



Bringing evidence to the world of policy making: Bioethics as midwifery


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Preamble

- Why is it important to include ethical analysis in HTA?
- ➡ Goals of HTA and of bioethics= Appraisal?
- ➡ Appraisal: contextualisation, values, ethical implications
- ➡ Recommendations?
- Reasons why these questions are linked:
 - Type of **evidence** needed for policy-making
 - **methods** needed to acquire this evidence

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Outline

- In HTA and in bioethics:
 - Goals
 - Evidence/methods needed for policy making

→ Shift between original goals and actual practice of HTA and bioethics

→ HTA and bioethics should be brought together in contextualisation

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Goals of HTA and bioethics



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Goal of HTA

- *Office of Technology Assessment* (1970)
- HTA: assist informed decision making, be it at the policy, administrative or practice levels, by gathering and synthesizing evidence on the benefits and risks and costs associated with technological change.
- Conducted by an independent body

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Definition of HTA

“Technology assessment in health care is a multidisciplinary field of policy analysis. It studies the medical, social, ethics and economic implications of the development, diffusion, and use of health technology »

INAHTA

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The theory and practice of HTA

- Narrow focus of HTA
 - Disciplinary background of assessors
- ➡ Neglecting contextual information limits the uptake of HTA results by decision makers

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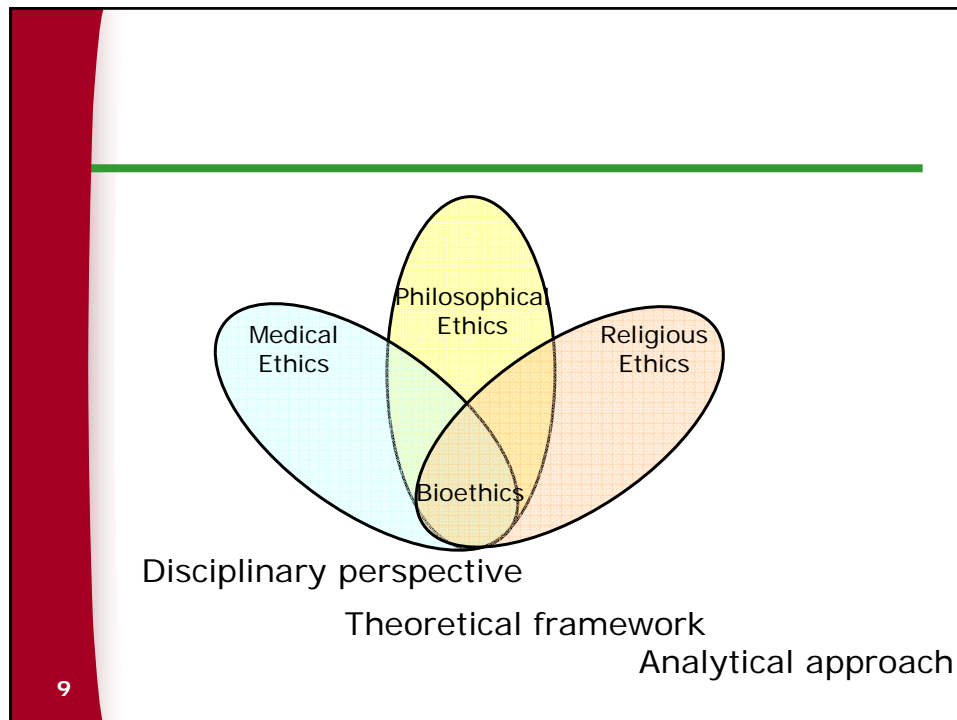
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Ethics

- Practical reasoning about human conduct: choices, values, worldviews
- Two approaches:
 - Analysis and explanation of various moral positions and their justification: descriptive approach
 - Appreciation and argumentation: formulation of specific propositions: normative approach

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Bioethics...

Van Rensselaer Potter (1971):

Bioethics: Bridge to the Future

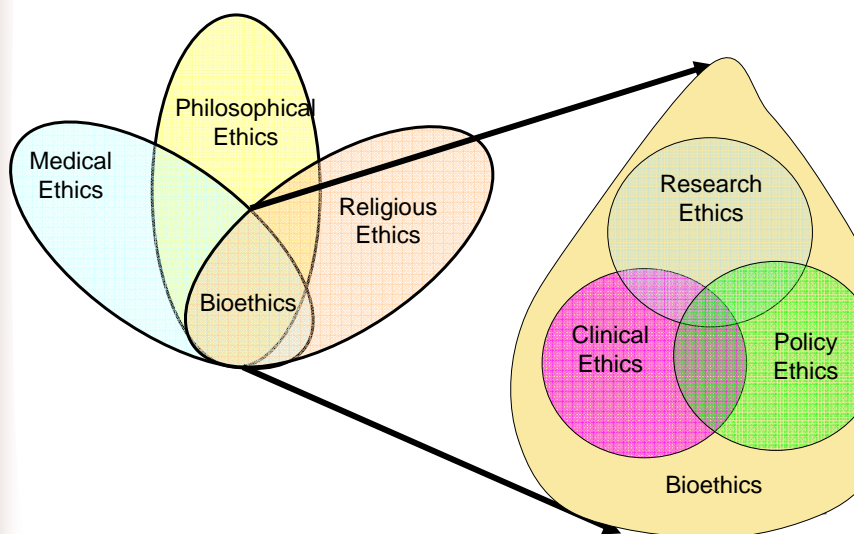
- A new ethics that would guide moral decision making in order to insure the survival of man and of the planet
- "Wisdom seeking": future oriented and inspired by the principle of responsibility

