

"Ethik in HTA" und "HTA-Ethik" - Ansätze und Herausforderungen
25. August 2017, Basel

Vorstellung internationaler Entwicklungen für „Ethik in HTA“ Ethics and HTA – an overview



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1800-1950

- Instrumentalization



1950-1980



Ethical challenges:

- | | | |
|---|--|--|
| Priority setting <ul style="list-style-type: none"> • Prioritization • Allocation • Rationing | Physician-Patient interaction <ul style="list-style-type: none"> Autonomy / Paternalism Dignity | <ul style="list-style-type: none"> • Social development • Ideology |
|---|--|--|

Responses

Governance

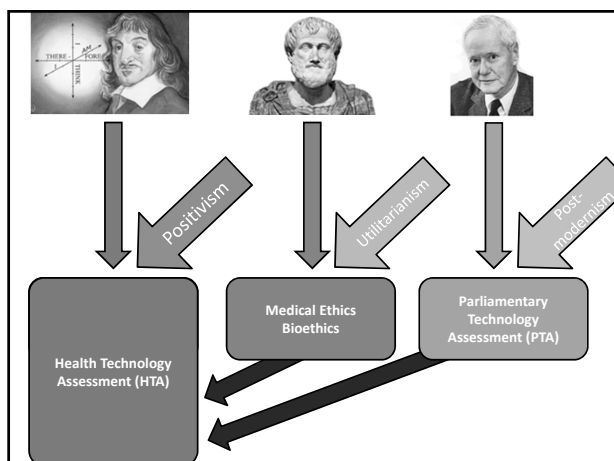
- Priority setting
- Health Technology Assessment (HTA)
 - Office of Technology Assessment (USA)

Profession

- Ethical dilemmas
- Medical Ethics
 - President's Commission,
 - Principle based ethics.

Theory

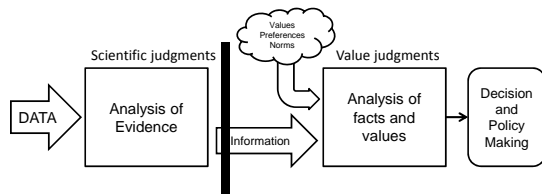
- Social development
- Science and Technology Studies (STS)



Phases of Ethics in HTA

1. Acknowledgement: Definition
2. Foul attempts: Initial stumbling tries
3. Professionalization: The ethicists arrive
4. Pluralism: No consensus
5. International collaboration (EUnetHTA; SEA-Q; INTEGRATE-HTA)
6. National Standards (NOKC, SBU, HAS, Synthesized framework)
7. HTA in Ethics

Facts and Values Assessment versus Appraisal



After Tunis 2007

Acknowledging values

Basic values	Personal values	Health values	HTA values	HTA values	Decision making values	Health Policy related values
Life	Functionality	Reliability	Technical	Systemic	Legitimacy	Health outcomes (population and individual health outcomes)
Health	Relativity	With	Frame	Trans	Justification	Increased effectiveness, including level of certainty of outcome or heterogeneity of treatment effect
Avoid pain	Hedonism	Pain	Endp	Oper	Robustness	Increased safety
Pursue pleasure	Moral values	Reduction	Economic	Evidence	Openness	Other patient, caregiver and/or population health benefits
	Change	Obstacles	Dissemination	Clarity	Sustainability	Reduction of uncertainty (e.g. following diagnosis)
	Esthetics	Therapeutic values	Participatory	Budget impact	Participation	Reduced caregiver burden/early return to normal activities and work (productivity)
	Non-	Intervention	Equity		Coherence	Technology meets unmet need
		Predictability			Participation	Greater treatment choice
		Reliability			Budget impact	Improved access to service
		Validity			Equity	Greater equity

Hofmann 2005; Hofmann et al 2015

Trends

- Facts ↔ Values
- Assessment ↔ Appraisal
- Synthesis of information
- Add on ethics, tool
- Amateurship
- Few methods
- "Pure" methods
- Liberal use of methods
- Ad hoc literature search
- Result oriented (report)
- Ethics in HTA
- Anything goes
- Facts ≈ Values
- Assessment ≈ Appraisal
- Evaluation
- Integrated ethics
- Professionalism
- Plethora of methods
- Eclectic
- Checklist
- Systematic literature search
- Process oriented (participation)
- HTA in Ethics
- Quality criteria

