NTNU
Norwegian University of Science and Technology

UNIVERSITY OF OSLO

How to address ethical issues: Methods for ethics in HTA

Bjørn Hofmann,
Norwegian University of Science and Technology at Gjøvik, and
Centre for Medical Ethics, University of Oslo
Norway

UNIVERSITY OF OSLO

Key question in health policy making, health technology management, and in HTA:

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

How to address ethical issues in HTA? Some broad types of approaches

Conventional approaches
- Traditional approaches in moral philosophy
  - Consequentialism
    - Utilitarianism
  - Deontology (Duty based ethics)
  - Virtue Ethics
  - Discourse ethics
  - Casuistry

Prosessual approaches
- Coherence analysis
  - Wide Reflective Equilibrium
- Parliamentary TA (PTA)
  - Expert methods (e.g., Delphi method)
  - Interactive methods (Consensus conf)
  - Communication m. (Dialogue confer.)
  - **Social Shaping of Technology**

Mixed approaches
- Principlism
- Ethics matrix
- Multi Criteria Decision Analysis (MCDA)
- Triangular method (deontology)
- Axiological approach,
  - Socratic approach,
  - EUnetHTA Core model
  - SBU Checklist
- Interactive, participatory HTA (iHTA)

UNIVERSITY OF OSLO

Utilitarianism

- Basic 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
  - You can predict outcomes and consequences

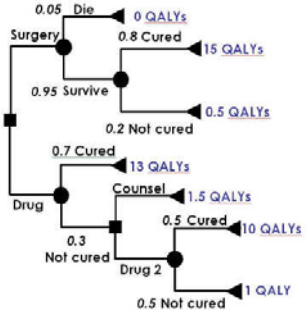
UNIVERSITY OF OSLO

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.

UNIVERSITY OF OSLO

Decision tree



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).

Bjørn Hofmann

Deontological ethics – Bariatric surgery

- What is the aim of the intervention - the persons themselves or their physical health?
  - E.g., Bariatric surgery may be conceived of as a symptom based treatment, forcing people to change their behaviour, i.e., a surgical disciplining of human behaviour.
  - The key question becomes if we respect them as (rational) persons or if bariatric surgery becomes a quick fix and a means for improving people's health.
  - Do we respect their autonomy and worth?
- General rule: Do we cut in people to change their behaviour in other comparable cases?

Bjørn Hofmann

Bjørn Hofmann

Principlism


Tom Beauchamp


James F. Childress

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

Beauchamp TL, Childress JF. Principles of biomedical ethics, 7th ed. New York City, NY: Oxford University Press; 2013.

Bjørn Hofmann

Principlism – Bariatric surgery

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. Obese persons may have reduced autonomy (eating), and surgery may increase autonomy.
2. The benefit appears greater than the harm.
3. Bariatric surgery is an intervention in an otherwise healthy body.
4. We do treat other persons with the same need, capacity for benefit, rights, merit

Bjørn Hofmann

Principlism – Bariatric surgery

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. Bariatric surgery is OK
2. Bariatric surgery is OK
3. Bariatric surgery is not OK
4. Bariatric surgery is OK

Bjørn Hofmann

Casuistry

- Is a case-based reasoning method.
- Starts from the description of a particular case.
- Compares ethical dilemmas around this case with examples of ethical dilemmas related to similar cases.
- Tries to identify the paradigm/example/analogue that best fits the case.
- The solution from the paradigm/example/analogue us used to solve the actual case.
- Does not refer to universal moral norms.

Bjørn Hofmann

Casuistry – Bariatric surgery

1. What are we perplexed about?
2. What has caused the perplexity?
3. Comparing this case with "paradigmatic" cases (analogues).

1. Should there be public funding for bariatric surgery?
2. Obesity appears to be self-inflicted.
3. Cases
   1. A colleague with burn-out.
   2. A suicide attempt

Bjørn Hofmann

From Saarni et al 2012

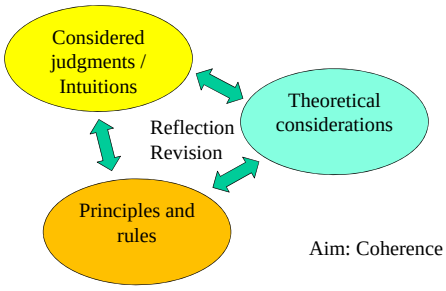
Wide reflective equilibrium

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

Bjørn Hofmann

Wide reflective equilibrium



Bjørn Hofmann

John Rawls, Norman Daniels

Wide Reflective Equilibrium Bariatric Surgery (BS)

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.