Biomedical principles

- Autonomy
- Beneficence
- Non-maleficence
- Justice

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Bioethics...

« Bioethics deals with biomedical techniques and sciences applied to humans, individuals and society. The object of bioethics is to **identify, define and clarify** ethical dilemmas posed by these techno-sciences and to **assist decision-making**. Methods used must be multidisciplinary and **interdisciplinary** in nature. »

Marie-Hélène Parizeau, *Bioéthique : méthodes et fondements*, Cahiers de l'ACFAS, no. 66, 1989

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Bioethics...

- **Main characteristics:**
 - Interrogative/appreciative
 - Educational/democratic
 - Assists Decision making
 - Interdisciplinary

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Morality and ethics

Latin and Greek:

Morals and manners, codes of conduct
and reflection on these

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Morality versus ethics

Today:

Morality

- rules of conduct
- prescription

Ethics

- critical reflection
and interrogation
- appreciation/critical
analysis

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Bioethics adrift

prescriptive

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Bioethics Adrift

- Institutionalisation of bioethics
- Birth of “expert bioethicists”
- The coming together: bioethics, professional practices and decision making spheres

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Institutionalisation of Bioethics

- Proliferation of ethics codes, committees, counsels and commissions



Ethics and law : Best buddies

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Expert bioethicists

- Proliferation of Bioethics training programs
- Bioethics: a new discipline?
- May “ethical knowledge” be acquired?
- Frequent consultation of bioethics experts



“de-responsibilisation” of society

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Ethics, Professional Practice and Decision Making Spheres

- **Critical distance vs. relevance?**
 - Assistance to decision making

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Shift in goals of HTA and Bioethics

- HTA: exclusion of contextual information and ethical, legal and social considerations in evaluations
 - Bioethics:
 - Orientation of ethical analysis: concrete resolution of ethical dilemmas
 - Shift in emphasis towards a more prescriptive function
- ➡ Type of evidence and approaches needed to acquire this evidence

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Evidence required for policy-making in HTA and bioethics

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Evidence based medicine

- '...the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients'

(Sackett , BMJ 1996),

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Why research falls short of informing policy decisions

- Two communities perspective
- Policy and research are processes
- Rational decisions vs sensible decisions

➡ Research information is not usable information but rather **potential** knowledge: it needs to resonate with contextual factors

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What is evidence?

- Most decision makers view evidence colloquially and define it by its **relevance**
- Most researchers view evidence scientifically and define it by its **methodology**

CSHRF, 2005

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What is evidence for policy-makers?

Evidence defined broadly: multiple sources

- The decision maker under the influence of political and institutional factors will interpret information to arrive at a **sensible response** in order to minimize conflict

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What is evidence for scientists?

- Context free universal truths (EBM): "what works"
- Context sensitive types of evidence: what works and how it might be implemented in specific circumstances

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What is evidence in the EBM movement?

- A function of the **quality** of the evidence: higher quality evidence leads to better decisions
- Claims to EBM often based on randomized controlled trials
- Such studies do not address how effective such interventions would be in real contexts (limitations with complex technologies)
- Evidence is static whereas technology is dynamic

What is evidence in the context sensitive view?

- Evidence has little meaning unless adapted to circumstances of its application: science needs to inform not only about potential action but **feasible** action
- Several sources of data to answer question: 'what factors contribute to...?'
- Social science methods frequently coined as being subjective and relativist

Context-free and context-sensitive evidence

- Both quantitative (context-free) and qualitative (context-sensitive) approaches have inherent strengths and weaknesses

→ Combining the two gives a more comprehensive account of reality

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Importance of Context in policy-making

- Decisions at the policy level affect a larger number of people, involve many conflicting interests, and are subject to greater public scrutiny

→ The sources and variety of evidence need to be increased

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In bioethics...

- An emphasis in practice on **context free evidence** to assist decision-making at the expense of more contextual and procedural sources of information is not only observed in HTA but in Bioethics as well.

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Evidence in bioethics...

- The reliance on principle based decision-making does not encourage the taking into account of the complexities surrounding the development and uptake of technologies.

