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
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

Goals of HTA and bioethics
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

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
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.

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
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
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. »


Bioethics...

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

Latin and Greek:
Morals and manners, codes of conduct and reflection on these

Morality versus ethics

Today:

<table>
<thead>
<tr>
<th>Morality</th>
<th>Ethics</th>
</tr>
</thead>
<tbody>
<tr>
<td>rules of conduct</td>
<td>critical reflection and interrogation</td>
</tr>
<tr>
<td>prescription</td>
<td>appreciation/critical analysis</td>
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</tbody>
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Bioethics adrift

prescriptive

Bioethics Adrift

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

- Proliferation of ethics codes, committees, counsels and commissions

  Ethics and law : Best buddies

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
Ethics, Professional Practice and Decision Making Spheres

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

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
Evidence required for policy-making in HTA and bioethics

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),
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

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
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.

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
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

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
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.

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.
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

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

An integrated contextualisation exercise is needed
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

**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
Bioethics: negative feedback

Members of society  →  Policy makers

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
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.

Conclusion

- Why is ethics important to HTA?
  - Ethics represents the function of integrating different sources of information within the contextualisation step in HTA.
HTA: How far do we go?

- Formulation of the question
- Data collection
- Critical Analysis of the evidence
- Synthesis of the evidence
- Conclusions
- Contextual Analysis
- Recommendations

Assessment

Appraisal

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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