



WASHINGTON DC 2014
11TH ANNUAL MEETING

PRE-CONFERENCE: JUNE 14-15
CONFERENCE: JUNE 16-18
WASHINGTON DC, USA



**WS06 - Introduction to Ethics in Health Technology Assessment
Sunday, June 15**

The Example of NIPD

Tanja Krones & Dario Sacchini

Summary NIPD

Some important facts - 1

- 1. NIPD = Non invasive prenatal diagnostics («near» diagnostic-screening)**
- 2. Out of the mothers blood at 10 weeks**
- 3. Early diagnostic, easy to perform for patients**
- 4. Early and less traumatic (vacuum extraction) abortion possible (within legal limits in many countries only with consent of pregnant women without «indication» of physician)**
- 5. Counts as genetic diagnostics; in some countries legally binding counseling; specific human genetics quality criteria; in some not («over the counter»)**

Summary NIPD

Some important facts - 2

6. False positive/negative rate dependent on target , different phenotypical consequences:
7. Down Syndrome/Trisomy 21, Trisomy 18:
 - false negative 1/100
 - false positive 0.2/100
8. Other Trisomies/sex chromosome numerical aberrations:
 - false negative 8-21/100
 - false positive 1/100
9. Micro-deletion syndromes: variable, also check of parental genome due to variable clinical regions necessary; Phenotype variation

Development -2014

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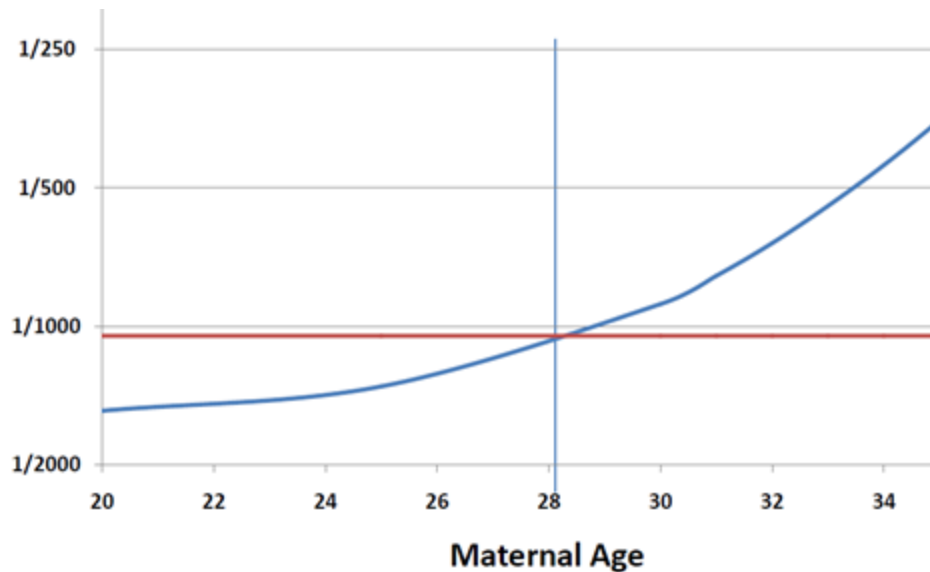
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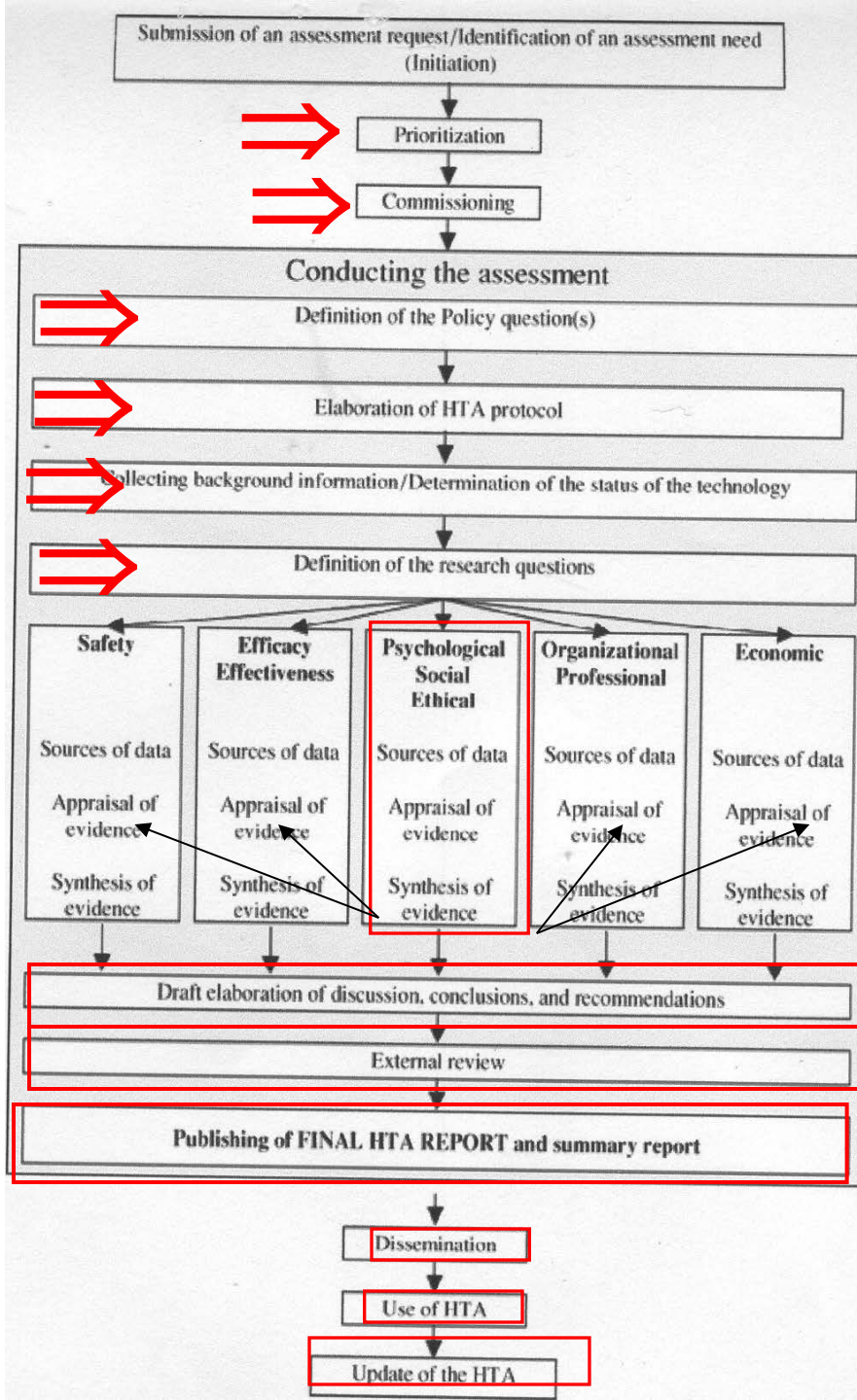
Conference Menu