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Context

- Important to render explicit the tensions between social values to determine the trade-offs and weigh their importance
- Nature of risks, who risk bearers are, distribution of risks and benefits among social groups, stakeholder interests, economic incentives, cultural and political factors

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Biomedical principles in practice

Difference between the intention behind the development of biomedical principles and their use:

- Have been applied to complex ethical dilemmas in a mechanistic way
- Are frequently considered in the abstract in relation to specific cases without integrating the considerations they raise in these cases



implications of different decisions?

An **integrated contextualisation exercise** is needed

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Bioethics in HTA

- Bioethics allows for the integration of different levels of evidence
- In the practice of HTA this integration function of bioethics goes hand in hand with the contextualisation step followed by the production of recommendations

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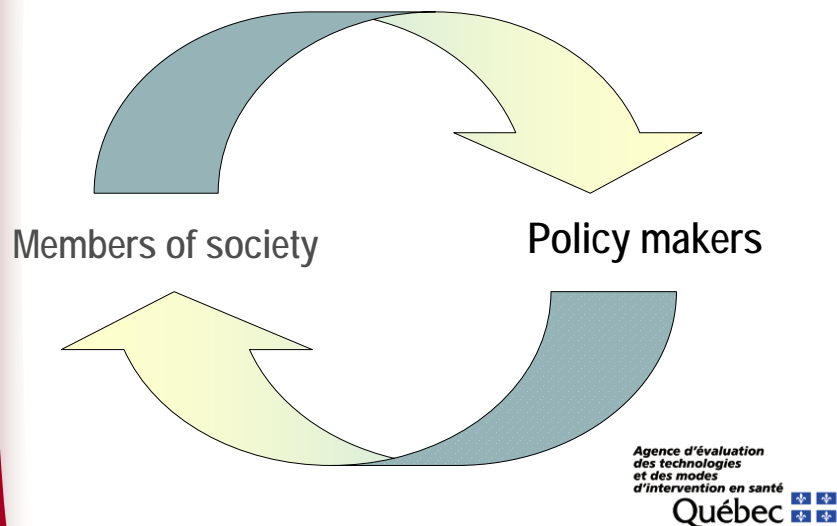
Bioethics in HTA

- **Contextualisation:** analysis of context of development and uptake of technology by relying on rigorous scientific interdisciplinary work
- **Recommendations :** appreciation step integrating information derived from the contextualisation step with overall assessment

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Bioethics: negative feedback



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Bioethics: social mediation

- Given the necessary conditions allowing for the expression of societal preoccupations and will (deliberation), bioethics represents **social mediation** between:
 - The stakeholders of the technology: providing up to date information concerning the technology
 - The policy-makers: presenting the social and ethical implications of the development and uptake of technology

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Conclusion

- Both EBM movement and biomedical principles emanated from biomedical practice
- The simple extension of these conceptions of reality to higher decision-making levels involving many more stakeholders, institutions and conflicting interests, does not allow to take into account the complexity inherent to the context of development and uptake of the technologies.

→ The assistance to decision making at the policy level is thus not as informed as it could be

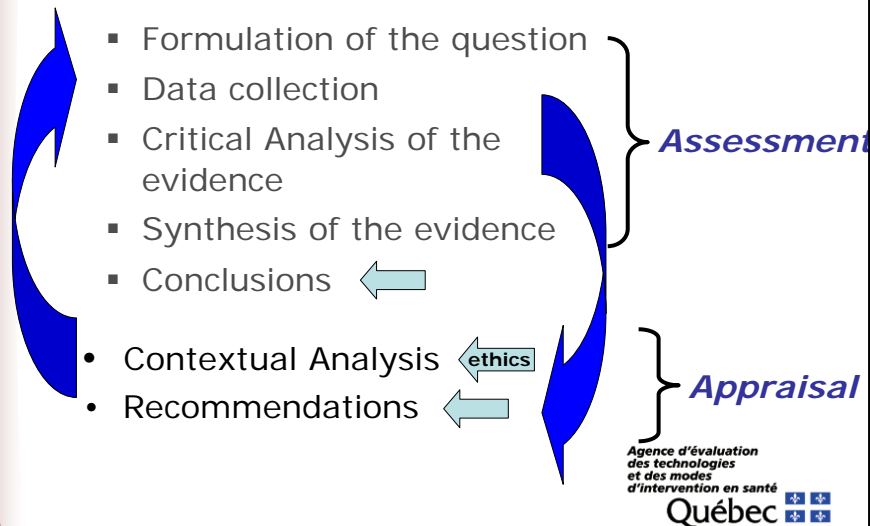
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Conclusion

- Why is ethics important to HTA?
 - Ethics represents the function of integrating different sources of information within the contextualisation step in HTA

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HTA: How far do we go?






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Conclusion

- Why is ethics important to HTA?
 - Ethics represents the function of integrating different sources of information within the contextualisation step in HTA
 - Recommendations that take into account both context-free and context sensitive evidence reduce the risk that decisions be based on technocratic grounds

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