1. BS is more in weight reduction than alternatives,
2. Beneficence, autonomy, justice, equity, dignity/worth
3. Utilitarianism, deontology
4. BS increases weight reduction, and can supplement alternatives. It can supplement other approaches where they fail.

Bjørn Hofmann

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.

Bjørn Hofmann

UNIVERSITY OF OSLO

Table 1. Morally Relevant Questions with Respect to Assessing Health Technology

1. What are the morally relevant issues related to the disease and the patient group?	Q1 What is the severity of the disease? May this change? Q2 What patient group is the beneficiary of the technology? (Are they particularly vulnerable, have low socioeconomic status or priority, or are they subject to prejudice? Are issues of underdiagnosis and undertreatment relevant?) Will any of these conditions change? Q3 Does the widespread use of this technology change the patient role? (Does it change the prestige or status of the disease, the conceptions, prejudice or status of persons with certain diseases?) Q4 Does the technology involve healthy persons (screening, asymptomatic cases, disease prediction), and how are potential challenges addressed (false test results, overdiagnosis, futile or harmful treatment)?
2. What are the ethical, social, cultural, legal, and religious challenges related to the health technology?	Q5 Does the implementation, use, or withdrawal of the technology challenge patient autonomy, integrity, privacy, dignity or interfere with basic human rights? Q6 Does the technology challenge social or cultural values, institutions, or arrangements or does it affect religious convictions? Q7 How does the implementation, use, or withdrawal of the technology affect the distribution of health care? (Justice in allocation, access, and distribution). Q8 What are the morally relevant *consequences* (benefits and harms) of the implementation, use or withdrawal of the technology? (In particular from a patient perspective). How should the harms be balanced against the benefits? Are there alternatives? Q9 Can the implementation, use, or withdrawal of the technology in any way conflict with existing law or regulations or pose a need for altered legislation? Q10 Will there be a moral obligation related to the implementation, use, or withdrawal use of a technology? (E.g., are there special difficulties with informing patients, with privacy, or confidentiality?)
3. What are the moral challenges with structural changes related to the health technology?	Q11 How does the assessed technology relate to more general challenges of modern medicine? (Underdiagnosis, undertreatment, medicalization, overdiagnosis, overtreatment, reduced trust) Q12 Does the technology in any way challenge or change the relationship between patients and health care professionals or between health professionals? Q13 Are there morally relevant aspects with respect to the level of generalisation?

Bjørn Hofmann

UNIVERSITY OF OSLO

4. What are the moral issues related to the characteristics of the health technology?	Q14 What is the characteristic of the technology to be assessed? (E.g., function, purpose, intention) Q15 Is the symbolic value of the technology of any moral relevance? (Prestige, status?) May this change as a result of the health technology? Q16 Are there moral challenges related to components of a technology that are relevant to the technology as such? Q17 Are there any related technologies that have turned out to be morally challenging? (Are the same challenges relevant for this technology?)
5. What are the moral issues related to stakeholders?	Q18 Are there third party agents involved? (E.g. donors, relatives) Q19 What are the interests of the users of the technology? Q20 How does the technology contribute to or challenge or alter health professional's autonomy? Q21 What are the interests of the producers of technology (industry, universities)? Q22 Are the users of the technology in the studies representative of the users that will apply it in clinical practice?
6. What are the moral issues related to the assessment of the health technology?	Q23 Are there morally relevant issues related to the choice of end points, cut of values, and outcome measures in the assessment? Q24 Are there morally relevant issues related to the selection (criteria) of studies to be included in the HTA? Q25What are the reasons that this technology is selected to be assessed? Q26 Are there morally relevant issues in the planning of the HTA (e.g., scoping process, expert group selection), in the structuring of the HTA work, and in selecting, synthesizing, and presening the results? Q27 What are the morally relevant presumptions made in the economic analysis (e.g., on justice, equity (the quasi-egalitarian presumption that "a QALY is a QALY"), definition of a target population, as well as in the choices of analysis perspective, outcome measures, discount rates, and (preference value) Q28 What are the interests of the persons participating in the technology assessment? Q29 At what time in the development of the technology is it assessed (and what are the morally relevant consequences)? What morally relevant challenges follow from knowledge gaps? Q30 Are there related or analogous technologies that have not been assessed? (Why not?) Q31 What are the moral consequences of the HTA? (What are the results of implementing/not implementing the health technology? Will other non-effective technologies be abandoned? Will certain sub-groups benefit more than others? Are calling for further studies justified?)
7. Are there additional moral issues?	Q32 Are there moral issues in research ethics that are important to the HTA? Q33 Are there morally relevant questions that have not been covered by this list, but that have been identified by the scoping process or literature search? (Which values and challenges do they pose?)

