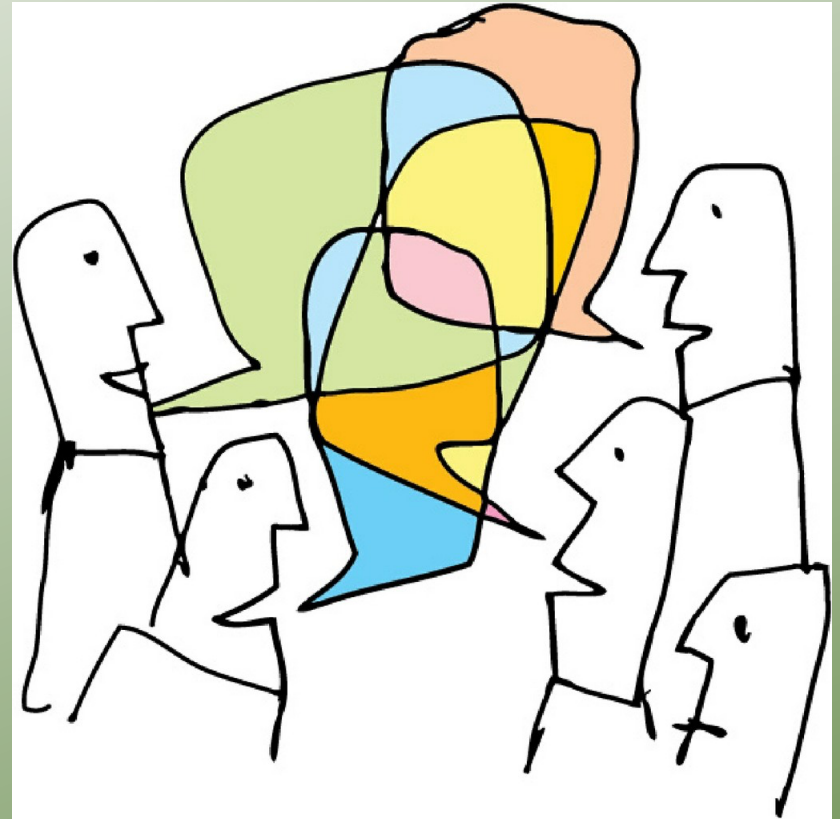


Ethical evaluation in HTA: Understanding the diversity of approaches

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INTRODUCTION

- The final goal of our InternE³LS research project is to propose an operational ethical evaluation tool to be incorporated to the HTA process.
- A **systematic review**¹ was first made in order to identify the main difficulties that are encountered in the integration of ethics in HTA
- **Two important difficulties** regularly mentioned in the literature are:

the diversity of approaches in ethics

and the difficulty of operationalizing them.

1 **(Vignette Presentation # 280):** Bellemare *et al.*, Integration of Ethics in Health Technology Assessment. XIVth Health Technology Assessment international HTAi 2017 Annual Meeting; Towards an HTA Ecosystem: From Local Needs To Global Opportunities. Rome (Italy), June 17-21, 2017.

AIM OF THE STUDY

Working hypothesis : To understand the diversity of ethical evaluations and their respective scope, **three components of ethical arguments** must be taken in consideration^{2,3,4}:

- a) The **disciplinary foundation** that grounds the validity of the ethical evaluation,
- b) The **characteristics** of the ethical evaluation,
- c) The **operational process** involved in applying the ethical evaluation to a particular case (practical reasoning).

2 Patenaude, J., Legault, G.A., Parent M. and Béland, J-P. (2011) Moral arguments in the debate over nanotechnologies: Are we talking past each other? *NanoEthics*, 5(3), 285-293.

3 Béland, J-P., Patenaude, J., Legault, G.A., Boissy, P. and Parent, M. (2011) The Social and Ethical Acceptability of NBICs for Purposes of Human Enhancement: Why Does the Debate Continue to Be Mired in Impasse? *NanoEthics*, 5(3), 295–307.

4 Legault, G-A., Patenaude, J., Béland, J-P. and M. Parent, M. (2013). Nanotechnology and Ethical Argumentation: A Philosophical Stalemate? *Open Journal of Philosophy*, 3(1), 15-22.

METHODOLOGY

- **Nine ethical approaches** were identified from our systematic review: Principlism, Casuistry, Coherence analysis, Wide reflexive equilibrium, Axiology, Socratic approach, Triangular method, Constructive technology assessment and Social shaping of technology.
- All the relevant citations were analyzed by a team of four philosophers, and **classified according to the three components**. After an individual classification, a consensus was reached on all classifications.
- Referenced works on these approaches were also referred to, in order to resolve conflicting perceptions on the approaches from our systematic review.
- The results were validated by the whole research team.

