Improving Ethics Analysis in Health Technology Assessment

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Outline

1. Background: HTA & Ethics
2. Importance of Ethics in HTA
3. Implications for Ethics Analysis
4. Three Areas for Improvement
   (a) ethical and legal issues
   (b) ethics theory
   (c) expertise
5. Steps Forward
HTA

- Multidisciplinary process
- Summarizes information about medical, social, economic, and **ethical issues** related to use of health technology
- Systematic, transparent, unbiased, robust
- Aims to inform formulation of safe, effective, patient-focused health policies
- Seeks best value (EUnetHTA 2008)

- Technology: drugs, devices, medical, and surgical procedures, interventions for prevention and rehabilitation of disease, and organizational and support systems
HTA

- Carries ethical consequences
  - 14% included objective of addressing ethics
  - 17% addressed ethical issues
  - 71% no explicit objective to address ethical issues
  - Frequently unclear who conducted analysis and what expertise were employed

- INAHTA Survey (2003): 36 HTA Agencies
  - 69% always/sometimes include ethics analysis
  - 75% no system or ad hoc approach to analysis
  - 17% have written instructions for analysis
  - 19% employ professional ethicist
Ethics: Issues & Analysis

Ethics

- Philosophical inquiry into the nature and grounds of morality (moral judgments, standards and rules of conduct both *actual* and *ideal*) (Taylor 1975)
- Examination of what one ought to do in the social world (Seedhouse 2009)

Ethical Issues in HTA

- Any issue with potential to cause real and significant consequences for others’ conceptions of the good and their abilities to pursue their projects in the world.

Ethics Analysis

- Process to identify and analyze ethics issues
- Requires philosophical reasoning and reflection
- Facilitated through philosophical frameworks and tools
Why Address Ethics in HTAs?

- Instrumentally valuable (Hofmann 2005)
  - Makes HTAs more **accessible** and **useful** to end users
  - Increases **transparency** → transferability

- Ontologically faithful (Veatch 2005, Saarni et al. 2008)
  - Reflects the fact that ethical issues arise in HTA

- Normativity (Saarni et al. 2008)
  - Given the ethical dimension of HTA, we have a **moral obligation** to raise and discuss these issues
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If these are reasons to include ethics analyses in HTAs...
Ethics Analyses Ought to...

- Be accessible to those without formal training in ethics or HTA
- Provide useful guidance or direction on the most significant ethical issues
- Follow a transparent process that is communicated between and among HTA producers and end users
- Raise and examine as many relevant moral issues as possible (moral obligation)
Three Improvements to Ethics Analysis

1. Separate ethical and legal issues

2. Make better use of ethics theory

3. Acknowledge the necessity of and make use of ethics expertise
1. Combining Ethical and Legal Issues

- This is problematic:
  - they *are* distinct
  - tools and analytic strategies to respond to each differ

- Has resulted in legal analysis subsuming ethics considerations

- Restricts the breadth and depth of ethical analyses and risks leaving certain issue unidentified or unexplored

- Challenges our obligations and jeopardizes HTA utility by generating HTAs that fail to raise and explore relevant moral issues
2. Use of Ethics Theory in HTA Literature

**Unsystematic eclecticism**: Approaches to ethics that encourage HTA producers to select from and combine tools that stem from divergent and sometimes conflicting routes in moral philosophy.

**Uncritical approaches to methodology**: General lack of discussion about which analytic methods to use and why.

**Problematic application**: Encouraging theoretical approaches that fail to encourage analysis result in cataloguing of ethical issues. This results in a general failure to provide direction.
3. Acknowledging Expertise

- Relevant expertise is bioethics expertise (DeJean et al. 2009) BUT
- Ethics analysis seldom completed by ethicists
- No guidance in Core Model or INAHTA Handbook about relevant expertise

Two possible reasons for this lack of discussion and guidance:
1. Belief there is no expertise for conducting ethics analysis
2. Belief that, if there is expertise, it is neither necessary nor helpful
Expertise in methods of ethics can be of great benefit but is neither necessary nor sufficient. (Saarni et al. 2008)

A challenge to integrating ethics into HTA has been a lack of consensus among philosophers, and a lack of methods applicable for non-philosophers. (Saarni et al. 2008)

An academically well-written ethical analysis may be completely incomprehensible to non-ethicists and have no impact on the practical implementation of the technology. (Hofmann 2005)
What is Expertise?

**Expertise**: the capacity to provide strong justification for claims in a domain (epistemic expertise) or to exercise a skill well (performative expertise). (Weinstein 1993)

- Expert has this capacity.
- Ethics expertise is epistemic
There Is No Expertise

*Subject matter resists development of expertise*

- Need to understand philosophical nature of ethics analysis
- The Core Model:
  - Need for “philosophical analysis of logic and coherence of argumentation”
  - Advocates philosophically demanding “integrated approach”

*The lack of consensus on ethics in HTA indicates that there is no real expertise*

- Lack of consensus sign of philosophical health
- Consensus of what, for whom, to what end?
Expertise: Unnecessary or Unhelpful

*Methods of ethical analysis ought to be available to the non-philosopher*

• These demands are not made of epidemiologists, biostatisticians, economists, etc.
• Assumes that the ordinary nature of philosophical questions entails quotidian methods

*Some analysis may require philosophical expertise, but not all*

• Core Model: Methods must suit the HTA organization, technology and its application, and context
• Presupposes broad knowledge of potential issues and familiarity and facility with various approaches
Expertise: Unnecessary or Unhelpful

Methods and vocabulary of professional ethicist incomprehensible to intended audience
• Assumes that ethicists cannot raise and discuss issues clearly
• Denies that every discipline has specialized concepts and vocabulary

Those working in other areas can easily acquire knowledge and skills required to conduct analysis
• “Disciplinary slip” (Benatar 2006) of researchers from area in which they have been trained to one in which they have not
• Underlying belief that doing philosophy well requires no special training or aptitude; depth of ethical questions hidden by apparent ordinary nature
Steps Forward

1. Establish Guidelines for Conduct, Reporting and Evaluation
   - Approaches to developing and reporting ethics analyses should mirror systematic reviews and economic evaluations (e.g. PRISMA, Drummond et al.)
   - Guidelines should:
     - Include methods to evaluate appropriateness and strength of ethics analyses in HTA
     - Require explicit discussion and documented a priori methodology
   - Analysis of ethical issues should not be limited to obviously ethically contentious technologies
2. Incorporate Expertise

- Act on importance of ethics analysis in HTA
- Develop a better understanding the skills/knowledge required
  - Expertise in moral philosophy, expertise in developing and forwarding arguments
  - Familiarity in related fields (philosophy of science/technology)
- Consider how ethics expertise can be more meaningfully brought into HTA groups
  - Staffing
  - Take advantage of existing interdisciplinary networks
  - Foster new relationships with people across academic disciplines
Steps Forward

3. Use Untapped Resources in Literature to Address These Issues

- Discussions about the requirement for consensus provided in the bioethics literature on ethics boards and committees

- Analyses of the potential impacts of technology available in the Philosophy of Technology literature

- Assessments of the role of expertise available in the bioethics literature
Conclusions

- Current guidance for ethics analyses in HTA is not consistent with views of the role of ethics analysis in HTA
- Ethical issues need to be considered separately from legal issues
- Unsystematic eclectic approaches ought to be set aside in favour of more reflective systematic ones
- Relevant ethical issues ought to be considered for all technologies
- Specific expertise is required to conduct ethics analysis
- Ethics analysis ought to provide direction on major ethical questions
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