Bjørn Hofmann

UNIVERSITY OF OSLO

EUnetHTA Core Model

- Topics
  - Principal questions about the ethical aspects of technology
  - Autonomy
  - Human dignity
  - Human integrity
  - Beneficence/ nonmaleficence
  - Justice and Equity
  - Rights
  - Legislation
- Issues:
  - Specific questions within each topic

Bjørn Hofmann

UNIVERSITY OF OSLO

EUnetHTA Core Model

ID	Domain	Topic	Issue	Clarification	Importance 3=critical 2=important 1=options	Transferability 3=complete 2=partially 1=not	Information sources	Reference	Relations	Status
FI001	Ethical analysis	Principal questions about the ethical aspects of technology	Is the technology a new, innovative mode of care, an "add on" to a standard mode of care or a replacement of a standard?	The consequences of totally new models of care are likely to be more difficult to predict than the consequences of replacing an old technology (for individual values, attitudes and expectations as well as for health care systems). Novel, innovative treatment modes may require extra emphasis on ethical analysis, although the literature and research base on the topic may be narrow.	3	2	Literature search Expert opinion	Mitcham 2004	technology description, organizational	Core
FI002	Ethical analysis	Principal questions about the ethical aspects of technology	Can the technology challenge religious, cultural or moral convictions or beliefs of some groups or change current social arrangements?	It is important to identify those groups within the society for whom the use of the technology may pose serious challenges due to their beliefs, convictions or current social arrangements (e.g. need of blood transfusion adjunct to the use of the technology, contraception). Identification of these conflicts and finding other acceptable possibilities to treat the condition in these groups is important. Identifying the conceptions behind the beliefs and values may help put them in perspective, when considering the overall acceptability of the technology. Technology may also change generally accepted social arrangements by challenging traditional conceptions (e.g. assisted reproductive technologies have expanded the concept of genetic, biological and social motherhood).	3	2	Literature search Expert opinion Stakeholder hearing	Ogbinbe 2004	Social	Core
FI003	Ethical analysis	Principal questions about the ethical aspects of technology	What can be the hidden or unintended consequences of the technology and its applications for different stakeholders.	In addition to intended use, the technology may be used for other purposes and have side-effects in addition to those following from the intended use. Unintended consequences are obviously difficult to predict, but the intended purpose and uses of the technology should be evaluated against the likely uses and consequences of the technology in the real world. New technologies tend to lead to new areas of inventions and give rise to new ethical questions (e.g. IVF and development of genetic testing has led to questions of preimplantation genetic diagnostics (PGD). As presymptomatic and prenatal genetic tests have become available, the health care system has to be prepared to handle moral issues raised by true positive and false negative findings.) Many treatments have indirect effects also on relatives.	3	2	Literature search Expert opinion Stakeholder	Ogbinbe 2004, Hofmann 2003b, Hofmann 2003b		Core

UNIVERSITY OF OSLO

2.3 Flowchart summarising HAS' method for assessing ethical aspects

2.3.1 The three stages of work

Stage 1: identification of the arguments

(Preparatory stage prior to writing the report)

Method:
- literature search
- literature review
- theoretical identification of arguments
- consultation with working group and/or peer review group

Stage 2: reporting arguments in the assessment report

(writing the first part of the text dealing with analysis of ethical aspects included in the report)

Method :
- choice of framework to classify ethical arguments identified during the first stage
- presentation and justification for framework if it is not the reference framework
- classification of arguments according to the framework chosen

Stage 3: examination of the arguments in the assessment report

(writing the second part of the text dealing with analysis of the ethical aspects included in the report)

Method:
- examination of the ethical arguments and conclusions of other dimensions of the assessment
- analysis of conflicts between arguments and classification of reasonable disagreements
- identification of decision nodes

Bjørn Hofmann

Framework for ethical evaluation in HTA (Assasi et al 2016)