Down
Syndrome Estimates
Microdeletions
(industry) Estimates

Ethics in HTA

Where facts meet values



*Working Group 4
report, p. 365*

Important Dimensions of HTA

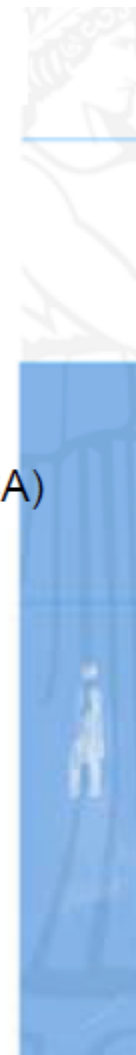
Moral issues	Proportionality-benefit-burden ratio, autonomy , societal values, values of vulnerable/affected subgroups, consequences of implementation, e.g. barriers of provision, stigmatization
Questions with respect to stakeholders	Benefit for: <ul style="list-style-type: none">• Patients = customers• Physicians, policy-, decision-makers, health Insurers, industry = users
Questions related to technology	Symbolic value, ethical implications, dependance on evaluation of other technologies
Moral aspects of methodological choices	Decision on endpoints, thresholds, quality criteria of studies included, representativeness of study population, external validity of results
Questions related to technology assessment	Decision on the assessment, interests of HTA providers, time of evaluation of the technology

Brainstorming: Important Issues

Macro Level	
Meso Level	
Micro Level	

Which Method?

Different methods for performing ethical analysis in HTA



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

Possible Systematization of ethics analysis results in the HTA process - 1

- **Dimension 1: *Medical implications***
 - **Principles:** Non maleficence / Beneficence/ Proportionality
 - **Outcomes:** efficacy, effectiveness, safety, benefit/burden, qualitative medical evaluations of patients
- **Dimension 2: *Setting***
 - **Principles:** Autonomy/Care/Veracity/Transparency
 - **Outcomes:** Treatment as a nice to have /to perform procedure
- **Dimension 3: *Economy/Institutional***
 - **Principles:** Justice-distributional, needs, equality of capacities
 - **Outcomes:** Economic evaluation-cost utility/effectiveness

Possible Systematization of ethics analysis results in the HTA process - 2

- **Dimension 4:** *Psychological/ social implications for patients/family*
 - **Principles:** Right to know /not to know, third parties, confidentiality
 - **Outcomes:** confidence in decision, possibility to decide
- **Dimension 5:** *Long term far reaching consequences for society/nature*
 - **Principles:** Responsibility, holistic views
 - **Outcomes:** slippery slope, concept of disease, other therapies