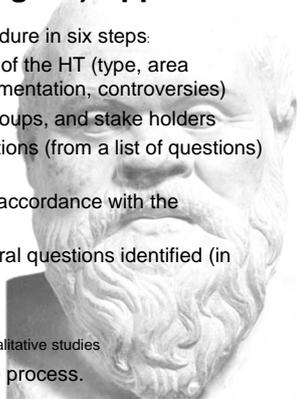
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The Socratic (Axiological) Approach

The method consists of a procedure in six steps:

1. Describe the characteristics of the HT (type, area (prevention, curative), implementation, controversies)
2. Identify involved persons, groups, and stake holders
3. Identify relevant moral questions (from a list of questions) and justify the selection
4. Perform literature search in accordance with the identified moral questions
5. Analyze and discuss the moral questions identified (in step 3) on the basis of
 1. The literature search
 2. Hearings of involved parties or qualitative studies
6. Wrap up and summarize the process.

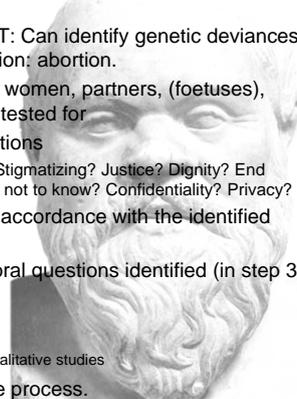
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The Socratic Approach - NIPT

1. The characteristics of the HT: Can identify genetic deviances in foetus. Possible intervention: abortion.
2. Persons involved: Pregnant women, partners, (foetuses), persons with the conditions tested for
3. Identify relevant moral questions
 - Consequences? Autonomy? Stigmatizing? Justice? Dignity? End point selection? Equity? Right not to know? Confidentiality? Privacy?
4. Perform literature search in accordance with the identified moral questions
5. Analyze and discuss the moral questions identified (in step 3) on the basis of
 1. The literature search
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Methods' merits?

- Which is the best method?
 - The one you find most suitable
- Who is best to perform ethical analysis?
 - A non-ethicist is better than no ethicist.
- When should we perform an ethical analysis?
 - Always (according to definitions of HTA). When needed.
- Take home message: An analysis with any method is better than no analysis with "the best" method.