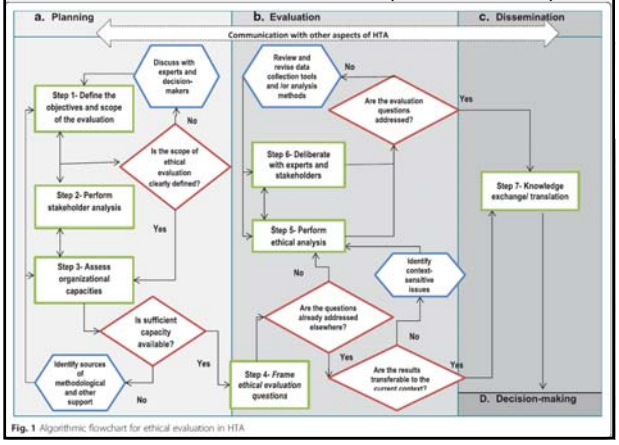
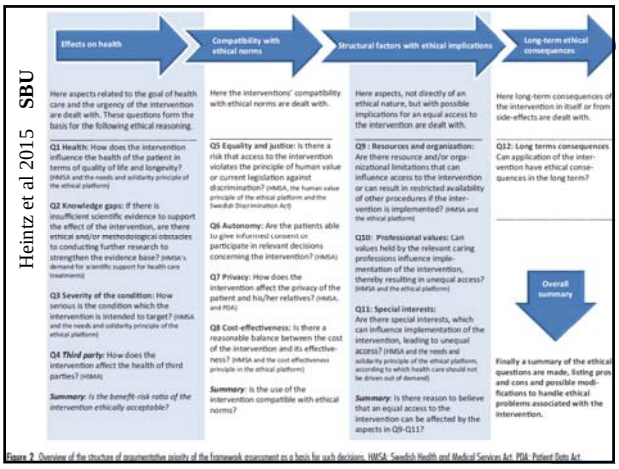
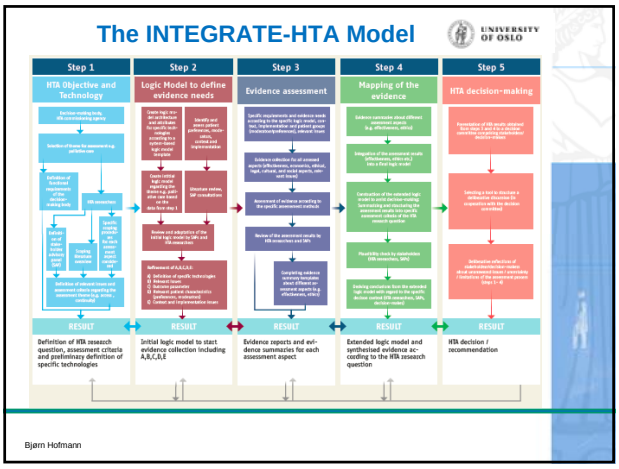
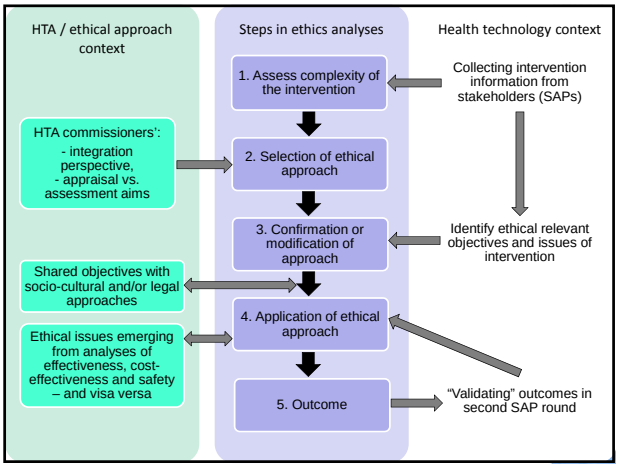
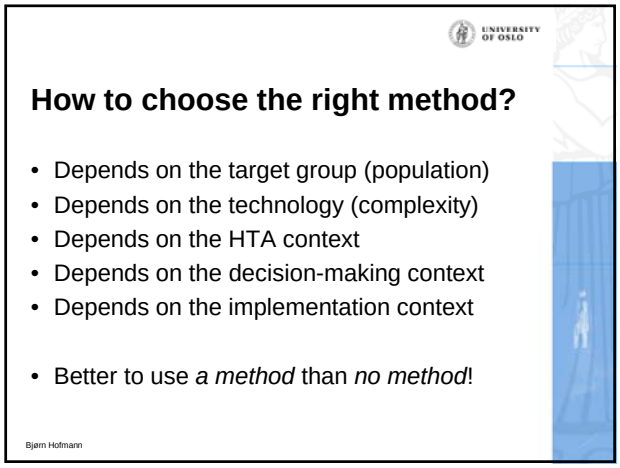