Approaches to address ethical issues with technology

Conventional approaches

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

Prosocial approaches

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

Mixed approaches

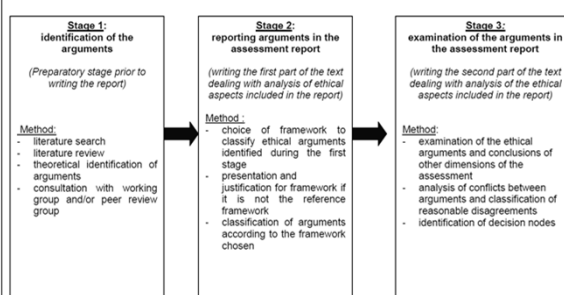
- Principlism
- Ethics matrix
- Triangular method (deontology)
- Interactive, participatory HTA (iHTA)
- Axiological approach,
 - Socratic approach,
 - EUnetHTA Core model
 - SBU Checklist
- Arguments analysis (HAS)
- Multi Criteria Decision Analysis (MCDA)

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
- Approach:
 - Clarify questions, consider their relevance, identify information sources, perform literature searches

2.3 Flowchart summarising HAS' method for assessing ethical aspects

2.3.1 The three stages of work



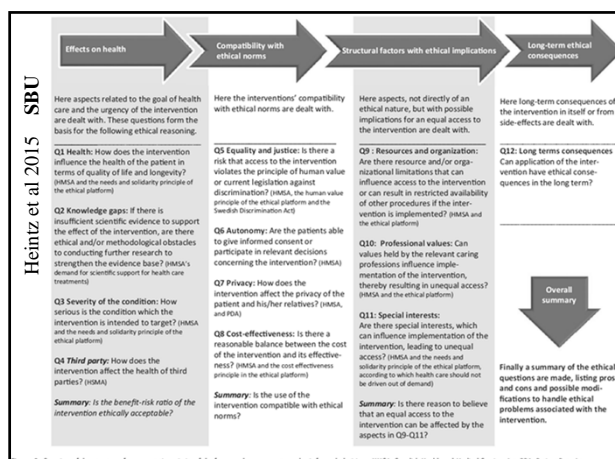
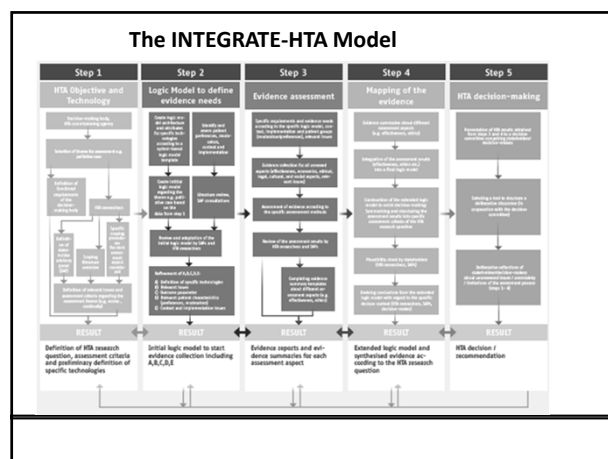
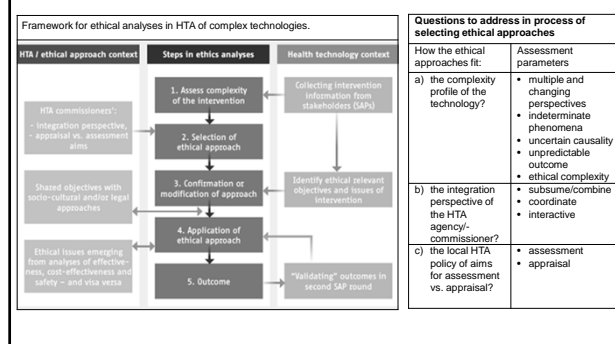


Figure 2 Overview of the structure of argumentative validity of the framework assessment as a basis for each decision. IMIA: Swedish Health and Medical Services Act, IMIA: Patient Data Act



Ethics in INTEGRATE-HTA



The Socratic (Axiological) Approach

1. Identify the intended purpose of the health technology and reveal the background for the assessment;
2. Identify involved persons, groups, and stakeholders (e.g., patients, relatives, professionals, industry);
3. Identify relevant moral questions (from a list of questions, Table 1) 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:
 - Existing literature;
 - Hearings / statements of involved parties (or their representatives) or qualitative studies (relevant qualitative studies should be included in the literature search);
6. Wrap up and summarize the process and the content.

