



FinOHTA

Finnish Office for Health Technology Assessment



**Towards a more uniform approach in addressing ethical issues in the context of HTA:
– the EUNETHTA core model experience on bariatric surgery**

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Layout

- What is EUNETHTA core model for ethical analysis?
- How did it work?
 - Case: bariatric (obesity) surgery
- What did we learn?
 - About bariatric surgery
 - About ethics and HTA



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What is EUnetHTA?

- European Network for Health Technology Assessment
 - 59 partners from 30 countries
- Strategic objectives
 - Better coordination of HTA activities, less duplication
 - Increase HTA output
 - Strengthen link between HTA and policy making
- EUnetHTA Core Model for HTA
 - attempt to define and standardise elements of an HTA.
 - shared understanding of what belongs to *core* HTA





The core model: 9 domains

- 1) Health problem and current use of technology,
- 2) Description and technical characteristic of technology,
- 3) Safety,
- 4) Clinical effectiveness,
- 5) Costs and economic evaluation,
- 6) *Ethical analysis,*
- 7) *Organisational aspects,*
- 8) *Social aspects,*
- 9) *Legal aspects.*





The Core Model: Basic concepts

- **Domain**

- wide framework within which the technology is considered.
- E.g. ethics

- **Topic**

- A specific area of consideration within the domain
- E.g. ethics / autonomy

- **Issue**

- Expressed as a question
- E.g. *Can the technology entail special challenges/risk that the patient/person needs to be informed of?*





EUnetHTA ethical analysis: integration and atomism

1) Consider: ethical issues of the HTA at planning phase

- Checklist

2) Assess / answer: every specific issue during the assessment

- Data collection: ethics separately + from other domains

3) Appraise: methodological pluralism

- Flexible: no ethicist necessary, local methods usable

4) Report: aim at open, balanced, expose values

- Depends on the aim, mandate of the HTA organisation





Planning: ethics of HTA process

Checklist

- The **driving forces** (and valued interests) to perform the assessment at this stage should be identified, including the stakeholders and the whole HTA organisation.
- The **morally relevant reasons** for performing / not performing a HTA on this topic should be identified.
- It should be identified whether there are **related technologies** that are morally contentious.
- The **interests of the content expert** group should be discussed openly
- The **choice of end points** in the assessment has to be carefully considered.
- The morally relevant issues related to the selection of **meta-analysis and studies to be included** in the HTA have to be identified.
- The **scope of the HTA and choice of research methods** (e.g. the expected importance of ethical analysis)





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The Core Model: ethics topics

Principal questions about the ethical aspects of technology

Autonomy

Dignity

Human integrity

Beneficence/nonmaleficence

Justice and Equity

Rights

Legislation

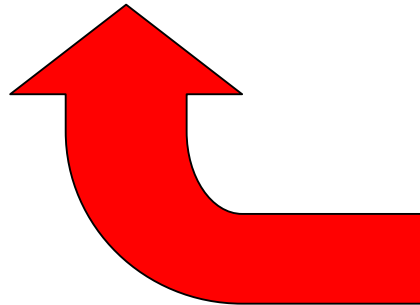
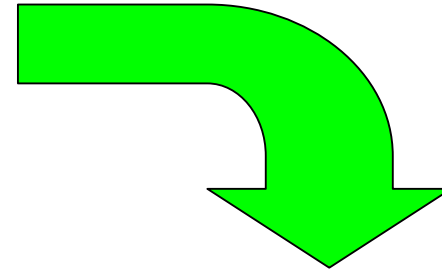


Process of core ethical analysis

Efficacy, safety, effectiveness etc. results

Literature search on ethical issues

Stakeholder hearings



Discussions among the working group

Filosofical analysis of arguments

Answering the core questions





No generally accepted method ≠ no methods

- The methods must be tailored to suit
 - | the HTA organisation
 - Resources (money / time / competencies)
 - Position of the HTA organisation
 - | the topic / technology under study
 - Difference in relative importance of ethical issues
 - Difference in methods of analysis
 - | local culture
 - | health care system
- Local variation is not necessarily problematic
 - | as long as transparent documentation is provided.





Methods in EUnetHTA

-as identified by INAHTA ethics working group

All emphasise the need to consider issues extending past utilitarian maximisation of (cost) benefits of technology

- | *Casuietry*
- | *Coherence analysis*
- | *Interactive, participatory HTA approach*
- | *Principlism*
- | *Social shaping of technology*
- | *Wide reflective equilibrium*
- | *Local approaches: AETMIS, FINOHTA, NKCHC*





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How did it work: Scoping phase

- Major public health problem with socioeconomic gradient
- (Fairly) novel approach to a problem
- Appears effective, but underused → pressure to increase massively
- Causes controversy among lay people and professionals

→ Ethical analysis probably important

→ Decision: Full core model HTA: including ethical, social, legal, organisational domains

LEARNT: not all technologies need this much emphasis on ethics



How did it work: Planning phase

Discuss the checklist in the planning committee

- Many driving forces: *"we know it works, but still need a full HTA"*, *"surgery vs internal medicine"*.
 - Obesity experts involved, not just bariatric surgery experts
- Strong feelings about the causes of obesity and responsibility for it – more than surgery itself. Medicalisation?
 - Consider on obesity and its treatments, not just surgery
- The endpoints?
 - patients complex psychosocial well-being (+weight, mortality, QALY)
- What will happen in health care organisations, financing, prevention?
 - Empirical enquiry to relevant hospitals.

L: Important to get everybody understanding, involved, participating

L: Must be prepared to transcend strict PICO

L: To really integrate ethics into HTA, it needs to be integrated into the HTA organisation



How did it work: Assessment phase

- Literature searches: not very systematic
 - | Little on ethics of very novel technologies
 - | Casuistic reasoning needed to identify relevant themes
 - Considered obesity, self-inflicted conditions in general
- Discussions among the working group
 - Ethicist as a catalyst, secretary, aim at full consensus

L: Systematic literature searches difficult: PICO not adequate

L: Discussions with *carefully selected* content experts (surgery + internal medicine, GP, psychiatry) invaluable

L: Consensus possible



How did it work: Appraisal phase

- FinOHTA strictly assessment, no appraisal
 - | No formal philosophical analysis conducted
 - In practice: casuistic, principlist, WRE
 - Aim for consensus within the workgroup
 - As little guidance as possible in the report, arguments pro and con included

L: Value-neutral assessment impossible

L: Content experts, HTA team got involved, motivated participants in the process



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What did we learn: bariatric surgery

- Concept of obesity as self-inflicted condition behind much of the controversy
 - | Little convincing arguments left after analysis
 - | Decisionmakers need to consider treatment of obesity, not just bariatric surgery
- Consequences of medicalizing obesity difficult to foresee
 - | May differ greatly between parties: obese or not
- Significant implications for justice and equality
- Rationing, organisational decisions needed



What did we learn: EUnetHTA model

- Flexible, easy to use
 - | May help get started with ethics and HTA
 - | Low philosophical expertise needed
 - | May help clarify ethics, values role in HTA
- Plurality of methods
 - | A strength or weakness?
 - | Replicability of the results?
 - | Transferability of the results into other contexts?
 - One EUnetHTA's main goals
- Will it make HTA more useful?
 - | Alone or with psychosocial, organisational, legal?



Thank you!

More information at:

www.eunetha.net

Saarni, Hofmann et al Bull Who 2008;86:617