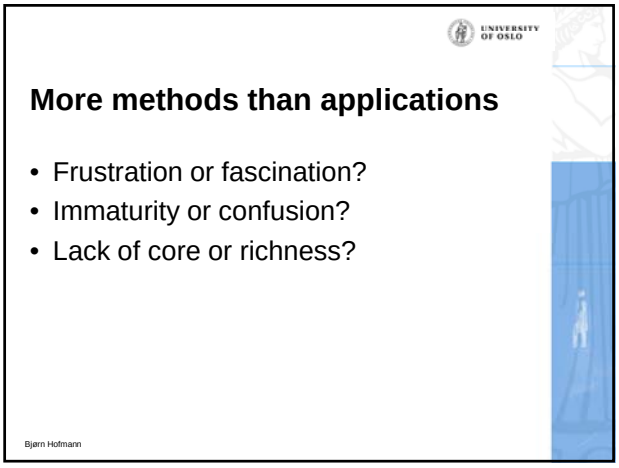
Fig. 1 Algorithmic flowchart for ethical evaluation in HTA

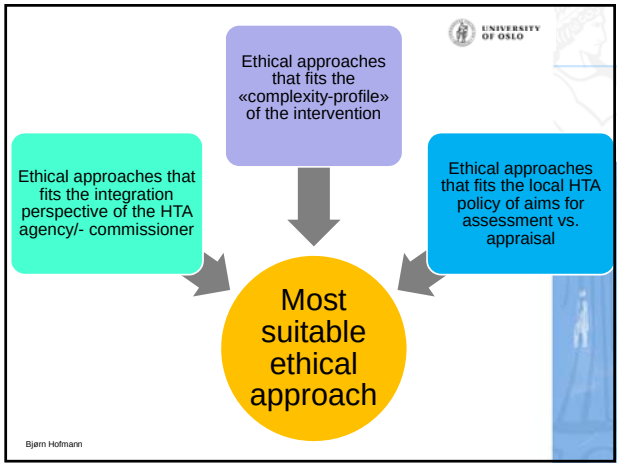

SBU
Heintz et al 2015
Effects on health
Compatibility with ethical norms
Structural factors with ethical implications
Long-term ethical consequences
Overall summary


The INTEGRATE-HTA Model
UNIVERSITY OF OSLO
Step 1
HTA Objective and Technology
Step 2
Logic Model to define evidence needs
Step 3
Evidence assessment
Step 4
Mapping of the evidence
Step 5
HTA decision-making
RESULT
Bjørn Hofmann


HTA / ethical approach context
Steps in ethics analyses
Health technology context
1. Assess complexity of the intervention
Collecting intervention information from stakeholders (SAPs)
HTA commissioners':
- integration perspective,
- appraisal vs. assessment aims
2. Selection of ethical approach
3. Confirmation or modification of approach
Identify ethical relevant objectives and issues of intervention
Shared objectives with socio-cultural and/or legal approaches
4. Application of ethical approach
Ethical issues emerging from analyses of effectiveness, cost-effectiveness and safety – and visa versa
5. Outcome
"Validating" outcomes in second SAP round


UNIVERSITY OF OSLO
How to choose the right method?
• Depends on the target group (population)
• Depends on the technology (complexity)
• Depends on the HTA context
• Depends on the decision-making context
• Depends on the implementation context
• Better to use *a method* than *no method*!
Bjørn Hofmann


UNIVERSITY OF OSLO
More methods than applications
• Frustration or fascination?
• Immaturity or confusion?
• Lack of core or richness?
Bjørn Hofmann


UNIVERSITY OF OSLO
Ethical approaches that fits the «complexity-profile» of the intervention
Ethical approaches that fits the integration perspective of the HTA agency/- commissioner
Ethical approaches that fits the local HTA policy of aims for assessment vs. appraisal
Most suitable ethical approach
Bjørn Hofmann