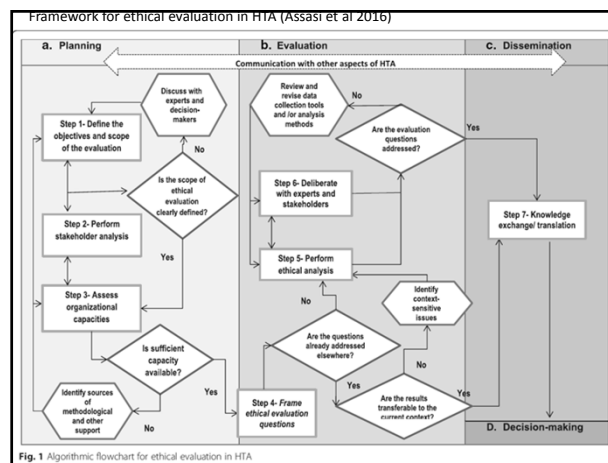
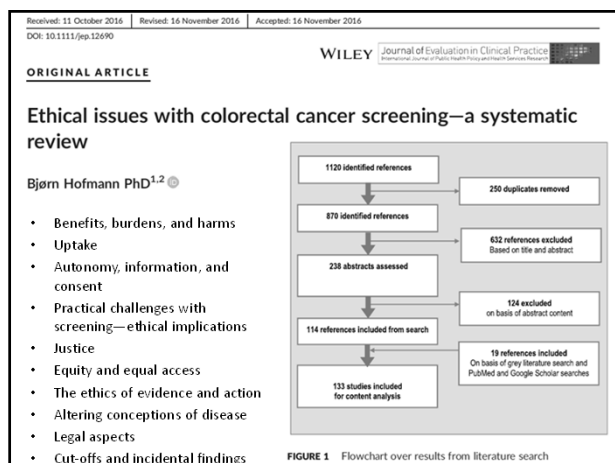


Fig. 1 Algorithmic flowchart for ethical evaluation in HTA

Scott et al. QSEA - a tool for quality assessment of ethics analyses ...

Table 1: Quality Standards for Ethics Analyses (QSEA) in HTA

Elements	Description	Rating	Where to seek
Process Domain			
i) Research question	Was research question clearly stated a priori?	Yes Partially (can be inferred) No	Introduction, objectives or methods section
ii) Literature search	Is the search for literature comprehensive?	Yes Partially (some omissions) No	Methods section
iii) Inclusion/exclusion criteria	Does the analysis clearly state inclusion and exclusion criteria?	Yes Partially (some unclear) No	Methods section
iv) Perspective	Is the analysis conducted from an impartial perspective? (i.e., considers how the technology impacts on various stakeholders: patients, health system, care providers, etc.)	Yes Partially (some omissions) No	Introduction or methods section
v) Ethics framework	Does the analysis identify which ethics framework(s) it has adopted?	Yes Partially (can be inferred) No	Methods section
Output Domain			
i) Completeness	Does the analysis acknowledge gaps in the ethical literature?	Yes Partially (some left unstated) No	Methods or discussion section (limitations)
ii) Bias	Are possible sources of bias identified?	Yes Partially (some omissions) No	Methods and discussion section
iii) Implications	Are policy implications identified?	Yes Partially (some omissions) No	Discussion section
	Are implications differentiated by stakeholder (e.g. patient, health professionals, policy-makers, health system, industry, etc.)	Yes Partially (some omissions) No	Discussion section
iv) Conceptual clarification	Have key terms in the analysis been defined?	Yes Partially (some omissions) No	Methods and results section
v) Conflicting values	Have potential conflicts of values been identified?	Yes Partially (some omissions) No	Results and discussion section

Pluralism: A problem?

Yes

- Small scientific ambitions
- No transferability
- Limited international quality control, peer review
- Low status or prestige

No

- Relevant evaluations are context dependent
- Some aspects may be transferrable, if not all
- Increased status through relevance for decisions

Normative Conclusion

- Awareness is important
- Better to use one method than to use none.
- Application and impact can increase if the value issues involved both in HTA and decision making process is acknowledged.