RESULTS: DISCIPLINARY FOUNDATION OF THE ETHICAL EVALUATION

Disciplinary foundation of the ethical evaluation	Approach
Sociology	Constructive technological assessment / Social shaping of technology
Philosophy (non-substantial ethics)	Axiology / Casuistry / Coherence analysis / Principlism / Socratic approach / Wide reflective equilibrium
Philosophy / Theology (substantial ethics)	Triangular model

RESULTS: CHARACTERISTICS OF THE ETHICAL EVALUATION

Characteristics of the ethical evaluation	Approach
Social processes (ethos)	Constructive technological assessment / Social shaping of technology
Common morality (shared norms in society)	Coherence analysis/ Principlism / Wide reflective equilibrium
Common sense (shared maxims)	Casualty
Maieutic (question based: fact/values)	Socratic approach
Values	Axiology
Substantial moral norms	Triangular model

RESULTS: OPERATIONAL PROCESS - PRACTICAL REASONING

Operational process: Practical reasoning	Approach
<i>No specified procedure</i>	Constructive technological assessment / Social shaping of technology
<p><i>Applying general norms to a specific case:</i></p> <ul style="list-style-type: none"> a) identifying the facts pertaining to the case b) identifying the norms applicable to the case c) resolving the conflict between norms (when present) d) establishing the conformity or non-conformity (actions/norms) e) justifying the final judgment on conformity 	Casuistry / Coherence analysis / Principlism / Triangular model / Wide reflective equilibrium
<p><i>Applying value judgments to a specific case:</i></p> <ul style="list-style-type: none"> a) question-based procedure 	Socratic approach
<p><i>Applying value judgments to a specific case: value analysis</i></p> <ul style="list-style-type: none"> a) identifying the facts pertaining to the case b) specifying the value judgments applying to the facts c) identifying the conflict between value judgments d) prioritizing the value judgments e) justifying the final value judgment 	Axiology

RESULTS: OPERATIONAL PROCESS - INTEGRATION IN HTA ANALYSIS

Operational process: Integration in HTA analysis	Approach
Expert ethical analysis required and report added to HTA assessment	Axiology / Casuistry / Coherence analysis / Constructive technological assessment / Principlism / Social shaping of technology / Triangular model / Wide reflective equilibrium
Expert ethical analysis not required and analysis integrated to the HTA assessment	Socratic approach

DISCUSSION

- 1) Our results clearly show that the **diversity of approaches** in ethics, often mentioned as a difficulty for integrating ethics in HTA, **rests primarily on the disciplinary foundation** of ethical evaluation (sociology, philosophy, theology).
- 2) In contrast to clinical trials or cost/benefit analysis, **ethical analysis is not uniform** and the fact that there is “**no settled proceedings** for ethical analysis”⁵ seems **unavoidable** to many.

5 **(Vignette Presentation # 280)**: Bellemare et al., Integration of Ethics in Health Technology Assessment. XIVth Health Technology Assessment international HTAi 2017 Annual Meeting; Towards an HTA Ecosystem: From Local Needs To Global Opportunities. Rome (Italy), June 17-21, 2017.

DISCUSSION

- 3) There are “Many ways to Rome” for integrating ethics⁶ and taking in consideration **the three components of ethical analysis can help** to justify a final choice.

- 4) The difficulty in operationalizing an ethical analysis is regularly mentioned as an important difficulty for integrating ethics in HTA. Our results show that there is **little information** in the literature **about the practical reasoning** required on the precise way of identifying the facts that are submitted to a norm-based or a value-based evaluation.

6 Hofmann, B., Oortwijn, W., Bakke Lysdahl, K., Refolo, P., Sacchini, D., van der Wilt, G. J. and Gerhardus, A. (2015) Integrating ethics in health technology assessment: many ways to Rome. *Int. J. Tech. Assess. Health Care*, 31(3), 131–137.

CONCLUSION

Applying the three components to ethical approaches in HTA helps understanding the complexity of these approaches and the difficulty to operationalize them into HTA tools.

The choice of any ethical evaluations is never neutral, it must be justified by a moral point of view.

Developing tools for ethics in HTA operationalizes a specific practical reasoning whereby the identification of the facts and the process of evaluation must be specified.

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